

Projecting Reliability and Robustness of the Symbiq™ Infusion System



Reliability of the Symbiq infusion system can be estimated based upon the probability that the product will perform satisfactorily over a period of time under specified operating conditions.

In order to assure a high level of customer satisfaction with the Symbiq system, a reliability plan was created at the onset of the development phase of the project. The reliability plan included several key items that have been successfully completed:

- Subsystem Reliability Testing
- System Reliability Testing (Mean Time Between Failures)
- Define Subsystem Critical to Quality Parameters (CTQ)
- Assure Critical to Quality Parameters are carried through and monitored by component vendors and/or the final manufacturing process

This paper will provide some of the results of the reliability and robustness testing efforts that have been conducted on both subsystems and the overall final product.

Results of Subsystem Reliability Testing

Before the final product design was reliability tested, individual subsystem testing was performed to assess the Symbiq system's reliability during development. Subsystem reliability testing included higher than normal levels of environmental stress (temperature and vibration) and operating cycles. As design improvements and component assembly changes were incorporated into the design, this reliability stress testing was repeated to identify operating limits and recommend additional design improvements.

The individual subsystems that were tested beyond their normal operating limits included the following:

- AC/DC Power Supply Subsystem
 - Thirty-five units were tested for two weeks at 70°C (normal operating ambient temperature is 20°C) to prove that the system operates properly within its spec limits and to determine the operating limits of the units
- Drive Train and Pressure Sensing Subsystem Life Test
 - Units exceeded mean time between failures (MTBF) goal for the subsystem by nearly 200 percent
- Speaker Life Test
 - Demonstrated reliability exceeding expected speaker life for the expected use profile

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Mean Time Between Failures (MTBF) for the Infusion System

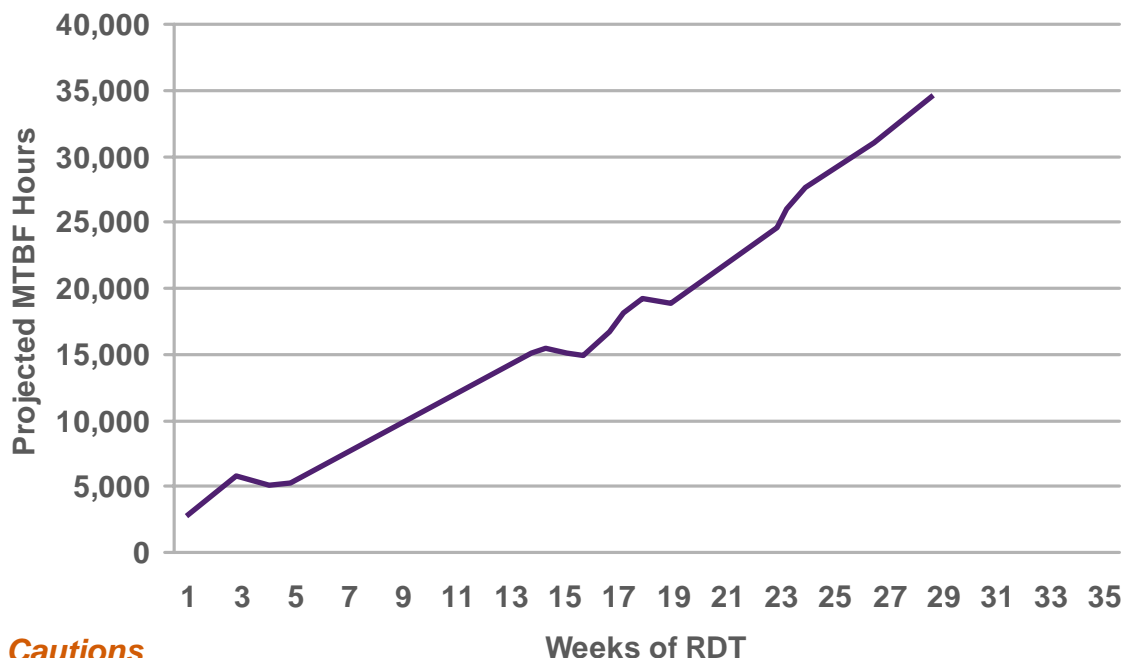
Reliability Demonstration Testing (RDT) was initiated utilizing MTBF to estimate infusion system reliability once subsystem testing was complete and pump prototypes were manufactured.

MTBF can be defined as the projected time, measured in hours, between failures experienced in the field. This is based on the run time for all the installed bases of pumps. For the Symbiq system, the target MTBF was established at 30,000 hours. A pump running 41 percent of the time (10 hours per day, every day) would translate into approximately 10 years before a failure would occur, on average.

During this testing, the pumps were run alternatively on AC power and the internal battery packs to stress the battery charging system and the battery packs themselves.

The chart below shows projected MTBF of nearly 35,000 hours for the Symbiq infusion system.

Symbiq Reliability Demonstration Testing Projected MTBF



Cautions

Caution is appropriate when evaluating the completed testing. The projected MTBF represents expected performance and should not be construed as a guarantee of system performance. The MTBF provides an indication of the stability of the hardware components and does not include an estimate of latent software defects. The MTBF projection has been obtained by conducting Reliability Demonstration Testing (RDT) in a population of 20 Symbiq infusion pumps running continually at elevated temperature (40°C) for over eight months. Normal operating condition is typically around 20°C.

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Continuous Reliability Improvement

After the release of the Symbiq infusion system, product reliability will continue to be monitored in several ways that include, but are not limited to, the following:

- Continued RDT testing beyond the initial targets to establish the limits of system reliability
- Examine RDT and field failures for potential preventive maintenance components/schedules
- Monitor initial customer complaints and conduct root cause analysis to identify opportunities for product design enhancements

In the long term, the Global Complaint Management organization and Global Device Operations Quality will monitor the reliability of the Symbiq product line as it does with all Hospira products.

Critical to Quality Parameters (CTQ)

For the Symbiq pump and each subsystem within the pump, CTQ were identified and a monitoring plan established for each third-party vendor to ensure that they stay within established bounds. By monitoring CTQ throughout the supply chain for this product, Hospira will have an early warning should the parameters indicate any changes in terms of quality or performance.

Verification Testing, Life Testing, Abuse Testing, Extended and Session-Based Testing

Verification testing was conducted to confirm that the Symbiq system meets the defined product requirements. The table below provides a summary of items verified in testing.

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TEST	PASS/ FAIL	RESULT SUMMARY
AC Power Cord and Battery Housing Verification	PASS	The battery pack is modular and accidental removal of the power cord is prevented.
Air Sensor Mechanical Verification	PASS	The air sensor mechanical design provides acceptable alignment of the crystals to allow sufficient transmission of signal.
Cassette Alignment Verification	PASS	The cassette loader sufficiently aligns the cassette inside the pump in allowing delivery accuracy requirements to be met.
Cassette Loader Force Verification	PASS	The cassette loader door provides enough force to properly seat a cassette.
Cassette Loader Function Verification	PASS	Loading a cassette into the pump is simple, intuitive and safe.
Fluid Ingress, Cleaning and Decontamination Verification	PASS	The pump withstands fluid spills, drips and cleaning.
Free-Fall Verification	PASS	The pump incurs no damage per IEC drop-test requirement.
Modularity and Channel Configurations Verification	PASS	The Symbiq single- and dual-channel infusers can be connected to create three- and four-channel pump arrays.
Off-Screen Keys and Touch Screen Verification	PASS	The touch screen and off-screen keys are accessible and easily activated.
Pole Clamp Verification	PASS	The pole clamp has the required strength to support four times the weight of two dual-channel pumps.
Shipping Verification	PASS	The pump functioned normally after simulated shipping conditions (vibration and drop testing).
Shock and Vibration Verification	PASS	The pump functioned normally after vigorous vibration and mechanical shock testing.
Syringe Set Verification Protocol	PASS	The syringe holder can be easily mounted to the pump and is robust.
Thermal Operating Verification	PASS	The pump surface temperatures < 50°C (met IEC requirement). The pump functioned normally at environmental extremes.
Thermal Storage Verification	PASS	The pump functioned normally after storage at extreme temperatures.
LCD Display Verification	PASS	The LCD display is readable in all lighting conditions.

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Life testing was conducted on several important elements of the Symbiq infusion system as summarized in the table below.

TEST	RESULT SUMMARY
Emergency Release Mechanism	The emergency release lever functioned normally after 2,080 cycles (4X margin).
Interconnection Mechanism	The dual-channel-to-single-channel pump connection mechanism was functional after 7,200 cycles (2X margin).
Pole Clamp	The pole clamp assembly was able to support four times the weight of two dual-channel infusers after 10,000 cycles (1.4X margin).
Silence Button	The silence button functioned normally after 100,000 cycles (5X margin).
Touch Screen	The touch screen functioned normally after 1,000,000 cycles (5X margin) at high force.
Syringe Holder/ Handle	The infuser handle exhibited an acceptable amount of wear after 3,650 connections (1X margin) with a syringe holder.
Pole Clamp/ Connectology	The pole clamp body rotated successfully in the connectology chassis for 5,000 cycles (1.4X margin).

Additional testing to measure device reliability in defined abusive conditions was also conducted. The results are summarized in the table below.

TEST	RESULT SUMMARY
Dynamic Pole Clamp Strength Test	The infuser was transported on an IV pole over various terrains and at various speeds without slipping down the pole.
Extended Cleaning Chemicals Test	The infuser withstood cleaning with numerous household cleaning products.
Extended Drop Test	The infuser functioned normally after a drop from 1 meter.
Foreign Object Test	A user is not able to insert a finger inside the pump enclosure.
Impact Test	The infuser withstood impacts into various objects (e.g., corners of tables, door jambs) when carried by hand or clamped on an IV pole.
Stacking/Storage Test	Infusers were stacked and stored without damage.
Tube Tugging Test	Tugging on an installed set did not result in damage to the infuser.

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Finally, extended use and session-based testing was conducted to test reliability in non-standard use conditions. The results of this testing is summarized in the table below.

TEST	RESULT SUMMARY
Air Sensor Mechanism Robustness	The air sensors functioned properly under different power configurations, after alarm and malfunction occurrences and after abuse.
Cassette Loader Robustness	The cassette loader functioned properly to close the cassette flow stop and prevented/mitigated accidental opening of the flow stop under all conditions, including abuse.
Emergency Release Robustness	The force required to activate the emergency release lever was acceptable and the pump software response to activation of the lever in different pump modes (door open, closed, pump delivering fluid, idle, etc.) was robust.
Emergency Stop Robustness	Delivery programs at all tested rates were successfully stopped via the emergency stop hard key.
Plunger Sensor Robustness	The plunger sensor functioned normally after abuse.
Pump to Pump Infrared Connectivity Robustness	Successful infrared connectivity was maintained between connected single- and dual-channel infusers after abuse (fluid residue on lenses, tubing obstructing lenses, etc.).
Air Sensor Mechanism Robustness	The air sensors functioned properly under different power configurations, after alarm and malfunction occurrences and after abuse.
Sensitivity to Ambient Light	The internal pump sensors were not sensitive to normal ambient light, indoors or outdoors.
Thermal Robustness	The cooling fan did not exhibit any intermittent cycling behavior at any ambient temperature. Abuse of the ventilation system of the pump did not result in any cooling problems.

Summary

The Symbiq infusion device is expected to be highly reliable and has conducted testing at the system and subsystem level to demonstrate expected reliability prior to market introduction. Reliability testing completed to date indicates that the Symbiq system design should be highly reliable. Monitoring of the system and subsystem performance will not end when the product is introduced. Critical to Quality Parameters have been established for third-party vendors and are also being monitored to assure consistent quality and performance. In addition, life testing, extended-use testing and abuse testing have been conducted and the results of this testing indicates that the Symbiq infusion system should be a very reliable device.