

Next Generation Medical Infusion Pump

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This case study summarizes the systems engineering aspects of the next-generation Symbiq™ IV (intravenous) medical pump development. Symbiq™ was developed by Hospira Inc. and documented in detail in Chapter 5 of the National Research Council book, *Human-System Integration in the System Development Process*. As described in the book, Symbiq™'s purpose was "to deliver liquid medications, nutrients, blood and other solutions at programmed flow rates, volumes and time intervals via intravenous and other routes to a patient, primarily for hospital use with secondary limited feature use by patients at home" (Pew 2007).



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Domain Background

This case study provides insight into the use of systems engineering practices in a medical application.

Case Study Background

The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

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Case Study Description

In creating a next-generation product, Hospira proposed to introduce new IV pump features, such as:

- multi-channel vs. single-channel liquid delivery;
- the ability to group multi-channeled devices together;
- associated user-programming capabilities and programmable drug libraries for specifying parallel delivery of liquids;
- use of color touchscreen devices;
- integration with numerous types of hospital information systems;
- ease of use for both medical personnel and patients at home;
- handling of potential hardware, software, and human-user faults;
- compliance with U.S. and international safety standards;
- use of alternating-current or battery power; and
- the ability to be cost-competitive and attractive to traditional medical and hospital administration personnel.

Many of these features are highly coupled, such as the

multi-channel hardware controls, concurrent software synchronization, distinctive displays and alarms for multi-channel devices, and rigorous medical safety standards.

Views of the resulting medical infusion pump can be found as Figures 5-5 and 5-6 in Chapter 5, page 107 of the Pew and Mavor (2007) book. Systems engineering for the device involved a great deal of concurrent analysis and engineering of its hardware, software, human factors, operational, business, and safety aspects. It has been a commercial success and won the 2006 Human Factors and Ergonomics Society's User-Centered Product Design Award and the 2007 Medical Design Excellence Award.

Not only were there numerous technical challenges in the development of Symbiq™, but there were also challenges in the systems engineering of a product with a life-cycle operational concept that would produce satisfactory outcomes for a wide variety of product and operational stakeholders whose value propositions were often in some conflict. Some stakeholders wanted numerous features that would require a complex user interface, while others wanted a simple and easy to learn interface. Some users wanted the most advanced color touchscreen displays available, while others wanted a simpler, less-expensive product that was harder to misuse due to inadvertent screen commands. Some organizations felt that a minimal interpretation of the required safety features would be acceptable, while others advocated ultrahigh assurance levels. Some marketing personnel wanted a quick development and fielding of the basic product to capture market share, while maintainers wanted initial built-in life cycle support, maintenance, and diagnostic capabilities.

In such situations, many organizations focus on making quick requirement decisions and rapidly proceed into development. However, Hospira's understanding of the uncertainties and risks caused them to pursue a risk-driven, incremental commitment course of buying information to reduce risk, as emphasized in the SEBoK Part 3 knowledge area on Risk Management. As described in Pew and Mavor (2007), Hospira used a version of the Incremental Commitment Spiral Model (ICSM) summarized in the SEBoK Part 3 Knowledge Area on representative systems engineering process models. The following sections describe the project's incremental system definition progress through the ICSM exploration, valuation, foundations, and Development phases. Some evolution of terminology has

occurred, the Pew and Mavor (2007) version uses ICM instead of ICSM and "architecting phase" instead of "foundations phase".

Symbiq™ Exploration Phase Summary

In the exploration phase, the project carried out numerous analyses on stakeholder needs, technical opportunities, and business competition. Using these analyses, the project team determined ranges of preferred options. Stakeholder needs analyses included contextual inquiry via shadowing of nurses using IV pumps and followup interviews, as well as creating task flow diagrams, use environment analyses, and user profiles analyses. Technical opportunity analyses included initial conceptual designs of multi-channel pump configurations, evaluation of commercially available single-color and multicolor display devices with touchscreen capabilities, and software approaches for specifying multi-channel delivery options and synchronizing concurrent processes.

Business competition analyses included hiring a management and marketing planning firm to examine next-generation pump competitor strengths and weaknesses with respect to such capabilities as the number of pump channels, therapies, programming options, air-in-line management, battery and alternating current capabilities, biomedical domain expertise, and alarms. Several key competitive advantages of a next-generation pump were identified, such as the ability to read bar-codes, small size, light weight, stand-alone functional channels, an extensive drug library, a high level of reliability, and clear mapping of screen displays and pumping channels.

Market research and market segment analyses also identified market windows, pricing alternatives, hospital purchasing decision-making trends, and safety aspects. These were iterated by focus groups of key thought leaders in critical care. The results were factored into a product concept plan, cost analysis, and business case analysis. These were independently reviewed by experts as part of the ICSM Valuation Phase Commitment Review process, which resulted in a go-ahead decision with an identification of several risks to be managed.

Symbiq™ Valuation Phase Summary

The valuation phase focused on the major risks

highlighted in the Valuation Commitment Review, such as the multi-channel pump options, the types of programmable therapies, the need for tailorable medication libraries, the display screen and user interface options, and the safety considerations. The valuation phase also elaborated the product concept plan for the most attractive general set of options, including a development plan and operations plan, along with an associated cost analysis, risk analysis, and business case for review at the Foundations Commitment Review.

The multi-channel pump options were explored via several hardware industrial design mockups and early usability tests of the mockups. These included evaluation of such desired capabilities as semi-automatic cassette loading, special pole-mounting hardware, stacking of and total number of channels, and tubing management features. The evaluations led to the overall all choice to use a semi-automatic cassette loading capability with a red-yellow-green LED display to indicate concerns with the loading mechanism and with the pump in general.

Field exercises with prototypes of the pole mountings indicated the need for quick release and activation mechanisms, which were subsequently implemented. Risk analyses of alternative stacking mechanisms and the potential number of channels available established a preference for side-by-side stacking, a decision to develop one and two channel units, and to support a maximum of four channels in a stacked configuration.

The types of programmable therapies considered included continuous delivery for a specified time period, patient weight-based dosing, piggyback or alternating delivery between the two channels, tapered or ramped-rate delivery, intermittent-interval delivery, variable-time delivery, and multistep delivery. These were evaluated via prototyping of the software on a simulated version of the pump complexes and were iterated until satisfactory versions were found.

Evaluation of the tailorable medication libraries addressed the issue that different hard and soft safety limits were needed for dosages in different care settings (e.g., emergency room, intensive care, oncology, pediatric care, etc.) which creates a need for hospitals to program their own soft limits (overridable by nurses with permission codes) and hard limits (no overrides permitted). Stakeholder satisfaction with the tailoring features was achieved via prototype exercises and iteration with representative hospital personnel.

A literature review was conducted to determine the relative advantages and disadvantages of leading input and display technologies, including cost and reliability data. After down-selecting to three leading vendors of touch screen color LCD displays and further investigating their costs and capabilities, a business risk analysis focused on the trade offs between larger displays and customer interest in small-footprint IV pumps. The larger display was selected based on better readability features and the reduced risk of accidental user entries since the larger screen buttons would help to avoid these occurrences. Extensive usability prototyping was done with hardware mockups and embedded software that delivered simulated animated graphic user interface (GUI) displays to a touchscreen interface that was integrated into the hardware case.

The safety risk analysis in the valuation phase followed ISO 14971:2000 standards for medical device design, focusing on Failure Modes and Effects Analyses (FMEAs). This analysis was based on the early high-level design, such as entry of excessive drug doses or misuse of soft safety limit overrides. Subsequent-phase FMEAs would elaborate this analysis, based on the more detailed designs and implementations.

As in the exploration phase, the results of the valuation phase analyses, plans, budgets for the succeeding phases, the resulting revised business case, evidence of solution feasibility, and remaining risks with their risk management plans were reviewed by independent experts and the ICSM Foundations Commitment Review was passed, subject to a few risk level and risk management adjustments.

Symbiq™ Foundations Phase Summary

During the foundations phase, considerable effort was focused on addressing the identified risks such as the need for prototyping the full range of GUI usage by the full range of targeted users, including doctors, home patients, the need for interoperability of the Symbiq™ software with the wide variety of available hospital information systems, and the need for fully detailed FMEAs and other safety analyses. Comparable added effort went into detailed planning for development, production, operations, and support, providing more accurate inputs for business case analyses.

GUI prototyping was done with a set of usability objectives, such as

- 90% of experienced nurses will be able to insert the cassette the first time while receiving minimal training;
- 99% will be able to correct any insertion errors;
- 90% of first time users with no training will be able to power the pump off when directed; and
- 80% of patient users would rate the overall ease of use of the IV pump three or higher on a five-point scale (with five being the easiest to use).

Similar extensive evaluations were done on the efficacy and acceptability of the audio alarms, including the use of a patient and intensive care unit simulator that included other medical devices that produced noises, as well as other distractions such as ringing telephones. These evaluations were used to enable adjustment of the alarms and to make the visual displays easier to understand.

Software interoperability risk management involved extensive testing of representative interaction scenarios between the Symbiq™ software and a representative set of hospital information systems. These resulted in several adjustments to the software interoperability architecture. Also, as the product was being developed as a platform for the next generation of infusion pump products, the software design was analyzed for overspecialization to the initial product, resulting in several revisions. Similar analyses and revisions were performed for the hardware design.

As the design was refined into complete build-to specifications for the hardware and the operational software, the safety analyses were elaborated into complete FMEAs of the detailed designs. These picked up several potential safety issues, particularly involving the off-nominal usage scenarios, but overall confirmed a high assurance level for the safety of the product design. However, the safety risk assessment recommended a risk management plan for the development phase to include continued FMEAs, thorough off-nominal testing of the developing product's hardware and software, and extensive beta-testing of the product at representative hospitals prior to a full release.

This plan and the other development and operations phase plans, product feasibility evidence, and business case analysis updates were reviewed at a Development Commitment Review, which resulted in a commitment to proceed into the development phase.

Symbiq™ Development Phase Systems Engineering Summary

The development phase was primarily concerned with building and testing the hardware and software to the build-to specifications, but continued to have an active systems engineering function to support change management; operations, production, and support planning and preparation; and further safety assurance activities as recommended in the risk management plan for the phase.

For hospital beta-testing, thoroughly bench-tested and working beta versions of the IV pump were deployed in two hospital settings. The hospitals programmed drug libraries for at least two clinical care areas. The devices were used for about four weeks. Surveys and interviews were conducted with the users to capture their “real world” experiences with the pump. Data from the pump usage and interaction memory was also analyzed and compared to the original doctors’ orders. The beta tests revealed a number of opportunities to make improvements, including revision of the more annoying alarm melodies and the data entry methods for entering units of medication delivery time in hours or minutes.

Usability testing was also conducted on one of the sets of abbreviated instructions called TIPS cards. These cards serve as reminders for how to complete the most critical tasks. Numerous suggestions for improvement in the TIPS cards themselves, as well as the user interface, came from this work, including how to reset the “Air-in-Line” alarm and how to check all on-screen help text for accuracy.

The above mentioned usability objectives were used as acceptance criteria for the validation usability tests. These objectives were met. For example, the calculated task completion accuracy was 99.66% for all tasks for first time nurse users with minimal training. There were a few minor usability problems uncovered that were subsequently fixed without major changes to the GUI or effects on critical safety related tasks.

The risk analysis was iterated and revised as the product development matured. FMEAs were updated for safety critical risks associated with three product areas: the user interface, the mechanical and electrical subsystems, and the product manufacturing process. Some detailed implementation problems were found and fixed, but overall the risk of continuing into full-scale production, operations, and support was minimal. Systems

engineering continued into the operations phase, primarily to address customer change requests and problem reports, and to participate in planning for a broader product line of IV pumps.

Overall, customer satisfaction, sales, and profits from the Symbiq™ IV pump have been strong and satisfaction levels from the management, financial, customer, end user, developer, maintainer, regulatory, and medical-community stakeholders have been quite high (Pew 2007).

Summary

In summary, the Symbiq™ Medical Infusion Pump Case Study provides an example of the use of the systems engineering practices discussed in the SEBoK. As appropriate for a next-generation, advanced technology product, it has a strong focus on risk management, but also illustrates the principles of synthesis, holism, dynamic behavior, adaptiveness, systems approach, progressive entropy reduction, and progressive stakeholder satisfying discussed in Part 2 of the SEBoK. It provides an example of an evolutionary and concurrent systems engineering process, such as the incremental commitment spiral process, and of other knowledge areas discussed in SEBoK Parts 3 and 4, such as system definition, system realization, system engineering management, and specialty engineering.

References

Works Cited

Pew, R. and A. Mavor. 2007. *Human-System Integration in the System Development Process: A New Look*. Washington, DC, USA: The National Academies Press.

Primary References

None.

Additional References

None.

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