Design Decision Support System toward Environmental Sustainability in Reusable Medical Equipment

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Abstract
Related to the recent issues on the environmental sustainability, the attention and importance of Reusable Medical Equipment (RME) has increased rapidly. As a part of System Redesign Project funded by Veterans Engineering Resource Center (VERC), “Design Evaluation for Reusable Medical Equipment” project has been conducted. This research project aims to develop new RME design assessment and evaluation framework and Design for Reusability (DFR) and Design for Sustainability (DFS) principles. In this paper, we will present a decision support system for RME design evaluation, based on DFR and DFS principles. To illustrate the proposed new framework, GI endoscope is used in this research. In the proposed system, we apply a Rough Set Theory to identify the relationships among design and reprocessing features. Also we use feature selection technique to select the customized features from the design features and reprocessing features to be used for design evaluation.

Introduction
Reprocessing of reusable medical equipment has been a great concern of manufacturers and medical organizations due to the environmental impacts and associated costs (Favero 2001). Related to the recent issues on the environmental sustainability, the attention and importance of Reusable Medical Equipment (RME) has increased rapidly. While the reprocessing tasks have the potential risk to trap bio-burden and debris, the processes of cleaning, disinfection and sterilization are critical considerations. Research results and reports identify that design configurations of medical equipment are interrelated to the risk to trap bio-burden and debris. The infection risk by RME is not only caused by failures in the sterilization process, but also caused by the lack of understanding of design characteristics. (Hogan & Colonna 1998; Chu, McAlister, & Antonoplos 1998) However, the current sterilization methods have been developed rarely or without considering critical factors with respect to design characteristics. As a result, optimized cleaning, disinfection, and sterilization processes cannot be expected by using the traditional methods.

As a part of System Redesign Project funded by Veterans Engineering Resource Center (VERC), “Design Evaluation for Reusable Medical Equipment” project has been conducted. This research project aims to develop new RME design assessment and evaluation framework and Design for Reusability (DFR) and Design for Sustainability (DFS) principles. In this paper, we will present a decision support system, which has been supported by this project, for RME design evaluation, based on DFR and DFS principles. To illustrate the proposed new framework, endoscope is used in this research. Because endoscopes are expensive and used for the serious diseases, such as gastric and colorectal cancers, the reprocessing procedure for endoscope is the one of critical decision-making issues in the medical organizations. In addition to the cost and usage issues, the complexity of design is another critical factor. An endoscope consists of insertion tube system, air, water, and suction systems, and illumination system, and each system is composed into very complicated subcomponents. In order to reprocess the endoscope, the reprocessing task requires significant resources, such as chemical materials and energy-consuming cleaning time.

To develop a design decision support system and to achieve environment sustainability for RME design, the product and process characteristics and associated requirements of ever-changing equipment design should be converted into the knowledge of design decision-making process. In the proposed system, we apply a Rough Set Theory to identify the relationships among design and reprocessing features. Second, using feature selection technique, we select the customized items from the design items and reprocessing items to be used for design evaluation. Because all designs of RME have their own objectives, usage intentions, and reprocessing procedures, they need to have their own customized design evaluation items. Then, we calculate the level of sustainability using the selected reprocessing and design items. Finally, the system provides the test result of the new design in the perspective of the level of sustainability to designers. Because this level of sustainability comes from the selected design and reprocessing items, the designers can improve
their design with the obtained level-of-sustainability result as the design decision reference.

Reusable Medical Equipment

RME is defined in the report of Department of Veterans Affairs as followed:

“RME is any medical equipment designed by the manufacturer to be reused for multiple patients. All RME must be accompanied by reprocessing instructions provided by the manufacturer.”

The importance of reprocessing RME is addressed in this definition and has the possibility of raising potential problems such as reprocessing costs and risks.

Disinfection and Sterilization of RME in the Cost Perspective

Disinfection and sterilization are critical procedures to reuse RME in medical organizations, since the failure of these procedures can lead to the serious problems such as secondary infections to other patients. Moreover, the reprocessing processes for disinfection and sterilization are connected to the time costs as well as economic costs. Several research efforts have been conducted to stress the importance of reprocessing processes in the economic and time cost perspectives. Sopwith, Hart, and Garner (2002) conducted about disinfection with alcohol to find best practice. They analyzed the effectiveness of it with time cost. Rutala and Weber (2004) addressed that the critical level of treated items could decide the cleaning process and time. Nanta et al. (2005) analyzed the costs of single-use disposable suction tubes and recycling of disposable tubes. Raltz et al. (1995) provided the proper number of reusable uses through the cost analysis.

Risk of Reprocessing Reusable Medical Equipment

Although the failure of conducting reprocessing processes cannot be accepted, the outbreaks of contamination for infections transmitted by RME are often reported. For example, the sources of contamination for infections (36 outbreaks) transmitted by the gastrointestinal endoscopes from 1974-2001 were Cleaning-3 (12%), Disinfection-19 (73%), Rinse, Dry, Store-3 (12%), and Etiology unknown-1 (3%). More than 96 percent of the sources come from the failure of reprocessing processes. Also the medical agencies such as FDA, CDC (Centers for Disease Control and Prevention), and VA (Department of Veterans Affairs) acknowledge the risks of improper reprocessing (BS&S Feature 2010). In the case of endoscope, known errors that have occurred during reprocessing of flexible endoscopic equipment include the improper reprocessing intervals for reusable endoscopy accessories.

Endoscope as Reusable Medical Equipment

Endoscope is lighted optical equipment used to get a deep look inside the body and examine organs such as the throat or esophagus. Since the endoscopes are developed depending on their specialized purposes and usage, types of endoscope are various. Most of the endoscopes consist of reusable main parts, single or re-used sub parts, and single used accessories. This complex configuration leads to more reprocessing procedures, more time cost, and more economic costs. Surface materials of the parts and the part connection types are also important in the reprocessing process of endoscopes. In this paper, Gastrointestinal (GI) Endoscope is considered as an example of RME. Screenshot and configuration example is shown below: Figure 1(a) and Figure 1(b).

Design for Sustainability in Product Perspectives

The concept of design for sustainability (DFS) in the product development domain is often used as the similar meaning of design for environment or design for life cycle. The objective of DFS is to design a product with minimum negative environmental impact throughout its whole product life cycle (Chiu 2007). Ljungberg (2006) provided the guidelines for sustainable products with ten items. In his guideline, he ad-
dressed that reducing the emissions, dispersion and creation of toxic elements during its lifetime is important. From this view, determining whether the developed RME is sustainable or not based on the relationship with the reprocessing process is important procedure to the RME designers. Howarth and Hadfield (2006) developed a model for product designers to review the product sustainability in the detail design phase. They provided the set of guidelines for helping sustainable product development to consider each element during life cycle.

**Framework of the System**

**Overall Framework**
The main purpose of this system is to help medical equipment designers to develop more sustainable devices. To do this, this system framework consists of following components: 1) designers as user group; 2) product design database; 3) sustainability knowledgebase, and result report with level of sustainability (See Figure 3.).

The system components are explained below:

**Designers as User Group.** To evaluate how the developing RME is sustainable, the characteristics of RME as a physical product are needed. The user group of system has the ability to input those characteristics. Therefore, RME product designers will be the proper user group of this system.

**Product Design Database.** Product design database has the design features of same or similar RME that are already established. Shape, material, and assembly feature can be examples of data elements.

**Sustainability Knowledge-base.** In this system, sustainability knowledge-base includes sustainability related information and knowledge that should be considered during RME reprocessing process. For instance, ingredients of detergent for sterilization and disinfection, economic costs, and non-economic costs such as reprocessing time.

**AI Engine.** AI Engine has three steps due to the complexity of RME development. The first step is to select feature for RME in the view of level of sustainability. Since RME (such as endoscopes) includes the complex equipment with many accessories, the elements to consider increase. Since the designers have difficulties to access all the needed information and the importance of the information are different, it is critical to select proper features.

**Level of Sustainability.** Level of sustainability means the way of providing the final results in this system. This system provides the level of development feasibility in the perspective of sustainability into three classes, i.e., highly feasible to develop, revision-needed to develop, and impossible to develop.

**Data**
The needed dataset for the system is consisted of three parts: 1) design feature, 2) reprocessing feature, and 3) result feature (Figure 4).

**Design feature.** We gather data for design features from the product design specification document (PDS). Also, it includes various design related data, e.g., the number of parts and accessories, the way of connection, material, surface treatment method, and so on.

**Reprocessing feature.** Reprocessing features include the data elements related to reprocessing process for reusing RME. Since reprocessing features can be gathered from the reprocessing process experts or RME manufacturers, not the product designers, those should be stored in the knowledge-base as datasets, cases, or any other knowledge forms.

**Result feature.** Result feature means the level of sustainability mentioned earlier. A classification into the three types of feasibility is provided as the result with the perspective of level of sustainability.

**Implementation Procedure of the System**
For the purpose of this work, we developed a formal approach that includes pattern recognition, feature selection with similarity, and rough set-based reasoning.

The procedure for implementing the system is shown in Figure 5. This figure illustrates detailed steps of the formal approach.
Discussion

Potential Obstacles

To implement the system for the project, some potential obstacles exist. One is that design feature data objects collection of the newly introduced RME design will be difficult to apply proposed procedure; it is because the universal data object does not have the new design features. For example, if the system developed for standard flexible GI endoscopes, it is difficult to treat the cases of the innovative endoscopes (such as capsule type endoscopes). Another potential difficulty is on the usage characteristics of RME. Since most of medical equipment is used for human body, it is critical to follow the proper reprocessing process. As the result of this system for development feasibility is based on the level of sustainability alone, the recommended reprocessing processes should be confirmed by reprocessing experts. These obstacles can be the topics of further research.

Further Research

To overcome the potential obstacles mentioned above and to meet the perspective of funding VERC project, some further research issues are remained. In this paper, the relationship between data features and reprocessing features are extracted by the matching effort based on the previous relationships. While reprocessing processing features are almost fixed, design features are very flexible. Therefore, research effort for relationship generation is needed, e.g., Design Structure Matrix (DSM) analysis about RME design features and reprocessing process features. Another further research topic is to give a weight to each reprocessing process data attribute. From the various perspectives of manufacturers, the recommended reprocessing process can be various and also from the difference of the strengths of manufacturers, the weight of each process can be different. Last, output data attributes should be more detail attributes for the later system. In addition to development feasibility based on level of sustainability, more attributes, e.g., functionality, use context, etc., are helpful to the designers for RME design process.

Conclusion

In this paper, we proposed a conceptual framework of design decision support system to determine the level of sustainability of RME. In this framework, Rough Set Theory is used to identify the relationships among design and reprocessing features. Using feature selection technique, the customized features from the design and reprocessing features are used for design evaluation. The anticipated outcome of the design support system is RME design feasibility analysis using the level of sustainability, based on the selected reprocessing and design features.

References

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