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Preliminary Hazard Analysis for a Hyperbaric Oxygen Chamber

고압 산소 치료기에 대한 예비위험분석

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Abstract

Reduction of risk plays a pivotal role in the development of medical instruments. A hyperbaric oxygen chamber, as a medical device, is known to help medical therapy for diversity of diseases through provision of high purity oxygen. The use of hyperbaric oxygen is expected to increase in the future and study to rigorously examine reliability and safety is needed. We have performed risk assessment for a newly developed hyperbaric oxygen chamber in this study. We first briefly discussed the system structure and concept of risk assessment for the study. Based on the hazards identified, we performed preliminary hazard analysis for the chamber.

Keywords : *risk, hyperbaric oxygen chamber, preliminary hazard analysis*
키워드 : *위험(도), 고압산소치료기, 예비위험분석*

1. 서론

Securing reliability and safety should be an important concern for medical devices as well as usual industrial products. Efforts to eliminate or reduce risk should be one of the top priorities for development of a reliable medical device. Hyperbaric oxygen chamber is a health/medical device which helps medical therapy by delivering high pressure purity oxygen into a human body and is known to used for diversity of diseases including cardiovascular diseases, myocardial infarction diabetes mellitus, cytothesis expedition etc[1]. More discussion about the hyperbaric oxygen chamber and its effects are given in the literature [2]~[4]. Recent trend indicates that wider and more frequent applications of hyperbaric oxygen chamber are expected and study concerning the reliability and safety of the chamber should be performed. Nam et al[5]. drew 5 performance and 5 safety evaluation items hyperbaric chamber, then presented test methods for each.

In this study, we present a risk assessment, especially PHA(preliminary hazard analysis) for a newly developed hyperbaric oxygen chamber. Specific attention has been put to identify possible hazards and to assess the significance of each in terms of risk. As known, risk may be defined by two elements the probability of a hazardous event and the severity of the

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consequences from that hazardous event. We first briefly review the proposed oxygen chamber, then discuss risk in terms of the probability and the severity of hazard events. For the chamber being considered in this study, we drew possible hazards and evaluate severity of risk for each. The results obtained from this study will serve a good basis for more reliable and safe product development.

2. Hyperbaric Oxygen Chamber and PHA

2.1 Hyperbaric Oxygen Chamber

Hyperbaric oxygen chamber keeps therapy effect through delivery of 1.5-3 times higher level of oxygen than atmospheric pressure into the cells of the human body and thus removal of bodywastes and suppress active oxygen. Many companies have developed diversity of chambers but most of them have the common shape, bed-type. Figure 1 depicts an existing bed-type chamber.

Figure 1 Existing Oxygen Chamber

A new seat-type chamber has been proposed in this research. As can be seen in Figure 2, it is designed for a patient easily to get in and out with minimal assist.

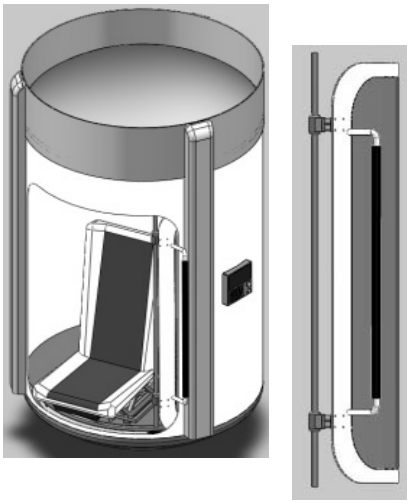
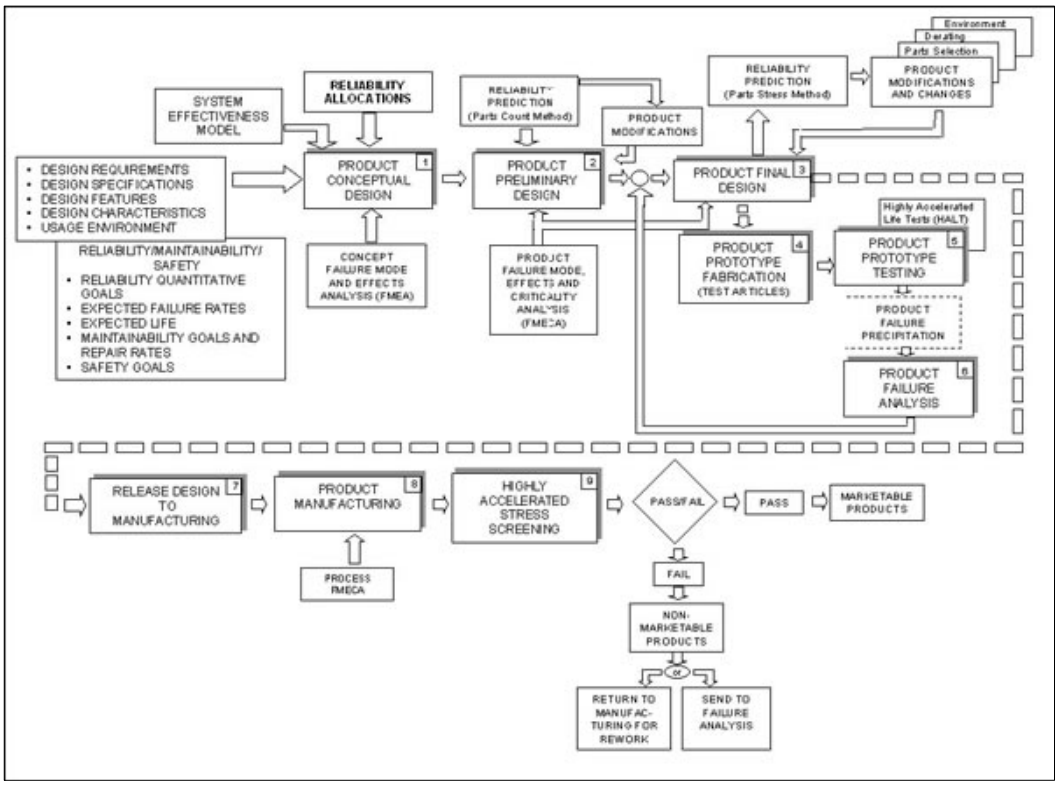


Figure 2 Proposed Oxygen Chamber

2.2 Preliminary Hazard Analysis

Reliability and safety should be fully considered throughout the product development phases - conceptual, preliminary, and final design. Figure 3 depicts the major reliability activities with regard to the development phases. Recent customers ask manufacturers to provide validated reliability data obtained from systematic approach. As seen in the figure, safety analysis as well as other reliability methods, reliability test (qualification test, accelerated test, HALT etc.), structure and fatigue test, and system reliability prediction should form an important step.

Safety is significantly important in the development medical instrument. Safety is partially obtained by risk assessment. As an undesirable result, risk may be defined by two elements - the probability of a hazardous event and the severity of the consequences from that hazardous event. PHA[6] is a qualitative analysis method usually performed in the early stages of product development. The purposes of this method are to identify hazards and to establish measures to treat hazards. PHA is performed by the following steps.



* source: www.theri ac.org

Figure 3 Reliability and Safety Activities through Product Development Phases

1) identification of hazards
2) determination of cause and effects of hazards
3) determination of the possibility that a hazard will be an accident
4) establishment of appropriate measures to get rid of the hazards

Figure 4 depicts the core part, risk as a function of these two variables. From this figure, risk may seen to be classified into 3 regions, broadly acceptable region, ALARP (as low as reasonably practical), and intolerable region.

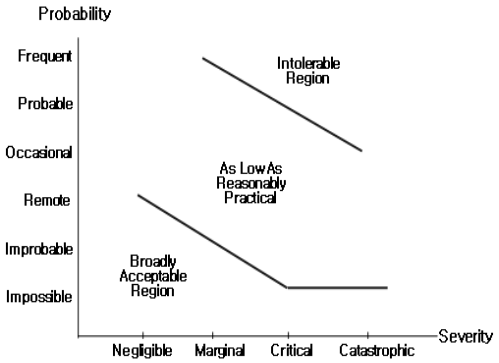


Figure 4 Risk Probability Regions

Table 1 and 2 show classifications of degree of severity and probability of occurrences with consequences. The letters, I through VI represent the symbols for degree and will be used in this research.

Table 1 Severity Levels and Consequences

Severity Level	Symbol	Consequence
Catastrophic	I	May result in serious injury or death
Critical/ Major	II	May result in some injury, exposure to harmful chemicals, or fire etc.
Marginal	III	May result in minor injury
Negligible	IV	May result in system damage or very minor or no injury

Table 2 Probability of Occurrence and Consequences

Prob. of Occurr-ence	Symbol	Consequence
Frequent	I	Likely to occur often
Probable	II	Likely to occur several times during device life time
Occasion-al	III	Likely to occur sometime during device life time
Remote	IV	Unlikely to occur, but possible
Improb-able	V	Almost indistinguishable from zero occurrence
Imposs-ible	VI	Zero occurrence

Risk within the intolerable region is generally considered as bad and an action to reduce the probability of occurrence and/or the severity should be called. For the region of ALARP, we need to reduce the risk as much as we can under constraint of cost and other considerations. For the risks within the broadly acceptable region, fair reason may be applied for reduction. Further discussion is given in the reference[6].

3. Risk Assessment for the Chamber

We are now to perform PHA for the hyperbaric oxygen chamber given in section 2. As discussed, PHA is performed at very early stages of product development and is initiated from identification of hazards. We drew possible hazards of the proposed chamber and assessed risks. The results are summarized in Table 3. The category column in the table shows the result of severity and consequence combination for each hazard and the associated regions, ALARP and BAR (broadly acceptable region). Decisions for these classifications were based on the discussion of the analyst and chamber experts in the company. Appropriate measure is followed in the last column. Figure 5 further helps visual display for the results.

Our results indicate that seven out of eight hazards are drawn within the region of ALARP and one lies in BAR in terms of risk probability region. This is seen from the plot of the category points in the (severity, probability) plane and represents that the identified hazards seem not to cause serious danger in terms of risk indicating that the proposed chamber is reasonably safe even if some corrective measures should be employed for a safer device. Furthermore, a lot of other reliability properties should also be involved in the analysis. Incorporation of reliability study into risk assessment will generate more reliable chamber. We, however, considered risk elements only in this study

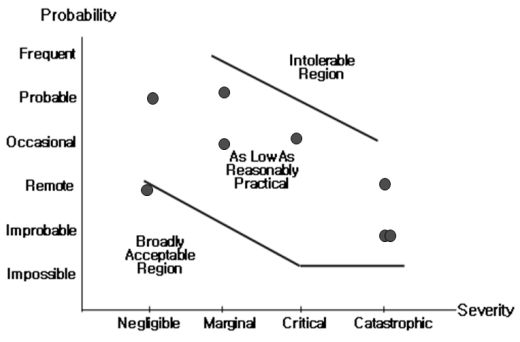


Figure 5 Results for the Analysis

Table 3 Preliminary Hazard Analysis of the Chamber

Hazard	Description	Possible Cause	Effect	Category (severity, probability) Region	Corrective/ Preventive Measures
Hydraulic Pressure	high O2 pressure within the chamber	- controller failure - compressor malfunction	- physical injury to the patient - safety problem	(Ⅱ, Ⅲ) ALARP	- reestablish controller and compressor specifications
Mechanical	slide rail lock or malfunction	- wheel broken - rail bending - bad adjustment between chair wheel and rail	- patient mental shock or stress - patient fall from the chair	(Ⅲ, Ⅱ) ALARP	- check material of the rail - redesign and specification recheck
Mechanical	chair malfunction	- bad design or manufacturing - part broken	- patient mental stress - patient lock or injury	(Ⅳ, Ⅱ) ALARP	- chair redesign
Mechanical	door won't open completely	- wire get tangled - door motor failure - door open switch failure	- patient lock - patient mental stress	(Ⅲ, Ⅲ) ALARP	- emergency call button - emergency handle
Mechanical	emergency handle malfunction	- failure due to bad design or manufacturing	- patient lock and flustered - safety problem to the patient	(Ⅰ, Ⅳ) ALARP	- redesign or remanufacturing
Electrical	electric shock	- electric leakage	- severe safety problem to the patient	(Ⅰ, Ⅴ) ALARP	- redesign - earth leakage circuit breaker
Fire	fire within the chamber	- electric leakage - over current	- severe safety problem to the patient	(Ⅰ, Ⅴ) ALARP	- design review - emergency fire extinguish equipment
Temperature	high temperature within the chamber	- controller failure - compressor malfunction	- mental/ physical stress to the patient	(Ⅳ, Ⅳ) BAR*	- reestablish controller and compressor specifications - emergency call button

* BAR - broadly acceptable region

4. Conclusion

In this study, we have performed PHA for a newly developed hyperbaric oxygen chamber. Specific attention has been put to identify hazards and severity of each hazard event has been figured out. As known, reliability and safety analysis should be secured from the beginning stage of product development process. Incorporation of the results in this study with other reliability analysis, reliability prediction [7] may form a good future research.

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