DESIGN CRITERIA AND EXTREME CONDITIONS

Narender P. Reddy

Department of Biomedical Engineering, University of Akron, Akron, OH, USA.
Email: npreddy@uakron.edu

Design defects due to inadequate requirements present a major problem in numerous industries. Inadequate requirements often result from a lack of consideration to extreme conditions. In addition, lack of an interdisciplinary and multidisciplinary approach may be a major factor leading to inadequate requirements related to extreme conditions. Inadequate requirements have been documented in the software industry. However, impact of extreme conditions and inadequacy of requirements has not been explored in other disciplines. The purpose of the present paper is to present the need for the consideration of extreme conditions and the need for avoiding inadequate requirements with examples from different disciplines including medical devices and the design of decision support systems.

Keywords: Inadequate requirements, Design defect, Product liability.

1. INTRODUCTION

Design defects constitute a major portion of product failures and the associated product liability cases in numerous disciplines ranging from transportation (aircraft, automobile, space) industry to software, and medical device industry. Certain design defects are often difficult to detect. Defects usually result from the inadequacy of the design to meet the design requirements. However, if the requirements are inadequate, the design is bound to be defective, eventually leading to product failure. Inadequate requirements may be the result of not identifying the functional requirements, user interface/human factors considerations, and failure to identify the multidimensional forces/interactions experienced by the product etc. Often, inadequate requirements result from the lack of consideration, from interdisciplinary/multidisciplinary points of view, of the extreme operating conditions the product experiences. The purpose of the present paper is to bring awareness of the importance of the need for consideration of the extreme conditions by discussing several case studies of product failure.

Lack of consideration to extreme conditions when identifying the requirements is a major problem in numerous disciplines including aerospace, medicine, facilities design, software industry, decision support systems, and facilities design etc. Recently in 2009, a marriage platform (stage), erected for the wedding of the daughter of a minister of Andhra Pradesh state (India), collapsed while the marriage was going on, much to the embarrassment of the minister. The company erected similar platforms in numerous other weddings but none of them collapsed. Usually, there are twenty people on the stage. However, several political VIPs felt their importance and did not leave the stage. Approximately, sixty to seventy people were on the stage which eventually led to the collapse. In South America, in a brand new hospital, several patients in the intensive care unit were dying in each weekend. It was discovered that due to the lack of a sufficient number of electrical outlets, the janitor was disconnecting the respirator machine from the outlet and was connecting the vacuum cleaning machine into the outlet. In the area of consumer products, the case of McDonalds's coffee is well known. An 82 year old lady accidentally spilled McDonald coffee and got a third degree burn. It was discovered that the company

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was serving coffee at 180° F. Although this temperature is permissible to the tissues of the mouth and the throat, it can damage the skin. This led to two million dollar settlement. Clearly, the designer did not consider accidental spilling on the delicate skin.

The NASA space shuttle challenger disaster occurred in 1986. The shuttle broke apart in 73 seconds into flight causing the death of all the seven astronauts. A vacuum seal failure was sighted as the cause of the disaster. The O-ring seal in ihe right solid rocket booster failed at lift-off. Later it was discovered that the design criteria did not take into account the extreme weather (temperature) conditions. The seal lost its flexibility at low temperature. Due to the loss of flexibility, the seal was not effective, and gases from within the solid rocket motor reached the outside causing bursting. Moreover, there was no escape path for the crew [1, 2]. In 2003, space shuttle Columbia was destroyed during re-entry. It was later discovered that during lift off, a piece of foam separated from the shuttle's external tank. This debris struck the leading edge of the left wing causing significant damage to the shuttle's thermal protection system. These two cases represent a lack of consideration to extreme conditions and gross inadequacy of requirements. On February 12, 2009, Continental Airline's Colgan air flight 3407 crashed in Buffalo, killing all 49 passengers. Inadequate FAA pilot training requirements have been cited as the cause of the crash. The above examples are well known general cases. Let us examine the inadequacy of requirements in medical devices, software and other disciplines.

2. INADEQUATE REQUIREMENTS, EXTREME CONDITIONS AND MEDICAL DEVICES

Safety is the most important consideration in the design of medical devices. While the cost benefit ratio may be a major consideration in the design of non medical devices, the major consideration in the design of medical devices it the risk-benefit ratio. If the risk associated with a medical device outweighs the benefit, then the device has no place in the market. Let us assume that by using an alternate method of treatment (say surgical treatment) for a certain medical condition there are three deaths in a thousand patients. Let us assume that treatment with a new medical device is noninvasive, does not require surgery, but it causes ten deaths in a thousand patients. Then, the new medical device has no place in the market as the risk associated with the new device is larger than the risk associated with the alternate treatment available; The manufacturer is liable for the failure of the device. Safety and adequacy of the device depends on the adequacy of the requirements. Therefore, it is very important to identify all the associated requirements in detail. Let us examine some cases of medical device failures due to inadequate requirements and the lack of consideration to extreme conditions.

The 1998 Dow-Corning breast implant case is well known and almost would have made the company bankrupt. Dow-Corning breast implants are made of silicone. Silicone has been known to be inert and is accepted as a biomaterial. It appears that the company used to test each batch for toxicity and biocompatibility. However, the company did not appear to have examined the long term effects of the breast implants. In the long term (e.g. 10 to 20 years of implantation) the implants led to breast cancer in numerous patients. It is a well known fact that for any tissue implant, particles from implant degradation enter the lymphatic system. The lymphatic system is essentially a drainage system of the human body [3]. Lymph nodes located along the lymphatic vessels act as filters to filter the particles and return the rest of the fluid to the blood circulation. Also, it is well known that lymph node is a germinal center for the immune system. Recent studies on the aging of silicone breast implants (implanted earlier from 1975–1985) have suggested that the silicone implants may undergo disintegration with migration of low molecular weight silicone and linear chain polymer material [4–6] Therefore, it is not surprising that long term accumulation of silicone (implant).particles could have compromised the immune system or could have led to the observed cancer in numerous patients [7]. On the other hand, the breast implants appear to have met all the design requirements. This appears to be a clear case of inadequate requirements and the designer perhaps did not consider extreme conditions and long term effects. Let us consider the case of another simple device.

Hiatus hernia patients often develop gastro-esophageal reflex which represents retrograde propulsion (in the esophagus) from the stomach toward the pharynx. They develop continuous hiccups. These

patients have difficulty eating as the food does not get transported from the throat into the stomach due to retrograde propulsion waves. The surgical treatment is to make a slight slit in the esophagus (close to the stomach) such that the retrograde propulsion wave does not pass beyond the slit. A number of years ago, a company developed a silicone device which is placed around the esophagus and tied with a strap such that the esophagus gets narrowed. The idea is that the sudden change in the esophageal radius (due to the esophageal strapping at the location of the device) reflects the retrograde propulsion wave back to the stomach so that the patients can eat normally. After significant testing to meet and to exceed the requirements, the company started implanting the devices. After few months, the straps broke and the device fell down on the stomach causing pain and suffering in numerous patients. Later investigation revealed that the device was designed to withstand an internal bursting pressure of 40 mm Hg. The normal esophageal pressure does not exceed 20 mm Hg. However, during sneezing, the thoracic cavity pressure reaches at least 100 mm Hg. If the patient is sneezing while stair climbing, the intra abdominal pressure could easily exceed 150 mm Hg. Again, this is a clear case of ignoring extreme conditions and inadequate requirements. Now, let us consider the case of laparoscopic surgical tools.

Laparoscopic surgery has minimized discomfort and the length of hospital stay. It is often referred to as minimally invasive surgery. In laparoscopic surgery, the stomach is expanded significantly using low pressure gas. There is an almost exponential increase in the abdominal cavity volume with increasing pressure in the abdomen. Three tiny holes are made in the abdomen and a trocar is first inserted through each of these holes. The trocar acts as a passageway to facilitate and to secure the insertion (and removal) of various laparoscopic surgical tools into the abdominal cavity. One hole is used for the camera and two holes are used for inserting the laparoscopic forceps [8], stapler, etc. After the completion of the surgery and removal of the gas, the holes collapse and disappear. The patient can go home the same day. In modern surgery, tissue cutting is performed through electro-cautery. In electro-cautery cutting, the surgeon holds the cutting tool with the active electrode. A large dispersive electrode (passive electrode) is placed underneath the patient. When the surgeon activates the foot switch, current flows through the active electrode, through the tissue and back from the large dispersive inactive electrode. Charges are concentrated in the tissue near the tip of the electrode (Figure 1). Least concentration is at the large dispersive electrode. Heat generation is proportional to the charge.

In the initial stages, in the first five years of introduction of the laparoscopic surgical tools, almost a hundred patients died on the operating table and a number of patients had suffered injuries during laparoscopic surgery. It was later discovered that the trocar has acted as a capacitor and caused short circuit through leakage currents [9]. Instead of current flowing through the tip of the electrocautery surgical tool (Figure 1), the current passed laterally through the insulation of the tool, through the trocar and to the nearby tissue to the dispersive electrode as shown in Figure 2. The trocar met all the specified design requirements. The requirements included mechanical strength, biocompatibility, etc,

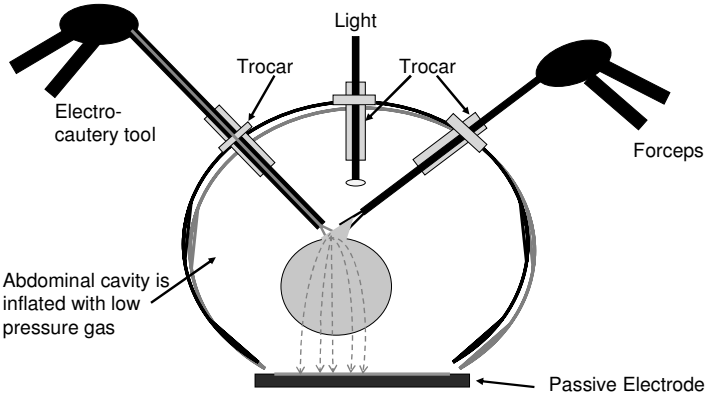

Figure 1. Laparoscopic Electrocautery. The current flows through the tip of the electrocautery tool (held in surgeon's hand) to the dispersive (passive) electrode underneath the patient.

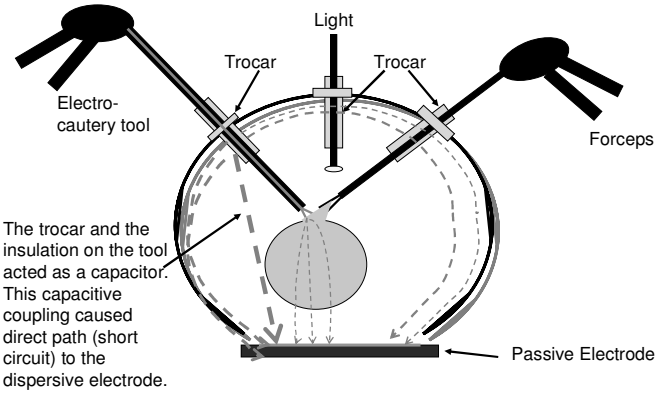

Figure 2. Laparoscopic Electrocautery: Current flow laterally though trocar. Electrical currents through the trocar when the trocar acted as a capacitor creating a direct path to the passive electrode.

but did not include dielectric properties and other electrical requirements of the trocar. The designer did not consider the insertion of electrical tools through the laparoscopic trocar and did not conduct any electric field analysis. This is a clear case of inadequate requirements arising from the lack of consideration to extreme conditions and the lack of interdisciplinary approach to the identification of the design requirements.

3. DESIGN OF INTELLIGENT DECISION SUPPORT SYSTEMS AND EXTREME CONDITIONS

It has been established that inadequate requirements are a major problem leading to software failure [10, 11]. However, the topic has not been addressed in the area of decision support systems. Neural network based intelligent decision support systems are being increasingly used in numerous disciplines including medicine, aerospace, industry, communication, image processing, banking and financial markets. Neural network based systems are used for classification and for control. The performance of an artificial neural network depends on the training data, the network structure (e.g. the number of hidden layers, hidden layer neurons), initial random weights and training algorithm etc. If the network is presented with data which is significantly different from the training data, the network may give significant errors. Reliability is important in medical and aerospace applications. In order to handle extreme conditions, we have developed the technique of committee neural networks in which numerous networks are trained with different structure, training algorithm etc and tested with initial testing data not used in training [12–15]. Few (5 or 7) best performing networks are then recruited into a committee based on initial testing with a limited testing data not used in training. The committee output is by majority opinion of the individual networks in the committee. The performance of the committee is evaluated using final testing data derived from subjects not used in training or in initial testing.

We have used the committee networks in numerous classification problems including patient diagnosis systems, signal processing, speaker verification and facial image based mood detection [12–14]. We have found that the committee decision is always better than individual member network decision. Table 1 shows an example of the performance of individual members and of the overall committee in the classification of facial expression (mood) using a eleven member committee system [14]. Numerous networks were trained using 139 images from 25 subjects and initially tested with 46 images from 10 subjects not used in training. An 11 member committee was recruited based on the results of the initial testing. The committee system was then finally evaluated with 282 images from 62 subjects not used in training or initial testing.

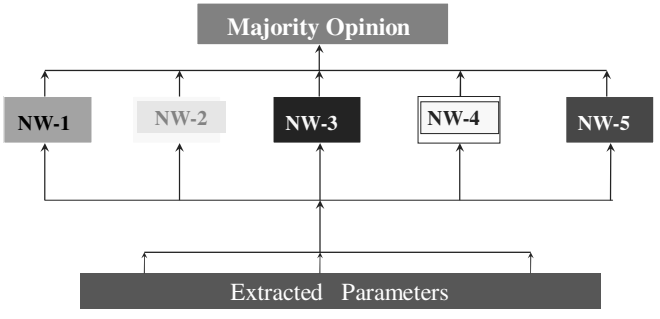

Figure 3. The Committee neural network system.

Table 1. Committee decision Vs individual network decision in facial image based mood classification [14].

Network Number	Number of Correct Classifications Out of 282 Expressions presented
NN-1	198
NN-2	182
NN-3	194
NN-4	191
NN-5	204
NN-6	206
NN-7	204
NN-8	213
NN-9	204
NN-10	217
NN-11	203
The committee system	255

For classification problems, the majority opinion works well. However, this technique can not be applied for non-classification problems, Control related problems are where the output of a network is a non-binary continuous number. For control applications, we have developed a similar committee network system but the fusion of the member network outputs is performed in a different way [15]. In a five member committee, for each time step, we have eliminated the two outputs furthermost away from the average and taken the average of the remaining three outputs as the committee output. A committee of neural networks can handle extreme conditions better than an individual neural network. Specifying only a single network for decision support systems represents the case of a gross inadequate requirements and a lack of consideration for extreme conditions.

4. DISCUSSION

Although inadequate requirements are a frequent problem leading to product failure, manufacturers often may not disclose or may not publicize this fact. In a product liability litigation, the legal liability, in the US and several other countries is based on the tort law. If any person or organization does causes injury or harm to an individual, that individual should be compensated. The theories of recovery include compensatory damages and punitive damages. The compensatory damages include both financial losses (lost wages, present and future medical costs etc.) and nonfinancial losses (suffering, pain, etc.). However, the punitive damages are to punish the individual or the organization for negligence. Inadequate requirements often lead to punitive damages in addition to compensatory damages. For example, not considering forces due to coughing and sneezing in herital hernia treatment device/prosthesis design is a clear case of inadequate requirements and negligence on the part of the

manufacturers which could lead to significant punitive damages. However, the manufacturers may be reluctant to provide the requirements data and such cases are quickly settled out of court with agreement from the plaintiff that they are not publicized. Therefore, it may take anywhere in the order of ten to twenty years for the cases to become known to the engineering community or they may never surface in the public domain.

Identification of all the essential requirements presents a major challenge and product manufacturers should put significant emphasis on identifying the right requirements for the product. The designer, specially of the medical products, should consider all conditions including extreme conditions. The requirements specification team should be interdisciplinary/multi-disciplinary and should be adequately trained to identify the key safety requirements. Risk/benefit ratio should be minimized with the highest priority. Another way to address the problem is to train the students in identifying all the requirements including the essential and safety requirements. The author has developed graduate and undergraduate courses in the design of medical devices in which FDA regulations (510 K and PMA approval process, design controls, etc.) are first discussed. Then, the principles of various medical devices are presented and the students are required to write the requirements and bench testing procedures. An informal survey of the graduates (of the course) later working in industry revealed that the course is significantly useful. The design/engineering students should be adequately trained to identify the adequate requirements so as to save the patients and other individuals from unnecessary pain, suffering and/or death. In addition, in the long run, this will save billions of dollars for manufacturers.

5. CONCLUSIONS

Inadequate requirements are a major problem in product design in numerous disciplines. Inadequate requirements often result from the lack of consideration to extreme conditions and inadequate inter-disciplinary/ multi-disciplinary considerations. The manufacturers should allocate sufficient budget for requirements engineering and constitute multidisciplinary committees to review the adeqauacy of the requirements. This will lead to significant cost savings in the long run. In addition, academic institutions should train engineering/design students to identify the adequate requirements. This may transform the corporate culture to be more cognizant about the importance of identifying the adequate requirements and at the same time save patient/individual lives or save them from unnecessary suffering and pain. Also, design teams adequately trained in requirements engineering will save billions of dollars (damages in legal liability due to product failure) for the manufacturers.

REFERENCES

1. McDonald, A.J. and Hansen, J.R., “Truth, lies, and Orings: inside the space shuttle challenger disaster,” University Press of Flordia, Gainsville, 2009.
2. Pelton, J.N., Menzel, A.P. and Sgobba, T., “Today’s challenges in space safety design and regulation,” *J. British Interplanetary Soc*., Vol. 62, pp. 238–240, 2009.
3. Reddy, N. P., "Lymph Circulation: Physiology, pharmacology and biomechanics." *CRC Critical Rev Biomed Engr*., Vol. 14, pp. 45–91, 1986.
4. Birkefeld, A.B., Eckert, H., and Pfeiderer, B., “A study of the aging of silicone breast implants using the Si-29, H-1 relaxation and DSC measurements,” *Biomaterials*, Vol. 28, pp. 4405–4413, 2004.
5. Peters, W., Pritzker, K., Smith, D., Fornsaier, V., Holmyard, D., Lugowski, S., Kamel, M., and Visram, F., “Capsular calsification associated with silicone breast implants: Incidence, determinants, and characterization,” *Annals of Plastic Surgery*, Vol. 41, pp. 348–360, 1998.
6. Feng, L.J., and Amin, S.AP., “Analysis of risk factors associated with rupture of silicone gel breast implants,” *Plast. & Reconst. Surgey*, Vol. 104, pp. 955–963, 1999.
7. Duvic M., Moore D., Menter A., and Vonderheid E.C., “Cutaneous T-cell lymphoma in association with silicone breast implants,” *J. Am. Acad. Dermatology*, Vol. 32, pp. 939–942, 1995.
8. Gupta, V., Reddy, N.P., and Batur, P., “Forces in laparoscopic tools,” *Presence: teleoperators and virtual environments*, Vol. 6, pp. 218–228, 1997.
9. Geddes, L., “Medical device accidents,” CRC Press, 1998.

10. Firesmith, D., "Generating complete unambiguous, and verifiable requirements from stories, scineros, and use cases," *J. of Object Technology*, 2004.
11. Macaulay, L.A., "Requirements engineering," Springer-Verlag, 1996.
12. Das, A., Reddy, N.P., and Narayanan, J. "Hybrid fuzzy logic committee neural networks for recognition of acceleration signals due to swallowing," *Computer Meth. Programming in Biomed*., Vol. 64, pp. 87–89, 2001.
13. Reddy N.P., and Buch, O., "Speaker verification using committee neural networks," *Computer Meth. Programming in Biomed*., Vol. 72, pp. 109–115, 2003.
14. Kulkarni S.S., Reddy N.P. and Hariharan S.I., "Facial expression (mood) detection from facial images using committee neural networks," *Biomedical Engineering Online* Vol. 8, No. 16, 2009.
15. Shrirao N.A, Reddy N.P, and Kosuri R., "Neural network committees for finger joint angle estimation from surface EMG signals," *Biomedical Engineering Online*, Vol. 8, No. 2, 2009.