International Journal of Scientific Research & Engineering Trends
Volume 6, Issue 3, May-June-2020, ISSN (Online): 2395-566X

Modeling and Simulation of Fuzzy Logic Based Expert System for Medical Device Risk Assessment

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Abstract – **Safety and reliability are essential issues in modern sciences. Modern devices and systems should meet technical, safety and environmental protection requirements. There are evidences and claims that the public hospitals of Ethiopia are suffering from a lot of problems related to medical device risk management. In this research risk assessment of medical device on safety in one of the public hospital has been conducted which is used as an input for the system. A structured questionnaire, interview of key informants and medical device maintenance were used to collect data from the hospital. From the collected data combined percentage rating of different functions of medical device risk and operational performance of medical device were calculated.**

The study reveals that there were medical device risks on safety caused from patients, health professionals, from medical device itself and the environment in which the health care is delivered. This study deals with modelling and design of fuzzy logic reasoning for medical device risk assessment model to enhance the Risk Assessment (RA) process while considering uncertainties in each phase of RA. The main advantage of using fuzzy reasoning approach is limitations of subjectivity in RA. This model makes risk assessment more convenient in the absence of suitable data. In addition, decision-making will be easier, since its results are more understandable than the results of classical methods. The proposed framework develops a model that optimizes the risk constraints.

Keywords– **Medical device, medical equipment, Risk assessment, fuzzy logic, risk analysis, risk constraints.**

I. INTRODUCTION

Medical device forms the core of any health care institution for the diagnosis, therapy and surgery. Therefore, it is crucial that medical device provides accurate information and operate to the optimum limit in order to allow proper diagnosis and ensure patient's safety during therapeutic and surgical interventions. On the other hand, in any health care institution medical devices consume greatest capital investment. This can be achieved only when these assets are used efficiently and effectively. Medical device management, in broader sense, is the right way to ensure patient's safety and obtain the maximum benefit out of these physical assets of a hospital [1].

A professional estimate the wastage of resources in relation to poor management of medical equipment indicates that purchase of technologically sophisticated device for countries which is not used due to lack of skills of operating accounts for 20-40% of the equipment cost. Short life of equipment due to maltreatment by operating and maintenance staff costs 30-80% of life time of the equipment, lack of standardization result in 30-50% extra spare parts cost and down time due to inability to use or repair costs 25-35% cost of the equipment. As indicated earlier, a large proportion of the existing stock of device in health facilities is not operational. The health care literature provides numerous examples of the poor performance of medical device in developing countries [5].

There are many probability-based methods by which risk is assessed but new techniques based on possibility methods were developed since mathematical relations and parameters for risk assessment were very difficult to model (Lees, 2001)[7].

Fuzzy logic has been successfully applied in many decision and control applications. Some more publications by Zadeh [7] were studied for a more thorough understanding of fuzzy logic and its applications in this study.

Fuzzy systems are made of a knowledge base and reasoning mechanism called fuzzy inference engine. A fuzzy inference engine combines fuzzy if-then rules into a mapping from the inputs of the system into its outputs, using fuzzy reasoning methods. Fuzzy systems represents nonlinear mapping accompanied by fuzzy if-then rules from the rule base. Each of these rules describes the local mappings. The rule base can be constructed either from human expert knowledge or designer intuition [7]. The fuzzy logics are suitable for white-box problems, based on expert knowledge of the system. A fuzzy controller consists of four main components as fuzzification, rule base, inference mechanism and defuzzification [6].

II. MODELLING AND DESIGN OF THE PROPOSED SYSTEM

Estimating risk involves identifying the events that present hazards and produce risk, communicating the magnitude of the consequences associated with these events and estimating the likelihood of a given risk. Since probability of likelihood and consequence of severity are not directly measurable, therefore risks are difficult to measure in crisp terms.

Fuzzy logic approach provides a new methodology to deal with these attributes that could only be estimated since exact values are impossible to determine.

Factors for the assessment of medical device risks

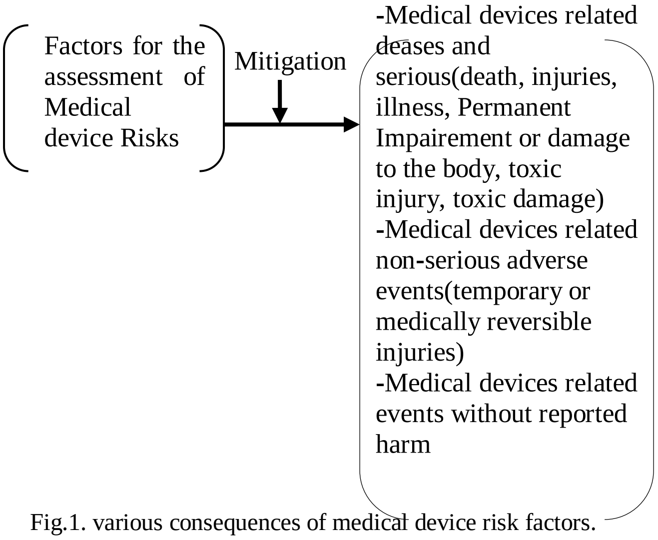


Fig.1. various consequences of medical device risk factors.

Fuzzy Logic Modelling

The structure of the overall fuzzy proposed for risk assessment is shown in the fig.2. Fuzzy systems represents nonlinear mapping accompanied by fuzzy if-then rules from the rule base. Each of these rules describes the local mappings. The rule base can be constructed either from human expert knowledge or designer intuition.

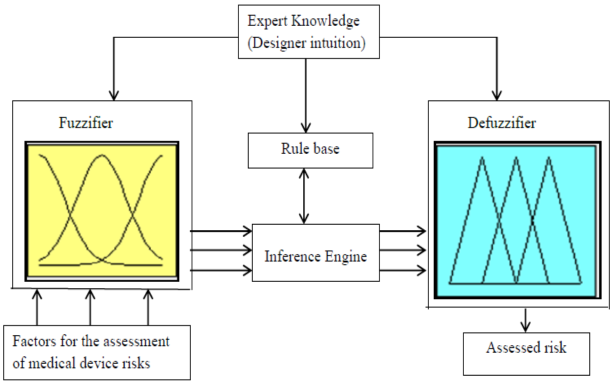


Fig.2. Over view of fuzzy controller steps.

The inputs and outputs which were used to make this FIS are detailed in fig.3. As shown, two FIS models were established to calculate the risk factor: a consequence model FIS and risk model FIS. Different types of consequences considered as inputs to the first FIS and final.

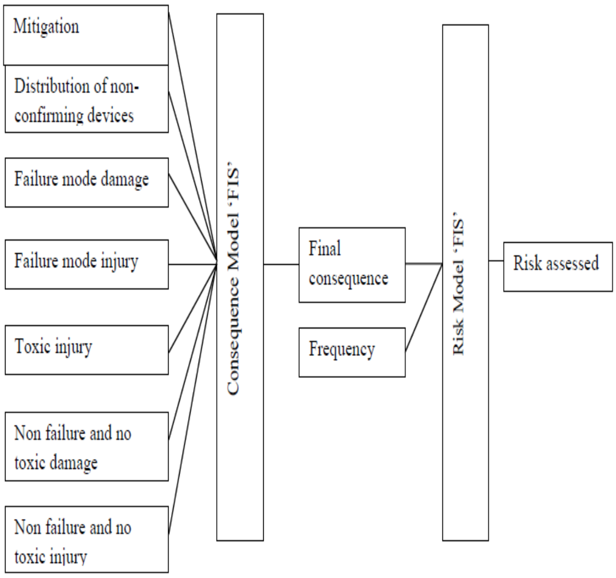


Fig.3 An Overview of the proposed system

As stated earlier risk can be defined as the function of seven risk categories in this thesis therefore, an overview of the proposed system is shown in fig.3. If we look at fig.3 then we can see that the seven inputs are combined to build risk analysis.

Defining Universe of Discourse (UOD), Fuzzification of constraints

In this study we have fuzzified each of the constraint with their respective linguistic variables (fuzzy sets) and universe of discourse (UOD) as shown in table.1. The Universe of Discourse is the range of all possible values for an input to a fuzzy system or sometimes referred to as an input space.

Table -I: Values of membership functions

Gaussian membership function				
Variable	**Universe of discourse**	**Membership functions**	**C**	**σ**
Mitigation	[0 100]	Perfect operation(PO)	0	10
		Good operation(GO)	25	10
		Medium operation(MO)	50	10
		Weak operation(WO)	75	10
		Very weak operation(VWO)	100	10
Distribution of nonconforming devices	[0 100]	Perfect confirming(PC)	0	10
		Good confirming(GC)	25	10
		Medium confirming(MC)	50	10
		Less confirming(LC)	75	10
		Very less confirming(VLC)	100	10
Failure mode damage Consequence	[0 100]	No damage(ND)	0	10
		Self-equipment devastation/damage (SED)	25	10
		Beside equipment devastation/damage(BED)	50	10
		Unit devastation/damage(UD)	75	10
		Device devastation/damage(DD)	100	10
Failure mode injury Consequence	[0 100]	No injury consequence(NIC)	0	21
		Injury of personnel(IOP)	50	21
		Death of personnel(DOP)	100	21

Toxic injury consequence	[0 100]	No injury consequence(NIC)	0	21
		Injury of personnel(IOP)	50	21
		Death of personnel(DOP)	100	21
Non failure mode and non-toxic damage consequence	[0 100]	No damage(ND)	0	10
		Self-equipment devastation/damage (SED)	25	10
		Beside equipment devastation/damage(BED)	50	10
		Unit devastation/damage(UD)	75	10
		System devastation/damage(SD)	100	10
Non-failure and non-toxic injury consequence	[0 100]	No injury consequence(NIC)	0	21
		Injury of personnel(IOP)	50	21
		Death of personnel(DOP)	100	21
Consequence (Severity)	[0 100]	Insignificant(I)	0	10
		Minor(Mi)	25	10
		Moderate(Mo)	50	10
		Major(Ma)	75	10
		Catastrophic(Ct)	100	10
Risk factor	[0 100]	Low risk(LR)	0	8.44
		Negligible risk(NR)	20	8.44
		Tolerable risk(TR)	40	8.44
		Undesirable risk(UR)	60	8.44
		Intolerable risk(IR)	80	8.44
		High risk(HR)	100	8.44

Trapezoidal membership function

Variable	Universe of discourse	Membership functions	A	B	C	D
Frequency (Probability of occurrence)	[0 10]	Impossible(Impo)	-1.79	-0.19	0.21	1.81
		Improbable(Impro)	0.18	1.78	2.18	3.78
		Remote(R)	2.20	3.80	4.20	5.80
		Occasional(O)	4.20	5.80	6.20	7.80
		Probable(P)	6.20	7.80	8.20	9.80
		Frequent(F)	8.19	9.79	10.19	11.79

Linguistic variables and design of membership function's (MF's)

Linguistic variables are the building blocks of FL. A membership function (MF) is a curve that defines how each point in the input space is mapped to a membership value (or degree of membership) between 0 and 1.

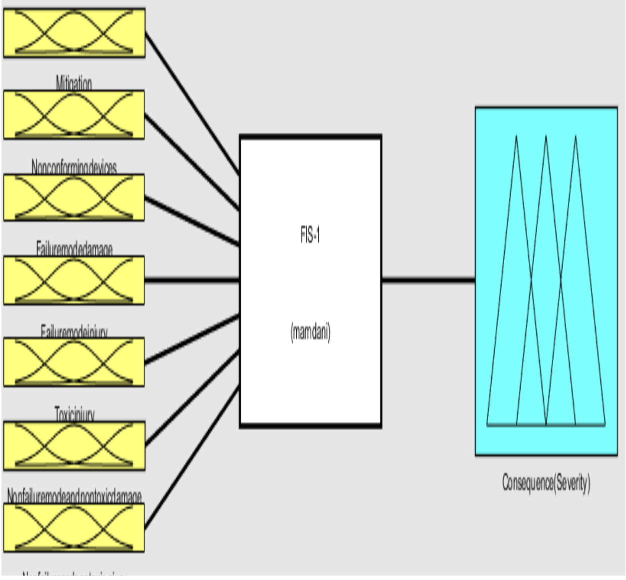
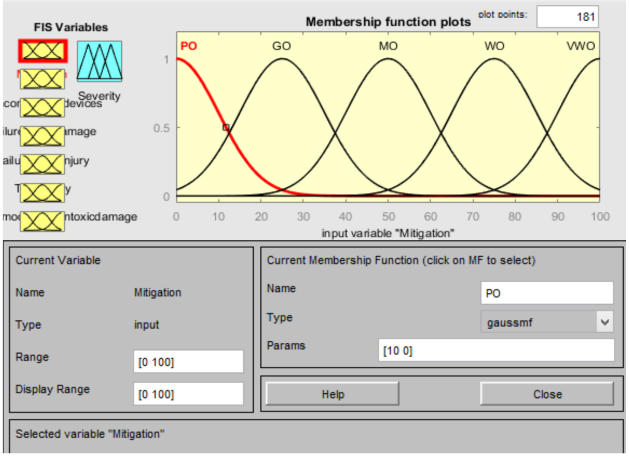


Fig.4. Fuzzy inference system-1 design.

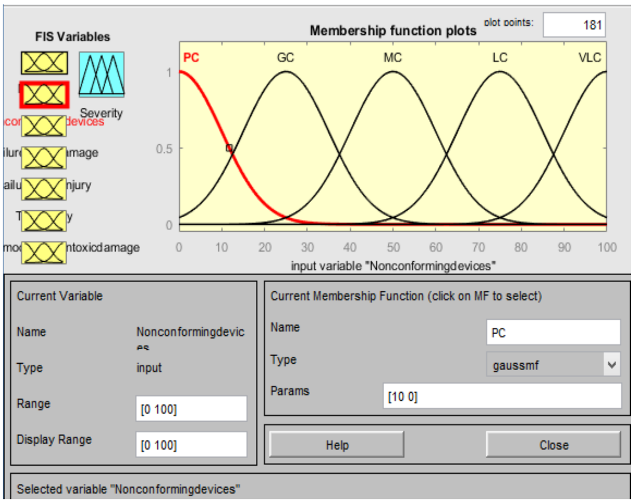


Current Variable
Name Mitigation
Type input
Range [0 100]
Display Range [0 100]

Current Membership Function (click on MF to select)
Name PO
Type gaussmf
Params [10 0]

Selected variable "Mitigation"

Fig.5. MF's for input – 'Mitigation'

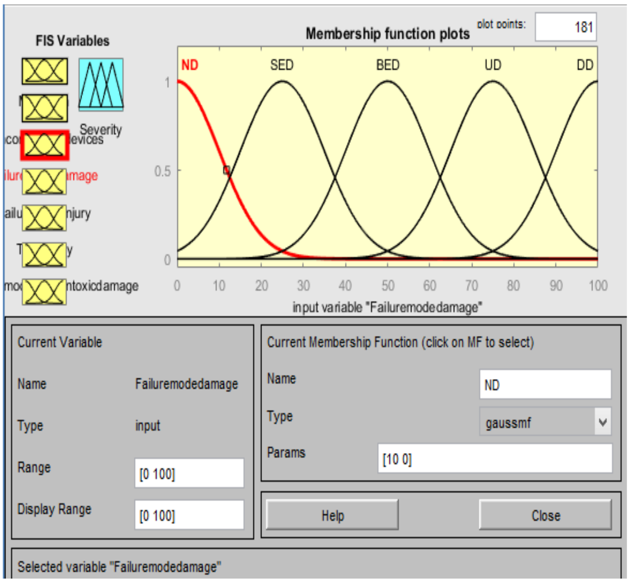


Current Variable
Name Nonconformingdevices
Type input
Range [0 100]
Display Range [0 100]

Current Membership Function (click on MF to select)
Name PC
Type gaussmf
Params [10 0]

Selected variable "Nonconformingdevices"

Fig.6. MF's for input – 'Non confirming devices'

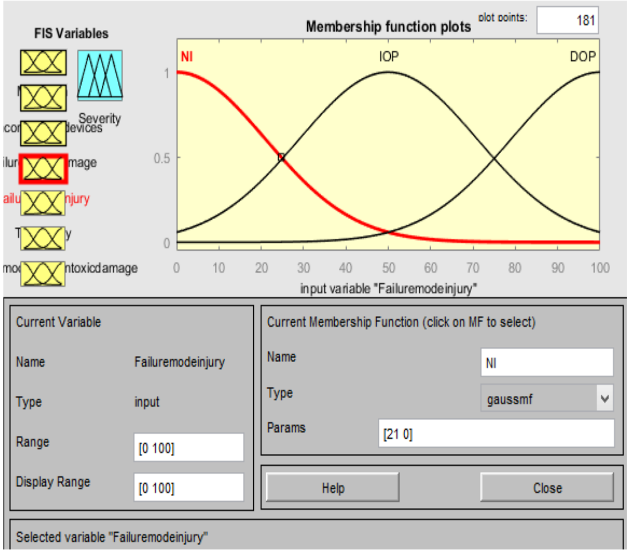


Current Variable
Name Failuremodedamage
Type input
Range [0 100]
Display Range [0 100]

Current Membership Function (click on MF to select)
Name ND
Type gaussmf
Params [10 0]

Selected variable "Failuremodedamage"

Fig.7 MF's for input – 'Failure mode damage'

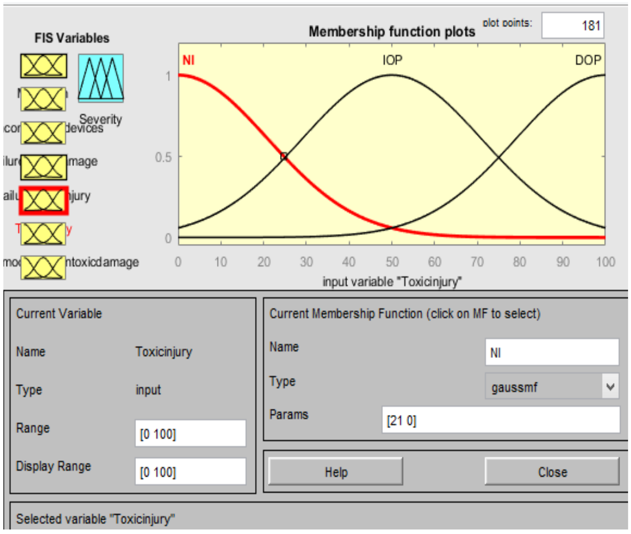


Current Variable
Name Failuremodeinjury
Type input
Range [0 100]
Display Range [0 100]

Current Membership Function (click on MF to select)
Name NI
Type gaussmf
Params [21 0]

Selected variable "Failuremodeinjury"

Fig.8 MF's for input – 'Failure mode injury'

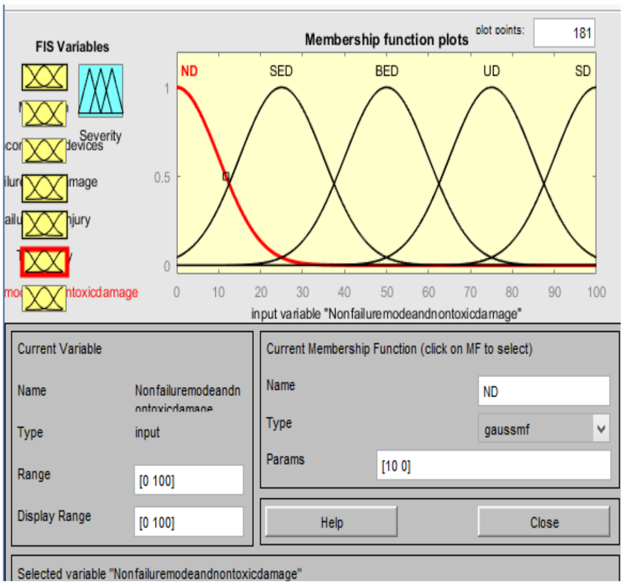


Current Variable
Name Toxicinjury
Type input
Range [0 100]
Display Range [0 100]

Current Membership Function (click on MF to select)
Name NI
Type gaussmf
Params [21 0]

Selected variable "Toxicinjury"

Fig.9 MF's for input – 'Toxic injury'

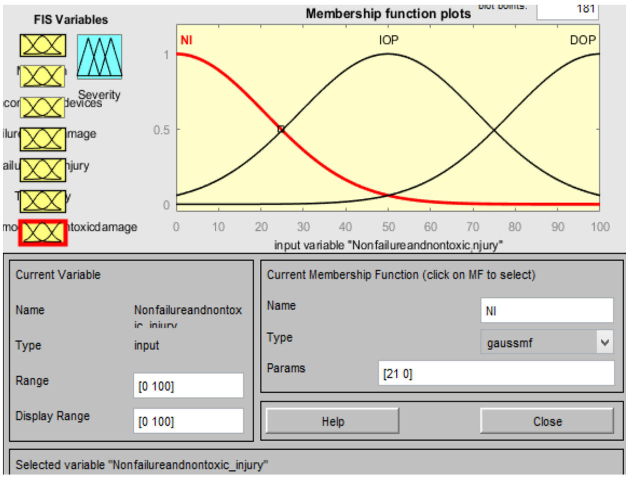


Current Variable
Name Nonfailuremodeandn ontoxicdamage
Type input
Range [0 100]
Display Range [0 100]

Current Membership Function (click on MF to select)
Name ND
Type gaussmf
Params [10 0]

Selected variable "Nonfailuremodeandnontoxicdamage"

Fig.10 MF's for input – 'Non failure mode & non-toxic damage'

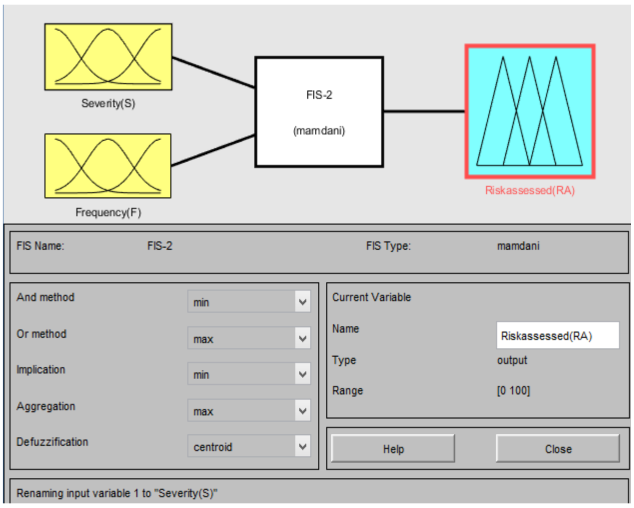


Current Variable
Name Nonfailureandnontox ic_injury
Type input
Range [0 100]
Display Range [0 100]

Current Membership Function (click on MF to select)
Name NI
Type gaussmf
Params [21 0]

Selected variable "Nonfailureandnontoxic_injury"

Fig.11 MF's for input – 'Non failure & non-toxic injury'



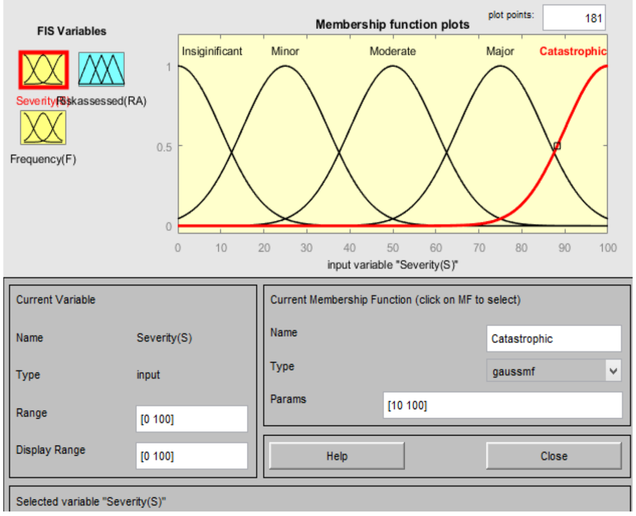
FIS Name: FIS-2
FIS Type: mamdani

And method min
Or method max
Implication min
Aggregation max
Defuzzification centroid

Current Variable
Name Riskassessed(RA)
Type output
Range [0 100]

Renaming input variable 1 to "Severity(S)"

Fig.12 "Fuzzy inference system-2" design

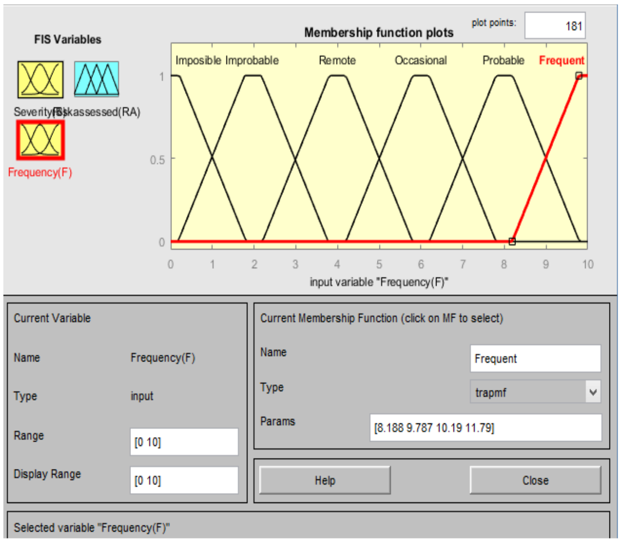


Current Variable
Name Severity(S)
Type input
Range [0 100]
Display Range [0 100]

Current Membership Function (click on MF to select)
Name Catastrophic
Type gaussmf
Params [10 100]

Selected variable "Severity(S)"

Fig.13 MF's for input – 'Final consequence/severity'

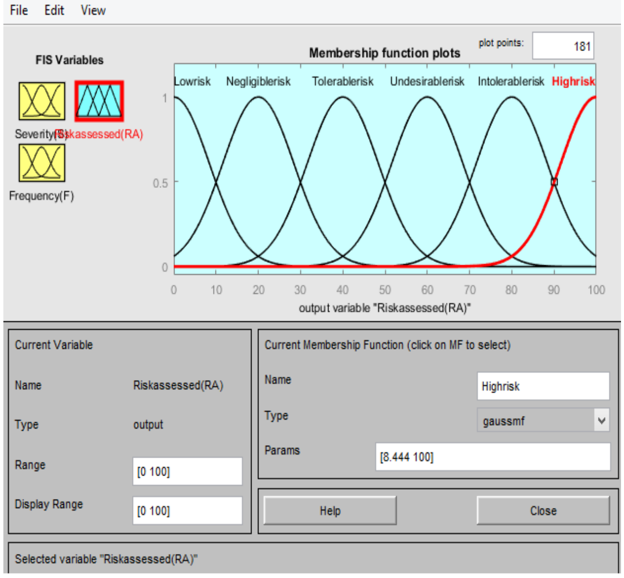


Current Variable
Name Frequency(F)
Type input
Range [0 10]
Display Range [0 10]

Current Membership Function (click on MF to select)
Name Frequent
Type trapmf
Params [8.188 9.787 10.19 11.79]

Selected variable "Frequency(F)"

Fig.14 MF's for input – 'Frequency'



Current Variable
Name Riskassessed(RA)
Type output
Range [0 100]
Display Range [0 100]

Current Membership Function (click on MF to select)
Name Highrisk
Type gaussmf
Params [8.444 100]

Selected variable "Riskassessed(RA)"

Fig.15 MF's for Output – 'Risk assessed'

Rule formats: Basically a linguistic controller contains rules in the if-then format, but they can be presented in different formats. In our systems, we have taken only four rules from the constructed rules for visualization purpose.

1. If (Severity((S) is Insiginificant) and (Frequency(F) is Imposible) then (Riskassessed(RA) is Lowrisk) (1)
2. If (Severity((S) is Insiginificant) and (Frequency(F) is Improbable) then (Riskassessed(RA) is Negligiblerisk) (1)
3. If (Severity((S) is Insiginificant) and (Frequency(F) is Remote) then (Riskassessed(RA) is Negligiblerisk) (1)
4. If (Severity((S) is Insiginificant) and (Frequency(F) is Occasional) then (Riskassessed(RA) is Tolerablerisk) (1)

A surface viewer for FIS is shown in fig.15 which demonstrates relationship among the seven inputs and risk factor output. To achieve the surface we have used the fuzzy rule bases and the MF"s of the FIS controller. As the figure indicates, this fuzzy risk surface, since it is a granulated version of the risk matrix, rather than just four discrete rankings, better reflects the differences associated with the risk category.

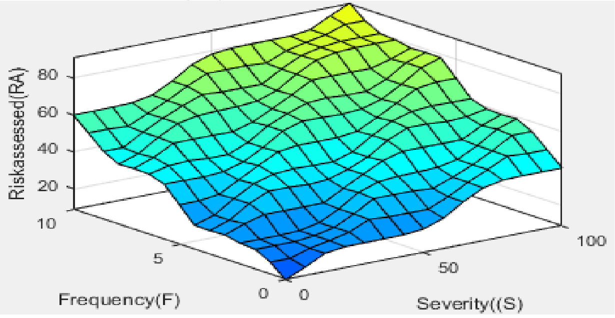


Fig.16 Surface viewer for 'FIS-2'

As can be seen from the figure 16 if one has numerical value of the inputs in the scale of [0-100] for all the seven inputs, frequency[0 10] respectively, we can obtain the amount of risk factor associated in the scale of [0 100].

III. SIMULATION RESULT AND DISCUSSION

The proposed fuzzy reasoning model was developed in Mat lab Simulink software using fuzzy logic toolbox as shown in fig.16.

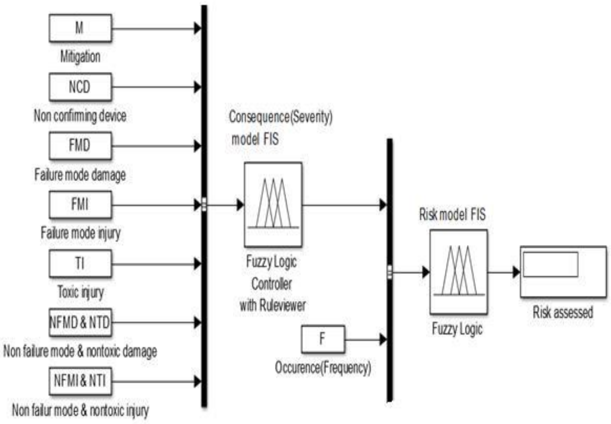
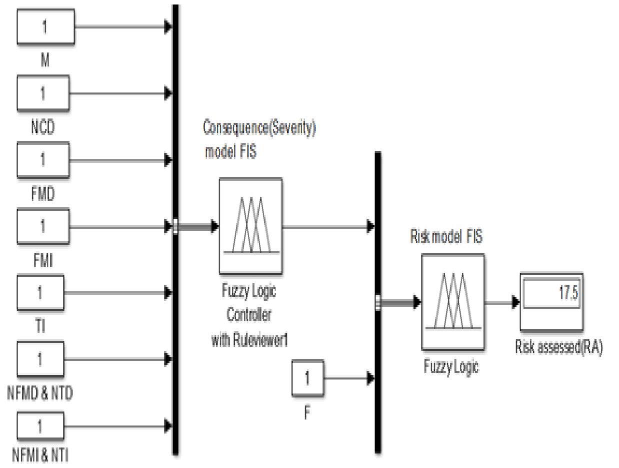


Fig.17 Overall Simulink Simulation Model

Results of various simulations for different sets of inputs are shown below:

Case 1: Set (M = 1; NCD = 1; FMD=1; FMI=1; TI=1; NFMD & NTD=1; NFMI & NTI=1 and F= 1). The simulation (t=2sec).



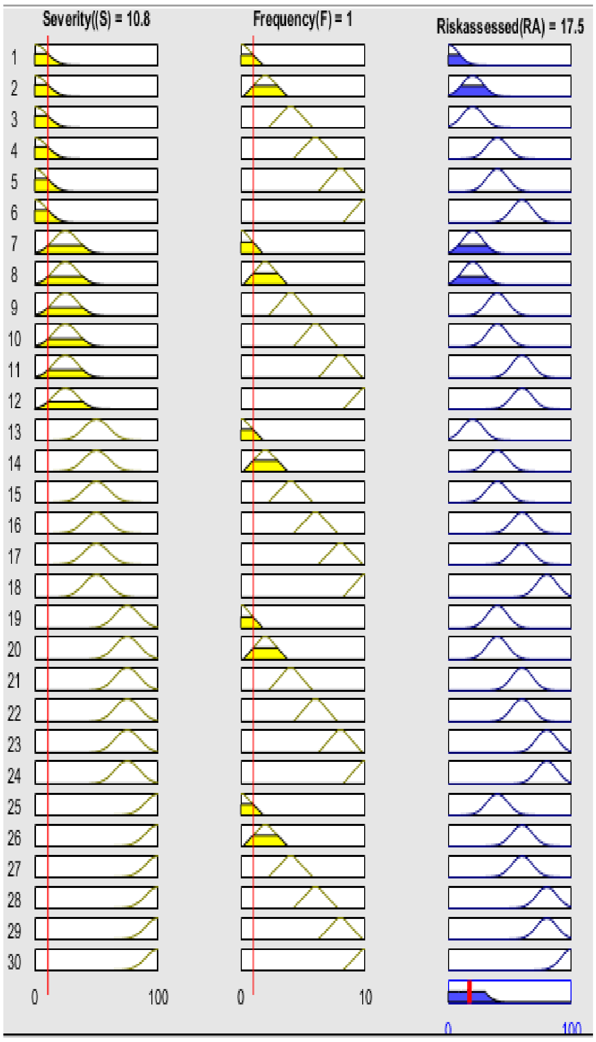


Fig.18 Simulation results

As can be seen from the fig.18 the assessed risk rating **is 17.5.**

Case 2: Set (M = 25; NCD = 25; FMD=25; FMI=25; TI=25; NFMD & NTD=25; NFMI & NTI=25 and F= 2.5). The simulation (t=2sec).

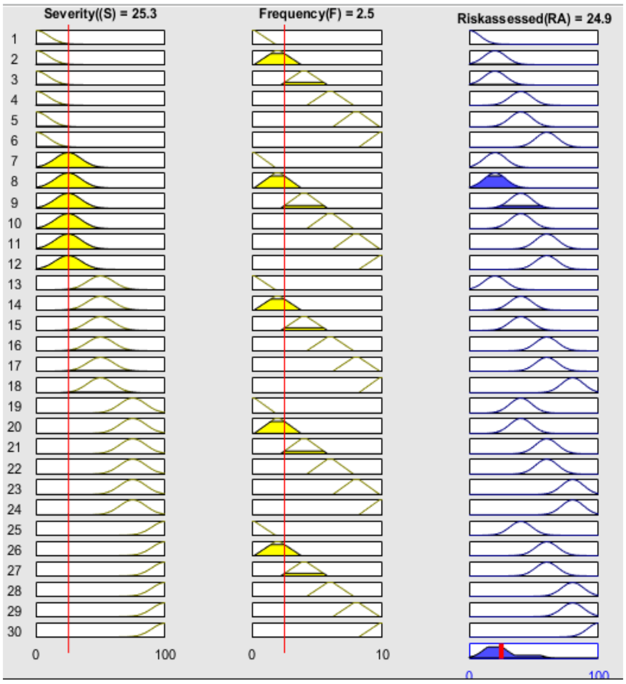


Fig.19 Simulation results

As can be seen from the fig.19 the assessed risk rating is **24.9.**

Cse 3: Set (M = 50; NCD = 50; FMD=50; FMI=50; TI=50; NFMD & NTD=50; NFMI & NTI=50 and F= 5). The simulation (t=2sec).

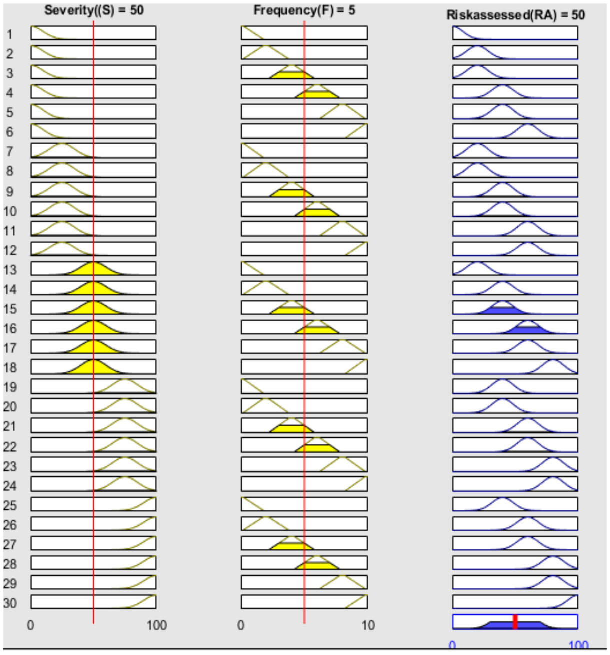


Fig.20 Simulation results

As can be seen from the fig.20, the assessed risk rating is **50.**

Case 4: Set (M = 99; NCD = 99; FMD=99; FMI=99; TI=99; NFMD & NTD=99; NFMI & NTI=99 and F= 9.9). The simulation (t=2sec).

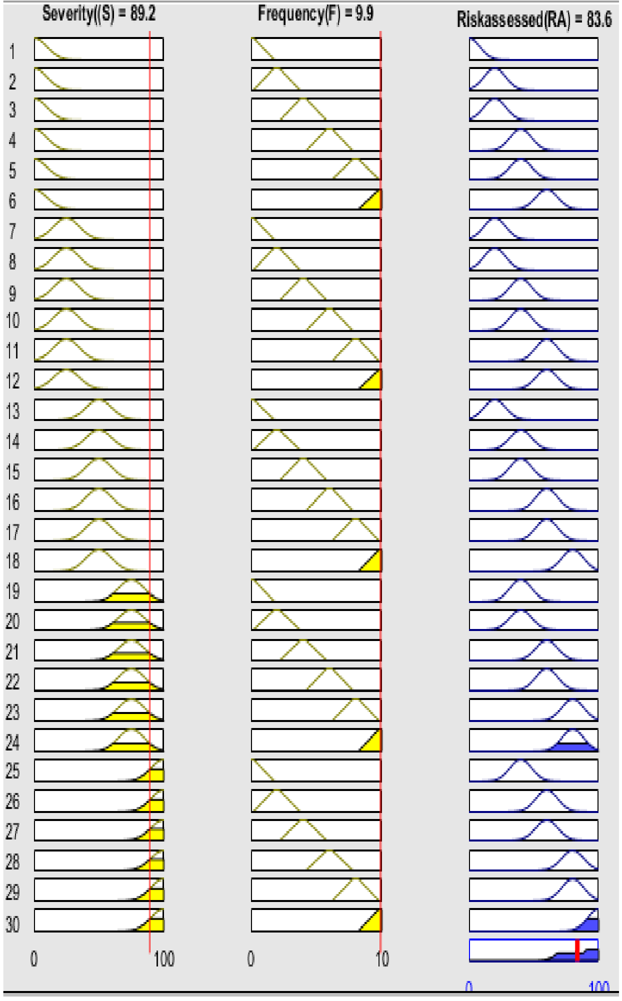


Fig. 21.Simulation results.

As can be seen from the fig.21, the assessed risk rating is **83.6.**

IV. CONCLUSION AND FUTURE WORK

A new approach for assessing medical device risk in the hospital using fuzzy logic reasoning has been proposed. Matlab Simulink models i.e. fuzzy logic risk assessment method has been developed and results were shown. We have used fuzzy techniques because human judgments are always subjective and uncertain.

The proposed frameworks develop a model that optimises the risk constraints and used in risk management system for the hospital. The developed fuzzy risk assessment model (FRAM) provides a new methodology for risk assessment (RA) by capturing expert knowledge and allowing description of the expertise in more intuitive manner. In addition, the proposed system has other advantages, presented as follows: the relation between inputs and outputs were linguistic terms. It made the model more flexible for changing in different conditions; it made the decision-making process simpler and faster, since its results were more understandable and reliable.

As an extension for future work one can also consider other constraints which effects RA, apply fuzzy ordinal approach in RA if the number of constraints are more, and we can also effectively apply fuzzy logic reasoning in other modern techno-management decision making problems.

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