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8 Profiling of medical equipment risk using fuzzy logic

Douglas Clarkson, Olivier Haas and Keith Burnham

8.1 Introduction

Models of risk generally struggle to cope with the complexities of healthcare, and in the context of medical equipment, it is apparent that several categories of 'risk' can be identified which are active concurrently. From previous development of a clinical risk simulation model within a Critical Care environment (Clarkson, 2009; Clarkson *et al.*, 2009), a specific implementation of fuzzy logic was found to provide a means of developing a 'risk engine' which referenced contributing factors and preventive factors of risk in the clinical environment. Components of this 'risk engine' model have been applied to the task of classification of risk associated with medical equipment. This in turn allows priorities to be identified in relation to management of a diverse equipment portfolio.

8.2 Identification of component risks

A series of separately existing risks associated with the clinical use of equipment is identified as:

a) unavailability risk

b) measurement accuracy risk

c) treatment accuracy risk

d) diagnostic function risk

e) intrinsic function risk

These are identified as risks which can be managed/mitigated through implementation of appropriate policies for equipment management and maintenance.

Unavailability risk is identified as arising out of non-availability of equipment before its intended use rather than failure or inappropriate function of the device during clinical use. This risk will be high where limited numbers of specialist equipment items are available to undertake potentially lifesaving clinical interventions – such as defibrillators or ventilators. This risk will be modified by the extent of surplus/spare equipment available and the level of reliability of the equipment as reflected in the value of device failure rate. The failure rate of each device was derived from its maintenance history (see Chapter 4, Section 4.5.5) via a specialised report using data from the Optim database and which calculated the failure rate of

all devices based on lifetime service history. This includes both 'accidental damage' and 'user error' components since both of these impact on equipment availability but excludes acceptance/commissioning and planned maintenance activity. A mean value of failure rate was derived for each equipment model. It would be a desirable feature of equipment management databases if the failure rate of devices could be a dynamically 'live' parameter for each inventory item and also for each model/brand.

Measurement accuracy risk is introduced to focus on equipment which is essentially measuring parameters relating to patient care. Specific examples include:

a) Tonometers (ocular pressure)

b) Blood Pressure (e.g. NIBP)

c) Pulse Oximeters (oxygen saturation, etc.)

d) Biometers (axial length, ophthalmology)

e) Patient monitors (heart rate, etc.)

This risk component assesses the potential clinical risk due to inaccuracy of measurements and can potentially highlight, for example, requirements for verification of device measurement accuracy within a planned maintenance programme and where test equipment has calibration traceability to national/international standards.

Treatment accuracy risk relates to equipment items which are delivering energy or other agents to the patient. Specific examples include:

a) Defibrillator

b) Infusion device (syringe driver, volumetric pump, nutrition, etc.)

c) Laser

d) Ultraviolet treatment unit (e.g. whole body psoralen plus UVA (PUVA) treatment cabinet)

e) Surgical diathermy

f) Anaesthetic machine (e.g. flow rates, gas concentrations)

g) Neonatal phototherapy

This risk component assesses the potential clinical risk due to device inaccuracy in terms of the level of treatment delivered. Again, this analysis will assist in identification of equipment items which may require verification of treatment function during planned maintenance.

Diagnostic function risk is introduced to focus on equipment which provides a degree of diagnostic function. Specific examples of 'complex' systems with diagnostic function include:

a) Defibrillator (e.g. identification of ventricular fibrillation (VF))

b) Arrhythmia analysis system (Holter system)

c) Endoscopic camera systems (e.g. quality of image important)

It has been identified that systems such as ophthalmoscopes, display screens, video processors, etc. have elements of diagnostic function since their performance influences clinical decision making. This risk component assesses the potential clinical risk in terms of accuracy level or quality of diagnostic function provided.

All medical devices are identified as having an intrinsic risk through failure of the unit while in use on a patient. This potential risk of failure will be high for life support equipment such as ventilators and anaesthetic machines but low for devices such as nerve stimulators where there is no life support role. This intrinsic failure rate will be lower than the reported device failure rate since it will exclude accidental damage and operator error codes and is specifically associated with failure of the device while in clinical use. Some examples of 'intrinsic risk' failures are:

- Operating table (collapse of support element with potential for patient injury)
- Defibrillator (risk of failure of device to deliver treatment energy)
- Failure of ventilator in Critical Care

All devices are identified as having an intrinsic risk element, though this will vary in significance over the types of equipment in use. A specific model can therefore have as few as two risk factors (unavailability and intrinsic) identified or as many as five. There is, however, a subtle difference between the specific types of risk. The 'unavailability risk' and 'intrinsic risk' can be considered within a time period of a year of use of the equipment. The 'measurement', 'treatment' and 'diagnostic' risks are active on each occasion of use of the equipment and where, for example, each use of a blood gas machine can be identified with a finite element of risk that parameter values may be inaccurate. The risk profile of a specific item of equipment will include a typical value for unavailability risk and intrinsic failure risk and can in addition include elements of risk associated with measurement, treatment and diagnosis and which can be summed over all uses of the equipment within a specific time interval. Within collaborative projects to collect and share data within equipment management databases, there should be a separate derivation/definition of unavailability risk and intrinsic failure rate.

8.3 Application of fuzzy logic

8.3.1 Two-parameter model

The risk determinations required for medical device risk can be implemented using a simple fuzzy building block of 'two input–one output', as indicated in Figure 8.1

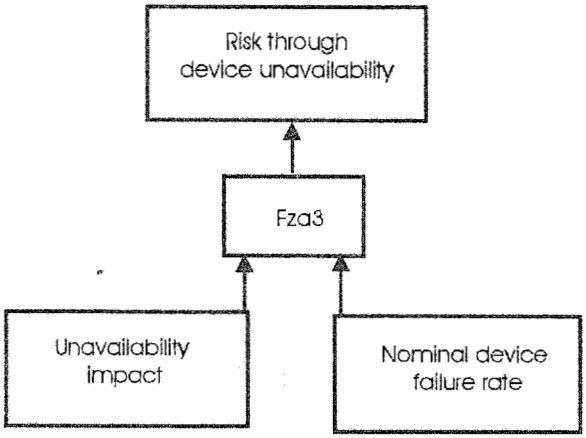

Figure 8.1 Model of 'risk of device unavailability'

where input and output parameters range between 0 and 10. The function Fza3 is effectively a lookup table derived using fuzzy logic methodology where, for example, input value (3.4, 5.7) maps to a unique output value.

Fuzzy logic is applied using basic building blocks of 'two input–one output' Mamdani fuzzy functions with five-level trapezoidal membership functions (Mamdani and Assilian, 1975). Such a framework has previously been described in relation to a system for simulation of clinical risk (Clarkson, 2009).

The specific format of the fuzzy model utilised is that of a five-level trapezoidal function as indicated in Figure 8.2. This function allows a single parameter value to be represented by more than one function. For input value 'e' in the figure, intersection takes place at function 4 (high) at 'b' and also at function 5 (very high) at 'd' as an example of a function with two inputs and one output.

8.3.2 Verbal reasoning assignments: Risk level

A key element of the risk model is to match 'verbal reasoning' descriptions of parameters with corresponding numeric values. Table 8.1 indicates the descriptions of risk states as applied to all five risk categories as a function of output risk value. The 'key' value is described as the 'characteristic' value associated with the specific fuzzy function. Thus, the 'key' value of 3.33 is associated with the peak of function 2 (Low). At this stage, the 'dynamic range' of the risk function is entirely determined by the user definitions within the application. This risk classification is very much 'response-based', where the anticipated response to a specific risk value is identified.

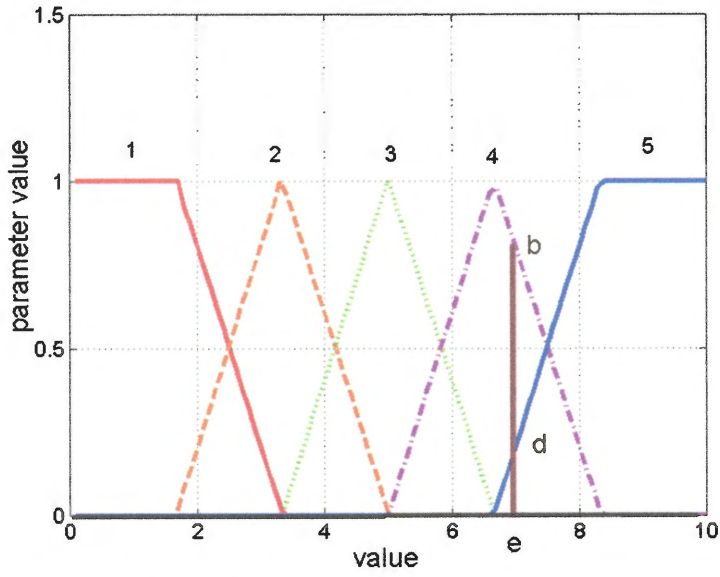

Figure 8.2 Identification of the specific component fuzzy functions 1, 2, 3, 4 and 5 which relate to the sequence 'very low', 'low', 'intermediate', 'high' and 'very high', respectively

A key aspect of the use of fuzzy logic in this application is the assignment of numeric values of input X and Y factors based on a linguistic reasoning assessment of the specific variable. The verbal reasoning elements are shown at specific single-value numeric values though the model allows for a continuum of values between 0 and 10.

8.3.3 Verbal reasoning assignment: Risk of unavailability

Table 8.2 summarises details of verbal reasoning descriptions relating to risk of device unavailability. A classification of nominal device failure rate (FR) of number of failures per year is derived from the Optim database and used to derive an input 'fuzzy' value to the fuzzy function as indicated in Table 8.3 and Figure 8.3. Constant values are assigned for failure rates <0.15 and >2.5.

8.3.4 Rule mapping: Risk unavailability

After the X and Y input components have been determined, it is necessary to derive the fuzzy rules which will map each X and Y input to a unique Z value. Table 8.4 summarises the fuzzy function mapping. This contains the information to map from any value of X (Unavailability impact) and Y (Likelihood of device failure) to an output Z value (Risk unavailability). Thus, in the example of rule 10 (Table 8.4), for

Table 8.1 Mapping of linguistic description of risk to numeric output value of risk

State	Function number	Key value	Verbal reasoning element (risk level)
Very Low	1	1.67	Very low level of risk, no action required
Very Low – Low		2.5	Very low to low level of risk, no action required
Low	2	3.33	Low level of risk, no action required
Low – Intermediate		4.17	Low to intermediate level of risk, review service history every 2 years
Intermediate	3	5.0	Intermediate level of risk, but procedures should be reviewed annually to identify further actions to reduce risk level
Intermediate to High		5.84	Intermediate to high level of risk, but procedures should be reviewed annually to identify further actions to reduce risk level
High	4	6.67	High level of risk – detailed risk analysis to be undertaken as soon as possible to identify origins with view to risk reduction
High – Very High		7.5	High to very high level of risk – detailed risk analysis to be undertaken as soon as possible to identify origins with view to risk reduction. Consideration of urgent removal of equipment from clinical use pending review or implementation of risk reduction action
Very High	5	8.33	Very high level of risk. Consideration of immediate removal of equipment from clinical use pending review or immediate implementation of risk reduction action

Table 8.2 Unavailability impact: Key value and verbal reasoning description

State	Function number	Key value	Verbal reasoning description (criticality unavailability risk)
Very Low	1	1.67	No impact on ability to carry out clinical activity
Very Low – Low		2.5	Very slight impact on ability to carry out clinical activity which can be very readily managed
Low	2	3.33	Slight impact on ability to carry out clinical activity which can typically be readily managed
Low–Intermediate		4.17	Slight to moderate impact which can be expedited through borrowing of equipment from other areas or use of alternative methods
Intermediate	3	5.0	Moderate impact on ability to carry out clinical activity, cancellation of clinics with delivery of less than optimal patient care but which is unlikely to affect patient outcome
Intermediate–High		5.84	Moderate impact on ability to carry out clinical activity, cancellation of clinics with delivery of less than optimal patient care and which may affect patient outcome
High	4	6.67	Significant impact on ability to carry out clinical activity, cancellation of clinics or theatre sessions or delivery of less than optimal patient care and which may affect patient outcome
High–Very High		7.5	Significant impact on ability to carry out clinical activity, cancellation of clinics or theatre sessions or delivery of less than optimal patient care and which is likely to affect patient outcome
Very High	5	8.33	Very significant impact on ability to carry out clinical activity with potential loss of patient

Table 8.3 Classification of risk in terms of fuzzy function

Function description	Failure rate: representative value	Key value	Failure rate (FR): range	Percentage of equipment items within range of failure rate values
Very Low	0.15	1.67	FR ≤ 0.15	68
Low	0.325	3.33	0.5 ⩾ FR > 0.15	18
Intermediate	0.875	5.0	1.25 ⩾ FR > 0.5	10
High	1.875	6.67	2.5 > FR > 1.25	3
Very High	2.5	8.33	FR ⩾ 2.5	1

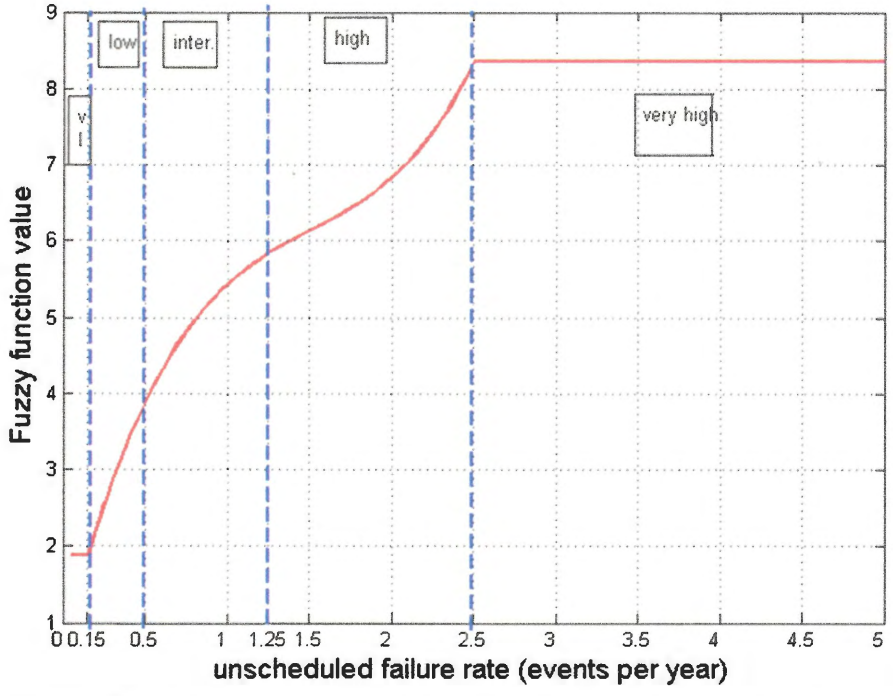

Figure 8.3 Transfer function of failure rate to fuzzy function based on cubic polynomial fit

Table 8.4 Fuzzy function mapping for the two input and one output function

Rule number	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**25**
Unavailability impact	5	5	5	5	5	4	4	4	4	4	3	3	3	3	3	2	2	2	2	2	1	1	1	1	1
'Modified' likelihood of device failure	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1
Risk of unavailability	5	5	4	3	3	4	4	4	3	2	3	3	3	3	2	2	2	2	2	2	1	1	1	1	1

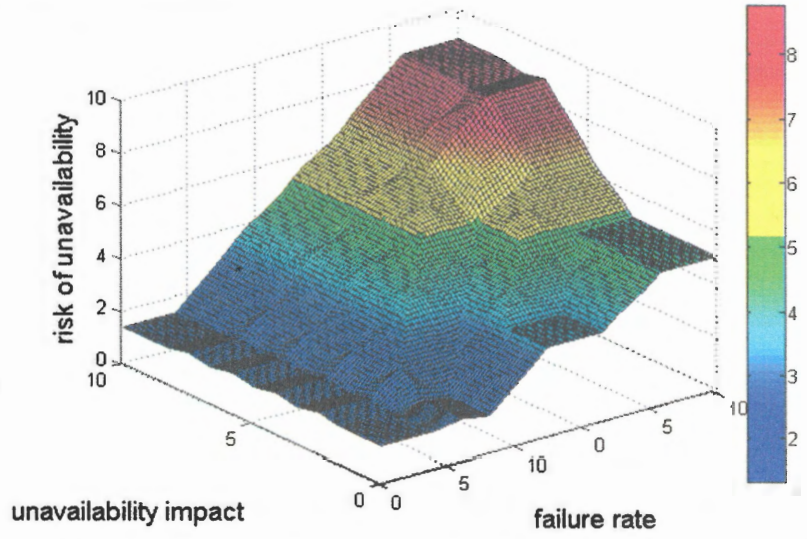

Figure 8.4 Three-dimensional surface derived for risk of unavailability based on input parameters of unavailability impact and device failure rate

a 'high' (function 4) level of 'Unavailability impact' and a 'very low' (function 1) level of 'Likelihood of device failure', the risk of unavailability is identified as 'low' (function 2).

Calculations in MATLAB® were then undertaken to determine output values of risk by incrementing inputs of X and Y between 0 and 10 with a step interval of 0.1 to essentially define a surface of function. The fuzzy calculations are essentially undertaken in one complete process to create a mapping profile as indicated in Figure 8.4. The fuzzy method can therefore be identified as a mechanism of structuring the surface of the interacting variables though other methodologies could also be used to derive such a surface.

8.4 Active use risk: Measurement, treatment, diagnostic and intrinsic risks

Figure 8.5 summarises the components of risk related to the 'active' use of the device on patients.

The descriptions of criticality of specific 'active clinical use' elements relating to 'measurement function', 'treatment function', 'diagnostic function' and 'intrinsic function' use a common set of descriptions as outlined in Table 8.5 and where the

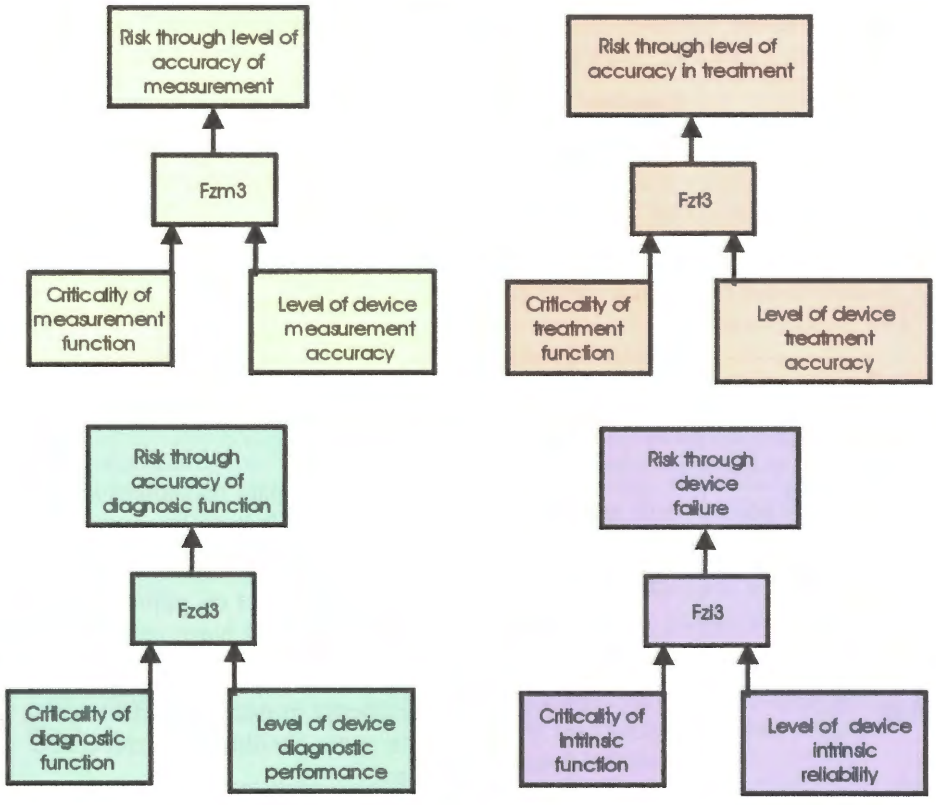

Figure 8.5 Summary of the components of risk (measurement, treatment, diagnostic and intrinsic) related to the 'active' use of the device on patients

'criticality' factor relates to the specific risk factor, such as 'measurement' or 'intrinsic'.

Table 8.6 indicates details relating to risk of measurement inaccuracy – level of accuracy of measurement function. A similar structure operates for treatment risk. Table 8.7 summarises the fuzzy function mapping to map from any value of X (Criticality of measurement function) and Y (Level of accuracy of device function) to an output Z value (Risk due to measurement function inaccuracy). This translates into the fuzzy surface outlined in Figure 8.6. Similar functions are derived for treatment, diagnostic and intrinsic functions.

Table 8.8 summarises details relating to level of accuracy of diagnostic function, and Table 8.9 summarises details relating to level of intrinsic function reliability.

Table 8.5 Details relating to criticality of 'active clinical use' elements of measurement, treatment, diagnosis and intrinsic risk

State	Function number	Key value	Verbal reasoning element
Very Low	1	1.67	No impact on patient status
Very Low–Low		2.5	Very slight impact on patient status which is reversible
Low	2	3.33	Very slight impact on patient status which is reversible
Low – Intermediate		4.17	Slight impact on patient status but harm is likely to be minor and reversible
Intermediate	3	5.0	Moderate impact on patient status but harm is likely to be minor and reversible
Intermediate–High		5.84	Moderate impact on patient status with chance that harm could be irreversible
High	4	6.67	Significant impact on patient status with some likelihood of irreversible harm
High–Very High		7.5	Very significant impact on patient status with high probability of irreversible harm
Very High	5	8.33	Very significant impact on patient status which is likely to be irreversible and with potential loss of patient

8.5 Results

8.5.1 Deriving output risk values

Details of coefficients are maintained in an Excel spreadsheet. Thus, each model is linked with up to 10 coefficients as indicated in Table 8.10. Analysis of risk is undertaken by review of all five potential risk contributions, though it is useful to identify one output as the maximum value of all contributions and another as the maximum of all 'clinical' elements. This allows flexibility in analysis of an equipment risk profile. Figure 8.7 indicates the distribution of risk within risk

Table 8.6 Details relating to risk of measurement inaccuracy – level of accuracy of measurement function

State	Function number	Key value	Verbal reasoning element
Very Low	1	1.67	Most measurement values are outside tolerance range, with some major deviations
Very Low–Low		2.5	A significant number of measurement values are outside tolerance range, with some major deviations
Low	2	3.33	Measurement values show significant variability, with some showing significant deviation
Low–Intermediate	2	4.17	Measurements show a wide variation of values
Intermediate	3	5.0	Measurement values are usually within the allowed tolerance range, but with some outlying points
Intermediate–High		5.84	Measurement values are usually within the allowed tolerance range, but with the occasional outlying point
High	4	6.67	Measurement values are consistently within the allowed tolerance range
High–Very High		7.5	Measurement values are consistently within the allowed tolerance range and close to target values
Very High	5	8.33	Measurement values are consistently within the allowed tolerance range, and with a close match to absolute accuracy values

categories of unavailability risk and maximum clinical risk for a range of equipment models and where the elements (equipment models) are sorted in order of maximum risk (of unavailability risk).

Figure 8.7 indicates the relative distribution of risk between these two risk criteria. The leading tail of high risk devices is the result of 'unavailability' risk triggered by relatively high failure rates of devices and implies mitigation of risk through a range of strategies which could include:

Table 8.7 Fuzzy function mapping for 'Risk due to measurement function inaccuracy'

Rule number	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**25**
Criticality of measurement function	5	5	5	5	5	4	4	4	4	4	3	3	3	3	3	2	2	2	2	2	1	1	1	1	1
Level of accuracy of device function	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1	5	4	3	2	1
Risk due to measurement function inaccuracy	3	3	4	5	5	3	3	3	4	5	2	3	3	4	4	2	2	2	3	3	1	1	1	2	2

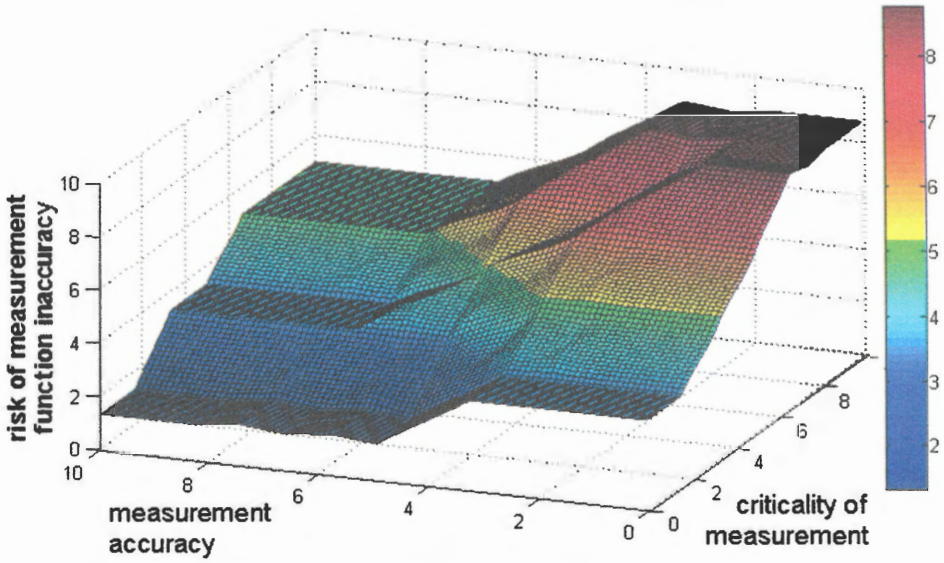

Figure 8.6 Risk associated with measurement function inaccuracy

- Provision of additional planned maintenance
- Purchase of additional equipment
- Review of user training
- Replacement with more reliable equipment

8.5.2 Application of the package: Risk classification high, medium and low

The fuzzy logic risk tool is intended to be used as a mechanism to assist in the risk management of maintenance of medical devices referenced within its analysis. Table 8.11 identifies a generic classification of devices based on the perceived risk of devices and which is used to identify priorities within planned maintenance activity and also scheduled maintenance activity. The value of r of 5.84 corresponds to 'intermediate to high' transition, and the value of r of 4.17 to 'low to intermediate' transition – as indicated within Figure 8.2.

8.6 Discussion

The fuzzy risk model is intended to be used as a risk tool for the risk management of maintenance of products referenced within its analysis. The risk levels determined are identified as triggers for review or intervention to manage/reduce the identified

Table 8.8 Details relating to level of accuracy of diagnostic function

State	Function number	Key value	Verbal reasoning element
Very Low	1	1.67	Diagnostic function has a very low level of performance
Very Low–Low		2.5	Diagnostic function has a very low to low level of performance
Low	2	3.33	Diagnostic function has a low level of performance
Low–Intermediate		4.17	Diagnostic function has a low to intermediate level of performance
Intermediate	3	5.0	Diagnostic function has a reasonable (intermediate) level of performance
Intermediate–High		5.84	Diagnostic function has a reasonable to high level of performance
High	4	6.67	Diagnostic function has a high level of performance
High–Very High		7.5	Diagnostic function has a high to very high level of performance
Very High	5	8.33	Diagnostic function has a very high level of performance

risk profiles and where different actions may be relevant for specific identified risks. High risk devices are typically managed by placing on planned preventive maintenance or on contract with external contractors. The quantification of risk in this context introduces a focus based on review of procedures to reduce the risk levels where they are identified as being too high. There are also impacts related to assessment of availability of equipment.

The derivation of risk classifications is related to selecting specific break points which are related to the fuzzy functions, e.g. at 'low–medium' crossover and 'medium–high' crossover as outlined in Table 8.11. This is considered to introduce a classification system consistent with the overall risk model and, in particular, with relative classification of 'high' risk devices.

The risk model identifies that knowledge of the levels of accuracy of performance is required, specifically of medical equipment which provides a measurement and treatment function. While this conclusion is entirely reasonable, it is also identified

Table 8.9 Details relating to level of intrinsic function reliability

State	Function number	Key value	Verbal reasoning element
Very Low	1	1.67	Intrinsic device reliability is very low
Very Low–Low		2.5	Intrinsic device reliability is very low to low
Low	2	3.33	Intrinsic device reliability is low
Low–Intermediate		4.17	Intrinsic device reliability is low to intermediate
Intermediate	3	5.0	Intrinsic device reliability is intermediate
Intermediate–High		5.84	Intrinsic device reliability is intermediate to high
High	4	6.67	Intrinsic device reliability is high
High–Very High		7.5	Intrinsic device reliability is high to very high
Very High	5	8.33	Intrinsic device reliability is very high

that this is not an area where a significant amount of data exists on which to base such risk assessments.

While it is entirely possible to derive device failure rates within a single organisation, there is also value in establishing common criteria for determining such failure rates and comparing values between equipment maintenance organisations. This process would be especially relevant as part of equipment evaluation. This confirms the recommendation outlined within Chapters 2 and 3 that improved device management programmes would result from a sharing between departments of information such as device reliability. It is identified as important that the routine data from equipment maintenance databases is available to derive reliability information which can in turn be used within such risk models. Device failure rate is utilised within unavailability risk and can be extracted satisfactorily where planned service activity can be separated from breakdown maintenance. Data on intrinsic failure rates may be more difficult to identify but is an important factor to determine. This requires discipline within the context of data collection within the equipment management database and in particular of definition of failure codes as outlined in Chapter 2.

The determination of various coefficients of the risk model requires a 'collective response' of experienced Biomedical Engineers and, where relevant, clinical users

Table 8.10 Details of coefficient file structure used to derive output risk parameter values and with indication of derived risk contributions

Model	**Datex Ohmeda (GE) Giraffe Omnibed**	**Specialised lab equipment SLE 5000**	**Alphamax**	**Babylog 200 transport incubator**
Equipment category	Infant incubator	Ventilator	Operating table	Infant incubator
Failure rate (annual average)	2.24	5.15	2.75	3.96
Criticality unavailability	7.5	7.07	7.07	7.07
Criticality measurement	5.84	7.07	0	5.84
Reliability measurement	7.5	7.07	0	7.5
Criticality treatment	5.84	7.07	0	5.84
Reliability treatment	7.5	7.07	0	7.5
Criticality diagnosis	5.84	7.07	0	5.84
Reliability diagnosis	7.5	7.07	0	7.5
Criticality intrinsic (failure)	7.02	7.07	5.84	5.84
Reliability (intrinsic failure)	7.5	7.07	7.07	7.5
Unavailability risk	7.7277	7.2567	7.2567	7.2567
Measurement risk	4.154	5	0	4.154
Treatment risk	4.154	5.487	0	4.154
Diagnostic risk	4.145	5	0	4.154
Intrinsic (failure) risk	5.4647	5.4987	4.1401	4.1401
Maximum risk (all elements)	7.7277	7.2567	7.2567	7.2567
Maximum risk (clinical)	5.4647	5.4987	4.1401	4.154
Risk code	HIGH	HIGH	HIGH	HIGH

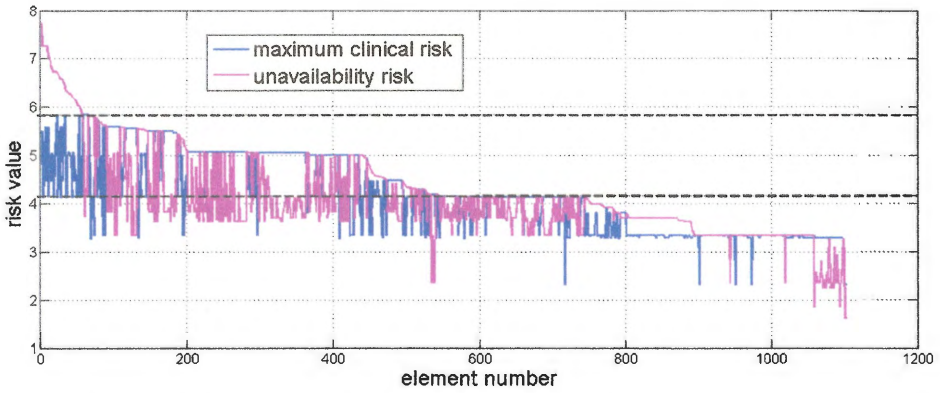

Figure 8.7 Distribution of risk within risk categories of unavailability risk and maximum clinical risk for a range of equipment models and where the elements (equipment models) are sorted in order of maximum risk of device unavailability

Table 8.11 Risk classification by estimated risk value

All maximum risk value criteria (r)	**Classification**
>5.84	High
5.84 ⩾ r ⩾ 4.17	Medium
<4.17	Low

based on understanding of the function of the equipment and more importantly, its role and associated risk in patient care. It is proposed, however, to develop a software application where the coefficients determining the risk elements of the clinical risk elements (see Table 8.10) are derived from 'smart dialogue' relating to the device function and clinical application. While the initial set of determinations of risk parameters have been undertaken using MATLAB™ programming using previously computed arrays of functions Fza3, Fzm3, Fzt3, Fzd3 and Fzi3, an implementation would also be possible using an Excel spreadsheet with macro functions to compute risk parameters from failure rate data and identified risk coefficients. In terms of size of data set required to configure such risk evaluations, details of 1000 models can be configured within an Excel™ file of around 100 kbytes.