



Using the Alert-iT Safe Scoring to assess client needs

Alert-iT has perfected a new method of risk assessment as applied to many of its products, which offers a more scientific probability basis than the conventional approach, while being much simpler to apply. In particular it makes it easy for a customer to assess the risk level of a client and then check a particular monitor can supply an acceptable safety level.

The essence of the system is to not make subjective judgements on the risk of any situation but to give a true probability value based on the known frequency of an event.

This information sheet is for customers wishing to use the technique to assess the suitability of a monitor. Full details on how this works for both products and clients are found in Technical Note [Risk assessment using Safety Scoring](#).

Client Risk

Let's begin with the risk of the client having an event that one of the Alert-iT products is monitoring. The scoring is very simple as shown in Table 1. This is based on the probability of the client having an event (eg seizure) on any day using the knowledge of the carer as to roughly how often the events occur over an extended period. The comment we often hear is that *"he has a minor seizure once a week but then a massive seizure every month or so"*. So at the start we will take the frequency as being Frequent with a score of 2.

Table 1: Probability of situation occurring

Description	Score ¹	Description	Frequency
Certain	0	Always present	More than 1 in 2 day
Very Frequent	1	Will Occur often	1 every 3-14 days
Frequent	2	Will Occur frequently	1 every 1-6 months
Probable	3	Likely To Occur	1 every 1-3 years
Occasional	4	Unlikely To Occur	More than 3 years
Remote	5	Very Unlikely To Occur	More than 30 years
Improbable	6	Assume It Will Not Occur	² More than 300 years

¹Note that normal risk scoring has a larger number for more dangerous situations. There are sound mathematical principles behind the system we use where the safer the situation, the higher the score.

²The addition of a category with only 1 event in 300 years may seem strange as no-one will live that long. However probability is based on a large number of people having a condition and a small number will have an event each year, even though not 300 years old. So a score of 6 relates to a condition where in a population of 1 million people, 1 person each year might suffer an event.

Client Harm

So on this basis the risk score for a client who has a seizure once a month is the same as that for a frail person who gets out of bed unaided once a month. But the consequence could be worse. The seizure could result in brain damage if allowed to continue beyond 2 minutes, while the frail person may break a bone. How can we create a number that adequately shows the difference in danger to the client.

For this we have derived a Harm Score that is simply added to the Risk Score to create a valuable Risk/Harm figure.

Table 2: Harm-Severity Score

Description	Val	Severity Of Hazard
Catastrophic	0	Death
Serious	1	Life Threatening
Critical	2	Severe Injury or Illness
Marginal	3	Minor Injury or Illness
Negligible	3	Less Than Minor Injury Illness
No Risk	7	No consequence

Some examples of this score are shown below:

Table 3 shows some typical examples

Frequency of Situation	Risk of Situation	Harm	Harm Score	Client Risk/Harm
Frequent 1 per month	2	Life Threatening	1	3
Probable 1 per year	3	Critical	2	5
Frequent 1 per month	2	Marginal	3	5
Occasional	4	Marginal	3	7

You will see that the method gives a similar rating for a critical event that happens once a year and a marginal frequent event. Which would not seem unreasonable.

Once the danger is so limited that the resulting score is 7, there is little need for monitoring.



Monitor Choice Evaluation

The preferred monitor will be chosen from the functionality and price profile. Once this is done it is essential to assess that the use of the monitor adequately meets the risk need for the client. As our monitors are Class 1 Medical Devices they should only be used to supplement the normal care arrangements in place. It is not unreasonable to adjust these arrangements in the light of experience, but only with the evidence of effective monitoring.

The monitors will have been evaluated for risk during the design process and the minimum client risk/harm figure chosen to ensure the overall risk probability is less than 1 in 10,000,000 for undetected death. This is considered a reasonable level in the international standard ISO14971.

In the table 4 below is the minimum acceptable risk/harm figure for each monitor. Provided the client's actual figure derived above is greater or equal to this figure, the monitor should be adequate for your need.

Table 4: Monitor minimum supported client risk/harm score

Epilepsy support for	Monitor	Client Score	Comment
Tonic/Clonic Seizures only	P176 Companion Mini		
Enhanced seizure types	P154 Companion	3	
Flexible configuration for difficult presentations	P139 Guardian		

