

## General System Risks

Frequency of user condition

Risk to user of incident

0.10000

Risk	Mitigation	Prob	Score
Radio network fails because of interference	Pager detects failed "heartbeat" signals	none	0.00000
Pager fails	2 Pagers can be used to remove any concern, but reliability very high. Failure to operate is visible	unlikely	0.00001
Pager battery goes flat	Pager has two levels of warning so unlikely to occur	none	0.00000
Total Score			0.00001

## General Monitor Risks

Frequency of user condition

Risk to user of incident

0.10000

Risk	Mitigation	Prob	Score
Monitor computer chip fails	Radio heartbeat will fail and be detected	none	0.00000
Monitor sensor detection fails	Carer required to test each night, hence probability of failure in one night very low	unlikely	0.00001
Sensor cable fails	The most likely failure, but carer required to test each night, hence probability of failure in one night should be low. Increased to 2 to allow for poor carer vigilance in this	1per year	0.00010
Monitor radio circuit fails	Radio heartbeat will fail and be detected	none	0.00000
Monitor too far from pager	Radio heartbeat will fail and be detected	none	0.00000
Monitor turned off	Radio heartbeat will fail and be detected	none	0.00000
Power to monitor removed	Battery power will maintain operation. Fault alarm will be sent if battery goes flat. Radio heartbeat will fail and be detected if battery fails	none	0.00000
Total Score			0.00011

## Tonic/Clonic Detection

Frequency of user condition

1per month

0.01000

Risk to user of incident

health risk

10.00000

0.10000

Risk	Mitigation	Prob	Score
Seizure detector fails or falls from bed	Carer required to test each night, hence probability of failure in one night very low	1per year	0.00010
User moves from central bed position	Sensor will still detect slightest bed movement even when user moves. Carer must test operation all over bed if user known to move	1per year	0.00010
User jerks become less strong	Carer must assess range of jerk strength expected and test sensor operates reliably	1per year	0.00010
User falls from bed	The Bed Vacation sensor should be added if such situation is predictable	unlikely	0.00001
Total Score*weighting	Only sensor =1	1.00000	0.00031

## Urination

Frequency of user condition

none

0.00000

Risk to user of incident

no risk

0.00000

0.00000

Risk	Mitigation	Prob	Score
Sensor fails	Carer required to test after washing, hence probability of failure very low.	unlikely	0.00000
Sensor cable disconnected	Mat tested in situ.	1per year	0.00000
User moves away from the sensor	Carer is required to assess sleeping pattern to ensure sensor positioned correctly	1per year	0.00000
Total Score*weighting	Only sensor =1	1.00000	0.00000

## Vomit

Frequency of user condition

none

0.00000

Risk to user of incident

no risk

0.00000

0.00000

Risk	Mitigation	Prob	Score
Sensor fails	Carer required to test after washing, hence probability of failure very low.	unlikely	0.00000
Sensor cable disconnected	Mat tested in situ.	1per year	0.00000
User moves away from the sensor	Carer is required to assess sleeping pattern to ensure sensor positioned correctly	1per year	0.00000
Total Score*weighting	Only sensor =1	1.00000	0.00000

## Sound

Frequency of user condition	none	0.00000	
Risk to user of incident	no risk	0.00000	0.00000
<b>Risk</b>	<b>Mitigation</b>	<b>Prob</b>	<b>Score</b>
Microphone fails	Carer required to test each night, hence probability of failure in one night very low	unlikely	0.00000
Background noise increases	Designed to reject background noise, which would cause false alarms	unlikely	0.00000
User vocalisation changes	Carer must assess range of noises expected and test sensor operates reliably	unlikely	0.00000
User moves away from microphone	Carer must assess sleep patterns expected and test sensor operates reliably	unlikely	0.00000
Total Score*weighting	Only sensor =1	1.00000	0.00000

### **Breathing**

Frequency of user condition	none	0.00000	
Risk to user of incident	no risk	0.00000	0.00000
<b>Risk</b>	<b>Mitigation</b>	<b>Prob</b>	<b>Score</b>
Sensor fails	Will cause false alarm	none	0.00000
User moves away from central bed position	Will cause false alarm	none	0.00000
Building subject to high vibration	Extremely unlikely, and will be noted at installation if for a considerable period.	unlikely	0.00000
Mattress moves (e.g. for pressure relief)	Performance of the monitor is tested in situ. Ripple may cause breathing monitoring to fail for the short tube inflation period	unlikely	0.00000
Total Score*weighting	Only sensor =1	1.00000	0.00000

### **Bed Vacation**

Frequency of user condition	none	0.00000	
Risk to user of incident	no risk	0.00000	0.00000
<b>Risk</b>	<b>Mitigation</b>	<b>Prob</b>	<b>Score</b>
Sensor fails as if vacant	Will cause false alarm	none	0.00000
Sensor fails as if occupied	Very rare fault, unless soaked in urine and the mat MUST BE protected if this is a risk	unlikely	0.00000
User moves away from sensor (mat type)	Carer must assess sleep patterns expected and choose and test sensor accordingly	none	0.00000
Heavy object placed on bed (leg type)	Unlikely but must be considered if user likely to take things into bed	unlikely	0.00000
Total Score*weighting	Only sensor =1	1.00000	0.00000

### **Result**

Total system score ("normalised" years).	3.04	0.00033
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Normalised years are calculated to reflect the potential severity of a missed incident. 1 can be interpreted as a minor incident every year or a major incident every 10 years.