

RISK RATING

The severity of the hazardous events, combined with their occurrence probability determines the total risk potential of a device.

This analysis uses the following risk class ratings:

Risk Class	Interpretation
Class I	Intolerable risk
Class II	Undesirable risk and tolerable only if risk reduction is impracticable or if the costs are grossly disproportionate to the improvements gained
Class III	Tolerable risk if the cost of risk reduction would exceed the improvement gained
Class IV	Negligible risk

Table 1: Risk Classes

These risk classes are linked to occurrence probability, and the consequence of the event:

Frequency	Consequence			
	Catastrophic	Critical	Marginal	Negligible
Frequent	I	I	I	II
Probable	I	I	II	III
Occasional	I	II	III	III
Remote	II	III	III	IV
Improbable	III	III	IV	IV
Incredible	IV	IV	IV	IV

Table 2: Risk Matrix

The device shall not generate a risk greater than Class III under normal operating and single fault conditions. However, frequent risks should not be tolerated, and incredible frequency will not be assumed. Catastrophic risks like the multiple deaths can be excluded due to the limited damage potential of the device. Therefore, the following sub-set from Table 3 is used:

Frequency	Consequence		
	Critical	Marginal	Negligible
Probable	I	II	III
Occasional	II	III	III
Remote	III	III	IV
Improbable	III	IV	IV

Table 3: Acceptable Risks (ALARP)

The shaded part of the table represents the risk area, which is considered to be within the ALARP range.

The final risk assessment grades the “risk of a device” based on the mitigated or controlled risks. To enhance clarity, and to better identify the effectiveness of the control/mitigation measures, the unmitigated risk is also graded using the same rating.