Hazard Analysis Report

Device Name/ Model Name

Confidentiality Statement

Document Authorisation

Task	Name	Signature	Date
Document Prepared By	Enter the In-charge Person's Name	Insert Signature	DD-MM-YYYY
Document Reviewed By	Enter the In-charge Person's Name	Insert Signature	DD-MM-YYYY
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Revision History

Version	Release Date	Change History
Version Number	DD-MM-YYYY	Changes made on the particular release date mentioned in previous column.

1. Scope

Name of the Manufacturer has conducted the hazard analysis for the device 'Device Name'. This document includes the full hazard analysis table.

2. Severity and Probability Definitions

For the purpose of hazard analysis, there are two general purposes namely quantitative analysis parameters are introduced: Severity and Probability. Definitions for these terms are provided below. The two parameters are then multiplied together to form the Risk Index product metric (RI) which quantifies the probability of severity of harm occurring as a result of a hazard arising within the system.

Severity: The severity of harm caused by the identified hazard when it occurs, rated from 1-5 using the scale provided below. It is referred to in **Table 4**. using the "S" symbol.

Table 1: Severity Score Definition Table

Severity	Description	Rating
Very Low	It would be unreasonable to expect that the minor nature of this failure would cause patient harm.	1
Low	The nature of the failure causes slight patient harm with no lasting effects.	2
Moderate	Failure causes or may cause a minor health hazard or minor injury to the patient.	3
High	Failure causes or may cause a serious health hazard or serious injury to the patient with lasting effects.	4
Very High	A potential failure could cause severe injury or patient death.	5

Table 1. Severity Score Definition Table.

Probability: The probability of harm posed by the identified hazard when it occurs, rated from 1-5 using the scale provided below. It is referred to in **Table 4**. using the "P" symbol.

Table 2: Probability Score Definition Table

Probability	Description	Rating	Harm Rate
Very Low	Failure is unlikely to cause patient harm. Isolated failure associated with almost identical systems	1	1 in 100,000
Low	Isolated failures associated with similar systems leading to patient harm.	2	1 in 10,000
Moderate	Patient harm occurs occasionally.	3	1 in 1,000
High	Patient harm occurs generally.	4	1 in 100
Very High	Patient harm is almost inevitable.	5	1 in 10

Table 2. Probability Score Definition Table.

NOTE: This is **NOT** the probability of the hazard occurring, but rather *the probability of harm occurring* as a result of the identified hazard. Thus, the final column on the right of **Table 2Error! Reference source not found.** is entitled "Harm Rate" rather than "Failure Rate".

Risk Index: Product of the Severity Score and Probability Scores used to determine the risk acceptability level. It is referred to in **Table 4** using the "RI" symbol. The two-dimensional matrix (probability of harm vs. severity of harm) used to determine the acceptability of risk as one of three categories:

Table 3: Risk Index Score Definition Table

Probability (P)	Severity (S)					
		1	2	3	4	5
	1	Low	Low	Low	Low	Moderate
	2	Low	Low	Low	Moderate	Moderate
	3	Low	Low	Moderate	Moderate	High
	4	Low	Moderate	Moderate	High	High
	5	Low	Moderate	High	High	High

Table 3. Risk Index Score Definition Table.

3. Hazard Analysis Table

Table 4: Hazard Analysis Table

Initial Assessment							Residual Risk			
HAZ#	**System**	**Hazard**	**Cause(s)**	**S**	**P**	**RI**	**Action/Mitigation**	**S**	**P**	**RI**
1	Mention the hazard type like General, Operational, Manufacturing, User Interface, etc… in this column.	Mention the specific hazard in this column.	Mention the cause for the hazard mentioned in the previous column.				Mention the action take to mitigate the hazard mentioned in the previous columns.			

Table 4. Hazard Analysis Table