Enhancing ISO 14971 Execution

A Comprehensive MBSE Language Extension for Medical Device Risk Management

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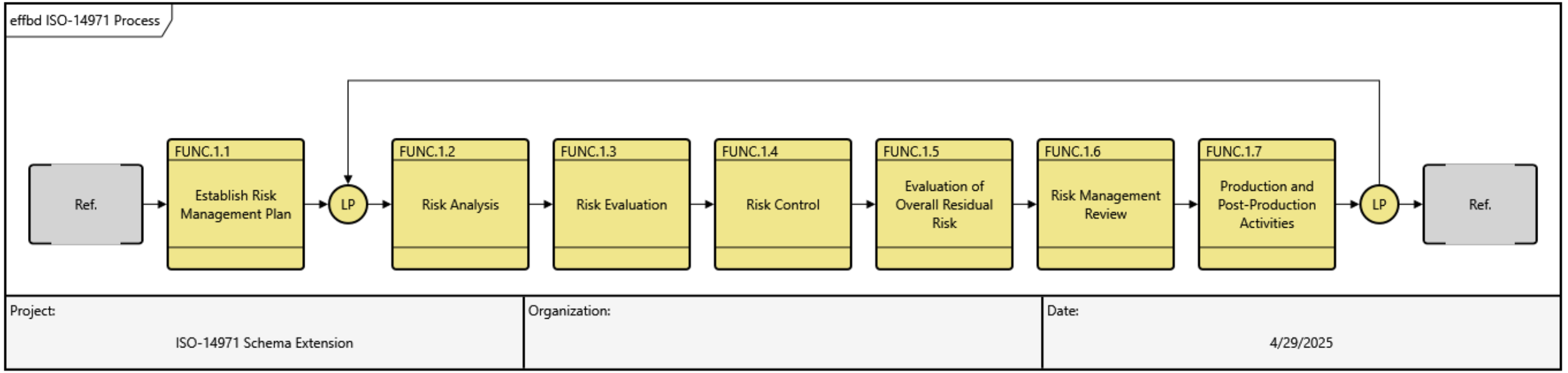
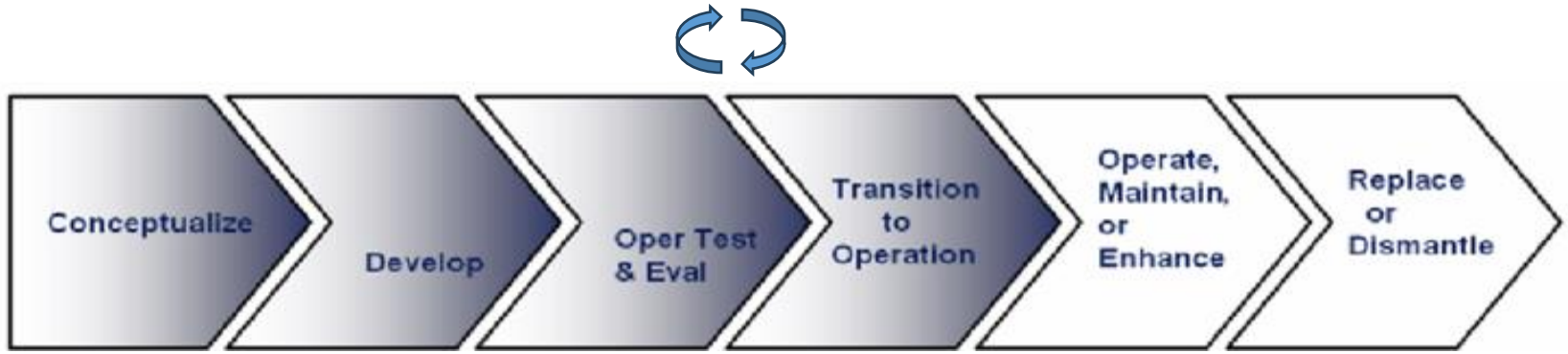
ISO 14971 Overview

- Provides a framework for managing risks associated with medical devices
- Primary goal is to ensure that they are safe for use by identifying, evaluating, and controlling risks throughout the device's lifecycle

ISO-14971 Process





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Common Challenges with ISO 14971

- Complex Documentation Requirements
- Integration with Existing Processes
- Traceability Gaps
- Continuous Monitoring and Updating
- Balancing Compliance with Innovation
- Treating Risk Management as a "Checkbox" Activity

Sources:
1. Risk management for medical devices and the new ISO 14971. bsi.
2. Risk management as an innovation catalyst: https://www.todaysmedicaldevelopments.com/article/risk-management-as-an-innovation-catalyst/

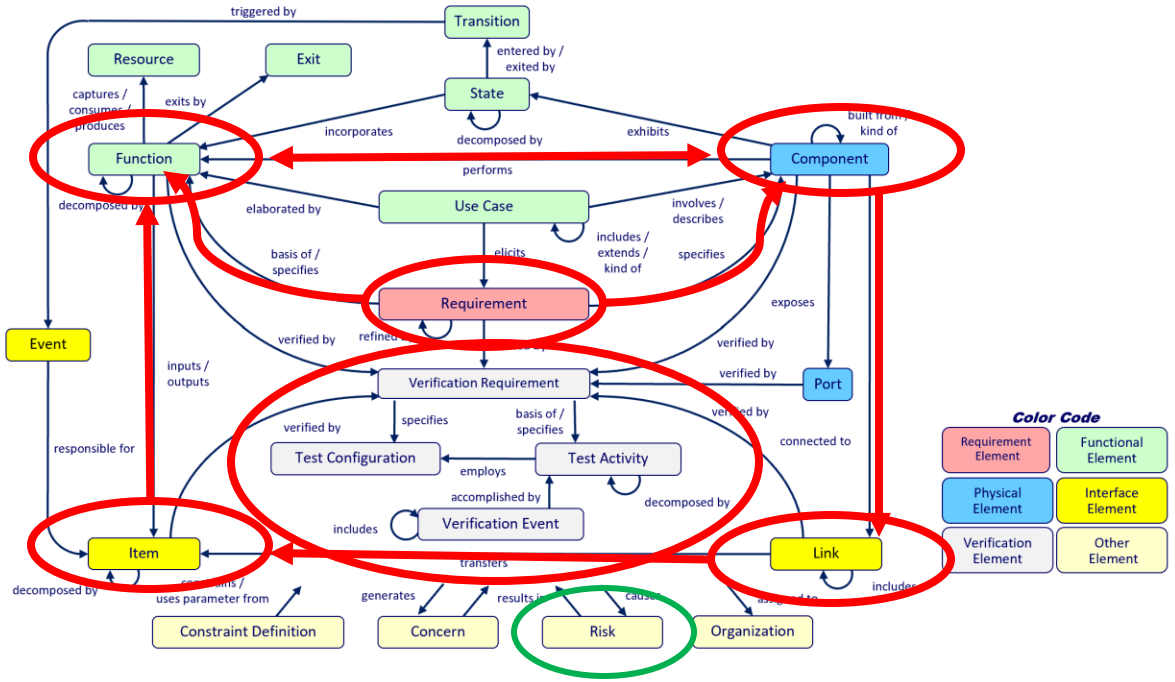
Introduction to CSDL

CSDL
COMPREHENSIVE SYSTEMS DESIGN LANGUAGE

Key Features:

- ✓Natural language
- ✓Semantic Precision
- ✓SE + PM + Specialty Engr.
- ✓Extensible/Translatable
- ✓"3-C" Automated Check
- ✓Supports:

SysML™ UAF® OMG UNIFIED ARCHITECTURE FRAMEWORK®



Concept Representation

Risk Management Concept	Description	CSDL Class (E / M / N)	Custom Attributes
Record	Document stating results achieved or providing evidence of activities performed	**Document** (E)	
Hazard	Potential source of harm	**Hazard** (N) *+ **Item** (E) – for activity sequencing*	
Intended Use (Normal Use)	Use for which a product, process (3.14) or service is intended according to the specifications, instructions and information provided by the manufacturer	**Use Case** (M)	• Type (Intended Use; Reasonably Foreseeable Misuse) • Disease Type • Part of Body • Intended Patient Population • Operating Principle
Reasonably Foreseeable Misuse (Abnormal Use)	Use of a product or system in a way not intended by the manufacturer, but which can result from readily predictable human behaviour.		

Concept Representation

Risk Management Concept	Description	CSDL Class (E / M / N)	Custom Attributes
Sequence of Events / Process	Set of interrelated or interacting activities that use inputs to deliver an intended result	**Function** (E) *+ functional flow constructs*	
Hazardous Situation	Circumstance in which people, property or the environment is/are exposed to one or more hazards.	**State** (E)	
Top Management	Person or group of people who directs and controls a manufacturer at the highest level	**Organization** (E)	
Medical Device	Instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s)	**Component** (E)	

Concept Representation

Risk Management Concept	Description	CSDL Class (E / M / N)	Custom Attributes
Risk / Risk Analysis / Risk Assessment ….	Combination of the probability of occurrence of harm and the severity of that harm / systematic use of available information to identify hazards and to estimate the risk.	**Risk** (M)	• Type • Last Assessed Date • Last Commit Note
Risk Control	Process in which decisions are made and measures implemented by which risks are reduced to, or maintained within, specified levels	**Mitigation Activity** (E)	• Last Assessed Date • Last Commit Note
Risk Management File	Set of records and other documents that are produced by risk management.	**Document** (E) *+ custom reports (future work)*	
Verification	Confirmation, through the provision of objective evidence), that specified requirements have been fulfilled	**Verification Requirement** (E) **Verification Activity** (E) **Test Configuration** (E)	

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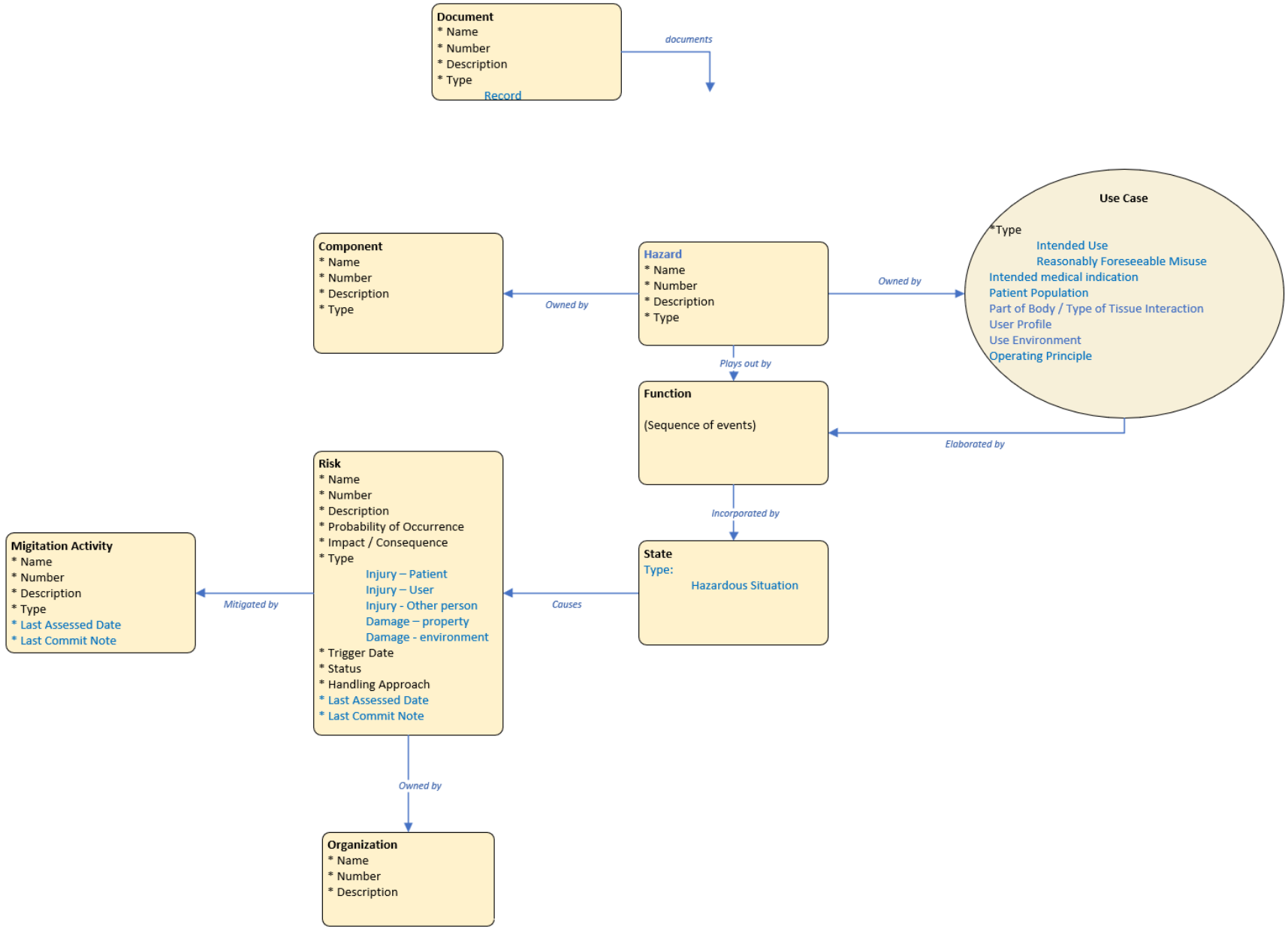
CSDL Extension for ISO-14971



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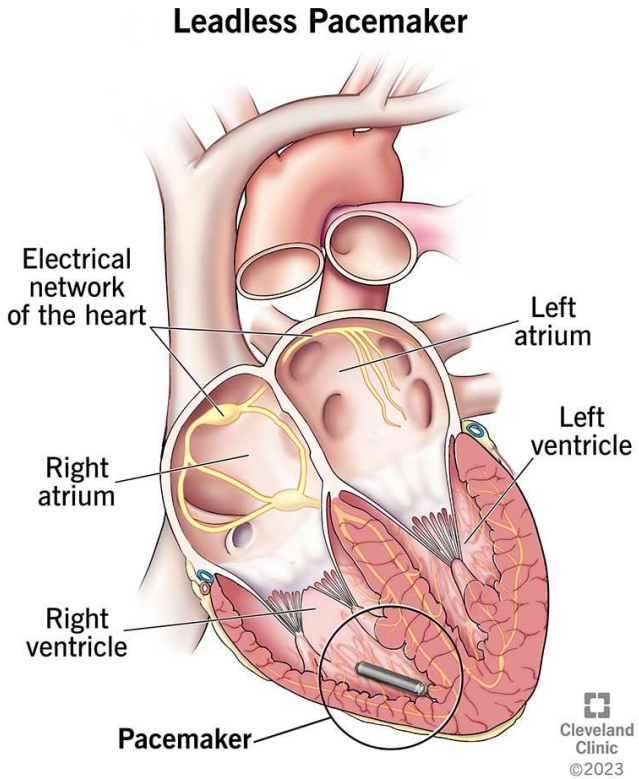

Leadless Pacemaker

Example

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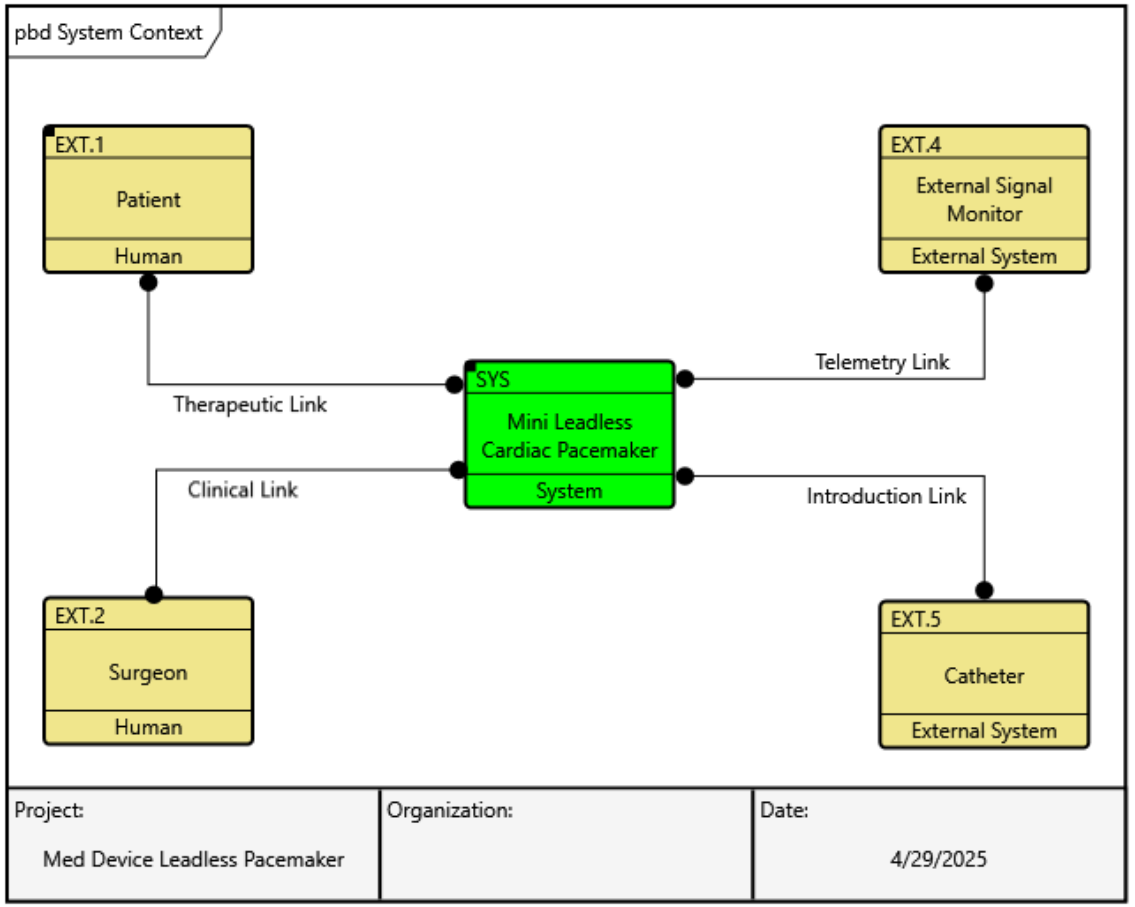
System Requirements

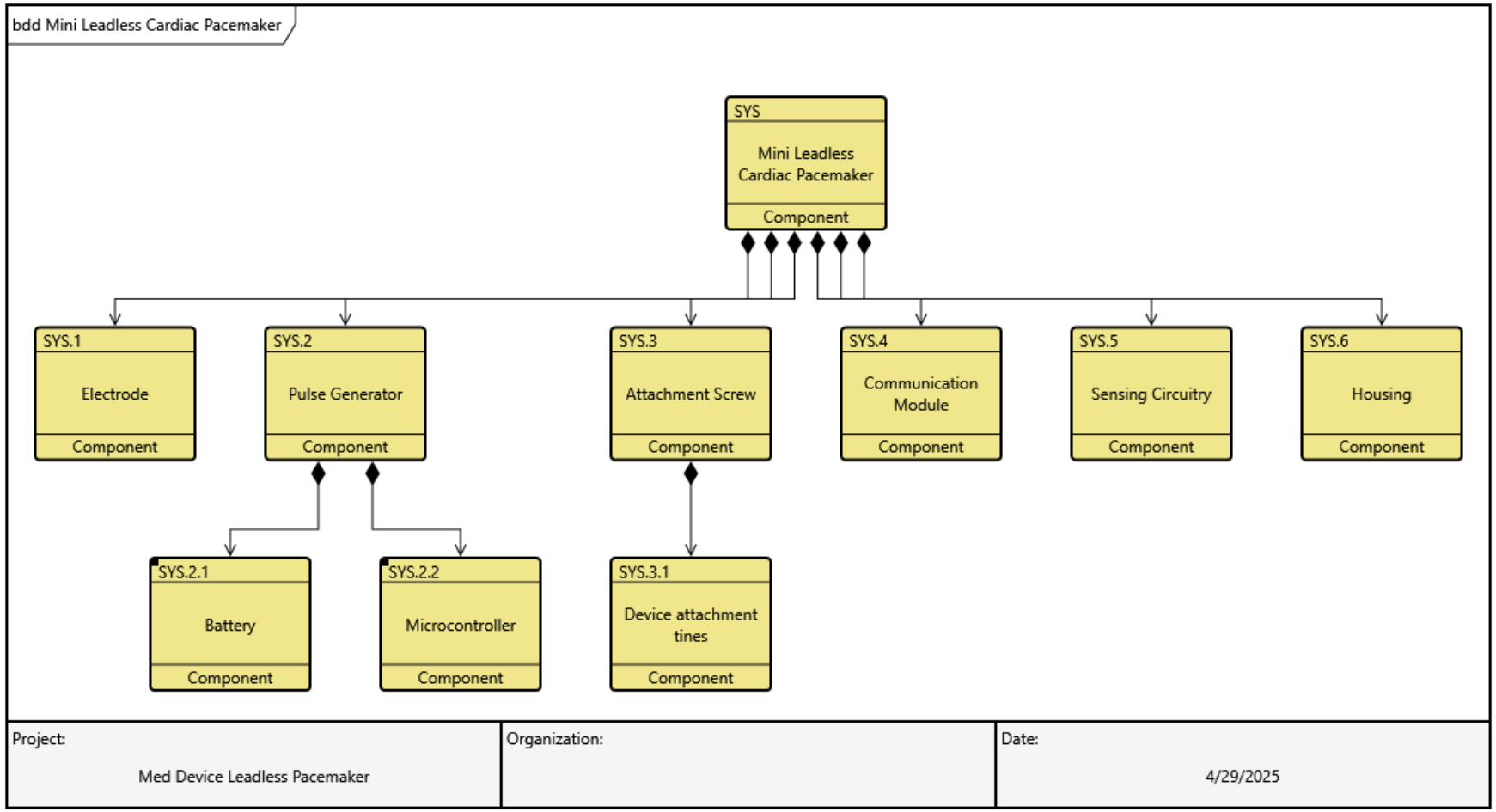
Table View Name: System Requirements

Number	Requirement	Type	Description	Parent Requirement
1.1.1	Surgical Introduction of Pacemaker into Patient	Functional	The system shall be implantable directly into the patient's heart ventricle via an introducer through the cardiac vessels and att...	1.1 Surgical Introduction of Pacemaker
1.1.2	Pacemaker Introduction via Catheter	Functional	The system shall be introduced surgically into the patient's heart by way of a trans-pectoral catheter.	1.1 Surgical Introduction of Pacemaker
1.1.3	Catheter Insertion	Functional	The trans-pectoral catheter for system introduction shall be inserted surgically	1.1 Surgical Introduction of Pacemaker
1.1.4	Catheter Guidance into Heart	Functional	The system shall be guided to the implantation site through the trans-pectoral catheter which remains in place for attachment adjustment during surgery.	1.1 Surgical Introduction of Pacemaker
1.1.5	Pacemaker Attachment into Heart	Functional	During surgery, the system shall be attached to a location within the endocardial tissue selected by the surgeon for optimal performance.	1.1 Surgical Introduction of Pacemaker
1.1.6	Pacemaker Release Post Attachment	Functional	The system shall be released by the catheter guidance equipment when sufficient attachment to the selected endocardial location...	1.1 Surgical Introduction of Pacemaker
1.1.7	Recapturing Pacemaker via Catheter	Functional	The system shall be recaptured by the catheter guidance equipment for location and orientation adjustments deemed necessary by the surgeon (per Post Introduction Adjustment requirements.)	1.1 Surgical Introduction of Pacemaker
1.2	Post Introduction Adjustment	Composite	The system shall be doctor adjustable post operation and initial programming for optimal performance.	
1.2.1	Pacemaker Attachment Test	Functional	The surgeon shall perform a pacemaker attachment test to confirm system attachment at the proper location, orientatio	1.2 Post Introduction Adjustment

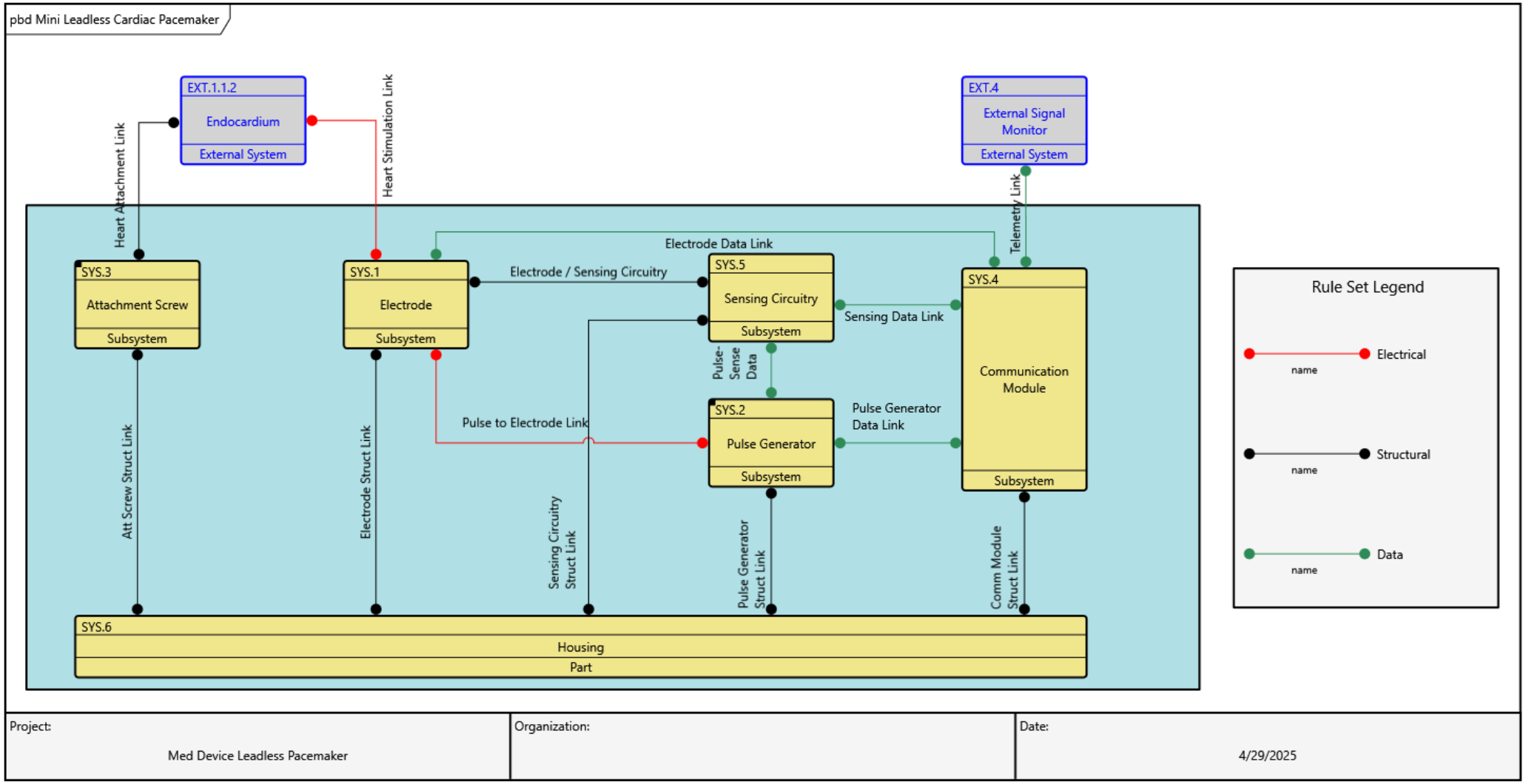
System Context



System Architecture: BDD

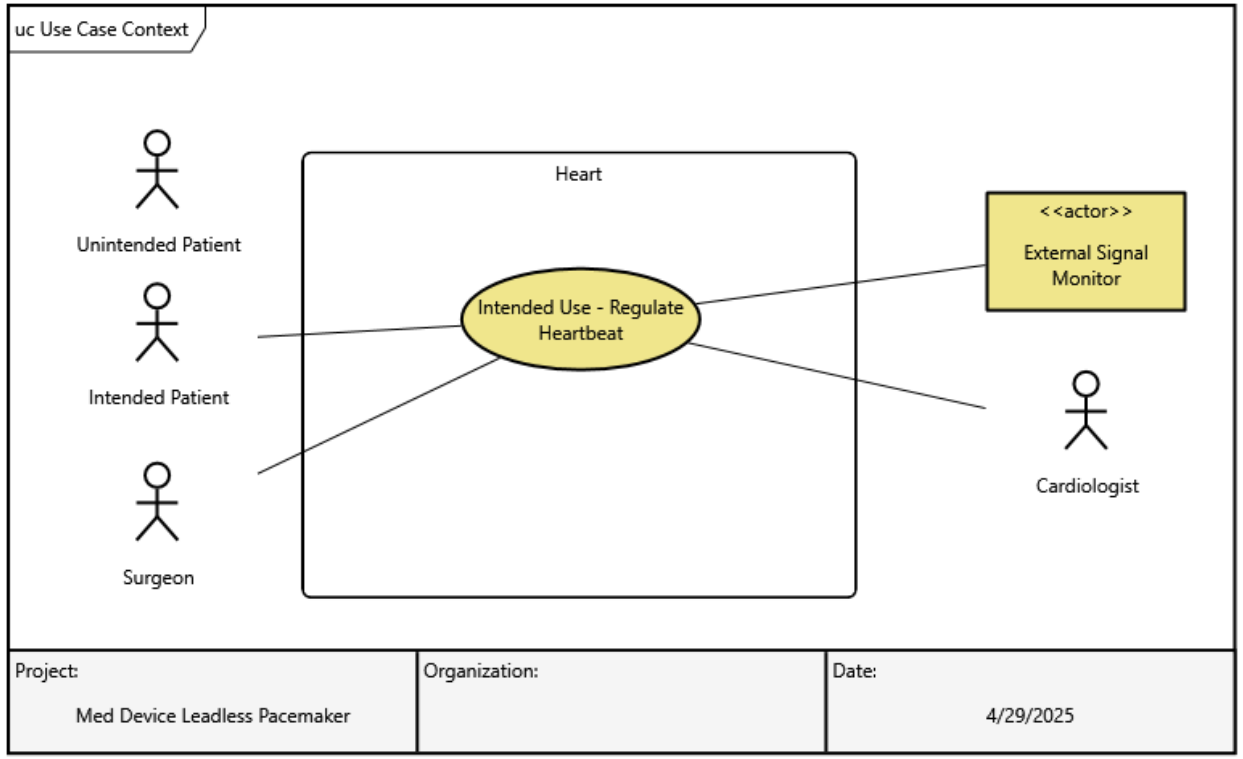


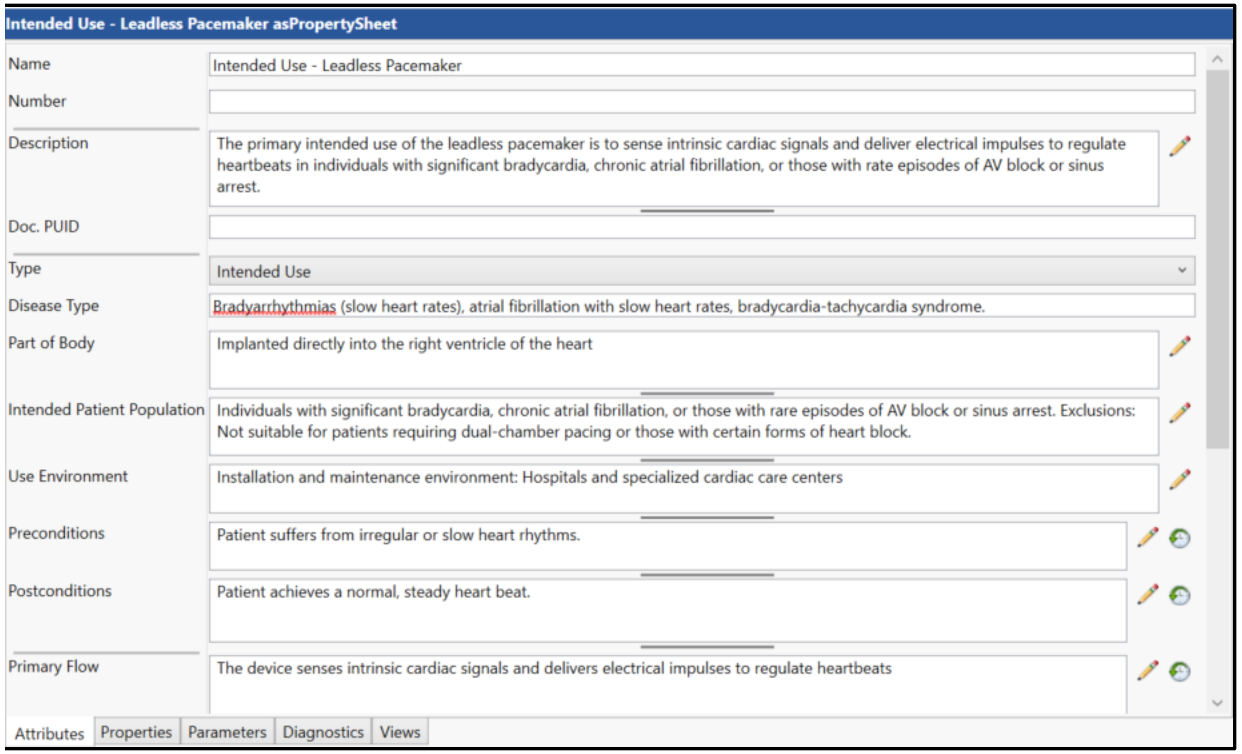
System Architecture: PBD



Risk Assessment: Risk Analysis

Normal Use ("Intended Use")





Risk Assessment: Risk Analysis

Abnormal Use ("Reasonably Foreseeable Misuse")

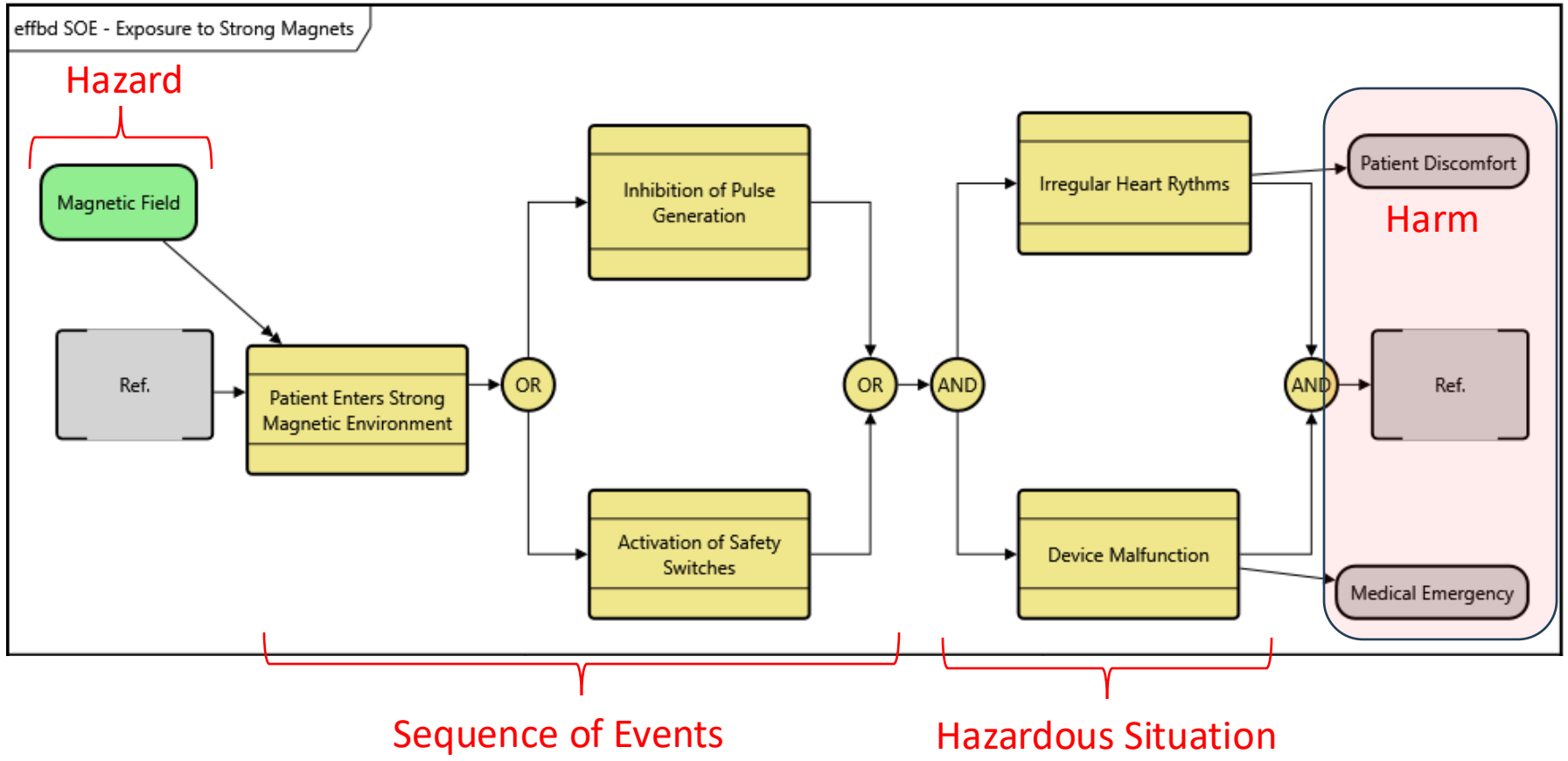
Name	Exposure to Strong Magnets
Number	
Description	Usage of the device outside the intended operational environment such as those with strong magnets including Magnetic Resonance Imaging (MRI), Extracorporeal Shock-Wave Lithotripsy (ESWL), Radiofrequency ablation (RFA), or high-frequency short-wave or microwave diathermy, may cause the leadless pacemaker to malfunction.
Doc. PUID	
Type	Reasonably Foreseeable Misuse

Name	Incorrect Implantation
Number	
Description	Errors during the implantation procedure, such as improper positioning or securing of the device, can lead to complications like cardiac perforation
Doc. PUID	
Type	Reasonably Foreseeable Misuse

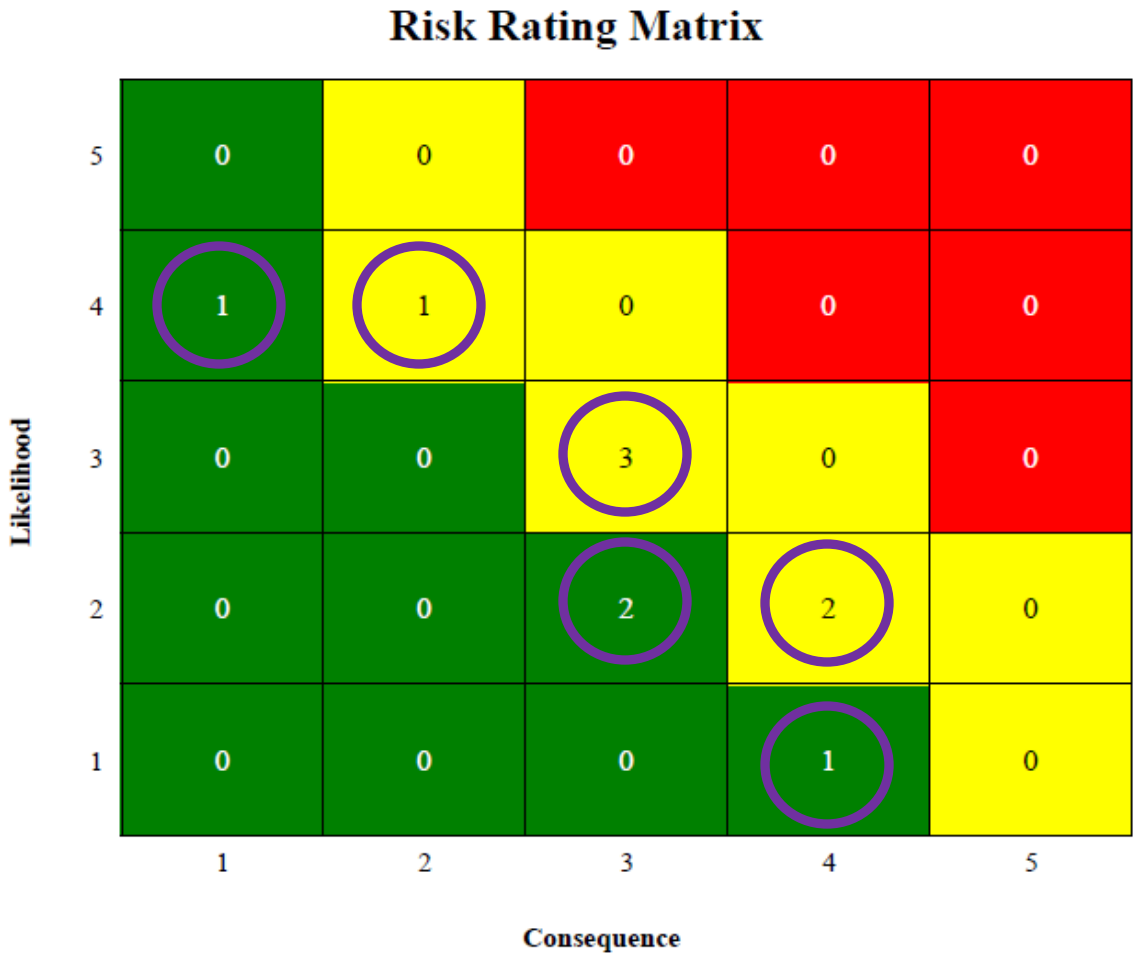
Name	Off-Label Use
Number	
Description	Using the leadless pacemaker for conditions or patient populations not specified by the manufacturer, such as patients requiring dual-chamber pacing.
Doc. PUID	
Type	Reasonably Foreseeable Misuse

Identify Hazards and Hazardous Situations

Hazard:
Magnetic Fields



Risk Matrix



Rating	Score	Name	Likelihood	Consequence	Status
Medium	9	Device Dislodgment	3 - Likely	3 - Moderate	Active
Medium	9	Infection	3 - Likely	3 - Moderate	Active
Medium	9	Irregular Heart Rhythms	3 - Likely	3 - Moderate	Active
Medium	8	Cardiac Perforation	2 - Low Likelihood	4 - Significant	Active
Medium	8	Pacemaker Malfunction	2 - Low Likelihood	4 - Significant	Active
Medium	8	Temporary Inhibition of Pacemaker Function	4 - High Likelihood	2 - Minor	Active
Low	6	Battery Failure	2 - Low Likelihood	3 - Moderate	Active
Low	6	Thrombosis	2 - Low Likelihood	3 - Moderate	Active
Low	4	Device Encapsulation	4 - High Likelihood	1 - Minimal	Active
Low	4	Permanent Damage to Pacemaker	1 - Not Likely	4 - Significant	Active

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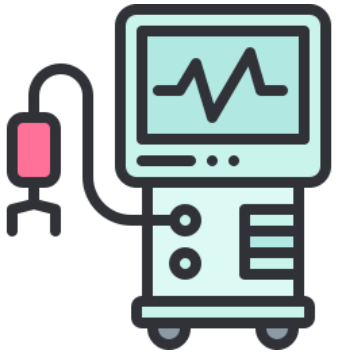
Risk Control (Mitigation Activities)

Risks and Harm - Risk and Mitigation

Table View Name: Risks and Harm

Risk	Description	Probability	Consequence	Risk Score	Status	Risk Control
Thrombosis	Blood clots can form around the device, leading to complications such as stroke.	2 - Low Likelihood	3 - Moderate	6	Active	Anticoagulant Therapy
Temporary Inhibition of Pacemaker Function	Symptoms: Short-term irregular heartbeats or pauses in pacing3. Consequences: Typically resolves once the magnetic field is removed, but can cause temporary discomfort and anxiety	4 - High Likelihood	2 - Minor	8	Active	
Permanent Damage to Pacemaker	Symptoms: Persistent irregular heart rhythms, device failure3. Consequences: May necessitate device replacement or reprogramming, involving additional surgical procedures	1 - Not Likely	4 - Significant	4	Active	
Pacemaker Malfunction	Symptoms: Similar to irregular heart rhythms, including potential cessation of pacing 3. Consequences: May require immediate medical intervention to restore normal heart function	2 - Low Likelihood	4 - Significant	8	Active	
Irregular Heart Rhythms	Symptoms: Dizziness, fatigue, palpitations, chest pain. Consequences: Can lead to decreased blood flow, fainting, or even heart failure if severe.	3 - Likely	3 - Moderate	9	Active	
Infection	Infection at the implantation site can occur, potentially leading to serious health issues and requiring device removal.	3 - Likely	3 - Moderate	9	Active	Sterile Technique and Prophylactic Antibiotics
Device Encapsulation	The pacemaker may become encapsulated in cardiac tissue over time, which can affect device retrieval but generally does not impact its function.	4 - High Likelihood	1 - Minimal	4	Active	Biocompatible Materials
Device Dislodgment	The pacemaker may become dislodged from its position in the heart, leading to malfunction and irregular heart rhythms.	3 - Likely	3 - Moderate	9	Active	Improved Fixation Mechanisms
Cardiac Perforation	Occurs when the pacemaker punctures the heart wall during implantation or repositioning. This can lead to serious complications such as cardiac tamponade or death.	2 - Low Likelihood	4 - Significant	8	Active	Enhanced Imaging Techniques
Battery Failure	The pacemaker's battery may fail, causing the device to cease functioning and necessitating replacement.	2 - Low Likelihood	3 - Moderate	6	Active	Regular Monitoring and Alerts

Summary



Benefits of Current Solution

- Natural language implementation
- End-to-end traceability
- Risk management is integrated into MBSE and the system architecture
  - Streamlined impact analysis

Future Work

- Solicit additional industry feedback
- Develop standard report templates
- Include scripts for monitoring assistance

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Thank you for attending!

Share your experiences at #HWGSEC