







# Systematisation of Security Risk Knowledge Across Different Domains: A Case Study of Security Implications of Medical Devices

Laura Carmichael<sup>1</sup><sup>a</sup>, Steve Taylor<sup>1</sup><sup>b</sup>, Samuel M. Senior<sup>1</sup><sup>c</sup>, Mike Surridge<sup>1</sup><sup>d</sup>, Gencer Erdogan<sup>2</sup><sup>e</sup> and Simeon Tverdal<sup>2</sup><sup>f</sup>

<sup>1</sup>IT Innovation Centre, University of Southampton, Southampton, U.K.

<sup>2</sup>Sustainable Communication Technologies, SINTEF Digital, Oslo, Norway

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**Abstract:** Shared terminology and understanding are vital for effective cybersecurity risk management for connected medical and in vitro diagnostic device systems, given that such processes are collaborative and require cross-domain expertise particularly, e.g., in the areas of patient safety, cyber-physical security, and privacy. However, fostering effective, interdisciplinary risk communication can be challenging — especially where, e.g., different terms are used with the same meaning, or the same risk management terms are interpreted differently across domains. In this paper, we focus on the systematisation of security risk knowledge across different domains related to the cybersecurity of connected medical and in vitro diagnostic device systems. This work relates to knowledge base extensions for a specified cybersecurity risk assessment tool—Spyderisk—as part of the NEMECYS project.


## 1 INTRODUCTION


A growing number of people depend on connected medical and in vitro diagnostic devices (Quigley and Ayihongbe, 2018) as part of wider “digital health practices” (Busnatu et al., 2022)—e.g., to “deliver medication, monitor body functions, or provide support to organs and tissues” (Food & Drug Administration (FDA), 2019). Medical devices need “connectivity” for various reasons—such as, to connect “multiple sensors and actuators in body”, to “[r]ecord data and transmit to practitioner”, to “[m]onitor health status and treat (e.g., artificial pancreas, pacemaker)”, and to store “[p]ersonal data for device operation (e.g., patient’s goal blood sugar level)” (Badrouchi et al., 2020). For instance, some connected medical devices contain sensors to “measure vital signals”, which are used to inform decisions made by patients and clinicians that “result


in an action on the body” (Sliwa, 2018). Whereas other connected medical devices contain “actuators” that “act directly on the human body”—such as, “pacemakers” and “insulin pumps” (Sliwa, 2018), and a subset of these are implanted in the human body (Tabasum et al., 2018).


While greater use of connected medical and in vitro diagnostic devices can enhance individual care and supported self-care practices, the increasing connectivity of such devices also comes with greater exposure to cyber threats that “can potentially lead to increased risk of harm to patients” (Therapeutic Goods Administration (TGA), 2022a). For instance, cyber security threats could lead to “denial of intended service or therapy”, “alteration of device function so that it can cause patient harm” and “loss of privacy or alteration of personal health data” (Therapeutic Goods Administration (TGA), 2022b). In extreme cases, “the consequences of inadequate cybersecurity for connected medical devices are perhaps some of the most dire, with the potential for serious harm or even death” (Strunk, 2017).


Due to the ubiquity of ICT hardware, software, and devices, cybersecurity concerns affect a widespread and varied set of related domains. These domains can be disciplines in their own right (e.g.,


<sup>a</sup> <https://orcid.org/0000-0001-9391-1310>

<sup>b</sup> <https://orcid.org/0000-0002-9937-1762>

<sup>c</sup> <https://orcid.org/0000-0002-3428-9215>

<sup>d</sup> <https://orcid.org/0000-0003-1485-7024>

<sup>e</sup> <https://orcid.org/0000-0001-9407-5748>

<sup>f</sup> <https://orcid.org/0000-0003-1660-4127>

privacy or safety), but they can also be sector-specific (e.g., the medical sector, which is the focus of this paper). Each domain has its own specialists and nomenclature, and there can be challenges in communication between the domains due to different naming schemes. Further, it is often the case that cybersecurity is related to risk management, as this offers an approach to assessing the likelihood and impact of the consequences of threats, such as cyber-attacks or system failures. Here, the threats may be in the cybersecurity domain, but their consequences and risks may affect entities and actors who understand the terminology of a related domain. There is thus a need to organise (systematise) knowledge concerning cybersecurity and risk management and across multiple areas.

Shared terminology and understanding are therefore vital for effective cybersecurity risk management for connected medical and in vitro diagnostic devices, especially given that a risk governance framework will involve multiple tools and approaches (Yaqoob et al., 2019; Wu and Kusnitz, 2015). Yet, establishing effective risk communication and fostering collaboration between individuals and organisations can be challenging in practice, as people from different organisations may use different cybersecurity risk management approaches and standards (Schmidt, 2023). Even where the same standards are used there may be different interpretations within an organisation (Wu and Kusnitz, 2015). Further, in some cases the same words can be used but with different meanings—for instance, consider how the term “*loss of availability*” can be interpreted differently in safety and security contexts for connected medical devices (Piggin, 2017). It should also be emphasised that cybersecurity risk management for connected medical devices requires collaboration between people from multiple domains with different levels of cybersecurity knowledge. However, “[c]urrent definitions of cybersecurity are not standardized and are often targeted towards cybersecurity experts and academics” (Neil et al., 2023).

In this paper, we focus on the systematisation of security risk knowledge across different domains related to the cybersecurity of connected medical devices as part of our work for the NEMECYS project where we are contributing to the development of “*tools and procedures to help device manufacturers, integrators and health care providers to ensure cybersecurity by design for connected medical and diagnostic devices*”<sup>1</sup>. As part of our research, we have been developing an initial framework that aims to integrate the terminologies, risk processes, and eval-

uation methods from both cybersecurity and medical device domains (from specified sources as outlined in section 3 of this paper) into a unified approach. The objective being to facilitate collaboration between e.g., cybersecurity professionals, device manufacturers, integrators and health-care providers, by fostering a shared understanding of risk concepts and their implications for patient care related to specified cybersecurity risk assessment tools being developed as part of the NEMECYS project. Our work is driven by four project use cases<sup>2</sup>.

This paper is structured as follows: Section 2 describes the key steps taken to develop the initial framework as part of the research method. Section 3 identifies the specific standards, regulations, and guidance that have been used to develop the framework. Section 4, outlines an initial framework to support the systematization of cross-domain knowledge. Section 5 provides a brief summary of related work. Finally, Section 6 concludes the paper.

## 2 RESEARCH METHOD

Our research approach consists of the following four steps to develop an initial framework supporting the systematization of cross-domain knowledge in the context of cybersecurity for connected medical and in vitro diagnostic devices.

**In Step 1, we integrated insights from literature and standards to support the validity of the proposed framework (Section 3).** This included reviewing some existing frameworks for risk assessment and management in both cybersecurity and medical device domains. The review of standards served as a backbone for the framework, ensuring that it aligns with established protocols and can be readily adopted by practitioners across fields.

**In Step 2, which was carried out in parallel with Step 1, we identified relevant definitions and terminologies across the two domains: cybersecurity risk management and medical device risk management (Section 3).** This involved collecting concepts and terminology from two international risk management standards ISO 27005 (ISO/IEC, 2022) and ISO 14971 (ISO, 2019), as well as aspects of the EU regulatory framework concerning connected medical and in vitro diagnostic devices. These sources were carefully examined to capture terms that address risk, harm, threats, and vulnerabilities. The goal was to identify overlaps, discrepancies, and unique terminologies within each domain, particularly where dif-

<sup>1</sup><https://nemecys.eu/overview/>

<sup>2</sup><https://nemecys.eu/about-us/use-cases/>

ferent terms are used for the same concept or the same term is used with varying meanings [e.g., (Schmidt, 2023)]. This collection laid the foundation for a comprehensive comparative analysis between cybersecurity and medical device contexts.

**In Step 3, we systematically mapped risk concepts to create a cross-domain understanding (Section 4).** By comparing frameworks like ISO 27005 (cybersecurity) (ISO/IEC, 2022) and ISO 14971 (medical devices) (ISO, 2019), key concepts such as risk assessment, evaluation, and control were analysed in detail to understand their structure, process flow, and any implicit assumptions in each domain. This mapping aimed to bridge conceptual gaps and provide a common basis for risk management in both fields.

**In Step 4, we developed an initial framework to support the systematization of cross-domain knowledge based on the mapping results (Section 4).** The initial framework integrates the terminologies, risk processes, and evaluation methods from both cybersecurity and medical device domains into a unified approach. It aims to enable consistent risk assessment by aligning the significant properties of assets (such as confidentiality, integrity, and availability) with the unique requirements of connected medical and in vitro diagnostic devices, like patient safety and clinical efficacy. This cross-domain framework is designed with the intention of facilitating collaboration between cybersecurity professionals, device manufacturers, integrators and health-care providers—through fostering a shared understanding of risk concepts and their implications for patient care.

### 3 SCOPE

For the purposes of the NEMECYS project, we are specifically focusing on two widely adopted international risk management standards in the domains of cybersecurity and medical device safety, which are:

- **ISO 14971:2019 Medical Devices — Application of Risk Management to Medical Devices** (ISO, 2019). The ISO 14971 risk management process applies “to all phases of the lifecycle of a medical device” and the risk associated with e.g., “biocompatibility, data and systems security, electricity, moving parts, radiation, and usability”.
- **ISO/IEC 27005:2022 Information Security, Cybersecurity and Privacy Protection — Guidance on Managing Information Security Risks** (ISO/IEC, 2022); part of the ISO/IEC

27000 family (ISO/IEC, 2018) concerning information security management. For instance, ISO 27001 certification is commonly required in business transactions.

The two processes for ISO 27005 and ISO 14971 are comparable, and follow similar structures—where risk management comprises risk assessment, risk evaluation and risk control (or treatment). For further illustration, see e.g., guidance on cybersecurity provided by the Medical Device Coordination Group (MDCG, 2019), the MITRE Playbook for Threat Modeling Medical Devices (MITRE and MDIC, 2021) and British Standards Institution (BSI) White Paper on Cybersecurity of Medical Devices (Piggin, 2017) which all map a security process with the ISO 14971 medical device safety risk process.

It is important to highlight that ISO 14971 explicitly mentions residual risk, which is the risk remaining after control measures have been employed to treat the risks identified, but residual risk is also highlighted in ISO 27005 as a determining factor towards risk acceptance or iteration of the process in order to identify more control measures to reduce residual risk.

It should be emphasised that “[r]isks related to data and security are specifically mentioned in the scope, to avoid any misunderstanding that a separate process would be needed to manage security risks related to medical devices” (ISO, 2019, p. 18), thus motivating the need to map cybersecurity risk assessment and medical device risk assessment. A starting point for this mapping is provided within ISO 14971, which provides examples of where “[b]reaches of data and system security can lead to harm, e.g., through loss of data, uncontrolled access to data, corruption or loss of diagnostic information, or corruption of software leading to malfunction of the medical device” (ISO, 2019, p. 19). Further, ISO 14971 is supported by guidance notes in the form of **ISO 24971:2020 Medical devices — Guidance on the application of ISO 14971** (ISO/TR, 2020). Annex F of ISO 24971 guidance (ISO/TR, 2020, pp. 55-59) specifically focuses on “risks related to security”. In addition to providing a general overview, Annex F focuses on four key aspects: “terminology”, “relation between ISO 14971 and security”, “characteristics of security risk management”, and “prioritising confidentiality, integrity, and availability”. While a brief overview of security risk management terminology is given by this informative guidance, more detailed mapping between these domains is required. The next section provides some examples of this mapping, including concepts and definitions from both domains.

It is important to emphasise that the principal fo-

cus of the NEMECYS project is on the EU regulatory framework related to cybersecurity of connected medical and in vitro diagnostic devices. In particular, **Annexes 1 of the Medical Device Regulation (EU, 2017a) and the In Vitro Diagnostic Devices Regulation (EU, 2017b)** contain cybersecurity requirements for connected medical and in vitro diagnostic devices. Further, the **Medical Device Co-ordination Group (MDCG) 2019-16** provides guidance on the cybersecurity for medical devices (MDCG, 2019). We have therefore also used the MDR, IVDR and relevant guidance issued by the MDCG as key sources for identifying risk management concepts and definitions.

## 4 INITIAL FRAMEWORK

In this section, we identify and describe some key risk management concepts from various sources in both cybersecurity and medical device domains—i.e., assets (section 4.1.1), significant properties (section 4.1.2), threats, hazards, events, incidents and hazardous situations (section 4.1.3), consequences and harm (section 4.1.4), and controls and corrective actions (section 4.1.5). Figure 1 provides a high-level view of the relationships between these cross-domain risk management concepts.

For purposes of illustration, we also discuss how this cross-domain risk concepts mapping has been interpreted for Spyderisk knowledge extensions in NEMECYS, providing examples of the different entity types that need to be modelled. Spyderisk (Phillips et al., 2024) is an existing knowledge-based expert system and automated risk simulator of cyber-physical systems. Spyderisk follows ISO 27001 and ISO 27005 (ISO/IEC, 2022), and is being extended in NEMECYS in terms of automated risk assessment related to the cybersecurity of connected medical and in vitro diagnostic devices. Such knowledge extensions require the systematisation of knowledge across different domains.

### 4.1 Key Concepts

#### 4.1.1 Assets

**Brief Description.** ISO 27005 takes an asset-based approach to risk assessment. An asset refers to “*anything that has value to the organization and therefore requires protection*” (ISO 27005). Connected medical and in vitro diagnostic device systems contain assets and the relationships between them. Asset types for ICT derived from ISO 27005 include e.g.,

data, software processes, computer hardware, computer networks. For modelling socio-technical systems involving the context in which these ICT components operate, asset types also include e.g., people, physical spaces and institutions, as these represent actors who may cause threats, be affected by consequences or describe the physical attributes of the environment.

**Definitions.** For *asset* see e.g., ISO 27005 (ISO/IEC, 2022), RFC 4949 (Shirey, 2007); and for *system* see e.g., ISO 27000 [Information System] (ISO/IEC, 2018), RFC 4949 (Shirey, 2007).

**Spyderisk Knowledge Extensions.** For connected medical and in vitro diagnostic device systems, three main Asset types need extension, which are: Human (people), Medical Device (which can be either subclasses of Computer Hardware or Software) and Data. Clearly, these map to Asset types described in the cybersecurity domain, but specific subtypes are required. **Table 1** describes typical subtypes in each of these Asset type categories. It should be noted that there are interrelationships and dependencies between these Asset types—e.g., different clinical workflows may determine process chains where different medical devices, data and people interact to achieve a specified clinical objective.

#### 4.1.2 Significant Properties

**Brief Description.** A significant property is viewed as an attribute of an asset that is regarded as important and needs to be upheld or preserved. In connected medical and in vitro diagnostic device systems, examples of significant properties include: ensuring the health, safety and wellbeing of patients and individuals, realising expected clinical benefits<sup>3</sup> associated with the use of such devices, and protecting the integrity, availability and confidentiality of data [e.g., (Ray, 2022b)].

**Spyderisk Knowledge Extensions.** As part of NEMECYS, we have been exploring different types of significant properties that are related to people—e.g., clinical benefits related to effectiveness, safety and timeliness of treatment, a person’s quality of life, and accuracy and timeliness of diagnosis with reference to e.g., MEDDEV 2.7/1 revision 4 (European Commission, 2016); MEDTECH 20 Ques-

<sup>3</sup>The term “clinical benefit” is defined by Art 2(53) of the MDR as “*The positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis, or a positive impact on patient management or public health.*” Of course, it should be noted that “*not all clinical benefits can be predicted*” (Wilkinson and van Boxtel, 2020).

Table 1: Examples of Asset Types.

Asset Type	Asset Subtype	Description
Human	Patient	Recipient of medical care.
Human	User	User of a medical device. May be Patient or other interested party such as carer.
Human	Clinician	Provider of and decision maker about medical care.
Human	Analytical Staff	Analysts of Measurement Data and produce Test Results.
Human	Medical Governance	Responsible for policy and governance of hospitals.
Medical Device	Sensor	Device that observes Patient. Generates Measurements / Sensed Data resulting from the observation.
Medical Device	Actuator	Device that administers energy (e.g., electricity for a pacemaker) or substances (e.g., medication) to the Patient.
Medical Device	Software (SaMD)	Software as a Medical Device (SaMD). Software tools used in monitoring / diagnosis / treatment of Patients.
Data	Sensed Data / Measurements	Observations resulting from Sensor monitoring / measuring specific attributes of Patient.
Data	Test Results	Analysis results of Measurements. Often used as input to diagnostic processes or to determine / adapt Treatment Plan.
Data	Diagnosis Result	Decision result of diagnostic process. Typically represents the identification of a disease.
Data	Care Plan	Documentation of process and resources for treatment of a Patient. Typically uses diagnosis as input.
Data	Actuator Configuration	Control data for actuator containing parameters specifying e.g., dosage, timing, duration etc.
Data	SaMD Configuration	Any control data required for operation of SaMD

tionnaire (Lesén et al., 2017). Refer to Table 2 for more information. Further, we have been examining significant properties related to data—e.g., “integrity”, “availability” and “confidentiality”, “authenticity”, “possession or control” and “utility” as presented by the “Parkerian Hexad” [see: (Andress, 2014); (Parker, 1998); (Piggin, 2017)], and “timeliness”. Refer to Table 3 for more information.

We have also been looking at existing significant properties related to connected medical and in vitro diagnostic devices that pre-exist in the Spyderisk Knowledge Base, known as the Spyderisk Network Domain Model. As shown in Table 4, the significant properties are grouped by the type of medical device—i.e., Sensor, Software and Actuator. Sensors are physical devices that measure quantities and generate data—and therefore incorporate the same significant properties as data (e.g., confidentiality, integrity, availability, authenticity, timeliness). Sensors may have software processes running within them, so have significant properties associated with software (e.g., availability, exploit trustworthiness, reliability and timeliness). Sensors are also physical devices, so have significant properties associated with devices (e.g., control). Similarly, Software as a Medical Device (SaMD) have the same set of significant properties associated with software processes. Actuators are physical devices that are controlled by software pro-

cesses, so have the subsets of significant properties associated with these subclasses.

#### 4.1.3 Threats, Hazards, Events, Incidents and Hazardous Situations

**Brief Description.** The term threat is used by ISO 27000 (ISO/IEC, 2018), which is defined as “*potential cause of an unwanted incident, which can result in harm to a system or organization*”. Whereas, the term hazard is utilised by ISO 14971 (ISO, 2019), which means a “*potential source of harm*”. Threats and hazards represent potential causes of unwanted incidents, adverse events or hazardous situations that lead to consequences. The risk management concepts of events, incidents and hazardous situations therefore can be grouped together, as they denote the actual manifestation of threats and hazards in the system under evaluation.

**Definitions.** See e.g., ISO 14971 [Hazardous Situation]; ISO 27000 [Information Security Incident]; MDR Article 2(57) [Adverse Event]; MDR Article 2(58); [Serious Adverse Event]; MDR Article 2(64); [Incident]; MDR Article 2(65) [Serious Incident].

**Related Spyderisk knowledge extensions.** Threats and Hazards are modelled inside the Spyderisk Knowledge Base as specifications describing the conditions under which the Incident or Event is possible (determined by a configuration of Assets

Table 2: Examples of significant properties related to individuals in terms of clinical benefit.

Category of clinical benefit	Sub-categories of clinical benefit and source	Derived significant properties
“positive impact on clinical outcome” (European Commission, 2016)	“reduced probability of adverse outcomes, e.g. mortality, morbidity”, “improvement of impaired body function” (European Commission, 2016)	Treatment Effectiveness, Treatment Safety, Treatment Timeliness
“patient’s quality of life” (European Commission, 2016)	“simplifying care or improving the clinical management of patients”, “improving body functions”, “providing relief from symptoms” (European Commission, 2016). [Also see: MEDTECH 20 Questionnaire (Lesén et al., 2017).]	Patient Life Quality
“outcomes related to diagnosis” (European Commission, 2016)	“allowing a correct diagnosis to be made”, “provide earlier diagnosis of diseases or specifics of diseases”, “identify patients more likely to respond to a given therapy” (European Commission, 2016)	Diagnosis Accuracy, Diagnosis Timeliness

and relations that need to be present in the System Model, known as a “matching pattern”) and the resulting Consequence. When the user of the tool builds a System Model, the Knowledge Base is consulted to determine the Threats / Hazards that are possible within the System Model, and those that are determined possible become Incidents (or Events). To illustrate the relationship between threats and hazards, incidents, events and hazardous situations, and consequences and harm, we consider the components of a serious incident as defined in Article 2(65) of the MDR. See Table 5 for a breakdown of this definition to show these relationships.

4.1.4 Consequences and Harm

**Brief Description—Consequences.** The term consequence is defined in ISO 27000 as “outcome of an event affecting objectives”(ISO/IEC, 2018). Each consequence has a risk level, which is determined by two contributory factors. First, the likelihood of the consequence is the chance of the consequence occurring and is determined by the Spyderisk automated risk assessment tool via examination of the likelihoods of all incidents leading to a consequence. Second, the impact (or severity) of the consequence is how severe or intolerable a consequence is to the objectives of the key stakeholders in the system under test. (Note: for Spyderisk, impact is usually set by the analyst using the tool, as it is a reflection of the preferences and tolerance of system stakeholders.)

**Brief Description—Harm.** When consequences affect the preservation or maintenance of one or more significant properties related to people—e.g. patients and other users of medical devices—this can lead to harm. The term harm is defined in ISO 14971 as “injury or damage to the health of people, or damage to property or the environment”. For the purposes of this discussion, we will specifically consider harms to pa-

tients and other users, such harm may either be direct or indirect.

Direct harm is actual injury to a person or damage to a person’s health caused by the device (e.g., an actuator device administers an incorrect dosage of medicine to a patient). However, in many cases harm to people will be considered as indirect<sup>4</sup>—as described by the MDCG (MDCG, 2024): “In most cases, harm or a deterioration of health will be indirect if arising from an incident linked to a medical decision, actions taken, or lack thereof, which are based on incorrect information, or results provided by a device.” For example, MDCG Guidance classifies different types of indirect harm resulting from in vitro diagnostic device usage and information—i.e. “a misdiagnosis”, “a delayed diagnosis”, “delayed treatment”, “inappropriate treatment”, “absence of treatment” and “transfusion of inappropriate materials” (MDCG, 2024).

**Definitions.** See e.g., ISO 27000 (ISO/IEC, 2018) and ISO 27005 (ISO/IEC, 2022) [Consequence, Likelihood, Risk]; ISO 14971 (ISO, 2019) [Harm, Risk and Severity]; MDCG (MDCG, 2024) [Indirect Harm].

**Related Spyderisk Knowledge Extensions.** As part of NEMECYS, we have been focusing on mod-

<sup>4</sup>As a further example, the UK MHRA states: “For software as a medical device (SaMD), indirect harm is the most probable outcome of adverse incidents and may occur as a consequence of the medical decision, action taken/not taken by healthcare professionals and/ or patients and the public based on information or result(s) provided by the SaMD” (Medicines & Healthcare products Regulatory Agency (MHRA), 2023). The MDCG 2022-2 also states: “Due to their nature, in the majority of cases, deficiencies of [in vitro diagnostic devices] IVDs do not directly lead to physical injury or damage to the health of people. If any, these devices may lead to indirect harm, rather than direct harm” (MDCG, 2022).

Table 3: Examples of significant properties related to data.

Significant property	Source
<b>Availability</b> means the data is accessible to authorised parties when they need it.	See definition of Availability in: ISO/IEC 27000. Also cited in: IEC Guide 120 (IEC, 2023) and Annex F to ISO 24971 (ISO/TR, 2020).
<b>Authenticity</b> is a special subclass of integrity—the difference being that integrity is concerned with correctness (freedom from errors and fit for purpose) whereas authenticity is also concerned with freedom from deliberate alteration or forgery. The Parkerian Hexad definition also highlights attribution as an important aspect of authenticity—i.e., whether the data’s author or creator can be accurately identified.	From Parkerian Hexad: Address (Address, 2014); Parker (Parker, 1998) (Also see (Piggin, 2017))
<b>Confidentiality</b> means the data is accessible only to authorised parties (and no others).	See definition of confidentiality in ISO/IEC 24767-1:2008, which is also cited in IEC Guide 120 (IEC, 2023) and Annex F to ISO 24971 (ISO/TR, 2020). Also see definition of data confidentiality in RFC 4949 (Shirey, 2007)
<b>Integrity</b> determines if the data is free from corruption.	ISO/IEC 27000:2018; and Annex F to ISO 24971 (ISO/TR, 2020)
<b>Possession (or control)</b> concerns access to copies of data on physical media. This relates to the significant property of availability—i.e., whether the only copy of the data is lost. Possession also refers to multiple copies of data that are present in different contexts. Each copy must be guarded to ensure that control over its management, which can affect its confidentiality (e.g., if one copy is leaked) and integrity (e.g., if one copy or more is corrupted).	From Parkerian Hexad: Address (Address, 2014); Parker (Parker, 1998) (Also see (Piggin, 2017))
<b>Timeliness</b> means that the data is up to date, and is related to the significant property of availability.	Spyderisk Network Domain Model
<b>Utility</b> refers to whether the data is useful for its given purposes. Data may be altered, which may impact its usefulness. Typical examples of alteration that may affect utility are encryption (e.g., the data is rendered useless if the recipient does not have the decryption key) or redaction (e.g., removing certain parts of the data for anonymisation purposes).	From Parkerian Hexad: Address (Address, 2014); Parker (Parker, 1998) (Also see (Piggin, 2017))

elling types of indirect harms in Spyderisk concerning use of connected medical and in vitro diagnostic devices for diagnosis and treatment. For purposes of illustration, **Table 5** describes these indirect harms and links them to the significant properties related to people introduced above in Table 2.

#### 4.1.5 Controls and Corrective Actions

**Brief Description.** The terms control and corrective action are both used to describe measures or actions taken that aim to modify risk by reducing the likelihood of incidents resulting from a threat.

**Definitions.** See e.g., ISO 27000 [Control] (ISO/IEC, 2018); ISO 27005 [Vulnerability] (ISO/IEC, 2022); MDR, Article 2(67), [Corrective Action] (EU, 2017a); ISO 14971 [Risk Control] (ISO,

2019).

**Examples.** For instance, a “*master set*” of twenty “*technical cybersecurity controls*” are outlined in (Ray, 2022a), which include: “*Role-based authorization and access control*”, “*Emergency access*”, “*Restrict access*” etc. For other examples, also see: (Badrouchi et al., 2020) and (Sametinger et al., 2015).

**Related Spyderisk Knowledge Extensions.** In Spyderisk, Controls are applied at Assets and a Control Strategy is a collection of Controls applied to Assets that are intended to work together. A Control Strategy also has an Effectiveness, which is the strength of the combined Controls working on the Assets they are applied on to lower the likelihood of Incidents. The greater the effectiveness of the Control

Table 4: Examples of significant properties related to medical and in vitro diagnostic devices.

Asset	Significant property	Description
Sensor	Authenticity	The data (which may be embedded in an IoT device) is what it claims to be, i.e. it is neither forged nor altered in a way designed to induce false behaviour in other assets consuming the data.
Sensor	Availability	The asset is able to carry out its function within the system, including being accessible by other assets that need to interact with it.
Sensor	Confidentiality	Signifies that data (which may be embedded in an IoT device) is only accessible to authorised users.
Sensor	Control	Trustworthiness of the actor or process managing a host (including control over access to the host) while it is connected to the system and fulfilling its system role (i.e. in some context).
Sensor	Exploit Trustworthiness	Free of software vulnerabilities that are accessible to attackers.
Sensor	Integrity	The data (which may be embedded in an IoT device) is correct and fit for purpose.
Sensor	Reliability	Means the asset will perform tasks correctly, with no functional errors, assuming the asset is not supplied with corrupt or inaccurate information as input (in the case of Human or Process assets).
Sensor	Timeliness	Represents a state in which a data asset is up to date, or a process or human has up to date inputs.
Software	Availability	The asset is able to carry out its function within the system, including being accessible by other assets that need to interact with it.
Software	Exploit Trustworthiness	Free of software vulnerabilities that are accessible to attackers.
Software	Reliability	Means the asset will perform tasks correctly, with no functional errors, assuming the asset is not supplied with corrupt or inaccurate information as input (in the case of Human or Process assets).
Software	Timeliness	Represents a state in which a data asset is up to date, or a process or human has up to date inputs.
Actuator	Availability	The asset is able to carry out its function within the system, including being accessible by other assets that need to interact with it.
Actuator	Control	Trustworthiness of the actor or process managing a host (including control over access to the host) while it is connected to the system and fulfilling its system role (i.e. in some context).
Actuator	Exploit Trustworthiness	Free of software vulnerabilities that are accessible to attackers.
Actuator	Reliability	Means the asset will perform tasks correctly, with no functional errors, assuming the asset is not supplied with corrupt or inaccurate information as input (in the case of Human or Process assets).

Strategy, the lower the Likelihood of the Incidents, and the Control Strategy Effectiveness specifies an upper limit on the Likelihood of the Incident it targets.

The Spyderisk Knowledge Base already has extensive controls and control strategies implemented from the cybersecurity domain. These controls cover the following areas: “Organisational Measures”, “Physical Security”, “Service Security”, “Software Security”, “Data Security”, “Network Security”, “Client Security”, “Device Security”, “Resource Management”, and “User Intervention” (Phillips et al., 2024). For more information about these controls refer to Phillips (2024). Many of these controls are expected to address medical devices, as they contain many of the components (hardware, software, networks, spaces, etc.) already in the Spyderisk

Knowledge Base.

From the type of controls illustrated in the examples section above, it is clear that there is (unsurprisingly) a strong crossover between the controls needed for the cybersecurity of medical devices and those needed for the cybersecurity of other application domains. However, additional controls will be added as necessary to accommodate specifics of medical and in vitro diagnostic systems, which can work alongside the existing cybersecurity controls. The controls may be identified from multiple sources, such as the above, other literature, consultation with experts or in experiments following the use cases as part of the NEMECYS project.

Table 5: Components of ‘serious incident’ as defined by Article 2(65) of the MDR.

Legal definition for the term ‘serious incident’ is given by Article 2(65) of the MDR as follows:	Spyderisk modelling approach
“Any incident”	An instance of a Threat / Hazard occurring in the System under evaluation.
“That directly [...] led, might have led or might lead to any of the following”	Link from Incident to Direct Harm Consequences
“That [...] indirectly led, might have led or might lead to any of the following”	Link from Incident to Indirect Harm Consequences
“(a) the death of a patient, user or other person”, [/] (b) the temporary or permanent serious deterioration of a patient’s, user’s or other person’s state of health, [/] (c) a serious public health threat”	Consequence / Harm
“(b) the temporary or permanent serious deterioration of a patient’s, user’s or other person’s state of health”	Consequence / Harm
“(c) a serious public health threat”	[Not Yet Modelled]

Table 6: Indirect harm consequence types resulting from IVD usage (from MDCG 2023-3 (MDCG, 2024)).

Types of consequences that may indirectly lead to harms (MDCG 2023-3)	Modelling approach in Spyderisk	Affected significant properties
“Misdiagnosis”	Modelled as a Consequence for Humans to represent incorrect diagnosis.	Diagnosis Accuracy
“Delayed Diagnosis”	Modelled as a Consequence for Humans to represent a diagnosis that is late.	Diagnosis Timeliness
“Delayed Treatment”	Modelled as a Consequence for Humans to represent late treatment.	Treatment Timeliness
“Inappropriate Treatment”	Modelled as a Consequence for Humans to represent incorrect treatment.	Treatment Effectiveness, Treatment Safety
“Absence of Treatment”	Modelled as a Consequence for Humans to represent the lack of treatment.	Treatment Effectiveness, Treatment Safety
“Transfusion of Inappropriate Materials”	Not modelled explicitly — ‘transfusion of inappropriate materials’ to be considered as a sub-case of ‘inappropriate treatment’.	Treatment Effectiveness, Treatment Safety

## 5 RELATED WORK

In terms of semantic interoperability for medical devices, Schütz et al. (Schütz et al., 2021) have sought to define a “core ontology for medical devices in Germany”. More broadly, in terms of the “risk analysis field”, the Society for Risk Analysis provide a Glossary of terms which incorporates “different perspectives and its systematic separation between overall qualitative concepts and their measurements” (SRA, 2018). It should also be highlighted that in terms of cybersecurity for medical devices, Ray (Ray, 2022b) provides an introduction to “basic cybersecurity concepts”. Further, the International Medical Device Regulators Forum (IMDRF) has a working group focused on “adverse event terminology”—with one of the aims being to “improve, harmonize and where necessary expand the terminology and systems being

used to code information relating to medical device adverse events” (International Medical Device Regulators Forum (IMDRF), 2024).

As previously mentioned, guidance on cybersecurity provided by the Medical Device Coordination Group (MDCG, 2019), the MITRE Playbook for Threat Modeling Medical Devices (MITRE and MDIC, 2021) and British Standards Institution (BSI) White Paper on Cybersecurity of Medical Devices (Piggin, 2017) all map a security process with the ISO 14971 medical device safety risk process. In relation to comparing risk management concepts and terms for information security, Schmidt (2023) reviews well-known standards and frameworks, including the ISO/IEC 27000 series, and examines some related work. A key concept diagram is also presented mapping the relationships between them (Schmidt,

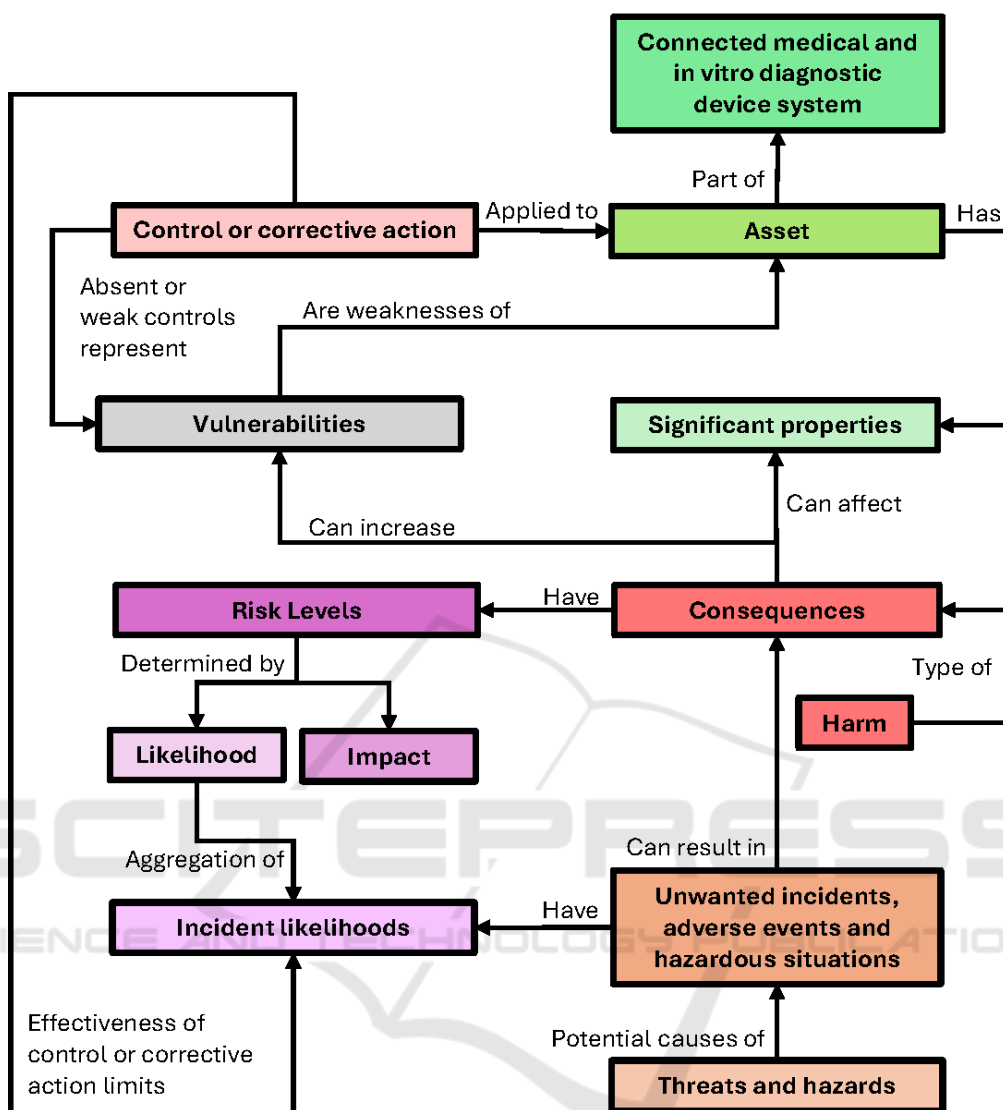


Figure 1: Overview of Some Key Risk Management Concepts.

2023). This comparison is centred on information security more generally, whereas our focus is on cross-domain concept mapping for cybersecurity of connected medical and in vitro diagnostic devices.

## 6 CONCLUSION

This paper presents an approach to systematizing knowledge related to risk management across the domains of cybersecurity and connected medical and in vitro diagnostic devices. This work relates to knowledge base extensions for a specified cybersecurity risk assessment tool, Spyderisk, as part of the NEMECYS project. Through a structured alignment of terminol-

ogy and risk concepts, based on the standards ISO 27005 (ISO/IEC, 2022) and ISO 14971 (ISO, 2019), our approach aims to support a shared understanding across diverse professional backgrounds.

The initial cross-domain framework proposed further highlights the importance of integrated cybersecurity measures within connected medical and in vitro diagnostic device systems, which are uniquely susceptible to threats that could compromise not only device functionality but also patient safety, health, and privacy. As future work, we intend to extend the reported systematisation to encompass additional healthcare-specific risks related to cybersecurity for such systems.

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