Electromagnetic Hazard Analysis Technique based on System-Theoretic Process Analysis

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***Abstract*—This paper presents a hazard analysis methodology based on systems thinking to address electromagnetic interference risks in complex systems. The presented methodology extends the recently proposed hazard assessment technique System-Theoretic Process Analysis to include hazards related to electromagnetic interference (EMI). This technique involves analyzing the control structure of the system to identify potentially unsafe control actions. The focus of this paper is on investigating how these actions can potentially arise due to the interaction of the system with its electromagnetic environment. Finally, the reasons why such unsafe interactions might occur are analysed, leading to the EMI loss scenarios. The proposed technique is applied to the use case of an insulin infusion pump to show its ability to identify new EMI hazardous scenarios. The traceability property of the proposed analysis technique allows to prioritize the EMI scenarios that might lead to the most critical losses.**

***Index Terms*— Electromagnetic Interference (EMI), systems thinking, hazard-and-risk analysis, system-theoretic process analysis.**

I. Introduction

Over the last decade, ensuring proper electromagnetic coexistence between devices and ensuring safety and functionality has become increasingly more challenging. The traditional way to deal with Electromagnetic Interference (EMI) is known as the "rules-based approach". This approach involves identifying relevant standards, implementing appropriate mitigation techniques, and testing for compliance with those standards. However, this strategy has severe limitations, including the potential for standards to become outdated or insufficient. Devices that meet the standards may still suffer from EMI in practice. A "risk-based approach", where the focus is on reducing the inherent risks of electronic systems to the lowest possible level, may offer a higher level of safety. Several studies [1], [2] have shown the importance of implementing this approach to increase electronic systems' safety, effectiveness and reliability.

The risk-based approach starts with an EMI hazard analysis to identify and evaluate hazards related to EMI by identifying sources of EMI and assessing their potential impact on the system. The final aim is to find measures to mitigate or prevent its adverse effects.

Over the years, many hazard analysis techniques have been developed. In general, these can be divided into three types, which should be applied together to the analysis of a system to ensure sufficient "failure coverage":

- "Brainstorming" methods, such as DELPHI or SWIFT.
- "Inductive" or "bottom-up" methods, such as FMEA, or Event-Tree [3].
- "Deductive" or "top-down" methods, such as Fault Tree Analysis [4] or HAZOP.

Unfortunately, at the moment, there are very few specific methods for analysing how hazards might be related to EMI. Therefore, selecting and adapting existing hazard analysis techniques to also address EMI issues is urgently needed [5].

In most traditional hazard analysis techniques, the basic approach is to divide the system into components and assume that accidents are caused by component failures. However, as system complexity increases, safety is becoming more and more an emergent property of the interaction between the systems' components. Such interactions can only be analysed and understood by looking at the system as a whole.

STAMP (System-Theoretic Accident Model and Processes) and STPA (System-Theoretic Process Analysis) [6] combine principles of systems thinking with a structured process for analysing and evaluating the safety of complex systems. Despite being only a decade old, these techniques have already demonstrated much greater effectiveness in identifying safety risks of complex systems compared to classical methods, like FTA or FMEA [7]. Recent studies have applied STAMP and STPA in the medical domain [8], robotics [9], [10] or aviation [11]. However, to the authors' knowledge, resilience against EMI has not been looked at with STAMP/STPA, nor have EMI-related risks been identified with this technique. Therefore, this paper proposes a way to extend STAMP/STPA to include EMI-related risks in complex systems and applies this to an insulin infusion pump.

The remainder of this paper is organised as follows. Section II presents the theoretical foundations of STPA. Section III presents the application of the EMI hazard analysis technique based on STPA to the use case of an insulin infusion pump. Section IV presents the results of applying this technique to the

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use case (i.e., EMI loss scenarios identification). Last, Section V draws concluding remarks.

II. System-Theoretic Process Analysis (STPA)

System Theoretic Process Analysis (STPA) is a hazard analysis method based on systems thinking and tailored to the needs of complex systems [6]. It heavily relies on system theory and control theory. The technique involves identifying the system's components, functions, and control structures, analysing the interactions between them, and evaluating the potential impact of these interactions on system performance and safety. The goal of STPA is to identify hazards and design measures to mitigate or eliminate them to ensure the safe and reliable operation of the system. To achieve this goal, STPA follows a structured process involving four steps (see Fig. 1).

The basic losses/accidents that must be prevented are identified during the first step. The second step is to build a model of the system's control structure (Step 2 of traditional STPA in Fig. 1). A control structure captures functional relationships and interactions by modelling the system as a set of control loops. Each control loop includes (i) a controller responsible for initiating the Control Action (CA), (ii) actuators for updating the control action, (iii) the controlled process, and (iv) sensors responsible for delivering feedback back to the controller.

The third step is to identify Unsafe Control Actions (UCAs), which might result in hazardous scenarios. These UCAs are used to create safety-related and functional requirements. The fourth step identifies the reasons why UCAs might occur in the system.

Once scenarios are identified, they can be used to create additional requirements, make design recommendations and new design decisions (if STPA is used during the initial design), evaluate/revisit existing design decisions and identify gaps (when STPA is applied during design iterations), or develop leading indicators of risk.

III. Use case: Insulin infusion pump

Diabetes Mellitus (DM) is a disease that affects the metabolism of nutrients due to a lack of insulin or the body's inability to use this hormone. One of the main types of DM are Type 1 (DM1), caused by lack of insulin production by the pancreas. Treatment for DM1 requires insulin administration, with the primary goal of achieving blood glycemic levels as close as possible to the non-diabetic range using Continuous Subcutaneous Insulin Infusion (CSII) [12]. Insulin administration introduces the risk of acute hypoglycemia (excessive blood glucose lowering), which may present severe consequences.

Traditional insulin pumps are battery-powered and contain an insulin reservoir, a pumping mechanism, and buttons or touch screens to program insulin delivery. Pumps send insulin through tubing into an infusion set that delivers the insulin to the user's body.

There are several reports about medical problems attributed to using a mobile phone near an infusion pump [13], [14]. The following infusion pump malfunctions were reported at [15]:

- February 21, 2006: Infusion pump with over-infusion, with the rate changing during the patient's infusion. The patient's cell phone rang, and the nurse at the bedside noticed that the rate of pitocin was displayed at 120 ml/hr rather than the prescribed rate of 20 ml/hr. The change was noticed in less than one minute, and there was no harm to the patient.
- June 19, 2006: The facility reported a pump that stopped infusing during patient use. The pump was infusing heparin, at which time the patient's family member used a cell phone close to the pump. The pump then stopped infusing. There was no patient injury or medical intervention.

Other cases reported in [15] also include:

- An electrostatic discharge damaged a patient-coupled infusion pump, but thankfully the alarm system was not affected and a nurse was alerted (EMI story 16, [15])
- Infusion pump caused interference with patient monitors (EMI story 250, [15]).
- An infusion pump changed the rate when a cellular phone was placed on the instrument stand (EMI story 446, [15]).
- Infusion pumps prone to alarms and error messages and even reversal in pump direction when phones were less than 1 m away (EMI story 453, [15]).
- Interference of RFID readers and tags with infusion pump was observed at 5 different frequency bands at a maximum distance of 136 cm (EMI story 879, [15]).

In this section, the proposed hazard analysis based on STPA is applied to this use case. The goal is to identify the EMI hazardous scenarios reported above to prevent them or minimise their occurrence.

A. EMI hazard analysis based on STPA

Traditional STPA [16] is limited in its ability to adequately address errors and malfunctions caused by EMI. In this section, the modified steps in STPA to include EMI-related hazards are explained (see Fig. 1) and applied to an insulin infusion pump to clarify the complete process.

1) Step 1: Identify losses/accidents: Within the STPA community, a hazard is defined as a system state or set of conditions that, together with a particular set of worst-case environmental conditions, will lead to a loss. Although EMI does not affect the hazards directly, it can affect their probability or severity, which is why EMI must be considered when trying to achieve risk levels that are acceptably low.

The first step (identical to traditional STPA), is to identify the losses on which the analysis will be focused, as well as the high-level hazards. Additionally, these losses can be ranked based on their severity. The criterion presented in Table I is based on standard ISO/TR 24971:2020 [17].

In our use case, the identified losses are shown in Table II, and Table III shows some of the identified high-level hazards and their link to losses. This use case is explained in [18], and the system characterization, losses and hazards presented in this section are partly extracted from that study.

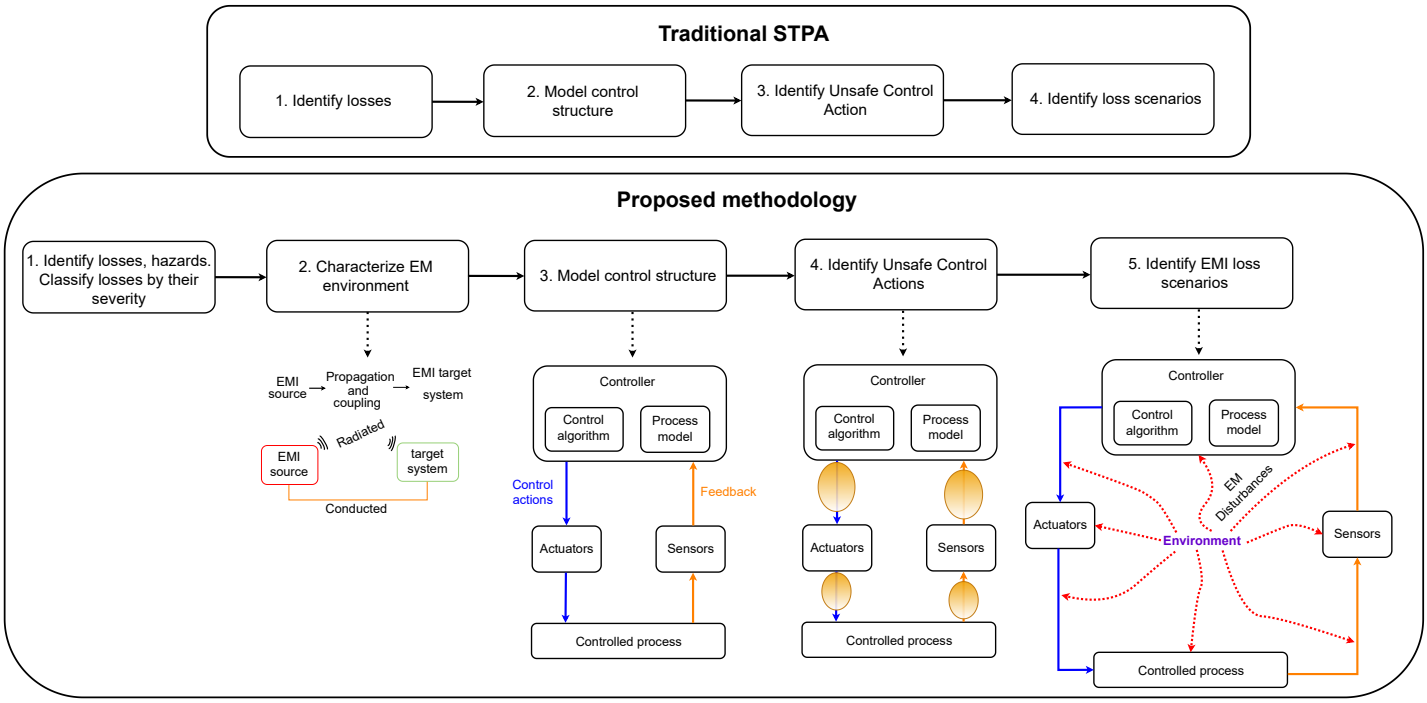

Fig. 1. Traditional STPA and proposed methodology steps

TABLE I
SEVERITY CLASSIFICATION

Severity	Effect on patient
Critical	Death, injury with a risk of death or permanent disability.
Moderate	Reversible injury without risk of death.
Negligible	Absence of injury.

TABLE II
LOSS/ACCIDENT OUTCOME LIST

[Loss]	Effect on patient	Severity
Hypoglycemia [L-1]	Blood glucose between 70 and 54 mg/dL	Moderate
Clinically significative hypoglycemia [L-2]	Blood glucose below 54 mg/dL	Moderate
Severe hypoglycemia [L-3]	Mental confusion, convulsions The patient needs external help	Critical
Hyperglycemia [L-4]	Blood glucose between 180 and 250 mg/dL	Moderate
Clinically significative hyperglycemia [L-5]	Blood glucose above 250 mg/dL Requires immediate action	Moderate
Severe hyperglycemia [L-6]	Blood glucose above 250 mg/dL May induce coma and even death	Critical
Loss of insulin infusion [L-7]	Insulin infusion interruption results in hyperglycemia	Critical

TABLE III
HIGH-LEVEL HAZARD LIST

[Hazard]	Description	Link to losses
[H-1]	Over infusion rate of insulin	[L-1], [L-2], [L-3]
[H-2]	Under infusion rate of insulin	[L-4], [L-5], [L-6]
[H-3]	Reversal in pump direction	[L-7]
[H-4]	Infusion interruption	[L-7]
[H-5]	Infusion pump alarm fails	[L-7]

2) Step 2: Characterize the EM environment: This step includes identifying potential EMI sources in the operating environment of the target system. EMI sources can be characterised by their possible location, operating frequency, bandwidth (narrowband/broadband), distance to the target system, mobility, duration of exposure (continuous/impulse EMI), and likelihood of occurrence.

To identify the potential EMI sources, we first need to characterize the intended environment of the device. In our use case, some insulin infusion pumps are designed mainly for stationary use at patient's bedside, while others are designed to be portable or wearable.

In the case of stationary use at patient's bedside, the following potential EMI sources can be considered:

- RFID tags and readers.
- Bluetooth or Wi-Fi applications which are integrated in smartphones and headsets for audio communication. Those may be used in the patient room by medical staff or the patient's family members.
- Base stations. Base stations for mobile communications can be in relatively close proximity to the hospital room.

- Implanted devices/defibrillators. Defibrillators can be placed at the patient's bedside in case of cardiac arrest and may also have Wi-Fi communication with a base station.
- Patient monitoring devices. Such as blood pressure monitors, they can transmit patient information wirelessly to their healthcare provider or other monitoring systems.

Regarding the EMI not coming from medical devices, a typical situation is using a mobile phone (e.g. GSM, UMTS,..) inside medical facilities. Some of the reported cases of EMI due to mobile phones are listed in Section III.

3) Step 3: Model the control structure.: During this step, the system is modelled through a sequence of control loops, as shown in Fig. 2.

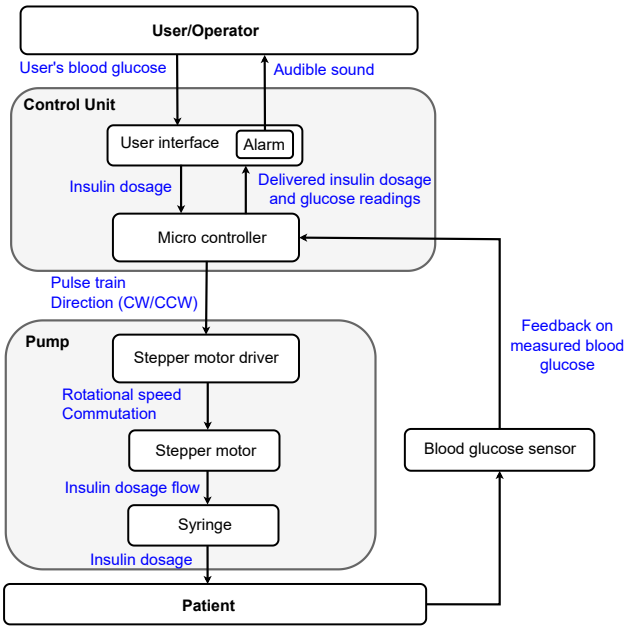

Fig. 2. Control structure of insulin infusion pump, based on [18]

First, the user provides their glucose level using the control keys on the user interface, which calculates the insulin dosage needed. For bed-side devices, the user interface is operated by a nurse and not directly by the patient. In the case of portable pumps, the user is the patient. Most pumps come with a built-in insulin dose calculator to assist the user in determining the amount of insulin needed based on their glucose levels. Then, the microcontroller commands the stepper motor (through the motor driver) to deliver insulin as programmed. The motor driver receives two signals from the microcontroller: a pulse train to specify the number of steps per second (specifying the speed of the stepper motor) and the direction in which the stepper motor rotates (clockwise or counterclockwise). With each pulse of the pulse train, the motor moves one step in the direction given by the direction signal. The mechanical transmission is used to transform the rotation of the stepper motor into linear movement of the syringe plunger. The syringe performs the interface for insulin delivery into the subcutaneous tissue of the patient. Last, the blood glucose sensor measures the blood glucose of the patient and gives feedback to the microcontroller, which changes the speed of the stepper motor accordingly to deliver more/less insulin.

4) Step 4: Identity Unsafe Control Actions: The pulse train and the stepper motor's direction, which control the flow of insulin delivered to the patient, are the most critical actuator signals in the system. Any disturbance that affects their normal operation might pose a risk to the user's health. Therefore, the following steps of the risk analysis mainly focus on the hazards that could arise from interruptions of alterations to these critical signals.

Some identified unsafe control actions from the control structure are listed below.

UCA-1: The user provides their blood glucose using the control keys on the user interface, but there is an error in the calculation of the insulin dose needed. This leads to the pump providing the wrong amount of insulin (over- or under-infusion). Link to hazards: Over infusion ([H-1]) and under infusion ([H-2])

UCA-2: Blood glucose measured by the sensor is not the actual blood glucose of the patient. If the measured glucose is higher than the actual value, the microcontroller might increase the speed of the stepper delivering more insulin to decrease the blood glucose level, leading to hypoglycemia. Link to hazards: Over infusion ([H-1]) and under infusion ([H-2])

UCA-3: Alarm sound fails to provide sound when insulin dose is higher/lower than expected, when infusion has stopped, when the insulin is empty, or when there is a sudden change in pump direction. This can be due to the slow time response of the blood glucose sensor in notifying these hazardous scenarios. One of the possible mitigation techniques for this UCA could be to provide a feedback signal for the actual insulin dose injected by the syringe. Link to hazards: Infusion pump fails to generate an alarm ([H-5]), over infusion ([H-1]), under infusion ([H-2]), infusion interruption ([H-4]) and reversal in pump direction ([H-3])

UCA-4: Modification of the pulse train, which impacts the stepper motor's speed. Each pulse sent to the stepper motor driver causes the motor to move one step clockwise or counterclockwise with a specific degree. If there is a disturbance imposed on the pulse train (i.e. continuous wave) and it increases its number of pulses, resulting in a faster speed (more insulin flow than intended). Link to hazards: Over infusion ([H-1]), under infusion ([H-2]) and infusion interruption ([H-4])

UCA-5: A change in the direction signal could potentially alter the direction of the stepper motor, such as switching from clockwise (CW) to counterclockwise (CCW). Link to hazard: Reversal in pump direction ([H-3]).

UCA-6: Insulin dosage reading on the user interface does not reflect the actual dosage delivered to the patient, and the alarm fails to notify the user about this mismatch. Link to hazard: Infusion interruption ([H-4]).

5) Identify EMI loss: The last step involves the identification of scenarios that may lead to UCAs and potential loss.

In this case, EMI is included as a reason why UCAs might occur in the system. EMI can lead to unsafe control action in the following cases:

- EMI affecting the controller. The control action sent by the controller is disturbed by EMI, leading to a transmission error.
- EMI affecting the communication path between the controller and controlled process. The control action is correctly sent by the controller but is disturbed in the communication path to the receiver.
- EMI affecting the controlled process (receiver). The control action is correctly received but wrongly executed because interference occurs on the receiver side.

Some of the identified EMI hazardous scenarios are listed below.

SC-1: The user provides their blood glucose using the user interface. However, due to an EMI (for example, caused by a mobile phone nearby) on the control path between the user interface and the microcontroller, the insulin dose is not correct, leading to an over- or under-infusion, which might be critical for the patient. Link to [UCA-1] and [UCA-3]
SC-2: Due to EMI on the blood glucose sensor, the measured blood glucose of the patient is not correct. If the measurement is higher than the actual levels, the motor speed will change accordingly and will reduce the dose rate, thus leading to an under-infusion, which might lead to hypoglycemia (H-1). Link to [UCA-2].
SC-3: The presence of a mobile phone near the infusion pump causes a displayed dose rate change during patient infusion. This scenario may arise from an induced voltage affecting the clock signal, resulting in a higher duty cycle and faster stepper motor speed, leading to an increase of insulin flow. That change may also be caused by EMI affecting directly the microcontroller. If that change is not noticed by the patient or the alarm system is also affected by EMI, this might lead to an over-infusion of insulin (H-1). Link to [UCA-4]
SC-4: A mobile phone placed close to the pump may also cause a reversal in pump direction, which causes the loss of infusion into the patient. (H-4). Link to [UCA-5].
SC-5: Alarm fails to notify the user when the insulin dose is higher/lower than expected, the infusion has stopped, the insulin tank is empty, or when there is a sudden change in pump direction. This can be caused by EM disturbance on the alarm system. Link to [UCA-3] and [UCA-6]

Once these scenarios are identified, they can be used to create safety requirements or mitigation techniques to avoid or minimise their occurrence. For example, for our use case:

- Alarms should be provided to identify over- and under-infusion, failure on the stepper motor, or a mechanical transmission failure. Additionally, the blood glucose sensor should provide updated values every few seconds (linked to [SC-1] and [SC-2]).
- Stepper motor should not provide a speed that leads to an inverse insulin flow and the alarm should notify when there is a change in pump direction (linked to [SC-5])

IV. STPA TRACEABILITY AND LOSS SCENARIOS PRIORITIZATION

One of the critical elements of STPA is traceability, which refers to the ability to trace the flow of information and decisions through a system, from identifying hazards to implementing control measures. STPA traceability also includes monitoring and evaluating the effectiveness of the controls that have been put in place. This helps to ensure that the controller continues to be effective over time and that any issues are identified and addressed in an early design phase. This traceability is important because it helps to ensure that all potential hazards have been identified and that safety requirements have been implemented to address those hazards.

Using STPA to analyse a complex system may result in the identification of several loss scenarios, each of which results in one or more UCAs. In some cases, not all of these scenarios lead to a significant loss. Hence, it is necessary to prioritise scenarios that may cause substantial losses.

The traceability in STPA works as follows:

- After the identification of the system losses and hazards, each hazard is linked to one or more losses.
- Each of the identified unsafe control actions is linked to one or more hazards.
- The EMI loss scenarios give reasons why UCAs might occur. As a result, we can establish the link between losses, hazards, unsafe control actions and EMI loss scenarios.

In our example, we will illustrate this traceability using the first three losses listed in II, which are related to hypoglycemia. Figure 3 shows the traceability between the EMI loss scenarios identified during step 5 and their losses.

To prioritise scenarios, we can start from the loss with the highest severity level and identify which EMI scenarios lead to this loss, as well as their effect on the system (UCAs). The UCAs linked to these scenarios can help to determine the weakest links in the system, on which a further risk analysis should be focused. For example, consider the critical loss of "severe hypoglycemia". Figure 3 illustrates that the UCA resulting from the majority of EMI scenarios ([SC-1] and [SC-5]) is [UCA-3]. This UCA is related to a failure on the alarm system during a critical situation. Thus, a disturbance affecting the correct functioning of the alarm system on the user interface has the most severe consequences on the patient's health, requiring additional measures to avoid an interference on this subsystem. Additionally, a failure in the blood glucose sensor caused by EMI (SC-2), leads to the incorrect calculation of motor speed by the microcontroller. Hence, measures such as providing a continuous update of the measured blood glucose might help to avoid this UCA.

V. CONCLUSIONS

The hazard analysis technique STPA was extended to include EMI-related hazards. A detailed explanation on how to modify STPA's basic steps was given and the technique was demonstrated on an insulin pump. First, the losses and

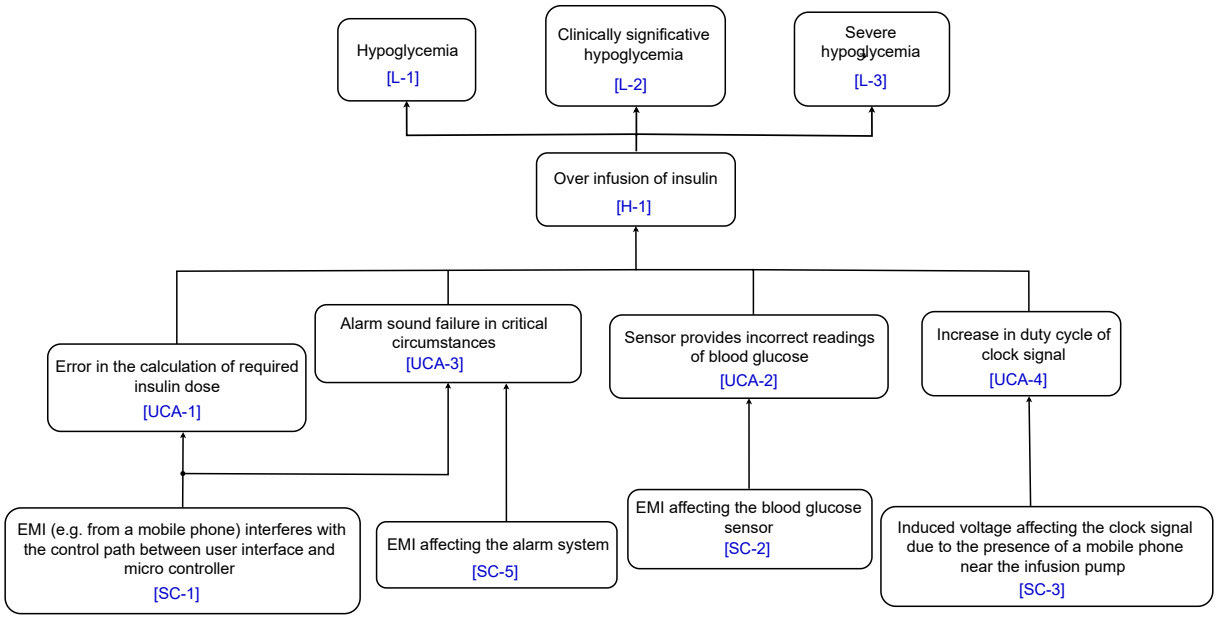

Fig. 3. Traceability between STPA outputs

hazards were identified and possible EMI sources were listed. Second, the system's control structure was modelled in terms of control loops. Third, unsafe control actions were identified, while reasons why they might occur due to EMI were listed in the fourth and last step (EMI loss scenarios). Once EMI loss scenarios are identified, they can be traced back to the losses. This traceability property helps to prioritize the EMI loss scenarios for their criticallity. Additionally, it helps to identify the reasons why these scenarios might occur in the system (EMI sources).

In future work, the proposed hazard methodology will be applied to a more complex medical system to identify EMI-related risks.

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