# QUALITATIVE APPLICATION OF OPERATION AND SUPPORT HAZARD ANALYSIS FOR SYRINGE INFUSION PUMPS

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**Abstract:** In this paper, we provide a qualitative analysis with an experimental viewpoint for the Operation and Support Hazard Analysis - O&SHA process applied to syringe infusion pumps as a cheap and accurate way of contributing with the mitigation of the safety problem in these devices. The proposed model takes as quality criteria the compliance within safety requirements defined by the Foods and Drugs Administration - FDA initiative Generic Patient Controlled Analgesia Pump - GPCA. We apply the results directly to the assessment of syringe infusion pumps available on the market and for improving new solutions under development in the NUTES project.
**Keywords:** Infusion Pumps, Risk Analysis, Patient Safety and Technological Trends.

## Introduction

The patient safety involves some aspects such as error prevention, elimination of potential mishaps and quality of care. In this context, and mentioning the development process of a medical device, the patient safety must drive the engineering activities mitigating foreseeable scenarios whether by non-intentional user error or a device failure.

Infusion pumps are electro medical devices with the aim of regulating the flow accuracy, employed in cases where there is a need of continuous therapy, such as analgesia, chemotherapy, sedation, antibiotics or nutrients. These devices work generating a liquid flow pressure over the patient blood pressure [1].

In the last years, smart infusion pumps became more and more sophisticated, providing software features for error reduction such as the drug library, allowing safer ways of programming medicines dosage and calculating delivery taxes. When correctly employed, these new resources supports the prevention of most human errors in drug administration [2]. These errors can happen in the medication process phases, that is: prescription, transcription, dispensation, with high probability of generating patient harms. According to [3], at least one patient is admitted per day victim of medication errors.

The FDA receives yearly thousands of Medical Device

Reports - MDR. These reports monitor the device performance; detect potential safety problems related to the devices such as deaths, severe injuries and breakdown. This contribution can give support to the use of new methods related to the cost-benefit of the patient. For this purpose, the FDA offers the Maude platform, with MDR database providing versions released from manufacturers, importers, users, patients, health professionals and so on [4]. With the huge number of harms in syringe infusion, pump devices reported in this platform and for improving our processes of safety engineering for prototypes that we are developing in the context of projects in the Center for Strategic Health Technologies (*Núcleo de Tecnologias Estratégicas em Saúde* - NUTES), we defined a model for applying the Operation and Support Hazard Analysis-"O&SHA" technique [5]. This model will be part of processes for a factory designed for manufacturing medical devices that will be ready in 2016 for the Brazilian Unified Health System (*Sistema Único de Saúde* - SUS).

The NUTES, located at the State University of Paraiba, in Brazil, is currently developing technological innovations for some existing devices, such as Automated External Defibrillators and Vital Signs Monitors. Among these developments we should mention for infusion pumps a remote actuation system [6], integration with Health Information Systems – HIS through a web service infrastructure [7], multichannel drivers for stepper motors and new approaches in verification and validation [8]. The resulting prototypes of these previous works are currently being submitted to a risk analysis and management process with the proposed model of this Work. In order to get reliable results, we provide the assessment in two distinct scenarios. The first one for the devices in use, during the application in intensive care unit. The last one, for a manufacturing environment in the NUTES biomedical engineering lab, where the device was submitted to controlled conditions in order to check the conformance between the FDA safety requirements and accuracy of the implementation of the features in the device and the

corresponding documentation.

## Materials and Methods

This work follows a qualitative approach as a functional analysis for the operation and support of syringe infusion pumps in the case of man-machine interface x human-machine interface [9].

Our method consists of the following activities: observation, registering, analyzing, classifying and interpreting the facts and phenomena. The goal is to verify the safety requirements and veracity of information contained in the user manuals, relating here two specific models of two distinct brands available for sale on the Brazilian Market.

For the identification of risks associated to the user and system operations, we applied an analysis of the safety requirements defined in the Generic Infusion Pump project for the Generic Patient Controlled Analgesia - GPCA pump model [10]. We documented the identification process through an Operation and Support Hazard Analysis O&SHA using recommendations available in manuals and the medical device itself.

O&SHA is a technique to assess the safety of operations, integrating the evaluation of operational procedures, the system design and the human system integration. The exhibited information by using this technique can be very useful for the system improvement, operational plans and tasks design [11, 5]. Its main usage is during the system development, in order to ensure safety in the system's operations and maintenance. According to [5], five criteria are mandatory:

1. Develop safety focusing on the viewpoint of operations and operational tasks.
2. Identify hazards in tasks or operations caused by the design process, hardware and software failures, human errors, temporal constraints, etc.
3. Assess the mishap risks during operations.
4. Identify safety requirements in order to mitigate hazards in operational tasks.
5. Guarantee that all operational procedures are safe.

Initially we defined and listed all the possible tasks with the device, identifying hazards, causes, effects, estimated and classified risks without any mitigation as Initial Mishap Risk Index - IMRI, recommended actions, estimated and classified risks after implemented the recommended actions as Final Mishap Risk Index - FMRI.

The tables identified new hazardous tasks, causal factors for harms, possible mishaps and other issues. These results are currently being sent to manufacturers and soon they will be available in the NUTES project website (nutes.uepb.edu.br).

Tables 1 and 2 show some identified hazards for syringe infusion pumps by following the O&SHA technique.

Table 1: Identified hazard for a given task.

| TID | Task | Hazard | Causes |
|---|---|---|---|
| T1 | Observe the correct placement of the flange of the syringe body. | Underdosage | Placement of the syringe tab is out of slot. |

Table 2: Specific hazard attributes.

| Hazard | Effects | IMRI | Mitigation | FMRI |
|---|---|---|---|---|
| Underdosage | Risks to the patient health due to the lack of medicines. | 1C | Use of a security key allowing the continuation of the operation only in case of well fixation of the syringe in the tab. | 1E |

## Results

The developed analysis provided a risk management report based on the safety requirements imposed by the GPCA model towards the commercial product distribution of the prototypes we are developing at NUTES. In such reports, we show information about risk monitoring for two models available in the Brazilian market. Tables 3 show excerpts of information about Probability x Severity as a concrete result of the model application. This application forecasts that most risks were assessed and are at acceptable levels ensuring the application of suitable methods for obtaining production and post-production information.

Table 3: Hazard Analysis with Probability x Severity.

| Severity | Probability | | | | |
|---|---|---|---|---|---|
| | Frequent (A) | Probable (B) | Occasional (C) | Remote (D) | Unlikely (E) |
| Catastrophic (1) | 1A | 1B | 1C | 1D | 1E |
| Critical (2) | 2A | 2B | 2C | 2D | 2E |
| Marginal (3) | 3A | 3B | 3C | 3D | 3E |
| Negligible (4) | 4A | 4B | 4C | 4D | 4E |
| Eliminated (0) | | | | | |

The adopted methodology starts by analysis of post-market events reported by the MAUDE platform [4] released by FDA, bringing the knowledge available in such platform for medical devices available in the brazilian market. The main hazards were identified and safety cases were built for dealing with appropriate risks, generating safety requirements. In this sense, we highlight the importance of a multidisciplinary team, composed of a very experienced nurse and some software, electrical and mechanical engineers. Tables 4 show excerpts of information about Probability x Severity as a concrete result of the model application.

Table 4: Excerpt of hazards in risky operations for common tasks in syringe infusion pumps.

| O&S HA/ I.P. | Hazard | Operation | I M R I | F M R I |
|---|---|---|---|---|
| 1/ A-B | Menu placing the syringe tabs inside the slots. | | 1 C | 1 E |
| 2/A | Advancing the plunger driver even after touching the syringe plunger causing an undesired bolus. | Syringe installation. | 1 C | -- |
| 3/A | Setting up and priming with equipo connected to the patient, causing air infusion to the patient. | Syringe installation. | 1 D | 1 E |
| 4/A | Setting up and priming with equipo connected to the patient causing undesired bolus. | Infusion Pump Programming | 1 D | 1 E |
| 5/ A-B | Incorrect choice of syringe type, causing imprecise volume to be infused. | Syringe install. | 4 D | 4 D |
| 6/A | Delay in the beginning of the infusion due to the lack of syringe implying in degradation of patient's condition. | Infusion programming. | 3 D | 3 D |
| 7/B | Loss of information about the volume to be infused. | Verification of the total volume to be infused. | 4 D | 4 E |
| 8/A | Unexpected change of flow for KVO, causing underdosage to the patient. | Infusion programming. | 2 D | 2 E |
| 9/ A-B | Air bubble not identified in the equipo causing pulmonary embolism. | Infusion programming. | 2 C | 2 E |

We transfer the results of this research to the design of new prototypes under development in the NUTES project. From these results, we apply our modeling productivity tools and quality model [12] in order to establish the appropriate traceability with engineering artefacts, such as functional requirements, architectural drivers, tests, source code and so on. Taking as example, we have the syringe infusion pump presented in Figure 1.

Figure 1: Syringe Infusion Pump Prototype under development. The system is triggered remotely by mobile applications that collect health information systems data tested by IDA 4 Plus Infusion Analyzer at NUTES.

The infusion pump programmer executes setup routines and the data collector gets the patient and drugs data. Moreover, we have developed a functional architectural specification able to specify system's behavior independently of technological choices. Among realizations of these specifications, we mention the following software products:

- Android application for communicating with ATmega 2560 Arduino microcontroller through Bluetooth technology;
- Software routines for triggering stepper multiple channels with different stepper motors.

The main product development activities in prototypes of syringe infusion pumps that are taking advantage of the analysis provided by this work are:

- Implementation of multiple channels, allowing the actuation of several motors and infusing diverse medicines simultaneously;
- Implementation of power electronics circuits for safe actuation of the device parts;
- Remote actuation through mobile devices and health information systems, requiring security and availability;
- Alarms components such as visual and audible, for monitoring the infusion process;
- Sensing several parameters such as begin and end of the infusion, pressure, air, occlusion, and so on.

**Discussion**

This work provides a discussion about risk analysis for infusion devices, and develops a risk analysis for

parameters of the main device models currently present in the Brazilian market. The risk analysis made viable the verification of infusion process parameters.

The main contribution of this work was a method for applying a hazard analysis technique to well-known syringe infusion pumps devices in order to get expertise on safety engineering when developing prototypes. We claim that this work can become a good reference guide for manufacturers towards the integration of design control and risk management processes required by the Brazilian National Surveillance Agency (*Agência Nacional de Vigilância Sanitária* – ANVISA). The developed risk analysis method will be used to guide all researches currently in progress at NUTES that are related to infusion pumps.

**Conclusion**

This work has presented a model for application of O&SHA method in the context of risk analysis and management for syringe infusion pumps. The results came from two popular models available in the Brazilian market and the results are being employed in prototypes that NUTES Project is currently developing. The application of this analysis can be directly transferred to industrial partners, with focus on the product. Finally, we can also integrate the analysis with other types of product documents such as requirements engineering, architecture, and usability tests, among others.
As future works, we are providing quantitative assessments using sophisticated analysis methods in tools such as ISOGRAPH and the RELIABILITY WORKBENCH, by means of techniques such as Failure Modes and Effect Analysis - FMEA, Fault Tree Analysis - FTA and Event Tree Analysis - ETA.

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