

## RISK-BASED TESTING APPROACH FOR MEDICAL DEVICES SOFTWARE

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**Abstract:** *A successful "medical device" development requires the collaboration between designers, developers, and quality engineers to be able to assess needs, functional requirements, specifications, and problems at every stage of development. The quality control of the developing process is achieved through a predefined set of policies, quality assessment, and the management of activities to eliminate defects and weaknesses wherever the development process.*

*The paper presents a successful approach to the development of a new medical device that will successfully pass all stages of certification to obtain a CE-mark.*

**Keywords:** *risk analysis, testing, CE mark, medical device*

### 1. INTRODUCTION

The development of a new product "medical device" is not an easy task because there are many special regulations. A successful "medical device" development requires collaboration between designers, developers, and quality engineers to be able to assess needs, functional requirements, specifications, and problems at every stage of development. This guarantees new product quality and correct risk management.

As with most innovative products, the most common reason for creating a successful new product is the discovery of an unmet need in the market while maintaining or improving the quality of the medical service or activity:

- Innovation can be something completely new that will save the lives of many people.
- The innovation may be due to a medicinal person he/she wants to make a certain medical procedure more accessible and more reliable.
- Innovation can be aimed at improving the quality of life of people with health problems.
- Innovation may be due to the desire of progress
- A provider of medical care service wants to improve the provision of the existing one or to present a new one.
- Sometimes the created product is not innovative, but an improvement of the realization of established ideas. In this case, a device realizes something already known but realizes it better, faster, or more accurately. In this way, this device expands the scope of application or significantly improves the quality of existing devices.

These reasons for creating new medical devices and systems are not always obvious to the target user, as common problems are seen as inconveniences that should be taken for granted. This daily neglect of the operational problems of the apparatus is justified by existing restrictions of an economic, technical, technological, or social nature. And this continues until someone imagines a way to solve the problem. The presentation of the respective innovation allows a given limitation or inconvenience in the application to become a solvable problem.

Regardless of the variety of reasons for creating a new medical device or system, the general is ultimately safe for the patient and can be used to improve his condition. Since the focus is on these devices and systems to benefit people who are not part of the production team, the requirement for minimum risk for patients and users is mandatory.

The design and development of medical devices is a complex process based on balanced solutions over multiple standards, medical specifications, specifications, specific requirements related to the needs of the end-user, and the peculiarity regulations in countries.

This makes the medical devices developing multifaceted: the development of a successful market product requires a much more innovative idea.

Medical devices now represent a wide variety of machines and systems: from simple health monitors to advanced diagnostic and life-saving machines. Therefore, safety is always a priority when creating new medical devices because the lives of patients most often depend on the safety and efficacy of a medical device. As a result, the design of medical devices is crucial to guarantee that the devices meet the objectives of functionality, reliability, and safety. This is a great responsibility for medical device manufacturers. This defines continuous and risk-oriented testing to be some of the most important phases of medical device development.

The presented paper aims to show a successful approach to the development of a new medical device that will successfully pass all stages of certification to obtain a CE-mark.

## **2. WHY QUALITY CONTROL OF DEVELOPING ACTIVITIES**

### **A) Devices' types classification task**

The rules and procedures for the new medical device certification are classified by the regulatory agencies depend on how the product being created. Each regulatory agency has defined several different classifications for medical devices. As a general rule, classifications are largely related to the risk for the patient or the medical staff will use the device to be certified.

The classification of the created medical device is of great importance for the design because it allows answering three main questions:

- The product classification will determine what you need to do before you can sell your product.
- Product classification will help you identify requirements during the product development phase, in particular design control.

- Product classification is an important component in determining how much your device will cost to market and give you an idea of how long it will take. In the most general plan of international regulations, the first big problem in the conceptual design of a new medical device is what kind it can be classified [1,2,8]:
- Component: it is generally defined as "a piece, part, software, firmware, or other elements" that are intended to be included as part of a finished, packaged, and labeled device.
- Accessory: it is a separate finished device designed to support, supplement, and/or augment the performance of at least one existing medical machine.
  - Accessories can be marketed separately or as part of a bigger system.
- Apparatus: it can be used separately.
  - It isn't a part of a bigger system.

The second very major classification of the new medical devices' point of view is how the device has interacted with the patient. An example of such a classification is the used MDR of the EU 2017/745. According to this classification medical devices are divided into three groups [9,11]:

- Non-Invasive: any device which does not penetrate the body through an orifice or the surface of the body.
- Invasive: any device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.
- Active: any device whose operation depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy.

## **B) Quality control task**

The quality control of the new medical device developing is achieved through a predefined set of policies, processes, and procedures targeting the management of activities, quality assessment, and the management of activities to eliminate defects and weaknesses wherever the development process. The choice of these rules directly depends on the classification of the medical device. Incorrect classification of the new product significantly increases the risk for the project and reduces the quality.

Most often, quality management activities for the developing of new products include four main activities:

- Quality management of device design
- Risk management
- Monitoring and control of design and developing artifacts
- Supply quality management from subcontractors

This allows quality management to achieve the following goals of a medical device developing activities:

- Be safe for patients and medical staff
- To meet defined requirements

- To meet the needs of end-users
- To be suitable for the subject area of application

Unfortunately, the statistics on incidents and problems with medical devices/systems are disagreeable and are invariably growing. This drives to a permanent change of regulations: the new regulations strengthen the requirements for manufacturers to increase the quality of the created products and to reduce the risk of their use. Good examples are the standard ISO 14971 (it defines the rules for risk assessment) and the standard ISO 13485 (it defines the rules for establishing a quality assessment system).

The applying of the provisions of risk management standards allows:

- to identify hazards associated with medical devices
- to make a correct assessment of the risks associated with them
- to monitor and manage identified risks
- to monitor the effectiveness of risk management activities

### 3. IEC 60601 STANDARD

The scope of the medical devices and systems industry is large-scale. Therefore, international and national regulations most often do not prescribe how manufacturers should produce new products. Instead, an approach is used in which regulations serve as a framework that defines the ultimate goal, but not the way to achieve it. This obliges manufacturers to follow this framework but to choose the path themselves. To this end, manufacturers have the task to use appropriate best practices, to define appropriate requirements for safety and efficiency devices, to develop methods and procedures for design, manufacture, and distribution of devices in accordance with the requirements of the quality system defined in the regulations.

It is necessary to know that in addition to the international standards for medical devices issued by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC), each country has additional regulatory provisions in this area. This significantly affects the development process and the quality assessment of the developed medical devices and systems. Therefore, in the production of medical devices that will be sold internationally, developers and manufacturers must know the applicable regulations for each of the specific markets.

IEC 60601 is a series of standards for the safety and effectiveness of medical electrical equipment [12]. They are technical standards.

The primary standard governing medical device design is formally known as IEC 60601-1. It is complex, and has become ever more complicated based on its many regional variations. Compliance with this standard has become a de facto requirement for bringing new medical devices to market in many countries.

More simply it is referred to as IEC 60601-1 or just “60601,” and compliance with this standard has become a de facto requirement for bringing new medical devices to market in many countries.

Within IEC 60601-1 (more simply it is referred to as “60601”), there are “collateral” standards that are denoted as IEC 60601-1-x:

- IEC 60601-1-2 is the EMC collateral standard mentioned above,

- IEC 60601-1-3, covering radiation protection for diagnostic x-ray systems,
- IEC 60601-1-9 relating to environmental design, and
- IEC 60601-1-11 recently introduced for home healthcare equipment.

There are also many “particular” standards: they are denoted as IEC 60601-2-x that define specific requirements related to particular types of products (e.g., 60601-2-16 covers blood dialysis and filtration equipment).

The IEC 60601 standard has a long history with a number of revisions:

- The original IEC 60601-1 for medical devices was published in 1977.
  - It has a significant impact on the product development process, going beyond performance test and verification: product complexity generally yields innumerable potential test cases, permutations, and combinations in both normal and abnormal operating modes, and these cannot be assessed in the final design alone.
- The 2<sup>nd</sup> edition (1988), focused on safety within the vicinity of a patient.
  - It established risk guidelines that applied when a device was within a 6-foot radius from the patient, referred to as the “patient vicinity.”
- The 3<sup>rd</sup> edition (2005), reflected a further change of perspective, looking at “means of protection” (MOP) both for patients and equipment operators.
  - It extends the patient focus to require an overall “means of protection” (MOP) that combines one or more “means of operator protection” (MOOP) and “means of patient protection” (MOPP).
  - It recognizes that the potential hazards seen by each user can be quite different.
  - A substantial amendment to the 3rd edition, known as Edition 3.1, was introduced in 2012. This addressed numerous ambiguities arising from evolving medical equipment technology.
- In 2014, the 4<sup>th</sup> edition of collateral standard IEC 60601-1-2, “Electromagnetic disturbances – Requirements and tests,” was published.
  - The 4<sup>th</sup> edition expands on the risk analysis approach developed previously by delving more deeply into what we might simply call “EMC concerns.”

#### 4. OUR APPROACH

The risk-based testing is based on risk analysis provided for the device. The device is a medical machine for extracorporeal plasma apheresis working as a “artificial single camera heart” exploiting the separation method using nanomembrane filter. The main task is to fill the artificial heart’s camera by patient’s blood and after that to transport it to the nanofilter and to separate the plasma from the other blood element keeping very exact level of pressure (better than 1%). The machine is very low invasive but can generate other risks for the patient. The risk-based analysis and testing were some of the most important elements of its design and implementation. Elements of this analysis are presented below. Table 1 represent generalizes risk acceptability policies.

According to this is provided multilayered risk analysis. Here is presented only the upper level of Table 2 as an example.

Risk analysis for RS\_B\_02 is as follows:

- The motor is moving in the wrong direction - it reaches the wrong end point
  - The direction of travel is not reversed when the correct command is given
  - The correct command was not sent
- The engine does not move when a travel command is sent
  - No feedback from motion sensor
  - No movement due to mechanical lock
  - No permission to drive to the motor controller
  - The motor is not powered
- The engine is running, there is no pressure
  - Disturbed integrity of the pipeline
  - Improper connection to the pressure sensor
  - Lack of filter flow resistance - breakdown
  - Leakage to plasma outlet
  - The pressure sensor does not work
  - Violation of the integrity of the pump piston
  - The outlet valve element (aortic valve) does not work (does not open)
    - Valve damage
    - Lack of power supply for the valve
  - Does not close the inlet valve element (mitral valve) - reverse blood flow
    - Valve damage
    - Lack of power supply for the valve
- The pressure exceeds the upper limit preset
  - The filter has no conductivity (congested)
  - No conductivity after the filter – clogging.

*Table 1. Risk acceptability policies*

Risk Acceptability Policy	
Probability	Severity
	1 2 3 4
1 Frequent	I I I I
2 Probable	I I I III
3 Occasional	I I II III
4 Remote	I II III III
5 Improbable	III III III III
I - Unacceptable	Reduce the risk further.
II - Risk Benefit	To be discussed. Reduce the risk further. If this is not possible, escalate to the clinical evaluation for risk benefit analysis.
III - AFAP	AFAP (as far as possible). Reduce the risk until no further reduction is possible.
<b>Severity of Harm</b>	
1 Catastrophic	potential of multiple deaths or serious injuries
2 Critical	potential of death or serious injury
3 Marginal	potential of injury
4 Negligible	little or no potential of injury
<b>Probability of Harm</b>	
1 Frequent	likely to occur frequently
2 Probable	will occur several times in life of an item
3 Occasional	likely to occur sometime in life of an item
4 Remote	unlikely but possible to occur in life of an item
5 Improbable	so unlikely, it can be assumed occurrence may not be experienced

**Table 2.** (RS\_B\_xx - Risk Situation Base xx)

Risk ID	Risk description	Risk effect	Risk cause	Caused by	Severity	Probability	Risk level
RS_B_01	No input flow to the camera	Circulation stopped	N/A	N/A	4	N/A	III
RS_B_02	Impossible pumping	Circulation stopped	N/A	N/A	4	N/A	III
RS_B_03	Impossible filtration	Circulation stopped	N/A	N/A	4	N/A	III
RS_B_04	Gas bubbles in the output stream	Dangerous for the patient	N/A	N/A	3	4	III
RS_B_05	Output pressure over the limit	Dangerous for the patient	N/A	N/A	3	4	III

According to this analysis are provided number of test each one covering the corresponding element of the risk analysis. The results were accepted by the CE mark granting legal body.

## 5. CONCLUSION

The provided formal and practical example of implementation of the risk-oriented analysis and risk-based testing covers real medical device and shows how the formal way of risk discovering generates a set of mandatory test each of which covering and answering to a specific risk (possible problem). This type of test generation is very different from the other formal test generation techniques and covers specific sides of the product production cycle. Moreover, they help to create more robust device design before any real implementation.

**Acknowledgment:** This work is funded by Bulgarian National Science Fund project DN 03/1 2016 and National Scientific Programme “eHealth in Bulgaria” – D01-200/2018.

## REFERENCES

- [1] U.S. Food & Drag Administration, Classify Your Medical Device, 2020, <https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device>
- [2] Registrar Corp, FDA Issues Guidance on Medical Device Accessories, Jan. 2018, <https://www.registrarcorp.com/fda-issues-guidance-on-medical-device-accessories/>
- [3] Johner Institute, Classification of Medical Devices, <https://www.johner-institute.com/articles/regulatory-affairs/classification/>
- [4] Emergo by UL, Medical Device Classification in Europe, <https://www.emergobyul.com/services/europe/european-medical-device-classification>
- [5] M. El Azzouzi, Complete Guide: Medical Device Classification EU MDR, April 2020, <https://easymedicaldevice.com/new-eu-medical-device-classification/>

- [6] News-Medical.Net, Test Methods for Medical Devices, 2018, <https://www.news-medical.net/whitepaper/20171018/Test-Methods-for-Medical-Devices.aspx>
- [7] A. F. Benet, A Risk Driven Approach to testing Medical Device Software, Advances in Systems Safety, Springer, Nov. 2010, pp 157-168, ISBN 978-0-85729-132-5
- [8] J. Speer, T. Rish , ISO 14971 RISK MANAGEMENT FOR MEDICAL DEVICES: THE DEFINITIVE GUIDE, Greenlight Guru, <https://www.greenlight.guru/blog/iso-14971-risk-management>
- [9] EU Directorate B Unit B2, MEDICAL DEVICES: Guidance document (Classification of medical devices), June 2010
- [10] N. Pontius, The Ultimate Guide to Medical Device Design and Development: From Discovery and Concept to Design Controls, Navigating Medical Device Regulations, Risk Management, Quality Assurance, and More, 2020, <https://www.pannam.com/blog/guide-medical-device-design-and-development/>
- [11] M. Strålin, Classification Of Medical Devices And Their Routes To CE Marking, March 2020, <https://support.ce-check.eu/hc/en-us/articles/360008712879-Classification-Of-Medical-Devices-And-Their-Routes-To-CE-Marking>
- [12] IEC, IEC 60601-1:2020, Medical electrical equipment, 2020, <https://webstore.iec.ch/publication/2603>
- [13] <https://support.ce-check.eu/hc/en-us/articles/360030495832-11-Types-of-Medical-Device-Design-Testing>

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