

## MEDICAL DEVICE SOFTWARE: IMPORTANT ISSUES

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### ABSTRACT

Software technology is an important technology in the present day. Software is proven for its usefulness in several purposes. In medicine, the software technology is also an important new technology for medical management. Of several kinds of medial software, medical device software is an important kind. In this specific article, the author specifically reviews and discusses on important consideration regarding medical device software.

**KEYWORDS:** Medical, Device, Software.

### INTRODUCTION

Software technology is an important technology in the present day. Software is proven for its usefulness in several purposes. In medicine, the software technology is also an important new technology for medical management. Of several kinds of medial software, medical device software is an important kind. In this specific article, the author specifically reviews and discusses on important consideration regarding medical device software.

### IMPORTANT CONSIDERATIONS ON MEDICAL DEVICE SOFTWARE

Similar to any medical objects, the important consideration for using is on effectiveness and adverse effect of the objects. Pashkov et al. noted that "Developers and manufacturers may not have initially appreciated potential risks to patients and users such situation could have dangerous results for patients or users. It is necessary to develop and adopt the legislation that will intend to define the criteria for the

qualification of medical device software and the application of the classification criteria to such software, provide some illustrative examples and step by step recommendations to qualify software as medical device [1]." Therefore, the legal issue on the medical software device is important. Pashkov and Harkusha noted that "It is necessary to develop and adopt guidelines on the qualification and classification of medical device software [2]."

This becomes a challenge in the present day. The considerations have to be recognized and it is related to several partners including to the medical device manufacturers. Pashkov et al. discussed on this specific issue in Ukraine context and noted that "such system allows to implement effective control of contractors in the sphere of production and sale of medical products and provide safety of medical devices that are introduced, on the other hand, it does not afflict contractors with excessive and total control, allowing them to choose behavior that is most acceptable, understandable and user-specific [3]."

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At present, another interesting consideration regarding medical device software device is on the new medical device Apps. Since Apps is also present recognized as part of medical device as class I device [4], therefore, regulation is required. Terhechte noted that “The future legal framework, the Medical Device Regulation, will strengthen the requirements and engage notified bodies more than today in the conformity assessment of software as a medical device. Manufacturers, health institutions, notified bodies and the authorities responsible are in charge of intensifying their efforts towards software as a medical device. Mutual information, improvement of skills, and inspections will lead to compliance with regulatory requirements [5].”

## **CONCLUSION**

The communication engineering technologies is applicable in biomedical field. This specific area of application is useful for further researching in both communication engineering and biomedicine.

**CONFLICT OF INTEREST:** None

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