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Industry 4.0 & medical devices - application of artificial intelligence for surveillance and management

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Abstract: *Industry 4.0 has revolutionized the world in a way that most tasks once done by hand are now done by a single click or swipe in one of many applications used every day by billions of people. The healthcare sector has also been impacted by this, and continuous improvements are made to medical devices used in daily medical practice. Automatization of diagnostic procedures that enables access to high quality medical decision making even in limited resource settings, as well as prediction of disease onset, exacerbations and course are both prominent applications of Industry 4.0. Medical device surveillance and management is also achieved by means of technology. The COVID-19 pandemic has highlighted the importance of high quality and performance of critical medical devices and raised the awareness of the society. Smart solutions, based on Internet of Things (IoT) are currently being developed for medical device surveillance and management Application of these solutions in healthcare would dramatically decrease the downtime of medical devices, the cost intensiveness of repairs and the number of adverse events resulting in patient injury.*

Keywords: *artificial intelligence, medical device, industry 4.0, surveillance, management.*

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1. Introduction

It is impossible to imagine the modern world without every single necessary piece of information being available at the palm of one's hand. Since the era of digitization begun in the late 20th century, continuous advancements have been made in the field [1]. Even though most people remained unaware of it, the 4th industrial revolution [2,3] has already impacted life as we know it and most of our daily activities rely on the advancements provided for humans by means of industry 4.0. People use it relentlessly to orient themselves, navigate through unknown areas, acquire information, read books, listen to music, control their home appliances, and pay their bills. Upon integration into simple daily tasks, the technology characterizing industry 4.0. has begun integrating into more complex fields of science [4-6].

One of the revolutions in the way scientists all around the world utilize to transfer data remotely is the Internet of Things (IoT) [7]. One cannot fathom data transfer without IoT nowadays. IoT represents a system of interconnected machines, computing devices,

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objects, animals or people that possess unique identifiers and are able to transfer data using a network that does not require human to human or human to computer interaction [8]. An IoT ecosystem is made out of smart devices connected to the Internet that gather, send and act upon the data present in their surroundings via embedded systems, sensors and communication devices [9]. Connection to an edge device or IoT gateway allows for sharing the collected sensor dana for local or cloud-based analysis (Figure 1). The hardware included in IoT systems can function both independently of human manipulation or together with human input. The importance of IoT lies in the fact that it makes all systems using it „smart" and smart means accelerated, automated and efficient [10].

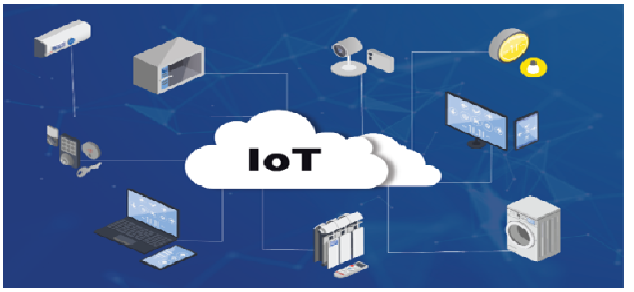


Figure 1. IoT based system integration

The healthcare sector is an inexhaustible source of data gathered every day through measurements of patient-related parameters. In the world we live in today, data is viewed as currency, and effective means of currency exchange have always been prominent topics for technological advancements. Every person, willingly or unwillingly pushes millions of datapoints into the world each day. Every step made while carrying a cellphone provides servers with loads of related data. Putting data into the context of healthcare, every medical device records patient related parameters and generates huge amounts of data daily. That data remains used only as means of better insight into the health status of the single patient, however it could be used for so much more and jointly with other data incorporated into advanced systems enable significant advancements in the field of healthcare.

2. "Smart" surveillance and management

Modern technology allows for expedite development of new diagnostic procedures as well as interventions, however, it remains under strict control of human operations. Medical devices, as tools used to aid medical practitioners in diagnosis and treatment of diseases have evolved significantly over time and were modernized along with modernization of all other devices used in practice [11]. The improvement of known medical devices has mostly been impacted by the fourth industrial revolution, that has paved the way towards digitalization of processes and utilization of data generated by devices networked by IoT. Understanding the data generated by medical devices, storing them long-term in cloud-based servers and using them selectively for development of "smart solutions" is a way to advance healthcare as we know it today.

Big data structures [12] lie in the center of all "smart" solutions as one of the ways of making devices smart is supplying them with artificial intelligence (AI) based algorithms [13]. Evaluation of AI based methods is done on the basis of their accuracy when compared to that of medical professionals. All AI models must be "trained" with a large dataset covering as much variation in input parameters as possible, and "validated" by comparing their outputs, when presented with a new combination of variables with that of an experienced consortium of medical professionals [14]. The AI model is considered as a potential candidate for further development once its accuracy is in the range above 92% [15]. Medical professionals working with medical devices every day are starting to understand the potential that technology advancements hold for patient diagnosis, treatment and prognosis. This field is of uttermost interest to researchers worldwide what can be seen from the graphics of interest in the topic from 1960s to 2021 that shows almost an exponential increase (Fig. 2).

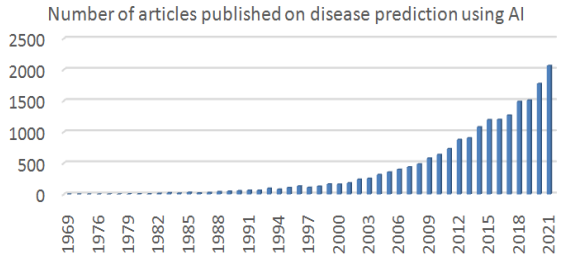


Figure 2. The rising interest in research in the field of disease prediction using AI

It would be impossible to mention all of the research done in the field of disease prediction using AI methodologies so only the research showing significant potential for application in clinical setting [16-24] will be presented it the following section. A research done by Stokes et al., (2021) [25] used machine learning (ML) for symptom-based referral and diagnosis of bronchitis and pneumonia in limited resource setting. The developed ML model has achieved an accuracy of 93% showing the potential ML holds in this field [25]. Priya et al., (2021) [26] have used an artificial neural network (ANN) based system to for asthma prediction based on weather conditions. This research is a clear representation how IoT can be used for disease management, as the input for the developed system consists of air-quality related parameters. Integration of IoT in the ANN architecture enables the continuous monitoring of air quality and sending alerts when high risk of asthma is present due to bad air quality [26]. As heart diseases present a significant burden on healthcare, a lot of interest is devoted to automating heart disease diagnosing and its prediction. One of those studies was performed by Nandy et al., (2021) [27] who have used an ANN to predict cardiovascular disease with an accuracy of 95,78% [27]. Cancer is a rising issue in the world, and a lot of effort is devoted to cancer risk assessment, early diagnosis and thereby complication prevention. Prostate cancer is the second leading cause of mortality of all cancers in men, and only in the US and Europe, 34 500 [28] and 75 000 [29] men died solely from prostate cancer respectively. Diagnosis of prostate cancer is based on histopathological exam which is invasive and conducted when the disease is already in its advanced stages [30]. However, there are metabolic parameters that change early in disease development and

that can be detected by routine screening. Spahic et al., (2019) [31] have developed an artificial neural network for prostate tissue classification based on levels of Prostate Specific Antigen and mitochondrial DNA copy number, both parameters found to be significantly elevated in prostate cancer. The accuracy of the developed ANN was 99,4% showing significant potential for further implementation [31]. The effects industry 4.0 has had on healthcare and society as a whole are remarkable and they have advanced the world as we know it. However, because of the fast research and development activities, some areas of the world have begun developing industry and society 5.0 [33].
Society 5.0 is a society where AI and all other smart solutions derived from industry 4.0 are perfectly blended into the real world and presented to people in a way that makes their lives even more easy [34]. Society 5.0 will display convergence between the virtual and physical world making them an inseparable unity [33]. All of the information gathered by individual sensors will be sent to IoT cloud servers, interpreted by AI and served to people in a variety of forms. This will provide for even more advanced information processing and intuitive machine decision making that will in the end make all processes much easier and less time intensive.

3. Predictive medical device surveillance and management

According to the definitions and requirements stated in Medical Device Directives (MDDs) [34] and international standards, activities related to the medical device (MD) market can be divided into pre-market and post-market surveillance (PMS). Pre-market and post-market surveillance processes have been defined by Medical Device Directives [35] since 1992. Medical Device Directives are documents that refer to all aspects of medical device life-cycle, starting from design, production, and testing to approval, certification and surveillance. However, due to the complexity of post-market surveillance, pre-market surveillance processess are better defined and are harmonized by international standards. These standards are classified as basic safety standards such as ISO 13485 Medical devices – Quality management, group safety standards [36] such as IEC 60601 – 1 Medical electrical equipment [37], and product safety standards [38]. In addition to international standards, CE marking is introduced as administrative marking indicating conformity of a device with health, safety, and environmental protection standards for products sold within the European Economic Area [39]. According to the MDDs, PMS is defined as the action requiring MD Manufacturers to proactively collect and review experience gained from their devices placed on the market with the aim of monitoring the performance of medical devices. PMS activities are designed to generate data regarding the device performance and preventively identify problems that could potentially arise during usage causing problems in patient monitoring or treatment [40,41]. Throughout the years, post-market surveillance has relied on MD manufacturers and users reporting adverse events involving MDs to relevant authorities in addition to performing regular servicing activities. All conformity assessment standards, including ISO 13485:2016 [36], now require manufacturers to maintain a PMS system regardless of how their medical device is classified. However, this approach has its limitations, which is noticeable by the number of reported incidents of the patient injuries and deaths including medical devices as presented in Table 1.

Table 1. Estimated number of medical device failures during a 10-year period based on Manufacturer and User Facility Device Experience (MAUDE) database [40]

Medical device	Deaths	Injuries
Infusion and perfusion pumps	>800	>1300
Defibrillators	>700	>1000
Mechanical ventilators	>300	>500
Therapeutic ultrasound	>200	>400

The European Commission has developed EUDAMED (European Databank on Medical Devices) [42] in order to supervise medical devices already in use. EUDAMED acts as a central database for information exchange between national authorities and the European Comission. Even though EUDAMED provides an interface and a module of medical device vigillance, the criteriafor reporting adverse events caused by medical devices differ from place to place thus the European Market is significantly fragmented, lacks coordination and finally responds poorly to challenges such as the COVID-19 pandemic. This is important to address because the healthcare sector is one of the most important aspects for the functionality of each country and directly affects the life of each individual. This has been already demonstrated and emphasized especially during the COVID-19 pandemic. The aforementioned highlights the problems posed by lack of standardization and harmonization of post-market surveillance leading to variability in safety and performance assessment of medical devices during their usage in healthcare institutions. This further results in lack of traceability of safety and performance assessment of medical devices. Standardized, independent, evidence-based methodology for ensuring medical device safety and performance needs to be defined. As regulators are becoming much more focused on post-market surveillance and risk management in the medical device industry it is important to develop strategies of effective post-market surveillance. Application of cutting-edge technology needs to be investigated in order to improve efficiency and sustainability of health systems in innovative ways. Application of cutting-edge technology in healthcare for managing medical devices lowers administrative expenditure and allows more avenues of exploration and research. Predictive maintenance of medical devices would enable predicting device failure long before it occurs and pinpointing the part of the device most likely to fail due to wear and tear or mechanical damage to the device [14]. Essential features for making these predictions are contained within the data collected during regular post-market surveillance conducted according to the metrological requirements, and that system is in place in Bosnia and Herzegovina. Analysis of this data is enabled by big data structures and cloud-based solutions that enable distributed computing power even for low resource settings [14]. The first step towards the development of these systems is in depth data analysis and selection of key parameters that indicate performance of the medical devices. The second step is the development of the intelligent system capable of predicting device failure. The final result are systems that require little to none human operation and decrease the downtime of medical devices. A lot of research has been

done on performance prediction of medical devices in Bosnia and Herzegovina in the last 5 years and the following chapters will summarize the obtained results.

3.1. Surveillance and Management of Infant Incubators

Two studies associated with performance assessment of infant incubators based on the data gathered during regular performance inspections in Bosnia and Herzegovina were conducted. The study performed by Kovacevic et al., (2019) [42] utilized a total of 140 samples of performance associated parameters of infant incubators and fed them into different machine learning algorithms such as Naïve Bayes (NB), Decision Tree (DT), Random Forest (RF), k-Nearest Neighbour (kNN), and Support Vector Machine (SVM). The highest accuracy was observed with DT algorithm, with an overall accuracy of 98,5% indicating that this ML methodology has a high potential for application in the field of surveillance and management of infant incubators. Another study, conducted by Spahic et al., (2019) [43] used an expert system based on ANN and fuzzy logic (FL) classifier (Fig. 2) to predict failure of infant incubators.

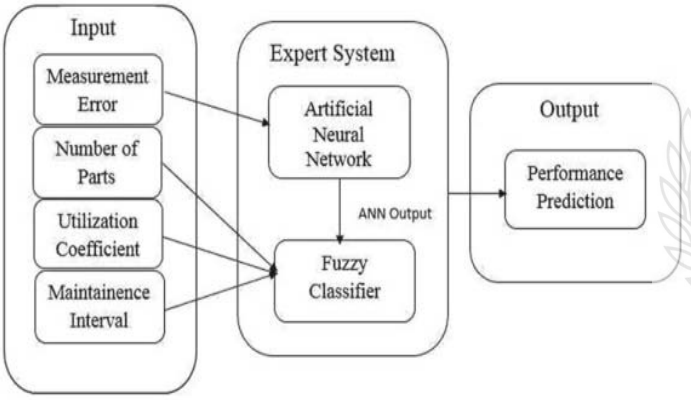


Figure 3. Architecture of the infant incubator surveillance and management expert system [43]

The overall performance was subsequently validated and resulted in system accuracy is 95.65%. System sensitivity is 97.23% while specificity is 88.89%, indicating that expert systems based on ANN and FL also have a significant potential for implementation in the field of management of infant incubators [43].

3.2. Surveillance and Management of Defibrillators

Research on surveillance and management of defibrillators was performed by Badnjevic et al. (2019) [44]. They have developed several ML algorithms based on 1221 samples of performance evaluation from medical institutions in Bosnia and Herzegovina. The architecture of the developed systems can be summarized as presented in Fig. 3.

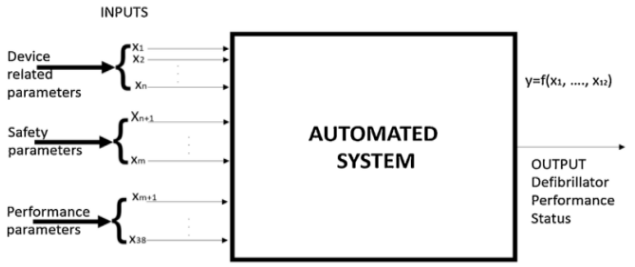


Figure 4. Architecture of the defibrillator surveillance and management expert system [44]

The accuracies of the developed algorithms ranged from 97,98% to 100% indicating that these methods have a significant potential for application in the clinical practice [44].

3.3. Surveillance and Management of Anesthesia machines

Surveillance and management of anesthesia machines using artificial intelligence was evaluated in a study by Hadzic et al., (2019) [45]. This study has utilized the data collected during regular performance inspections of anesthesia machines and showed the development of an expert system based on an artificial neural network and a fuzzy classifier. The architecture of the system is presented in Fig. 5.

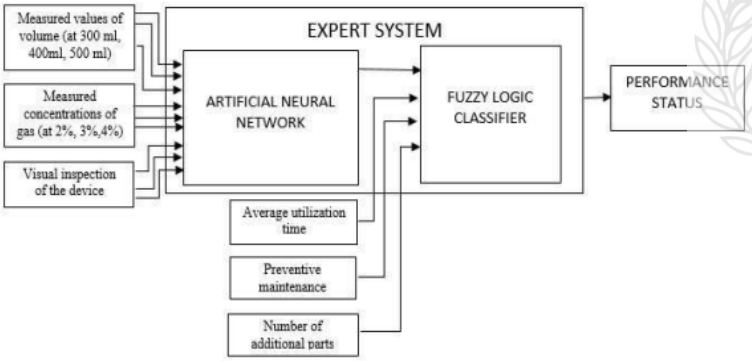


Figure 5. Architecture of the anesthesia machine surveillance and management expert system[45]

The performance evaluation resulted in 97.44% accuracy of the developed system indicating its high potential for future use and implementation [45].

3.4. Surveillance and Management of Infusion and Perfusion Pumps

Surveillance and management of infusion and perfusion pumps was conducted using an ANN in the study by Hrvat et al., (2020) [46]. The system was developed using 1391 samples of conformity assessment data points collected over a four-year period in Bosnia and Herzegovina. Performance evaluation for perfusion and infusion pumps showed a 98.06% and 98.8% accuracy indicating that ANN-based systems are a promising candidates for future implementation [46].

4. Conclusion

The fourth industrial revolution has modernized and changed the entire world in a direction towards digitalization and full automatization. These results were mainly facilitated by means of IoT and distributed computing. As constructs of industry 4.0 have penetrated all pores of the society, they have managed to impact healthcare as well. The contribution of smart solutions in healthcare in practice is yet to be seen due to a significant amount of skepticism surrounding the use of artificial intelligence. As the pandemic of COVID-19 has shifted the way people perceive healthcare, a lot of attention has been devoted to medical devices and their performance assessment. Integration of AI-based algorithms for surveillance and management of medical devices can bring upon a significant decrease in device malfunction, downtime and injuries to the patient caused by malfunctioning medical devices. Research on AI application in the field of medical devices done in Bosnia and Herzegovina has a potential to pave the way towards full digitalization of medical device management world wide. In order to achieve the goals of society 5.0 all aspects of healthcare must be integrated and coordinated in a way to send uniform data to cloud-based servers and provide AI solutions with high quality data that will in conclusion lead to reliable models capable of accurate predictions. That can be facilitated by integrating sensors that would perform continuous performance checks on medical devices, communicate with AI based cloud servers and deliver timely results thereby preventing medical device performance deterioration.

5. References

[1] Cowan, R. S. (1976). The" industrial revolution" in the home: Household technology and social change in the 20th century. *Technology and culture*, 1-23.

[2] Xu, M., David, J. M., & Kim, S. H. (2018). The fourth industrial revolution: Opportunities and challenges. *International journal of financial research*, *9*(2), 90-95.

[3] Philbeck, T., & Davis, N. (2018). The fourth industrial revolution. Journal of International Affairs, 72(1), 17-22.

[4] Karabegović, I., Karabegović, E., Mahmić, M., & Husak, E. (2019, June). Implementation of industry 4.0 and industrial robots in the manufacturing processes. In International Conference "New Technologies, Development and Applications" (pp. 3-14). Springer, Cham.

[5] Banjanović-Mehmedović, L., & Mehmedović, F. (2020). Intelligent manufacturing systems driven by artificial intelligence in industry 4.0. In Handbook of Research on Integrating Industry 4.0 in Business and Manufacturing (pp. 31-52). IGI global.

[6] Karabegović, I., Karabegović, E., Mahmić, M., & Husak, E. (2020, June). Dissemination of Patents of the Base Technologies of the Fourth Industrial Revolution-Industry 4.0. In International Conference "New Technologies, Development and Applications" (pp. 3-15). Springer, Cham.

[7] Wortmann, F., & Flüchter, K. (2015). Internet of things. Business & Information Systems Engineering, 57(3), 221-224.

[8] Patel, K. K., & Patel, S. M. (2016). Internet of things-IOT: definition, characteristics, architecture, enabling technologies, application & future challenges. International journal of engineering science and computing, 6(5).
[9] Mazhelis, O., Luoma, E., & Warma, H. (2012). Defining an internet-of-things ecosystem. In Internet of things, smart spaces, and next generation networking (pp. 1-14). Springer, Berlin, Heidelberg.
[10] McEwen, A., & Cassimally, H. (2013). Designing the internet of things. John Wiley & Sons.
[11] Badnjević, A., Gurbeta, L., Bošković, D., & Džemić, Z. (2015). Measurement in medicine–Past, present, future. Folia Medica, 50(1).
[12] Biswas, R. (2014). Data Structures for Big Data. International Journal Computing and Optimization, (2), 73-93.
[13] Ristevski, B., & Savoska, S. (2021). Healthcare and medical Big Data analytics. In Applications of Big Data in Healthcare (pp. 85-112). Academic Press.
[14] Badnjević, A., Avdihodžić, H., & Gurbeta Pokvić, L. (2021). ARTIFICIAL INTELLIGENCE IN MEDICAL DEVICES: PAST, PRESENT AND FUTURE. Psychiatria Danubina, 33(suppl 3), 101-106.
[15] Litjens, G., Sánchez, C. I., Timofeeva, N., Hermsen, M., Nagtegaal, I., Kovacs, I., ... & Van Der Laak, J. (2016). Deep learning as a tool for increased accuracy and efficiency of histopathological diagnosis. Scientific reports, 6(1), 1-11.
[16] Nuhić, J., Spahić, L., Ćordić, S., & Kevrić, J. (2019, May). Comparative study on different classification techniques for ovarian cancer detection. In International Conference on Medical and Biological Engineering (pp. 511-518). Springer, Cham.
[17] Spahić, L., Šehović, E., Šećerović, A., Đozić, Z., & Smajlović-Skenderagić, L. (2019, May). Lactose intolerance prediction using artificial neural networks. In International Conference on Medical and Biological Engineering (pp. 505-510). Springer, Cham.
[18] Alić, B., Gurbeta, L., Badnjević, A., Badnjević-Čengić, A., Malenica, M., Dujić, T., ... & Bego, T. (2017). Classification of metabolic syndrome patients using implemented expert system. In CMBEBIH 2017 (pp. 601-607). Springer, Singapore.
[19] Catic A., Gurbeta L., Kurtovic-Kozaric A., Mehmedbasic S., Badnjevic A. "Application of Neural Networks for classification of Patau, Edwards, Down, Turner and Klinefelter Syndrome based on first trimester maternal serum screening data, ultrasonographic findings and patient demographics", BMC Medical Genomics (2018) 11:19, DOI: 10.1186/s12920-018-0333-2
[20] Aljovic A, Badnjevic A, Gurbeta L, „Artificial Neural Networks in the Discrimination of Alzheimer's disease Using Biomarkers Data", IEEE 5th Mediterranean Conference on Embedded Computing (MECO), 12 – 16 June 2016, Bar, Montenegro
[21] Alic B, Gurbeta L, Badnjevic A, et.al., "Classification of Metabolic Syndrome patients using implemented Expert System", CMBEBIH 2017. IFMBE Proceedings, vol 62. pp 601-607, Springer, Singapore. DOI: 10.1007/978-981-10-4166-2_91

[22] Muhamed Karajic, Edin Begic, Emina Hrvat, Lejla Gurbeta Poković. Application of Artificial Intelligence tools in classification and diagnosis of heart disease: general review. Badnjevic, Gurbeta Poković (Eds.) Proceedings of the International Conference on Medical and Biological Engineering, CMBEBIH 2021, April 21 – 24, 2021, Mostar, Bosnia and Herzegovina, ISBN 978-3-030-73909-6

[23] Bećirović, L. S., Deumić, A., Poković, L. G., & Badnjevic, A. (2021, October). Aritificial Inteligence Challenges in COPD management: a review. In 2021 IEEE 21st International Conference on Bioinformatics and Bioengineering (BIBE) (pp. 1-7). IEEE.

[24] Hafizović, L., Čaušević, A., Deumić, A., Bećirović, L. S., Poković, L. G., & Badnjević, A. (2021, October). The Use of Artificial Intelligence in Diagnostic Medical Imaging: Systematic Literature Review. In 2021 IEEE 21st International Conference on Bioinformatics and Bioengineering (BIBE) (pp. 1-6). IEEE.

[25] Stokes, K., Castaldo, R., Franzese, M., Salvatore, M., Fico, G., Pokvic, L. G., ... & Pecchia, L. (2021). A machine learning model for supporting symptom-based referral and diagnosis of bronchitis and pneumonia in limited resource settings. Biocybernetics and Biomedical Engineering, 41(4), 1288-1302.

[26] Priya CK, Sudhakar M, Lingampalli J, Basha CZ. An Advanced Fog based Health Care System Using ANN for the prediction of Asthma. In2021 5th International Conference on Computing Methodologies and Communication (ICCMC) 2021 Apr 8 (pp. 1138-1145). IEEE.

[27] Nandy, S., Adhikari, M., Balasubramanian, V., Menon, V. G., Li, X., & Zakarya, M. (2021). An intelligent heart disease prediction system based on swarm-artificial neural network. Neural Computing and Applications, 1-15.

[28] Annals of oncology, retrieved from: https://www.annalsofoncology.org/article/S0923-7534(20)36056-7/fulltext#:~:text=Prostate%20cancer%20is%20the%20third,%E2%88%927.1%25%20since%202015).

[29] Cancer.org, retrieved from: https://www.cancer.org/cancer/prostate-cancer/about/key-statistics.html#:~:text=The%20American%20Cancer%20Society's%20estimates,34%2C500%20deaths%20from%20prostate%20cancer

[30] Humphrey, P. A. (2017). Histopathology of prostate cancer. Cold Spring Harbor Perspectives in Medicine, 7(10), a030411.

[31] Spahić, L., & Ćordić, S. (2019, May). Prostate tissue classification based on prostate-specific antigen levels and mitochondrial DNA copy number using artificial neural network. In International conference on medical and biological engineering (pp. 649-654). Springer, Cham.

[32] Fukuyama, M. (2018). Society 5.0: Aiming for a new human-centered society. Japan Spotlight, 27(Society 5.0), 47-50.

[33] Nair, M. M., Tyagi, A. K., & Sreenath, N. (2021, January). The future with industry 4.0 at the core of society 5.0: open issues, future opportunities and challenges. In 2021 International Conference on Computer Communication and Informatics (ICCCI) (pp. 1-7). IEEE.

[34] EU Medical Device Directives: Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices; Council Directive 93/42/EEC on Medical Devices (MDD); Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) [Online] Available at: https://eur-lex.europa.eu/homepage.html
[35] Internal Market, Industry, Entrepreneurship and SMEs, Single market and standards, Medical Devices. Available at: https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices_en
[36] ISO 13485 standard: Medical devices — Quality management systems — Requirements for regulatory purposes. [Online] Available at: www.iso.org/standard/59752.html
[37] IEC 60601 Medical electrical equipment - all parts. [Online] Available at: https://webstore.iec.ch/publication/2603
[38] ISO 80601 Medical electrical equipment - all parts. [Online] Available at: https://www.iso.org/standard/72069.html
[39] CE marking. [Online] Available at: https://ec.europa.eu/growth/single-market/ce-marking_hr
[40] MAUDE database, Avaliable at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm
[41] EUDAMED database [Online] Available at: https://ec.europa.eu/tools/eudamed/#/screen/home
[42] Kovačević, Ž., Gurbeta Pokvić, L., Spahić, L., & Badnjević, A. (2020). Prediction of medical device performance using machine learning techniques: infant incubator case study. Health and Technology, 10(1), 151-155.
[43] Spahić, L., Kurta, E., Ćordić, S., Bećirović, M., Gurbeta, L., Kovacevic, Z., ... & Badnjevic, A. (2019, May). Machine learning techniques for performance prediction of medical devices: infant incubators. In International Conference on Medical and Biological Engineering (pp. 483-490). Springer, Cham.
[44] Badnjević, A., Pokvić, L. G., Hasičić, M., Bandić, L., Mašetić, Z., Kovačević, Ž., ... & Pecchia, L. (2019). Evidence-based clinical engineering: machine learning algorithms for prediction of defibrillator performance. Biomedical Signal Processing and Control, 54, 101629.
[45] Hadžić, L., Fazlić, A., Hasanić, O., Kudić, N., & Spahić, L. (2019, May). Expert System for Performance Prediction of Anesthesia Machines. In International Conference on Medical and Biological Engineering (pp. 671-679). Springer, Cham.
[46] Hrvat, F., Spahić, L., Pokvić, L. G., & Badnjević, A. (2020). Artificial Intelligence for prediction of medical device performance: Infusion and perfusor pumps case study. In 9th Mediterranean Conference on Embedded Computing MECO.