HEALTH, ENVIRONMENT, DEVELOPMENT

THE HUMAN FACTOR ISSUES IN BIOMEDICAL SYSTEMS

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Summary
The consequence of insufficient attention of specialists to the human factor in the development of biomedical technologies is the lack of awareness of biomedical engineering students with the cognitive aspects of human-machine interaction, which does not allow the design of safe and reliable biomedical systems. The paper shows the need to consider the human factor at all stages of the life cycle of biomedical systems and the need to introduce a discipline dedicated to the phenomenon of the human factor into the training program for biomedical engineers. Thus, the consequence of the development of biotechnologies is the necessity for teaching students to consider the human factor at all stages of the biomedical technologies life cycle. The motivation is to bridge the gap between the theoretical concepts proposed to eliminate human factors problems in the modelling and design of biomedical systems and the practical implementation of human activities in them. It is necessary to consider the issues that may arise due to the human factor in the operation of biomedical systems in order to move forward in solving these problems.
Key words: human factor, safety, reliability, biomedical system, biomedical engineer, human-machine interaction, training.

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1. Introduction

One of the problems of modern medical information technologies is the problems of biosafety, bioethics and bioprotection *(Sanders & McCormick, 1993; Emanuel et al., 2003; Beauchamp, Childress, 2001)*. The issues of biosafety and bioprotection impose increasingly strict requirements on scientific and technical developments, which in turn prompts scientists and industrialists to develop safer and more advanced technologies. The safety of technologies, equipment and human activity is a sign of the highest qualification of a person, which is present in all stages of the life cycle of any technology. The ability to prevent risks and minimize their consequences, related to the human factor, is one of the essential professional skills today.

Well-known that achieving absolute safety is impossible. However, medical technologies and equipment do not pose a danger before a person's decision-making is not involved *(Nachreiner, 1995; Hancock & Drury, 2011)*. At the same time, modern technologies, methods and means, and medical equipment do not guarantee safety without proper human functioning – developers, personnel, employees, their awareness and adequate knowledge *(Fedota, Parasuraman, 2010; Carayon, 2006)*. Safe equipment causes a false sense of security and safety, which increases the risk if you do not take into account the peculiarities of the nature of the human factor during design, installation, material and technical maintenance and operation. That is, the emphasis on the issue of human training at all stages of the life cycle of biomedical technologies is relevant. Thus, the consequence of the rapid development of biotechnology is the need not only for management, their legal regulation but also for teaching students to take into account the human factor at all stages of the life cycle of medical technologies, which is the purpose of this work.

The motivation is to bridge the gap between the theoretical concepts proposed to address human factors issues in modelling and designing complex biomedical systems and the practical implementation of human activities in biomedical systems. It is necessary to consider the problems that may arise due to the human factor in the operation of biomedical systems to move forward in solving these problems.

2. The role of the human factor in biomedical systems

One of the crucial issues is ensuring the safety and reliability of biomedical systems. The challenges of the modern information world that directly affect the safety of biomedical systems and technologies are:

1) peculiarities of human-machine interaction in unpredictable and complex conditions of operating;

2) increasing informational complexity of systems (informational, technical, physical, biological, etc.);

3) person's cognitive capabilities (individuality of perception, imagination and thinking) and cognitive distortions under stress conditions.

These challenges are directly related to the problems of the development of medical systems and their further use, for example, the diagnosis of the state of human health or the functional state of the operator of complex systems.

Ishikawa's diagram shows the background and multifaceted nature of the human factor problem. It is clear that the safety and reliability of biomedical systems under complex conditions are connected, on the one hand, with the growth of information complexity of systems, on the other – with the manifestation of the phenomenon of the human factor in education, design, activity and people-to-people communications.

In the functioning of biomedical systems under conditions of unforeseen situations occurrence, the problem is the spatio-temporal inconsistency of information flows, which significantly complicates their analysis and decision-making. At the same time, a person, as an element of a biomedical system, is a source, receiver and analyser of information. It significantly affects the reliability and efficiency of the system's functioning *(Kleiner, 2006; Protasenko, Mygal, 2021)*.

The human factor manifests at all stages of the life cycle:

1) creation of biomedical systems and technologies;

2) selection and measurement of informative parameters;

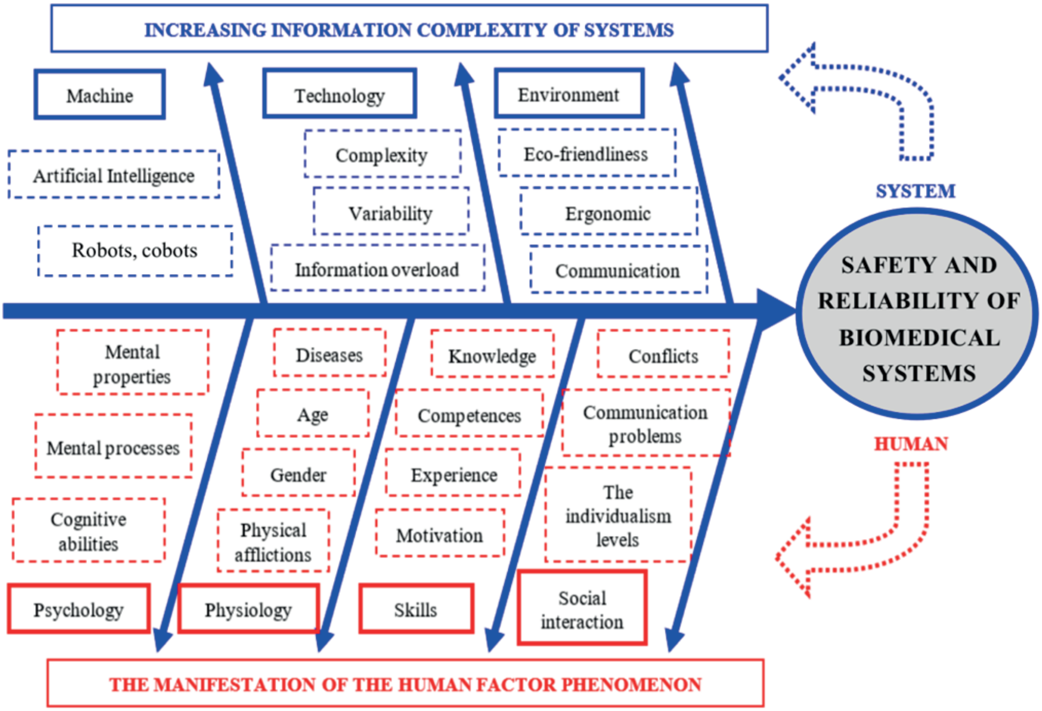

Fig. 1. Factors affecting safety and reliability of biomedical systems (an adapted version of the Ishikawa diagram)

3) selection of relevant information;

4) processing of information, its analysis and generalization on the basis of previously set or formed evaluation criteria;

5) making a decision based on the analysis of the informational and conceptual model;

6) implementation of the adopted decision using a sequence of actions.

Therefore, the human factor is the cause and the consequence of accidents. Human is the cause of accidents because:

1) wrong decisions of a person due to an incorrect perception of information by him;

2) development of systems or technologies without considering the person's individuality.

A person is a consequence of the occurrence of accidents because there are:

1) limited cognitive and psychophysiological capabilities of a person;

2) use specific cognitive patterns during design that do not correspond to activity conditions.

All this leads to the individuality of human-machine interaction and the appearance of cognitive problems (distortion of information, etc.).

Therefore, it is essential to consider the necessity to take into account ergonomic principles to ensure the reliability, safety and stability of human work in biomedical systems. The solution to this problem requires the identification of interdisciplinary connections and the formation of a "new type" of an engineer who considers the person's individuality and cognitive capabilities during design and the laws of ergodynamics and neuroergonomics (Fig. 2).

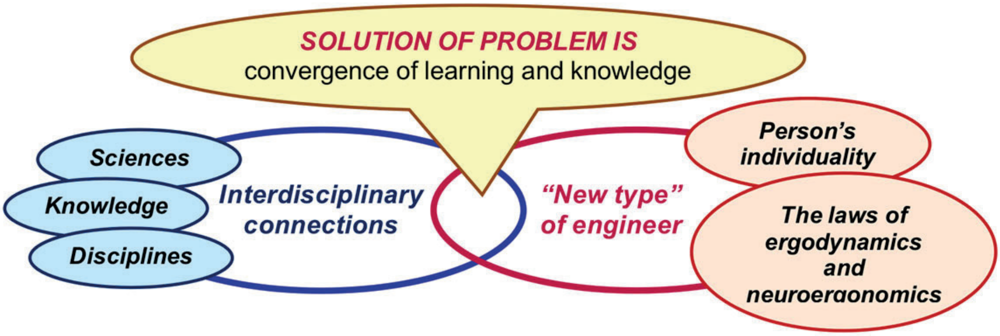

Fig. 2. Solution of the human factor problem

Under normal conditions, the reliability of systems is ensured by the requirements of various standards, which implement different approaches, methods, parameters, criteria, algorithms, and programs. Divergent learning is sufficient for this. However, under the influence of external and internal stress factors, neuroergonomic, psychophysiological and psychological aspects of human perception of information affect the reliability of systems. As a result, we have the human factor manifestations. Thus, most of the problems today are related to the differentiation of knowledge. However, reliable and viable systems require the convergence of information in education, interdisciplinary approaches and strategies. Preventing the manifestation of the human factor is possible only with the help of convergent learning and interdisciplinary approaches *(Mygal et al., 2021, 2022)*.

3. The problem of training biomedical engineers

A feature of the biomedical engineer's training is the presence of a person at all stages of the life cycle of technologies and equipment. The implementation of the requirements of bioethics and biosafety is carried out by specialists who carry out scientific and technical developments – create new technologies, develop biotechnological products, carry out their implementation and maintenance and operate them. Human in biotechnology acts as the goal and as a "means" of scientific study. However, an obstacle to the design of viable biomedical systems is ignorance of the cognitive aspects of human interaction with technologies and equipment. It means the need to consider the human factor at all stages of the life cycle of biomedical systems. That is why an integral component of the educational training of future biomedical engineers is the study and research of a number of biosafety and bioprotection issues related to the human factor. Thus, there is a need to introduce a discipline dedicated to the phenomenon of the human factor.

Today, there is a cycle of safety-related disciplines in the biomedical engineering curriculum. This cycle reveals problems and aspects of safety in the development, maintenance and operation of biotechnologies and medical equipment. For example, bioethics considers philosophical knowledge about human rights and the creation of new medical and biological technologies, which give rise to many problems that require solutions from the point of view of law and morality. Thus, students learn to prevent consequences and study the potential danger of biotechnologies at various stages – from technology development to industrial implementation. However, all this happens without considering the reasons underlying the safety of biotechnology and medical equipment. And the reason lies in the plane of the human factor, that is, the peculiarities of the interaction of human and technology in the system "human – machine", "human – educational environment" and "human – technology – environment".

This plane is the intersection of a person's psychological characteristics, psychophysiological limitations, awareness and motivation, the desire to use his resources and knowledge. At the same time, the safety, reliability and efficiency of biomedical systems designed and used by humans depend on the consideration of the human factor. The cognitive perception of technologies is at the core of the discipline "Human factor engineering"

Today, in the leading universities, there are many disciplines aimed at solving the problem of the human factor. These are "Human Factors and Ergonomics", "Human factors engineers", "Human Computer Interaction", "Human-Machine System", "Using Virtual Reality", "Humans in Extreme Environments", etc. Successful and competitive Bachelor's, Master's, Doctoral programs in Human Factors Engineering and Ergonomics (HFEE) deals with ways of designing workplaces, machines, operations and work environments to be compatible with human capabilities and limitations.

Human factors engineering is a systematic analysis of the systems functioning and considers ergonomic information about human capabilities and limitations in connection with machines, workplaces and environment. Such a discipline is necessary for any engineer (developer, designer, manager), who must consider the peculiarities of human-machine interaction, the activity style, and the influence of stress factors of the environment and activity under designing *(Dul, Bruder et al., 2012; Lee et al., 2017; Mygal & Protasenko, 2019)*. The key goal of the discipline "Human factor engineering" is to ensure the effectiveness of human activity in the human-machine system at all stages of its life cycle – from design to operation.

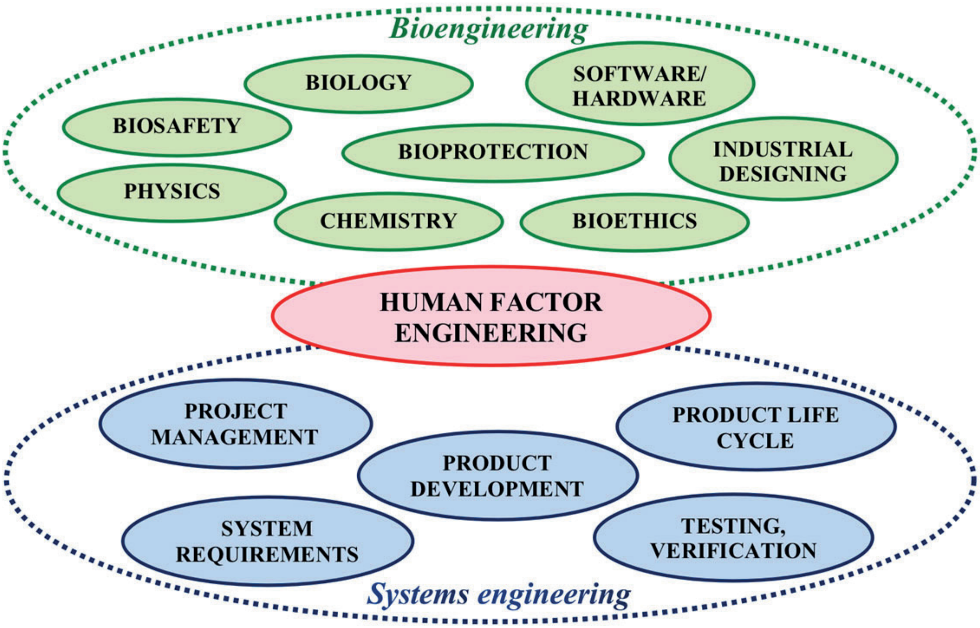

Fig. 3. Interdisciplinary connections and interaction of sciences

Interdisciplinary human factor engineering combines cognitive ergonomics, neuroergonomics, cognitive psychology, human biomedical engineering and other sciences *(Dul, Bruder et al., 2012; Lee et al., 2017; Mygal & Protasenko, 2019; Dempsey, 2006)*. So, it is a union of engineering sciences, information technologies, psychology, neuro- and cognitive sciences to ensure the safety, reliability and stability of human-machine systems, human-dependent technologies and processes (Fig. 3).

To consider the human factor at all stages of the life cycle of biomedical systems, developers need to be familiar with ergonomic laws and cognitive aspects of human-machine interaction. It led to the flexible systems development, which have cognitive and cyber-physical resistance to threats in control systems. Designing such systems requires interdisciplinary solutions involving cognitive psychology and neuroergonomics, control engineering, and human factors engineering.

4. The individuality of human factor: approaches to solving the problem

Today, there are two approaches to managing the human factor – an individual (or personal) way and a systemic (or organizational) one *(De Vasconcelos, V. et al., 2018; Mygal et al., 2022; Parasuraman, 2003; Parasuraman, Mehta, 2013)*.

The individual approach focuses on the mistakes of individual people for personal reasons – forgetfulness, inattention, poor motivation, carelessness and imprudence. Countermeasures to prevent the realization of risks related to the human factor are training, professional selection, motivation and reduction of undesirable behaviour by means of intimidation (disciplinary measures, fines, retraining).

However, the formula “knowledge + skills + motivation + experience” does not guarantee the absence of errors and risks. Therefore, the systemic approach is more widespread because it allows you to get closer to solving the human factor problem.

The systems approach focuses on the organisational aspects of human activity – an arrangement of the process in such a way as to prevent errors and mitigate the consequences. The errors are consequences of the poor organisation of the working process but not causes. The roots of this are not so much in the complexity of human nature as in systemic organisational factors. The countermeasure is to change the conditions of human existence in technologies and systems.

It is clear that the main factor hindering the implementation of the system approach is certain shortcomings and problems in the education of modern engineers, which are manifested in all areas where a person must not make mistakes, starting with the existence of a safety culture.

Thus, the management of the human factor through training also has two ways: individual and systemic. An individual way is the decrease dangerous mistakes through training, career guidance and professional retraining.

The system approach is implemented through the training of specialists to create such systems that better tolerate the occurrence of errors and contain their destructive consequences. In other words, to create a system safety management program.

The infographic shows that 80% of problems in systems are caused by the human factor (Fig. 4). At the same time, of this 80%, only 10% are individual manifestations of personality. It is the so-called triad of human behavioural aspects: can not, does not know, does not want. And 90% are organizational deficiencies that lead to the realization of risks. And the only way to master this problem is to study.

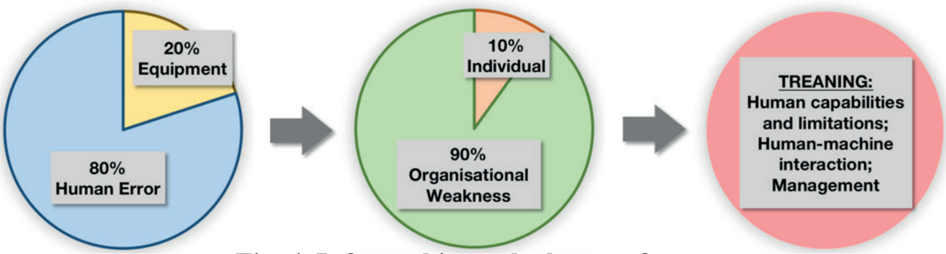

Fig. 4. Infographic on the human factor

Modern concepts of human factors engineering are the awareness and consideration of the laws associated with the emergence of new system concepts - viability, survivability, reliability and dependability. This allows solving the urgent tasks of reducing risks in biomedical systems by understanding the role of a person and his cognitive, behavioural and psychophysiological features. Thus, solving the human factor problem is possible based on the following concepts.

Considering the human factor at all stages of the life cycle of systems. According to Scott A. Snook's theory of "Practical Displacement", the expected properties of a system – warranty capacity, viability, and reliability - always differ significantly from the obtained result. The main reason for practical displacement is the influence of the human factor. At the same time, considering this influence reduces this "displacement" and brings the result closer to the predicted one.

Considering the distribution of random and systematic risk factors. It is the organisational factor that has a decisive influence on the functioning of systems in extreme conditions.

Considering the dependence of the system's viability on three levels of risk management strategies: retrospective, proactive and predictive management, which allows for the development of highly reliable biosystems.

Thus, the quality, reliability and safety of biomedical systems:

1) directly depends on taking into account the human factor at all stages of the life cycle of systems;

2) the human factor directly depends on the convergence of training.

Thus, an interdisciplinary view of human capabilities in technical systems will create the foundation for improving biosystems' quality, reliability and safety *(Roco, Bainbridge, 2002; Rigolot, 2020; Sanders & McCormick, 1993; Mygal et al, 2019, 2020, 2021, 2022)*.

4. Conclusions

Today, despite the focus on training biomedical engineers, there are consequences of insufficient attention to the human factor under considering biosafety problems and the development of modern biomedical technologies. It indicates that specialists are not familiar with the cognitive aspects of human interaction with technologies and equipment, which does not allow the proper design of reliable biomedical systems. Therefore, the introduction of a training course devoted to issues of human factor engineering as a mandatory component of the training programs of biomedical engineers is relevant today.

It will ensure a higher qualification for future specialists in their multifaceted activities under the design and operation of biomedical technologies. "Human factor engineering" is an interdisciplinary view of human capabilities in technical systems. Its implementation will create the basis for improving the quality of training of biomedical engineers.

The development of ergonomic thinking in future biomedical engineers should be given considerable attention because:

1) it is a system of views of an individual on the development of human-machine systems and the role of humans in them;

2) it is the ability to predict risks in these systems and plan the development of systems with a preliminary consideration of these risks.

Ultimately, ergonomic thinking for a biomedical engineer, along with ecological and critical thinking, is a sign of education and a guarantee of the high qualification of a specialist.

References

1. Beauchamp, T., Childress, J. (2001). Principles of Biomedical Ethics. Oxford; New York: Oxford University Press, 456 p.

2. Carayon, P. (2006). Human factors of complex sociotechnical systems. Applied Ergonomics, 37 (4), 525–535.

3. De Vasconcelos, V., Soares, W.A., & Marques R.O. (2018). Integrated Engineering Approach to Safety, Reliability, Risk Management and Human Factors. Human Factors and Reliability Engineering for Safety and Security in Critical Infrastructures, (pp. 77–107). Switzerland: Springer Int. Publishing AG.

4. Dempsey, P.G., Wogalter, M.S, & Hancock, P.A. (2006). Defining ergonomics/human factors. Retrieved from https://peterhancock.ucf.edu/wp-content/uploads/sites/12/2014/06/Defining-Ergonomics-Human-Factors-Dempsey-Wogalter-Hancock2006.pdf

5. Dul, J., Bruder R. and all. (2012). A strategy for human factors/ergonomics: developing the discipline and profession, Ergonomics, 55, № 4, 377–395.

6. Emanuel, E.J., Crouch, R.A., Arras, J.D. et al. (2003). Ethical and Regulatory Aspects of Clinical Research. Baltimore; London: Johns Hopkins University Press, 490 p.

7. Fedota, John R., Parasuraman, R. (2010). Neuroergonomics and human error. Theoretical Issues in Ergonomics Science, 11 (5), 402-421. DOI: 10.1080/14639220902853104

8. Hancock, P.A., & Drury, C. G. (2011). Does human factors/ergonomics contribute to the quality of life? Theoretical Issues in Ergonomics Science, 12(5), 416–426.

9. Kleiner, B. M. (2006). Macroergonomics: Analysis and design of work systems. Applied Ergonomics, 37 (1), 81–89.

10. Lee, J.D.; Wickens, C.D.; Liu Y.; Boyle, L.N. (2017). Designing for People: An introduction to human factors engineering. Charleston, SC: CreateSpace.

11. Mygal, G., Mygal, V., Protasenko, O., Klymenko, I. (2022). Cognitive Aspects of Ensuring the Safety, Dependability and Stability of a Dynamic System's Functioning in Extreme Conditions. In: Nechyporuk M., Pavlikov V., Kritskiy D. (eds) Integrated Computer Technologies in Mechanical Engineering – 2021. ICTM 2021. Lecture Notes in Networks and Systems, vol 367. Springer, Cham. https://doi.org/10.1007/978-3-030-94259-5_18.

12. Mygal, H.V., & Protasenko, O.F. (2019). Inzheneriia liudskoho chynnyka v suchasnii osviti [Human Factor Engineering in Modern Education]. Vcheni zapysky TNU imeni

V.I. Vernadskoho. Seriia: Tekhnichni nauky – Scientific notes of Taurida National V.I. Vernadsky University. Series: Technical Sciences, 6, 30(69), 1–6 [in Ukrainian].
13. Mygal, V., Mygal, G., Mygal, S. (2021). Transdisciplinary convergent approach – human factor. Radioelectronic and Computer Systems, no. 4(100), doi: 10.32620/reks.2021.4.01.
14. Mygal, V., Mygal, G., Mygal, S. (2021). Transdisciplinary convergent approach – human factor. Radioelectronic and Computer Systems, 4(100). doi: 10.32620/reks.2021.4.01.
15. Mygal, V., Mygal, G., Mygal, S. (2022). Cognitive Space for Online and Offline Learning: A Convergent Approach. The Educational Review, USA, 6(4), 109-123. DOI: http://dx.doi.org/10.26855/er.2022.04.001.
16. Mygal, V.P, & Mygal, G.V. (2019). Problems of Digitized Information Flow Analysis: Cognitive Aspects. Information & Security: An International Journal, 43(2), 134–144.
17. Mygal, V.P., Mygal, G.V. & Illiashenko, O. (2021). Intelligent Decision Support – Cognitive Aspects. Digital Transformation, Cyber Security and Resilience of Modern Societies. Studies in Big Data. T. Tagarev, K. T. Atanassov, V. Kharchenko, & J. Kacprzyk (Eds.). Springer.
18. Nachreiner, F. (1995). Standards for ergonomic principles relating to the design of work systems and to mental workload, Applied Ergonomics, 26, № 4, 259–263.
19. Parasuraman, R. (2003). Neuroergonomics: research and practice. Theor. Issues Ergon. Sci., vol. 4, no. 1–2, 5–20.
20. Parasuraman, R., Mehta, R. (2013). Neuroergonomics: a review of applications to physical and cognitive work. Front Hum Neurosci., № 7, 889. DOI: 10.3389/fnhum.2013.00889.
21. Protasenko, O. F., Mygal, G. V. (2020). Human Resources Are a Factor in Applying of Man-Machine Systems Safety. Municipal economy of cities, 6 (159), 139–146.
22. Protasenko, O., Mygal, G. (2021). Human Factors: The Problem of Man-machine Interaction in the Digitalization Conditions.. Scientific journal of polonia university. Periodyk naukowy akademii polonijnej (PNAP), 48 № 5, 198–210. Czestochowa 2021. DOI: https://doi.org/10.23856/4825.
23. Rigolot, C. (2020). Transdisciplinarity as a discipline and a way of being: complementarities and creative tensions. Humanities and Social Sciences Communications, V. 7. https://doi.org/10.1057/s41599-020-00598-5
24. Roco, M., Bainbridge, W. (2002). Converging Technologies for Improving Human Performance: Nanotechnology, Biotechnology, Information Technology and Cognitive Science. Journal of Nanoparticle Research, 4, 281–295.
25. Sanders, M. S., & McCormick, E. J. (1993). Human factors in engineering and design (7th ed.). New York, NY: McGraw-Hill.