Some Aspects of Developing Sensory Networks for Medical Purpose

IGOR I. KOLTUNOV[1], ANTON V. PANFILOV[2], IVAN A. POSELSKY[1], NIKOLAY N. CHUBUKOV[2] and IVAN V. KRECHETOV[1]

[1]Moscow Polytechnic University, Moscow, Russia.
[2]Tradition Group LTD., Moscow, Russia.
*Corresponding author E-mail: v-pos@yandex.ru

http://dx.doi.org/10.13005/bpj/1327

(Received: November 02, 2017; accepted: November 27, 2017)

ABSTRACT

The work objective is to study variants of hardware-software and design-layout solutions for creating a noninvasive wearable biosensor platform for monitoring physiological indicators of a person's health in a routine wearing mode, taking into account the application features: high-noise environment, motion activity, complexity of factoring a priori biomedical information in. The relevance of the work is due to an expected significant improvement in the quality of medical services provided to the population of Russia, as well as to a reduction in their cost through mainstreaming the most advanced IT solutions based on modern discoveries of fundamental science in armamentarium of medical institutions. Until now, a well-formed ideology of biosensor network development for current non-invasive diagnostics has evolved, which determines the novelty of the studies. The proposed approach is a development of the telemedicine idea aimed at solving problems of functional diagnostics with a high degree of automation. The article shows the main aspects and challenges of building effective models for current diagnosis and diagnostic prognosis of a patient's health status – the object of non-invasive monitoring based on routine analysis of characteristic combinations of their in-life data in terms of ICD codes and results of long-term collection, processing, and semantic classification of biomedical data. The practical and theoretical significance of the findings is that a scientific and technical basis and a methodological basis have been formed for further improvement of the design work efficiency.

Keywords: Biosensor, Biosensor platform, Diagnostic informative value, Diagnostic prognosis, non-invasive monitoring, Nosology, cloud technologies, Sensory body network, Telemedicine.

INTRODUCTION

Problem description

The quality of healthcare services delivered to the population of Russia has increased significantly over the past two decades. A new level of service is achievable as a result of mainstreaming the most advanced technical solutions based on modern discoveries of fundamental science in armamentarium of medical institutions. The modern market of medical equipment offers a variety of new high-tech products applicable for addressing a wide range of healthcare challenges.

Published by Oriental Scientific Publishing Company © 2017

However, in terms of personal health monitoring systems, the Russian market is at the early stage. There have been no developments that would provide comprehensive management of a patient, management of their health, control of prescription safety yet. Meanwhile, the future of functional diagnostics, an important therapy area, whose subject is an objective assessment of a human body state, revealing pathologies, and analyzing the degree of their severity, is associated by experts with designing intelligent surface sensory networks fastened on the body with special devices.

Routinely wearable biosensors are able to permanently monitor round-the-clock the health of many patients simultaneously on the basis of continuous remote analysis of a set of biometric indicators. A promising outlook of such systems is determined by their multifunctionality, efficiency, reliability, and a high degree of applicability to a wide range of tasks solved by diagnostic medicine. The proposed approach is the development of the idea of telemedicine. The design concept based on this idea provides for the ability to create a scalable, geographically dispersed client network for simultaneous servicing of a large cohort of patients. The modeling tools used in the development of the system presuppose achieving a high degree of automation of procedures for remote diagnostic analytics and prognostics.

A theoretical basis for the design is a methodology of optimal control that assumes a structural and parametric identification of a statistical diagnostic model based on solving extremum multi-criteria choice problem [1]. Collection of actual biomedical data is carried out automatically without discontinuing a patient's everyday social life, while data packet communication to the electronic processing medical center, indicating the location and an individual personal identifier, is performed instantly by a telemetric communication channel.

The research objectives are determined by meeting the requirements of the technical design specification for the 'sensory body network' hardware and software complex (HSC SBN) to exercise the following functions:

- Scaling the centralized monitoring system to create client networks of different configurations;
- Automatic collection and analysis of biomedical data at the receptor level;
- Accurate and high-quality object dispatching, operating remote control of the processes;
- Information support for the operation of special medical units and medical personnel;
- Generation of standard reports for any period of time (day, week, month, quarter, etc.) by patient category;
- Generation of non-standard reports on event-driven requests of an operator.

The HSC SBN modular architecture provides:

- The software execution on any server architecture;
- Operation of any operator automated workstation (AW) on any computer without updating the operating system;
- Data exchange with hardware peripherals via a telemetry channel;
- Automatic internal testing of the system components;
- Storage of information in a database;
- A high performance and a high-speed response of HSC SBN;
- A user-friendly and self-explanatory user interface;
- Automatic device search;
- Adding and removing clients;
- The ability to enter the user interface from your computer (tablet, smartphone) through an Internet browser.

MATERIALS AND METHODS

Layout solutions

The research has been carried out at the laboratory test base of the Moscow Polytechnic University.

The HSC SBN layout solutions have been offered out of a set of standard unified elements on the analogy with 'LEGO' designer. This approach to engineering allows for implementation of the open architecture principle and, based on routine analysis of disease patterns of the population, formation of

HSC SBN specified target properties and sensory network modifiability against its specific application.

The base platform can be scaled to any number of users and is plastically modified to physiological characteristics of any population categories: athletes, pregnant women, school-aged children, diabetic patients, patients with cardiac arrhythmia, bedridden patients, the aged ones, etc. Under this approach, a flexible pricing policy of service delivery according to the solvency of various social groups of the population becomes possible.

The research method is based on the on-going monitoring and effective control of the network users' health status. The monitoring is provided by accurately recording events of patients' critical physiological parameters overranging, testing patients in case of detecting specific symptomatology, correcting diagnoses according to newly incoming data, diagnostic prognosis management. The control is achieved by developing recommendations for prevention of a disease or a choice of therapeutic strategies.

Diagnostics is complicated by the fact that the monitored parameters are represented by a set of interdependent time functions that collectively characterize a complex multidimensional deterministic process. The degree of correspondence between this process and the monitoring objects is determined by an adequacy of individual physiological status models of the patients observed, each of them coordinating:

Temporal retrospective expressed by

- A priori health information stored in an electronic clinical record and obtained during medical examinations and with a previous diagnosis by HSC SBN (gender, age, chronic diseases, immune status, etc.);
- External and internal pathogenic factors that influence the development of a disease in one way or another;
- A formalized anamnesis based on the results of a patient's visit to a doctor or generated following the results of a telemedical consultation.

Current monitored parameters of the physiological status of a remotely observed patient represented by

- Biomedical information from the sensory network;
- Findings of a diagnostician according to the results of the HSC SBN data processing;
- Results of a laboratory test at a request automatically generated by HSC SBN or by a referral from a diagnostician.

Temporal perspective expressed by estimated scenarios on critical time horizons with estimated probabilities of possible outcomes.

Drawing up recommendations for improving the current physiological status of a medical observation object in the course of solving the extremum problem of optimal control of human health.

The optimum area of the biomedical model of a human body is determined by levels of acceptable risk guaranteeing the lowest probability of disease occurrence, or bringing the body to a sound condition the most quickly if reliable signs of the onset of a disease are found.

The specified level of technical implementation and high competitiveness of the HSC SBN are achieved by strict observance of the requirements for development in terms of: reliability, safety, personal data protection, non-invasiveness, high-speed response, remotability, intellectuality, upgradability, automation, integrity and completeness of information use, ergonomics, reduction of the medical personnel's work load, hygienic and easy for patients, identifiability of pathologies, diagnostic accuracy, and prognostic efficiency.

HSC SBN refers to complex systems operating under conditions that prevent diagnostic process. A disturbing background is formed by a shortage of information, dynamically changing external conditions (climate, fluctuating physical loads, etc.), local black-outs, instability of reception contacts. To increase the resistance to operating conditions, the monitoring, control, and decisionmaking processes are based on the methodological principle of hypothesis verification, and are recursive and transactional in nature.

The hardware includes the following main components

1. A server is the main device of a network designed to support a launch of group tasks, to perform the functions of restriction and granting access to files and documents, to distribute the rights of network users, to ensure personal security and anti-virus protection, etc.
2. An aggregator is the final link of the HSC SBN wearable part and the key element of a dispatching system. It is a multichannel piconet controller based on Bluetooth Smart 4.2/5 IoT protocols. It exercises the function of data collection from the receptor level. It carries out a preliminary analysis of the patient's body condition based on personal profiles of acceptable indicators and submits the data to the cloud service for analysis. The aggregator is built on the basis of a smartphone software application that provides global access to the cloud service. Based on the monitoring results, a personal dynamic model of the scope of a patient's admissible states is specified taking into account the individual diagnostic data, gender, age, and race peculiarities.

The personal model is occasionally updated in the wearable device responding to critical deviations, even if there is no contact with the cloud service. If a technical capability of data communication fails be ensured, the data is stored in the local device memory for subsequent downloading. The degree of protection of the aggregator from environmental exposure according to [2] is in line with class IP67.
3. Hubs operate as multichannel intermediate measuring transducers, are in charge of dispatching the data communication channels between sensory groups and the aggregator, and constitute a secondary layer of the network. The hub output signals are fed to the input of the aggregator.
4. The primary SBN layer is formed by the receptor level biosensors. The diagnostic reliability and accuracy is largely due to uninterrupted operation of the sensor layer. By changing the composition of sensors, a sensory network can be flexibly configured. The search for methods to combine biosensors is dictated by the need to find the best sampling of biomedical data differing in the nature of appearance. Discrete samples from parallel measurement channels (MCs) are grouped according to the following characteristics:

- Dynamism (rapidly or slowly changing);
- Statistical properties (stationarity, ergodicity, gaussianity);
- Being powered from a common source of energy;
- Co-processing feasibility.

Depending on the characteristics of the groups, the following is determined: the discretization of the MC inquiry, moment characteristics of the samples with sufficient informativity while having maximum compactness, methods for calculating mathematical expectation (weighted mean, moving median, mode, empirical moments of the distribution of the first order), values of normalization coefficients, etc.

In SBN, the following MC groups are represented:

- A Holter sensor cluster that has an independent diagnostic value and combines up to 12 cardiograph electrodes;
- A group of motion activity sensors;
- Biosensors for biological fluid analysis (sweat, saliva, etc.);
- A family of physiological parameter recorders in terms of the body state (temperature, pressure, skin moisture, etc.).

Sensor clusters are powered from a self-contained supply, while their interaction with hubs is ensured either through a wired data link or a wireless one based on Bluetooth Low Energy (BLE) technologies.

The ability to optimally adapt the sampling frequency to a current task reduces the computing load on the network and lowers the weight and size of the SBN wearable part. The BLE standard concept is also aimed at reducing power consumption by limiting the communication bandwidth (the data transfer rate is no more than 1 Mbit/s with a packet size of 8 ÷ 27 bytes). For those sensor groups working at higher sampling frequencies, electro- and encephalography, an intermediate controller for data collection and communication to the aggregator is available using the Bluetooth 2.1/3.0 interface, which maintains a speed of up to 24 Mbps.

At the aggregator level, primary analysis of the recorded data is performed in terms of extreme values. Such cross-diagnostics instantly identifies critical deviations in a patient's body, and timely registers and spots operation failures of the sensory network. In response to detection of signal levels beyond permissible, alarm messages with priority status are generated and transmitted to the remote operator's panel.

Metrological aspect of the research

HSC SBN is an entity of metrological support (MS) subject to the standard [3]. This requirements document covers issues of calibration and calculation of MC metrological characteristics, metrological examination of technical documentation, type approval, verification; it also contains basic vocabulary of the knowledge domain and regulates some organizational and legal aspects of MS for measuring systems.

Primary data are collected by small-sized biosensors mounted at the body areas that are most sensitive to the respective physical parameter. Biosensors are in charge of transforming physical quantities into proportional measuring signals suitable for further co-processing. The reception scope is clearly identified by the condition of non-invasiveness: the system sensors are 'forbidden' to compromise the integrity of a human body or to injure it. The biosensor contact stability remains the cornerstone in ensuring the reliability of the complex. Qualitative selection of bio-information is also associated with inconveniences for an individual caused by the need to apply sound-conducting gels on the skin, embarrassment of local ventilation of the body surface, sweat removal difficulty, local skin irritation, allergic reactions.

Steady cooperation of all MCs ensures uninterrupted communication of information about the current health status of the network subscribers to the remote server. Depending on a cohort, the set of sensor devices may not only vary in composition, but also in construction, mounting mode, physical measurement principle, number of registered parameters by one device, accuracy.

Hubs and the aggregator constitute links of the measuring circuit and are MS entities subject to all metrological procedures provided for by the current requirements documents.

Metrological certification of programs and algorithms for processing biomedical data has been singled out as a separate MS task for complex MCs. The meaning of this procedure is to identify and fix the errors introduced in calculation as a result of a loss of accuracy due to intermediate results rounded off or using deliberately approximate calculation methods (transcendental equations, iterative procedures, Taylor approximation, etc.).

One of the significant components of an overall processing error is an inherited error. Its source of origin is that intrinsic errors of simple MCs conditioned by their accuracy class are modified and accumulated when translated to the subsequent links of a measuring circuit. These errors sometimes reach levels whereby the sense of measurement is lost. A mathematical description of the origin, the mode of demonstration, and the methods for eliminating inherited errors is given in [4].

Exclusive requirements for HSC SBN reliable operation, in turn, place exacting demands on calibration of SBN measurement channels. The calibration function is the principal metrological characteristic of MCs that determines a one-to-one correspondence between the signal value at the MC output and the corresponding size of a measured parameter. The calibration function allows one to restore by mathematical calculations the value of a body physiological parameter according to the registered electric signal.

The factors complicating calibration by increasing material, labor, and time costs include complexation of multiple MCs within a single measurement module and the need to employ special reference equipment designed to operate the complex under a wide range of external conditions.

A drastic measure to overcome these obstacles is a development of typical calibration methods containing generalized technical data based on the most automated unified procedures for groups of similar MC types. Accordingly, when selecting biosensor nomenclature, consideration should be given to the best possible constructive and methodological compatibility of sensors. Fulfillment of these requirements answers the fundamental metrological principle of measurement unity [3].

A solid reason for the methodological complexity of organizing calibrations is their being in the category of inverse problems of mathematical statistics [5]. The need to solve an inverse problem arises from remote diagnostics of an assembly of selective biomedical data when the current set of electrical signals at the output of the measurement channels observed with inaccuracies needs to reestablish the respective vector of physical parameters at the SBN input, and then determine a medical diagnosis or predict the development of a disease according to the identified symptomatology.

The incorrectness that arises in the calculation is objective and occurs for an arbitrarily accurate method of measurement. It is attributed to inevitable non-compliance with applicability prerequisites for statistical methods [6]. The need to eliminate the respective errors arises every time a physical magnitude is transferred from the reference standard to a calibrated MC. An ill-posedness tolerant method to solve the inverse problem of calibration is described in [7].

In general, throughout the process of HSC SBN development, the following MS tasks are solved:

- Research and methodological justification of the composition of monitored parameters;
- Justification of the requirements for the measurement parameter accuracy;
- Selection of measurement methods ensuring the required accuracy;
- Pre-selection of MC composition;
- Preliminary set of reference standards for MC verification;
- Packing a set of verification means.

Complication of a measuring circuit due to the inclusion of the wearable sensory network loop in the external health control loop actualizes the task to determine the effect of the reception accuracy on the diagnostic reliability and diagnostic prognosis in general.

Considerations of developing medical sensory networks

In the design of medical sensory networks, there are many poorly developed issues. The acutest problem for taking weak biological signals is interference caused by the actual motion activity of a patient, their level being many times as high as a valid signal. Developers propose methods of adaptive filtering, the essence of which is a combination of correlated data with parallel MCs and their comparison with the reading of concomitant activity intensity sensors using heuristic processing methods.

It is difficult to meet the compulsory requirements on development of the sensor part of the network coming into direct contact with the body, which can potentially harm a person or cause inconvenience when worn. Despite its non-invasiveness and low energy consumption, it is difficult to eliminate the risks of short-circuiting in the case of a mechanical damage or the cloth base soaking. To minimize risks, it is necessary to ensure not only mechanical protection, but also tightness of contacts and conductive surface insulation resistance according to the electrical safety standards [8, 9, 10]. The issues of choosing detachable connections for sensor configuration, data aggregation methods, and provision of uninterrupted power supply to the sensory network remain ambiguous.

To manufacture such clothing and SBN elements, fire- and explosion-proof materials are required that would be resistant to climatic factors and sweat aggressivity, and would conform to the standards of hygiene and toxicology [11]. Also, the SBN operation must not be accompanied by a detrimental effect on a monitoring object and surrounding persons via electromagnetic fields or an exposure to fungal infections. During the development, particular attention is paid to the SBN suitability to sterilization and disinfection, its resistance to sanitation.

These issues require careful consideration and do not only seriously complicate the development and production of the essential part of HSC SBN, but also the processes of its maintenance service in operation. Therefore, only qualified personnel with medical education, having successfully passed training courses on the HSC SBN operational procedures, should be admitted to the maintenance of the wearable component of the complex.

These difficulties are gradually overcome. The advanced technologies for polymer fabric weaving already allow for underclothing with built-in concentrators and aggregators, miniature sensors and elastic conductors that are made on the basis of flexible electronics. The layout diagrams of the developed samples structurally exclude movable elements and buttons that are capable of causing accidental activation of unintended modes or short circuits. In the medium term (2 ÷ 5 years), clothing meeting the guidance standards for medical equipment development is expected to appear on the market [12, 13].

Manufacturers' websites have been advertising information about clothes for SBN on offer, in a variety of designs in terms of their spatial compositional solutions to provide satisfactory mounting accuracy and reliability of fastening sensor nodes without an individual adjustment to a patient. The small size of sensors built into SBN makes it convenient and wearable for a required amount of time, since there are no surface imperfections to cause discomfort, if not even chafing and callosities, to the skin. Hypoallergenic textiles the clothes are made of, as well as the tightness of contacts and sensory nodes do not only allow for prolonged wearing, but also for hygienic treatment through routine automatic delicate washing.

The design of the complex body area allows for natural movements without restrictions just like ordinary loose clothing it does not look different from. Its ventilating capacity suggests sufficient wearing comfort as well. To attract the attention of a patient, if necessary, hypoallergenic T-shirts, shirts, and turtlenecks ensure an unobstructed transfer of modulated signals from the aggregator to the sensory organs of the person in the form of intermittent acoustic trills or a vibration with a frequency of 1 ÷ 2 bps. Despite the sophistication of critical technologies demonstrated by market leaders, it is not yet possible to buy a finished product to include in HSC SBN.

An important task to be solved in the design is to develop measures to ensure the safety of personal data in accordance with the Federal Law [14] by encrypting or cryptographic processing of transmitted and stored information using special algorithms into a form unavailable for unauthorized use. A promising approach consists in applying the distributed ledger technologies where critical information is not present in a complete form at any of the intermediate nodes of a network and is personified only at the site of an authorized assembly.

A number of unresolved issues involve developing and provisioning a medical knowledge database (MKD) that would represent a semantic network organized on the basis of ICD codes and would contain arrays of personal clinical data of the network clients. MKD should provide the most accurate simulation of risk factors, take the etiology and pathogenesis of diseases into account, provide early recognition, and choose an optimal therapeutic strategy.

The MKD reference and methodological provisioning should best correspond to the range of HSC SBN tasks and be adapted ultimately to extraction of real time data already formalized, which would ensure the operability and adequacy of diagnostic algorithms with respect to diagnostic tasks and diagnostic prognosis. The main impediment to MKD development is the need to take into account and formalize a variety of external and internal factors, with each of them having an impact on a disease progression to some extent.

The algorithms for comparing the incoming data from remote objects with information of private and reference nature extracted from the MKD are not amenable to strong mathematization. In this connection, the development of diagnostic effectiveness of the complex is hampered by a lack of methods to identify an explicit affinity of the monitoring object status vector to a certain diagnosis due to controversial symptoms of most diseases owing to:

- Intersection and overlap of multidimensional areas of diagnostic signs that cause compatibility of one sign to a variety of

alternative diagnoses;
- The need to bring heterogeneous information to a single semantic context for comparison or co-processing;
- Complexity of taking into account health factors and external conditions essential for diagnosis and not encompassed by the network sensorics;
- Volatility of an object, as the limits of normal health range for a lying, standing, walking, and running human are distinctly different;
- Absence of strict rules for the formation of a vector of effective control actions stabilizing the state of the body;
- The need for clarification and follow-up examination of patients for a final decision.

The task to develop methods for visualizing integral assessments of patients' physiological status for effective information support of medical personnel is closely related to formalization. The matter is that, on legal and ethical grounds, medical professionals cannot be excluded from a diagnostic process because a technical system, no matter how perfect it is, cannot be held responsible for possible errors. In this regard, the current monitoring results should be in a certain way generalized, processed, and visualized in a form readable for medical professionals to make decisions.

A physician should be able at any time to reasonably intervene in a diagnostic process, which presupposes the availability of a comprehensive explanatory mechanism in the complex data intelligence for a medical operator to develop a holistic view of a relationship between parameters and their interconnection, as well as ways to reduce the probability of an erroneous diagnosis. For this purpose, the software for visualization of monitoring results and the graphic editor within the complex must meet the system requirements of objectivity, reliability, completeness, consistency, and unambiguity. Interpretability of the biomedical information acquired by medical staff is achieved through the use of an intuitive interface and presentation methods in the form of diagrams, tables, graphs, as well as data hierarchization, visual fragment series feed, color solutions.

RESULTS AND DISCUSSION

The following results have been obtained during the project:
- the HSC SBN functionality has been refined;
- aggregation of the complex implemented on a modern hardware and software platform using 'cloud' technologies has been performed;
- ways of formalizing biomedical data and visualization of relevant information in a human-readable form have been identified;
- conditions for creating a scalable client network of remote real-time medical monitoring have been worked out;
- a structural criterial synthesis of the mathematical model of the complex to the approximation of extremum operators has been carried out;
- methods of statistical data processing have been defined.

To estimate confidence intervals, interquantile range of the statistical stability 'tube' obtained on the basis of statistical diversity of diagnostic models while searching for an optimum zone where the true value of a test parameter with a specified probability is guaranteed to be found is used. Confidence boundaries are to be reckoned from the median, and are generally asymmetric.

When choosing data processing methods, preference has been given to non-parametric statistical methods: bootstrap analysis [15], sampling [7], group method of data handling [16], etc., which have the highest tolerance to noise of baseline data, as well as sufficient statistical power in terms of applicability to a wide class of distributions.

The HSC SBN development prototype is currently at the stage of engineering tests. Simultaneously, based on the basic modification of HSC SBN, the system is being assembled, capable of providing a sufficient competitive quality standard to saturate the domestic market of finished medical products, as well as 'bringing' the complex to the external market.

In the course of research, the authors of this article have laid a scientific and technical groundwork and created a methodological basis for further improvement of the operation performance and the project development based on modern approaches to the creation of artificial intelligence systems [17, 18].

CONCLUSION

The publications over the past decade reviewed in course of the topical survey reflect the research by engineers in terms of the narrow tasks to design sensory networks: hypoallergenic clothing, wireless communication, a simplified diagnosis through a separate measurement channel or a family of homogeneous biosensors, etc. The research carried out by the authors covers the entire array of challenges in the development of sensory networks for medical purpose, and their results are consistently set out in a form that allows for further specification and detailed engineering study of HSC SBN.

The scientific novelty is determined by the conceptual approach to design within the framework of the optimal control theory, providing for a rigorous mathematical problem statement in the form of a set of interrelated structural model quality operators, while finding their extreme values ensures statistical identification of the most definite diagnosis out of a set of alternatives on currently monitored parameters.

Further studies suggest testing the automatic diagnostication algorithms in groups of patients with a clearly expressed symptomatic specificity. Special attention will be paid to predictive models for limited biomedical information, as well as for preliminary symptoms of a disease to ensure early diagnosis and to generate effective preventive measures to reduce the risk of the onset of a disease or alleviate its severe course.

In the course of research, questions have remained undetermined on current technical solutions relating to:

- Designing comfortable clothes with built-in biosensors that would have high service properties;
- Metrological compatibility of heterogeneous biosensors used in diagnostic groups to detect symptoms of diseases;
- Sustainable and secure power supply to the network components;
- Security of the network customers' personal data.

ACKNOWLEDGMENTS

The authors would like to acknowledge the Ministry of Education and Science of the Russian Federation for the financial support under the agreement No.14.577.21.0232 of September 29, 2016 (unique number RFMEFI57716X0232), the applied scientific research is conducted on the subject *'Research into scientific and technical solutions and development of an intelligent wearable biosensor platform for preventive monitoring and evaluation of vital signs of a human body 'Sensory body network' capable of correlating the data received from various sensors in a high-noise environment'.*

REFERENCES

1. Rastrigin LA. *Extreme control systems*. Moscow: Nauka, Chief Editorial Board of Physics and Mathematics (1974).
2. GOST 14254-96 IEC 529-89. Degrees of protection provided by enclosures (IP code). Interstate Council for Standardization, Metrology and Certification, revised ed. 2007. Moscow: Standartinform, (1996).
3. GOST R 8.596-2002. GSI. Metrological support for measuring systems. Basic provisions. Moscow: Standartinform, (2002).
4. Chubukov NN. Analysis of problems and prospects of intellectualization transport networks. *Mechatronics, Automation, Control*, **8:** 28-36 (2014).
5. Tikhonov AN, Arsenin VYa. *Methods for solving ill-posed problems*. Moscow: Nauka, Chief Editorial Board of Physical and Mathematical Literature, 2nd ed. (1979).
6. Linnik YuV. *The least squares method and*

the foundations of the mathematical and statistical theory of processing observations. Moscow: Chief Editorial Board of Physical and Mathematical Literature (1958).
7. Chubukov NN. Algorithmization of calibrations of mechatronic systems using sampling. *Mechatronics, Automation, Management*, **6:** 36 – 42 (2013).
8. GOST 30324.0-95 (IEC 601-1-88). Medical electrical equipment. Part 1. General safety requirements. Moscow: Standartinform, (1995).
9. GOST R 50267.0-92. Medical electrical equipment. Part 1. General safety requirements. Moscow: Standartinform, (1992).
10. GOST R IEC 60601-1-2010. Medical electrical equipment. Part 1. General requirements for basic safety and essential performance (IDT). Moscow: Standartinform, (2010).
11. GOST R 52770-2007. Medical products. Safety requirements. Methods of sanitation-chemical and toxicological tests. Moscow: Standartinform, (2007).
12. GOST R 15.013-94. System of products development launching into manufacture. Medical products. Moscow: Standartinform, (1994).
13. RD 50-707-91. Methodical Guidelines. Products of medical equipment. Requirements for reliability. Rules and methods for monitoring reliability indicators. Moscow: Izdatelstvo Standartov, (1992).
14. 152-FZ. Federal Law “On Personal Data” of 27.07.2006.
15. Efron B. *Nontraditional methods of multivariate statistical analysis*: Collected articles: Translated from English. Moscow: Finansy i Statistika, (1988). [in Russian]
16. Ivakhnenko AG, Muller IA. *Self-organization of predictive models.* Kiev: Tekhnika, (1985).
17. Alpaydin E*. Machine Learning: the New AI.* Translated from English. Moscow: Tochka Publishing Group, (2017). [in Russian]
18. Shanahan M. The Technological Singularity. Translated from English. Moscow: Tochka Publishing Group, (2017). [in Russian]