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Системы искусственного интеллекта в клинической физиологии: как сделать их обучение эффективным?

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АННОТАЦИЯ

Клиническая физиология — раздел медицинских наук о роли и характере изменений физиологических процессов, происходящих в организме при предпатологических и патологических состояниях, — предполагает полное, комплексное, многостороннее исследование функций как поражённых, так и здоровых органов, что позволяет оценить компенсаторные возможности организма.

Программное обеспечение и различные программно-аппаратные комплексы, созданные с использованием технологий искусственного интеллекта, всё активнее применяются в различных отраслях медицины, в том числе и в клинической физиологии. Этому способствуют появление наборов медицинских данных, увеличение вычислительных мощностей, развитие облачных сервисов, а также многочисленные публикации, демонстрирующие эффективность и перспективность применения подобных интеллектуальных решений.

Несмотря на то, что в целом подход к формированию медицинских наборов данных схож, в клинической физиологии имеется целый ряд ключевых особенностей и существенных отличий. Соблюдение предлагаемых нами правил по формированию наборов данных потенциально позволит эффективно обучить системы искусственного интеллекта в области клинической физиологии и применять их на практике.

Вступивший в силу национальный стандарт Российской Федерации ГОСТ Р 59921.9-2022 входит в комплекс стандартов «Системы искусственного интеллекта в клинической медицине» и устанавливает дополнительные требования к алгоритмам анализа данных и методам испытаний систем искусственного интеллекта, применяемых в области клинической физиологии. Важной особенностью нового стандарта является его квазиметрический тип (прилагается обязательный набор демонстрационных данных).

Россия одной из первых стран в мире приступила к разработке квазиметрических стандартов, и уже в текущем году вступят в силу 15 отраслевых стандартов в сфере искусственного интеллекта (из них два — по медицине).

Ключевые слова: набор данных; электрокардиография; клиническая физиология; аннотирование; автоматический анализ ЭКГ.

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Artificial intelligence in clinical physiology: How to improve learning agility

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ABSTRACT

Clinical physiology involves a complete, comprehensive, multilateral study of the functions of both affected and healthy organs, which allows us to assess the compensatory capabilities of the body.

Artificial intelligence is increasingly being used in medicine, including in clinical physiology. This is facilitated by the increase in computing processing power, development of cloud services and datasets, and numerous scientific articles demonstrating the effectiveness and viability of such intelligent solutions.

Although the approach to medical dataset development is generally similar, there are a number of key features and significant differences in clinical physiology. Artificial intelligence systems in clinical physiology may be effectively trained and applied in practice by following the recommendations in this study.

The national standard of the Russian Federation GOST R 59921.9-2022, which has entered into force, is included in the set of standards "Artificial Intelligence systems in clinical medicine" and establishes additional requirements for data analysis algorithms and test methods of artificial intelligence systems used in the field of clinical physiology. A crucial feature of the created standard is its qualimetric type (i.e., it has a mandatory set of demonstration data).

Russia is one of the first countries to start developing quasi-metric standards worldwide, and 15 industry standards in the field of artificial intelligence (2 of them in medicine) will come into force this year.

Keywords: dataset; electrocardiograph; clinical physiology; annotation; automated ECG interpretation.

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临床生理学中的人工智能系统：如何使其训练有效？

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简评

临床生理学是关于在病理前和病理情况下身体内发生的生理过程变化的作用和性质的一个医学科学分支，它要求对患病和健康器官的功能进行完整、全面、多边的研究，从而允许评估身体的补偿能力。

使用人工智能技术创造的软件和各种硬件系统更积极地被用于医学的各个领域，包括临床生理学。医疗数据集的出现、不断提高的计算能力、云服务的发展以及证明这种智能解决方案的有效性和前景的众多出版物都有助于这个过程。

虽然医学数据集的形成方法大体相似，但临床生理学有一系列关键特征和显著差异。遵守我们提出的数据集形成规则将有可能使临床生理学中的人工智能系统接受有效的训练并得到实际应用。

生效的俄罗斯联邦GOST R 59921.9-2022标准被纳入“临床医学中的人工智能系统”这套标准，这种标准对临床生理学中使用的人工智能系统的数据分析算法和测试方法提出额外要求。新标准的一个重要特点是其拟度量类型（附有一套强制性的示范数据）。

俄罗斯是世界上最早开始制定拟度量标准的国家之一，人工智能方面的15项行业标准（其中两项是与医学方面有关的）将于今年生效。

关键词：数据集，心电描记法，临床生理学，注释，心电图自动分析。

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INTRODUCTION

Clinical physiology is a branch of medicine that studies the role and nature of physiological changes in the body during pre-pathological and pathological conditions. Clinical physiology is a complete, comprehensive, multifaceted study of the body's functions (not only of affected organs but also of healthy ones), allowing us to assess the body's compensatory capabilities.[1]

Artificial intelligence (AI) systems are increasingly being used in almost all fields of medicine: [2] there is a significant number of works on electrocardiography (ECG) evaluation, including through smart watches, [3–7] and an increasing amount of research in the field of computer vision around the world,[8, 9] as well as the development of various smart solutions[1]. PhysioNet[2], for example, includes a large number of open data sets pertaining to various pathologies. The largest open ECG data sets contain 21,837 [10] and 10,646 ECGs, [11] respectively; however, despite the importance of the issue, the formation of such data sets remains a major challenge that necessitates a thorough approach.

We identified the following major issues while analyzing public open ECG data sets:

1. Differences in technical conditions for ECG recording: sampling rate, least significant digit value, analog-to-digital converter bit depth, recording duration, and number of channels
2. Incompatible descriptive languages (thesauri): different "schools," different patiet populations, and different end-user goals
3. Imbalance in ECG disorder classes within the data set and in data sets with the general population
4. Concerns about the quality of the annotation/classification
5. Lack or absence of clinical data (metadata)

These issues can be worsened when other diagnostic and control methods in clinical physiology are used. This is due to the fact that the following data can be used to create a data set and then train AI systems in clinical physiology[3]:

1. Physiological parameter values (blood pressure, heart rate, and saturation level)
2. Digitized biological signals (electrocardiogram and vessel pressure indicator)
3. Induced and returned signals (neuromyogram, rheogram, Doppler curve, and ultrasound M-scan)
4. Dynamic images (cine loops)
5. Complex data

DATA SET FORMATION METHODOLOGY: ARE THERE ANY DIFFERENCES?

Data set formation methodology in clinical physiology is broadly similar to that of radiodiagnosis [12]: planning; creation of a thesaurus or glossary and inclusion and exclusion criteria; selection of experts and moderators; data analysis for compliance with inclusion criteria; annotation approval; and multilevel moderation. However, there are several key differences as follows:

1. The order in which the data array is processed differs significantly. The work sequence for preparing a data set (number series, graphs, and individual measurements) is as follows:
   - Data segmentation (separation)
   - Data measurement
   - Data annotation: a method of providing verbal (semantics) meaning to an object or set of data
   - Data classification
2. A dictionary (glossary) is sufficient for classifying simple (binary) properties of objects, and a thesaurus is required for multiclass objects.
3. Moreover, some less evident and difficult-to-categorize factors can lead to significant errors when creating a data set[4, 5]:
   - Highly qualified operators are required to conduct clinical physiology research; one of the most important factors in source data generation is operator dependence.
   - When forming the final data set, the presented array of studies should be analyzed for the following factors: sufficient recording duration, number of channels, disabling signal filtering, as well as compliance with accepted technical parameters, dynamic range, signal-to-noise ratio, and results storage format.
   - Experts and moderators involved in data separation must be qualified: while data anonymization is permissible, details of their qualifications and contributions must be included in the AI system test report.
   - A set of equipment and software for AI system tests in clinical physiology should be developed; at the same time, the characteristics of hardware and software must exceed the minimum requirements set by the AI system manufacturer and consider the typical characteristics of a specific or potential user's computing facilities.

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[1] Center for Diagnostics and Telemedicine [Internet]. AI services in radiodiagnosis. Available at https://mosmed.ai/.

[2] PhysioNet [Internet]. The Research Resource for Complex Physiologic Signals. Available at https://physionet.org/.

[3] GOST R 55036-2012/ISO/TS 25237:2008. National Standard of the Russian Federation. Health informatics. Pseudonymization. Available at https://docs.cntd.ru/document/1200100339.

[4] GOST R 55036-2012/ISO/TS 25237:2008. National Standard of the Russian Federation. Health informatics. Pseudonymization. Available at https://docs.cntd.ru/document/1200100339.

[5] GOST R 59921.5. National Standard of the Russian Federation. Artificial intelligence systems in clinical medicine. Part 5. Requirements for the structure and application of data set for training and testing algorithms. Available at https://docs.cntd.ru/document/1200183858.

INCLUSION AND EXCLUSION CRITERIA FOR RECORD SELECTION IN CLINICAL PHYSIOLOGY DATA SET FORMATION

Exclusion criteria (absolute; only one is required):

- The records are provided in a proprietary format, and the manufacturer refuses to create a matching layer
- Noncompliance with technical specifications for saved data (for example, the recording duration for a digital ECG is less than 10 s, the sampling rate is less than 500 Hz, the least significant digit value is greater than 5 μV, and the analog-to-digital converter bit depth is less than 10 bits).
- Access to metadata is either impossible or significantly restricted
- Less than 70% of the ECGs in the final data set are annotated and classified appropriately

Inclusion criteria (all must be met):

- The records are provided in one of the following formats: WDBF, EDF, aECG (HL-7), SCP-ECG, DICOM-ECG, and XML
- Compliance with the technical specifications for saved data (for example, for a digital ECG, the recording duration must be at least 10 s, the sampling rate must be at least 500 Hz, the least significant digit value must be 5 μV, and the analog-to-digital converter bit depth must be at least 10 bits)
- Access to metadata is not restricted
- At least 90% of the ECGs in the final data set are annotated and classified appropriately

It appears that data sets for AI system training should include the full range of possible phenomena (syndromes, diagnoses, and outcomes) from the most rare (casual) to the most common. The type of data set determines the need to respect the variability of gender and racial differences in patients (for example, these metadata are required for assessing respiratory function parameters). The incidence of phenomena (syndromes) in a population is given less weight in the data set formation. It is recommended to use additional metrics when using unbalanced data sets for rare (casual) phenomena.

NORMATIVE DOCUMENTS REGULATING THE DEVELOPMENT AND APPLICATION OF DATA ANALYSIS ALGORITHMS AND TEST METHODS OF ARTIFICIAL INTELLIGENCE SYSTEMS IN CLINICAL PHYSIOLOGY

The national standard of the Russian Federation GOST R 59921.9-2022[6], which became effective on January 1, 2023, is included in the set of standards known as "Artificial Intelligence Systems in Clinical Medicine" and establishes additional requirements for data analysis algorithms and test methods of AI systems in clinical physiology.

Developers of AI systems for clinical physiology and other interested parties will be able to study the requirements:

- Data set generation, preparation, segmentation, measurement, detection, annotation, and classification for AI system testing
- Data set structure, application procedures, and access conditions
- Organizing terminological resources and presenting data analysis results
- Information exchange between medical devices, intelligent systems, and other healthcare automation systems
- Technical, bench, laborator, and clinical test processes and results, as well as postregistration and operational control of software and hardware–software systems based on artificial intelligence technologies
- The form and content of software and hardware–software systems based on artificial intelligence technologies, in accordance with the tasks being solved in the field of medicine and healthcare

The prescribed requirements for data sets distinguish the new national standard from other GOST R standards and English-language counterparts. Three scenarios are proposed in particular: clinical trials conducted only on a test site (bench) using data sets; clinical trials conducted within a health facility; and combined clinical trials. All scenarios are illustrated with flowcharts (Figure 1).

The standard also includes test options for assessing AI system resistance to errors in input data and testing using synthetic and combined data. The new GOST K standard allows the testing of AI systems that are compatible with various data types and presentation formats. The following can be used for AI system testing in clinical physiology:

- Measured physiological parameter values (blood pressure, heart rate, and saturation level)
- Digitized biological signals (electrocardiogram and vessel pressure indicator)
- Induced and returned signals (neuromyogram, rheogram, Doppler curve, and ultrasound M-scan)
- Dynamic images (cine loops, for example, in an ultrasound examination mode and motion video recordings)
- Complex data containing data of several types listed above (synchronized and in-phase)

The data can represent the results of single measurements (patient studies), or they can be chosen to systematically represent the development of pathological processes (a time series of homogeneous measurements), or they can reflect changes upon presentation of graduated stimuli, or they can reflect changes in parameters depending on external

[6] GOST R 59921.9-2022. National Standard of the Russian Federation. Artificial intelligence systems in clinical medicine. Algorithms for data analysis in clinical physiology. Testing methods. General requirements. Available at https://docs.cntd.ru/document/1200193730.

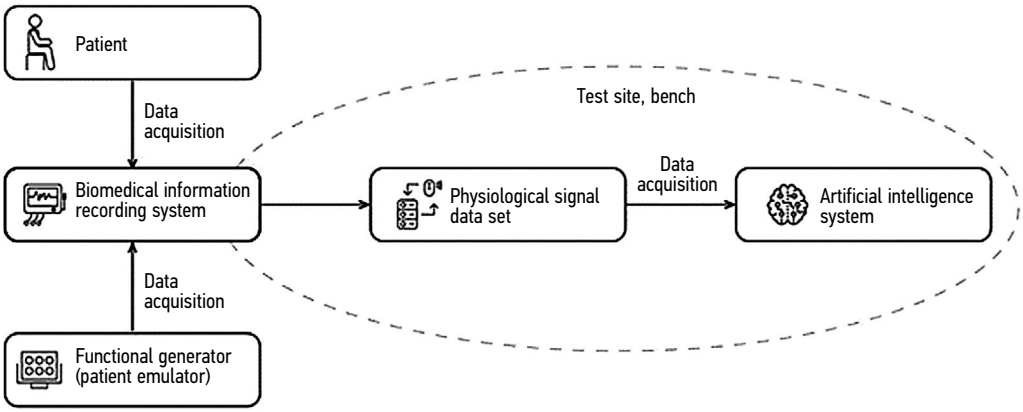

Figure 1. Flowchart for conducting clinical trials with data sets (one implementation option)

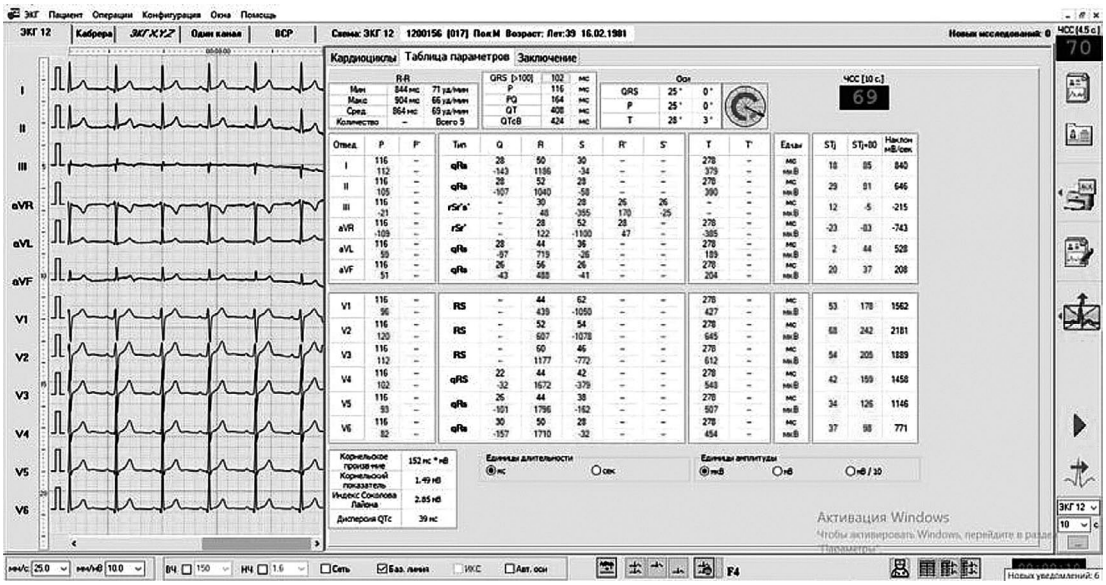

Figure 2. An example file from the demo data set of GOST R 59921.9-2022, Artificial Intelligence Systems in Clinical Medicine. Algorithms for data analysis in clinical physiology. Testing methods

conditions (during sleep, at rest, during physical or mental stress, distress, etc.).

The fact that the new standard is a quasimetric GOST R (i.e., it comes with a mandatory set of demo data) is also an important feature (Figure 2).

Russia was one of the world's first countries to develop quasimetric standards. In the field of artificial intelligence, 15 industrial standards will come into force in 2023, with two of them in medicine.[7, 8]

CONCLUSION

Compliance with the aforementioned rules will allow for the acquisition of a data set for AI system training in such a way that all three phases of clinical trials are potentially passed, namely, (a) testing to ensure the accuracy of the input data (recognition of signals received with a violation of the study technology, as well as those containing artifacts and noise); (b) testing to ensure the accuracy of the recognition of syndromes, phenomena, clinical equivalents, and/or the formation of a conclusion (annotation) according to an agreed thesaurus or glossary; and (c) testing on synthetic and combined data (recognition of a synthetic stimulus signal that initiates or amplifies natural signals and evaluation of stimulation efficiency or inefficiency).

ADDITIONAL INFORMATION

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[7] GOST R 59921.7-2022. National Standard of the Russian Federation. Artificial intelligence systems in clinical medicine. Algorithms of medical images analysis. Testing methods. General requirements. Available at https://docs.cntd.ru/document/1200193728.

[8] GOST R 59921.9-2022. National Standard of the Russian Federation. Artificial intelligence systems in clinical medicine. Algorithms for data analysis in clinical physiology. Testing methods. General requirements. Available at https://docs.cntd.ru/document/1200193730.

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Authors' contribution. All authors made a substantial contribution to the conception of the work, acquisition, analysis, interpretation of data for the work, drafting and revising the work, final approval of the version to be published and agree to be accountable for all aspects of the work. D.V. Shutov, D.V. Drozdov — work concept and design, editing and approval of the final version of the manuscript, advisory support; D.E. Sharova — work concept and design, data analysis, writing the text of the article, editing and approval the final version of the manuscript; L.R. Abuladze — writing the text of the article, editing.

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