INFORMATION TECHNOLOGY IN MEDICAL DIAGNOSTICS III

Information Technology in Medical Diagnostics III

Metrological aspects of biomedical research

Editors

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Routledge
Taylor & Francis Group

Routledge is an imprint of the Taylor & Francis Group, an informa business

Typeset by MPS, Chennai, India

Published by: Routledge
Schipholweg 107C, 2316 XC Leiden, The Netherlands
e-mail: Pub.NL@taylorandfrancis.com
www.routledge.com – www.taylorandfrancis.com

ISBN: 978-0-367-76586-6 (Hbk)
ISBN: 978-1-003-16766-2 (eBook)
ISBN: 978-0-367-76589-7 (Pbk)
DOI: 10.1201/9781003167662

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Preface

The science of a complex system of biomedical measurements is experiencing a period of rapid development. Progress in the right direction in solving metrological problems in medicine is possible if we systemically consider medical technology, using the formal approach. Its main principle is to determine the elements and rules of their interaction, which allows to introduce a mathematical system and represent any technology or object in the form of a structure on which it is possible to formulate necessary estimates and to declare synthesis processes, including metrological ones.

Development of effective measuring technologies and measuring tools of any complexity begins with the analysis of the information space of the object of observation. In the monograph, this part of the research is examined on the example of the analysis of the information space used for the study of knee joints of the organs of motion.

Within the framework of any medical technology, the following semantic link is valid: (state or result) = (therapeutic effect) · (state of the subject). Thus, the set of results of the technology is equivalent (with a confidence of 0.99) to the set of maps of the therapeutic effects of the set of states of the subject itself. Reliable diagnoses, measurements as well as therapeutic or surgical technologies must all be implemented with a small margin of error. The error is a numerical value. Thus, there is a need to form the notion of error for medical measurements, medical diagnostics or medical technology. The problem of biomedical measurements is associated with the solution of successive problems, which can be named in the following order: the problem of structuring, the problem of observability, the problem of measurability. Let us analyse how issues of structuring, observability and measurability are considered within the metrological aspects of biomedical measurements. The solution of metrological problems in medicine is possible if we consider medical technology systemically with the application of structural formal ideology. Its main principle is to determine the elements and rules of their interaction, which allows us to introduce an algebraic system and represent any technology, any object in the form of a structure on which it is possible to formulate the necessary estimates and declare processes of synthesis, including metrological ones.

This approach considers many examples. The first one is the metrological characteristics of the design of a pathospecific glaucoma diagnostic device. Glaucoma is an intraocular pressure pathology that causes irreversible neurodegenerative changes in retinal and optic nerve structures. It consists of “fast” and “slow” components. The significant spread of the disease and the degree of disability due to it are caused not only by the lack of therapy, but also by the inadequacy of diagnosis including the “painful” stage of the disease, the absence in the arsenal of a practical doctor of an accessible and sufficiently accurate automated method for assessing the state of compensation for hydro and hemodynamic parameters of the eye. This leads to untimely and inadequate administration of treatment and, as a consequence, to the progression of the disease. As before, the issues of distinguishing between the concepts of “health” and “norm” as applied to glaucoma remain insufficiently illuminated in the scientific literature. In medicine, an opinion is widespread about the state of “norm” as a single state, “the best of really possible homogeneous states”. At the same time, studies in adult healthy people have shown that the “norm” in one age population can be heterogeneous and should be evaluated taking into account individual and typological properties and the peculiarities of the organisation of the systemic activity of the organism. This determines the purpose of the research, which consists in the development of a pathospecific measuring device for the diagnosis of glaucoma.

The principles of the structural information approach are also realised within the framework of metrological analysis in haematological studies. A class of bio-instrumental information and measurement systems is used in which the primary converter of the input is the biological object under study. It makes possible to specify the study of the properties of the bio object.

At present, laboratory diagnostics is an independent branch of medical science, which can claim objectivity if laboratory research is metrologically correct. The provision of clinical and laboratory research at the level of the clinical diagnostic laboratory is to develop and implement measures to prevent the negative impact of factors at the preanalytical, analytical and post-analytical stage. Development of an efficient and cost-effective management system for clinical and laboratory research is a modern solution to the issue of harmonisation of results and prompt correction of current clinical and laboratory diagnostic problems.

The study of the relationship between the size of uniaxial anisotropy formed in the electromagnetic field in haemoglobin solutions and its level in blood is also devoted to the issue of increasing the accuracy of laboratory tests. This is important in the study of blood chemical composition. The results obtained in this study indicate a close correlation between the hybrid parameters of optical radiation conductivity and tensors of haemoglobin material characteristics. This allows characterizing its composition employing magnetooptical reaction.

The development of adequate reference test signals for electroencephalographs is devoted to the issues of metrological certification of medical measuring instruments. It is realised based on structural schemes of algorithms for measuring the probabilistic characteristics of the stationary segment of the electroencephalogram in the simulation of the test signal. Numerous studies using EEG segmentation have found that EEGs consist of relatively stationary segments whose duration of the main mass varies between 0.2 and 12 seconds. Their classification according to spectral characteristics indicates the existence of a fairly compact set of typical segments, up to several dozen. As a result of the analysis of the research data, it can be concluded that to obtain an electroencephalographic signal model, non-parametric segmentation should be applied first, and then the statistical estimation of the obtained segments should be performed. The technology of non-parametric EEG segmentation has been developed based on the theory of analysis of moments of rapid changes or disturbances in time series with a clearly expressed chord-setting structure. The discrepancies thus determined are signs of boundaries between quasi-stationary fragments. The methodology of non-parametric analysis is based on two ideas. It has been proven that defining changes in any decomposition function of probabilistic characteristics can be reduced (with arbitrary accuracy) to determine changes in mathematical anticipation of some other sequence created from the original. The obtained structural diagrams of algorithms for calculating probabilistic characteristics will allow for metrological analysis and subsequent evaluation of errors at each stage of data processing.

Based on the developed concept, it is possible to conduct accelerated tests of electroencephalographic devices without the need to disconnect from the current operation and to automate all measurement processes, which significantly simplifies the service technician’s work and minimizes the risk of human factor influence on the technical research process.

The metrological aspects of medical measurements are also considered in radiothermography in the complex diagnosis of inflammatory processes of the abdominal cavity. There is a need for accurate and timely diagnosis of inflammatory processes in the abdominal cavity by a non-invasive method in a form convenient for the physician without harmful effects on the body. At the same time, the polymorphism of clinical symptoms in combination with atypical manifestations of the disease imposes errors due to the method of conducting the study and subsequent hardware processing of the thermographic picture. In the work, a comparative metrological analysis of various methods of conducting thermographic studies was carried out. Such factors were considered as thermal imager resolution, thermal sensitivity, noise level (signal-to-noise ratio), affecting the quality of the received thermal image. A distinctive feature of non-invasive methods for studying the thermal radiation of bioobjects is their complete harmlessness and high information content. Radiotermometry (RTM-method) is a new method of medical diagnostics. The essence of the method is the non-invasive measurement of the deep temperatures of biological objects by recording the radio emission power of objects. The difference between the RTM method and the well-known physical methods of investigation (palpation, x-ray studies, ultrasound methods, tomography) lies in the fact that deviations are studied not in the anatomical structure of internal tissues but in deviation from normal metabolism processes that, in the case of inflammatory processes, affect the distribution temperatures in internal tissues.

Experimentally, the RTM method has been successfully tested in various fields of medicine: neurology and neurosurgery; cardiology; gastroenterology; traumatology and orthopaedics; combobustology; diagnosis of ENT diseases; endocrinology or gynaecology. The RTM-method has special perspectives in oncology – it is used for early diagnosis of breast cancer.

In each of the following cases, the infrared radiation method can be used. However, in the case of contact analysis of the reception of thermal radiation from biological objects, an unavoidable measurement error that arises from the reflection of radiation at the antenna-object boundary. The reflection coefficients can differ significantly from the differences in the dielectric properties of the radiating tissues. With absolute temperature measurements, it is necessary to take into account the effect of the mismatch between the contact antennas and the human body on the accuracy of measuring the radio-resistant temperatures of deep tissues or internal organs.

Temperature anomalies of internal tissues generate inflammatory and other processes, often preceded by structural changes, which is important for early diagnosis. In the early 1970s research was carried out for the first time on the visualisation of infrared radiation of the epigastric region and its dependence and distribution on the functional states of the stomach. This was followed by studies were that were crucial for substantiating the clinical application of remote thermal methods. Subsequently, thermography was widely used in non-invasive diagnostics in abdominal surgery, angiology, neurology, neoplasms of the breast, skin, muscular and bone tissue as well as the thyroid gland.

The first step in the determining of the medical system is its structuring. That means isolation of certain functional elements and a definition of all links between them. This is the basis for determining the functions of the whole system and assigning a system formal parameter. This formal parameter will be an exit of an output element: the output element assigns an output parameter. Then we choose the system function which can be formed by sequentially transferring of the input action, that is, the action of the environment from the entrance to the selected output. That was obviously for us that the entrance would be the place of contacting with the outside medium. Two chapters are then dedicated to the knee joint – the information space needed to describe its operation and objective parameterisation of the load on it. All this to prevent diseases associated with the violation of the distribution of loads on the knee joint, as well as in the case of correction of axial deformities of the lower limbs, surgical interventions were attempted in order to increase growth, with endoprosthetics, the manufacture of individual endoprostheses, in some cases the selection of orthopaedic footwear and insoles, or the load on the components of the knee joint.

The anatomical parametrisation of the passive exoskeleton of the upper limbs is devoted to the objective parameterisation of the biological information space as the basis for its effective work. The study presents the possibility of anatomical parametrisation of the EXZAR passive exoskeleton of the upper limb used for habilitation and rehabilitation of patients with upper flaccid vapours (mono) paresis. Interest in exoskeletons of extremities is dictated by practical necessity. From the military area, where all developments are strictly classified, exoskeletons have recently moved to the field of medicine, where both active and passive varieties are used. For all their innovative component, active exoskeletons have a number of disadvantages – high cost, dependence on power sources, high weight, low mobility. Passive exoskeletons use residual muscle strength. To strengthen them, various elements are used (rubber thrusts, springs, etc.), but the latter cease to work or violate the function of the affected limbs even more with abnormal anatomical and mechanical correspondences.

Enrichment of metrological principles in the development of new biotechnological technologies and bioinformatic measuring tools is the application of quantum mechanical methods in biotechnical research. Any process that takes place in a living organism can be modelled with the help of the apparatus of quantum mechanics. In our opinion, this is a very promising direction of preclinical research, which can significantly reduce the number of real, as a rule expensive, experiments. The purpose of this study is to consider the possibility of using quantum mechanical methods for the development of effective osseointegration technology for bone-implant interaction. The external influence of the high-pitched laser on a surface of the material was assessed, and the metrological aspects of the process of an efficient merging of an implant and a bone tissue were taken into account. Described research will form the base for improvement of quality of life of the patient.

The last chapter considers the problem of increasing the efficiency of diagnosis and prevention of the development of nervous, musculoskeletal and cardiovascular diseases, diseases that often lead to disability, especially at a young age. An analysis is made of approaches to solving this problem, associated with the need to process a large pool of unstructured data that requires the use of modern intellectual methods. An integrated approach is proposed which includes the theoretical study of the problem and the practical implementation of research, the creation of methods for finding interdependent factors and the development of special equipment and software. The chapter details the problems associated with the lack of a theoretical study describing the process of biofeedback functioning. A model of biofeedback is presented with elements of the theory of automatic control. A software is developed for the implementation of experimental research of the proposed model of biofeedback. Methodologically, a three-level ontological structure is used to examine analytical decision models of an inclusive process. Based on the ontological description of the process of inclusion, a generalised structure of the information-analytical system was developed, the core of which is the knowledge base, built on the databases on the physical and psychological characteristics of students. A practical implementation of the analysed approach to building an intelligent information system of support for the educational process will allow the creation of individual learning paths for students, which will improve the quality of the educational process and prevent the risk of developing nervous, musculoskeletal and cardiovascular diseases.

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CHAPTER 1

Problems of structurability, observability, and measurability in medical measurements

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ABSTRACT: The authors investigate the possibility of the anatomical parameterisation of the EXZAR passive exoskeleton of the upper limb, used for habilitation and rehabilitation of patients with upper flaccid couple (mono) paresis.

1.1 INTRODUCTION

There has been a sharp rise in the development of new technologies in the field of medical practice. At the same time, the technical boom in medicine, biology, and biophysics is accompanied by an increase in specific problems related to the lack of objective criteria for the effectiveness of the implementation of these tools and estimate of this effectiveness. In addition, any medical or experimental technology in medicine, biology, and biophysics is based on using a large number of different instruments, systems, and measuring aids. However, there are no ideas of their joint use from the metrological point of view. There are not even approaches to solving the problems that arose from this. Thus we would like to give some examples from different areas of medical practice.

1.2 MEDICAL MEASUREMENTS

1.2.1 *Blood pressure measuring devices (blood pressure monitors)*

The main sources of errors are: the physical process of air flowing from the cuff bag; the physical process of transformation of the pulse wave of the vessels into a change in the pressure in the space of the bag; diaphragming of the input to the chamber of the measuring transducer; process of formation of indicators of the measuring device. The mentioned sources have a multiparameter character, and the total number of factors causing the measurement error reaches several tens in this case.

1.2.2 *Cardiographic measurement complex*

The main sources of error are: a non-spot area of a tap electrode, which leads to the integration of potentials; the process of positioning the tap electrode, which significantly changes the level of the input signal; the final conductivity of the gel between the skin and the metal (and on a bowl without using of a contact composition); the final conductivity of the conductors connecting the electrodes to the inputs to the cardiographic measuring system; measuring procedure on an electronic elementary medium of a cardiograph. The total number of errors is several dozen.

1.2.3 *Hematologic analysis*

The hematological analysis is an analytical measurement technology with the simplest review of sources of errors formalised in the form of limitations in the measurement technique demonstrated about 50 causes of errors, including such exotic like the length of the smear on the glass and the distribution of thickness along the length of the smear.

1.2.4 *Orthopaedic techniques and technologies for surgical correction of upper and lower extremities*

Such techniques (e.g. The Ilizarov apparatus) uses equipment that does not (from the measuring point of view) have correct means of adjustment. As a result, the reason for the errors is the lack of equipment for determining the exact distance between bone fragments, accurate tension on the spokes, etc. The source of errors is the impossibility of accurately determining the angles of bone fragments for fixing them.

1.3 MEDICAL TECHNOLOGIES

1.3.1 *Evaluation of hemodynamics in glaucoma*

It is generally recognised that one of the most important signs of glaucoma is an increase in intraocular pressure (IOP) above the upper limit of the average statistical rate. However, many authors show insufficient reliability of the tonometric method of investigation, not only in diagnostics but also in monitoring the effectiveness of glaucoma treatment. In 1975 A.M. Vodovozov introduced the concepts of tolerant and intolerant intraocular pressure (IOP) to overcome those difficulties in connection with the orientation toward the average statistical standards of the ophthalmotonus.

Tolerant IOP indicated an individually tolerated pressure that does not cause any functional changes in the optic neural apparatus of the eye. An intolerant IOP indicated that the patient has a characteristic visual impairment, regardless of is this pressure higher or lower, than the average statistical rate of IOP. The disadvantages of the well-known methods of determining the tolerant pressure include a significant element of subjectivity, a long time of the examination of patients, the lack of automatic quality control of sphygmograms, and the level of tolerant IOP inspected manually. All these factors reduce the accuracy of the obtained results and limit the scope of the practical application of these methods. There are a lot of questions about the relationship between tolerant intraocular pressure and the state of general and regional hemodynamics of the eye in patients with glaucoma and its criterial (metrological) evaluation which are still unexplored.

1.3.2 *Diagnosis of the pathology of organs of motion*

The main role of legs are the support and movement of the body in space, which is ensured by the functional unity of all its elements. Legs can perform three functions: to give the body a stable position; work statically, lengthen and shorten the longitudinal axis of the body and rotate it in different directions, and, finally, act independently. The indicator of the distribution of static loads on the knee joint is the mechanical axis of the lower limb, which is normally projected on to the centre of the knee joint. It is important in practical terms to restore the anatomical axis of the thigh and lower limb as the main condition for the projection of the mechanical axis of the lower limb to the centre of the knee joint for normalising of the load on the knee joint during the operative correction of the frontal curvatures of the knee.

To solve these problems, we developed a new system of biomechanical assessments of the human body and methods for determining them and also the creation of a tool for determining biomechanical estimates of human movement organs that are distinguished by high metrological qualities.

We presented a lot of examples. And all of them will testify to the relevance of metrological aspects in medical measurements and in medical technologies in general.

1.4 FORMULATION OF THE PROBLEM

The analysis of all the cited examples were reduced to one: we can build a reliable strategy for therapeutic or surgical methods of treatment on reliable diagnosis and veracious monitoring. This strategy will be realised with the use of reliable measuring tools. Generally, we will understand reliability like a prior confidence in the feasibility of appearance of concrete phenomenon excluding any doubt.

Reliability characterises the feasibility of an event, noting its highest probability value (Vinogradov 1977). The derivative concept of reliability is the concept of accuracy, and the numerical, estimative concept is the error. We will make the highest level of the accuracy to get less level of error. In other words, it turns out that a reliable diagnosis is a diagnosis with a small error; a reliable measurement is a measurement with a small error; a reliable therapeutic or surgical technology is a technology implemented with a small error. The error is a numerical value. Thus, we need to form the notion of an error: medical measurements, medical diagnostics, and medical technology.

Metrological assessments in the solution of a variety of modern medical problems: monitoring, therapy, diagnosis, rehabilitation, etc. are either faintly developed or not examined at all in many cases. We explain this situation by the multidimensionality and systemic complexity of medical tasks. Lately, the problem always arises: "What to measure?" Hence as a consequence: "How to measure?"

1.5 PROBLEMS OF STRUCTURABILITY, OBSERVABILITY AND MEASURABILITY

Professor Akhutin V.M. (Akhutin 1976) defined the biotechnical system (BTS), which is the subject of this work: "Biotechnical system is a combination of biological and technical elements, combined in a single functional system of purposeful behaviour." At the same time, a class of biotechnical measuring and computing systems (BTMCS) was singled out within a variety of options for creating and using biotechnical systems (Popechitelev 2006). Measurements must be executed with the subsequent processing of the experimental data with the use of the BTMCS (Popechitelev 2006). However, it is necessary to concentrate attention on the peculiarities of medical measurements, which are connected with the use of plot images (images containing information) as the main kind of impact on the person on whom his reaction arises. This circumstance determines that the BTMCS is always a specialised measurement tool that allows you to adapt it to the object of measurement.

Thus, the problem of biomedical measurements is associated with the solution of successive problems, which can be named in the following order: the structuring problem, the observability problem, the measurability problem, the controllability problem (Mukha et al. 2017).

There is a very large number of definitions of a structure (Mesarovic & Takahara 1978, Nikolayev & Brooks 1985, Volkova & Denisov 2013). Let us dwell on the fact that a structure is a composition of certain functional elements and connections between them. The function of the structure as a whole is completely determined in this case by the set of the functional elements and their interrelationships.

Structurability is the ability to define a set of functional elements in the system and assign relations between them in such a way that the external function of the system remains unchanged, i.e. it must be independent of the choice of sets of elements and connections between them. Obviously, the choice of the system parameter is essentially determined by the effective procedure for designating of the structure.

So we understood that observability is the possibility of isolating in a multicomponent system a multiply-connected type of certain fundamental parameters. Parameters included in all displays of input quantities at the output. Thus, if such a condition is not met, then the system becomes not completely observable for the selected set of fundamental parameters. We solve the problem of choice of a system parameter by the structurability of a multicomponent multiply connected system, so the observability turns into a criterion for selecting a system parameter. It allows us to correct, direct the process of structurability within the framework of a kind of feedback.

The choice of the system parameter in the solution of the structurability problem, corrected at the stage of solving the observability problem, creates a basis for solving the measurement problem. So we solve all tasks of choosing a system of measured standards for a system parameter (most often a vector) and constructing a scale for the measuring system. In other words, we synthesise a set of algorithms for processing measurement information that allows a metrological analysis process to be performed and to estimate of the reliability of the obtained measurement results.

Finally, the measuring process should differ in controllability. Controllability means the possibility of transferring a representative point from any area of the state space to the origin if the system is characterised by a certain state represented by the position of the representing point in the state space (Besekersky & Popov 1977). Thus, the controllability problem is the basis for carrying out the measurement tests, the measuring experiment, for creating a measuring experimental setup.

Then we analyzed how issues of structuring, observability and measurability were considered within the metrological aspects of biomedical measurements.

1.6 STRUCTURISATION OF COMPLEX MEDICAL SYSTEMS

Measurements in medical practice occupy one of the leading places, and they have a diverse character: from the metabolic level to the level of individual functional physiological systems (FUS) and the whole organism as a whole. However the more complex the technology of the experiment is, the more metrological idea is obscured. The estimated and measured components of the experiment are lost. In addition, there is no systemic focus of measurements: the therapeutic effect is the evaluation of the reaction of the organism, that is, the one-dimensional study of the “impact-response” connection. The existing technology of medical measurements connects the measured signal with the process of detecting a signal of artefact origin and it’s clustering in order to determine the connection of the signal with the disease. This technology does not involve the processes associated with the physiological state since it does not take into account the structural relationships of complex medical subsystems. In this case, the physiological state of the body should be understood as an integral set of coordinated physiological systems defined on a system-wide metabolism and existing on a system-wide set of goals. However, it should be noted that it is difficult to use structural relations at the content level of their description, as it is at the moment (Cardman & Vogt 1977). At the same time, the application of formalisation is possible here and its principles are in our following conclusions.

The semantic relation is valid within the framework of any medical technology: (state or result Re) = (therapeutic impact or TI) (state of subject Sb), or from a formal point of view: $Re = TI\ (Sb)$. All elements of the relation are sets. Thus, the set of results of the technology *Re* is equivalent (with confidence 0.99) to the set of mapping of therapeutic effects TI of the set of states of the subject Sb itself. Then the technology as a whole can be represented by combining all the *i*-results in to set of results *Re*:

$$\mathrm{Re} \equiv \mathrm{TI_m}\ (\mathrm{TI_{m-1}} \cdots (\mathrm{TI_1}(\mathrm{Sb}) \cdots)) \tag{1.1}$$

where $TI_{i(i \in \overline{1,m})} \subset Z_\nu$ is the set of therapeutic effects. At the same time, an effective technological medical process satisfies the condition that the result at each step of Re_i with high reliability (for example, $D > 0.9$) belongs to the family of nominal states of the subject $SSbN:\ D[\mathrm{Re}_i \in SSbN] \geq 0.9$, where S is a set of states; Sb is a subject, and N is a nominal.

The main difference of the considered inequality is the introduction of structural formalisms (through sets and their elements) representing a generalised medical technological operation. We used an algebraic topology as the apparatus of system formalisation in this case (Speneur 1971). The multiple-theoretic apparatus evidently transform a meaningful description of the medical object into the language of the formal representation: the main objects of formalisation, the set and the complex of sets, admit this. At the same time, the adequacy between the formal systems and the material systems of the world, including medical systems (for example, physiological systems), consists in the presence of a structure, its elements with certain functions and connections between them. Thus, the first step in determining the medical system is its structuring, which is the isolation of certain functional elements and the links between them. This forms the basis for determining the functions of the system as a whole and assigning a system formal parameter. It is the exit of the output element: the assignment element assigns the output parameter. Then the system function becomes the one that is formed due to the consecutive transmission of the input action, the action of the medium from the input side, to the dedicated output. Obviously, it is advisable to consider the place of environmental impact as input.

The proposed scheme of sequential formalisation makes it possible to make the transition from a meaningful description to a formal description at levels of considerably greater complexity, and then to simplify stepwise by the adoption of analytic-algorithmic descriptions preceding metrological analysis with using of natural formal transformations of category-functor and graph schemes. In a broad sense, we mean that the information about the process is changing of a certain parameter (IP_i), which is adequate to the changes in the process itself. Under the information flow (IPt_j) we mean the movement of information about a certain process through the environment in which this process is realised, including in the measuring system. Under the information network (IN) we mean a special organisation of the environment in which the information process develops and any information flows exist. The above statements can be illustrated formally:

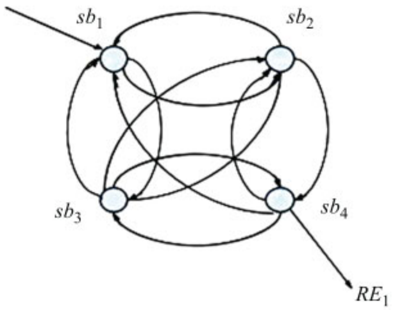
$$\left.\begin{array}{l} (IP'_1 \cup \ldots \cup IP'_n) = IPt_1 \\ (IP''_1 \cup \ldots \cup IP''_n) = IPt_2 \\ (IP''_1 \cup \ldots \cup IP''_n) = IPt_2 \\ \quad \ldots\ldots\ldots\ldots\ldots \\ (IP^k_1 \cup \ldots \cup IPt^k_n) = IPt_k \end{array}\right\} \Rightarrow IPt_1 \cup IPt_2 \cup \cdots \cup IPt_k = IN. \tag{1.2}$$

In this case, one can distinguish the observed process in the environment:

$$A \to B \Rightarrow F : (A, B) \& B = F(A) \& A = F^{-1}(B)$$

Then the information process can be represented as follows: μ: $F(A) \to F(B)$. In this case, $F(A)$ and $F(B)$ are the adequate changes of the objects A at the input of the process F and B at the output of the process, which in the pair characterise the changes occurring adequately to the process F, that is μ: $[F(A),\ F(B)]$. In other words, μ is a parametric copy of process F, information copy. The category of the measuring parameter of a certain measurement process is the homology $H = [F(A),\ F(B);\ \mu]$. It is a construction, which mapping a synthesised process in the form of consecutive images (modules, groups, concepts, add-ons, and so on) for any process. The distinctive quality of the marked process should be the "simplicity" of the analysis. That means, that the structure of such a process is easily formalised with the use of the developed apparatus.

The formal links in accordance with the physiological structure is represented by a graph:



(1.3)

Here (sb_i) are the elements of the physiological structure; LV_i – i-th medical effect; RE_i – is the result of the response of the physiological structure.

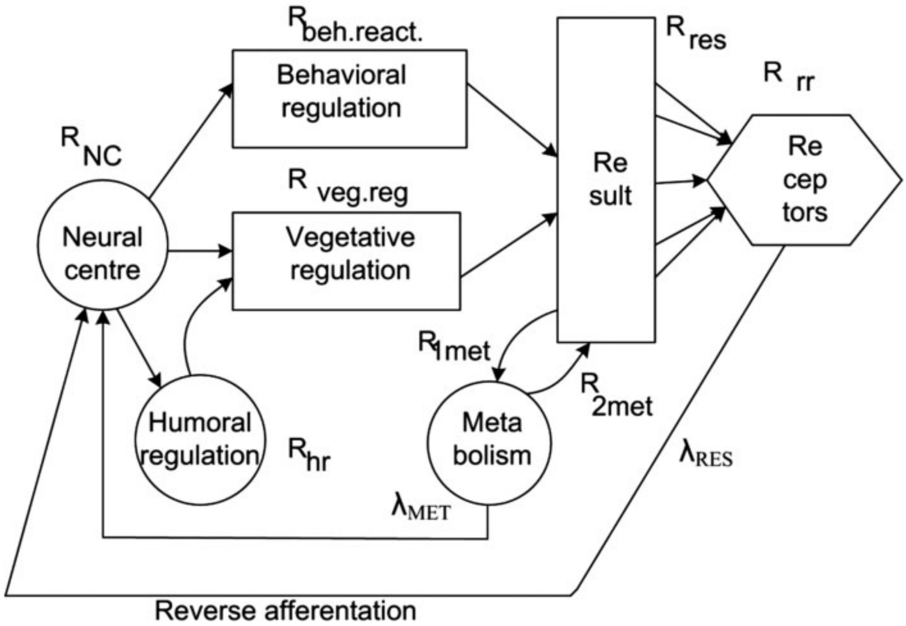


Figure 1.1. Block-diagram of the functional physiological system.

Then the operational form of the treatment effect sequence can be written as follows:

$$\begin{cases} TI_1(Sb_1, Sb_2, Sb_3, Sb_4) \equiv RE_1 \\ TI_2(RE_1) \equiv RE_2 \\ \dots \\ TI_m(RE_{m-1}) \equiv RE_2 \equiv RE \end{cases} \tag{1.4}$$

An example of the effective determination of interrelated elements in the form of physiological systems is the functional physiological systems (FUS) of Anokhin-Sudakov (Sudakova 1999) (Figure 1.1):

Here the following notations are accepted: R_{RES} – the operation of obtaining the results; R_{VA} is a vegetative adjustment operation; R_{1MET} – metabolism operation in the RES channel; R_{2MET} – metabolic operation in the λ_{MET} channel; R_{PREG} – an operation of behavioural regulation; R_{HR} is the humoral regulation operation; R_{NC} – operation of the functioning of the nerve centre; $\lambda_{MET}(t)$ is the output parameter in the metabolic canal; $\lambda_{res}(t)$ is the output parameter in the result channel of the functionally physiological system; $<R_{RES} \cup R_{1MET}>$ – specific of the joint value of the operations R_{RES} and R_{1MET}.

The operational formalisation of TI on the basis of the structure of the physiological system must be presented in the following equations:

$$R_{C\mathrm{MET}} \begin{cases} \boldsymbol{\lambda(t)}_{\mathrm{MET}} = R_{2\mathrm{MET}} < R_{RES} \cup R_{1\mathrm{MET}} > \\ \boldsymbol{\lambda(t)}_{RES1} = ||R_{\mathrm{PP}}||R_{\mathrm{KPP}}||R_{RES}||R^1_{\mathrm{K}RES} \begin{Bmatrix} R_{\mathrm{PREG}} \\ R_{\mathrm{BPET}} \end{Bmatrix} R_{\mathrm{KHLI}} R_{\mathrm{HLI}}(LV_1) \\ \boldsymbol{\lambda(t)}_{RES2} = ||R_{\mathrm{PP}}||R_{\mathrm{KPP}}||R_{\mathrm{PE3}}||R^2_{\mathrm{K}RES}||R_{\mathrm{BPE3}}||R_{\mathrm{KTPET}} R_{\mathrm{TPET}} R_{\mathrm{HLI}}(LV_1) \end{cases} \tag{1.5}$$

Here $R_{C\mathrm{MET}}$ is the operation of commutating the outputs of the results receptors; R_{CRES} – the operation of commutating the results; R_{CR} – operation of commutation in channels of vegetative regulation; R_{CNC} is a switching operation for controlling of the nerve centre.

An important feature of the apparatus of structural formalisation is the lack of the necessity of any analytical description for the function, which was reproduced because the functional ligaments are given in the form of mappings. However, while all other attributes of the function will remain: the domain of definition and existence, the features of their task, the conditions for the existence of mappings, and the ways of their transformation. The most effective representation of the structure is way through the consideration of information flows and nodes of the transformation of the information parameter by sort, form, intensity, character (deterministic/random), places of multiplication and de-multiplication, rings of iteration (Tsvetkov 2005, Ferreira et al. 2016).

Structural formalisation contributes as a basis for the formation of metrological concepts in medical technologies. The main principles of structuring are as follows:

- Metrological assessments are of a structural nature (evaluation principle);
- Measurement is the model of the observed process (the principle of identifying a system parameter);
- A measuring instrument is an identical converter (basic principle).

Structural formalisation becomes more efficient in the framework of the system-technical approach when the system S is considered a subset of the quadruple of the form $S \subset <X, Y, F, Z>$, and the input objects X and output objects Y are formed as Cartesian products of arbitrary objects,

$$\begin{matrix} V_i : X \subset V_1 \times V_2 \times \ldots \times V_k \\ Y \subset V_{k+1} \times V_{k+2} \times \ldots \times V_n \end{matrix} \quad \textit{and}$$

which are used to describe all knowledge about the system. Moreover, it is assumed, that the pair $(x, y) \in S$ forms a system element if an element c of the state space of a system $c \in C$ exists (known from its meaningful descriptions) when there is an equality $Y = R(c, X)$. Here $R \subset F$ is the operating principle of the system, which makes it possible to realize the necessary complex F of system actions (for example, medical technology) under the conditions of implementation of Z.

We formalized the measurement situation with all the stated assumptions within the framework of medical technology as follows:

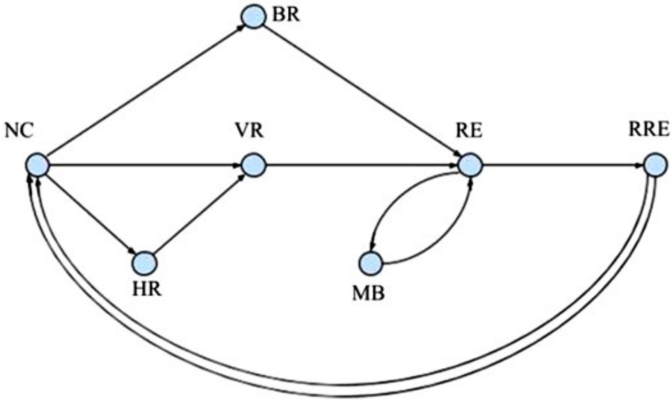
$$\begin{aligned} &M_{measur.sit.} = \{RE = Lv(C, v_{sz}); \\ &M_{fus} \subset Z;\ M_y \subset v_{medium} \equiv X; \\ &Lv \subset LV_m \ldots V_1(v_{medium}) \Rightarrow \\ &\Delta RE \subset RE_R - RE_{NOM} \in C_{NOM}\} \end{aligned}$$

Here v_{medium} is the effect of the medium; RE_{NOM} – the response of the physiological system in a healthy state C_{NOM}.

Summarising, we note that the structuring process includes the following steps:

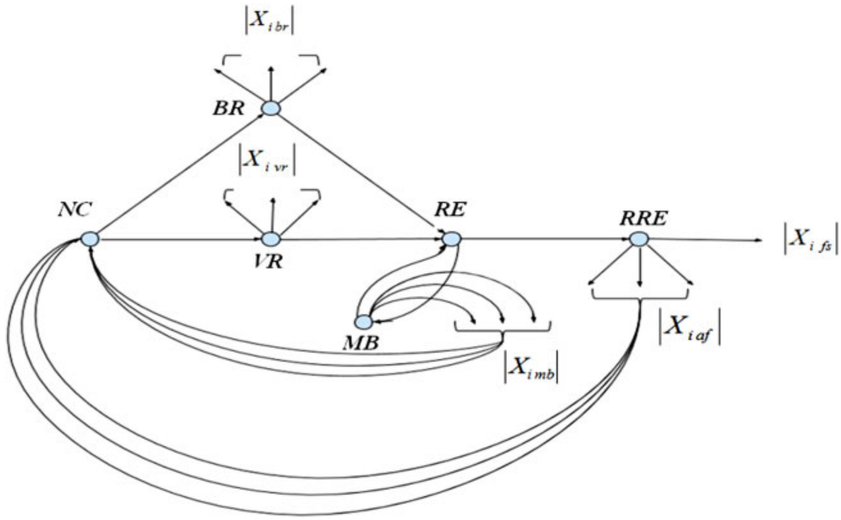
1. We defined the set-theoretic formalism of the phase space (state space): a set of elements that determine the state of the object was established. Then we got the set of operations on the set of the state elements (set-theoretical maps of any kind, including various algebras), and the set of rules for realising mappings in the state space.
2. We analyzed the phase space in order to establish possible set-theoretic structures of mapping operations defined earlier.
3. Information flows were formed, admissible essential set-theoretic mapping structures were established.

Thus, structuring from a formal point of view is the establishment of successive transformations in the phase space in the form specialised categories. All the considerations on structuring are well illustrated by the definition of systemic physiological functions within the framework of multidimensional measurement technology. The general architecture of the functional system (Vinogradov 1977) contains information flows associated with the activity of the nerve centre (NC) within the framework of behavioural regulation (BR), vegetative regulation (VR), and humoral regulation (HR). Information was demonstrated in the results (RE) of this activity, in the results of the metabolisms accompanying all kinds of regulation (RRE) and activity. This information was obtained in the feedback channels in the form of humoral influences and reverse afferentation. The graph of general architectonics by P. K. Anokhin looks like this:



(1.6)

Each of the mappings of the graph (1.6) is associated with the transfer of information, each of the vertices of the graph is conjugated with the processing of information. We took into account that both of the processing of information and its transmission are performed in synchronous and asynchronous modes, and the functioning of the functional system takes place under conditions of the constant influence of the external environment. Then it became clear for us why the problem of integral measurements of the system parameters of biomedical objects requires the detailed elaboration for the possible formalisation of measurement technology. The formalisation of the behavioural space of the object (organism) plays a significant role in this case. It was possible for us to determine the structure of information flows that form the information portrait of a complex system based on the structure of the functional system (1.6) and the concepts of the metabolic process. This structure includes information vectors for all types of regulation (BR and VR) along the channel of reverse afferentation and the loop of metabolisms.



(1.7)

It follows from the structure (1.7) that the information portrait of the FUS consists of groups of information regulation vectors $|X_{i\,br}|$ and $|X_{i\,vr}|$, metabolic loop vector $|X_{i\,mb}|$, the vector of the channel of the back afferentation $|X_{i\,af}|$, and the resulting vector FUS_i within the framework of the implemented stasis $|X_{i\,fs}|$. In real conditions, there is a relationship between the concrete elements of *FU-Sistem* (for example, $\{X_{i\ breath}\}$ and $\{X_{i\ motion}\}$). Therefore, the structure of the information portrait has the form shown in Figure 1.2.

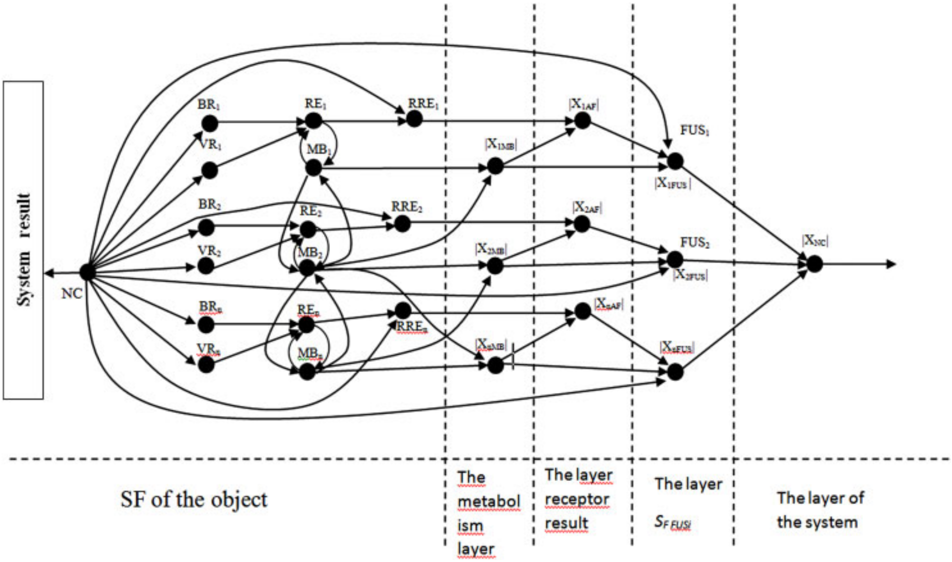


Figure 1.2. Structure of the information portrait.

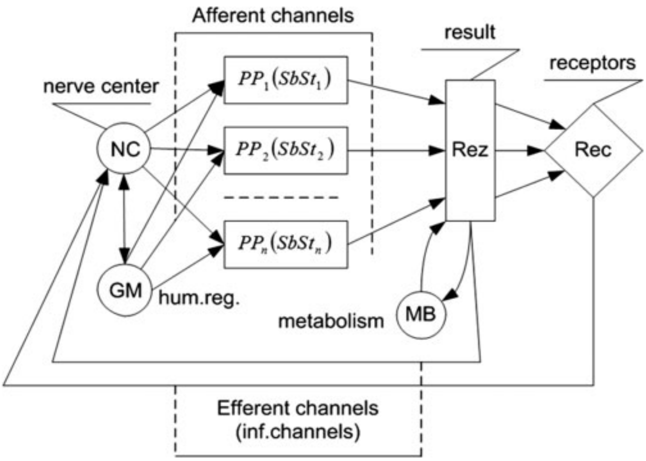


Figure 1.3. General structure of the FUS.

1.7 THE OBSERVABILITY PROCEDURE

“Physiological functional systems in an organism are dynamic centrally peripheral organisations, selectively united in self-regulating by the corresponding needs” in accordance with (Sudakova 1999). Thus, it is extremely important to establish the features of the formal representation of physiological stagnations and their hierarchical relationship. Physiological stasis is always adequate for concrete FUS. It is also connected by a constant function with realisation. The structure of any FUS (Fly 2011) includes a management centre, attracted sub processes, information channels, receptors (sensors), control channels, a subsystem of metabolisms, a subsystem for determining the result of the FUS (Figure 1.3).

The involved sub processes form the result space, and the subsystem of metabolisms is the cellular sub processes in this case. Therefore, any FUS is a set of processes that differ in their own stasis,

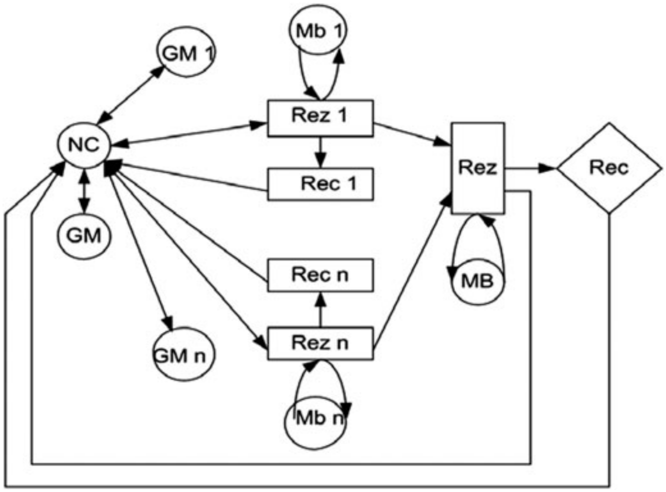


Figure 1.4. Structure of the FUS with the involved processes.

the output parameter of which is used to form the result space (Figure 1.4). In this case, the system parameter of the FUS can be represented by the following relation:

$$\lambda_{\text{FUS}}(\text{St}) = \text{NCU}\{\text{PP}_\text{i}(\text{SbSt}_\text{i}) \cup \text{INFC}_{\text{EF}} \cup \text{CUP}_{\text{AF}} \cup \text{REZ} \cup \text{MB} \cup \text{REC}, \tag{1.8}$$

where *St* is the stasis state of the FUS; $\lambda_{FUS}(St)$ is the system parameter of the stasis state; PP_i is the system parameter of the i-th involved process $SbSt_i$; $INFC_{pF}$ –the state of an effective information channel; CUP_{AF} – the state of the afferent control channel; *NC* – the state of the nervous centre; *Rez* – the state of the FUS for the elements of the preparation of results; *MB* – state of the FUS for the organisation of the metabolic processes; *Rec* – the state of the receptors for the elements of the FUS.

The operational mapping for the functions of the system signal transmission is in the follows equation (1.9) in accordance with the relation (1.8) and the structure of the FUS (Fly 2011), shown in Figure 1.4.

$$\lambda_{NC}(t) = (REC_9)\,(REZ_8)\,K_2 \left\{ \begin{array}{l} K_1' \left\{ \begin{array}{l} (REC_6')\,(REZ_5')\,(NC_3', GM_4') \\ MB_7' \end{array} \right. \\ K_1'' \left\{ \begin{array}{l} (REC_6'')\,(REZ_5'')\,(NC_3'', GM_4'') \\ MB_7'' \end{array} \right. \\ (MB_7) \end{array} \right\} K_0(NC_1, GM_2) \tag{1.9}$$

In this equation, all K are commuting operators realising the hierarchical order of transmission. So K_0 is an activation operator for the channels of the involved processes ($'$) and ($''$) through the departments of the brain NC_3' and NC_3'' respectively. The operator K_0 works with the involvement of the humoral control operations GM_3' and GM_3' respectively. K_1' – the commuting operator for activating the system signal of the involved process $\varphi_{NC}'(t) = (REC_6')\ (REZ_5')\ (NC_3',\ GM_4')$ and $\varphi_{MB}'(t) = MB_7''$. Similarly to all that, the activation of another involved channel occurs: $\varphi_{NC}''(t) = (REC_6'')\ (REZ_5'')\ (NC_3'',\ GM_4'')$ and $\varphi_{MB}''(t) = MB_7''$, using the commutative operator K_1'. Finally, the operator K_2 form out the hierarchical ordering in forming of the system signal $\lambda_{NC}^*(\text{t})$ among all the signals:

$$\varphi_{NC}'(t), \quad \varphi_{NC}''(t), \quad \varphi_{MB}'(t), \quad and \quad \varphi_{MB}(t) = MB_\text{B}.$$

Thus, the equation of transformation of physiological dimensions (1.9) is a model of the hierarchical interrelation between the physiological stasis of the basic physiological system and the involved physiological systems. At the same time, the law of the specific interrelation between the FUS, FUS′ and FUS″ is determined by the law of commutation in this case:

$$K(t) = K_2(K_1')(K_0) \cup K_2(K_2'')(K_0). \tag{1.10}$$

We took into account the relationship between physiological processes through their synchronisation using the commutation law (1.10).

1.8 SYNCHRONIZATION OF PHYSIOLOGICAL PROCESSES

The complete set of physiological systems are organised so that their structures contain components that work in several physiological systems at once. We made that conclusion based on the definition of the physiological state. Then we formulated the following thesis: systemic physiological stasis is a state of dynamic equilibrium, the effectiveness of which is higher the greater the coordination of dynamic processes in the physiological system. We executed an assessment of the level of coherence of these dynamic processes only within the framework of the formalisation of the interaction for the dynamic physiological systems (Mukha et al. 2010). We set the following definition to formalise the interaction: the physiological situation is the set:

$$M_{FPS} = \{M_{\mathrm{FUS}}, M_{\mathrm{DDEF}}, M_{PC}, M_{COS}, M_{\mathrm{SP}}, \},$$

where M_{FUS} is a categorical model of the functional physiological system; M_{DDEF} is a model of the domain of the definition of a functional physiological system; M_{PC} is the set of physiological constants; M_{COS} – a set of conditions for the functioning of the FUS; M_{SP} is a model of the system parameter.

In accordance with the definition of the formal-physiological situation, the dynamic synchronisation method of the FUS can be represented in the form of the following set of steps (Mukha 2006).

Step 1. We construct the categorical models of the FUS, $M_{\mathrm{FUS}\ i}$, which are considered in the task of dynamic synchronisation.

Step 2. The dynamic components are distinguished and their domains of definition and existence are determined among the $M_{\mathrm{FUS}\ i} \subset M_{FPS}$.

We consider such subcategories that realise their mappings within the framework of periodic or periodised processes in this case. The argument parameters and the boundaries of their changes are determined for these processes, as well as the kind of parameters for the results of subcategory mappings and the boundaries of their changes. It corresponds to the construction of the sets and M_{DDEF} and M_{SP}.

Step 3. We identify the components that are complex or common for the under consideration for $M_{\mathrm{FUS}\ i} \subset M_{FPS}$. The representation of these components is realised through the parameters of metabolism, nervous and hormonal regulation of physiological parameters in this case.

Step 4. The task of dynamic characteristics is realised by performing the presentation of components at the previous stage at the biophysical and biochemical level. We consider a physical description of metabolic reactions and their construction in a mathematical form on this step. We determine the physical nature of periodic or periodised processes (biophysical description) and specify a formal representation of dynamic characteristics using the consideration of the $M_{\mathrm{FUS}i}$. In addition, we make it possible to determine physiological constants and conditions for the realisation of metabolic processes using the examination of biochemical reactions that exist within the complex of the periodised processes (and so to form a set of and M_{PC} and M_{COS}.

Step 5. We make an experiment to form the set for adjacent physiological functional systems and perform a spectral analysis to identify the boundaries of the norm.

Step 6. Then we use a method for controlling dynamic characteristics, find the correspondence between the experimental characteristics and optimal characteristics, and, if necessary, assign a correction.

Thus, the observability procedure consists of the following steps (Mukha et al. 2003):

1. Graph structures are constructed in correspondence to the full space of states (a complete state graph).

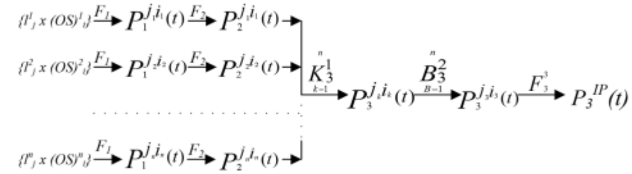


Figure 1.5. Structure of measurement of integral parameters.

2. If it is necessary, the set of least external stability of the complete state graph is determined.
3. The replacement state graph (the second-order graph of the complete state graph) is restored.
4. Many observable system parameters are formed on the basis of substitution complexes.
5. The set of the parameters-complexes for replacement are unconditionally significant observable parameters: they depend on all state parameters and cover all sets of the state elements.

We should take into consideration that it is possible for the complete space of states to be a FUS (or a set of FUS: $\{FUS_i\}$) according to the definition of physiological states. The section of FUS (spatio-temporal) fixes a concrete state. We represent information flows by categories of FUS on the basis of the object by its state parameters.

1.9 MEASURING PROCEDURE

A method of observation is important in this procedure. An ideology of systemic measurements is a base for it (Fly 2011). The concept of system measurements or measurements of the integral parameter were mentioned in the introduction. The heterogeneous information flows exist in the observed object. They are distinguished by an individual measure, have different information conversion channels and individual numerical transformations. However they are combined into the common algorithm at the stage of forming the result of the measurement by the system measurements of the integral parameter. This leads to the synthesis of the combined output system parameter. So, multidimensional studies of assessing the physiological state of the body require a specific organisation of the measurement procedure (Mukha 2003).

All well-known methods of measurement are represented by the apparatus of variable structures. Such structures are obtained from the most complex structures by the switching (changing) of the component parts-mappings.

We used the fundamental cybernetic principle of object representation, the "black box", in constructing of the structures for measurement methods: the initial set of parameters – the function of the input-output connection – the resulting set of parameters.

We concluded that many structures of measurement methods are not investigated. This sphere is open to the formation of new structures. Thus, we make all measurements with subsequent processing of the experimental data using the BTMCS (Popechitelev 2006). However, it is necessary to concentrate attention on the peculiarities of medical measurements, which are connected with the use of plot images (images containing information) as the main kind of impact on the person on whom his reaction arises.

We can determine with the final circumstance that the BTMCS are always specialised measuring tools. It will be adjusted to the object of measurement. We represented such a measurement process in the most complete form using the category of integral measurements (Mukha 2003).

We used a principle of measuring the integral parameters for the subset $P_2^{ik\,jk}(t)$ form the intermediate values of the parameters $i_k j_k$, which are used for a calculation of a generalised parameter for full characteristics of the technological process at an object. So, we added the mappings, K_3^1, B_3^2, F_3^3 that compress the object information (see Figure 1.5). $P_3^{IP}(t)$

Here K_3^1 is the sub-operator of the operator F3 ($K_3^1 \subset F_3$), switching the subsets $P_2^{jn\ in}(t)$; the number of switches is determined by the content of the operator K_3^1, therefore j and i have been obtained the indices k; B_3^2 is the sub-operator of $F_3(B_3^2 \subset F_3)$, the analytic or numerical maps of the subsets $P_2^{jk\ ik}(t)$; the number of the mapping is determined by the content of the operator B_3^2, therefore j and i have been obtained the indices B, F_3^3– the sub-operator of the operator $F_3(F_3^3 \subset F_3)$, which maps the subsets $P_2^{jB\,jB}(t)$ to the set of indication of the integral parameter.

The operators, K_3^1, B_3^2, F_3^3 satisfy an equation:

$$K_3^1 \cup B_3^2 \cup F_3^3 = F_3 \tag{1.11}$$

The formation of a systemic parameter will be considered using the example of the joint work of a functional physiological system that maintains blood pressure (*BP*) in the body at the optimal level for metabolism, and a functional system that determines the volume of circulating blood (*VB*) at the optimal for tissue metabolism.

Then we gave an example of our previous consideration. Here is an organisation, which may be well illustrated by this measurement category (Mukha & Slugin 2008):

$$\begin{Bmatrix} BP_1(t) = WH(t) \times \|l_1\| \\ BP_2(t) = DB(t) \times \|l_2\| \\ VB_1(t) = BD(t) \times \|l_3\| \\ VB_2(t) = BF(t) \times \|l_4\| \end{Bmatrix} \rightarrow \begin{vmatrix} \xrightarrow{F_1^{WH}} \mathrm{P}_1^{\mathrm{PC}}\|l_1\|(t) \xrightarrow{F_2^{WH}} \\ \xrightarrow{F_1^{DB}} \mathrm{P}_1^{DB}\|l_2\|(t) \xrightarrow{F_2^{DB}} \\ \xrightarrow{F_1^{BD}} \mathrm{P}_1^{BD}\|l_3\|(t) \xrightarrow{F_2^{BD}} \\ \xrightarrow{F_1^{BF}} \mathrm{P}_1^{BF}\|l_4\|(t) \xrightarrow{F_2^{BF}} \end{vmatrix}$$

$$\times \left\{ \mathrm{P}^{WH}_{2\|l_1\|}(t) \times \mathrm{P}^{DB}_{2\|l_2\|}(t) \times \mathrm{P}^{BD}_{2\|l_3\|}(t) \times \times \mathrm{P}^{BF}_{2\|l_4\|}(t) \right\}$$

$$\rightarrow \times \times \rightarrow p_3^{j_k i_k} \rightarrow p_3^{j_B i_B} \xrightarrow{F_3^3} p_3^{IP}(t) \tag{1.12}$$

$||l_1||$, $||l_2||$, $||l_3||$, $||l_4||$ – measures of the parameters of the heart, blood depositing, blood loss and blood formation, respectively; F_1^{WH} – initial mapping for the parameters of the work of the heart in a convenient form for measuring transformations; $F^{WH}_{1||l_1||}$(t) is the set of results for the initial mapping of the work of the heart, F_1^{DB} – the initial mapping of the parameters estimating the mass of the deposited blood into a form, which is suitable to implement measurements; $F^{DB}_{1||l_2||}$(t) is the set of results of the initial mapping for the parameters of the volumes of the deposited blood; F_1^{BD} – the initial mapping of the parameters evaluating the characteristics of the process of blood destruction; $F^{BD}_{1||l_3||}$(t) is the set of results of the initial mapping for the characteristics of the process of blood destruction; $F^{BD}_{1||l_4||}$(t) – the initial mapping of parameters evaluating the characteristics of the process of blood formation; $F^{BF}_{1||l_4||}$(t) is the set of the results of the initial mapping for the characteristics of the process of blood formation; F_1^{WH} is an intermediate mapping for the result set $\mathrm{P}^{WH}_{1||l_1||}$(t) in form, which is the same to uniform of the measurement standard; F_2^{DK} – is an intermediate mapping of the result set $\mathrm{P}^{DB}_{1||l_2||}$(t) into a form of the same type as the measurement standard; F_2^{BD} – the intermediate mapping of the result set $\mathrm{P}^{BD}_{1||l_3||}$(t) to a form of the same type as the measurement standard; F_2^{BF} is an intermediate mapping of the result set $\mathrm{P}^{BF}_{1||l_4||}$(t) to a form of the same form as the measurement standard; $\mathrm{P}^{WH}_{2||l_1||}$(t) is the set of results of the intermediate map for parameters of the heart; $\mathrm{P}^{DB}_{2||l_2||}$(t) is the set of results for the intermediate map of blood deposition parameters; $\mathrm{P}^{BD}_{2||l_3||}$(t) is the set of results for the intermediate map of the parameters of the blood destruction process; $\mathrm{P}^{BF}_{2||l_4||}$(t) is the set of results for the intermediate mapping of the parameters of the blood formation process; $\underset{k=1}{\overset{4}{K_3^1}}$ – a mapping that determines the hierarchical commutation of the results of $\mathrm{P}^{M}_{2||l_i||}$(t) depending on the organization of the algorithm for the process of forming the integral parameter (IP); $\mathrm{p}_3^{j_k i_k}(t)$ is the set of results of the commuting mapping in the database management form; $\underset{B=1}{\overset{4}{B_3^2}}$ – display of the results $P^{M}_{2||l_i||}$(t) in the form of numerical values of the integral parameter placed in the database under the control of the map k_1^3; $\mathrm{p}_3^{j_B i_B}(t)$ is the set of results of the numerical map B_3^2; F_3^3– the mapping of the results $\mathrm{p}_3^{j_B i_B}(t)$ in a form, which is suitable for documenting the values of the integral parameter; $p_3^{IP}(t)$ – the set of the results for the integral parameter in the documented form: magnetic, paper, video.

Category (1.12) has a structure that is the initial both for the organisation of the measurement experiment and for the synthesis of the structure of the measuring and computing complex. Thus, we solve the problem of polygraphic (i.e., multiparameter) studies to assess the physiological state of the organism in accordance with the definition given earlier.

Our purpose of synthesising IIS-structure was to construct an operator for the converting input information for any number of inputs (sources of measured information parameters) into output values for any number of outputs, which were equal to the number of receivers-consumers of the output information. Such an operator was called a measuring convolution.

1.10 CONCLUSIONS

We summarised all our results and note that the science of complexly organised systemic medical dimensions is experiencing a period of rapid development. We consider medical technology systematically with the application of structural formal ideology. So, we got an advance in the right direction when solving metrological problems in medicine. Our main principle was to determine the elements of a system and rules of their interaction. Such way of the investigation allows us to get an algebraic system and represent any technology, any object in the form of a structure, on which it is possible to formulate the necessary estimates and declare synthesis processes, including metrological ones.

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