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Basic Principles of Organization of System Software for Multifunctional Noninvasive Spectrophotometric Diagnostic Devices and Systems

D. A. Rogatkin

Optical diagnostic systems find increasing application in modern medicine due to such advantages as high sensitivity of modern optoelectronic detectors of radiation and wide variety of available inexpensive laser and LED light sources. In particular, optical diagnostic systems are widely used for noninvasive spectrophotometry [10], which includes optical pulsoximetry, biophotometry, fluorescence diagnosis, as well as various combined diagnostic techniques [6-11]. These methods meet the worldwide trend toward introduction into medical practice of effective diagnostic methods minimizing invasiveness, radiation load, and other physiologically and psychologically undesirable effects. Complex noninvasive spectrophotometric techniques make it possible to perform real-time monitoring of the functional and pathophysiological state of tissues using special contact sensors. This can be done by measuring the levels of accumulation and functional activity of different biochemical components (flavin enzymes, porphyrin, glucose, etc.) in soft tissues with simultaneous detection of the parameters of blood microcirculation and oxygen exchange. This provides unique possibilities for real-time monitoring of the dynamics of biochemical parameters during various therapeutic procedures or diagnostic tests [8-10].

Considerable efforts are being devoted to development of new methods and equipment for noninvasive spectrophotometry. Many problems concerning development of radiation sources and receivers for noninvasive spectrophotometric diagnostic systems (NSDS), fiber-optic systems for radiation transmission, etc., have already been solved [11]. Problems of development of mathematical models and algorithms for describing the interaction of optical radiation with biological tissues and media and calculating the levels of accumulation of various substances in tissues are widely discussed in the literature [9, 11-13].

Special software is one of the most important components of diagnostic equipment for noninvasive spectrophotometry. Diagnostic hardware provides detection and primary processing of light signals: spectral decomposition, conversion to electric signal, amplification, filtering, and digitization. The main computational and/or interpretive algorithms for processing and analysis of diagnostic information can be implemented only using special software [15]. The efficiency of the computing facilities of NSDS (especially multifunctional diagnostic systems) is the main factor determining their functional capabilities. That is why it is especially important to develop the basic principles of organization of system software for NSDS. This problem has been discussed only slightly in the literature. The goal of this work was to consider this problem in some detail.

Let us consider how various noninvasive spectrophotometric techniques are implemented in current medical practice, paying special attention to the procedures for processing and imaging of diagnostic information. It is more convenient to analyze the principles of operation of multifunctional diagnostic systems, because such systems make it possible to implement and combine various diagnostic procedures.

Spectrophotometric techniques for noninvasive medical diagnosis are based on the dependence of photometric properties of biological tissues and fluids (coefficients of spectral absorption, scattering, fluorescence, etc.) on the anatomical and morphological structure of tissues and the content of various biochemical components (hemoglobin, collagen, fat, water, natural porphyrins, carotenoids, etc.). On the other hand, these biochemical components also exhibit optical behavior typical for them, which makes it possible to detect them

Vladimirskii Moscow Regional Scientific-Research Clinical Institute, Moscow, Russia; E-mail: laserrog@mtu-net.ru

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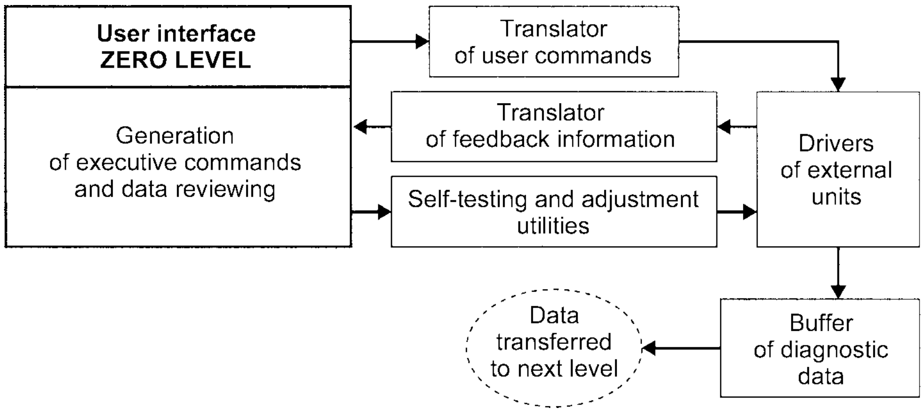

Fig. 1. Structure of zero-level software.

using optical methods. The levels of accumulation of these components in superficial tissues (skin, mucous membranes of organs) vary according to the functional and pathophysiological state of tissues and organs (for example, malignant tumors often lead to changes in tissue morphology). Variations in the ratio between oxidized and reduced forms of many respiratory enzymes lead to changes in the general photometric properties of tissues. Such changes can be detected using methods of laser spectral analysis and scattering spectroscopy. For this purpose, the examined region is exposed to low-intensity optical radiation. The spectral composition of radiation is varied, and the secondary radiation produced by multiple light scattering in tissues is detected and subjected to amplitude and spectral analysis. Thus, multifunctional NSDS should include radiation sources, optical systems for radiation generation and transmission to the site of examination and back to NSDS, and optoelectronic units for radiation detection [10]. The systems for radiation generation and transmission should be implemented so as to provide the required amplitude and spectral resolution of signals in the optical range, spatial resolution of signals over the examined area, and time resolution providing detection of signal fluctuations in the frequency range of ~0-30 kHz. The latter is necessary to provide detection of changes in blood supply to tissues and the Doppler shift in the spectrum of incident probing radiation.

All systems and units listed above require external control to select and adjust the modes of their operation. Thus, a set of drivers providing data transfer between the controlling computer and the device units is one of the main zero-level software resources of the NSDS system software (Fig. 1). This set of drivers should include a unit for translation of user commands to digital driver commands and macrocommands, which are transferred to the external units. The translation unit should also provide translation of feedback information about the modes of the operation of the device units into the form understandable to the user. The low-level software also includes utilities for self-testing, adjustment, and autonomous testing of all systems before measurements. Each adjustment and testing utility can be implemented as a set of standard scripts for running executive commands and a procedure for comparing the feedback data from external units with reference data stored in the device memory. It should be noted that, according to GOST R 50276.22-2002, medical laser apparatuses of safety type 3B or higher should be supplied with systems providing two- or three-stage pre-starting procedures. In NSDSs using lasers of these types, pre-starting procedures can be implemented based on testing and self-testing utilities.

The user (physician) interface should provide easy and flexible control of all units of the NSDS. It should be possible to view primary diagnostic information from NSDS detectors in graphical form, analyze feedback information from drivers, and select and execute procedures for processing and analysis of primary diagnostic data. The user interface should also make it possible to browse the results of calculation and store the obtained information with comments on hard disk. The control parameters for each measuring session should also be stored together with diagnostic information obtained during this session. It should be possible to enter text information into the patient's record and print the obtained diagnostic information as a hard copy. These functions of the interface and corresponding functions of the system software can be organized and implemented based on structuring of software in levels of collection, presentation, and interpretation of diagnostic information. The principles of structuring are similar for all types of NSDS [14, 15].

The zero level of the NSDS software provides data exchange with external units. At this level, digital data from detectors containing diagnostic information encoded, for example, in binary form are transferred to the diagnostic data buffer (Fig. 1). These data should be arranged and translated into the form of functional dependences (amplitude vs. time, amplitude vs. wavelength, etc.), in which they can be presented to user. Translation can be performed by a special data decoder. The obtained functional dependences can be presented in graphical form on the monitor screen. For this purpose, the NSDS software should include standard programs for data visualization. The optimal mode of graphical presentation (including color mode, scaling, etc.) can be selected from the user interface. The data decoder and visualization programs constitute the first software level providing presentation and interpretation of diagnostic data in terms of amplitude, spectral parameters, etc. (Fig. 2). Software of this level can be used to browse the results of measurement and to estimate the sensitivity of the measuring channels, quality of obtained data, noise level, etc. The data selected at this level (for example, curve segments, points on curve, etc.) are processed and analyzed at the next software level.

The next (second) level provides processing and interpretation of diagnostic data received from the first level. The results obtained at this level should be presented in biophysical and biochemical terms (concentration, velocity, flow rate, frequency, depth, etc.). This level can be designated as the level of biophysical or biochemical interpretation of data. The main results of diagnosis are formed at this level [10, 14]. The main computational capabilities of the NSDS software implement this level of data interpretation.

The computational algorithms of the NSDS software should be based on the methods for solution of inverse problems of scattering media optics [4, 5]. These methods are used to estimate the main optical and physical characteristics of biological tissue from the light signals reflected by this tissue. The obtained characteristics are compared with reference data on optical spectra of biomolecules, which makes it possible to calculate the contributions of various biochemical components to the optical properties of the tissue under examination. Thus, the percentage or volume content of these components in tissue can be determined. The dynamic data obtained through channels for detection of radiation intensity

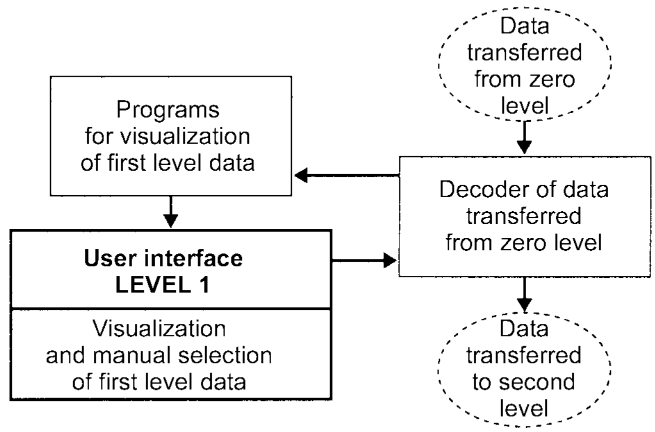

Fig. 2. Structure of the first level of data presentation.

fluctuations can be subjected to spectral or Fourier analysis, which makes it possible to estimate typical variations in the content of biological components as correlated with cardiac and cardiovascular rhythms (Fig. 3).

In modern theoretical diagnostics, inverse problems are conventionally referred to as tomographic problems [3]. They are considered as especially difficult. In the beginning of XX century, Radon developed the principles for the solution of inverse problems, which can occur in X-ray tomography (Radon problem). However, inverse problems occurring in noninvasive medical spectrophotometry remain virtually unstudied. Inverse problems are often incorrect [5] and require regularization of the final solution. Thus, the NSDS software should provide special regularization procedures. In multifunctional NSDSs, the problem of regularization can be solved by collection of excess primary data with subsequent multivariant solution of the problem and minimization of deviations using, for example, Nelder–Mead simplex algorithm [1]. Moreover, taking into account complex biochemical composition of tissues, detection of a single parameter (component) in such a multicomponent medium as biological tissue can be considered as a virtually unsolvable problem. Attempts to solve it directly lead to considerable diagnostic errors or fail completely. Thus, NSDS should provide integrated estimation of a set of intercorrelated parameters [13]. All parameters should be detected simultaneously (during the same procedure) because of their high variability. The primary diagnostic data should form a closed set required for successful implementation of computational and regularization algorithms. This imposes additional requirements on the NSDS hardware.

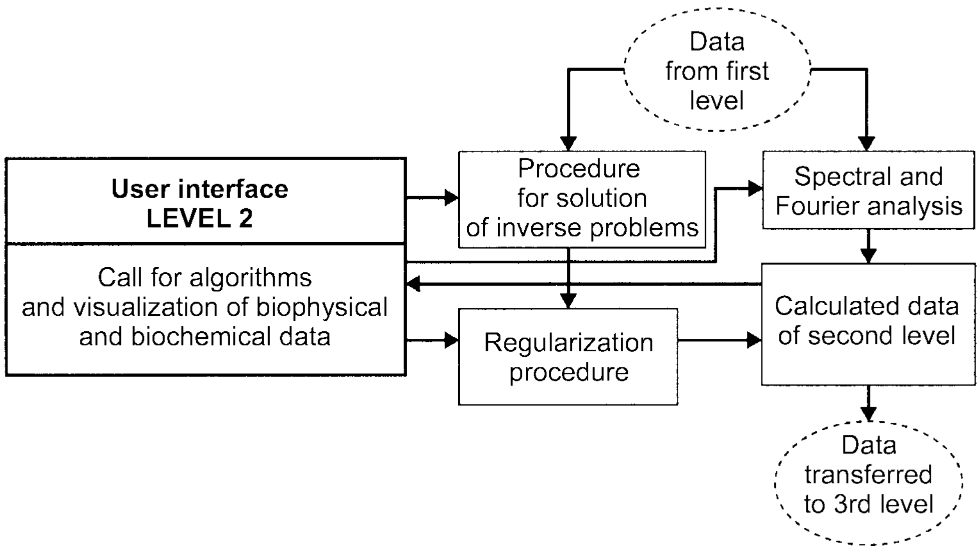

Fig. 3. Structure of the second level of data presentation and interpretation.

The results obtained at the second level of diagnostic data interpretation can be presented to user via a multilevel and multiwindow interface with special windows for diagrams, data tables, etc. At this level of interpretation, the numerical value (or range of values) of each diagnostic parameter should be presented to the user.

However, the information obtained at this level cannot be effectively used by physicians. Additional reference information about the significance of each of the measured parameters, normal contents of detected components, typical deviations in parameters accompanying various disorders, etc., is required for diagnosis. Such additional information is taken into account at the third software level providing medical interpretation of the results of measurements. Software of this level helps physician to make a diagnostic conclusion based on data obtained at the second level. Medical interpretation performed at this level is based on various general and specific reference data. Software can generate help messages indicating the probability of presence of various disorders in an examined organ or tissue (for example, probability of irreversible necrosis, inflammation of certain severity, vascular atrophy, capillary circulation disorders, etc.). The final diagnostic conclusion is made by the physician. The system also can be used to print the diagnostic results as a hard copy, fill in the patient record, etc. (Fig. 4).

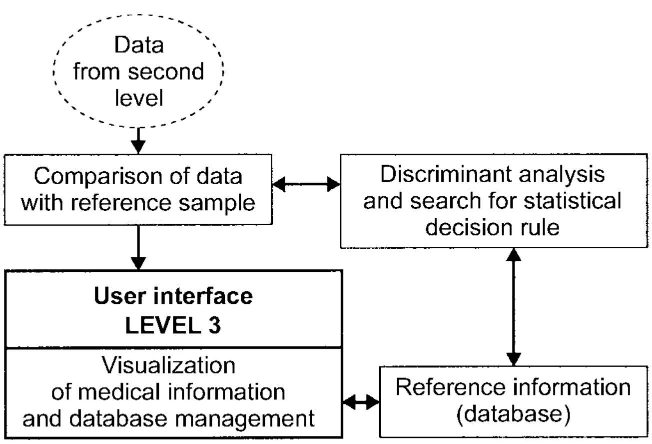

Fig. 4. Structure of the level of medical interpretation of the results.

The procedures for data processing at the third software level can be implemented on the basis of analytic databases including both measured parameters and physiological, biophysical, and biochemical reference data. The interpretation procedure should previously undergo thorough experimental testing. Databases used by the NSDS software should be structured and optimized to search for optimal combinations of compared elements. Optimization and testing of databases is the main task of software developers at the stages of design and experimental and clinical testing of NSDS.

The statistics and prognosis unit of the database should provide prognosis of the functional state of the examined object. Prognosis is based on information available from the literature and statistical data accumulated by the NSDS in the process of its clinical use. This unit implements the functions of decision-making and identification of cases as belonging to one of specific diagnostic groups. For example, tissues can be identified as malignant tumor, benign tumor, or healthy tissue. For this purpose, data transferred from the second level should be organized into a learning sample: a table containing measured values of parameters, where each vector of parameter values corresponds to a certain diagnosis. Such statistical data can be analyzed using identification methods of applied mathematical statistics [2]. For example, identification can be performed using methods of discriminant analysis, which generates decision rules for identification of parameter vectors. For this purpose, the set of possible parameter vectors is divided into disjoint regions, each of which corresponds to a certain diagnostic group. The identification procedure should be implemented to minimize the probability of false diagnosis. A decision rule is generated based on the learning sample. This decision rule is applied to the object to be identified, and the probability that the object belongs to the given group is calculated for all diagnostic groups. When already identified, an object is added to the corresponding diagnostic group, and the decision rule is corrected to take into account new boundaries of the classification groups.

The computational algorithms of the second and third levels will be improved in the process of development and updating of NSDSs. Thus, it seems expedient to implement the NSDS software as a set of software modules, which can be easily updated and supplemented with new modules. The NSDS software should provide easy integration of new algorithms and software modules in the form of libraries and subprograms. It also should contain a special utility for assembling mathematical programs for data processing (a dynamic link library can be used for this purpose).

The control computer of the NSDS can use MS Windows NT 2000 Professional system software. It supports dynamic volume expansion and distributed link tracking. The component object model COM+ facilitates implementation of applications and makes them more flexible and adaptable to systems available from different manufacturers.

Thus, the systemic approach to the development of the NSDS structure, main principles of hardware operation, and methods for data collection and processing showed that the NSDS software should have multilevel and multiunit structure including the following basic components:

– sets of drivers and user utilities for control of the system operation;

– multilevel graphical user interface including control interface; interface for visualization of diagnostic information of the first, second, and third levels of interpretation; and interface for compiling text comments and patient records;

– set of algorithms and programs for processing and analysis of diagnostic results at the second level of data interpretation (algorithm for solution of inverse problems);

– regularization procedures;

– user database with reference information (this database is supplemented in the process of clinical use of NSDS);

– set of statistically probable decision rules for the database;

– dynamic library for assembling additional algorithms and procedures.

In our opinion, the software structure suggested in this work would make it possible to develop effective and easily upgradable software for all types and modifications of NSDSs.

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