

Complex Measurement Systems in Medicine: from Synchronized Monotask Measuring Instruments to Cyber-Physical Systems

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Abstract—Design problems of flexible computer systems for physiological researches are discussed. The widespread case of employing of commercial medical devices as parts of the resulting computer system is analyzed. To overcome most of the arising difficulties, we propose using of the universal synchronizing device and the modular script-based software. The prospects of such computer systems are outlined as an evolution of them into cyber-physical systems with on-demand plugging in of required hardware modules.

Keywords—cyber-physical systems; integration; aggregation; medical systems; synchronization

I. INTEGRATION AND AGGREGATION OF MEDICAL INFORMATION-MEASUREMENT SYSTEMS

Modern information-measurement systems (IMS) which are used in medicine can solve a wide variety of diagnostic, prognostic, monitoring and treatment problems. However any highly specialized system, even being the most adapted for the performance of a specific objective function, is limited in the possibilities of increasing the accuracy of measurements and, consequently, of reducing the probability of errors of the first and second kind and making the wrong decisions by the system and, as a result, by its user. The combining of IMS into complexes allows to essentially expand the capabilities of IMS, to improve their accuracy and probabilistic characteristics and, thereby, to increase the effectiveness of the work. This combination can be either static, not involving a frequent modification of the complex or not allowing it at all, or dynamic, allowing adaptation of the complex for the changing goals.

Being combined into complexes makes IMS, as a rule, integrated. Integration implies a reasonable elimination of hardware and software redundancy (duplication of the same nodes, blocks, and designs as well as software, partially). So, for example, it becomes expedient to have a common timekeeper and frequencies generator, some of computational means, and sometimes a secondary power source and design elements. Reliability, built-in control and initial installations issues should be addressed taking into account the integrated nature of a system. However, in the case of dynamic,

situational integration, the importance of such elimination of hardware and software redundancy is reduced. Moreover, it can significantly reduce the ability to change the configuration of the complex and its reliability in the event of failure or incorrect operation of one of its parts.

Integration should not be confused with aggregation (complexing). In contrast to the first, at the heart of aggregation lies the idea of beneficial use of some hardware redundancy. Redundant devices should be measuring the same parameters. This is especially effective in case of the heterogeneous physical principles that underlie the functioning of the sensors since it provides a different character of the error spectra of the measured values. Aggregation provides greater accuracy and robustness of estimates and greater reliability of the whole IMS. Usually, an aggregated system brings up the qualities that are not inherent to any of the comprising it measuring devices.

In IMS, aggregation can be carried out at different levels, which are different stages of registration, processing, analysis, and interpretation of data. If in one system, while solving one task complex processing is carried out on several levels, the aggregation becomes hierarchical and can sometimes be completed only at the decision-making stage. Today high-level aggregation is usually done by software.

In general, the most effective processing is the primary complex one (processing of directly recorded signals), since it makes it as easy as possible to work in conditions of heavy interferences and artifacts of different origin, which is especially important for monitoring systems. However, primary aggregation is not always possible (in the case, for example, of the invasiveness or extreme expense of the measurement procedure) and requires much more computational cost than complex processing of a higher level. In addition, the primary aggregation is more difficult to implement technically and, as a consequence, the resulting system turns out to be less flexible: a change in its design may be required to change the set of aggregated devices. Therefore, if it is impossible or inexpedient to implement aggregation at the first level, and also when it is not enough to fulfill the objective function, it is needed to organize the aggregation at a higher level or consecutively at several levels. An example of such aggregation (if terms “measurement” and “aggregation”

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is treated as widely as possible) is one of the newest, prospective and most difficult to implement diagnostic and research technologies — EEG-fMRI [1, 2].

Structurally, the IMS complex can be:

- A) a single device;
- B) a set of devices specially adapted to co-work on the solution of a specific task;
- C) a set of specialized devices, combined in a complex based on the synchronizer;
- D) a set of independent devices having compatible interfaces and exchange protocols for control commands and data.

The A and B variants (Fig. 1, A and B, respectively) require significant time and material expenses, as well as employing qualified specialists in the field of instrumentation, electronics and computer technology. Therefore, such solutions are used mainly in cases where it is assumed that serial production of highly reliable devices is expected, or if technical conditions for some reason do not allow other options.

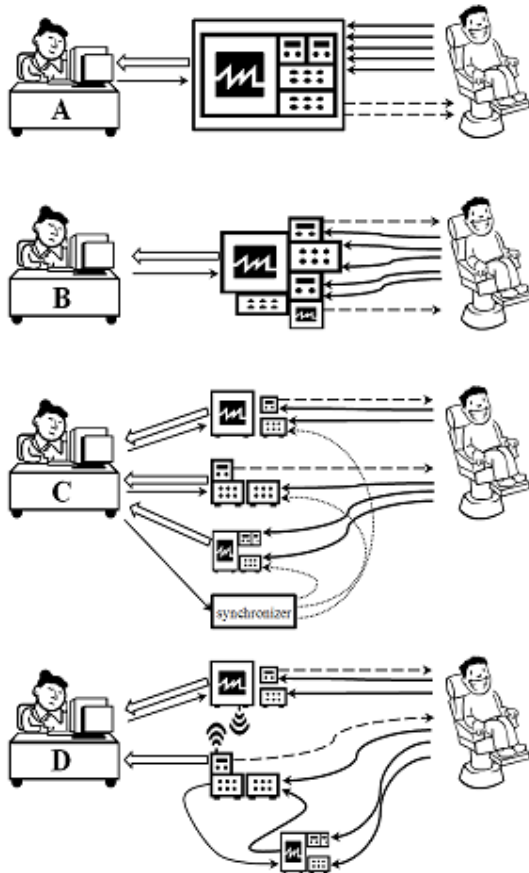


Fig. 1. Variants of IMS complexes structure. (Synchronizing pulses — dotted lines, stimuli and/or intervention — dashed lines, control actions — thin solid lines, recorded signals — thick solid lines, asynchronous flow of registered and preprocessed data — wide arrows)

The C variant (Fig. 1, C) gives the flexibility of the

composition of the complex at a low cost of its creation and modification due to the possibility to use already owned equipment, including one of different manufacturers, not necessarily readily compatible. The central, integrating element of such a complex is a specially designed device — a synchronizer — that provides functions that are important for solving the task: synchronization of recorded signals, generation of control signals, sometimes user interface, etc.

The D variant (Fig. 1, D) — a set of compatible equipment — can include the master device, initially optimized for this function. However, the master device can be situationally set during the formation of the complex and the assigning of the next task to it. At the same time, management can be both centralized and decentralized. In the latter case, control actions are generated by that part of the complex that (for example, in response to detection of a given event) initiates the execution of actions by actuators. The topologies of such complexes can be different, depending on the distribution of functions between devices, directions of information flows, as well as the risk and significance of the consequences of possible errors. Component software can also be based on different architectures, mathematical and logical principles, but necessarily — on a compatible protocol (or set of protocols) for external data exchange and commands. A set of specifications for different clinical or research tasks and hardware compatibility are provided by the “plug-and-play” properties of the hardware [3].

II. MEDICAL CYBER-PHYSICAL SYSTEMS

Complexes of the fourth type of situationally assembled compliant information-measuring devices have acquired properties of cyber-physical systems in the past two decades (for review see, e.g., [4]). Their main difference is highly reliable hardware and software automation, which provides flexibility and multitasking of the entire complex without direct user intervention. To date, medical cyber-physical systems (MCPS) are vital, context-based, networked systems of medical devices (for review see, e.g., [5]). These systems are used more and more often in hospitals to provide status monitoring and continuous automated patient care [5, 6, 7].

Moreover, the recent rapid development of inexpensive low-power communication, sensing and impact technologies further intensified the automation of medical diagnostics and treatment, including the using of the MCPS. Massive implementation of the MCPS can lead to another revolution in medicine, giving more reliable warning systems, supporting clinical solutions, advanced diagnostics, minimally invasive surgical care, timely, situationally dosed administration of drugs and physical effects on the patient's body, while ensuring safety and high productivity [8, 9]. In a routine work process in medicine, which relies on people who make all decisions, the patient is often exposed to danger due to a subjective factor — human errors and miscalculations. If the patient's condition is stable (or varies within specified limits), the automatic system can be used to create partially closed circuits by controlling the equipment and/or influencing the patient. Due to this, caregivers can focus on making the most important decisions, even in critical situations, without being distracted by false alarms of warning systems or on the monitoring duties [10].

In the monitoring MCPS, measurements collected by several devices are combined at different levels to reliably provide early detection of critical states [8, 9]. According to forecasts, in the next decade there will be a surge of remote monitoring systems based on wearable monitors. These MCPS will be able to transfer data to a private or public cloud for storage and processing, and machine learning algorithms that work in the cloud and process this data will provide decision support to medical personnel [11]. And patients will not be restricted by the borders of medical institutions [12].

However, at the same time, the requirements for the MCPS, especially of their software, also changed. This is due to the increase of depending on the functionality of MCPS software, higher levels of aggregation of measurements, increasing use of networking, distributed computing (grid technologies) and, on the other hand, the growing need for continuous monitoring of patients also ensuring a high degree of autonomy, safety, and confidentiality [5, 6, 11, 13]. In addition, the behavior of MCPS is characterized by a complex nonlinear interaction between discrete computational and continuous physiological processes [14]. In each case of practical application of the MCPS, one need to make sure that it is assembled correctly (by the user or automatically) and works in accordance with its specification. In this instance, some unacceptable situations, including dangerous ones, may be unique for this complex and not inherent to other variants of its configuration, and even more so — to its individual components. To prevent these situations, or at least timely detect them and alarm about them, special methods are developed [3, 9, 15, 16].

In addition, unknown or unrecognized physiological processes (human physiology is too complicated, non-linear and not fully observable) can lead to short-term deviations from the set clinical monitoring scenarios, causing a false alarm or a malfunction in the system. To resolve such situations adaptive methods are developed with the use of computer simulation and learning [10].

When designing the MCPS, which widely uses network and cloud technologies, the protection of medical data at each level of such system and the patient's safety in the event of a network failure with the switching off some devices from information exchange become critical problems. Due to the differences in hardware and communication capabilities of each level, the single encryption scheme may not be applicable [11]. The design and software of the closed network MCPS should provide security when one of the data streams or control signals ceases [7].

III. PROBLEMS OF SYNCHRONIZATION OF RECORDING EQUIPMENT AND A VARIANT OF THEIR SOLUTION

In many tasks based on the processing of physiological signals, synchronization of information-measuring devices is required along with preservation of information about the temporal relations during registration and storage of these signals. The more rapid physiological processes are subjected to analysis, the greater the accuracy of synchronization must be ensured. In case of complex processing with aggregation at low levels, the required accuracy can be provided only by hardware. However, when aggregation is at a higher level,

including the use of MCPS, it can be difficult and extremely costly to implement, especially when the independent IMS are temporarily combined in the complex, and the integration itself is programmed in quasi-real or post-production time. In addition, for the creation of the MCPS, as described above, a high degree of device compatibility is required, i.e. they must be initially designed for permanent or temporary functioning as parts of the complex. Therefore, if it is required to combine the equipment that was not designed for this purpose avoiding the high costs, the MCPS is not an option. Especially often this problem arises in research teams, when the complex can be assembled only once and for a brief time, and reliability issues are of no importance, and also at the initial stages of introduction of new diagnostic techniques into clinical practice (before commercially grounded production of more technologically sophisticated equipment is started).

In such cases, as well as for end-to-end data synchronization, special solutions may be required. The united time in which the information and measuring devices function does not eliminate the problem of synchronization of data already recorded on the medium, since significant delays can occur in each device, especially if the signal is processed in a quasi-real or post-production time. We came to the conclusion that the use of a more or less universal synchronizer as an integrating element would be the optimum from the standpoint of the flexibility of the entire complex and the cost savings in its creation [17, 18]. The rationale for this solution for the least favorable initial situation is as follows.

Each of the recorded signals (electro-, mechano-, phono- or videogram, stimulation parameter of the investigated object, a mark of a significant event, an indicator of the operation of the equipment, etc.) in the general case is a time series or can be reduced to it with an acceptable accuracy. Ready-made systems capable of synchronously registering all signals of interest to the researcher can be easily selected from serially produced equipment, but it only can be used for conducting routine diagnostic procedures. The equipment originally intended for solving research problems associated with the recording of non-standard signal sets is virtually absent on the market and is most often manufactured on a special order, which requires a long time and high material costs.

Therefore, as a rule, information is collected by the researcher with the use of the recording instruments at his disposal. Currently most of these devices happens to be an IMS, which includes a personal computer (PC) running an operating system (OS) with time-sharing (for example, Microsoft Windows, UNIX-based systems). In the OS environment the application software created by the device developers interacts with its instrumental part: it sets up the recording parameters, receives the data stream (measurement results), etc. This software is usually closed to the user.

All this leads to the problem of synchronization of signals recorded by various devices, especially if the synchronization accuracy must be high. All signals are recorded by unconnected devices, each of which functions in its own time. Even if you can install the software of all the devices to one PC, or synchronize the system timers of all used PC, the time for all the devices will not be the same as they work under the OS with time-sharing, while they themselves are closed

systems with an unknown and, moreover, variable delay. Thus, it is impossible to note in the recordings the time of significant events for the study (e.g. planned external impact — audio, visual or other stimulus, drug administration, etc.) only by means of involved in the process devices.

In such a situation it is advisable not to change completely the instrument base when the need in new channels appears, but only to fill it with lacking instruments, while maintaining, if necessary, the already available ones. However, in order to produce multi-channel recording with the help of diverse devices in the united time, it is necessary to synchronize all interconnected devices. In cases when devices that are being synchronized do not require any special measures to ensure the compatibility on the physical layer, we propose to implement this using a special external device — the synchronizer. (In some cases however physical compatibility is essential, e.g. when combining EEG equipment and functional magnetic resonance imaging, which should be partly spread in time and space [2, 19].) The main function of this device is the formation of pulses for supply to the spare inputs of the recording devices or, if no such inputs are available, superimposing pulses on the signal measured by devices. The proposed solution overcomes the limitations inherent to all implementations of software synchronization, because the pulses generated by the synchronizer are connected to the same time scale as the signals detected by devices; the pulses being subjected to the same initial processing, filtering, digitization, and other transformations that the primary measured signal is. Moreover, pulses going through the whole signal channel allow to track the state of the recording devices.

This synchronizer, as an open architecture device, becomes the basis of a complex of recording devices, easily adaptable for a variety of research tasks. In this case, specific requirements for synchronized hardware are minimal: either (better) to have one free digital or analog channel, or the technical capability to overlay pulses on one of the recorded signals. The power, duration, shape, and repetition rate of the pulses are set based on the characteristics of devices to be synchronized, research schemes and planned methods of subsequent data processing.

To remove the limit of the number of devices to be synchronized, the support for cascading at the hardware level in the synchronizer circuit must be provided. Due to this N synchronizers interconnected through a separate interface will be visible from the point of view of the high-level software and the end user as a single device having N times more inputs and outputs than one synchronizer [17, 18].

In 2010–2012 the authors have developed and successfully tested the device “Polygraph-synchronizer LBMI-001” [17], which combines the functions of the synchronization of external devices and a number of features common to traditional polygraphs as recorders of physiological signals. To be able to change and expand the list of devices to be synchronized, several free channels with customizable features to a set of inputs and outputs of the synchronizer were added. Scope of IMS on the basis of such synchronizer is broader than purely scientific research: firstly, if diagnostic task being solved in a medical facility has not been established as a

routine procedure yet, considerable material and technical means can be saved by recombination of equipment while maintaining the core of the complex and some plugged in devices (modularization principle); secondly, after the effective (from the point of view of diagnostics) configuration options are found and tested, the IMS can be commercialized by releasing this successful configuration as an independent diagnostic device with a predetermined set of functions.

IV. SOFTWARE OF FLEXIBLE COMPLEXES BASED ON THE INTEGRATOR-SYNCHRONIZER

The functions of considered flexible situationally (re)configurable systems do not include only the collection of “raw” data. Data processing in the course of research is mainly carried out not in real time, because the methods capable of solving a specific problem are not always known beforehand. Nevertheless, some computations should be performed immediately at the time of measurement. Such computations include, for example, the estimation of traditional medical diagnostics average characteristics of the patient, calculated using a sliding time window (heart rate, respiratory movements, etc.), recognition of pathological patterns, requiring intervention, in monitored signals or parameters of the signals on which depends the further experiment course. It is not always possible to determine the desired set of computational procedures in advance, so they should be embeddable in the software of the complex during its usage. Thus, the architecture of the software should be modular, with the possibility of adding when necessary the existing new modules, as well as specially developed ones.

However, the requirements for the software are not limited by modularity: while using the same configuration of equipment, different research scenarios can be implemented. When software is developed it is difficult or impossible to determine what sequence of functional tests, which set of parameters measured, and what conditions an operator-physiologist will choose. The wider range of complex functions, the greater the uncertainty. Due to the extensibility and cascading of “LBMI-001”, a complex built on its base demonstrates one of the extreme variants of this uncertainty. On the other hand, the wider the flexibility of architecture of the complex, the higher the probability of incorrect configuration of complex and of appearance of technical artifacts in the recorded data. Respectively, the higher level of expertise required from its user, too.

Uncertainties described (hardware configuration, scenario of studies and methods of operative data processing) lead to a number of problems in the development of software; the most significant include the choice of the user interface and the choice of storage structures for data obtained during the investigation.

When designing the user interface it is needed to be aware that the IMS end user, as a rule, is not an expert in information technology. Therefore, the most obvious solution for providing interface flexibility — integration of programming language into the software and providing an access to the basic functions of the complex and graphic users controls — in this case is not sufficient. It is desirable to use a higher level of abstraction and offer the user a kind of “interface

constructor”. A higher level of abstraction is the script that controls the underlying storage system and user interface.

The storage structure for data obtained in investigations is also requires versatility. It requires from IT specialist, serving the complex, a good knowledge of the characteristics of data generation in each software module, otherwise even the slightest mistake can go unnoticed and give rise to secondary artifacts at the stage of data processing and analysis. A better solution is to develop a universal storage structure that accommodates all possible scenarios of the use of the complex. At the same time, giving the complexity and multidimensionality of (and sometimes — the uncertainty and omissions in) the data, unique identifiers for the patient, the patient's visit, test in the framework of the visit, a set of the similar data in the test are necessary.

In addition, to minimize the chance of missing a significant event when using such a flexible complex, it is necessary to provide for recording of the two protocols: unswitchable off complete log of all events (including the actions of the user and the configuration and condition of the equipment), as well as customized user protocol, recorded at his request.

To improve the quality of the physiological measurements, in many cases it is desirable to provide a sufficient level of automation, which minimizes the influence of random factors on the characteristics of presented stimuli, feedback control, and the measurement processes. Consequently, every new test scenario must be supported by the software, preferably at the level of the user interface. For example, if, according to the experiment plan, various functional tests are performed sequentially, the automation of firing of respective software modules will not only provide equal delays between tests in different patients, but also eliminate the human factor. When, for example, new types of physiological signals appear, or the known tests should be repeated, the system continues to operate transparently for the user, when the underlying systems are restructured automatically.

There are at least two types of script: recording and processing ones. Wherein processing scenarios are divided into operative — implemented in the real-time — and delayed: in the former processing and analysis of the known methods is performed at once (e.g., to provide information to the patient or for archiving), and in the latter some part of the recorded data is set aside for further processing and in-depth analysis.

V. CONCLUSION

Although so far it is not possible to create a fully universal system and research software using closed parts produced by different manufacturers, nor to reach the technological level of medical cyber-physical systems in full, the proposed approach to the construction of the flexible architecture of research complexes and the introduced levels of abstraction allow to overcome the main difficulties. It provides the researcher with a fundamentally new opportunity — easy handling of all the available instruments as an adaptive (to the current task) matrix of diagnostic resources. The key features of such information-measurement system must be:

- integration of the recording, control and actuating

apparatus on the basis of an external synchronizing device;

- cascading of synchronizers supported at the hardware level;
- use of configurable pulses, that propagate along the same channel the recorded signal does;
- a modular software architecture with a uniform interface (adapted to the tasks of each module) and the ability to plug in the new modules;
- use of custom user scripts of the investigation involving different hardware configurations and different algorithms for data collection and processing;
- universalization of identifiers system and databases of recorded data.

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