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The DC-SQUID-based magnetocardiographic systems for clinical use

Yu.V. Maslennikov*, M.A. Primin, V.Yu. Slobodchikov, V.V. Khanin, I.V. Nedyayvoda, V.A. Krymov, A.V. Okunev, E.A. Moiseenko, A.V. Beljaev, V.S. Rybkin, A.V. Tolcheev, A.V. Gapelyuk

The CRYOTON Co. Ltd., 142190, Troitsk, Moscow Region, Russia

Abstract

The new line of dc-SQUID-based magnetocardiographic (MCG) systems (named as the “MAG-SCAN”-family) is designed, fabricated and tested. These systems are intended for routine MCG investigations of patients at conditions of real clinical electrophysiological labs. The “MAG-SCAN”-family includes the line of MCG devices compatible in terms of hardware and software with number of measuring channels from 1 to 36. Experimental prototypes of 7- and 9-channel MCG-systems (the models “MAG-SCAN-07” and “MAG-SCAN-09” fabricated at CRYOTON Co. Ltd.) were installed in a few hospitals of Moscow city and operated in an unshielded environment of usual clinical labs. Well balanced second-order gradiometers have been used for MCG data recording. They demonstrated an intrinsic noise level better than 5 fT/√Hz. The total noise level of about 20-40 fT/√Hz was measured at urban conditions of Moscow city. The package of special software (named as the “SOFTMAG”) was developed as two autonomous subsystems that allow the preprocessing of the heart magnetic signals and the spatio-temporal analysis of the field characteristics and the field sources. The software employs the algorithms for the analysis and estimation of the spatio-temporal characteristics of the heart magnetic field and the correspondent electrical currents distributions. More than 2000 investigations of different volunteers including healthy persons, patients with high blood-pressure, ischemic disease (IHD), chronic obstructive pulmonary disease (COPD) and bronchial asthma (BA) were carried out and sets of MCG-parameters specific for each group were found.

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* Corresponding author.
E-mail address: cryoton@trtk.ru
1. Introduction

In the last decade, magnetocardiography (MCG) becomes one of the new tools in the diagnostics of heart diseases. The magnetocardiographic systems that can work in clinics without an additional magnetic shielding open prospects for the real clinical applications of magnetocardiography and the creation of the new effective diagnostic methods in cardiology [1].

The existing experimental and clinical data show that the magnetocardiography is more sensitive (in comparison with the methods based on the measurements of electric potentials) to the local currents that are generated at the interfaces of myocardium fragments with different electrophysical properties (i.e., different shapes and durations of the action potential). Such currents affect the magnetic and electric fields but the corresponding variations in the magnetic field are significantly stronger. The sensitivity of the MCG-systems to local currents allows the estimation of the uniformity and homogeneity of myocardium with respect to electric properties. Moreover, the magnetocardiography makes it possible to distinguish between the myocardium regions with fast and slow conductivity, which also depend on the properties of the action potential.

The MCG measurements are noncontact and the magnetometric system does not affect the electrophysiological processes in the heart, since the acquisition of the diagnostic data does not require the emission of energy.

In this paper we report the results obtained in the development of practical magnetocardiographic dc-SQUID-based systems and their clinical applications in the cardiodiagnostics.

2. Equipment and methods

2.1. Hardware for the MAG-SCAN MCG-systems

The “MAG-SCAN” MCG-systems contain up to 36 dc-SQUID-based channels for the recording of magnetocaridosignals (MCSs) [2]. The systems employ similar hardware components, grid of measuring points for the MCS recording, and the package of the original software for the processing and analysis of the MCG data. Each MCG-system incudes the low-noise fiberglass cryostat, the cryogenic probe(s) with the dc-SQUID-sensor(s) and well balanced axial second order gradiometers, the electronic units with the electronic noise suppression system (ENSS) and the data acquisition system (DAS). MCG-systems are equipped also by the gantry for the cryostat placement and its movement in Z-direction and moveable in the XY-plane patient bed (Fig.1a).

2.2. Software for the MAG-SCAN MCG-systems

To handle the MCG signals the specialized package of software named as the “SOFTMCG” was developed and tested in clinical investigations of patients [3]. This package is intended for the following tasks: - non-invasive mapping of the magnetic field of the heart over the patient's chest with a regular grid in unshielded space with the simultaneous MCG and ECG data input into PC; - filtering, sorting and averaging of MCG data; - interpolation of averaged MCG signals and creation of a dynamic sequence of "instantaneous" distribution maps for the parameter values of the magnetic field measurements; - analytical solution of the inverse problem of magnetostatics and the localization of the electrical activity sources for given points of time of the cardiocycle; - reconstruction of biomagnetic source in the form of the spatial distribution of current density vectors in the plane crossed the heart and parallel to the plane of measurements; - spatio-temporal analysis of the MCG signals and the numerical evaluation of the heart
magnetic field without the solving of the inverse problem; - development of the user-friendly graphical interface and flexible database of MCG measurements and analysis (Fig.1b).

Fig. 1. The 9-channel magnetocardiograph of the model “MAG-SCAN-09” (a). The parameters used for MCG data analysis in the package of the software “SOFTMAG” (b).

3. Experimental results

In the development of practical MCG-systems we tried to reach the maximal quality of each of system’s components. Following to this idea, the developed fiberglass cryostats for the “MAG-SCAN” MCG-systems provided more than one-week operation of the system between the re-filling with liquid helium and exhibited a record-low intrinsic noise level of less than 1 fT/Hz^{1/2}. Thus, the cryostat of the model LH-11.5-B developed for the MCG-systems with up to nine channels, had the neck diameter of 150 mm, the total volume of 11.5 liters and showed the evaporation rate less than 1,35 l/day with inserted measuring probe. The cryostat of the model LH-32-B, intended for the 36-channel MCG-systems, had the neck diameter of 300 mm, the total volume of 32 liters and the evaporation rate less than 3 l/day.

Because the spatial filtering of the external magnetic interference is needed in the measurements of heart magnetic fields in the unshielded environment we applied the axial second order gradiometers as the input flux transformers. We developed and tested two types of the measurement probes for the “MAG-SCAN” MCG-systems. The probe of the first type contained one SQUID-sensor with the axial second order gradiometer flux transformer [2] and was mounted as an individual cylindrical insert. Such inserts were placed inside the cryostat and fixed on the top-flange in accordance with the given grid of measurement points. The probe of the second type was developed as a single module that accommodates all of the SQUID-sensors and gradiometers in accordance with the measurement grid. The distance between channels was of 40 mm for both types of probes. Signal channels contained dc-SQUID-sensors of the model “CE2Blue” (fabricated at the SUPRACON AG, Germany) and axial symmetrical second order gradiometers with the input loop’s diameters of 20 mm and the base line of 55 mm. The
gradiometers used niobium wire wound on the graphite former and are balanced to an accuracy better than 0.1 %.

In the practical systems, it is expedient to employ the electronic balancing of gradiometers with the aid of an additional reference XYZ magnetometer. In the case of the individual measurement probes of the type one, the reference XYZ magnetometer was located in one of the inserts above the SQUID sensor of the gradiometric channel. In the case of a single module probe, the XYZ magnetometer was placed in the probe as an independent unit.

The flux locked loop (FLL) units of MCG-systems contained up to 12 similar electronics channels assembled in a single box (four such boxes for the 36-channel MCG-system). During the measurements the FLL-unit(s) was located in the gantry near the top-flange of the cryostat. The system control unit contained stabilized power source, additional output signal amplifiers, band filters, the electronic noise suppression system (ENSS) and means for system tuning and for mode of operation switching. The data acquisition system (DAS) was designed at CRYOTON Co. Ltd. also, included necessary amount of independent 24-bit AD-convertors with a basic sampling rate of 4000 Hz and incorporated into the control unit of the system.

In the basic version of the 9-channel MCG-system “MAG-SCAN-09” the nine gradiometric channels are arranged in a “rectangular” (3×3) nodes configuration [4]. Each of the four 9-channel measurements takes about a minute, averaging about 60 cycles. An area of 20 ×20 cm² over the patient’s chest is covered. A patient is moved from one position to the other on a movable bed under the stationary cryostat with sensors. The magnetic field signal waveform and amplitude (the green traces) are seen to differ for different measuring positions, with the strongest signal for positions closer to the heart.

The total duration of MCG measurements was about 4-6 minutes. Concurrently with the magnetic field measurements, the ECG from the second standard lead is taken for use as the reference signal. If no change from one rhythm type to another takes place in the patient’s heart, the signal was processed using an on-line averaging procedure. Otherwise, an off-line averaging procedure was applied, with its algorithm based on the cluster analysis. In data analysis, the degree of similitude of cardiac cycles was determined by calculating the cross-correlation function or by an algorithm based on a semantic description of the ECG signal. As each step of the program is carried out the results obtained are displayed on the monitor and stored in the database.

In the software package “SOFTMCG” we used existing specific methods for the processing of multidimensional arrays of input MCG-data [5] and developed new original algorithms of the MCG-data analysis (fig.2 a,b) [6,7]. The resulting table of analyzed parameters contained from several tens to several hundreds of parameters (depending on the classification hypotheses), and a few of them (most specific for investigated groups of patients) were applied for the determination of decision rules using the methods of multivariate statistics.

The developed original methods and algorithms of MCG data analysis made it possible to obtain automatically the diagnostic decision based on the determined decision rules. The decision rules resulted from the analysis of a group of healthy patients and a groups of patients with the verified cardiological diseases. The results of this automatic analysis are presented as the final report of the investigation. At the first page of the report for each patient, one can find the general information and the analysis of the ECG using the second standard lead. The second page contains the classification results (groups 1,2,3 correspond to the normal state, deviation from the normal state, and intermediate state, respectively) and the graphical comparison of the “normal” and current results, which is used for the classification.

We investigated few different groups of volunteers including healthy persons, patients with high blood-pressure, ischemic disease (IHD), chronic obstructive pulmonary disease (COPD) and bronchial asthma (BA). More than 2000 investigations were carried out. As an example the group of 32 patients having the high blood-pressure was classified with the sensitivity of 86% and specificity of 98% using this technology of data analysis.
We first show that such an important property of the myocardium, as its ability to stretch against the background of increasing preload and/or afterload, can be evaluated qualitatively and quantitatively in intact myocardium. It was shown that the partial activation time of the right ventricle and the partial activation of the left ventricle during a phase of depolarization of ventricular myocardium (QRS interval) are important parameters of MCG, which allow us to estimate changes in the rate of excitation front in the stretch of ventricular blood volume. First proposed an integrative approach to studying the impact that changes in the mechanical properties of the myocardium on its electrical properties. This makes it possible, in a new way to approach the study of the nature of these important diseases, such as prolonged QT syndrome, Brugada syndrome and, as well as a number of mechanisms of paroxysmal tachycardia, including ventricular fibrillation.

Fig.2 3-D distribution of magnetic dipoles density (layer with highest density is marked) (a); “Layer-to-layer” inverse problem solution (b)

4. Discussion

The basic versions of dc-SQUID-based MCG-systems suitable for operation in an unshielded environment and giving a new diagnostic information about electrical processes in the human heart were developed and successfully tested at real clinical conditions. They demonstrated a stable operation without of an additional magnetic shielding. These MCG-systems were installed in few different hospitals of Moscow city and showed the total noise level in the outputs of gradiometric channels equivalent to 20-40 fT/√Hz in all places. This level of noise was good enough to get the required “signal-to-noise” ratio during MCG investigations of patients. It was found that the first order gradients of external magnetic fields are most important sources of additional noises in the output signals of measuring channels. Effective suppression of such noises was reached by the combine application of the electronic noise suppression system and well balanced gradiometers (in terms of the magnetic field and its first order gradient balance). This improvement increased the quality of the MCG-data analysis and made it comparable to the results obtained in magnetically shielded rooms.

The clinical investigations showed that the “MAG-SCAN” MCG-systems make it possible: (i) to determine the presence and to characterize the ischemia of myocardium in the absence of exercise testing even at the early (asymptomatic) stage, (ii) to determine the efficiency of and to individually choose the
therapy for cardiovascular diseases, (iii) to assess the risk of the supraventricular and ventricular tachycardia and to predict the stability of rhythm after the paroxysm of fibrillation, and (iv) to assess the risk of cardiac decompensation, and, hence, to significantly improve the quality of cardiodiagnostics. Note the absence of contraindications, since the MCG method is noninvasive and contactless.

5. Conclusions

We have finished the R&D stage in the development of basic versions of MCG-dc-SQUID-based systems intended for clinical use. Analysis of operation of multi-channel MCG-systems under conditions of real clinics showed that the developed hardware and applied mathematical methods and algorithms for MCG data processing and analysis give valid results in cases of localizing arrhythmogenic zones in human heart and estimation of degree of ischemic and non-ischemic damage of myocardium. The capability of the MCG method and equipment to register an instantaneous cardiac summary magnetic field which the intact heart is generating at every moment of the PQRST cardiocycle provides a novel approach to noninvasive studies and assessment of some well-known as well as new electrophysiological phenomena in the heart.

The “MAG-SCAN” MCG-systems obtained the Approval of the Federal Service on Surveillance in Healthcare and Social Development of the Russian Federation as the medical devices and recommended for the application in cardiological centers and cardiologic departments of large clinics and hospitals.

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