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Fetal magnetocardiography: clinical relevance and feasibility

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Abstract

We investigated the feasibility of a high-T_c SQUID system for fetal magnetocardiography (fetal MCG) aiming at a system without a magnetically shielded room and cooled by a cryocooler. The targeted SQUID resolution was 50 fT/$\sqrt{\text{Hz}}$ (1–100 Hz). The research was performed along three lines: environmental noise suppression, cooling and low-T_c experiments. Environmental noise can be suppressed by forming second-order gradiometers from individual magnetometers. Concerning cooling, we investigated the applicability of commercially available coolers. In the low-T_c experiments, the medical relevance of fetal MCG was clearly shown. However, they also indicated that, in order to fully exploit the medical potential, the targeted resolution has to be 10 fT/$\sqrt{\text{Hz}}$. This increased resolution, in combination with the required high reliability of the sensors, will be hard to realize in high-T_c technology. This paper describes the results of the project and discusses the feasibility of a clinical system.

Keywords: Fetal magnetocardiography; SQUID; Cryocooler; Noise suppression

1. Introduction

In 1997, the so-called FHARMON project was started at the University of Twente. The aim of this project was to investigate the feasibility of a high-T_c SQUID based system for fetal magnetocardiography (fetal MCG), a Fetal HeARt MONitor. Fetal surveillance in hospital at that time was, and still is, based on ultrasonography, including 3D-techniques and echo/Doppler. These ultrasonographic techniques are able to monitor the anatomy and mechanical activity of the fetal heart. The underlying electro-physiological processes in the fetal heart are not recorded. As an alternative, the fetal electrocardiogram can be recorded by means of electrodes attached at the maternal abdomen. The reliability of this straightforward approach, however, is quite poor and furthermore on average the resolution is too low for clinical purposes. This is mainly caused by the fact that, during a relatively long period of the pregnancy, the fetus is more or less electrically insulated from the mother because a fatty layer surrounds the fetus [1–3]. Fetal MCG might be the solution for this problem.

In our feasibility study, the target was a fetal heart monitor that should be simple to operate and

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relatively low cost (order of magnitude € 100.000). For these reasons, a magnetically shielded room cannot be applied. Furthermore, in order to simplify the cryogenic handling, we planned to use high-T_c SQUIDs that can be cooled by small cryocoolers. The targeted SQUID resolution was 50 fT/$\sqrt{}$Hz, and the relevant frequency band for fetal MCG is 1–100 Hz.

The research in the FHARMON project was carried out along three lines: environmental noise suppression, cooling and low-T_c experiments. In this paper, the activities and results along these research lines are reviewed in separate sections. At some points, results of other research teams are included or referred to. Based on these results, the clinical relevance and feasibility of a fetal heart monitor is discussed in the concluding section of this paper.

2. Environmental noise suppression

In the beginning of the project, noise spectra were recorded in clinical environments. Based on these spectra and data presented in literature [4–6], we assume an environmental noise field of 0.1 nT/$\sqrt{}$Hz with a first-order gradient of 30 pT/m/$\sqrt{}$Hz, and a second-order gradient of 10 pT/m^2/$\sqrt{}$Hz. The targeted SQUID resolution of 50 fT/$\sqrt{}$Hz, therefore, requires a second-order gradiometer with an imbalance below 10^{-3}.

Since we planned to work with separate magnetometers, we applied electronic gradiometer formation. First-order gradiometers are formed by taking the difference of two magnetometer outputs. Analogously, a second-order gradiometer is configured as the difference of two first-order gradiometer outputs. This concept is, among other also applied and further developed at CTF [5,6] and PTB [7]. We have tested this concept by means of high-T_c RF-SQUIDs manufactured at the research center of Jülich [8]. The test setup is schematically depicted in Fig. 1. In addition to the three SQUID magnetometers needed to form a second-order gradiometer, a 3-axis fluxgate magnetometer was used as a reference. Its outputs were used to correct for undesired off-axis sensitivity of the three SQUID magnetometers. The noise level of the gradiometer as determined by the intrinsic noise of the SQUIDs was 120 fT/$\sqrt{}$Hz [8]. The environmental noise suppression was tested in a quite noisy environment: the EL/TN building at the University of Twente housing the faculties of Electronics and Applied Physics. The straightforward formation of the second-order gradiometer resulted in a noise suppression by a factor of 100, as shown in Fig. 2. A further factor of two was gained by balancing the gradiometer using the fluxgate outputs. Magnetocardiograms of adult subjects were successfully recorded as depicted in Fig. 3. In this setup, we worked with frequency-independent factors in the

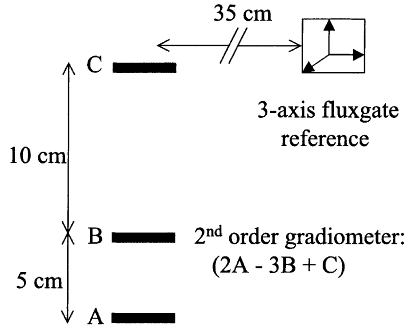

Fig. 1. Magnetometer setup applied for testing electronic gradiometer formation; a second-order gradiometer is formed as $2A - 3B + C$.

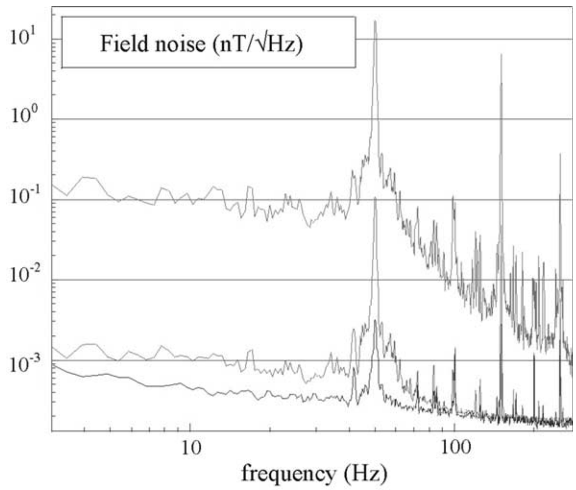

Fig. 2. Noise spectra recorded in EL/TN building. Top: magnetometers; middle: unbalanced second-order gradiometer; bottom: balanced second-order gradiometer.

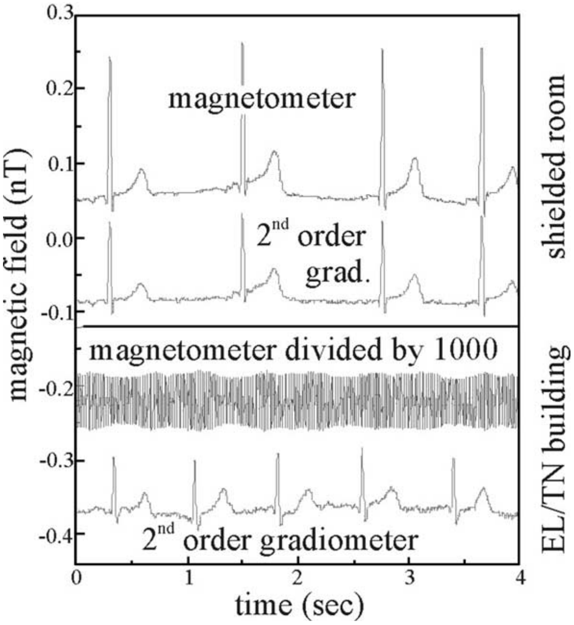

Fig. 3. Magnetocardiograms of different adult persons measured with a second-order gradiometer and magnetometer in magnetically shielded and harsh unshielded environments (bandwidth 0.1–47 Hz).

formation of the gradiometer and the application of the references. Thus, an overall noise suppression by a factor of 200 was realized. However, at 50 and 150 Hz the suppression was far more than a factor of 1000! Therefore, we anticipate that adequate noise suppression can be established by incorporating frequency-dependent software-based balancing methods which we are currently investigating [5,6].

As an alternative to magnetometers, thin-film gradiometers can be applied. Again, the differential of two of these gradiometers generates a second-order gradiometer output. The main advantage of applying gradiometers as a starting point is that the SQUID electronics involved can be much simpler. The requirements with respect to dynamic range, linearity and frequency response are much less stringent than for electronics coupled to magnetometers. A further advantage is that the loss of resolution compared to a single SQUID is less. When combining two SQUIDs to form a first-order gradiometer, the noise powers of the SQUIDs should be summed. As a result, the intrinsic noise of the gradiometer is about 40% above that of a single SQUID. With thin-film gradiometers this increase in noise can be limited to a few percent [9]. Concerning fetal MCG it should, however, be noted that the baseline of the gradiometer has to be several cm, preferably in the range of 6 cm or even more, depending on the noise conditions [10]. In this respect, the thin-film gradiometers developed in Berkeley are of great interest since they have an effective baseline of almost 5 cm [9,11].

3. Cooling

As mentioned in the introduction, we prefer to use cryocoolers rather than liquid cryogens in order to realize an easy-to-handle system. In this project, we focused on commercially available coolers. The options of interfacing such a cooler to the SQUID measuring head were discussed elsewhere [12]. Based on that discussion, we selected the APD-Cryotiger for demonstration purposes [13,14]. The selected version has a so-called non-magnetic high-performance cold head, which is connected to the compressor by means of flexible gas lines with a length of 7.5 m. We have extensively tested the cooler in terms of performance and interference [15]. These evaluations showed that both the available cooling power and the temperature stability are adequate. Furthermore, mechanical and magnetic interference also appeared to be sufficiently low. The one remaining concern is the relatively high permanent magnetic field of the cold head (~0.5 μT, which is rather high for a "non-magnetic" cold head). However, as we planned to connect the SQUID holder to the cold head in a rigid manner, holder and cold head are expected to move in unison. Therefore, the permanent field of the cold head should not contribute to the system noise.

The sensor head of the FHARMON demonstrator consists of an alumina (poly-Al_2O_3) SQUID holder that is attached to the cooler and located in a vacuum space (Fig. 4). The alumina holder contains three primary measurement SQUIDs and two reference SQUIDs. These are

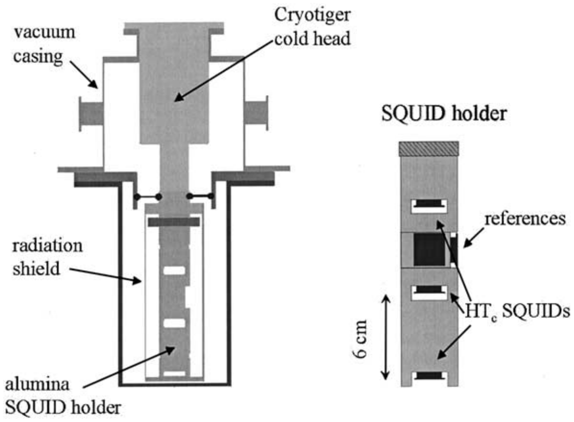

Fig. 4. Sensor head of FHARMON demonstrator.

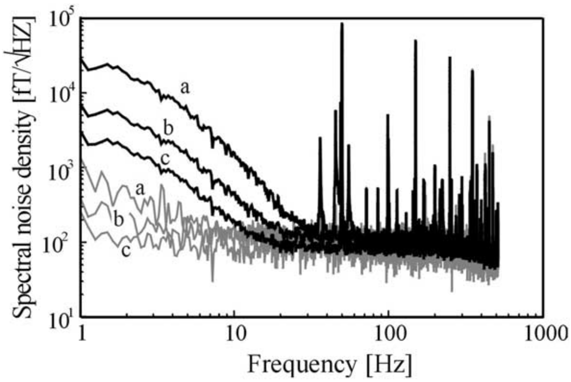

Fig. 5. Magnetic field noise spectra of the three SQUIDs as measured inside the magnetically shielded room. The black lines are recorded with the cooler running (compressor outside room); the gray ones with the cooler switched off: (a) top SQUID; (b) middle SQUID and (c) bottom SQUID, see also Fig. 4.

single-layer inductively shunted DC-SQUIDs based on bicrystal grain boundary junctions [16]. The three primary SQUIDs can be combined electronically into a second-order gradiometer with 6 cm baseline. The two references can be used to correct for imbalance in the off-axis directions. Multi-layer insulation is added to reduce the heat load on the cooler and to reduce the effect of environmental temperature fluctuations on the temperature of the SQUID holder.

After the system was assembled, it was tested inside our magnetically shielded room [17] in order to verify that the cooler does not add to the intrinsic sensor noise. Fig. 5 shows the magnetic field noise densities of the three primary magnetometers as measured with the cooler on and off. In this experiment, the cooler compressor was placed outside the shielded room. The door of the room could, therefore, not be closed, resulting in relatively large high-frequency peaks in the spectrum. Furthermore, with the cooler operating, a significant increase in noise is observed below about 20 Hz. As this contribution decreases for increasing distance from the cooler cold head, we expect the source to be located in this cold head. It is most probably due to local remanent magnetization of the cold head, leading to the relatively large permanent magnetic field, mentioned above. Vibrations of the SQUIDs with respect to this field lead to additional noise. This is supported by similar results obtained by Hohmann [18]. Because of the large gradient in this remanent field, gradiometer operation of the SQUIDs does not adequately suppress it. It is obvious from Fig. 5 that a second-order gradiometer configured as 1-2-1 does not make sense since it is limited by the low-frequency cooler noise. As an alternative, we formed a first-order gradiometer of the bottom SQUID and the middle SQUID, and corrected for the cooler noise in it by means of the first-order gradiometer output obtained from the middle SQUID and the top SQUID. The resulting corrected first-order gradiometer is roughly: bottom $- 1.2 \times$ middle $+ 0.2 \times$ top. As an illustration, we measured the MCG of an adult inside the shielded room as depicted in Fig. 6. In this experiment, the compressor was also inside the room (about 2.5 m from the cold head). Because the compressor has a 49 Hz asynchronous motor powered with 50 Hz [18], a clear 1 Hz noise contribution results (top curve). By forming a first-order gradiometer this contribution is significantly suppressed. The remaining noise is dominated by the low-frequency cold-head noise (middle curve). The corrected first-order gradiometer shows a nice MCG with clear QRS-complexes and T-waves (lower curve). Here, the low-frequency noise is caused by breathing of the subject.

Next, the system was operated outside the shielded room (Fig. 7). In order to get proper

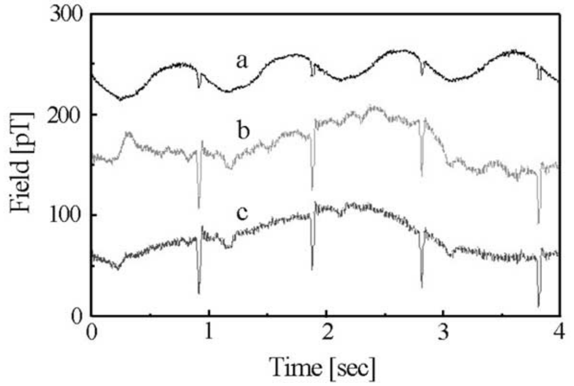

Fig. 6. MCG recorded inside shielded room with the cooler operating and the compressor inside the room: (a) magnetometer (divided by 5); (b) first-order gradiometer and (c) corrected first-order gradiometer (filters: digital, 0.5–100 Hz band; powerline notches; analog 500 Hz low-pass, 0.25 Hz high-pass).

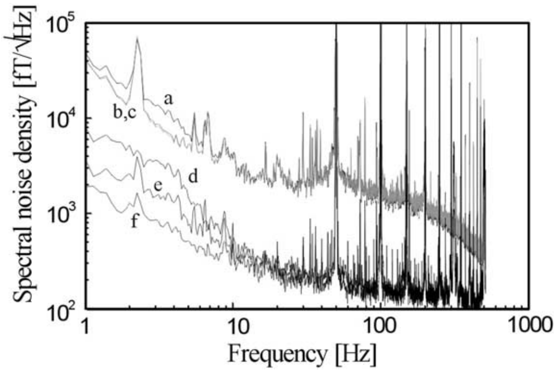

Fig. 7. Magnetic field noise spectra in unshielded environment with the cooler operating: (a) top SQUID; (b) middle SQUID; (c) bottom SQUID; (d) second-order gradiometer $(c - 2b + a)$; (e) first-order gradiometer $(c - b)$ and (f) corrected first-order gradiometer $(c - 1.2b + 0.2a)$.

SQUID operation, the background Earth magnetic field had to be compensated. This was done with a coil that was designed to fit around the sensor head and give the same field at all three sensor locations. The spectra show that the second-order gradiometer was indeed dominated by the same low-frequency disturbance as seen inside the shielded room. As the cooler noise exceeded the environmental disturbances, the first-order gradiometer had a lower noise than the second-order gradiometer. Moreover, a substantial improvement was obtained by constructing the corrected gradiometer, as discussed above. This indicates that even the first-order gradiometer was dominated by the low-frequency cooler noise. In these experiments the references were applied to improve the balance of the gradiometer (1–2% of the reference outputs).

In the near future, we will attempt to identify the source of the remanent magnetic field and try to demagnetize it. If this is not successful, an additional SQUID sensor is required to form a corrected second-order gradiometer. Apart from the low-frequency cold-head noise, the cooler appears to perform satisfactory.

4. Low-T_c experiments

Parallel to the instrumentation development described in the previous sections, low-T_c experiments were carried out in our Biomagnetic Centre Twente. This laboratory, located at a low-noise site of the campus, is equipped with a μ-metal magnetically shielded room [17]. Experiments were performed with a low-T_c 19-channel neuromagnetometer (noise level about 10 fT/$\sqrt{\text{Hz}}$ [19]) and a 3-channel vector gradiometer (about 2 fT/$\sqrt{\text{Hz}}$ [20]). The aim of these experiments was to investigate and to further develop the clinical relevance of fetal MCG. This research was carried out in direct cooperation with the hospital Medical Spectrum Twente in Enschede and other hospitals in the Netherlands. Results of various studies were presented elsewhere (e.g., Refs. [21–24]). In this paper, we consider two illustrative cases related to a so-called atrioventricular-block (AV-block).

A normal heart cycle as depicted in Fig. 8, starts with the depolarization of the atria (P-wave in the cardiogram), followed by the depolarization of the ventricles (QRS-complex in the cardiogram). Repolarization of the ventricles gives the so-called T-wave. Usually, the repolarization of the atria coincides with the depolarization of the ventricles and cannot be recognized in the cardiogram as it is obscured by the relatively large QRS-complex (see further Ref. [25]). A crucial element in the cycle is the AV-node that conducts the atrial impulse into the ventricles. Poor conduction through this node

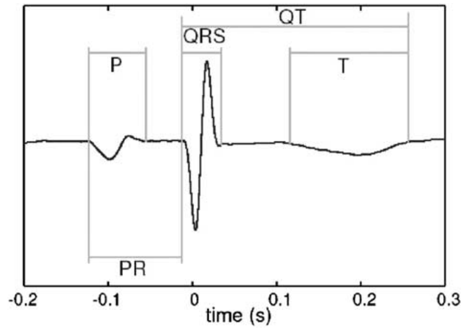

Fig. 8. An averaged fetal magnetocardiogram recorded in the 22nd week of gestation with a low-T_c system inside a magnetically shielded room.

generates an AV-block, of which three degrees are distinguished. In the first degree, every pulse is conducted through but with some delay. This results in an increased PR-time interval. In the second degree, not every pulse passes the AV-node. It takes two or more atrial impulses to stimulate the ventricular (QRS) response. In a two to one block, two P-waves show up followed by a single QRS-complex. Finally, in the third degree none of the atrial impulses is conducted through the AV-node. As a result, the ventricles or AV-node are stimulated by an ectopic pacemaker and the atria and ventricles operate fully asynchronously (complete heart block).

In fetal MCG, we have recorded AV-blocks in a number of patients. Two illustrative cases are given in Fig. 9. These are part of a study that we recently presented elsewhere [24]. In this study, fetal MCGs were recorded and discussed on 21 patients with either an arrhythmia or a congenital heart disease. Four fetuses showed a complete AV-block, two atrial flutter, nine ventricular extrasystoly, and one a completely irregular heart rate. Five fetuses had a suspected congenital heart defect. In the recorded fetal MCGs, obviously, signal amplitudes vary between patients, measurement positions and measured field components. However, the QRS-complex in fetal MCG is typically a few picoTesla in amplitude. In contrast, in adult MCG the QRS-complex is in the order of 100 pT.

5. Clinical relevance and feasibility

Over the last few years, fetal MCG has proven to be a useful tool for the detection and classification of arrhythmias and the study of congenital heart diseases [3,21–24,26–31]. As arrhythmias come in different forms, from innocent to life threatening, the classification is crucial to the treatment. The choice of drugs that can be prescribed depends on the type of arrhythmia. One has to keep in mind that intra-uterine pharmacological treatment involves a cardiac medicine to the mother, so one has to be extra careful with the prescription. As for congenital heart diseases, one can decide that the birth has to take place in a clinic with a department for pediatric cardiology. Clinically relevant information in the fetal MCG may be found in the duration of a certain wave or interval. An example mentioned above, is the PR-interval, of which a too high value indicates a first-degree AV-block. A database with data from many groups on the duration of the various waves and intervals is maintained by our research team

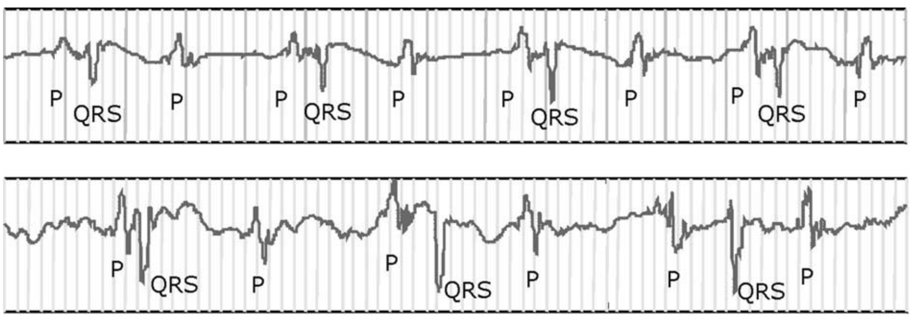

Fig. 9. AV-blocks recorded in fetal MCG (36th week of gestation). Top: second degree; bottom: third degree.

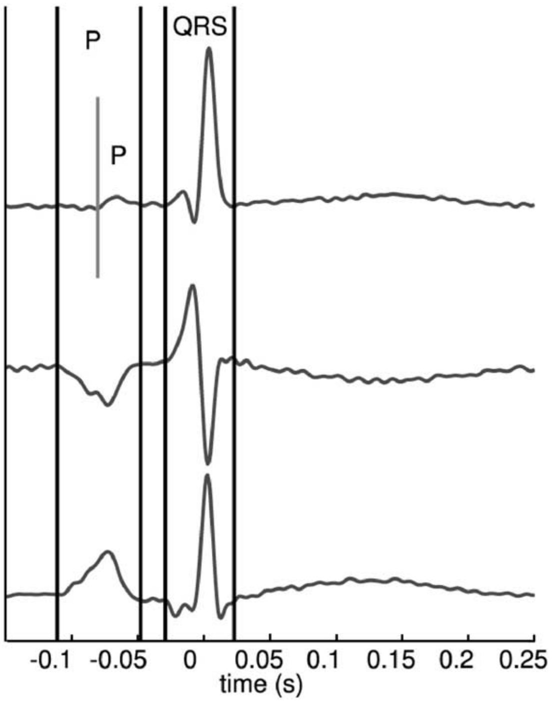

Fig. 10. Averaged fetal MCG signals from the 3-channels of a vector gradiometer [3,20].

[32]. Two important remarks have to be made with regard to relevance and feasibility.

Firstly, due to volume conduction effects the detected peak durations and intervals depend on the sensor position, orientation, and geometry. This was already studied and indicated for adult MCG by the PTB group [33,34]. An example for fetal MCG is given in Fig. 10 where averaged simultaneous signals from the three channels of our vector gradiometer are depicted [3,20]. Note the differences in timing, especially on the duration of the P-wave and on the PR-interval. As a result, fetal MCG will require multi-channel systems, preferably measuring multiple field components. The required number of channels, however, is quite low compared to clinical MEG systems. Probably, about 10 sensors spread over the maternal abdomen are adequate [35].

The second important remark on relevance and feasibility is that for adequately recognizing the QRS-peak and even more the P-wave in the raw data, the targeted SQUID resolution of 50 fT/$\sqrt{\text{Hz}}$ is not good enough. Based on our low-T_c experiments and data collected from other groups, we conclude that a field resolution of at least 10 fT/$\sqrt{\text{Hz}}$ is required. This will be hard, if not impossible, to realize in high-T_c technology, certainly for a commercial product. This is even more so since a resolution of 10 fT/$\sqrt{\text{Hz}}$ in unshielded environment will require a third-order gradiometer with a baseline of several centimeters. We conclude, therefore, that it is attractive to investigate a 4 K FHARMON: a fetal heart monitor with the same characteristics as our original monitor, but operating with low-T_c SQUIDs at about 4 K with a resolution of 10 fT/$\sqrt{\text{Hz}}$. This resolution is possible at 4 K also in unshielded environment as was shown by Vrba of CTF [6]. It is obvious, however, that in our FHARMON target a "no-noise" cooler is required. Unfortunately, that is not available at present. With proper interfacing, perhaps a pulse-tube cooler may be applied [36]. Alternatively, we see good possibilities for our sorption-cooler technology [37,38].

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