35th Annual International Conference of the IEEE EMBS
Osaka, Japan, 3 - 7 July, 2013

An optically coupled system for quantitative monitoring of MRI gradient currents induced into endocardial leads.

E. Mattei, G. Calcagnini, M. Triventi, A. Delogu, M. Del Guercio, A. Angeloni and P. Bartolini
Department of Technology and Health, Italian National Institute of Health, Rome, Italy

***Abstract*—The time-varying gradient fields generated during Magnetic Resonance Imaging (MRI) procedures have the potential to induce electrical current on implanted endocardial leads. Whether this current can result in undesired cardiac stimulation is unknown. This paper presents an optically coupled system with the potential to quantitatively measure the currents induced by the gradient fields into endocardial leads during MRI procedures. Our system is based on a microcontroller that works as analog-to-digital (A/D) converter and sends the current signal acquired from the lead to an optical high-speed light-emitting-diode transmitter. Plastic fiber guides the light outside the MRI chamber, to a photodiode receiver and then to an acquisition board connected to a PC. The preliminary characterization of the performances of the system is also presented.**

INTRODUCTION

Magnetic resonance imaging (MRI) has become the imaging procedure of choice for extensive clinical evaluation and diagnosis. Thanks to its no-ionizing nature, MRI is considered safe for the majority of patients; however, it is contraindicated in patients with implantable devices such as pacemakers (PM) and implantable cardioverter/defibrillators (ICD). Even when the implant is labeled as MR-conditional, great care is still needed and the examination can be safely performed only if a series of conditions, given by the manufacturer, are met. The most concerning MRI-related hazards derive from the radiofrequency (RF) and the gradient fields used to obtain the images of human body. The high-frequency (64 MHz for 1.5T MRI systems; 128MHz for 3T systems) RF field potentially can transfer energy into implanted electronic devices and cause thermal injury to tissue, near the tissue–electrode interface. MRI gradient fields, on the other hand, have a much lower frequency (1–10 kHz) and are used to provide spatial information. The interaction between the time-varying MRI gradient field and the conductive loop formed by the implanted lead can be considered an instance of electromagnetic induction, per Faraday's law. Whereas a large body of excellent works have been published about the RF-induced heating into endocardial lead, few studies have specifically addressed, to date, the amount of the current induced by time-varying gradient fields [1,2]. Clinical studies have reported ectopic beats in patients with PM or ICD undergoing MRI scans [3,4]. Indeed, whether the gradient-induced currents represent an actual risk for patients with endocardial leads undergoing MRI is still unknown. This is due to the difficulties to measure directly the amount of gradient-induced currents during an MRI examination.

This paper proposes the design of a sensor that can form the basis for an external gradient fields *in-vitro* monitoring system during MRI procedures.

I. DESIGN OF THE CURRENT MONITORING SYSTEM

The overall scheme of the current monitoring system is reported in Fig 1. The circuitry is placed inside a sealed PVC (Polyvinyl Chloride) box that allows the system to be immersed in saline solutions that are typically used to simulate body tissue in MRI safety *in-vitro* studies. The whole circuit is realized on a 3x4 cm board, with SMD (surface-mount device) components, to allow the compatibility with the MRI conditions.

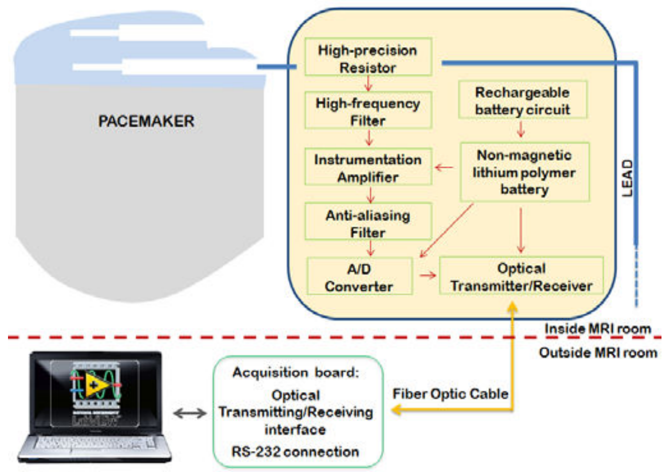

Figure 1. Schematic representation of the gradient-induced current monitoring system.

A. *The sensing resistor*

The current signal is picked up as the voltage drop across a high precision resistor placed between the pulse generator (PM or ICD) and the lead. The resistor used as current sensor must be chosen to allow for a signal-to-noise-ratio fair enough to be correctly interpreted by the system, but at the same time not to affect the overall impedance seen by the stimulator. Given an equivalent resistance of the body tissue of about 300 Ohm and assuming to be able to detect current greater than 1 mA, a tradeoff value of 10 Ohm was chosen.

B. *The High-frequency Filter*

The first conditioning block of the monitoring system is a low-pass filter to reduce the high-frequency components of the signal, in particular those generate by the pulsed RF field. The filter is a 2°-order low pass filter, obtained by two RC networks that realize a cut-off frequency of 1MHz. At 64 MHz (RF used in 1.5T MRI system), the attenuation is more than 60 dB. On the other hand, in the gradient fields band (1-10kHz) the attenuation is negligible.

C. *The instrumentation amplifier*

The signal from the high-frequency filter is amplified by an instrumentation amplifier (INA327, Texas instrument, USA). The INA327 circuit is a precision, rail-to-rail input/output instrumentation amplifier, which can be driven by a single supply. This latter feature is compatible with the use of a single battery feeding the whole circuit. Since the input signal can be both positive and negative (the current induced by the gradient fields can flow along the lead in both directions), it is necessary to shift the inputs of the amplifier to a positive resting value. Using a positive single supply, indeed, a resting value of 0V will not allow for the detection of the negative portion of the alternating signal. In particular, the inputs shall be shifted to almost half of the voltage supply: given a supply of 3.7V (compatible with all the components of the monitoring system), a voltage reference of 2.048V (REF3120, Texas Instrument, USA) was used. The rail-to-rail input/output of the amplifier increases the signal immunity to common-mode disturbances and guarantees the maximum range at the output stage. A gain factor of 5 was chosen, as a function of the following A/D converter input stage.

The INA327 can also operate in sleep-mode and reduce its power consumption till a wake-up signal is applied.

D. *The Anti-aliasing filter*

Before the A/D conversion of the signal, an anti-aliasing filter was implemented to meet the requirements of the Nyquist–Shannon sampling theorem. The filter consists of a 2°-order RC low-pass filter, with a cut-off frequency of 5kHz. The attenuation of this filter can be neglected up to 1kHz, and is about -14 dB at 10kHz. The choices adopted for the anti-aliasing filter will be better explained in the following sections.

E. *The A/D converter*

The optical transmission of the current signal requires its analog-to-digital conversion. It is obtained by the A/D converter module of a microcontroller (PIC16F876, microchip, USA). The microcontroller operates a 10-bit A/D conversion of the signal acquired at one of its input channels and then sends the digital data to the USART (Universal Synchronous Asynchronous Receiver Transmitter) output port. In order to obtain an appropriate sampling frequency, the baudrate of the USART port was set to the highest available value, i.e. 460800 bit/s. An external clock operating at 14.4756 MHz was used to minimize the bit-error rate (BER) at the desired baudrate (theoretical BER at 460800 bit/s =0%). When not operating, the microcontroller enters the sleep-mode operation to preserve the battery charge and starts the A/D conversion only when an external wake-up signal is applied to one if its input channels. The transmission of the digitalized signal to the USART interface requires 8 bits data codes: it implies that the result of each A/D conversion (10 bit) needs two data blocks, for a total of 16 bits. The bits that do not represent the result of conversion are used to create a transmission mask useful to properly decode the signal and check for potential transmission errors. In particular, the code adopted to transmit the digitalized data to the USART port is described in Fig. 2.

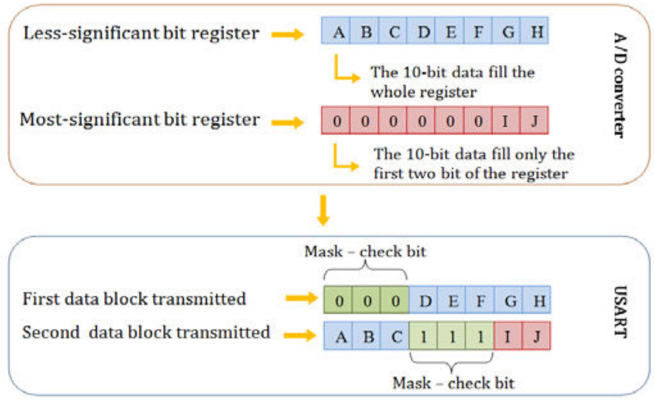

Figure 2. Transmitting code scheme.

The transmission rate, and therefore the sampling frequency of the system, is affected not only by the baudrate of the USART port, but also by the time that the microcontroller requires to complete the A/D conversion. Neglecting such delay, a baudrate of 460800 bit/s corresponds to a theoretical sampling frequency of about 23 kHz: the result of a A/D conversion cycle is made up of two blocks of 8 bit, each one with two additional bit of start and stop, for a total of 20 bit per cycle. The cut-off frequency of the anti-aliasing filter that precedes the A/D converter has been chosen to limit the frequency band of the input signal to about ¼ of the final sampling frequency. The firmware of the microcontroller can be programmed directly from the circuit, using the ICSP (in-circuit serial programming) connections and tools (MPLab 2, microchip, USA).

F. *The optical transmitters/receiver*

The USART port of the PIC16F876 drives a transmitting photodiode integrated inside a fiber optic link (AFBR-1522, Avago Technology, USA). Beside the transmitting line that guides the light signal outside the MRI chamber, a receiving line for the wake-up interrupt was also implemented: a photo Darlington (SD1410, Honeywell, USA), placed inside a custom-made plastic housing that couples the light with a standard fiber-optic connector, was used to convert the external light signal into a TTL compatible signal that wakes up from the sleep-mode both the INA327 and the PIC16F876.

G. *The battery circuit*

The whole system is supplied by a single non-magnetic lithium polymer battery (PGEB-NM053040, PowerStream Technology, USA). The battery is extremely light (11g) and its dimension are comparable to those of a standard PM (5x30x50 mm). Its nominal voltage is 3.7V, and the rated capacity is 600 mA/h. The absence of magnetic components allows for its use inside the MRI room, even inside the scanner bore. A rechargeable circuit was implemented to recharge the battery without the need to remove it from monitoring system.

In order to constantly monitor the battery status before each measurement session, two inputs channels of the microcontroller (different from the one used to acquire the current signal) have been connected to the negative pole of the battery (virtual ground) and to the voltage reference value at 2.048V. Before starting the conversion of the signal acquired from the sensing resistor, the microcontroller generates a square wave having as low level the voltage read at the input channel connected to the virtual ground and as high level the reference voltage at 2.048 V. Since, the range of the A/D module is limited by the positive voltage of the battery (3.7V) and the virtual ground, the square wave can be used to check the actual value of the battery voltage:

$$V^{+}_{batt} = \frac{V_{ref} \cdot 1024}{HL} \qquad (1)$$

Where V_{ref} is 2.048V, 1024 the full-scale of the 10-bit A/D converter, and *HL* the high level of the square wave at the output of the converter. The ratio V_{ref}/HL defines also the conversion factor to express in terms of voltage (V) the digitalized current signal.

H. The acquisition board

A 10-m long fiber optic cable guides the light signal outside the MRI room, where an acquisition board converts it into an electrical signal compatible with standard RS-232 serial data. The board converts also the wake–up signal into a light beam to be transmitted to the monitoring system. A couple of receiving/transmitting photodiodes (AFBR-2522 and AFBR-1522, Avago Technology, USA) was used to optically couple the acquisition board with the monitoring system, and a SN65C3223E (Texas Instrument, USA) was used as RS-232 line driver/receiver. The acquisition board can be supplied from a standard 12V power supply and it is connected to a RS232 serial port of a PC laptop.

A LabView-based (National Instruments, USA) software interface was developed to display, analyze and save the data acquired from the monitoring system and to generate the wake-up signal for enabling the instrumentation amplifier and the microcontroller.

Fig. 3 shows the schematics of the current monitoring system. Surface-mount components were chosen to reduce the size of the circuit in order to minimize the coping with RF and gradient fields, as well as the amount of metallic materials.

II. CHARACTERIZATION OF THE CURRENT MONITORING SYSTEM

A. Power consumption

One of the main constrain of the monitoring system is the need to operate with low power consumptions. When the system operates in sleep-mode, the overall consumption of the system is limited to few µA. In normal operation mode, the power consumption increases up to almost 15 mA; the most demanding component is represented by the transmitting photodiode, which, in case of continuous transmission, drains up to 15 mA. In normal conditions, however, the consumption is about 7 mA (duty cycle of the transmitted signal=50%). The lithium polymer battery chosen to supply the circuit, having a capacity of 600 mA/h, guarantees enough energy for several hours of operation.

B. Range of the input signal

The potential for an electrical current to induce myocardial capture depends upon the current frequency and the stimulus duration. At the frequency of MRI gradient fields (1-10kHz) and given the typical duration of a gradient sequence (several ms), a capture of the myocardium can be expected with currents higher than few mA. Preliminary measurements were performed by applying sinusoidal signals varying from DC to 10 kHz. The monitoring system is able to detect signal > 1mA, which correspond to a voltage across the sensing resistor of 10 mV.

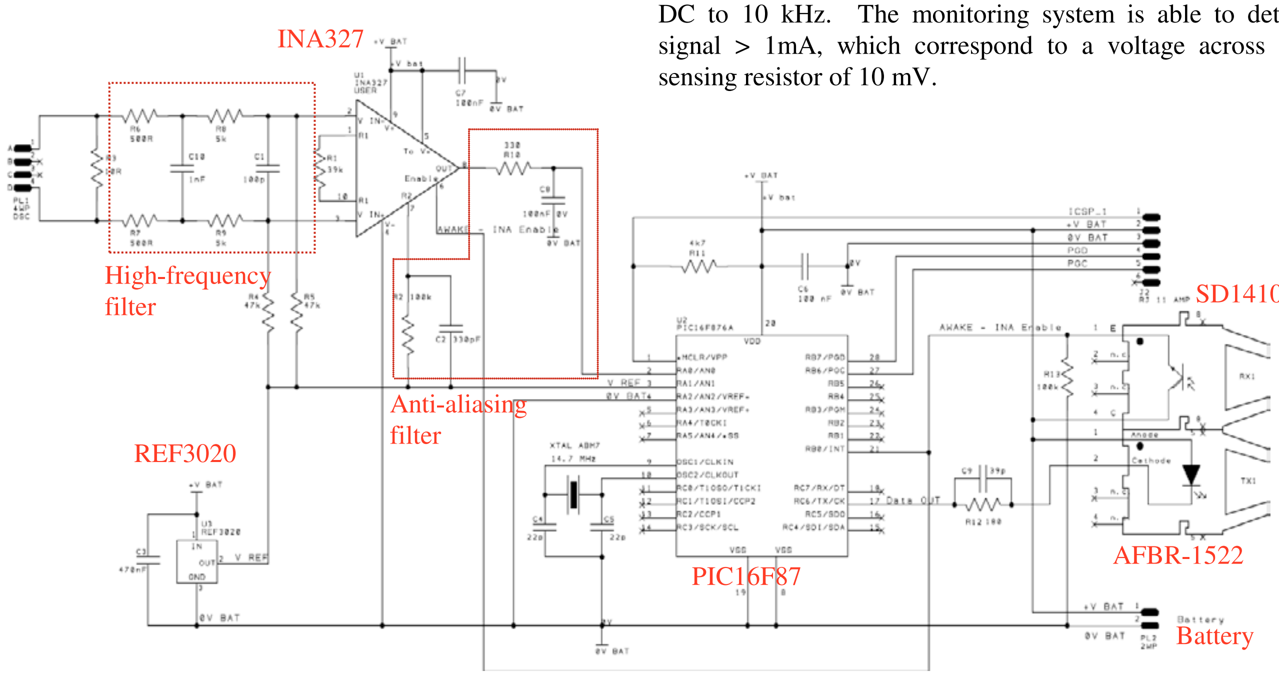

Figure 3. Schematics of the current monitoring system.

The instrumentation amplifier can correctly operate when the input signal rage (V_{max}-V_{min}) is between:

$$V^{-}_{batt} < V_{min} < V_{ref} \quad \rightarrow \quad 0\ V < V_{min} < 2.048\ V \qquad (2)$$

$$V_{ref} < V_{max} < V^{+}_{batt} \quad \rightarrow \quad 2.048\ V < V_{max} < 3.7\ V \qquad (3)$$

We can thus define the maximum rage allowed for the proper detection of the induced current:

$$I_{min} > -205\ mA\ ; \quad I_{max} < 165.2\ mA \qquad (4)$$

Actually, the maximum amplitude of the current signal detectable without distortions is lower than what indicated in (4), given the gain factor of 5 set for the instrumentation amplifier and the input range of the microcontroller, limited by the battery voltage (3.7 V).

C. The Sampling Frequency

The actual sampling frequency of the system has been calculated by acquiring a sinusoidal signal at a given frequency, and then by computing the FFT of the signal, as a function of the sampling frequency. The latter has been varied till the peak of the FFT matched the frequency of the acquired signal. In this way, a sample frequency of 20.5 kHz was obtained. This value is a little lower than the theoretical one of 23 kHz, and it is justified by the time needed by the microcontroller to complete the A/D conversion before sending the data to the USART port. Fig. 4 reports the acquisition of a 1 kHz sinusoidal signal and the computed FFT for the calculation of the sampling frequency.

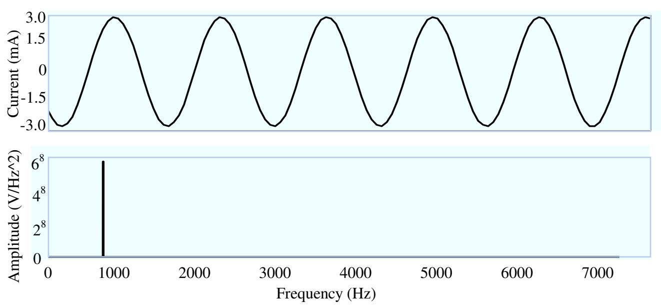

Figure 4. Calculation of the sampling frequency of the system. A 1 kHz sinusoidal signal is acquired and its sampling frequency is computed from the FFT analysis.

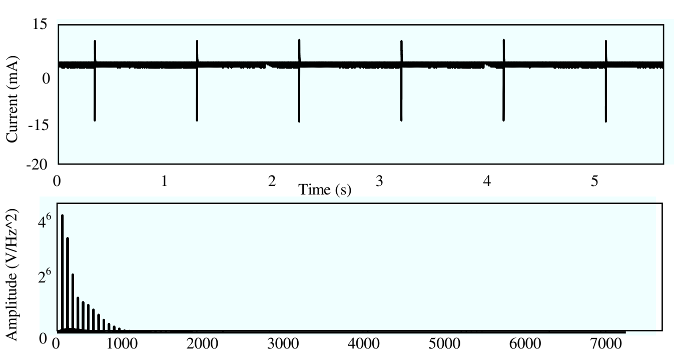

Figure 5. PM activity recorded by the current monitoring system during the MRI scanning (upper panel); FFT of the acquired signal (lower panel).

D. Measurements inside the MRI scanner

In-vitro measurements were performed inside a clinical MRI-scanner (Philips Achieva X series, *Philips Healthcare* – 3T) to verify the system performances. The PM and the monitoring system were placed inside a plexiglass box (40x20x20 cm^3) filled with saline solution to simulate the RF properties of human tissues. Fig. 5 show the recording of the PM pulses during the generation of the MRI sequence.

III. Conclusions

The final circuit for the gradient-induced current monitoring is depicted in Fig.6.

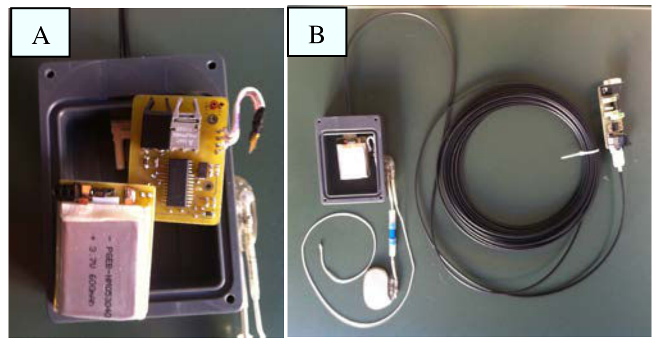

Figure 6. Pictures of the gradient-induced current monitoring system: A) circuit components; B) overall system.

The monitoring system represents a research tool that can be used to obtain quantitative information about the amount of gradient-induced current along endocardial leads, during *in-vitro* sessions. Such information is critical to continue pursuing MRI scanning of patients with PM, ICD or similar active implantable medical devices. In particular, the limitations that today are given for MR-conditional implant, mainly based upon a pure precautionary principle, could be removed or at least made less strict. The proposed system can also be used to monitor PM or ICD activity during MRI procedure or in any other similar environments, where the presence of metal wired connection could affect the measurements and the quality of the data acquired.

Acknowledgment

The research is part of the strategic project "Direct and indirect risks for the safety of workers and patients from new electromagnetic sources in the healthcare environment", funded by the Italian Ministry of Health.

References

[1] Tandri H, Zviman MM, Wedan SR, Lloyd T, Berger RD, Halperin H. Determinants of gradient field-induced current in a pacemaker lead system in a magnetic resonance imaging environment. Heart Rhythm. Mar; 5(3):462-8, 2008.

[2] Bassen HI, Mendoza GG. In-vitro mapping of E-fields induced near pacemaker leads by simulated MR gradient fields. Biomed Eng Online. Dec; 15:8-39, 2009.

[3] Fontaine JM, Mohamed FB, Gottlieb C, et al. Rapid ventricular pacing in a pacemaker patient undergoing magnetic resonance imaging. Pacing Clin Electrophysiol; 21:1336 –1339, 1998.

[4] Mollerus M, Albin G, Lipinski M, Lucca J. Ectopy in patients with permanent pacemakers and implantable cardioverter-defibrillators undergoing an MRI scan. Pacing Clin Electrophysiol. Jun; 32(6):772-8, 2009.