A novel heart/trunk simulator for the study of electromagnetic interference with active implantable devices

A. Angeloni V. Barbaro P. Bartolini G. Calcagnini F. Censi

Biomedical Engineering Laboratory, Istituto Superiore di Sanità, Roma, Italy

Abstract—*This paper describes a portable heart simulator for the study of electromagnetic interference with active implantable devices. The simulator consists of plexiglas™ box divided into three chambers simulating the left atrium and the ventricles, plus a lateral compartment for the implantable device. The box is linked to a laptop computer by an analogue-to-digital convertor board, and the three chambers are monitored and driven by dedicated hardware and software interfaces. Synthetic endocardial atrial and ventricle signals for 13 cardiac rhythms are stored in the computer. They are applied to the cardiac chambers by AgCl plates. Sensing electrodes are in the form of AgCl needles inserted in saline. The simulator was able to demonstrate the behaviour of three pacemakers tested in the absence and presence of electromagnetic interference, generated by mobile phones (European GSM 900 and 1800 MHz) that emitted up to 2 W (1 W at 1800 MHz). Pacemakers can be programmed with sensitivity from 0.1 mV to 5 mV, pulse width from 0.1 ms to 1.5 ms and pulse amplitude from 0.5 V to 5 V. The structural separation in three cardiac chambers (plus the one for the device) allowed a fast analysis procedure for dual- and tri-chamber implantable devices.*

Keywords—*Electromagnetic compatibility, Cardiac implantable devices, Heart/trunk simulator*

Med. Biol. Eng. Comput., 2003, **41**, 550–555

1 Introduction

When a device containing electronic circuitry is exposed to electromagnetic fields, electromagnetic interference (EMI) may occur. Since the first report by Furman *et al.* (FURMAN *et al.* 1968), the problem of EMI between mobile phones and pacemakers has continued to interest physicians (BARBARO *et al.* 1995, HAYES 1996, CARILLO *et al.* 1995, IRNICH *et al.* 1996, BARBARO *et al.* 1996), as the effects of EMI on patients with pacemakers or defibrillators are potentially life-threatening. Given the continuous changes in the telecommunications field, it has been felt necessary to monitor the adverse effects of electromagnetic fields radiated from mobile phones on implantable heart-pacing devices. Several investigations have been carried out, both *in vivo* and *in vitro* (IRNICH *et al.* 1996, BARBARO *et al.* 1996, CHILADAKIS *et al.* 2001, BASSEN *et al.* 1998, FETTER *et al.* 1998, BARBARO *et al.* 1999). *In vitro* studies are needed in various interrelated fields such as the design of new devices, premarket approval testing and certification, accident investigations and electromagnetic compatibility testing of non-medical devices operated in close proximity to implantable devices. The experimental setup used for *in vitro* studies has typically consisted of simulators for simulating the electrical activity of the heart and the electrical characteristics of the human torso, where the heart signal propagates. (BARBARO *et al.* 1995, IRNICH *et al.* 1996, BASSEN *et al.* 1998, RUGGERA *et al.* 1997). The torso simulators consisted of plastic boxes filled with saline solution with both sensing and stimulating electrodes. This reproduced the electrical activity of one single cardiac chamber. Pacemaker operation was monitored, and spontaneous heart activity was simulated by avoiding any ohmic connections between the pacemaker lead and signal sources. The saline solution prevented radio frequency signals from reaching the lead as a result of coming into contact with the instrumentation and wiring used to generate the synthetic signals.

Due to the technological evolution of active implantable devices, dual-chamber devices are widely used, and triple-chamber devices have been recently introduced. These are due to sense and stimulate the right atrium and both ventricles. The latest devices use sophisticated arrhythmia-detection algorithms and electric therapies, and new procedures are necessary to test their performance and robustness with regard to EMI. In addition to the various forms of telecommunications equipment, a number of other apparatuses (magnetic resonance equipment, metal detectors, electronic article surveillance systems, security systems) can interfere with active implantable devices.

So as to account for such a rapidly developing technological scenario, we have designed a novel simulator of the electrical

Correspondence should be addressed to Dr Giovanni Calcagnini; email: giovanni.calcagnini@iss.it

Paper received 23 January 2003 and in final form 25 April 2003

MBEC online number: 20033806

activity of the three cardiac chambers and its propagation into the human trunk, capable of detecting pacemaker electrical activity in response to both bipolar simulation and unipolar simulation (where the titanium case of the pacemaker is used as the reference).

2 Design and realisation of the triple-chamber cardiac simulator

2.1 *Previous heart/trunk simulators*

The torso simulator previously used in our laboratory to test cellular phone interference with pacemakers was similar to the one developed at the Center for Device and Radiological Health (BASSEN *et al.* 1998, RUGGERA *et al.* 1997); except for the size of the tank and the conductivity of the solution. This simulator reproduced the electrical activity of one single cardiac chamber. It consisted in a saline-filled plastic box with sensing and stimulating electrodes. The saline (with a conductivity as similar as possible to that of the human trunk) simulated the tissue surrounding the implantable device. The electrical activity of the heart was simulated using a pulse generator and applied to two electrode plates on opposite sides. Two sensing electrodes were positioned at opposite sides, connected to an oscilloscope and used to monitor the electrical output of the device.

The pacemaker was submerged in the solution and made to rest on a plastic grid. The lead connected to the device was arranged into a spiral and anchored to the grid. The cellular phone was placed on another plastic grid on top of the box.

2.2 *Triple-chamber heart/trunk simulator*

The cardiac simulator is composed of the following blocks shown in Fig. 1.

(a) A plexiglas^{TM} box divided into three chambers simulating the right atrium and the ventricles, plus a lateral compartment for the implantable device.
(b) A hardware interface consisting of a board (PCMCIA DaqCard 6062E)[†] and electronic circuits that monitor and stimulate the three chambers.
(c) A software interface developed in Labview 6.0[‡]

2.2.1 *Triple-chamber box*

The design of the plexiglas^{TM} box ($18 \times 25 \times 14$ cm, 5 litres) accounts for the physiological, electrical and anatomical features of the heart, such as the stimulation of heart tissue and the electrical insulation of the cardiac chambers. The plexiglas^{TM} box contains a 0.9% saline solution. It is actually divided into four chambers as shown in Fig 2, one chamber simulates the right atrium, two others simulate the ventricles and a lateral one serves as a compartment for the implantable device.

Five connecting openings (between the lateral chamber and the atrium, between the lateral chamber and one of the ventricles, between the atrium and both the ventricles and between the ventricles) account for the blood actually passing through the cardiac chambers and for the conductive tissue existing between the device implant site and the heart. Since the real cardiac chambers are electrically isolated, the channels are opened at the bottom of each chamber, where the electric field generated by the plates is at its lowest. The channels are also necessary for the lead of the implantable device to be placed in one of the chambers submerged in saline, avoiding open air exposure. Atrial and ventricular signals are simulated by a laptop computer through the analogue output of the ADC board, and applied to the cardiac chambers by AgCl plates, in order to reduce the possibility of polarisation. AgCl plates were chosen for their high level of performance in terms of polarisation and noise reduction and positioned in the upper part of the inner walls of each chamber, just below the saline surface, on opposite sides.

Fig. 3 shows a picture of the triple-chamber plexiglas^{TM} box. A dual-chamber pacemaker is positioned in the lateral compartment and the two leads are anchored to the grids, in the right atrium and in the right ventricle.

Fig. 4 shows the spatial distribution of the electric field in the three chambers, and the peak-to-peak electrical field values reported in V m^{-1}, when a sine wave (30 Hz, 10 Vpp) is applied to the silver-chloride square plates. The spatial distribution of the electrical potential is measured using a pen-shaped, sealed AgCl electrode. Each chamber is equipped with a plastic grid, adjustable from 0 to 5 cm below the saline surface, that supports the device and the leads. A plastic top covers the entire box.

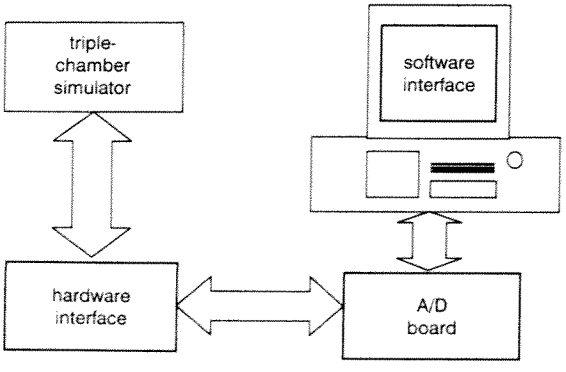

Fig. 1 *Block diagram of cardiac simulator*

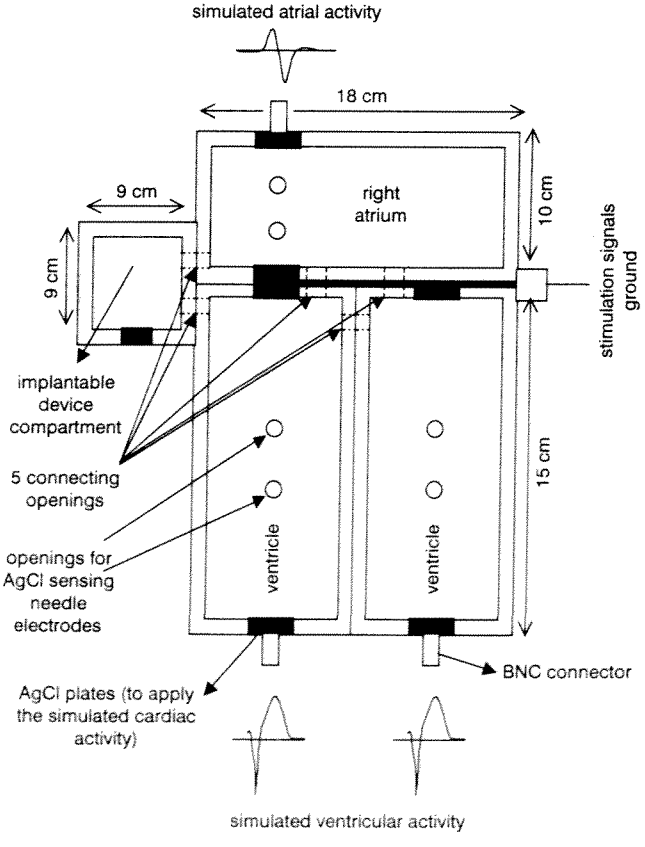

Fig. 2 *Planar view of plexiglax^{TM} box*

[†]National Instruments, Texas, USA
[‡]National Instruments, Texas, USA

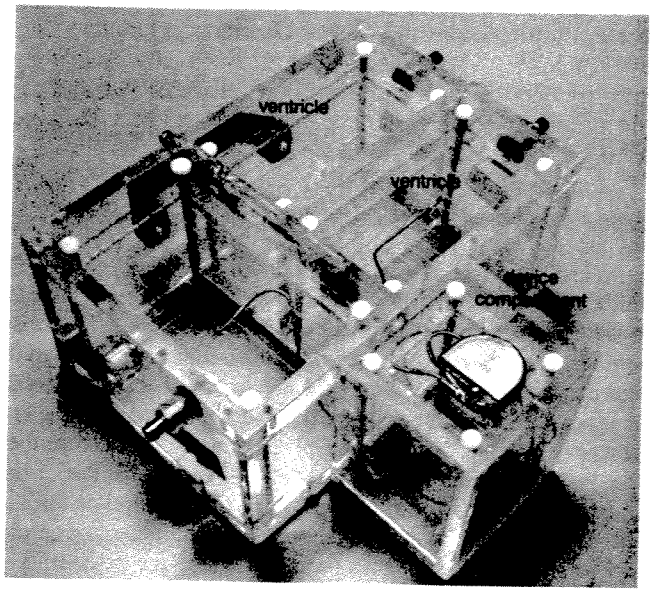

Fig. 3 *Picture of triple-chamber plexiglas™ box*

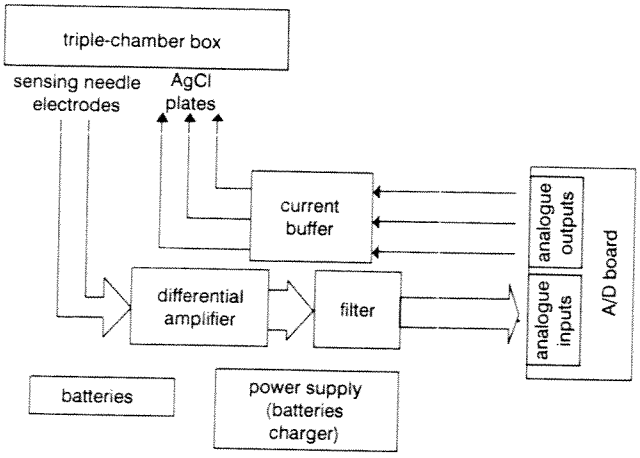

Fig. 5 *Block diagram of hardware interface module*

2.2.2 *Hardware interface*

The hardware interface module allows for both the acquisition and generation of the cardiac signals inside the box. The block diagram of this module is reported in Fig. 5.

Generation of stimulation signals: Typical bipolar pacemaker leads use a ring-shaped electrode and a tip electrode, at variable distance (about 1 cm apart). As the sensitivity of these implantable devices ranges between 0.1 and 7.0 mV, an electric field as high as 7 mV cm^{-1} must be generated inside the box. The stimulation signal in the simulator is applied to the pair of AgCl plates positioned at opposite sides of each chamber and separated by the saline solution. We found that 40% of the signal is lost at the plates owing to interface polarisation phenomena; a further loss occurs inside the solution.

In order to pick up the strongest possible stimulation signal, the lead was always positioned parallel to the electric field lines and anchored to the plastic grid.

Since the simulator has a relatively low resistance (about 500 Ω), the maximum output current typically provided by the ADC boards (<10 mA) was not sufficient to properly drive the chambers. Thus, a current buffer was introduced, which allows for higher current and voltage stimulation. We used an EL2001C buffer[†] that provides up to 100 mA, connected to a ±12 V power supply.

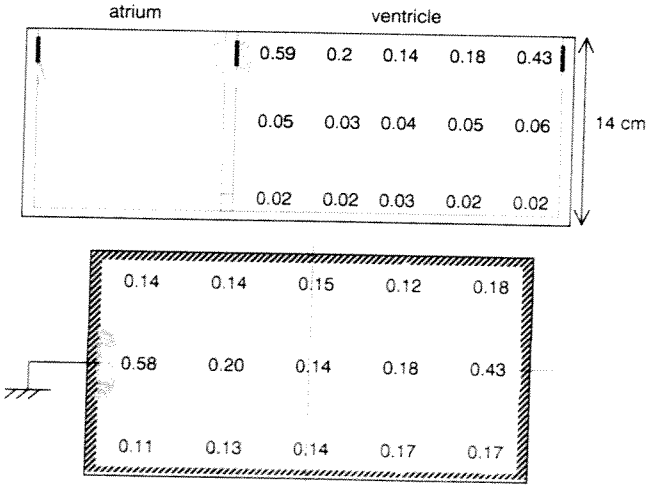

Fig. 4 *Electrical field lines inside simulator: (a) lateral view; (b) planar view of ventricle. Peak-to-peak electrical field values reported in V m^{-1}, when a sine wave (30 Hz, 10 V_{pp}) is applied to chloride-silver square plate.*

Signal acquisition and monitoring: The sensing electrodes took the form of AgCl needles inserted into the saline through openings in the plastic top, at 5 cm intervals. The sensed signals were amplified using a low-noise instrumentation amplifier (INA114AP)[‡] DC connected to the electrodes. With a common mode voltage (up to 300 mV) inside the box, we set the gain at 10. To increase low-frequency noise rejection, an active shielding configuration was used. A low-pass filter stage (−3 dB frequency, 500 Hz, second-order Butterworth) was also used to band-limit the signal for the AD conversion. The currents supplied to the chambers were also estimated and displayed by measuring the voltage drop across a 10 ohm resistance. The voltage and current signals were also recorded on hard disk for off-line analysis. Zener diodes were used to protect both the output and input channels from defibrillation shocks in the event of tests on defibrillators.

2.2.3 *Software interface module*

The software interface module was developed in Labview 6.0. It manages the graphic interface, and controls and records the simulator signals. Thirteen possible cardiac rhythms can be selected by the user, including normal sinus rhythm, atrial and ventricular fibrillation and various arrhythmias. We used actual endocardial signals for the atrium and ventricles, which we recorded using a patient simulator[†] and stored in the computer.

In addition, the simulator reacts to the electrical therapy delivered by the device under test, as does the heart (e.g. synchronisation after pacing and sinus rhythm restoring after defibrillation or cardioversion). This function mimics the behaviour of the heart and ensures that the devices can be more effectively tested.

3 Performance evaluation

To asses the performance of the system, we conducted experiments on three pacemakers (Minor 100*, Living 1 Plus[†], and Millennium D,[†]), with and without radio frequency interference. An oscilloscope was also used to monitor the signals delivered to, and coming from, the box.

[†]Elantec, California, USA
[‡]Burr-Brown, Texas, USA
[†]Biotronik, Berlin, Germany
*Sorin, Saluggia, Italy
[†]Sorin, Saluggia, Italy
[‡]Medico, Padova, Italy

The three pacemakers had 0.4 mV atrial sensitivity and 1.2 mV ventricle sensitivity. The stimulation amplitude for both the chambers was 1.4 V, with a duration of 1 ms. Stimulation and sensing were performed in bipolar mode. The experiments were repeated, changing the pacemaker programming to evaluate the simulator functioning over a wide range of conditions.

The stimulation cases were:

(a) No cardiac signal.
(b) Normal sinus rhythm that inhibits the pacemaker in the atrium.
(c) Various cardiac arrhythmias.

The setup for measuring the RF interference of a base station simulator[¶] and a commercial mobile phone[§]. The latter emits up to 2 W (1 W at 1800 MHz). The mobile phone antenna was positioned parallel to the device, at a distance of 0.5–2 cm, in order to ensure that the signal picked up was as strong as possible.

So that it was treated under worst case conditions, the implantable device was set to maximum sensitivity. The base station was set to transmit at 900 MHz, with the mobile phone was set at its maximum transmission power. The inhibition signal amplitude was set above the sensing threshold.

We analysed three situations:

(a) Call from mobile and short talking period.
(b) Call to mobile with no answer (ringing).
(c) Call to mobile with answer.

4 Results

Fig. 6*a*, shows the atrial and ventricular pacemaker stimulation signals (at 45 beats min^{-1}) separated by the typical atrioventricular delay, when no cardiac signals are delivered to the chambers.

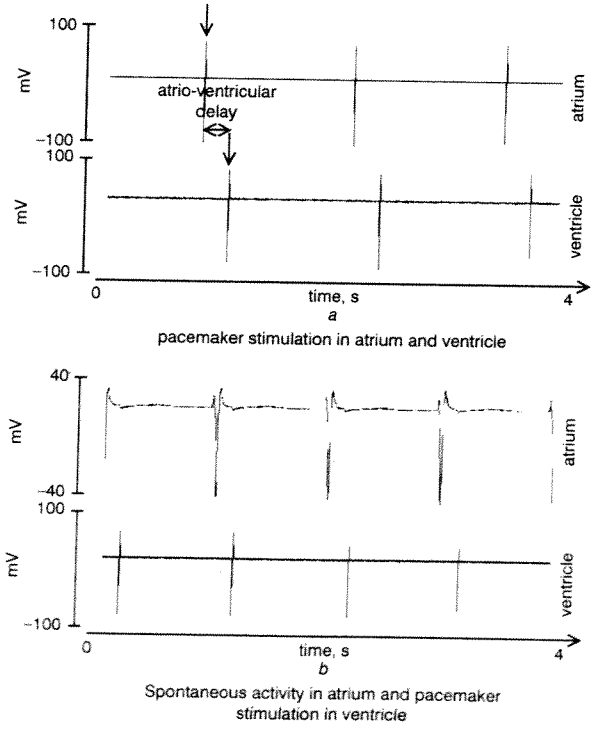

Fig. 6 *(a) Pacemaker stimulation in atrium and ventricle at 45 beats min^{-1}, with typical atrioventricular delay and when no cardiac signals are delivered to the chambers, (b) spontaneous sinus rhythm at 60 beats min^{-1} in atrium, followed by synchronous pacemaker stimulation in ventricle*

[¶]Rohde & Schwarz, mod. CMD 55)

[§]Ericsson SH888, European GSM 900 and 1800 MHz

Fig. 6*b* shows that a spontaneous sinus rhythm at 60 beats min^{-1} inhibits the pacemaker in the atrium and that the pacemaker stimulates the ventricle synchronously with the atrium. With this multiple-chamber simulator, atrial and ventricular sensing and pacing of implantable devices can be tested using a single procedure. Previous work using single-chamber simulators, meant that several tests had to be carried out. Fig. 7 highlights the capability of the multiple-chamber simulator in assessing particular features of a modern dual-chamber pacemaker. Fig. 7*a* shows the behaviour of the pacemaker during atrial fibrillation. When the atrial activity is lower than the pacemaker sensitivity threshold (until time t_0), the pacemaker stimulates both the atrium (atrial spike, A_1) and the ventricle synchronously, i.e. with the programmed atrioventricular delay (first ventricular spike, V_1). When the atrial activity exceeds the sensitivity threshold, the pacemaker recognises it as atrial fibrillation and (by means of a mode-switching algorithm) changes to non-tracking mode: it inhibits activity in the atrium and starts stimulating the ventricle at the programmed rate, regardless of the atrial activity. Figure 7*b* shows the behaviour of a different pacemaker that this time fails to recognise the atrial fibrillation. Before the onset of atrial arrhythmia (i.e. when atrial activity is lower than the pacemaker threshold, time t_0) this pacemaker stimulates both the atrium (first two atrial spikes, A_1 and A_2) and the ventricle synchronously (first two ventricular spikes, V_1 and V_2). The onset of atrial fibrillation goes unnoticed and the ventricle is stimulated either synchronously with the atrial spike (if present, V_3, V_4 and V_5) or in a random manner (V_{random}).

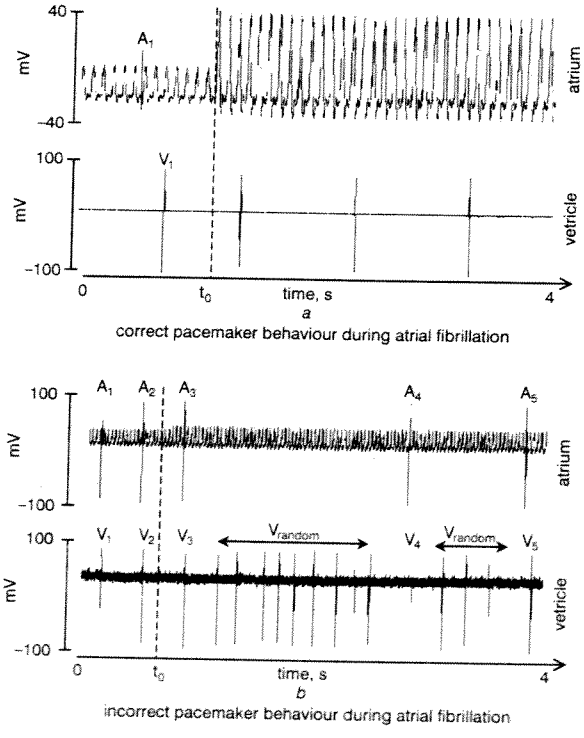

Fig. 7 *(a) Correct behaviour during atrial fibrillation of pacemaker in multi-chamber setup. Atrial fibrillation onset at time t_0. Before t_0 the pacemaker stimulates both atrium and ventricle (A_1,V_1); after t_0 the pacemaker detects atrial fibrillation and changes to a non-tracking mode by means of a mode-switching algorithms: it inhibits atrial activity and starts stimulating the ventricle at the programmed rate, regardless of atrial activity. (b) Incorrect behaviour during atrial fibrillation using single-chamber setup. Before t_0 the pacemaker stimulates both the atrium and the ventricle synchronously (A_1–A_2, V_1–V_2); after t_0 the pacemaker does not recognise atrial fibrillation and stimulates the ventricle either synchronously with the atrial spike (if present, V_3, V_4 and V_5) or in a random matter (V_{random}).*

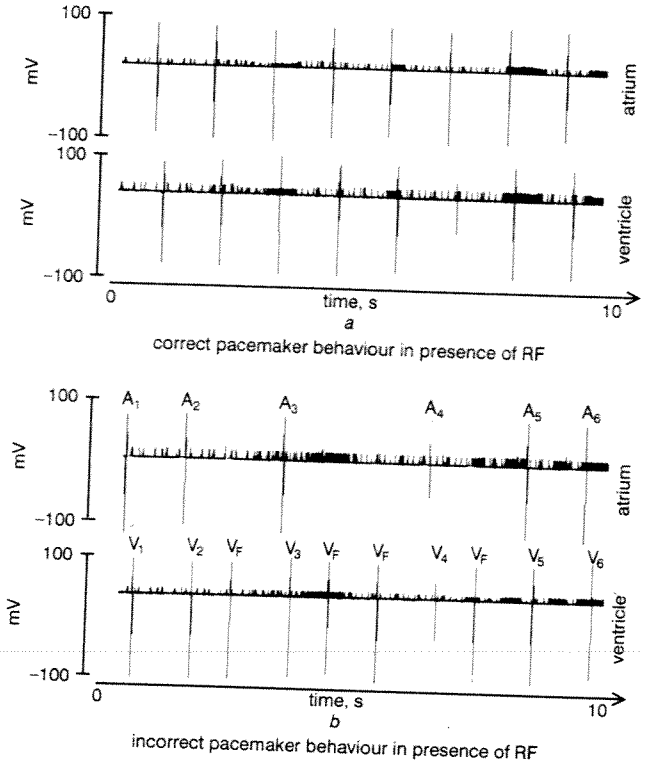

Fig. 8 *Correct (a) and incorrect (b) behaviour of two different pacemakers in presence of RF radiation. No spontaneous cardiac activity is simulated. (a) Multi-chamber setup. This pacemaker stimulates both atrium and ventricle at its programmed rate (45 beats min^{-1}). (b) Single-chamber setup. In this pacemaker electromagnetic interference during talking occurs: GSM signal causes intermittent pacemaker inhibition in the atrium. Ventricle is stimulated synchronously either with pacemaker atrial spike (V_1–V_6), or with false detected atrial activity (V_F)*

Fig. 8*a* shows an example where RF interference does not alter pacemaker operation. As no spontaneous cardiac activity is simulated, this pacemaker stimulates both the atrium and ventricle at its programmed rate (45 beats min^{-1}). Fig. 8*b* shows an episode of electromagnetic interference of another pacemaker during talking into a mobile phone: the GSM signal causes intermittent pacemaker inhibition in the atrium. The ventricle is stimulated synchronously either with the pacemaker atrial spike (V_1–V_6), or with the false atrial activity detected (V_F).

5 Discussion

In this paper, we have presented a cardiac simulator composed of three chambers and a compartment for the implantable device. The three cardiac chambers are stimulated by typical atrial and ventricular signals in sinus rhythm, and during several arrhythmias.

The simulator allows for the study of implantable mono-, dual-, and tri-chamber devices, in real time, in a number of cardiac arrhythmias, and under several experimental conditions. The simulator can be used either in a laboratory or for open field testing, on metal detectors, electronic article surveillance systems and security systems. In particular, the triple-chamber structure enables faster and easier analysis procedures for dual and tri-chamber devices.

To our knowledge the simulators used to date can only simulate one cardiac chamber, preventing the testing of all such pacemaker functions related to multiple chambers (e.g. atrio-ventricular delay, post-ventricular atrial refractory period, mode-switching algorithm, etc.). In addition, most of the present simulators do not react to the electrical therapy delivered by the device under test, as the heart does. Some advanced features of modern pacemakers, such as anti-tachy pacing, require a simulation as similar as possible to the electrical activity of the heart. These limitations are overcome by the simulator presented in this paper. The intended use of the proposed simulator is to investigate the potential effect of EMI between RF sources and implantable active devices. We have not intended it as a tool for certifying the electromagnetic compatibility of these devices. As far as we are aware, the regulations and prescriptions in this field do not take into account the use of realistic heart/trunk simulators nor procedures with radiated EM fields.

The geometry of a real human trunk is not emulated by the simulator and the atrial and ventricular leads may have different positions to those in the human body. Thus interference originating from loops created by the leads could not be properly investigated by the proposed simulator. Most of the evidence collected, so far indicates that, for mobile phone interference, the pacemaker header is the likeliest site to be affected, suggesting that most of the lead length plays a minor role (RUGGERA *et al.* 1997). For lower frequencies, the geometry of the implant (pacemaker and leads) may play an important role and a simulator with proper geometry should be used.

Acknowledgments—The authors wish to thank Ms Monica Brocco for the linguistic revision of the manuscript, and Mr Enrico D'Amico for his support in the development of the hardware and software interfaces. This paper was partially supported by the CNR-MURST 95/95 project "Electromagnetic interference characterization in laboratory and health care facilities".

References

BARBARO, V., BARTOLINI, P., BELLOCCI, F., CARUSO, F., DONATO, A., GABRIELLI, D., MILITELLO, C., MONTENERO, A. S., and ZECCHI, P. (1999): 'Electromagnetic interference of digital and analog cellular telephones with implantable cardioverter defibrillators: *in vitro* and *in vivo* studies', *Pacing Clin. Electrophysiol.*, **22**(4 Pt 1), pp. 626–634

BARBARO, V., BARTOLINI, P., DONATO, A., and MILITELLO, C. (1996): 'Electromagnetic interference of analog cellular telephones with pacemakers', *Pacing Clin. Electrophysiol.*, **19**(10), pp. 1410–1418

BARBARO, V., BARTOLINI, P., DONATO, A., MILITELLO, C., ALTAMURA, G., AMMIRATI, F., and SANTINI, M. (1995): 'Do European GSM mobile cellular phones pose a potential risk to pacemaker patients?', *Pacing Clin. Electrophysiol.*, **18**, pp. 1218–1224

BASSEN, H. I., MOORE, H. J., and RUGGERA, P. S. (1998): 'Cellular phone interference testing of implantable cardiac defibrillators *in vitro*', *Pacing Clin. Electrophysiol.*, **21**(9), pp. 1709–1715

CARILLO, R., SAUNKEAH, B., PICKELS, M., TRAD, E., WYATT, C., and WILLIAMS, D. (1995): 'Preliminary observation on cellular telephones and pacemakers', *Pacing Clin Electrophysiol.*, **18**, p. 863

CHILADAKIS, J. A., DAVLOUROS, P., AGELOPOULOS, G., and MANOLIS, A. S. (2001): '*In-vivo* testing of digital cellular telephones in patients with implantable cardioverter-defibrillators', *Eur. Heart J.*, **22**(15), pp. 1337–1342

FETTER, J. G., IVANS, V., BENDITT, D. G., and COLLINS, J. (1998): 'Digital cellular telephone interaction with implantable cardioverter-defibrillators', *J. Am. Coll. Cardiol.*, **31**(3), pp. 623–628

FURMAN, S., PARKER, B., KRAUTHAMER, M., and ESCHER, D. J. (1968): 'The influence of electromagnetic environment on the performance of artificial cardiac pacemakers', *Ann. Thorac. Surg.*, **6**(1), pp. 90–95

HAYES, D. L. (1996): 'Wireless phones and pacemaker interaction', *Pacing Clin. Electrophysiol.*, **19**(10), pp. 1405–1406

IRNICH, W., BATZ, L., MULLER, R., and TOBISCH, R. (1996): 'Electromagnetic interference of pacemakers by mobile phones', *Pacing Clin. Electrophysiol.*, **19**(10), pp. 1431–1446

RUGGERA, P. S., WITTERS, D. M., BASSEN, H. I. (1997): '*In vitro* testing of pacemakers for digital cellular phone electromagnetic interference', *Biomed. Instrum. Technol.*, **31**(4), pp. 358–371

Authors' biographies

ANGELO ANGELONI joined the Laboratory of Biomedical Engineering of the National Institute for Health 1994. His main interests concern electronic circuit design and realisation

VINCENZO BARBARO received the M.S. degree in Physics from the University of Rome, in 1963. He joined the Laboratory of Biomedical Engineering of the National Institute for Health in 1967. His research has been focused in the field of cardiovascular medical devices.

PIETRO BARTOLINI received the M.S. degree in Electronic Engineering from the University of Rome, in 1982. He joined the Laboratory of Biomedical Engineering in 1984. His main area of research lies in the field of active implantable devices.

GIOVANNI CALCAGNINI received the M.S. degree in Electronic Engineering in 1993, from the University of Rome, and the Ph.D in Biomedical Engineering from the University of Bologna, in 1997. He joined the Laboratory of Biomedical Engineering in 1998. His research interests lie in the area of processing techniques for cardiovascular signals.

FEDERICA CENSI received the M.S. degree in Electronic Engineering from the University of Rome in 1996 and the Ph.D degree in Biomedical Engineering from the University of Bologna, Italy, in 2001. Her research covers the field of non-linear analysis of cardiovascular signals.