In vitro tests of electromagnetic interference of electromagnetic navigational bronchoscopy to implantable cardioverter defibrillators

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Aims
To characterize the electromagnetic field emitted by the electromagnetic navigational bronchoscopy (ENB) superDimension® Bronchus system (SDBS) and to determine whether current implantable cardioverter defibrillator (ICD) systems are suitable for use in conjunction with SDBS.

Methods and results
The electromagnetic emission of the SDBS location board were measured using a field strength meter connected to a low-frequency (5 Hz–100 kHz) electric and magnetic field analyser; the static magnetic field was measured using a three-axis Tesla meter. A human torso simulator was used in the in vitro experiment: a polyethylene plastic box (61 cm length × 43 cm depth × 16.5 cm height) was filled with a semisolid gel and a 0.45% saline solution to provide electric conductance similar to tissue. The ICDs were immersed 1 cm into the gel and connected with a dual-coil integrated bipolar pacing/sensing/shock lead. Tip and right ventricular coil of the lead were connected to an arrhythmia simulator using low-impedance cables. The system transmits electromagnetic waves of 2.5, 3.0, and 3.5 kHz frequency. The maximum magnetic fields measured were $B = 53$ and $12 \mu T$ at location board plane and at ICD plane, respectively. Corresponding figures for the electric field were $E = 16.6$ and $4.4 V/m$. None of the tested ICDs recorded any noise signal during the period in which the location board was switched-on. Stored electrogram analysis confirmed the correct detection of simulated tachyarrhythmia and therapy delivery by every tested ICD.

Conclusion
The results of this study demonstrated that tested ICDs are compatible with ENB performed with SDBS. They also suggest that these results may be extended to all ICDs manufactured in compliance with current EN regulations.

Keywords
Electromagnetic navigation bronchoscopy • Implanted cardioverter-defibrillator • Electromagnetic interference

Introduction
Electromagnetic navigational bronchoscopy (ENB) is an emerging technology used to improve the clinical utility of fibre optic bronchoscopy in the management of lung cancer.1 Electromagnetic navigational bronchoscopy is a real-time navigation system that combines three-dimensional computed tomography (CT) imaging with real-time fibre optic bronchoscopy using a low-frequency electromagnetic field locator to guide the bronchoscope and bronchial tools to a target in or adjacent the bronchial tree. This technology was incorporated in the superDimension® Bronchus system (SDBS) (superDimension; Hertzliya, Israel) and has been shown to be capable of reaching peripheral lung masses beyond the reach of the standard bronchoscope in an animal model.2 The data are still insufficient to determine whether use of ENB will avoid surgical biopsy procedures in surgical candidates because of its low negative predictive value.3–6 However, if done by a skilled bronchoscopist, ENB appears to offer promise for
patients in whom a diagnostic bronchoscopy has failed and in whom more invasive procedures pose a significant risk, or patients who are medically inoperable or those with non-resectable disease.

Due to the use of an electromagnetic field, ENB has been considered contra-indicated by the manufacturers in patients with implantable cardioverter defibrillator (ICD) system who, nonetheless, belong to the category of patients in whom invasive procedures pose a significant risk. Concern about possible electromagnetic interactions has lead until now to exclusions of patients with implanted ICDs from clinical studies of SDBS.3–5,7,8

The technology of implantable pulse generators has evolved to devices with titanium shielding, noise rejection circuits, improved sensing algorithms, and feed through filters. These implantable pulse generators are highly sensitive low-frequency receivers that monitor physiological signals at levels as low as 0.15 mV. Their susceptibility to emitters depends primarily on the emitter’s carrier frequency, modulation scheme, duty cycle, field strength, proximity, and duration of the exposure. The implantable cardiac device pass band is 3 dB points between 30 and 70 Hz and corresponds to the frequency content of the physiological signal of interest. Sustained electromagnetic interference (EMI), including modulation content occurring in this physiological pass band, may be interpreted by the device as a signal of interest from the heart, potentially altering therapy. Implantable pulse-generators are in many cases life-sustaining devices and implications for patient safety are taken seriously by both device manufacturers and clinicians.

The aim of this study was to characterize the electromagnetic field emitted by SDBS and to determine whether current ICD systems are suitable for use in conjunction with SDBS. To evaluate the safety and feasibility of devices and leads subjected to SDBS fields, we conducted in vitro experiments and measured EMI.

Methods

Electromagnetic navigational bronchoscope system

The SDBS is an image-guided localization device that assists the endobronchial accessories in reaching the desired areas of the lung. A detailed description of the system was previously reported.2 Briefly, it is composed of an electromagnetic location board, a sensor probe, and a computer software. The system transmits sinusoidal and continuous electromagnetic waves of 2.5, 3.0, and 3.5 kHz, that are emitted from an electromagnetic board (56 cm length × 47 cm depth × 1 cm height) that is placed under the cephalic end of the mattress of the bronchoscopy table. A sensor probe (diameter 1 mm; length 8 mm) mounted on the top of a flexible metal cable constitutes the main assembly of the device. Once placed within the electromagnetic field, its position in the X, Y, and Z planes as well as orientation (roll, pitch, and yaw movement) is captured by the SDBS. This information is then displayed on a monitor in real time, superimposed on previous acquired CT images. The bronchoscopist is able to view the reconstructed three-dimensional CT images in coronal, sagittal, and axial views together with superimposed graphic information depicting the position of the sensor probe as well as the pre-identified anatomic landmarks and the position of the target lesion.

SuperDimension® Bronchus system electromagnetic field measurements

The static magnetic field emitted by the SDBS location board was measured using a three-axis Tesla meter ETM-1 (Metrolab Instruments, Geneva, Switzerland). The instruments can measure static magnetic fields in the range 0.01 mT–2 T with an accuracy of ±2% of reading. The electromagnetic emission of the SDBS location board were measured using a portable field strength meter PMM 8053 (Narda Safety Test Solutions, Segrate, Italy) connected to a low frequency (5 Hz–100 kHz) electric and magnetic field analyser PMM EHP-50B.

![Figure 1](https://academic.oup.com/europace/article-abstract/14/7/1054/475113/13) Drawing of torso simulator together with location board, measuring probe, and implantable cardioverter defibrillator plus lead system in top and front view (arrhythmia simulator connection not drawn in front view).
The EHP-50B probe can measure the intensity of electric fields in the range of 10 mV/m–100 kV/m with 1 mV/m resolution and magnetic flux density in the range 1 nT–10 nT with a 1 nT resolution, with an accuracy of ±0.5 dB. The spectral analysis of the signal is obtained by mean of a powerful digital signal processor; it is performed on six different span values and displayed on the PMM 8053 field meter display; in selective mode the test frequency can be selected with a marker. The EHP-50B external dimensions are 96 × 96 × 115 mm and is connected to the PMM 8053 through a fibre optic cable. A grid of 4 × 5 elements each of 10 × 10 cm was superimposed to the SDBS location board and measurements were collected by placing the EHP-50B probe directly in contact with the location board in a fixed point of the underlying grid. The probe was next moved in each point of the measurement grid. For each point three measurements were collected and the results were averaged. This reduced sampling region with respect to the physical dimensions of the SDBS location board was adopted in order to avoid border effects due to the physical dimensions of the EHP-50B probe.

Implantable cardioverter defibrillators

Implantable cardioverter defibrillators explanted for various reasons (e.g. elective replacement, system upgrading, infection) were used for in vitro testing of potential EMI of SDBS. Devices were excluded from the study if the elective replacement indication had already been reached or if suspected device malfunction had been the reason for explantation. Seven ICDs models were tested: Alto 2 (ELA Medical Sorin, Milan, Italy); Epic II HF V-357 and Atlas II HF V-367 (St Jude Medical, St Paul, MN, USA); Insync Sentry 7258; Maximo VR 7232; EnTrust D154VRC (Medtronic, Minneapolis, MN, USA); Vitality T175 (Guidant Boston Scientific, Natick, MA, USA).

Implantable cardioverter defibrillators testing setup

The testing setup is a modified version of the AAMI PC69 Standard, a standard recognized for developing in vitro electromagnetic compatibility test protocols for implantable pacemakers and ICDs.9 A human torso simulator was used. A polyethylene plastic box (61 × 43 × 16.5 cm) was filled with a semisolid gel prepared to simulate the dielectric properties of human tissues. This was accomplished using a gelling agent and a 0.45% saline solution, which provides electric conductance similar to tissue.10 The simulated torso did not contain discontinuity barriers since the measure of real pacing and shock impedances were not within the aim of the study. The device under testing was immersed 1 cm into the semisolid gel and connected with a dual-coil pacing/sensing/shock lead Endotak Reliance 0148 (Boston Scientific, Natick, MA, USA). This lead operates in an integrated bipolar configuration, which has been reported as more prone to over sensing of far-field signals,11,12 with right ventricular (RV) coil acting as pacing/sensing anode. Lead configuration was positioned in an anatomical pattern, mimicking lead bends in the vascular system. Tip and RV coil of the lead were connected to an arrhythmia simulator ARSI-4 (ARSI, HKP, Bannewitz, Germany) using low-impedance cables. Lead heating was measured with a digital thermometer with a range of −20–85 °C and resolution of 0.1 °C. The probe was connected to the electrode tip.

A drawing of torso simulator together with location board, measuring probe, and ICD system in top and front view is reported in Figure 1.

To better approximate the real coupling fields into the lead systems, the electromagnetic field measurements were repeated using a polyethylene plastic box (61 × 43 × 15.5 cm) filled with a saline solution and covered with a plastic sheet to support the EHP-50B probe. Electric and magnetic fields were reported not only as root-mean-squares (RMS) but also as X, Y, and Z components. Indeed, magnetic fields in the Z-axis (perpendicular to the lead) and electric fields in the X–Y plane (iso-planar with the lead) are expected to be the most influencing.

Implantable cardioverter defibrillators testing procedure

The testing procedure included:

- Connection of ICD to implanted lead and location of the device in a ‘left subclavear’ position. When necessary, ports for atrial and left ventricular lead were closed with plugs.

Figure 2 Three-dimensional surface graphs of \( B (\mu T) \) (A) and \( E (V/m) \) (B) emitted by superDimension™ Bronchus system and measured at the surface of the location board with respect to the coordinate system of the location board. Surfaces were fitted to experimental data using a distance-weighted least square smoothing algorithm. Also displayed in this graph are the experimental points measured.
• Programming of brady pacing to low rate (30–40 b.p.m.) VVI mode with maximum sensitivity (to operate in the worst case scenario as for noise detection) and standard pacing voltage/pulse duration.
• Programming of tachy section with rate detection >160–180 b.p.m. and shock delivery after tachycardia confirmation.
• Measure of sensing amplitude, pacing impedance, and shock impedance.
• Telemetric monitoring of ICD RV pacing/sensing channel to assess the lack of EMI.
• With the SDBS system switched on a few minutes navigation session was simulated during 'sinus' rhythm of 65 b.p.m. generated by the arrhythmia simulator. During this phase, measures of sensing amplitude, pacing impedance, and shock impedance were repeated and, again, telemetric monitoring of ICD electrogram was performed.
• Arrhythmia simulator activation to generate a 30's ventricular fibrillation.
• SDBS switched-off.
• ICD interrogation to verify programmed parameters and to assess noise detection during 'sinus' rhythm, recognition of simulated arrhythmia, and therapy delivery.

According to our institutional policies Institutional Review Board approval was not requested since this is an in vitro study, not involving human patients.

Results
The static magnetic field emitted by the location board of the SDBS was below the instrument sensitivity of 0.01 mT. The system transmits electromagnetic waves of 2.5, 3.0, and 3.5 kHz. The maximum magnetic field measured is 8 = 53 μT, while the maximum electric field amounts to 1 = 16.6 V/m. In Figure 2A and B are displayed the three-dimensional surface graphs of the measured 8 (mT) and E(V/m) with respect to the coordinate system of the location board. A surface was fitted to experimental points using a distance-weighted least square smoothing algorithm. The U-shape of the magnetic field across the coordinate system of the location board and the decrease of the electric field with increasing X values allow the localization of the probe during the endoscopic navigation.

The maximum electric field measured at 15.5 cm above the location board with the torso phantom interposed was 1 = 4.4 V/m (12 = 3.9 V/m, 13 = 2.1 V/m). The corresponding figures for the magnetic field were 8 = 12 μT (82 = 3.9 μT, 83 = 1.9 μT, 81 = 11.5 μT).

None of the tested ICDs recorded any noise signal during the period in which the location board was switched-on, even though a high sensitivity level was programmed (Figure 3). Stored electrogram analysis confirmed the correct detection of simulated tachycardia and therapy delivery by every tested ICD (Figure 4). Lead temperature in vitro did not show any measurable increase.

Discussion
In recent years, implantation of rhythm devices and cardioverter defibrillators has been proven to supersede the effectiveness of other therapeutic approaches and their application is increasing. In turn, this increasing number of patient implanted with ICD raises the probability that some of them may warrant a diagnostic or therapeutic EMB.

Magnetic and time-varying electromagnetic fields such as those emitted by the SDBS might interfere with the correct functioning of the implanted devices. Electromagnetic interference may change the functioning of the implanted devices because of spurious signals induced by electromagnetic coupling. These signals may be recognized by the logic of the ICD as physiological signals. A major difference between the electromagnetic and the magnetic tests concerns the mechanism of coupling with the device: the major influence of electromagnetic fields is through induced voltages and currents in the leads; magnetic fields could cause malfunctions due to direct effects on the internal circuitry of the device.

All marketed ICDs are approved according to either the international standard ANSI/AAMI PC69:2007 or to the medical device European Norms EN 45502-2:15 and EN 45502-2-16 which establish procedures for EMI check on implantable devices on different ranges of frequency. However, it is impossible for the producer to test the devices in all different EMI environments that can occur.

As long as the EMI levels are below the reference levels for general public exposure to time-varying electric and magnetic fields set by the International Commission on Non-Ionizing Radiation Protection (ICNIRP), there should be no problem for the
In Table 1 such reference levels are reported in the frequency range emitted by the SDBS. According to EN 45502-2-1 and EN 45502-2-2 protection from exposure to weak and strong static magnetic fields and to varying magnetic fields which patients may encounter in the general public environment is addressed according to the tests reported in Table 2.

Interference of the SDBS location board with ICDs due to static magnetic fields can be definitely ruled out on the basis of our measurements since magnetic fields $\leq 10 \mu$T cannot cause any interference for devices that are planned to work properly in static magnetic fields as high as 1 mT.

Time-varying magnetic fields emitted by the SDBS location board are above the 6.25 $\mu$T reference levels for general public exposure of ICNIRP 1998. The ICNIRP standard of 1998 with its 6.25 $\mu$T reference level is now in revision with a reference level of 20 $\mu$T for 0.8–150 kHz according to ICNIRP draft 2009. Moreover, there is one paper with measured interference for continuous sinusoidal voltages: between 1.2 and 4 kHz the calculated peak value of the magnetic induction is 37.8 or 31.5 $\mu$T (26.7 or 22.3 $\mu$T RMS), respectively, demonstrating that our 12 $\mu$T measured field is sufficiently below.

Indeed, all tested ICD did not show any spurious noise signal in the integrated bipolar sensing configuration while inserted in the torso phantom during the period in which the location board was switched-on. Correct recognition of ventricular tachyarrhythmia and therapy delivery should allow carrying out ENB without preliminary reprogramming of the ICD and should grant implanted patients with greater safety during ENB procedure, as patients who should suffer a ventricular tachyarrhythmia episode while undergoing ENB will receive a correct electrical therapy.

### Study limitations

The sampling of the time-varying electric and magnetic fields emitted by the location board of the SDBD was only coarse due to the physical dimensions of the EHP-50B probe. However, the accurate determination of the spatial variation of electromagnetic fields was beyond the aims of the study. For the purpose of characterizing maximal amplitude of varying magnetic fields emitted by the location board, we believe that our measurements are sufficiently accurate.

One set of ICD leads was chosen for test reproducibility; however, varying the lead length, make, or type of lead could affect implantable ICD electromagnetic compatibility.

In vitro testing may not be predictive of the clinical experience. Past experience with electromagnetic compatibility testing
between cell phones and pacemakers indicates that if the bench test detects interference, interference will also be seen clinically. 19

In vitro testing of a torso simulator represents a static environment in which the patient is still.

Conclusions
The results of the present in vitro study demonstrated that tested ICDs are compatible with ENB performed with SDBS in the integrated bipolar sensing configuration. True bipolar sensing configuration was not tested in the present work and may lead to other results. They also suggest that these results may be extended to all ICDs manufactured in compliance with current EN regulations. Further in vitro studies and carefully monitored patient studies are needed before firm recommendations can be made.

Conflict of interest: none declared.

References
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