Extra-cardiac stimulators: what do cardiologists need to know?

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For several decades, treating patients with pacemakers has been the privilege of cardiologists. However, in the last 30 years, researchers have found new targets for electrical stimulation in different clinical subspecialities, such as deep brain stimulation (for the treatment of Parkinson’s disease, essential tremor, dystonia, and some psychiatric illnesses); spinal cord stimulation (for refractory angina, chronic pain, and peripheral artery disease); and sacral (for diverse urologic and proctologic conditions), vagal (for epilepsy), and phrenic nerve stimulation (for sleep apnoea). The purpose of this article is to familiarize cardiologists with these ‘extra-cardiac pacemakers’ and to discuss potential issues that must be addressed when these patients undergo cardiac procedures.

Keywords

Pacemaker ● Deep brain stimulation ● Spinal cord stimulation ● Sacral nerve stimulation ● Neuromodulation ● Phrenic nerve stimulation

Introduction

For almost 50 years, the heart has been the main target of electrical stimulation with an implanted device since the first cardiac pacemaker (PM) was implanted in 1958. Therapy with electrical stimulation has later been applied to other organs, i.e. the brain, the spinal cord, and other peripheral targets. Extra-cardiac devices are nowadays implanted for treatment of various non-cardiac conditions, usually as a second-line or symptomatic treatment. Their efficacy and their indications are increasingly being recognized and, as the population ages, we can anticipate that a growing number of patients with extra-cardiac devices will also need cardiologic investigations and/or treatment. As some cardiologic procedures may be contraindicated or may necessitate precautions in these patients, we believe that cardiologists should be aware of these devices. The first part of our review will summarize the types of the different extra-cardiac devices available and their indications. In the second part, the implications of each device for the cardiologist will be discussed.

Part I: extra-cardiac devices—history and indications

A list of the currently available devices is shown in Table 1 with a schematic depiction shown in Figure 1. A more detailed version is available in the Supplementary material online, Table S1.

Spinal cord stimulation

The spinal cord was one of the first extra-cardiac sites to be targeted for electrical stimulation therapy. Spinal cord stimulation (SCS) was first introduced in the 1960s for pain control. Today, common indications include refractory back pain, refractory migraines, refractory angina, and pain due to peripheral vascular disease.1,2 It is being investigated for treating heart failure. The electrical impulses that are delivered to the spinal cord are thought to interfere with the propagation of painful stimuli (via ‘gate control’), but the precise mechanism of action remains unknown.3 The site of stimulation depends on the indication. Commonly, electrodes are introduced under fluoroscopic guidance into the lumbar epidural space and advanced up to the desired level (usually high thoracic or low cervical) and connected to an external stimulator during a test phase. Depending on the clinical response, a permanent stimulator is implanted subcutaneously in the lower back or upper buttock region—an example is shown in Figure 2.

Deep brain stimulation

The process of stimulation of various sites in the basal ganglia—the thalamus, the internal globus pallidus, or the subthalamic nucleus—for the treatment of hypo or hyperkinetic neurologic disorders is known as deep brain stimulation (DBS). The first report of a potential efficacy of repetitive electrical stimulation for Parkinson’s disease...
Table 1  Indications and technical characteristics of extra-cardiac devices

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>IPG site</th>
<th>Leads</th>
<th>Output amplitude</th>
<th>Pulse width</th>
<th>Frequency</th>
<th>Cycle</th>
<th>MR conditional</th>
<th>Rechargeable</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCS: refractory back pain, peripheral vascular disease, refractory migraine, refractory angina, and heart failure</td>
<td>Medtronic</td>
<td>Buttocks, flank, abdomen</td>
<td>1 or 2 quadri- or octapolar lead(s)</td>
<td>Min: 0 V Max: 10.5 V</td>
<td>Min: 60 μs Max: 450/1000 μs</td>
<td>Min: 2 Hz Max: 130/1200 Hz</td>
<td>Cyclic or constant</td>
<td>Some models</td>
</tr>
<tr>
<td></td>
<td>St-Jude Medical</td>
<td>Upper buttock</td>
<td>1 or 2 octapolar lead(s)</td>
<td>Min: 0 mA (or 0 V) Max: 25.5 mA (or 25.5 V)</td>
<td>Min: 50 μs Max: 500/1000 μs</td>
<td>Min: 2 Hz Max: 1200 Hz</td>
<td>Constant (± burst)</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Boston-Scientific</td>
<td>Upper buttock</td>
<td>2 or 4 octapolar leads</td>
<td>Min: 0 mA Max: 25.5 mA</td>
<td>Min: 0 μs Max: 1000 μs</td>
<td>Min: 2 Hz Max: 1200 Hz</td>
<td>Cyclic</td>
<td>Some models</td>
</tr>
<tr>
<td></td>
<td>St-Jude Medical</td>
<td>Upper chest</td>
<td>1 or 2 quadripolar lead(s)</td>
<td>Min: 0 mA Max: 25.5 mA</td>
<td>Min: 50 μs Max: 500/1000 μs</td>
<td>Min: 2 Hz Max: 1200 Hz</td>
<td>Cyclic or constant</td>
<td>Head only</td>
</tr>
<tr>
<td></td>
<td>Boston-Scientific</td>
<td>Upper chest</td>
<td>2 octapolar lead(s)</td>
<td>Min: 0.1 mA Max: 20 mA</td>
<td>Min: 10 μs Max: 450 μs</td>
<td>Min: 2 Hz Max: 255 Hz</td>
<td>Cyclic or constant</td>
<td>Yes</td>
</tr>
<tr>
<td>DBS: Parkinson’s disease, essential tremor, some forms of dystonia, and obsessive–compulsive disorder</td>
<td>Medtronic</td>
<td>Upper chest</td>
<td>1 or 2 quadri or octapolar lead(s)</td>
<td>Min: 0 V Max: 10.5 V</td>
<td>Min: 60 μs Max: 450 μs</td>
<td>Min: 2 Hz Max: 250 Hz</td>
<td>Cyclic or constant</td>
<td>Some models</td>
</tr>
<tr>
<td></td>
<td>St-Jude Medical</td>
<td>Upper chest</td>
<td>1 or 2 quadripolar lead(s)</td>
<td>Min: 0 mA Max: 12.75 mA</td>
<td>Min: 50 μs Max: 507 μs</td>
<td>Min: 2 Hz Max: 240 Hz</td>
<td>Cyclic or constant</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Boston-Scientific</td>
<td>Upper chest</td>
<td>2 octapolar lead(s)</td>
<td>Min: 0.1 mA Max: 20 mA</td>
<td>Min: 10 μs Max: 450 μs</td>
<td>Min: 2 Hz Max: 255 Hz</td>
<td>Cyclic or constant</td>
<td>Yes</td>
</tr>
<tr>
<td>Sacral nerve neuromodulation: urinary and faecal incontinence, urinary retention, and urgency frequency</td>
<td>Medtronic</td>
<td>Upper buttock</td>
<td>1 quadripolar lead</td>
<td>Min: 0 V Max: 8.5/10.5 V</td>
<td>Min: 60 μs Max: 450 μs</td>
<td>Min: 2 Hz Max: 130 Hz</td>
<td>Cyclic or constant</td>
<td>Head only</td>
</tr>
<tr>
<td>Vagal nerve stimulation: epileptic seizures and some forms of depression</td>
<td>Cyberonics</td>
<td>Upper left chest</td>
<td>1 bipolar lead</td>
<td>Min: 0.25 mA Max: 3.5 mA</td>
<td>Min: 130 μs Max: 1000 μs</td>
<td>Min: 1 Hz Max: 30 Hz</td>
<td>Cyclic</td>
<td>Yes (exclusion zone C7–T8)</td>
</tr>
<tr>
<td>Vagal nerve stimulation: heart failure</td>
<td>BioControl Medical</td>
<td>Upper right chest</td>
<td>1 multicontact lead</td>
<td>NA Max: 8 mA</td>
<td>NA</td>
<td>NA</td>
<td>Constant</td>
<td>No</td>
</tr>
<tr>
<td>Carotid sinus nerve stimulation: resistant hypertension and heart failure</td>
<td>CVRx</td>
<td>Upper chest (right &gt; left)</td>
<td>1 or 2 unipolar lead(s)</td>
<td>Min: 2 mA Max: 8 mA</td>
<td>NA</td>
<td>NA</td>
<td>Constant</td>
<td>No</td>
</tr>
<tr>
<td>Gastric electrical stimulation: gastroparesis</td>
<td>Medtronic</td>
<td>Left abdomen</td>
<td>2 quadripolar leads</td>
<td>Min: 0 V Max: 10.5 V</td>
<td>Min: 60 μs Max: 450 μs</td>
<td>Min: 2 Hz Max: 130 Hz</td>
<td>Cyclic</td>
<td>No</td>
</tr>
<tr>
<td>Vagal nerve block therapy: obesity</td>
<td>Enteromedics</td>
<td>Upper left abdomen</td>
<td>2 leads</td>
<td>NF</td>
<td>NF</td>
<td>NF</td>
<td>NF</td>
<td>Yes</td>
</tr>
<tr>
<td>Diaphragmatic/phrenic stimulation: respiratory insufficiency</td>
<td>Atrotech</td>
<td>Lower chest, bilateral</td>
<td>2 quadripolar leads</td>
<td>NF</td>
<td>NF</td>
<td>High</td>
<td>Cyclic</td>
<td>No</td>
</tr>
<tr>
<td>Transvenous phrenic nerve stimulation: central apnoea syndrome</td>
<td>Respicardia</td>
<td>Upper chest</td>
<td>2 leads</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
<td>Cyclic</td>
<td>No</td>
</tr>
<tr>
<td>Bone stimulation (invasive): non-union/delayed union fractures</td>
<td>EBI™ OsteoGen™</td>
<td>Long bones</td>
<td>1 or 2 multicontact lead</td>
<td>20 or 40 μA</td>
<td>NA</td>
<td>NA</td>
<td>Constant</td>
<td>No</td>
</tr>
<tr>
<td>Biomet™ Spine</td>
<td>Spine</td>
<td>2 multicontact leads</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>Constant</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

NA, not applicable; NF, information not found; ND, information not disclosed by the manufacturer.
was published in 1963, but the development of the technique was slowed down by the discovery of levodopa and other antiparkinsonian drugs. Later studies demonstrated the efficacy of DBS for drug-resistant tremors and Parkinson’s disease. The therapy was approved by the Food and Drug Administration (FDA) in 1997 and is now a well-recognized treatment option for Parkinson’s disease, essential tremor, some forms of dystonia, and obsessive–compulsive disorder. New indications will probably emerge in the near future as DBS has shown efficacy in Tourette’s syndrome, depression, and epilepsy, and is being evaluated for various other conditions (dementia, some forms of headache, and addictions). It is estimated that >100 000 patients have been treated worldwide with DBS. The lead is implanted surgically under computed tomography (CT) or magnetic resonance imaging (MRI) guidance, and electrodes extend subcutaneously into the neck and are connected to a pulse generator generally located under the clavicle. Some conditions require bilateral stimulation—which is usually the rule in Parkinson’s disease—but unilateral stimulation is sufficient for other indications. Once the device is implanted, the next step is to find the best programming parameters to maximize response. The selection of different parameters is usually a process of trial and error, but recently, novel computational techniques have become available to guide the clinician. The pulse frequency is generally high (between 100 and 200 Hz); the other programmable parameters are stimulus amplitude (usually between 2.0 and 5.0 V), pulse width, mode of stimulation (uni vs. bipolar), and electrode selection. The patient can turn the device on and off with a programmer. The implantable pulse generator (IPG) needs to be replaced every 2–8 years. New rechargeable IPGs have a longevity estimated at 9–25 years.

**Sacral neuromodulation**

Electrical stimulation of the sacral nerves was introduced in the late 1980s and is an efficacious second-line therapy for patients with urological (urinary urge incontinence, urinary retention, and urgency frequency) and proctological (faecal incontinence) conditions. The Medtronic InterStim and Interstim II IPGs are now approved in Europe (CE marked since 1994) and in the USA (approved by FDA in 1997). The availability of quadripolar tined leads (the tines avoid migration in the subcutaneous tissue, and the multipolar design allow better thresholds and bipolar pacing) and IPGs with technical innovation (different programme settings) has led to a wider use of the technique. In 2014, it was estimated that >125 000 patients worldwide had been treated with sacral nerve neuromodulation.

The implantation of the sacral neuromodulation device and leads is performed under local or general anaesthesia, in a two-stage procedure. First, a lead is introduced percutaneously in the S3 foramen via fluoroscopic guidance aiming for a sensory response (if implanted under local anaesthesia) and motor response (contraction of the anal sphincter) with the lowest possible pacing output and the greatest number of electrodes. The lead is then connected to an external neurostimulator for a test phase during ~2 weeks. If there is clinical improvement (>50% reduction in symptoms), a permanent device is connected to the leads and implanted in the upper buttocks. Bilateral stimulation is sometimes needed (connected to two IPGs or a single IPG with two connectors, similar to a dual-chamber PM). Sacral nerve stimulation is currently only indicated in idiopathic cases, i.e. not secondary to Parkinson’s disease or multiple sclerosis, etc. (although it is sometimes also used ‘off label’ in these instances). An example of unilateral sacral neuromodulation is shown in Figure 3.

The frequency and current can be adapted, based on sensory and motor responses, but no evidence-based guidelines exist to guide programming. Output may be programmed up to 8.5 V/450 μs, 2–130 Hz, continuous or cyclic and bipolar or unipolar. Settings

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**Figure 1** Schematic illustration of some of the currently available extra-cardiac stimulators.

**Figure 2** Thoracic and lumbar spine radiography of a patient with a thoracic SCS device.
are then adapted based on patient symptoms. The patient is given a programmer that may be used to activate/inactivate the device (which is usually constantly activated), modify output or check battery status. The battery longevity is estimated to be \( \sim 6\text{–}8 \text{ years} \).

**Vagal nerve stimulation and vagal nerve block therapy**

Stimulation of the vagus nerve was first performed in 1988 in a patient with intractable epilepsy.\(^{11}\) The Cyberonics (Houston, TX, USA) device was approved by FDA in 1997 and, to date, >75 000 patients have been implanted. It can be used for the treatment of epileptic seizures that are refractory to medical treatment, and for some severe forms of depression. Other potential indications—heart failure, migraine, intractable hiccups, Alzheimer’s disease, and tinnitus—are currently being investigated. The device is implanted under general anaesthesia, below the left clavicle, and a bipolar cuffed lead is positioned in the neck to stimulate the left vagal nerve in the carotid sheath (or the right vagal nerve for treating heart failure). The stimulation is intermittent (usually 30 s ‘on’ and 300 s ‘off’), at a frequency of 30 Hz (programmable 1–30 Hz), with an output of 0.25–3.5 mA and a pulse width of 130–300 s.\(^{12}\) A separate magnet can be used by the patient to boost electrical stimulation when symptoms are worse. Complications after vagal stimulator insertion include stimulation-induced symptoms such as vocal hoarseness and dysphagia. Complete heart block with transient ventricular asystole requiring removal of the device is a rare complication; however, the incidence of bradycardia/rhythms is low (\( \sim 0.1\% \)).\(^{13}\) Right-sided vagal nerve stimulation is being investigated using the CardioFit (Biocontrol Medical, Yehud, Israel) for treating advanced systolic heart failure using a device equipped with a right ventricular lead for synchronizing nerve stimulation to the R-wave (and also to prevent excessive bradycardia).

Recently, a device blocking transmission of the vagal nerve impulses (vBloc Maestro, Entero Medics, St Paul, MN, USA), and thereby potentially reducing the sensation of hunger, has been tested for treating obesity. Based on the results of the ReCharge study,\(^{14}\) showing a statistically greater weight loss in 162 patients treated with vagal nerve blockade compared with 77 patients treated with a sham population, the FDA approved the use of this device in January 2015 as a second-line treatment for obese patients with a body mass index between 35 and 45 kg/m\(^2\) and at least one further obesity-related condition. The implantation of the system is performed laparoscopically under general anaesthesia. The electrodes are sutured around the vagal nerve at the gastro-oesophageal junction, and the device is implanted subcutaneously in the lateral thoracic wall. The device is programmed to deliver high-frequency stimulation during the day (12 h) and is recharged twice a week.

**Other stimulators**

Other devices have been approved by regulatory authorities. However, since they are less frequently used, the medical literature regarding potential interactions with cardiac procedures is sparse.

**Gastric stimulation**

Gastric stimulation (Enterra I and II, Medtronic, MN, USA) involves the implantation under laparoscopy of two bipolar leads into the walls of the stomach, and of a pulse generator, generally placed in the upper abdomen. Since 2000, it is an FDA-approved treatment of gastroparesis refractory to medical therapy. The American College of Gastroenterology recommends gastric electrical stimulation for palliative treatment in patients with refractory symptoms of gastroparesis, but with a low level of evidence of efficacy.\(^{15}\) The therapy consists of high-frequency (14 Hz) and low-energy stimulation. Programming is set by the physician with an external programmer; no patient-controlled programmer is available.

**Diaphragmatic or phrenic nerve stimulation**

In patients with respiratory insufficiency needing long-term mechanical ventilation, electrical stimulation of the diaphragm or the phrenic nerves (Atrostim, Atrotech, Tampere, Finland) has a transvenous pacing lead positioned adjacent to the phrenic nerve in the right brachiocephalic or left pericardiophrenic vein for unilateral phrenic nerve stimulation, along with an optional lead implanted in the azygos vein for sensing respiratory rate. The safety and effectiveness of this system have recently been demonstrated.\(^{16}\)
Table 2 Summary of issues between extra-cardiac stimulators and cardiological procedures and recommendations for management

<table>
<thead>
<tr>
<th>Cardiac procedure</th>
<th>Limitations</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surface ECG</td>
<td>ECG artefacts caused by electrical stimuli from the extra-cardiac device.</td>
<td>Activation of ECG low-pass (e.g. 40 Hz) filters. Temporary inactivation of the extra-cardiac device.</td>
</tr>
<tr>
<td>Electrical cardioversion</td>
<td>Injury to the patient or damage to the device.</td>
<td>Inactivate the extra-cardiac device.</td>
</tr>
<tr>
<td>PMs and ICDs</td>
<td>Oversensing of the electrical stimuli of the extra-cardiac device (pacing inhibition, inappropriate shocks). Damage to the extra-cardiac device after an ICD shock. Magnet effect and interaction by the programmer head. Interaction with the charging head of rechargeable extra-cardiac devices.</td>
<td>Proper patient education (e.g. for the use of magnets, programmer, or recharger header). For ICDs, programme the shock pathway as far as possible from the extra-cardiac stimulator (may require programming a ‘cold can’ configuration, i.e. using a dual coil lead with the shock vector between the RV and SVC coils. Favour a true bipolar over an integrated bipolar lead (less risk of EMI). Test for the ‘worst-case’ scenario of sensing and pacing configurations.</td>
</tr>
<tr>
<td>Cardiac MRI</td>
<td>Safety to perform a cardiac MR in a patient with an extra-cardiac device is not established.</td>
<td>Choose an alternative diagnostic method unless the device is full-body MRI-conditional.</td>
</tr>
<tr>
<td>Ablation procedures</td>
<td>Possible heating of the electrodes and tissue damage caused by induced electrical currents.</td>
<td>The risk is probably low and should be discussed in an individual basis with a multidisciplinary approach.</td>
</tr>
</tbody>
</table>

Bone stimulation

Electrical bone stimulation (invasive or non-invasive) can enhance bone growth and is a therapeutic option for non-union or delayed union in patients with fractures. Other recognized indications include failed arthrodesis and failed spinal fusions. The invasive technique involves surgical implantation of electrodes in contact with the bone and implantation of the generator in the nearby subcutaneous tissue.18,19

Carotid sinus stimulation

This system is indicated in resistant hypertension and is being investigated to treat systolic heart failure. The Barostim Neo system by CVRx (Minneapolis, MN, USA) received the CE mark approval in 2011. The system uses a single unipolar patch electrode implanted over the right carotid sinus and tunnelled down to the IPG positioned in the prepectoral region. The device delivers a current of 2–8 mA at a constant voltage.20

Part II: Important considerations for cardiologists

A summary of the interactions and considerations is shown in Table 2.

Electrocardiographic interference

The electrical impulses delivered by extra-cardiac devices can be recorded on the surface electrocardiogram (ECG).21–23 These artefacts can sometimes mask the underlying rhythm, be misinterpreted as atrial fibrillation, or mimic cardiac PM dysfunction. Some authors recommend recording a baseline ECG tracing after the implantation of an extra-cardiac device, which can be used as a future reference.24 Figure 4 shows an example of electrocardiographic interference in a patient with a sacral neuromodulation device.

As with cardiac pacing, the presence and the degree of ECG artefacts are principally influenced by pacing polarity, with unipolar pulses generating artefacts of large amplitude, and bipolar pacing causing almost invisible spikes.24,25 In addition, pulse amplitude, pulse width, proximity, and orientation of the pacing vector with respect to the recording leads affect the amplitude of the artefacts. Filter settings of the electrocardiograph may significantly affect the electromagnetic interference. The standard bandwidth of ECG recordings is 0.05–150 Hz, which includes the pulse frequencies of all the extra-cardiac pacing systems. Activating a low-pass filter of 40 Hz (which is essentially used to filter out myopotentials) may significantly attenuate artefacts (depending on the programmed pacing frequency) as shown in Figure 5.23,24

It should also be kept in mind that most devices can be temporarily turned off using the patient programmer in order to record an interpretable ECG. It may also be necessary to temporarily inactivate a device for other cardiological procedures for which an ECG tracing is needed, for example echocardiography, ergometry, coronary angiography, electrophysiological procedures, cardiac CT, or MRI. Problems related to inactivation of the device—e.g. tremor or incontinence—may, however, arise. In the case of bilateral DBS, unilateral inactivation of one of the two stimulators may allow for sufficient ECG quality, while limiting tremor. For longer interruptions (e.g. during Holter recordings), it is advisable to obtain a specialist’s opinion to determine if a prolonged interruption of the device or change in the output parameters (e.g. programming from unipolar to bipolar stimulation) is possible.
External/internal cardioversion or defibrillation

Reports published since the 1980s have demonstrated that external cardioversion or defibrillation has the potential to damage cardiac PMs, despite the presence of diodes that shunt current away from the generator housing.26,27 This risk has been questioned in more recent studies using bipolar implantable defibrillators and PMs, due to a reduced antenna effect.28 Unfortunately, little information exists in the literature regarding consequences of external cardioversion or defibrillation on non-cardiac devices. A case report has been published of a 59-year-old patient, treated with a thalamic DBS system for intractable tremor, who suffered thalamotomy and developed central dysesthetic pain following cardioversion (100 and 200 J) for atrial fibrillation, presumably due to cerebral lesions resulting from conducted current.29 Importantly, the defibrillation paddles were placed very close to the device, which was not turned off before the procedure and which was equipped with a radiofrequency receiver implanted in the anterior chest wall, making it potentially more prone to transmit electrical currents than more modern devices. In a series reporting patients with DBS, the authors identified two patients treated with electrical cardioversion for atrial fibrillation; neither of them suffered neurological damage, and no hardware dysfunction of the devices was apparent.30

In their technical manuals, many manufacturers warn of potential risks—for the hardware and for the patients—of electrical currents induced by cardioversion or defibrillation. Most of them recommend that the device should be turned off—for at least 5 min for some models—before the procedure, and the precautions listed in Table 2 should be followed.

Concerning internal shocks delivered by implantable cardioverter-defibrillators (ICDs) or by electrophysiological catheters designed for cardioversion of atrial fibrillation, the amount of energy is much lower and is potentially less likely to damage the non-cardiac device. No dysfunctions of the device or injuries to patients have been reported.

In an emergency setting, cardioversion/defibrillation should be done whenever necessary as patient survival is the priority.

Interference with cardiac devices

Due to aging of the population, expanding indications for cardiac and extra-cardiac devices, the cardiologist will increasingly encounter situations with simultaneous indications for both types of devices.

Electrical impulses from the extra-cardiac stimulator may be sensed by the PM/ICD and result in the inhibition of pacing, noise reversion with asynchronous pacing, or inappropriate shocks. The interference may also result in inappropriate modeswitch. As mentioned above, ICD shocks may cause hardware damage or electrical reset of an extra-cardiac device. Another potential source of complications may be related to telemetry control or magnet application.31 Indeed, some extra-cardiac devices can be activated by a magnet, which, if placed at proximity to the PM or ICD, may result in a magnet response (i.e. asynchronous pacing of a PM and inactivation of ICD therapies). Conversely, the PM or ICD programmer header may result in a magnet response of the extra-cardiac device. Furthermore, charging headers for rechargeable extra-cardiac devices use the same radiofrequency signal as the programmer header and may interact with the PM or ICD. Finally, the extra-cardiac device may be positioned in a very similar location as the PM or ICD generator, which may be an issue for implantation.

Because of these concerns, patients with cardiac devices have probably been denied therapy by an extra-cardiac stimulator.32

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**Figure 4** Electrocardiogram artefacts in a patient with sacral nerve stimulation.
However, there are a number of reports of simultaneous extra-cardiac devices and PMs or ICDs. In a retrospective analysis published in 2011, Ooi et al. identified six patients with an implantable cardiac device (four PMs and two ICDs) and a neurostimulator (three SCS, two DBS, and one peripheral nerve stimulator). After a mean follow-up of 31.7 months, no interactions between the devices could be identified. In this study, all cardiac devices were set to bipolar sensing and bipolar stimulation was chosen for the neurostimulators. The devices were implanted on opposite sides and separated by at least 18 cm. No interaction could be identified despite temporarily programming maximal sensitivity on cardiac devices and maximal tolerated amplitudes on the neurostimulators. The authors performed an additional review of previously published case reports. They found reports of 57 patients with cardiac devices and neurostimulators: 51 patients with a PM (41 SCS and 10 DBS) and 6 with an ICD (3 SCS and 3 DBS). Only two cases with interactions were reported. One patient with a SCS had intermittent PM inhibition when high amplitudes were used on the SCS and both systems were programmed to unipolar settings. In the second patient, a shock delivered by his ICD affected the programming of his bilateral DBS, resulting in a reset of the amplitude and voltage and of the electrodes’ polarities. A series of five patients with concomitant implantation of a SCS device and an ICD could not identify any interactions between the devices after a mean follow-up of 83 months. Another series reported no adverse effects over a 7-month follow-up in 9 patients implanted with an ICD or CRT-D and SCS. Despite these reassuring findings, there has been a case report of interference between a SCS set to bipolar stimulation and an ICD which required inactivation of the SCS.

Less evidence is available for the concomitant use of sacral neuromodulation and cardiac devices. Because of the distance between the sacral nerves and the cardiac devices, the risk of interaction is likely to be lower compared with DBS or SCS devices. Two series with a total of eight PM patients and one report of a patient with an ICD concluded that sacral neuromodulation was safe in these patients.

Generally, manufacturers issue warnings to physicians and patients regarding the potential risk of interference between cardiac and extra-cardiac devices. For the majority of them, the concomitant use of cardiac devices is not prohibited, but should be evaluated with caution, including a multidisciplinary approach. According to the manufacturers’ manuals, only some devices from St. Jude Medical and the VBLOC therapy system from Enteromedics are contra-indicated in patients with PMs. Therefore, as a general rule, the simultaneous use of a cardiac device and an extra-cardiac device is not contra-indicated. A careful selection of patients, in an experienced centre, with case-by-case evaluation and a multidisciplinary approach is mandatory. Sufficient time must be spent informing patients about the proper use of devices and the potential risk of interactions. Patients should be properly instructed regarding the use of a magnet for their extra-cardiac device (which ideally should be avoided if possible). The use of a programmer header and/or a recharger header carries a risk of interferences if erroneously placed over a cardiac device. A detailed control of both devices, cardiac and extra-cardiac, should be done after implantation of the second device, while attempting to create a ‘worst-case scenario’ to identify interactions, i.e. temporarily programming maximum sensitivity of the cardiac device and maximum tolerated output of the extra-cardiac device, also using unipolar stimulation. Interference should be continuously evaluated by analysing the electrograms and marker channels of the cardiac device. Implantable cardioverter-defibrillator therapies should be temporarily inactivated, and cardiac device programmers have an emergency asynchronous pacing button that can be activated if necessary in PM-dependent patients.
Magnetic resonance imaging
Cardiac MRI has become a powerful non-invasive diagnostic tool, and the indications have grown in recent years. The subject of MRI conditionality of extra-cardiac devices is a source of controversy. Potential concerns include induced electrical currents and heating of the tissue, damage to the devices, and interactions with the magnetic field. There have been cases of neurological damage in patients with DBS devices undergoing a head MRI.11,43 On the other hand, performing an MRI following recommended precautions has been proved to be safe in patients with a sacral nerve device or vagal nerve stimulator.44,45 Only Medtronic® devices with the SureScan™ MRI technology for pain therapy are considered eligible for full-body MRI scans. The other devices are either MR unsafe or MR conditional for head-only scans (cf. Table 1). Because of the potential of serious harm to the patient and the possibility of performing an alternate diagnostic test in the great majority of cases, cardiac MRI should probably not be performed in patients with extra-cardiac devices, until specific recommendations are made or until technology evolves and permits the development of MRI-conditioned devices.

Radiofrequency ablation procedure
Based on the manufacturer’s manuals, there is a possibility that radiofrequency could induce electrical currents that may cause heating of the electrode and thus, tissue damage. To our knowledge, no studies or case reports of such procedures in patients with an extra-cardiac stimulator have been published. It should, however, be noted that in patients with cardiac devices, radiofrequency ablation procedures are safe. As for the surface ECG, the signals may be affected by artefacts due to the stimulation pulses. This may require programming bipolar pacing or temporary inactivation of the device. The indirect electrode for delivery of radiofrequency current should be placed at distance from the IPG of the extra-cardiac device.

Conclusions
Extra-cardiac stimulators treat patients with a wide variety of non-cardiac conditions. As the population ages and with new targets and growing evidence of efficacy, an increasing number of our patients will be treated with extra-cardiac devices. The most frequent issue is the presence of ECG artefacts resulting from pulses delivered by the extra-cardiac stimulator, which may be temporarily inactivated or programmed to bipolar pacing. In addition, these patients may be addressed for cardiac procedures that may carry risks to the extra-cardiac device (e.g. electrical cardioversion and cardiac MRI). Finally, these patients may require a PM or an ICD, with a risk of interference between devices, which requires careful evaluation. In the future, technical advances will probably reduce the number of limitations (for example with the development of MRI-conditional devices, filters on PMs and ICDs to avoid electromagnetic interference). In addition, with the growing number of indications and use of these devices, more evidence regarding safety of cardiological procedures should hopefully be available.

Supplementary material
Supplementary material is available at Europace online.

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References