CARDIAC PACEMAKERS DO A LOT MORE THAN JUST TICK.

Tick, tick, tick

By Gary Legg, Contributing Editor

FEW ELECTRONIC DEVICES seem as technically simple as an implanted cardiac pacemaker. A pacemaker's job, basically, is to speed up a heart that beats too slowly. It does that by stimulating the heart with regular, small shocks to make it beat at an appropriate rate. Tick, tick, tick. An easy job, seemingly.

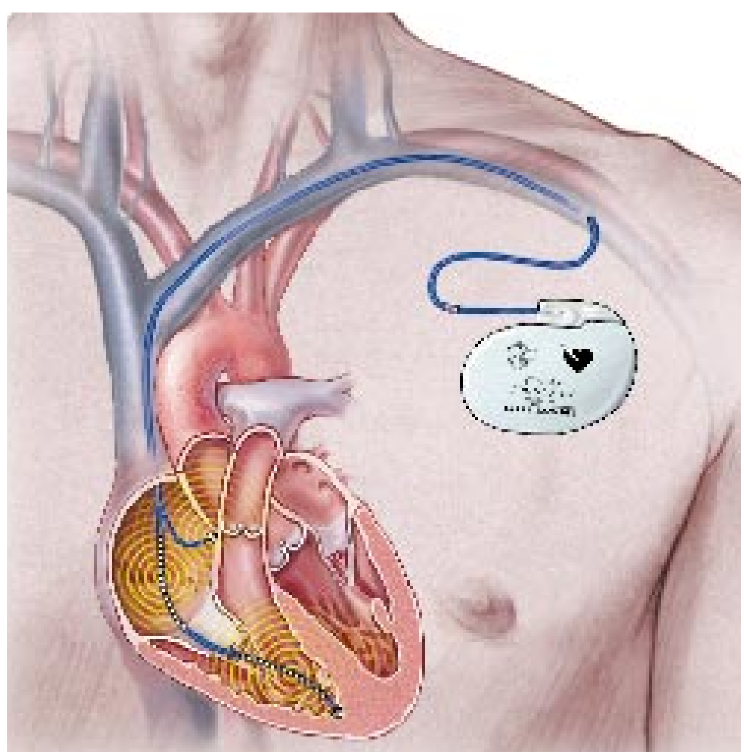
A pacemaker's circuitry can seem simple, too. Basic components include a battery, a pulse generator, and a simple microprocessor for control. One or two electrical leads extend from the pacemaker to heart muscles. Not a complex device.

Or so it would seem. In reality, pacemakers aren't simple at all, and their job is anything but easy. Consider, for example, that a pacemaker has to function inside the human body, a notoriously corrosive environment, and that it must be absolutely reliable. Consider, too, that a pacemaker has to run for as long as 10 years on a single, small battery. Otherwise, heart patients would need replacement surgery far more often than they or their insurance companies would like. And consider that a pacemaker must be capable of being implanted in the body and connected to the heart without open-chest surgery and without general anesthesia. Those conditions impose some very significant design constraints.

And here's another reason why a pacemaker can't be a simple device: A simple, unvarying "tick, tick, tick" type of heart stimulation just doesn't cut it. A constant-rate heartbeat would be too fast for resting and sleeping and too low during physical exertion, so the heart patient would neither rest well nor work or play well. In one case, the heart would outpace the body's physical demands; in the other, it wouldn't keep up, leaving the patient feeling fatigued. A pacemaker, then, needs to adapt to a heart patient's level of physical activity. In other words, it needs to be smart. Simple device? Hardly.

SIMPLE SURGERY

Modern pacemakers do simplify matters for the heart patients who receive them, however. For example, the latest pacemakers are matchbook-sized, titanium-encased devices that are small enough to



Miniature low-power electronics and special electrical leads enable cardiac pacemakers to be implanted under the skin rather than in the chest cavity (Illustration courtesy of Guidant Corp, created by gmedmedia.com).

implant under the skin, near the collarbone, instead of inside the chest cavity or in the abdomen. The procedure takes about an hour and requires only local anesthesia and a sedative. The patient usually remains hospitalized for only one or two days.

What complicates this procedure, however, is that the electrical leads of a pacemaker, which is outside the chest cavity, must connect to the heart, which is inside. The solution is to thread the leads through a vein from the implant area to the inside of the heart. The leads must be small in diameter, slippery enough to thread through a vein, highly resistant to corrosion, and capable of withstanding flexing for years without breaking. They must also meet precise electrical requirements. For example, they must have the ability to sense very small electrical signals that accompany a heart's natural activities while also remaining immune to noise introduced by outside sources.

FOR MORE POWER SAVINGS, MOST PACEMAKER PROCESSORS REMAIN IN SLEEP MODE AS MUCH AS 99% OF THE TIME.

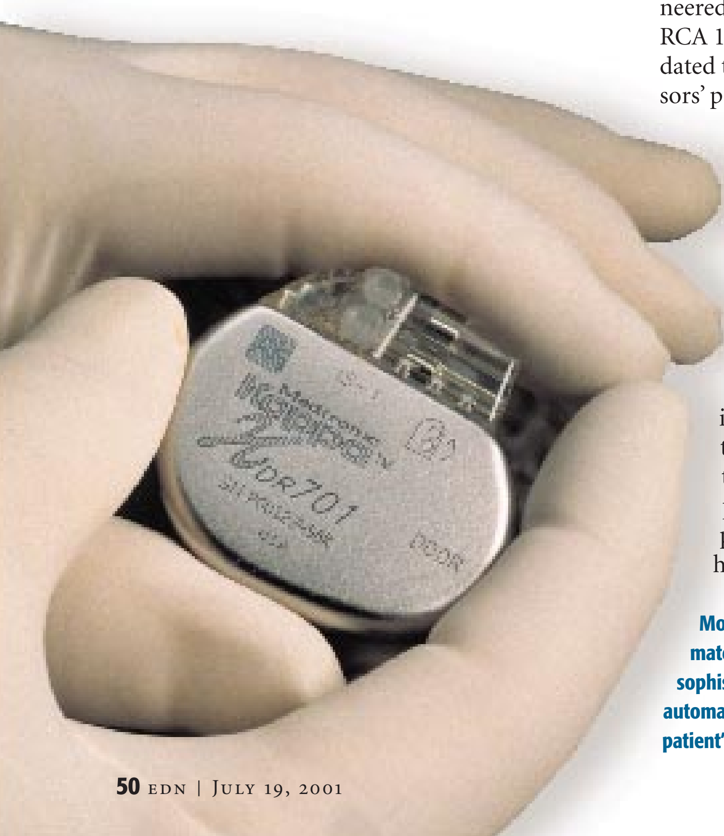
The leads that meet all these requirements are almost marvels of mechanical design. They're made of titanium and silicone, and some have an extra-slippery coating of a different silicone to make them easy to thread. Each has a mechanism at one end for attachment to a heart muscle, but a surgeon has to make the attachment while manipulating the other end, sort of like pushing a string. Fortunately, the attachment mechanisms make this possible. Some leads even have the ability to administer a small amount of a steroid at the attachment point.

Pacemaker leads usually have one of two mechanisms for holding their electrodes in place against a heart muscle. One type of lead has a screw-in tip that looks like a tiny corkscrew. This tip simply screws a short distance into the muscle. The other type of lead has tiny, flexible, rubber tines that press outward against the sides of muscle crevices in the heart's interior. Either type can have a steroid-eluting tip that administers a small, controlled dose of a steroid to minimize inflammation and scarring of the heart at the attachment point. The steroid dose, typically 1 mg, is administered over a period of several weeks. Perhaps surprisingly, the steroid can help extend pacemaker-battery life by almost 50%, because less scar tissue means lower resistance and thus less current required for the shock that stimulates a heartbeat.

SAVING POWER

The all-important power savings in a pacemaker begin with a custom-designed, very-low-power microprocessor. The processors in use aren't high-performance devices; many, in fact, are reverse-engineered versions of very early processors, such as the RCA 1802 and the Motorola 6805, but they are updated to run on lower voltages. To keep the processors' power consumption to a bare minimum, their designers stripped away every feature and function that isn't absolutely essential. And because the workload on a pacemaker processor isn't heavy, clock speed is low—typically 3 MHz—to further reduce power consumption. Code storage typically requires about 40 kbytes of ROM.

For even more power savings, most pacemaker processors remain in sleep mode as much as 99% of the time. Processing begins when a sensor in the pacemaker detects a heartbeat (by detecting electrical activity in the heart, via a lead) and wakes up the processor. When processing is complete, the processor goes back to sleep until the next heartbeat.



Modern cardiac pacemakers are barely larger than a matchbook and yet contain a surprising amount of sophisticated electronics. The Medtronic Kappa DR 701 automatically varies a patient's heart rate according to the patient's level of physical activity.

Still more power savings accrue through the use of smart pacemaker algorithms that provide shocks to the heart only when necessary. If a sensor determines that the heart is beating fast enough on its own, which is the case most of the time for many heart patients, then the pacemaker doesn't intervene, thus conserving battery power.

Modern pacemakers also slow the heartbeat during sleep or rest, just as the body does with a normally functioning heart. Early pacemakers could slow down only during a predetermined, fixed time period—from 10 p.m. to 6 a.m., for example. That was a problem if you wanted to party late or if you were a traveler crossing time zones. Modern pacemakers get around that problem with sensors that detect physical activity and the frequency and depth of breathing. For example, a sensor bonded to the inside of a pacemaker's metal case detects pressure waves caused by muscle movement or body motion. Other sensors used in pacemakers include devices that measure heart motion, body temperature, changes in body acidity, and pressures inside the heart chamber.

Many pacemakers today come packaged with a defibrillator, a device that intervenes when the heart beats very rapidly—the opposite of the condition treated by a pacemaker. The combination device is often necessary, because an occasional very rapid heartbeat, indicating a potentially lethal condition known as fibrillation, is not a rare occurrence even in heart patients whose normal rhythm is often too slow. The pacemaker function of an implanted cardiac device occurs regularly in most cases; the defibrillator function occurs only in a cardiac emergency.

SHOCKING!

A basic difference between a pacemaker and a defibrillator is in the shock applied to the heart. A pacemaker applies a steady stream of very mild shocks—typically a 3.5V, 0.4-msec pulse; a defibrillator applies one or a few big wallops of as much as 30J each. Although a large shock from a defibrillator can feel like a kick in the chest to a heart patient, it can restore a heartbeat's regular rhythm. Without defibrillation, a patient experiencing fibrillation can go into cardiac arrest and die within minutes.

Not surprisingly, it takes a big capacitor to pack the punch of a defibrillator. Early defibrillators, in fact, used a photoflash capacitor—the kind that produces the flash for a camera. Defibrillator capacitors now are custom designs, because of regulatory requirements that manufacturers of photoflash capacitors don't want to contend with. Also, medical-device manufacturers make these capacitors in flat versions, instead of rolled, to fit in a thin cardiac device's case.

Pacemaker and defibrillators have benefited from overall advances in technology. Lithium batteries, for example, are largely responsible for the long times between surgical replacement of cardiac devices. Some of the batteries in use are also "smart"—capable of monitoring their remaining power capacity and of sending an alert signal when it drops below a certain level. Advances in sensor technology have been of particular benefit to cardiac-implant devices, enabling adaptation to patients' different and varying conditions.

TECHNOLOGY FROM MANY SOURCES

Advances in cardiac-device technology have come from all quarters, even NASA. For example, the two-way communications capability that allows a physician to instruct and query a cardiac device with an external programmer is based on a method of bidirectional telemetry developed for communication between Earth stations and orbiting satellites. Communication with an implanted device—setting its operating parameters and reading its stored record of cardiac activity—occurs via radio waves through a wand that's held close to a heart patient's chest.

What's perhaps most amazing about pacemaker technology is simply that all of it exists and works in a tiny package that can weigh as little as an ounce and be as small as four credit cards cut in half and stacked together. Almost equally amazing is that a device can keep on functioning inside the human body, without intervention, for years at a time. And, of course, it's impressive that a cardiac implant can adapt so well to the complexity of an individual human being.

And all of this happens in a device that most people expect simply to go "tick, tick, tick." That expectation shouldn't be surprising, given that the first solid-state pacemaker was based on the design of a transistorized metronome, but pacemakers have come a long way since then. Pacemakers may look simple, but they're not.□

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FOR MORE INFORMATION...

Interesting and useful information about pacemakers and defibrillators is available on many Internet Web sites. Here are some of the better ones.

Medtronic Inc
www.medtronic.com
Enter No. 322

St Jude Medical
www.sjm.com
Enter No. 323

Guidant Corp
www.guidant.com
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HeartWeb
www.heartweb.org
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