ABSTRACT
The Implantable Cardioverter Defibrillator (ICD) is a complex implantable medical device that treats ventricular tachycardia and fibrillation. It is equipped with a basic micro-computer that serves as the overall controller of all diagnostic and therapeutic functions. The ICD has a number of sections and components that are unique to the device, such as a high voltage charging section and a high voltage output section. The miniaturization asymptote for the minimum size of an ICD is probably 25 cubic centimeters. New unconventional therapeutic options with reduced power levels may make further miniaturization and cost reduction possible.

Key words:  ■ ICD  ■ ventricular fibrillation  ■ ventricular tachycardia

Background
The Implantable Cardioverter Defibrillator (ICD) is an implantable medical device that is used to treat ventricular tachycardia and fibrillation with high voltage therapy. It has the capability to deliver low voltage pacing therapy as well. The device has a basic onboard micro-computer that serves as the overall controller of all diagnostic and therapeutic functions, a high voltage charging section, a high voltage output section, and a connector top header that connects the device to the cardiac leads.

While the basic conceptual work on a fully automatic implantable defibrillator began in the 1950s, the practical embodiment of the device only began to take shape in 1971 with the work of Michel Mirowski and Morton Mower. After overcoming the skeptics, Mirowski and Mower demonstrated a prototype in a canine subject in 1979. This led to efforts to develop the device in the early 1980s by Intec Systems, which produced the AID™, and then by Cardiac Pacemakers Inc., which produced the Ventak®. These early devices were fully automatic and implantable and had a displacement volume in the range of 150 to 200 cubic centimeters (cc). Other companies then began product development efforts that led to widespread commercialization of the ICD in the early 1990s.
**Figure 1.** Examples of ICDs (pictures are not to scale).

**Technology Status**

In devices that have Cardiac Resynchronization Therapy (CRT) capability, devices that represent the current state of the art in ICD technology have an overall displacement volume in the range of slightly less than 30 cc to over 40 cc. Various physiological shapes are available to the designer to minimize the pectoral pocket size, shape, and bulge. The incision length for the insertion of the device into the pocket can also be minimized. The device shape is chosen to maximize the patient’s comfort and to minimize pocket erosion over time (Figure 1).

The devices are packaged in a biocompatible enclosure that is formed from commercially available pure Titanium sheet stock. A laser welding process is used to seam-weld the enclosure, which ensures that the components packaged within it are hermetically sealed from body fluids. A thermoplastic or thermostet epoxy resin is used to form the connector top header, which serves as a fixture for connection to the endocardial leads.

The miniaturization of ICDs took place quite rapidly in the 1990s. Significant technological developments in commercial electronics facilitated the miniaturization of ICD electronic packaging. The ability to configure the unique larger components into custom shapes that fit within the device also helped to dramatically decrease its overall volume. Currently manufactured ICDs appear to be converging on an asymptote volume of 25 cc (Figure 2).
**Figure 2.** ICD miniaturization trend over time.

**Why is an ICD bigger and more expensive than a pacemaker?**

The components and circuits within an ICD are designed and shaped to fit quite efficiently within the device to minimize wasted space and to conform to the overall profile of the device enclosure. Very dense electronics packaging techniques, a dense circuit-to-circuit interconnect, and high performance materials are employed to minimize the size and maximize the device’s reliability.

However, the ICD has a number of unique components that add to its overall size and dramatically increase its cost of manufacture. A special Lithium Silver Vanadium Oxide (LI SVO) battery is used as the charging supply for its high voltage therapy function. This type of battery typically adds approximately 3 cc of volume as compared to a conventional pacemaker battery. A special Aluminum Electrolytic capacitor set is charged in order to serve as the high voltage energy reservoir for defibrillation therapy. This capacitor set, which is not present in a conventional pacemaker, adds approximately 8 cc of volume to the device. A special DC-to-DC converter takes the low-voltage high-current input from the battery
and converts it to a high-voltage low-current source that charges the high voltage capacitor set. This DC-to-DC Converter is also not present in a conventional pacemaker, and it adds approximately 2 cc of volume to the device (Figure 3).

The most critical section of the ICD is the high voltage output circuit (Figure 4). It controls the delivery of defibrillation therapy to the patient. The actual flow of current is typically controlled by 4 large Insulated Gate Bipolar Transistors (IGBT). Because these transistors switch instantaneous voltages that can be as high as 900 V, they must be sized in accordance with high voltage standoff design rules that prevent arcing and shorting within the transistor during the switching operation. In addition, each of the transistors must be placed at a specific spacing from the other to prevent arcing and shorting between transistors. These (4) transistors are not present in a conventional pacemaker, and together, they add approximately 5 cc of volume to the device. In addition, these special transistors, along with their special electronics packaging, add a significant cost to the device (Figure 4).

**Future Generations of the ICD**

The current state of the art in ICD packaging has reached technological maturity. Increased miniaturization will probably yield just a marginal decrease in the overall displacement volume of the device, which will be accompanied by a significant increase in manufacturing cost. The cost of the precious metals used in the device continues to rise. Because the ICD has a number of components that are unique to its application, it is doubtful that the current advances being made in the high volume personal electronics revolution would be of use in reducing its size and cost.

If the clinical requirements for an ICD could be modified or relaxed, it would be possible to conceive of a new generation of devices that are smaller and that cost less. Relaxation of the design constraints could lead to the modification or complete elimination of the components within the ICD. Special batteries, high voltage capacitors, and high voltage output circuits could become smaller and less costly to manufacture.

The first example of a future generation ICD is

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**Figure 3. Inside a typical ICD.**

DC: direct current, HV: high voltage, SVO: siver vanadium oxide
one that allows for a significant increase in its charge time in preparation for the delivery of therapy to the patient. The device would charge at a lower input power. A reduction in the maximum target charging voltage would make possible a significant reduction in the size of the device circuits and their respective components. In this case, alternative battery chemistries could be employed, such as Carbon Monofluoride (CFx). The size of the battery, the high voltage capacitor set, and the high voltage output circuit could also be reduced, bringing about a significant cost reduction as well. It is recognized that this new ICD may not be suitable for all patients.

The second example of a future generation ICD is one that is more disruptive and unconventional in its design approach. This device is able to sense and detect tachyarrhythmias just before their onset. One class of therapy regimen would consist of low voltage pace trains that would decelerate the arrhythmia into a normal sinus rhythm. Another class of therapy regimen would stimulate the autonomic nervous system via thoracic spinal cord stimulation in a way that would prevent the onset of an arrhythmia. This new generation of devices has the function of a low voltage implantable pulse generator, and it looks more like a pacemaker or a spinal cord stimulator. It would make possible a significant size and cost reduction relative to the design of the conventional ICD.

Summary

The current state of the art in ICD technology has reached its maturity. The ICD has a number of components and circuits that are unique to its application, and a significant size and cost reduction of the conventional ICD is unlikely. Changes in the clinical requirements of the ICD could lead to the development of a future generation of devices that would be much smaller and less costly to manufacture.
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References


