EXPLORING MINIATURIZATION IN BIOELECTRONIC MEDICAL DEVICES

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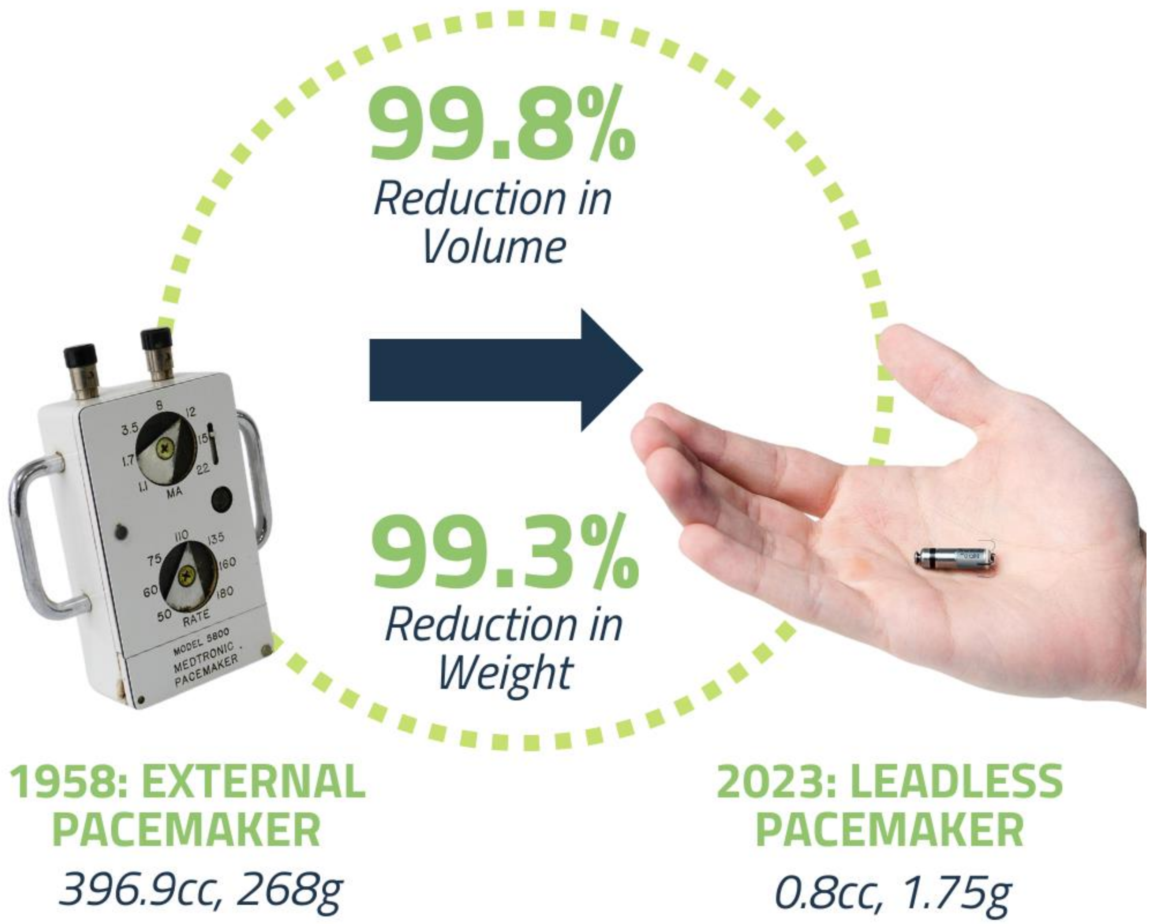
INTRODUCTION

In 1958 an external pacemaker was introduced, 65 years later the leadless pacemakers are on the market. Over that period the volume of the pacemaker was reduced by 99.8%, and the weight was reduced by 99.3%, all while adding additional functionality such as rate **responsive pacing**, **wireless programmability**, **increased battery longevity**, **sensors**, and **MRI compatibility**.



WHAT IS MINIATURIZATION?

Miniaturization refers to the process of **designing** and **manufacturing** smaller versions of devices, components, or systems while maintaining or enhancing their functionality and performance. This trend is prominent in various industries, including electronics, **medical devices**, and bioelectronics, where advancements in materials, precision engineering, and technology enable the development of compact, lightweight, and efficient products. In the medical device industry, for example, miniaturization allows for the creation of smaller, less invasive devices, such as implantable sensors or bioelectronic devices, which improve patient comfort and reduce recovery times.

WHY IS MINIATURIZATION IMPORTANT?

One of the most important benefits of this incredible **miniaturization of biomedical devices** is significantly less invasive surgery for patients. In 1958, implanting pacemaker leads, or a pacemaker required open heart surgery which required cutting through the breastbone and spreading the ribs to reach the heart and carried a significant risk of complications and lengthy recovery periods. Today, leadless pacemakers can be placed via catheter through the femoral vein with reduced risk of complications, and significantly faster recovery periods.

Longer battery life is critical for patients. Leadless pacemakers have a median longevity of 16.7 years, which allows a single pacemaker to last for the lifetime of most patients, rather than having to undergo a pacemaker replacement surgery. In contrast, the early pacemakers lasted only hours when operating off batteries.

With miniaturization comes the possibility of adding in additional features such as **rate adaptive pacing**, which adjusts the pacing rated based on the activity level of the patient, increasing cardiac output during exercise. This feature is enabled by miniaturized sensors such as **accelerometers**, **intrathoracic impedance measurement**, and **heart rhythm analysis**. Other features such as wireless programmability, MRI compatibility, and heart rhythm data collection/analysis are also enabled by the ability to cram more functionality into a smaller form factor.

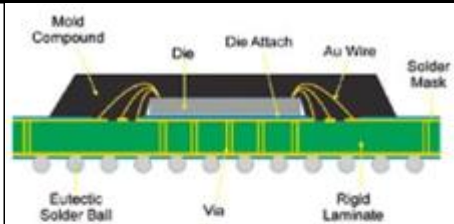
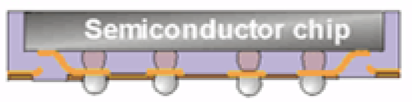
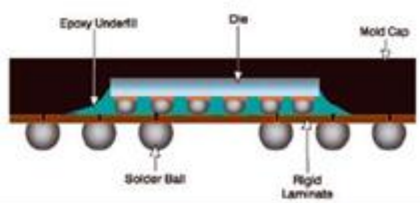
WHAT TECHNOLOGIES ENABLE MINIATURIZATION?

TRANSISTOR DENSITY

The primary driver of this miniaturization goes hand in hand with the significant advances in electronics and electronics packaging across all industries. The best-known example of this is "Moore's Law" coined by Gordon Moore of Intel, which postulates that the number of transistors doubles roughly every two years. In the early 1970's state-of-the-art semiconductor processing technology would allow transistor densities of up to 200 transistors per mm^2, while transistor densities exceeding 100 million transistors per mm^2 are possible with current semiconductor processing technology. This continual reduction in transistor size also benefits battery life, with less energy required to change the state for each transistor.

IC PACKAGING

Along with the reduction in transistor size have come advances in IC (Integrated Circuit) packaging such as:

Technology	Example:
BGA – Ball grid array, allows the entire bottom surface of the IC package to be used for interconnection via solder balls.	
Chip Scale Packaging – a miniaturized IC packaging technology where the IC package is no more than 20% larger in area than the original die and is a direct surface mountable package.	
Flip Chip - A type of IC packaging where pads are metalized on the top surface of the chips, solder balls are applied, and then the chip is "flipped" so that solder balls are facing the external circuitry.	
Stacked die - Stacking of multiple dies within a single package.	
Package on Package – Stacking multiple packages in the same footprint.	

(Images courtesy of Amkor Technology, Inc.)

PCB\FLEX\RIGID-FLEX

Advances in PCB (Printed circuit board), Flex Circuits, and Rigid-Flex Circuits are also required to take full advantage of the increasing density of Integrated circuit connections. Rigid-Flex and HDI (Density Interconnect) enables a single flat circuit assembly to be assembled with rigid sections for mounting components, and flexible interconnections without using bulky connectors to be folded into a small volume.

Figure 1 - Fully assembled endoscopy capsule

(Image courtesy of EDN)

Figure 2 - Unfolded endoscopy capsule

(Image courtesy of EDN)

BATTERIES

In most bioelectronic systems, the batteries are the largest single component by volume, so reducing battery size is critical to miniaturization. Batteries come in two broad categories: Primary Cell (aka non-rechargeable), and Secondary Cell (aka rechargeable).

Primary Cell		**Secondary Cell**	
Pros	Cons	Pros	Cons
Higher energy density than secondary cells	Battery\device replacement may have significant patient impact (ex. implantable devices)	Frequent periodic recharge schedule can significantly reduce the size of battery cell(s).	Requires the patient to periodically recharge batteries.
Reduced support circuitry (ex. recharging, wireless power)	Non-replaceable batteries, unexpected usage patterns can significantly reduce predicted battery life	Allows devices to be completely sealed (ex. wireless power, or insert molded contacts)	Lower energy density than primary cells

Allows use of common off-the-shelf patient replaceable batteries (ex. wearables)	User replaceable batteries require more parts, and requires careful design to prevent water ingress	May allow use of common smartphone charging infrastructure (ex. USB-C)	Battery capacity degrades with repeated charge/discharge cycles.
Long shelf life (10yrs+ for some chemistries)	Frequently replaced batteries can end up costing significantly more over the life of the device	Over the life of the medical device can be more cost effective than replaceable batteries.	Limited shelf life (recommended 6 months)

- Regardless of battery type, the key to reducing the size of the battery is reduction in power consumption of the overall system which typically include several the following techniques:
- Use lower power/sleep modes on Processors. Keep processing to a minimum. Use event drive architectures rather than polling. Wake up the system only when necessary
- Turn off or put into low power mode processor peripherals when not in use.
- Wireless – Turn off wireless interfaces when not in use. If possible, avoid continuous connection, instead batch all communication into a periodic (hourly, daily, weekly, etc.) transmission.
- Utilize switching power supplies with high efficiency and avoid the use of linear power supplies if possible. For light duty loads use supplies with a burst or pulse skipping mode. For intermittent loads allow power supplies to be turned on only when needed.
- Allow software to power down circuitry when not in use.
- Offload processing to Hardware Accelerators, such as Direct Memory Access (DMA), Cyclic Redundancy Check (CRC), and Digital Signal Processing (DSP).

WIRELESS COMMUNICATIONS

Over the last decade, **Bluetooth Low Energy** (BLE) has become the dominant wireless communication standard for wearable medical devices and some implantable medical devices, displacing other medical device-specific wireless standards such as **Medical Implant Communication Service** (MICS) **Medical Device Radiocommunications Service** (MedRadio), and **Wireless Medical Telemetry Service** (WMTS) due to its low power design, widely available hardware and software, ability to communicate directly with smartphones and tablets, and allowed usage outside of health care facilities.

SENSORS

Miniaturization of sensors, especially so called **Micro-electromechanical systems** (MEMS) sensors, has allowed the inclusion of low power, low cost, smaller sensors than previous generations of medical devices. MEMS sensors fabrication technology has progressed in concert with semiconductor fabrication, which allows microscopic moving components. Accelerometers (measuring x/y/z-axis linear acceleration) are among the most commonly MEMS sensors in medical devices, enabling low-cost measurement positioning, respiration, heart rate, and activity level. Accelerometers are often combined with gyroscopes (measuring x/y/z-axis rotational acceleration) and/or magnetometers (measuring x/y/z magnetic field) to form inertial measurement units (IMU).

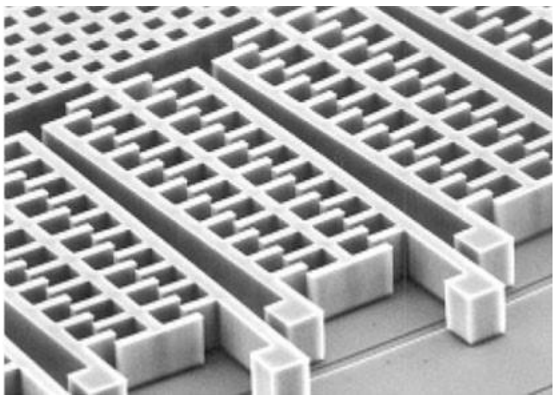


Figure 3 - MEMS Accelerometer (Image courtesy of STMicroelectronics)

Other common MEMs sensors found in medical devices include:

- Pressure sensors
- Humidity Sensors
- Microphones
- Temperature Sensors

HOW CAN NEXTERN HELP?

At Nextern, we have a dedicated team of expert electrical, software, mechanical, systems, and process engineers who can help optimize the size, battery life, and cost of your **bioelectronic medical device**. With experience in developing **compact**, **wearable**, and **implantable** medical devices, we leverage advanced **design** and **manufacturing** processes to meet the growing demand for miniaturized solutions in the **bioelectronics** sector. Partner with **Nextern** to bring cutting-edge, miniaturized bioelectronic devices to market faster and more efficiently.