Thin-Film Piezoelectric Film Technology in Medical Device Applications

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A growing need for sensors within the medical device market has illustrated renewed OEM focus on design efficiencies, patient comfort and enhanced quality of life. The application environment itself is uniquely stringent, with regulatory compliance standards, such as FDA approvals on Class III implantable medical devices, that can require up to four years of biocompatibility and performance testing before prototype implementation and approvals. These requirements can ultimately lead to fewer new market introductions, and leave little margin for error. Additional OEM supplier quality requirements, such as ISO13485 certification, can make sensor technology choices especially challenging, and also somewhat limiting.

There are several sensor technologies on the market that can be successfully integrated into medical devices. Among them, piezoelectric film presents some of the most unique design capabilities and advantages.

Piezoelectric film is made from a polyvinylidene fluoride, which is both chemically inert and biocompatible. Because of its piezoelectric properties, film material contains multiple, tiny, interlocking crystal domains, which have both positive and negative charges. When stress is put onto these elements, symmetry is broken, generating voltage in proportion to compressive or tensile mechanical stress or strain, making the film an ideal dynamic strain gauge. Piezo film also possesses a unique ability to be configured into an infinite number of shapes and sizes, for extreme application versatility. The manufacturing of custom sensors from piezoelectric film incorporates simple, low-cost screen printing and die-cutting processes, another key advantage when incorporating the technology into the design of mass-produced, disposable medical sensors.

As the film is lightweight, flexible, and unobtrusive, there is also no significant patient discomfort. Because of these attributes, as well as its ability to detect voltage signals when physically stressed, piezoelectric film becomes an ideal material for patient health monitoring of physical, human motions of interest. These include vital signs such as heart rate, respiration, and other involuntary motions of the human body. Examples of the successful application of piezoelectric film technology within medical device applications include:

Electronic Stethoscopes – Piezoelectric film is used as a unique contact microphone for electronic stethoscopes, with the film held tight in a small enclosure. A button protrudes from the enclosure and positioned, so that when pressed against a patient’s chest, heart sounds are coupled from the chest, through the button, to the film. The enclosure also contains a microphone preamplifier to detect acoustic signals. Successful technology implementation within this device

allows for exceptional volume and sound discrimination for medical personnel in particularly noisy environments, such as emergency medical transport vehicles or emergency rooms/triage areas.

In-hospital Patient Monitors – Piezoelectric film has been successfully laminated into large flexible waterproof pads (2 ft x 2 ft), placed atop a hospital bed mattress, beneath the pad, for unobtrusive in-hospital patient monitoring. Pads are designed so that when a patient lies on the bed, sensor elements pick up both heart and respiration rates, which are sent to and displayed on a patient monitor. Signals can also be sent simultaneously to a monitor at the nurses' station, allowing for continuous, real-time remote monitoring of basic patient vital signs by hospital personnel. Design advantages include increased patient mobility, greater freedom and comfort via absence of connections, wires, tubes or other restrictions, and increased efficiencies by hospital staff, which ultimately enhance overall patient care quality.

Cardiac Pacemakers – Piezoelectric film is also an effective patient activity monitor within cardiac pacemakers. In this type of application, the film is configured into a small cantilever beam, mounted inside the pacer. One end of the beam is attached to the pacer, while the opposite end is allowed to move back and forth, or "flops", in reaction to patient activities. Small masses are added to the free end of the beam to amplify its motion and improve sensitivity. As the beam flexes, piezoelectric film is strained, generating signals that are representative of patient activity. The medical device uses these signals to adjust cardiac stimulation rate. As patient activity increases, the pacer increases heart rate. As the patient becomes less active, heart rate is reduced. A cardiac pacemaker operates from its own internal battery, making power consumption a critical concern. As the piezoelectric film consumes no external power and produces its own voltage signals, it is ideal for use within this application.

Piezoelectric Film Kits for Medical Device Prototype Design

The unique physical properties, size, and performance characteristics of piezoelectric film make it especially useful for implementation within medical device design applications, as an alternative to a standard-sized piezoelectric accelerometer, where space constraints, cost or design flexibility may be of concern, or where multiple film configurations are required within the same application.

For medical device prototype design evaluations, in which cost-savings and design versatility are prerequisites, use of the Measurement Specialties piezoelectric film design kit is recommended. Kits offer various types and thicknesses of film, allowing the design engineer to find the best possible technology application for their unique requirements.

Measurement Specialties are industry pioneers in the successful integration of medical device sensing technologies. With manufacturing facilities that are both FDA registered for medical device manufacturing and ISO13485 certified, the company regularly collaborates with OEM's on the design and development of life-sustaining, implantable medical devices and equipment, and the successful

incorporation of piezoelectric film technology within these challenging application environments.

The Digi-Key/Measurement Specialties Piezo Film Basic Design Kit includes various sizes and thicknesses of piezo film, and serves to demonstrate the various practical application of technology, in the form of microphones, switches, speakers and acoustic pickups. Each provided sample is fully operational, and able to be integrated into new or existing prototype designs, for assessment of performance within a given application environment. All included film samples can be used to properly test applicability and performance of each technology type. For customers requiring additional technical support, Digi-Key offers 24-hour live chat assistance. For more information on available Piezo Film Basic Design Kits, please visit www.digikey.com [1].

About Measurement Specialties, Inc.:
Measurement Specialties offers a large variety of sensor products to meet application requirements in off-road, medical, industrial, consumer, military/aerospace, test/measurement and traffic applications. Measurement Specialties offers multiple sensor technologies to medical device manufacturers, including: disposable and reusable silicon MEMS pressure sensors, low cost load cells, SpO2 Sensors, NTC thermistors for temperature sensing, thermopiles for non-contacting temperature sensing, capacitance-based humidity sensors, piezoelectric polymers as vibration sensors, magnetic encoders, LVDTs, RVDTs, magneto resistive, flow, vibration and acceleration sensors. http://www.meas-spec.com [2]
About Digi-Key Corporation:
One of the world's fastest growing distributors of electronic components, Digi-Key has earned its reputation as an industry leader through its total commitment to service and performance. As a full-service provider of both prototype/design and production quantities of electronic components, Digi-Key has been ranked #1 for Overall Performance for 17 consecutive years from among the nation's more than 200 distributors (EE Times Distribution Study/August 2008). Offering more than 1.5 million products from nearly 400 quality name-brand manufacturers, Digi-Key's commitment to inventory is unparalleled. Access to the company's broad product offering is available 24/7 at Digi-Key's top-rated website, www.digikey.com [1].

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