Message from the Director:
Advancing Medical Electronic Reliability

The US, with its highly skilled workforce and strong high-tech base, dominates the lucrative and steadily growing medical device manufacturing industry. Currently, there are around 550 medical device manufacturers in the US. In 2015, these companies generated $40 billion in revenue, and this number is expected to grow 6.5% annually to reach $55 billion per year in 2020 (Jocelyn Philips, “Medical Device Manufacturing in the US”, IBISWorld Industry Report 33451b, October 2015).

The 2015 review of the Medical Device Manufacturing industry for IBISWorld highlights the growing importance of product reliability. General well-being of the end users is directly influenced by the efficiency and quality of products in this industry. Thus, superior quality and reliable performance of products, offer more advantages for competition among medical manufacturers, rather than affordability. A medical device must provide reliable and consistent outcomes and satisfy quality requirements set forth by doctors. However, the reliability assessment in medical device industry has not kept the same pace with the increase in the sophistication of products.

CALCE has been deeply involved in helping the Medical Device Manufacturing industry to achieve their reliability goals in a timely manner and thus cost-effectively enhance their market performance. Our clients and partners have included the top players in the industry: Abbott Laboratories, Advanced Bionics, Boston Scientific Corporation, Cochlear, General Electric, Johnson & Johnson, Medtronic, Nevro, Philips Medical Systems, Philips Healthcare, Physio-Control, Respironics, Sensors for Medicine and Science, St. Jude Medical, and MED-EL.

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CALCE possesses the intellectual capital and the technical infrastructure to help the Medical Device Manufacturing industry meet their reliability requirements. The top players in this industry have already worked closely with CALCE, and many other companies are reaching out to us for assistance. By developing and applying the latest reliability, supply chain, parts selection, and testing strategies and technologies, we are helping the Medical Device Manufacturing industry to produce reliable, safe and cost-effective healthcare products and systems.

Michael G. Pecht, Ph.D., PE
October 28, 2015
Investigating the Electrostatic Discharge (ESD) Failures of Medical Electronics

The recent ASHRAE 170 standard, titled “Ventilation of health care facilities,” reduced the minimum allowable relative humidity of anesthetizing locations in healthcare facilities to 20%. This standard has been recently adopted by several organizations and federal agencies involved in designing healthcare facilities. However, because low humidity levels increase the susceptibility of medical devices to electrostatic discharge (ESD) failures, these new guidelines actually put the electronic devices used in these areas at risk of destruction of parts, premature failure, and erratic software behavior. Mehdi Kohani, a Ph.D. student at CALCE, is collaborating with Food and Drug Administration (FDA) engineers to investigate the impact of lowering the minimum relative humidity on the ESD failures of medical electronics. The goal of this research is to evaluate the technical reliability and safety concerns for the new guidelines.

In addition to relative humidity issues, Mr. Kohani is investigating the effects of aging on the antistatic performance of static dissipative coatings in medical devices, as one of the most overlooked root causes of ESD. Antistatic materials are used to dissipate the accumulated static charge and minimize the risk of ESD. A reliability concern for these materials is loss of antistatic property over time. The objective of this research is to develop an accelerated aging test plan for life estimation of medical-grade antistatic materials. For more information about this research, contact Prof. Michael Pecht (pecht@calce.umd.edu).

CALCE Graduates Present Medical Papers at the IEEE 2015 PHM Conference in Beijing

Two of the former PhD students of Professor Pecht, Yan Liu (a lead engineer at Medtronic) and Bo Song (lead reliability engineer at Dräger) presented on Bayesian methodology for system reliability assessment and challenges to reliability practices in the medical device industry, respectively. Dr. Liu’s keynote presentation was focused on development of a Bayesian model in the Design for Reliability process to predict the system reliability of medical devices with confidence. It is necessary for manufacturers to accurately estimate the reliability of their product in the design process and before releasing it to the market. Bayesian models incorporate uncertainties in model parameters, information about use conditions and component-level reliability data to provide a system reliability prediction model with improved accuracy. This approach can be advantageous over conventional frequentist methods which may be approximate or not available for some medical devices. Moreover, a Bayesian framework can provide an accurate estimate the reliability when sample size is limited or potential biases are present in the data.

In her keynote presentation, Dr. Bo Song explained how medical device manufacturers can adopt reliability programs in their design phase to enhance efficiency of their products. A significant challenge for medical industry is lack of reliability requirements in European and US standards such as ISO 3485 and FDA 21 CFR Part 820 that regulate medical devices. Delivering a high quality, reliable and durable product is essential for manufacturers since it affects customer satisfaction and market share. Performing reliability analysis during the design phase rather than verification testing, enables rapid identification of failure root causes and lead to reduced lifecycle cost of the medical product. A new trend in reliability analysis of medical devices is the health management of critical components in the system which reduces unexpected failures and also improves preventive maintenance.
Field Reliability of Cochlear Implants Analyzed by CALCE

Cochlear implants are implantable devices that electrically stimulate nerve fibers within the inner ear to produce useful hearing sensation for patients with profound hearing loss. Patients and clinicians are concerned with safety and reliability when they select different models of cochlear implants. However, comparing reliability of devices from different manufacturers is difficult, due to lack of a formal method for classifying and quantifying failure data from field-returned cochlear implants. CALCE researchers developed a classification scheme for reporting failures of cochlear implant wherein each malfunction report is classified according to the failure site, cause, mode, and mechanism [1]. This information can be obtained through failure modes, mechanisms, and effects analysis (FMMEA). Using three-parameter Weibull analysis, reliability analysis of cochlear implants for each failure mechanism, can be performed.

The benefit of the developed reporting scheme is the determination of clear and quantitative information on failure causes and failure sites for a given implant. This approach also helps clinicians select the most appropriate implant for a given patient and aids regulatory agencies in tracking field reliability of the device. Click here or here to read more about this work, or contact Mr. Bhanu Sood (bpsood@umd.edu).

CALCE Contributes to AAMI Standards Development for Cochlear Implants

Safety, performance, labeling, and reliability of cochlear implants are major concerns for patients, clinicians, and manufacturers. However, there is no industry-accepted standard that addresses such requirements for cochlear implants. CALCE has been actively collaborating with the Association for the Advancement of Medical Instrumentation (AAMI), as well as the FDA, clinicians, academic experts, and device manufacturers to develop an American standard for cochlear implants, titled “AAMI CI86, Cochlear implant systems: Requirements for safety, functional verification, labeling, and reliability reporting.” Specification of basic safety and performance criteria of cochlear implants is the main focus of the standard. Using the standard, manufacturers will be able to verify the functionality and labeling of their devices. The standard provides information on how to gather field failure data and to identify root causes of suspected failure for both medical and non-medical reasons. It also sets uniform requirements on how to analyze and report system failures to the FDA, the professional healthcare community, and the public. In addition, general guidelines for characterizing a cochlear implant system are included in the standard. For more information about this CALCE-AAMI collaboration, contact Mr. Bhanu Sood (bpsood@calce.umd.edu).

CALCE Researchers Develop Embedded 3D RF BioMEMS Sensor

Detection of biological indicators (biomarkers) associated with different stages of disease development can result in early detection of diseases. However, widespread use of such biomarkers in disease diagnosis is limited due to lack of low-cost point-of-care biosensor devices that allow real-time, label-free, and multiplexed detection of biomarkers with high selectivity and sensitivity. To solve this problem, CALCE researchers explored innovative approaches to develop BioMEMS sensors for real-time in-situ detection of multiple biomarkers, which has not been attained with any existing label-free detection schemes [2], [3]. Under this effort, an approach for multiplexed detection of biomarkers using a distributed microfluidic embedded RF MEMS system was developed. This research led to the development of four patents on the new BioMEMS device. Click here or here to read more about this work.
Patents for 3D RF MEMS Biosensors for Multiplexed Label-Free Detection

**Patent 1 No.** 9151723

**Patent 2 No.** 20140011697

**Summary:** These two patents describe the design of an innovative RF MEMS-based biosensor capable of sensing the presence of biomarkers by manipulating both its mechanical and electrical characteristics. The immunoassay region of the chip consists of RF MEMS shunt capacitors embedded in microfluidic channels and is customized for the detection of multiple biomarkers. This a single RF MEMS capacitive structure configured as a coplanar wave guide approach that provides 3D sensing of the target. It uses two parallel modes of sensing by incorporating a single RF MEMS capacitive structure configured as a coplanar wave guide. It was demonstrated that the RF-MEMS-based biosensor was able to detect *Staphylococcus aureus* (*S. aureus*) using monoclonal IgG3 antibodies prepared from mice. Finally, the description of the multiple biomarkers (multiplexed detection) by integrating microfluidics with RF MEMS sensors for extending a single immunoassay, is specified.

This invention describes a novel, inexpensive and noninvasive approach for clinical diagnosis. The biomarker concentration estimation using this approach will be more reliable, due to combination of two parallel sensing modes, i.e., RF signal loss detection with surface stress based detection using a deflection membrane. In fact, even if one of the two sensing modes could not be recovered, valuable information about biomarker concentration can still be determined.

This invention hold the potential to address the need for a handheld biosensor device that provides rapid, label-free and in-situ measurement of multiple biomarkers. For more information about this patent, click [here](#) and contact Prof. Michael Pecht ([pecht@calce.umd.edu](mailto:pecht@calce.umd.edu)).

**Patent for a MEMS Barcode Device for Monitoring Medical Systems at Point of Care**

**Patent No.** 20120018514

**Summary:** This patent relates to a novel wireless prognostic monitoring MEMS device that can be used to monitor the health of other electronic devices or systems, such as medical equipment. The MEMS device acts as a canary, which is a system or device that, when subjected to harsh conditions, fails ahead of time and acts as a precursor to system failure. The barcode canary consists of conductive barcodes with various thicknesses and communicates by means of RFID technology. When the canary is exposed to harsh conditions, the conductive materials deteriorate, providing advance warning of system failure. The relationship between the healthy state of the barcode and its degradation to that of the electronic system and the components can be used to predict the remaining useful life of the system (e.g., by means of data-driven approaches). A complete wireless sensor node can be formed by integration of the barcode canary (as a sensing unit) with a wireless transceiver module. The state of health of a point-of-care system can be obtained from the canaries using wavelet analysis or built-in self-tests. For more information about this patent, click [here](#) and contact Prof. Michael Pecht ([pecht@calce.umd.edu](mailto:pecht@calce.umd.edu)).
Patent for a Wireless Biosensor Network for Point-of-Care Preparedness for Critical Patients

Patent No. 20120019386

Summary: This invention specifies the construction of a novel wireless BioMEMS sensor for point-of-care (POC) applications that is capable of simultaneously sensing environmental effects as well as the presence of biological entities in the environment of concern. The BioMEMS sensor is made of biomaterials whose material properties are sensitive to environmental changes such as concentration of harmful biomolecules. These material changes are represented as modification of the impedance and dielectric constant of the MEMS structure. Using wireless techniques, a network of novel BioMEMS sensors can be employed to monitor and record environmental conditions in a more accurate and robust manner than a single sensor. This biosensor network can be integrated into a wireless body surface network to provide a patient’s health information and exposure rate. Such a sensor can be used for evaluating POC environmental preparedness for a specific patient through continuous monitoring of patient health performance due to environmental exposure. For more information about this patent, click here and contact Prof. Michael Pecht (pecht@calce.umd.edu).

CALCE Methods and Devices Improve Electrocardiogram Monitoring

Wearable cardiovascular devices such as electrocardiogram (ECG) monitors enable timely detection of precursors to cardiovascular diseases (CVD), and therefore, reduce the mortality rate due to CVD. However, the effectiveness of ECG monitors can be significantly impaired by motion artifacts, which can trigger false alarms, cause misdiagnoses, and lead to inappropriate treatment decisions. Skin stretch associated with patient motion is the most significant source of motion artifacts in current ECG monitoring. CALCE investigators proposed an approach to adaptively filter motion artifacts using skin strain as the reference variable [6, 7, 9-12]. The motion artifacts were then measured, noninvasively, using a light emitting diode (LED) and an optical sensor integrated into an ECG electrode. The sensitivity and measurement range of the strain sensor was calibrated using animal skin samples and also in-vivo.

The results demonstrate the feasibility of using an optical technique as a wearable skin strain sensor for noninvasive and cost effective ambulatory monitoring. It was found that the wearable system and method can reduce 85% of induced motion artifacts, on average, in continuous ambulatory conditions such as raising the arm, running and walking. This approach offers other advantages such as providing high-resolution, high sampling rate and real-time measurement which can be used in ambulatory applications. The same optical sensor can be used in other applications where skin strain rate can aid in disease diagnostics such as dermatology. For more information about this work click here or here.
Using FMMEA to Investigate Medical Device Adverse Events

The US Food and Drug Administration (FDA) requires medical device manufacturers and device user facilities such as hospitals, to report of device malfunction that resulted in or has the potential to cause an adverse event such as death/serious injury. Manufacturers perform evaluation of the malfunctioned devices, to determine the root cause of the event, and submit the outcome of the analysis to FDA. However, FDA does not have any guideline for manufacturers on the best practices for failure tracking analysis. Thus, root cause analysis device performed by device manufacturers might not be effective and lead to misidentification of failure mechanism, and eventually to reoccurrence of failures. At the International Conference on Biomedical Ontology (ICBO), CALCE researchers presented an approach for medical device evaluation by using failure modes, mechanisms, and effects analysis (FMMEA) to identify the root causes and failure mechanisms and improve the failure analysis and efficient identification of root causes of the adverse events [4].

Using FMMEA in device evaluation process can reduce the number of medical device-related adverse events. By combining failure mechanisms and models obtained though FMMEA analysis with manufacturer’s knowledge of device’s life cycle loading, enables a more accurate assessment of device reliability. Moreover, potential adverse events can be updated by monitoring product’s life cycle environmental and usage conditions.

This method can also help medical device manufacturers to generate an internal evaluation report for medical device evaluation, which can improve the reporting process to the FDA. Click here or here to read more, or contact Dr. Diganta Das (diganta@umd.edu).

CALCE Studies Storage Conditions of Battery-Powered Medical Devices

As more medical devices become compact and mobile, the number of battery-powered medical devices will continue to increase. Unexpected depletion or failure of a battery can cause a device to stop functioning properly, preventing the device from delivering life-sustaining or life-saving therapy. The storage conditions of battery-powered medical devices impact the reliability and performance of the battery. CALCE’s Battery Group has recently carried out studies to investigate the optimum storage conditions of lithium-ion batteries, which have wide applications in medical devices. CALCE researchers study the effect of storage conditions (such as storage temperature, time of storage, and state of charge) on the performance degradation of battery cells in terms of capacity loss. To determine the amount of irreversible capacity loss that a cell will experience during varying storage conditions, a storage life model that quantifies the capacity loss as a function of storage conditions is being developed. For more information about this study, contact Dr. Laura Xing (vxing3@calce.umd.edu) or Prof. Michael Pecht (pecht@calce.umd.edu).

CALCE Presents at FDA Workshop on Battery Issues of Implantable Medical Devices

Batteries are among the most critical components in implantable devices and play a significant role in their safety, effectiveness, performance, and reliability. The FDA organized a Battery-Powered Medical Devices Workshop to create awareness of the potential challenges related to battery-powered medical devices and to collaboratively develop ways of ensuring the continued performance and reliability of these devices. Bhanu Sood, director of the Test Services and Failure Analysis Laboratory, participated in a panel discussion at FDA. He presented CALCE’s battery team research on the development of analytical techniques for detecting failures in lithium-ion batteries, including innovative prognostics and health management (PHM) algorithms to ensure the safety and reliability of lithium-ion batteries. For more information about the FDA workshop, contact Mr. Bhanu Sood (bpsood@calce.umd.edu).
CALCE Presents Short Course at FDA on Reliability Assessment of Medical Devices

CALCE offered a short course at the FDA on reliability assessment of medical devices, including reliability, reliability capability, prognostics and health management (PHM), and counterfeit electronics. This course introduces classical reliability concepts and is related to the concepts of the physics-of-failure (PoF) approach. The information provided in this course is useful for implementing a PoF methodology for the life cycle of a product. The participants learn how to develop and migrate to PoF-based reliability assessment programs. The course also teaches how to facilitate the introduction of the PoF methodology among the complete supply chain of the product, which in this case is a medical device. For more information about the reliability course, contact Dr. Diganta Das (diganta@umd.edu) or Prof. Michael Pecht (pecht@calce.umd.edu).

CALCE Work on Medical Device Component Selection

Every electronic component that is purchased for high-reliability medical products such as implantable devices must be individually qualified. However, there is no common standardized specifications for the qualification of electronic components or their suppliers. Moreover, there is a lack of standards for reliability testing of implantable medical devices. Thus, medical device manufacturers need to develop their own qualification testing plan, which may not meet the requirements of medical applications. This situation increases costs for component manufacturers, since medical device OEMs (original equipment manufacturers) can have different requirements, which often makes them unresponsive to the medical device market or causes delays in introducing new products. Drs. Diganta Das and Michael Azarian, led a project to develop a method for establishing a test and screen matrix for electronic components used in implantable medical devices. This test can be used to qualify the reliability performance of components for electronic medical devices, and is accepted by OEMs and supported by suppliers. For more information, contact Dr. Diganta Das (diganta@umd.edu) and Dr. Michael Azarian (mazarian@calce.umd.edu).

CALCE-iNEMI Project on Component Specifications for Medical Products

CALCE collaborated with the international electronics initiative (iNEMI) to develop a methodology for component specification in medical device industry. This project consisted of five tasks, including identification of the coverage of the selected components, determination of the most common failure mechanisms and defects, screens and tests for precipitation of failure mechanisms, identification of a minimum set of test standards that cover the various screens and tests found in previous tasks, and, finally, methodology description on the process of developing the tests and screens for other components or parts. This project resulted in a set of component-level reliability qualification methods that can be implemented by medical device manufacturers within their component management process.

In order to develop an industry standard, relevant failure mechanisms and the performance requirements of critical components of the medical system, needs to be clearly identified. The developed methodology was applied to a case study of a specific critical component (tantalum capacitors), to obtain the level of understanding required to develop necessary specification for that component, develop a methodology for test and screening of these components, and assess how this approach can be applied to other components or parts.

The overall goal of this collaborative effort was to develop recommendations for common specifications for electronic components for use in medical devices that meet the test, performance, and reliability needs of implantable and wearable medical products. Establishing common specifications for medical products reduces the costs of testing to unique requirements, and also enable the faster introduction of new components and suppliers into the supply chain and enhance the relationships along the supply chain. For more information about this work, contact Dr. Diganta Das (diganta@umd.edu).
CALCE-FDA Intern Program

The goals of the CALCE internship program are to provide graduate students in the Electronic Products and Systems Program with first-hand exposure to the types of engineering challenges that confront many segments of the electronics industry and to directly couple their academic and research program with industry’s needs. The industry internship is carefully tailored for each student so that the activities pursued contribute directly to the mission of CALCE and to the career objectives of the students.

Shunfeng Cheng and Kaushik Chatterjee, interned at the Food and Drug Administration. During their internship, they were involved in a project to evaluate the failure modes and mechanisms of medical devices and test methods, and then to set up a hierarchy for the Manufacturer Evaluation Code of medical devices. They won a fellowship from the ORISE Foundation after being recommended by the FDA. They both attended the CALCE short course on reliability assessment. For more information about the CALCE internship program, contact Dr. Diganta Das (diganta@umd.edu) or Prof. Michael Pecht (pecht@calce.umd.edu).
Selected CALCE Medical Device Research Publications


