Innovation and Design: Pollution Prevention Opportunities in Medical Device Design

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A wide variety of materials and chemicals are used in the development, production, cleaning, packaging, sterilization and shipment of medical devices. Some of these materials are used in large quantities and are often a source of waste. Some materials, such as poly vinyl chloride (PVC) plastics, have toxicity concerns. Additionally, many chemicals including chlorinated solvents and ethylene oxide are carcinogenic or highly toxic and can be detrimental to the environment and public health. While the medical device industry is highly regulated in the United States by the Food and Drug Administration, new green initiatives in the European Union are modifying the regulatory oversight of chemicals, materials, and their manufacture. In addition, hospitals are working to reduce waste and pollution as part of their operations and are increasingly asking vendors to assist them. Minimizing waste and pollution associated with medical devices can improve a company's environmental performance and save money. The primary focus in medical device manufacturing is patient safety and compatibility. Environmental considerations, which can include potential cost savings, are often overlooked in the design and process development phases. Numerous pollution prevention and energy efficiency options exist for medical device manufacturers. These options can be integrated into the development, design and process protocols, and engineering change orders when designing a new product or improving an existing part. By having a process design evaluation plan that includes environmental considerations, companies can effectively manage the creation of waste streams, toxicity of material inputs, and process efficiencies as a mechanism at both the front-end and the duration of the product line. These options often cut costs and can help reduce current and prospective regulatory burdens. The Minnesota Technical Assistance Program (MnTAP) at the University of Minnesota has been assisting businesses with pollution prevention and cost savings for 25 years. MnTAP's engineers and scientists have worked with the medical device industry to reduce the quantity of packaging and waste associated with cardiac catheters, reduce the use of toxic cleaning solvents, minimize the use of PVC, and research safer disinfection and sterilization methods. This poster includes case studies of the above mentioned projects, an overview of less toxic sterilization methods, and tools for medical device manufacturing that meet FDA requirements, but reduce waste and toxicity during production and use.

Separating Aortic Stenosis From Nornal Heart Decision Spaces Using a Quadratic Model

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Automated diagnosis of heart pathology is extremely desirable in today's medical environment. The sounds of auscultation collected through a stethoscope are the simplest, fastest, and least invasive way to detect heart pathology. Upgrades in microphones, digital signal processing techniques, and computing power are making the translation of the sound into a digital medium complete. It is this completeness that allows separation between various heart states. Using a digital stethoscope available on the market, the researchers were able to separate aortic stenosis (AS) and normal (N) heart sounds using a modified Eigen classifier based upon the assumption that the data is drawn from multivariate Gaussian distributions with different means and covariance matrices. Human heart sound data was collected by a cardiologist using a commercially available Littmann Model 4000 electronic stethoscope (3M, Maplewood, MN). All data was collected via an approved Human Subjects Institutional Review board protocol. Auscultation data from 69 supine patients (36 female, 33 male, age range 18–93, average 54 years, Body Mass Index (BMI) range 16–47, average 29) from the second right intercostals space on both N and patients with AS. Diagnosis was confirmed using a standard trans-throacic echocardiogram. Eighteen normal and fourteen AS patients were used to develop normal and AS decision spaces. For each patient, approximately seven cardiac cycles were collected. The data was segmented into systole and diastole through a computerized playback program. The cardiologist determined location of S1 and S2. After segmentation, a mean heart cycle S1, systole, S2, diastole for the patient was calculated. The means for all fourteen AS patients was used to normalize the data. The normalized seven heart cycles were placed into a $[3400 \times 98]$ matrix that defined AS. The same was done for the normal population. These matrices were used as input for the singular value decomposition. Each measured auscultation signature was projected on the dominant scaled principal components. Eigen vectors were scaled to get the unit variances for the principal components. The entries of the feature vectors are the distances between the projected measured signatures and the centroids of the N and AS clusters. Distances between the resulting hyperspheres were calculated and projected on a two-dimensional graph of distance versus number of cycles. The first application of the Quadratic Model yielded some overlap between N and AS data. However, the data clearly separated. The input auscultation signatures were then segmented according to S1, systole, S2 and diastole and clearly aligned in the input matrices. The signatures were re-sampled to a 70 BPM cardiac cycle. Events within each segment were not aligned. The result of the standardization and alignment was clear separation between the N and AS decision spaces. There is great interest in the research community in algorithms that can be used to determine heart pathology from auscultation based heart sounds. The Quadratic Model shows 100% separation between N and AS data when S1 and S2 are properly segmented and re-sampled. When systole is isolated as the decision making attribute, separation increases by a hundred–fold.