

Thesis Portfolio

The DEPART System: A Continuous Ambulatory Blood Pressure Monitor
(Technical Report)

**Medical Devices in the Regulatory System: Factors Contributing to the Recall
Crisis**
(STS Research Paper)

An Undergraduate Thesis

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Bachelor of Science in Engineering

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SocioTechnical Synthesis

Growing up, commercials from law firms concerning some implanted device that caused bodily harm to people was a common occurrence on the television. Those devices were devices that were recalled devices and the patients who had trusted the product were enticed by the thought of getting retribution against the manufacturing companies that allowed the device to be put on the market. Those companies were not the only factor in these people's pain, however, and there is more to the regulation system than what is seen by consumers wishing to get settlements from medical device manufacturers. The Food and Drug Administration (FDA) is responsible for regulating and monitoring medical treatments. They ensure that the treatments demonstrate both safety and efficiency before they are released to the public. The FDA has introduced many laws that provide different avenues for regulating novel devices, of which many were met with pushback from biomedical device companies and independent inventors. The STS portion of this thesis aims to investigate the socio-economic and political factors involved in the medical device regulatory process and subsequent recalls. What is it about the relationship between the FDA, companies, and medical practitioners that contributes to a higher rate of recalls? Three case studies on medical devices in the FDA system will be addressed and analyzed. The technical portion of this thesis will explore the initial stages of the FDA regulatory process with a team of students performing clinical testing of a medical device. The goal of this study is to collect data using the DEPART System and a criterion device, the Human NIBP Nano System, and use MATLAB to process the data and model blood pressure under different conditions. The models were evaluated relative to established standards as well.