

DESIGN OPTIMIZATION OF AN ERGONOMIC LEAD GARMENT

THE IMPACT OF LEGISLATION ON THE MEDICAL DEVICE INDUSTRY

An Undergraduate Thesis Portfolio
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By

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SOCIOTECHNICAL SYNTHESIS

With the search for greater patient health care and treatment the medical device industry has grown worldwide expecting to reach \$612.7 billion by 2025, however, the industry has key design and manufacturing issues as well as incompetent laws and regulations. The technical project, presented in a research style paper, aimed to design a novel hook brace in response to a medical device design issue in the lead garment which is protective equipment used by medical teams to deter the harmful effects of radiation. This project was undertaken in response to the decade old patents and significant ergonomic challenges caused by the device. The Science, Technology, and Society project, presented in a journal style paper, assesses the impact of legislation on medical devices. The project was undertaken in response to the rise of MedTech and the Internet of Medical Things and the inadequate laws and data privacy regulations in place to guide them. The technical and STS project are loosely coupled as the technical research creates a new medical device and the STS research assesses legislation on remote medical devices.

Many medical devices such as laparoscopic instrument handles, catheters, and the lead garment cause significant ergonomic pain to the medical professionals who use them. The lead garment in particular weighs 20 pounds causing a significant amount of ergonomic challenges on the shoulders and backs of medical professionals many of whom have to receive treatment because of the injuries. This technical project aimed to alleviate some of these challenges by getting feedback from medical teams at the University of Virginia Hospital allowing a mock prototype and Computer Aided Design to be created to test. Feedback was obtained from health teams through an iCoreQuestionnaire to establish design needs. A test prototype was created and preliminary pressure sensor testing was conducted to determine how much pressure the lead

garment was weighing down on individuals. Due to unfortunate circumstances volunteer testing with medical teams was unable to be completed. However, pressure sensor simulation testing was completed through the software, Autodesk Inventor, which tested the amount of pressure experienced on a human body model with and without the novel hook brace. The results indicated that the test prototype would be able to alleviate and redistribute pain. However, further research needs to be completed, particularly human testing, to account for comfort, ease of use, height, weight, etc. This project will hopefully advance the technical capability in the healthcare field of surgery and medicine by highlighting the need for better ergonomic devices.

The Science, Technology, and Society project aimed to highlight the inadequacies of the legislations and regulations that currently guide the medical device industry. The research aimed to prove that the patent and privacy laws established by the Food and Drug Administration and Health Insurance Portability and Accountability Act, which are over 25 years old are inadequate to guide the new remote patient monitoring systems used today. Various news articles, research journals, legislation, company statistics, patents, and regulations were analyzed and assessed.

The research concluded that without major changes to legislation health privacy data can be used improperly to discriminate during employment hiring procedures, as evidenced by a Walmart company hiring scandal. The current legislation also has many loopholes allowing it to be tracked, used without patient permission, and easily hacked shown through reports by the American Medical Collection Agency. Greater protection can be provided through data anonymization and encryption as well as adopting facets from the General Data Protection Regulation in the United Kingdom which can also help in updating laws and regulations. Educating the general public and engineers is also needed to bring about greater change and safer and more empathetic devices. In order for this to occur the Social Construction of Technology

Model needs to be adopted to allow for greater integration in the medical devices industry. The interconnectedness of laws and technology has never been a more pertinent issue as it is today and adequate measures are needed to keep pace with technological change.

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PROSPECTUS

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