



Automating Pressure Ulcer Care

M&T Integration Lab Final Report

Team 17

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Executive Summary:

Empathera's mission is to revolutionize pressure ulcer care through its product StimSense, an automated pressure injury prevention system. StimSense reduces healthcare costs and nursing burdens while improving the quality of care for patients through precise risk detection and treatment.

Pressure injuries, commonly called bed sores, are wounds caused by prolonged pressure that depletes oxygen to areas of tissue. This results in open wounds and, in severe cases, deep tissue and bone damage. Despite the severe and expensive impacts of pressure ulcers, the current standard of preventative care is highly manual, requiring nurses to flip patients in two-hour intervals. This standard is not scientifically backed, and places an immense physical strain on caretakers who often spend over 30% of their busy days conducting preventative pressure ulcer care.

The market for pressure injury prevention devices is large and continues to grow, especially in opportunities for lower-cost and automated devices. To take advantage of this gap in the market, StimSense will be positioned as a solution for long-term care facilities, as they have a high incentive to prevent pressure injuries in long-term stay patients and reduce labor burden on staff.

StimSense is a closed-loop system that continuously monitors high-risk areas in patients and delivers automated pressure relief treatment with high customizability. The main system components are a cost-effective pressure sensing sheet that detects pressure changes across the patient's body and modular actuation cuffs that apply targeted vibration to drive blood flow, driven by underlying software with an intuitive user interface.

Value Proposition:

Empathera's StimSense is an automated pressure injury prevention system that reduces healthcare costs and labor while improving quality of care for patients through precise risk detection and treatment.

Current pressure ulcer care costs 20% of total nursing time and over \$17,124 per nurse in annual labor costs alone. The current standard of care for pressure injury prevention is manually flipping a patient in 2-hour intervals. This treatment plan is not scientifically backed, and is an artefact of Florence Nightingale-era nursing practices. Ineffective prevention can lead to treatment costs of over \$20,000 per ulcer, costing the U.S. healthcare system \$26.8 billion each year.

The StimSense system is easy to use for nursing staff as it is automatic and compatible with current wound care practices. The pressure sensing pad is placed directly on a patient's mattress, and can be easily cleaned between uses. The modular automatic treatment system is customizable to a patient's needs while reducing the burden on healthcare providers.

StimSense is a low-cost system compared to other automatic pressure-relief products, made possible by the modular approach and material selection. The information collected by pressure profiles will also allow for continuous improvement of care plans. Through precise risk-detection and automated treatment, Empathera aims to prevent pressure injuries accurately and consistently.

Stakeholders:

As a medical device, StimSense has the following stakeholders:

Customers:

Healthcare Facilities/Systems

Healthcare facilities have a vested interest in inexpensive, effective pressure injury prevention. Pressure injuries are considered malpractice as they occur due to the standard of care – this means hospitals and other healthcare facilities are liable for the costs of pressure injuries, resulting in an estimated \$26.8 billion in costs per year. Healthcare facilities such as hospitals currently spend an estimated \$20,000 on pressure injury treatment per patient. As the ultimate purchasers of StimSense, healthcare facilities are the stakeholder with the greatest power. An effective, low-cost alternative to current alternating pressure or pressure reduction devices is an important consideration for healthcare facilities.

End Users:

Nurses

Nurses perform pressure injury prevention on a daily basis. Currently, many nurses are overworked during their shifts, treating upwards of ten patients at a time. Current prevention practices are labor-intensive, time-consuming, and may lead to patient conflict. Pressure ulcer training is also often incomplete, leading to nurse injuries and poor patient outcomes. Alarm fatigue is also a major concern for nursing staff. As the direct users of StimSense, nurses want an automated, precise solution that reduces labor burden while providing high-quality care. An easy-to-use interface and hardware components are also vital to increase nurse adoption.

Patients

Pressure injuries lengthen a patient's time spent in a hospital and make treatments and recovery more complex, limiting mobility and leading to other complications. Though hospitals are liable for pressure injuries, the downstream additional treatments or necessary hospital time may be billed to patients, leading to additional excessive costs. Current pressure injury treatments such as turning, repositioning, and alarms can be uncomfortable for patients and disturb their quality of sleep, while many pressure-adjusting beds can be uncomfortable and limit mobility. Patients are interested in a comfortable, non-invasive solution that does not limit mobility while providing high quality care.

Market Opportunity and Target Segment:

The target customer segment in the short-term for the introduction of StimSense to the market is North American long-term care facilities. These include primarily nursing homes, as well as long-term acute care and other assisted living facilities. The US long-term care market is estimated to be \$490.6 Billion, with a projected 10-year growth rate of 6%. The aging population and growth of long-term care facilities after a post-COVID dip are both positive indicators for the customer segment.

Many nursing homes are overcrowded, with scarce nurses and high employee turnover rates. This makes nurse care training and consistent treatment of patients difficult. As patients remain in long-term care facilities longer than they would in a hospital, for example, the risk of pressure injury development also compounds over time. The prevalence of pressure injuries in long-term care facilities is equal to, or even greater than that in hospitals, yet a wide range in resources and coverage do not fill this gap. As a vibrating product with historic FDA approval, StimSense may be considered a Class 1 medical device, which would not require FDA preapproval.

Size and Growth of Market Segment:

In addition to the growth of the long-term care market, the pressure injury prevention market is growing due to an aging population and increasing prevalence of chronic conditions. The calculated TAM is \$8.66 billion based purely on the current state of long-term care in the United States. Since our product focuses on pressure injury prevention in North American long-term care, our TAM is calculated based on the number of beds and the number of patients per year in care facilities with mobility-limiting conditions. As our strategy

moves to hospital bed settings, home care, and potentially even wheelchair-bound patients, our accessible market will continue to grow.

Competition:

Alternating pressure mattresses are a commonly used pressure-redistribution device for injury prevention. Those used in hospitals range from \$5,000 to \$10,000 per system, though increased competition in the space has reduced price points. These mattresses rely on movement of air or fluids through pockets within the mattress to constantly modify pressure areas on the body. These are widely viewed as an effective preventative measure, but are cost-prohibitive for healthcare facilities and uncomfortable for patients due to the constant motion. It is automated, but still requires nurse actuation and input.

Another product currently on the market is the LEAF patient monitoring system, a sensor placed on the patient's chest that sends alerts to staff when the patient has not changed orientation according to the care plan. After the alert is sent, the patient must reposition themselves or nursing staff must reposition them. LEAF is lightweight and disposable, costing \$250 for each patient. It has been implemented in several healthcare systems, and has shown increases in turn adherence. However, this system is widely hated by nurses due to alarm fatigue. It is also not automated, and instead requires increased nursing labor as staff must reposition the patient and also enter the LEAF patient system to turn off the alarm. The accuracy of LEAF on measuring the repositioning of bigger patients has also been debated.

Cost:

The estimated cost of the sensing sheet is \$109.62. The estimated annual software cost per system is \$795.03. The estimated price per actuation cuff is \$29.58. These are based on the pure material costs to produce our devices.

IP:

A possible opportunity for IP is in the StimSense system integration of sensing, risk assessment, and vibrational therapy treatment.

Revenue Model:

Our revenue model is a combination of a one-time hardware sale, a software subscription, and recurring purchases of disposable components.

- (1) Customers pay a one-time fee of \$1,500 for the sensing sheet.
- (2) Customers pay an annual software subscription fee to access injury risk data for their StimSense devices. Pricing will start at \$2,000 per system per year.
- (3) Disposable actuation cuffs will be sold at \$60 per unit, with potential large-bundle discounts applied for healthcare systems. Approximately 5 cuffs will be used for a single patient, though a variable number can be used depending on patient need.

Combining a small upfront cost to the customer with a larger recurring revenue stream allows us to generate consistent revenue streams as patients cycle in and out of the healthcare system. A software subscription also allows us to offset inference costs that scale with use. As usage data is collected from customer behavior, actuation cuffs could potentially be bundled with the software subscription to increase customer satisfaction and system simplicity. We plan to pursue a penetration pricing strategy in order to first gain a customer base and build loyalty among users.

For our go-to-market strategy, we plan to pursue direct sales to healthcare systems, due to the current structure of the medical device purchasing landscape. We plan to build connections to medical device purchasing pipelines through industry conferences and events, finding users and building relationships.

Future Product Outlook:

Technology Goals:

Empathera strives to implement electrical muscle stimulation (EMS) technology within actuation cuffs, as this has been shown to be an effective preventative measure and treatment mechanism in clinical environments. We have conducted initial research and literature reviews in this space, and hope to integrate EMS within StimSense when we can conduct clinical trials and apply for IRBs. An additional area of product research is the use of conductive and expansive gels for pressure reduction and current propagation in actuation cuffs. We have also conducted initial research in this space, and hope to develop working prototypes with the integrated structure. Usage of expansive gels and EMS would potentially require greater levels of FDA oversight and approval due to lack of consumer precedent. Another potential area for growth is integrating more advanced computer vision into the system, in order to more accurately identify regions of high risk in the body.

Leveraging the Modular System:

The StimSense system allows for autonomous pressure injury care, from sensing to treatment. However, pieces of the system can be used independently in different use cases. If indicated by customers, actuation cuffs and the activating software could be sold separately from the sensing sheet, in cases where people determine accurate risk assessment is not necessary. This allows for increased customer personalization and potential access to additional markets, such as for wheelchair users or in the home care space.

After establishing StimSense in the long-term care space, Empathera can leverage its features as a self-contained, low-cost product in two main ways: entering the hospital care space and entering the home care space as a direct-to-consumer product.

StimSense could be positioned as a low-cost solution to be widely deployed across hospitals for medium-risk patients. The current standard of care across many hospitals is to place high-risk patients on large, expensive alternating pressure mattresses while they are in the ICU. After patients leave the ICU to enter general wards, they are often then turned by nurses. StimSense could replace nurse repositioning in these hospital settings.

The home care space has grown quickly since the COVID-19 pandemic and the rise of telehealth. As patients remain at home with limited mobility, pressure injuries can become a large problem if patients do not follow proper repositioning practices. In the future, StimSense could become a product for home care use with changes for ease of application and ease of use for non-healthcare professionals.