



Contract Book

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DESIGN OF BIOMEDICAL INSTRUMENTS AND SYSTEMS

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1 Biographies



Daniel Chong

Daniel Chong is an undergraduate student at the Johns Hopkins University from East Brunswick, NJ and is studying Electrical Engineering and Computer Science. His interests are in biomedical applications of signal processing and machine learning.



Stephen Zhou

Stephen Zhou is a graduate student at the Johns Hopkins University from South Hadley, MA and is currently studying Electrical and Computer Engineering. His interests are in digital hardware design, embedded systems and signal processing.

2 Abstract

The invention, Pneu-mo, is a new monitoring device that aims to solve the many problems tied to the traditional three-chamber chest drainage system used in pneumothorax treatments. The biggest issues with the three-chamber chest drainage system include the device not being able to display and track pneumothorax patients' conditions. This results in the patient needing many unnecessary x-ray and CT scans to observe their current condition, which leads to prolonged stays at hospitals in addition to the expensive costs of scans. The solution to these problems is a system that combines hardware and software. The hardware is attachable and adaptable to any three-chamber chest drainage system on the market and wireless transmits real-time statistics about the patient's condition to proprietary software. The software is also able to predict a patient's recovery time based on their current condition. Pneu-mo will reduce duration of hospital stays and the unnecessary amount of x-ray and CT scans needed for pneumothorax patients. Hence, saving hospitals and patient's significant amount of time and resources.

3 Introduction

Pneumothoraces are life-threatening conditions in which the pockets of air on the lung tissue burst causing air to leak out and fill the thoracic cavity. From here, the air in the thoracic cavity adds pressure onto the lung causing it to collapse even further which causes more air to seep out into the thoracic cavity.

The current industry standard for pneumothorax patient treatment is the three-chamber chest drainage system. A tube is inserted into the patient's chest to drain out excess fluid and air from the thoracic cavity. The air and fluid then flows into the three-chamber chest drainage system, which ensures a unidirectional flow of air and fluid out of the patient.

The three-chamber chest drainage system collects fluids in its fluid chamber and air in its air chamber. To monitor air flow leakage, a tiny liquid chamber is present such that when air enters this chamber, the liquid chamber bubbles. As such, it is often the case where monitoring the pneumothorax patient's condition is very difficult because in order to observe progress, one needs to rely on determining the intensity and frequency of bubble formation in the liquid chamber.

There have been modifications to the standard three chamber chest drainage system with additions such as a pressure source and a valve configured to relieve pressure in the fluid pathway. There have also been inventions with modifications for the chest tubes used in order to eliminate or reduce clogging in the primary flow tube with an improved terminal structure. However, what is needed is a device that can track air and fluid leakage in real-time so that doctors and patients can be more certain about the patient's lung condition.

4 Field Survey

There are 4 primary different ways to classify pneumothoraces. They can either be iatrogenic, from blunt trauma, from underlying respiratory issues (Secondary Spontaneous Pneumothorax), or random (Primary Spontaneous Pneumothorax).

In the United States, 18 per 100,000 men and 6 per 100,000 women will experience a primary spontaneous pneumothorax each year. 6.3 per 100,000 men and 2 per 100,000 women experience secondary spontaneous pneumothorax. There are 5 per 10,000 cases of Iatrogenic pneumothoraces in US hospitals per year, with there being about 36,000 hospital admissions per year in total.

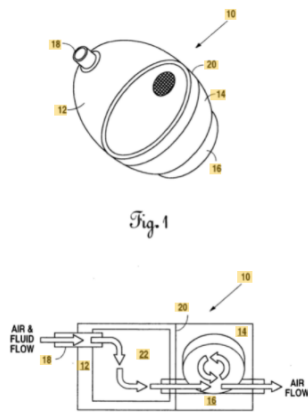
In addition to the standard rates of pneumothoraces in the United States, pneumothoraces have high recidivism rates with 37% within the first year and 52 % within 3 years. This means that patients that have it once, are highly likely to have it again. This is important for us to consider as with proper monitoring systems that may aid with treatment operations, we would be able to reduce recidivism rates, and therefore the rates of pneumothoraces altogether each year.

In order to further validate the need for our product as well as refine the approach that we had towards solving this problem of creating a better monitoring system, we spoke with other former pneumothorax patients, nurses, as well as Dr. Ziv Gamliel, the chief of Thoracic Surgery at The Angelos Center for Lung Diseases at Medstar medical center. It became clear from our conversations that not only was a better monitoring system absolutely needed, but perhaps one that is cheap and does not interfere with the standard operation of the standard-three chamber chest drainage system would be ideal.

5 Patent Survey

Our team has done an extensive search regarding relevant patents in order to ensure proper originality and intellectual property rights for our product. A cursory overview of several of these patents is found below.

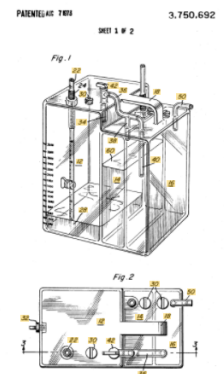
US20060036221: Chest Tube Drainage System

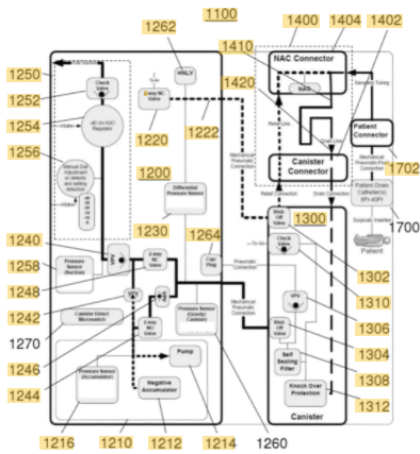


This product is designed to be a system consisting of a portable suction device and chest tube in order to drain the chest cavity of a patient, or be used during surgery within the chest. It has a small disposable bottle chapped motor/pump, and a power supply in order to run the system. The chest tubes themselves are unique in that fenestrations are positioned between “dead” and “live” lumens in order to prevent clogging in the test tubes from fluids.

US3750692A: Chest Drainage System

This is a patent for the standard chest drainage system. It has three different components consisting of a water-sealed chamber, pressure regulating chamber, and a trap chamber. It has a control valve to control the connection between the water-sealed chamber and the other two chambers. All three chambers have an accessible opening which allows for the addition or removal of water, as well as easy access to cleaning the chambers.



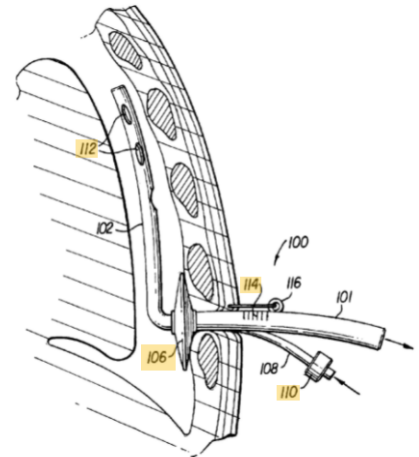


US20130110057A1: Chest drainage system and methods

This is another variation of the three chamber chest drainage system with unique aspects including a pressure source with an accumulator set to provide sub-atmospheric pressure to the fluid pathway. A valve is present to relieve pressure from fluid pathway. It is set to automatically open the valve and create a sub-atmospheric pressure when a user configurable pressure differential is detected from the proximal and distal portions of the fluid pathway.

US6849061B2: Method and Apparatus for Pleural Drainage

This device is an apparatus made for evacuating material from the body cavity. IT has a distal section and a proximal section where the distal section has openings for receiving air and liquids from the body. The proximal section receives and discharges the fluid and air from the body. It has a cuff for positioning the tube in the patient's body and preventing the openings from being blocked.



6 Intended Use

The pneumothorax monitoring device, Pneu-mo, is intended to monitor and provide the pneumothorax patient's condition through real-time statistics regarding fluid and air leakage from the thoracic cavity.

The invention aims to provide enhancement of the three-chamber chest drainage system without needing to replace the entire device, as the invention is attachable to any three-chamber chest drainage system and adaptable to any tube size.

7 Regulatory Issues

Our device is an external monitoring device that uses pre-existing technology in order to monitor the patient's progress. The preexisting technology that our device uses include the standard chest tube, or thoracic catheter, that is already widely used for many different operations, as well as the standard three chamber chest drainage system that exists to receive the excess fluid and air leakage from the patient. However, we do recognize that there is risk involved with making sure that our device does not interfere with the standard function of the thoracic catheter, but merely as an enhancement. As a result, our team will thoroughly test and make sure that the monitoring component of our device does not interfere with the drainage of fluids and air that the standard thoracic catheter provides.

Our device will require FDA approval, and will be marked as a Class 1 device with a regulation description of "Introduction/drainage catheter and accessories". It will be 510(k) exempt and will be classified under General and Plastic Surgery.

8 Design

The system's hardware design is composed of a max air flow sensor, a fluid sensor, an adapter to match different size tubes, and a wireless low power RF transceiver. A covering is created to encapsulate the sensors and low power RF transceiver and ensure a waterproof seal for the circuitry. This allows reuse for the main component of the hardware and be cleaned between each treatment.

The hardware device has a detachable chest tube adapter that allows the main component to fit any chest tube size on the market, as shown in Fig #. This medical grade adapter is intended for single-time use only and can be purchased in every tube size.

For the proprietary software, a user interface is implemented and viewed on an external monitor to view the real time statistics gathered and transmitted from the hardware device.

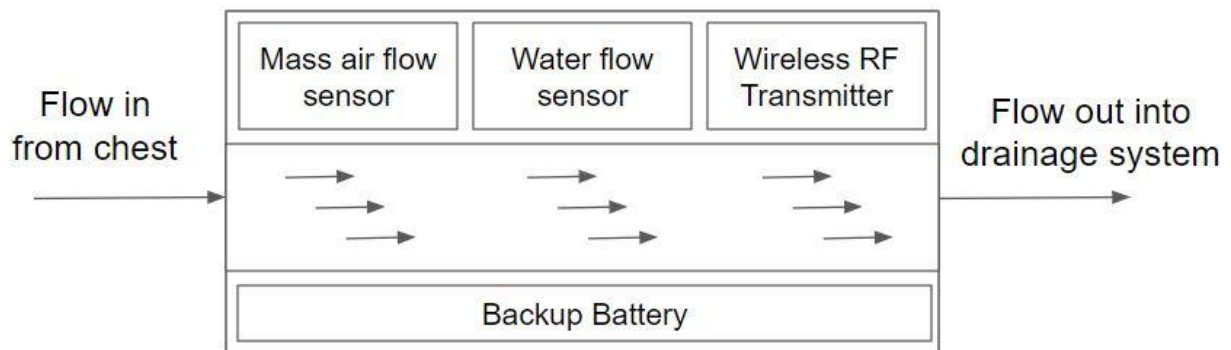


Fig 1. The diagram above shows the different parts that make up the hardware device of the product

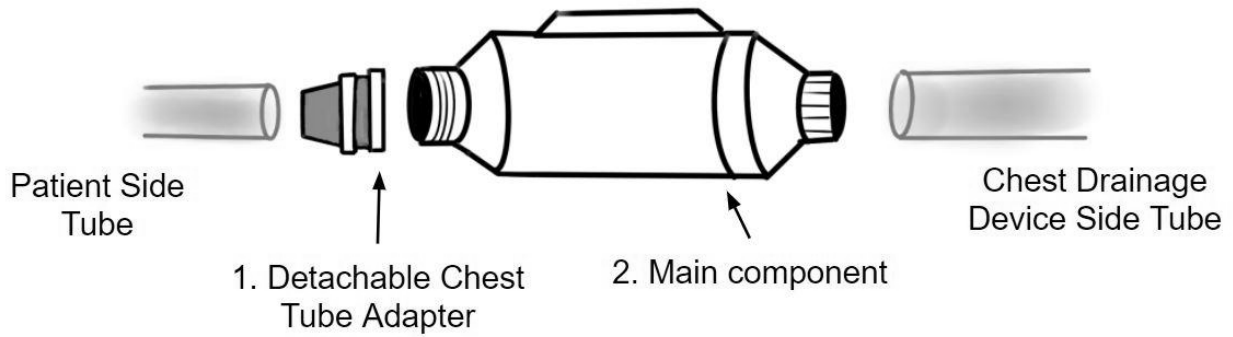


Fig 2. The drawing above shows the detachable chest tube adapter that can be replaced and fit all chest tube sizes on the market

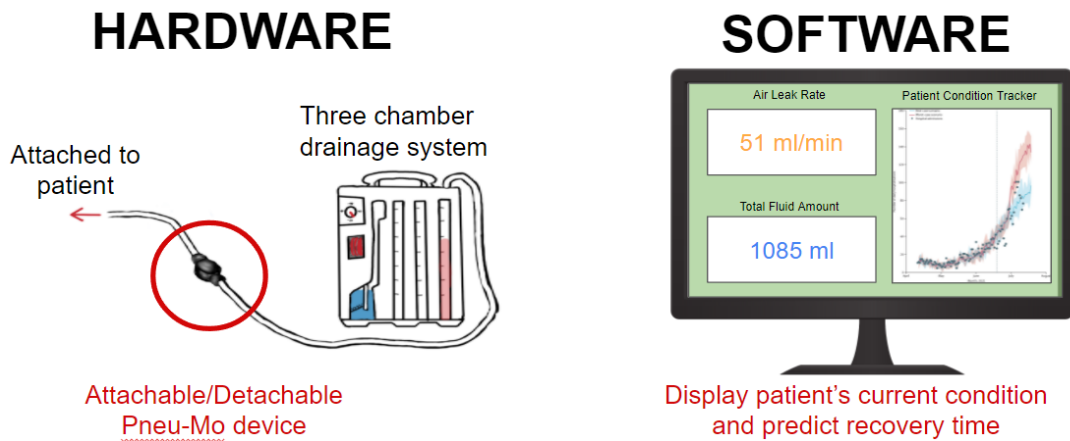


Fig 3. The drawing above shows the interaction between the hardware and software components of the device.

9 Business Model

Pneu-mo aims to reduce the medical costs spent on unnecessary x-ray and CT scans during pneumothorax treatments through a more practical monitoring method. To accommodate for the small size of our growing company, a two-part business model will be used, which includes directly selling the product to healthcare providers and collaborating with other medical device companies.

The first part of the business model involves breaking into the market and establishing credibility within the medical community, Pneu-mo will be initially sold directly to hospitals, EMTs and other healthcare providers. The hardware device will be compatible with all three-chamber chest drainage systems that are currently being used by healthcare providers. The hardware will come with a 2 year license for the software, which is required to display real-time statistics captured by the hardware device and predict patient recovery time. Additional annual fees will be charged after the first 2 years in order to continue using the software.

The Pneu-mo device will have a low upfront cost to make the device more appealing to healthcare providers. The main revenue is projected to come from the single-use tube adapter used to connect the hardware component to the chest tube, which will be sold independently from the Pneu-mo device. The adapter will need to be disposed of after each treatment and purchased from our company directly.

The second part of the business plan is to transition towards collaboration with larger medical device companies and distributors, specifically manufacturers of three-chamber chest drainage systems. The plan involves incorporating the Pneu-mo hardware with the three-chamber chest drainage system to be sold as a bundle, which saves costs in marketing and distribution. The software license and tube adapter will continue to be purchased directly from our company.

10 Market Research

Our company, Pneu-mo, looks to break into a segment of the patient monitoring market within the United States. From our research, the patient monitoring systems market is projected to be approximately 34.3 billion USD in the next 5 years. While pneumothorax monitoring may be a small portion of this significant market, our company is a pioneer in this area and can take advantage of the market before larger biomedical companies attempt to do the same.

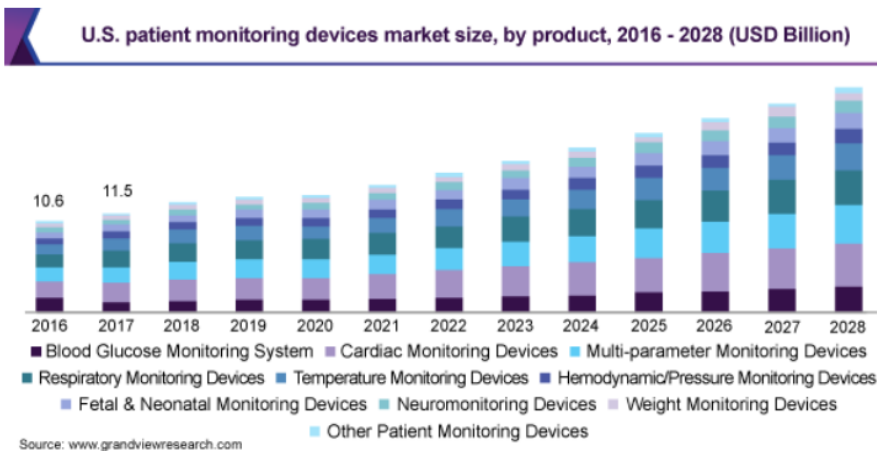


Fig 4: The chart shows patient monitoring systems projected to be worth 34.3 billion by 2026 (more attention now due to covid, another illness connected with pneumothoraces)

The only other company to attempt to digitize and create a monitoring system for pneumothoraces similar to us is a company called Medela Health. They created a product called Thopaz Digital Chest Drainage and Monitoring system. This product is a recreation of the standard three chamber chest drainage system that contains a small LED display on the three chamber chest drainage system that displays statistics regarding patient air leak from the past few days. It is highly expensive, and does not provide ample amounts of data for doctors and patients to work with in order to create tailored treatment plans for patients. Therefore, we are looking to overcome this competition by making our monitoring device affordable by simply allowing it to add onto the already widely standardized three-chamber chest drainage system that every hospital is already accustomed to.

11 Financial Plan

Based on our financial projections, our company is asking for \$1,000,000 for the first two years of operations. Our expenses allocate salaries for a team of three full time employees, who will work on product development, marketing and company operations. A large portion of the finances will be allocated towards research, marketing and also legal fees, which will include filing for patents over the course of two years. We do not anticipate having physical office spaces, as we have found working virtually feasible and cost-effective. Lastly, we have projected 20% of our budget to go towards contingency funds, which will be spent on any additional extraneous expenses.

2 Year Expense Breakdown

| | |
|----------------------------------|--------------------|
| Salaries (Engineering and Sales) | \$275,000 |
| Production and Distribution | \$100,000 |
| Legal fees | \$150,000 |
| Advertising and Marketing | \$75,000 |
| Research and Development | \$150,000 |
| Physician Consulting | \$50,000 |
| Additional Extraneous Expenses | \$200,000 |
| Total | \$1,000,000 |

12 SWOT Analysis

Strengths:

The pneumothorax monitoring device, Pneu-mo, is a proven concept that tackles a serious medical problem that has been largely overlooked by other medical device companies and manufacturers.

Weaknesses:

There is currently a lack of capital for marketing and distribution. Research and Development also need to be further expanded and will take time.

Opportunities:

Pneu-mo breaks into a market that has been mostly untouched, and will have many opportunities to collaborate with larger medical device companies to sell and market the pneumothorax monitoring device.

Threats:

Working with other companies and hospitals to accept this new idea and method of monitoring will be a potential threat.

13 Reimbursement

We have considered a reimbursement plan wherein hospital and emergency care facilities can receive our product for a discounted price, or the hospitals can purchase these devices and then be reimbursed later. This is done such that hospitals will be incentivised to purchase our product as well as our consistent software updates.

14 Pitch

In the summer of 2018, and spring of 2020, I had what is called a spontaneous pneumothorax. In short, I had a collapsed lung. What that means is that first it was random, but second little sacs of air on my lung tissue decided to rupture leaking air into the thoracic cavity surrounding my lungs, which then creates pressure on the lung and then it collapses further. It made breathing almost impossible, and surely was the worst pain that I had ever gone through. In both instances, I was rushed to the emergency room, hooked onto additional air support, and had a tube inserted into my thoracic cavity such that air would be able to leave and my lung would be able to expand again. I was hooked onto this machine called the 3 chamber chest drainage system, which was supposed to help monitor my progress. Unfortunately, between the almost month that I spent in the ICU, as well as going for checkups post release, one thing remained clear to me. It was really really hard to monitor how I was improving. It's going to sound ridiculous, but as per my doctor's instruction, the only way to monitor improvement was to see if there were “more or less bubbles” in the water chamber. Between my friends and family who stayed with me for weeks, as well as the doctors and nurses who came by, everybody would stare at this small 2x2 inch chamber and make their best “guess” as to if more or less air was flowing. Of course, to accurately monitor progress I took x rays and ct scans, but the problem was that I took them way too often. I would hear my doctors argue about whether it showed clear progress for healing, but also whether they were necessary at all as it was interrupting my treatment plans. Waking up at early hours to be “ahead” of the queue of people waiting for x rays and ct scans, myself, my family, the nurses and doctors how it affected my sleep schedule, and also the other exercises and treatments that were planned for my recovery and all grew frustrated at how there was no better solution. .

As a result, we have come up with a one-of-a-kind solution called Pneu-Mo, a new Pneumothorax monitoring device. One million individuals will experience a spontaneous pneumothorax each year worldwide, and no one should need to use such out-dated methodology to monitor their physical condition. Pneu-mo allows these patients to monitor their recovery progress through real time statistical data and provides estimated recovery time.



Pneu-Mo is a product that builds on top of the current industry standard medical device for treating Pneumothorax, which is the three chamber drainage system. We have created an attachable device that tracks the rate of air flow and liquid leaving the patient's chest cavity before going into the three chamber drainage system. Pneu-Mo is able to wirelessly transmit the collected data and display it on a monitor in real time. The patient can then see how their condition changes through the real time visualized statistics, and gone are the days of counting the number of bubbles in a tube. In addition to being able to monitor their progress, we have proprietary software that is able to predict and estimate how long a patient will take to recover based on their current condition. Doctors can use our data and predicted timeline to plan out x-ray and CT scans less frequently, so as to not interrupt pre-existing treatment plans, by doing so, also saving resources. This opens the door for hospitals and researchers to study how different treatment methods and people recover from pneumothoraces. And most importantly, families and doctors would have a more accessible way to monitor progress and feel secure in the transparency of the recovery process.

Pneu-mo is just the beginning to a future of medical monitoring and will play a key part in making sure that pneumothoraces are treated in the most efficient way possible in hospitals. We hope you can invest in the future of medical monitoring with us to rethink and revolutionize medical treatments.



15 Patent Application

APPLICATION FOR UNITED STATES LETTERS PATENT

Title: ATTACHABLE PNEUMOTHORAX PATIENT MONITORING SYSTEM

Inventors: Daniel Chong
Stephen Zhou

Patent Lawyer Name

Patent Lawyer Reg. Number

Assignee Name

Assignee Address

Assignee City, State, Zip

Assignee Phone

References Cited:

Patents

- [1] US20130110057 A1 01/2011 Croteau et al
- [2] US3750692 A 01/1972 E Tibbs
- [3] US20060036221 A1 R. 08/2025 Watson

FIELD OF THE INVENTION

[0001] The present invention relates to the monitoring of a pneumothorax patient's condition, which collects data and transmits the information to an external monitor displaying real-time statistics regarding the patient's fluid and air leakage from the thoracic cavity as well as predicting potential recovery time.

BACKGROUND OF THE INVENTION

[0002] The current industry standard for pneumothorax patient treatment is the three-chamber chest drainage system[2]. A tube is inserted into the patient's side to drain out excess fluid and air from the thoracic cavity. This air and fluid then flows into the three-chamber system, which ensures a unidirectional flow of air and fluid out of the patient.

[0003] The three-chamber chest drainage system collects fluids in its fluid chamber and air in its air chamber. To monitor air flow leakage, a tiny liquid chamber is present such that when air enters this chamber, the liquid chamber bubbles[1]. As such, it is often the case where monitoring the pneumothorax patient's condition is very difficult because in order to observe progress, one needs to rely on determining the intensity and frequency of bubble formation in the liquid chamber.

[0004] There have been modifications to the standard three chamber chest drainage system with additions such as a pressure source and a valve configured to relieve pressure in the fluid pathway[1]. There have also been inventions with modifications for the chest tubes used in order to eliminate or reduce clogging in the primary flow tube with an improved terminal structure[3]. However, what is needed is a device that can track air and fluid leakage in real-time so that doctors and patients can be more certain about the patient's lung condition.

OBJECTS OF THE INVENTION

[0005] The object of this invention is to monitor and provide the pneumothorax patient's condition through real-time statistics regarding fluid and air leakage from the thoracic cavity.

[0006] The advantage of the invention is the enhancement of the three-chamber chest drainage system without needing to replace the entire device, as the invention is attachable to any three-chamber chest drainage system and adaptable to any tube size.

SUMMARY OF THE INVENTION

[0007] Main device containing mass air flow sensor and water sensor to detect the rate of air flow and liquid leaving the patient's thoracic cavity.

[0008] Low power wireless transceiver to communicate with software on external devices.

[0009] An adapter detachable from the main component that comes in three different sizes to accommodate the fit of three different chest tube sizes.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] FIG. 1 is a detailed diagram of the main component and its parts.

[0011] FIG. 2 is a drawing showing the main component and the detachable adapter, with the respective tubes that attach to each end of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0012] The main component of the invention, as shown in FIG. 1, is a reusable device that contains a method for air and liquid flow detection. The component also contains a wireless low power RF transceiver to communicate the patient's condition with software on an external device. The main component has an airtight seal with the tube that connects to the three-chamber drainage system. The component can be submerged within water to be cleaned for reuse.

[0013] On the chest tube end of the device, the invention includes a detachable adapter that can be screwed on for an airtight seal, as shown in FIG 2. The adapter is intended for single use and disposed of once a patient's treatment is complete. The detachable adapter has different sizes to accommodate for varying sizes in chest tubes.

ABSTRACT

[0014] The invention is a pneumothorax monitoring system that employs air and fluid sensors to determine how a pneumothorax patient's lung is healing.

[0015] The system is composed of an air monitoring component, a fluid monitoring component, an adapter to match different size tubes, and a wireless low power wireless transceiver. A covering is created to encapsulate the sensors and low power wireless

transceiver and ensure a waterproof seal for the circuitry. A user interface is implemented and viewed on an external monitor to view the real time statistics gathered from the invention.

What is claimed:

1. A method for detecting the improvement of a patient's pneumothorax condition by the use of max air flow and liquid flow sensors that connect to a standard three chamber chest drainage system.
2. A tube adapter that can fit any size chest tube to be attached to the main component of the invention.

16 Summary

As the patient monitoring system market grows in the next decade, there are many opportunities opening up in the field. Pneumothorax patient monitoring is a crucial segment that has been largely overlooked by large biomedical companies and manufacturers. The current treatment method for pneumothorax patients has lacked any form of practical monitoring system, resulting in a significant amount of superfluous resources and time used to fill in such gaps. Pneu-mo promises to provide a proven and practical solution to these problems by creating an effective hardware device that is easy to use and adaptable to any three-chamber chest drainage system on the market. Our product stands out in the market, as it is a proven and viable option to improve upon traditional treatment methods. We truly believe that our product will revolutionize the way that pneumothoraces are treated by increasing hospital efficiency and improving quality of patient care.

17 References

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- 2) <https://www.ncbi.nlm.nih.gov/books/NBK441885/>
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- 4) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4692894/#:~:text=The%20risk%20of%200recurrence%20of.at%20the%20first%206%20months.>
- 5) <https://cardiothoracicsurgery.biomedcentral.com/articles/10.1186/s13019-020-01233-9>
- 6) <https://www.marketsandmarkets.com/Market-Reports/patient-healthcare-monitoring-systems-devices-market-678.html>
- 7) <https://www.grandviewresearch.com/industry-analysis/patient-monitoring-devices-market>
- 8) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4203987/>