RESEARCH PROTOCOL

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Title	**Non-invasive tidal volume monitoring using the Linshom Respiratory Monitoring Device**
Faculty Sponsor	Madhankumar Sathyamoorthy, MD
Principle Investigator/Co-investigators	Madhankumar Sathyamoorthy, MD George E. Abraham III, MD
Abstract	Many post-operative complications arise from patients who breathe inadequately. Inadequate respiration, whether the result of surgery or the anesthesia, causes a decrease in blood oxygen saturation and an increase in carbon dioxide partial pressure. Both of these surrogate measurements of respiration may pose a challenge to measure. Some administer exogenous oxygen to all patients as they leave the operating room in order to maintain the blood oxygen saturation. This renders the oximeter a less sensitive metric of depressed respiration. In the face of decreased respiration, the carbon dioxide levels continue to increase slowly and often go undetected unless blood gases are measured. Indeed carbon dioxide blood levels are the only metric to detect inadequate ventilation using this surrogate index. Monitoring ventilation is a serious challenge outside of critical care settings. In fact, there are no monitors available that can measure tidal volume or relative tidal volume outside of these settings. Linshom is a novel instrument that tracks relative respiration by measuring the excursions of the temperature swings between inspiration and expiration and normalizing them to the patient's breathing. This monitor may be the first non-invasive monitor to measure relative tidal volume in non-critical care settings.

Background	Oxygenation – the process of delivering oxygen to the lungs – is often much simpler to achieve than ventilation, since only a small volume of oxygen must be delivered to oxygenate the patient and provide a reserve. Carbon dioxide, however, constantly accumulates and depends on ongoing ventilation to eliminate it from the lungs. Direct automatic ventilation monitors tend to be cumbersome. They typically require chest straps or EKG-type stickers to be placed on the patient's chest. EKG signals themselves can be used to detect inhalation and exhalation, but the noise of EKG monitors tends to make this method unreliable. In most cases, the patient needs to be lying quite still in order for accurate ventilation monitoring and even then they measure respiratory rate and not tidal volume. The gold standard method to measure the adequacy of ventilation is to measure the exhaled carbon dioxide concentration. Exhaled gas almost always contains carbon dioxide that may be measured using either sidestream or mainstream capnography. However, the carbon dioxide tension is only a surrogate measure of ventilation since it is the changes in tidal volume per breath or minute ventilation that determines the adequacy of respiration and therefore the carbon dioxide tension. Capnography accurately measures the respiratory rate and the net effect of ventilation without reporting the tidal volume. Knowing the tidal volume before the carbon dioxide tension begins to increase provides an opportunity to intervene before the clinical situation has deteriorated too much. Linshom is a reliable, effective patient ventilation monitor that is minimally invasive, simple, inexpensive, fast responding and tracks relative tidal volume outside of critical care settings.
Purpose	To determine whether a non-invasive, temperature-based respiratory instrument could track tidal volume (V_t) in patients.
Specific Aim(s)	The primary purpose of this investigation is to evaluate whether a non-invasive, thermodynamic temperature-based instrument, Linshom, can accurately and consistently track tidal volume as measured by closed loop mechanical ventilator.
Study Period (inclusive years)	The study will be completed over a period of one week.

Study Design	Flyers advertising the study will be placed around campus on designated bulletin boards. Individuals interested in the study will be able to call the number (PI Office Number: 601 815 7066). If the individual meets the study criteria, then he or she will be scheduled for a study session, which will take place in room N200-13 of the respiratory therapy department. After completing the visit, the volunteer will receive a $10.00 gift card. The Linshom detector, which is comprised of two rapid responding medical-grade thermistors in close proximity to the mouth/nose (sensor) and a thermistor remote to the airway, will be mounted in the CPAP facemask to measure the temperature during breathing. The CPAP will be connected to a Servo-I ventilator (Maquet) with a circuit and disposable filter. The volunteers will be instructed to breathe normal through the CPAP mask on room air. The excursions of the thermistor tracings (from valley to peak) will be recorded by the Linshom device and displayed continuously on a laptop monitor in a waveform. The tidal volume will also be measured by the ventilator and the data downloaded in a Compact Flash card. The temperature profiles from the sensors and the relative tidal volume will be correlated with the tidal volumes measured by the ventilator.
Inclusion Criteria	Healthy volunteers 18 years of age or older will be recruited from the Medical School at the University of Mississippi.
Exclusion Criteria	Individuals who are pregnant, suffer from claustrophobia, or who have had a recent respiratory or gastrointestinal illness will be excluded. Volunteers deemed not to have the capacity to provide informed consent will not be enrolled.
Number of Subjects (anticipated)	40.
Outcome Measures	Every volunteer recruited in this study will be monitored by the study investigators during data collection. Linshom readings showing the temperature changes and tidal volume measured by ventilator will be collected.
Study Endpoints	The subjects will breathe through the mask for about 5 minutes, and will be observed during this time by the study investigators. Continuous data for tidal volume and temperature will be collected during this time and the data will be analyzed post-hoc.

Private Health Information	No medical record information will be collected – no other volunteer information will be recorded. Volunteer numbers will be paired with study numbers in a single Microsoft Excel spreadsheet. All study information will thereafter refer to study numbers.
Statistical Methodology	We shall correlate the tidal volumes measured with the Linshom detector with the respective tidal volumes from the mechanical ventilator. A least squares regression analysis (with the coefficient of determination r-squared) and a Bland Altman plot will be prepared. $P<0.05$ will be accepted.

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