Evaluation of a Novel Positive Airway Pressure System in Volunteers

NCT07246538

Informed Consent Form

10/1/2025

Study Summary

You are being asked to take part in a research study that is entirely voluntary. The purpose of the study is to evaluate the accuracy of a newly developed system that takes respiratory measurements while delivering breathing support and may eventually be a useful tool during sedation surgeries.

The system being studied administers Positive Airway Pressure therapy, which involves delivering supplemental oxygen into a mask fitted tightly to the face over the mouth and nose. The amount of oxygen flow is continuously adjusted to maintain specific pressures. The system also detects inhalation and exhalation of each individual breath and estimates the volume of air inhaled as well as the frequency of breathing. The system also has an option to remove the pressure support as the individual receiving it exhales, which may improve comfort and also improve the accuracy of exhaled carbon dioxide monitoring. The system is an investigational medical device that is comprised of software and a disposable oxygen mask that is added on to an existing FDA-cleared medical device.

The goal of the study is to evaluate the system in these different aspects, including the accuracy of the pressure control, accuracy and consistency of inhaled volume measurements and respiratory rate measurements, improvements in exhaled carbon dioxide monitoring, and opinions about the general comfort of the system, particularly when pressure support is removed during exhalation.

Risks of participating in this study are minimal. There is a minor risk of discomfort from the pressure support of the system or from the strap of the mask. If you feel uncomfortable at any time during the study, you may remove the mask from your head and discontinue participation in the study.

There are no direct benefits to participants for taking part in this study. We hope the information we get from this study will help to improve health care.

Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read this information carefully. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you would like to participate in this study.

Study Procedure

Your participation in the study is expected to last less than 30 minutes. After signing this informed consent document, you will be seated in a chair and an air-cushioned mask will be fitted to your face with a strap that goes around the back of your head. We will place a flowmeter for a respiratory monitor on the mask inlet and then connect our system that will deliver breathing support to the mask. We will begin to administer breathing support, and you will be

University of Utah
Institutional Review Board
Approved 10/1/2025
Expires 9/30/2026
IRB_00190165

asked to take a few deep breaths and hold your breath for just a few seconds while we calibrate the data collection system. After this we ask that you only touch the mask if you wish to remove it because of discomfort. You will then be asked to simply breathe normally while you relax and occupy yourself on your phone. We will administer a few different settings on the system while you breathe, and after we finish all of them (approximately 12-15 minutes) we will discontinue the air flow to the mask, and we will inform you to remove your mask. You will then be asked to answer a brief survey on the computer. We will also record your gender, age, height, and weight. When you have completed the survey, your participation in the study will be complete.

Confidentiality

Another potential, but unlikely, risk is a breach of confidentiality. Many steps have been taken to make sure that the confidentiality of all data collected is protected. No identifiable information about you will be collected for this study, and thus the risk is minimal.

Because this study is investigating the use of a medical device, there is also a possibility that the United States Food and Drug Administration (FDA) may inspect the records from this study.

Person to Contact

If you have questions, complaints, or concerns about this study, you may contact Kai Kuck, a professor in the Department of Anesthesiology at the University of Utah, at kai.kuck@hsc.utah.edu or at Tel. (801) 581-6393.

Institutional Review Board: Contact the University of Utah Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

Voluntary Participation

It is up to you to decide whether you would like to take part in this study. There will be no penalty if you refuse to participate or decide to withdraw from this research. This will not affect your relationship with the investigator or study staff in any way.

Compensation

University of Utah
Institutional Review Board
Approved 10/1/2025
Expires 9/30/2026
IRB_00190165

You will receive $50 paid through ADVARRA at the conclusion of your participation in the study.

Conflict of Interest

Trey Blackwell, a member of the research study team, is collecting the data for this study and discloses a financial interest as an employee of Dynasthetics LLC, receiving employee compensation and benefits. Dynasthetics LLC is the company that is sponsoring this study, and has provided the equipment being used to carry out the study. Kai Kuck, the primary investigator overseeing the study declares no conflict of interest. The member of the Department of Anesthesiology Clinical Research Staff that is collecting consent also declares no conflict of interest. All data and results of this study will be reviewed and verified by non-conflicted members of the study team.

Consent

I confirm I have read the information in this consent document and have had the opportunity to ask questions. I will be given a signed copy of the consent form to keep. I voluntarily agree to participate in the study.

_____
Participant's Name

_____ _____
Participant's Signature Date

_____
Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

University of Utah
Institutional Review Board
Approved 10/1/2025
Expires 9/30/2026
IRB_00190165