Protocol Title: **Engineering Evaluation of the Helix Ventilator**

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Confidential

Protocol Approval

Investigator Statement

As Investigator of the study titled Engineering Evaluation of the Helix Ventilator , I agree to:

(i) conduct the Study in accordance with: this Investigator Agreement; the Study's Protocol as approved by the IRB (the "Protocol"); all applicable laws and regulations; Good Clinical Practice and the Declaration of Helsinki; and any IRB or FDA conditions of approval;
(ii) await IRB approval for the Protocol before obtaining informed consents;
(iii) ensure that all requirements for informed consent are met and not let any subject participate in the Study before obtaining that subject's informed consent;
(iv) not make modifications to the Protocol as supplied to me by Respironics, Inc. (the "Sponsor"), without first obtaining the written approval of the Sponsor;
(v) provide the Sponsor with accurate financial information as required by appropriate regulations;
(vi) supervise all testing of investigational devices that involves any Study subject;
(vii) maintain Study documentation for the period of time as required by appropriate regulations; and
(viii) supply to the Sponsor, as part of this Investigator Agreement, my curriculum vitae.

INVESTIGATOR

Signature: _____

Printed Name: _____

Date: _____

TABLE OF CONTENT

Glossary of Definitions and Terms

Active with Flow Circuit Type: A single limb circuit with an active exhalation valve and proximal flow sensor.

Active with Proximal Flow Circuit Type: A single limb circuit with an active exhalation valve with proximal pressure.

BI-Flex: A comfort feature of a Bi-Level PAP device that provides additional pressure relief during the later stage of the inspiration and during active exhalation.

CPAP Pressure: pressure needed to maintain an open airway in a sleep apnea patient treated with CPAP, expressed in centimeters of water (cm H20). The positive pressure can range from 4 - 25 cm H20. Different patients require different pressures. The value is determined in a CPAP titration study.

CPAP Therapy: Continuous Positive Airway Pressure – delivers a constant pressure during inspiration and expiration.

Dual Limb Circuit Type: A dual limb circuit with an active exhalation valve and proximal flow sensor.

EPAP: Expiratory Positive Airway Pressure-Physician prescribed pressure for the expiratory (breathing out) phase of an individual on Bi-level PAP therapy

Hypersomnolence: Excessive daytime sleepiness.

IPAP: Inspiratory Positive Airway Pressure - Physician prescribed pressure for the inspiratory (breathing in) phase of an individual on Bi-level PAP therapy.

Mode of Ventilation: represents a combination of control, phase and conditional variables that establish a set pattern of spontaneous and/or mandatory breaths.

Noninvasive Positive Pressure Ventilation (NPPV): mechanical ventilation provided noninvasively (by mask or similar interface) rather than through an endotracheal tube or tracheostomy.

Passive Circuit Type: A single-limb circuit with an exhalation port.

Positive End-Expiratory Pressure (PEEP): addition of positive airway pressure during the exhalation phase.

Pressure Control Ventilation: mode of ventilation in which airway pressure is set and remains constant with changes in resistance and compliance; may prevent localized alveolar over distention with changes in resistance and compliance.

Spontaneous Breath: inspiration that is patient triggered and patient cycled.

Volume Control Ventilation: mode of ventilation in which the ventilator controls the inspiratory flow and tidal volume is determined by the flow and the inspiratory time; in practice, the tidal volume in this mode is delivered regardless of resistance or compliance.

DOCUMENT CONTROL PAGE

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PROTOCOL REVISIONS

Rev Level	Changes Made for	Date	Contributors
0.0	Original Release	05/26/2017	C. Cain, M.McDermott, C.Vogler
1.0	Protocol updated per IRB comments - Updated primary objective - Change in inclusion criteria from age to weight class >5Kg - Clarification on study staff roles during testing - Other administrative language changes	09/21/17	C. Cain
2.0	Protocol updated to reflect registration on clinicaltrials.gov	10/26/2018	J. Hughes, C. Cain,

I. Background and Significance

History of Ventilators

A ventilator's main purpose is to assist or replace the patient's respiratory muscles in performing the work of breathing **(1).** Ventilation started during the polio epidemic in Scandinavia and the United States. Negative pressure ventilators such as the Iron Lung, were the most commonly used mechanical ventilators throughout the 1950's. After control of the Polio epidemic, invasive positive pressure ventilation via endotracheal tube or tracheostomy was predominant over non-invasive ventilation, largely because of its reliability and provision of direct access to the airway. Invasive positive pressure ventilation means that positive pressure is applied to the patient's airway through an endotracheal or tracheostomy tube and causes gas to flow into the lungs until the ventilator breath is terminated. As the airway pressure drops to zero, the elastic recoil of the chest pushes the tidal volume out, accomplishing passive exhalation **(2).** The major difference between invasive and noninvasive ventilation is that with noninvasive ventilation, gas is delivered to the airway via a mask or "interface" rather than via an invasive conduit (endotracheal or tracheostomy tube) **(3**). With noninvasive ventilation, the positive pressure to the patient is partially or fully provided by the ventilator.

Noninvasive Ventilation

Types of diseases that have been successfully treated with noninvasive ventilation include, but are not limited to, obstructive lung diseases (chronic obstructive pulmonary disease (COPD), asthma, cystic fibrosis, upper airway obstruction), restrictive lung diseases (chest wall deformity, neuromuscular diseases, obesity hypoventilation), parenchymal lung disease (AIDS-related pneumonia, acute respiratory distress syndromes (ARDS), infectious pneumonia) and cardiogenic (acute pulmonary edema) **(3).** Patients with these types of diseases may develop chronic derangement of daytime gas exchange yielding daytime hypoxia and hypercapnia. Such patients are said to have chronic respiratory insufficiency. Patients with chronic respiratory insufficiency fail to achieve adequate ventilation and gas exchange, especially during sleep and such ineffective breathing disrupts nocturnal sleep and manifests as daytime sleepiness (hypersomnia), early morning headache (due to hypercapnia), dyspnea, fatigue and cognitive dysfunction. Pulmonary hypertension and right heart failure can develop as well. Correction of such ventilatory and gas exchange abnormalities using noninvasive positive pressure ventilation (NPPV) is an increasingly popular method for improving sleep quality, heath-related quality of life, functional status (cognitive and physical), and daytime gas exchange. In addition, the use of nocturnal NPPV has been associated with an improvement in quality of life and overall survival in certain patient populations, such as Amyotrophic lateral sclerosis (ALS).

NPPV is often used for patients prone to respiratory muscle fatigue and respiratory failure. As the respiratory muscles work harder to meet the need for oxygen, they tire and become less efficient. That in

turn causes O_2 to drop and CO_2 to rise, eventually precipitating respiratory acidosis. Respiratory acidosis only further impairs respiratory muscle activity and increases the drive to breathe in an already exhausted patient. The system is able to adequately support the ventilation and oxygen needs of patients who are able to breathe spontaneously but whose efforts are unable to meet their total respiratory requirements.

Invasive Ventilation

Many of the disease states listed above for noninvasive ventilation are progressively declining disease states that may ultimately lead to the need for invasive ventilation. Invasive ventilation is indicated when the patient's spontaneous ventilation and non-invasive ventilation are not adequate to sustain life. Some common indications for employing invasive ventilation include, but are not limited to **(2):**

- Apnea with respiratory arrest
- Acute lung injury
- Chronic obstructive pulmonary disease (COPD)
- Chronic restrictive pulmonary disease
- Neuromuscular Disease

Many of these disease states will require invasive ventilation in the home. Invasive ventilators used in the home setting aid in augmenting or replacing spontaneous ventilatory efforts to achieve medical stability in a non-acute setting. This capability allows the tracheotomized patient to return home and still receive adequate ventilatory support **(4).**

The goals of home invasive mechanical ventilation (via tracheostomy) are to sustain and extend life, to enhance the quality of life, to reduce morbidity, to improve or sustain physical and psychological function and to provide cost effective care **(4).**

The device that will be used in this study is intended to supply the support that is needed for all phases of the patient's disease from noninvasive to invasive ventilation.

Study Device (Helix Ventilator)

The Helix ventilator is a non-FDA cleared ventilator device. Helix is the next generation Trilogy ventilator platform. The Helix ventilator has similar modalities to the Trilogy ventilator, which has FDA clearance. The Helix device has improved algorithms, controls, and features to enhance the therapy delivery. Additionally, Helix has an updated hardware platform which has been adequately tested to ensure that the device specifications are met. No pre-clinical or developmental clinical work was required because of Trilogy being the established predicate.
The Helix ventilator provides invasive and non-invasive positive pressure ventilation for the care of patients ≥2.5 kg through adults. The ventilator can measure, display, record, and alarm SpO2, FiO2, CO2,

Respiratory Rate, and Heart Rate data when integrated with the appropriate accessories. The ventilator is suitable for use in institutional, home, and transport settings

The Helix ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician according to its technical specifications.

The Helix ventilator delivers pressure or volume ventilation through a controlled leak valve or a passive exhalation port. The Helix system accepts data from external sensors (pulse oximetry, capnography) and provides monitoring capability with or without ventilation.

Therapy Modes for Helix Ventilator

The device that is being evaluated in this study can provide many different modes of therapy in both pressure support and volume controlled ventilation.

The following is a list of modes that may be provided with these devices, dependent on patient prescriptions:

- Continuous Positive Airway Pressure (CPAP) with optional C-Flex
- Spontaneous Pressure Support (S) with optional Bi-Flex
- Spontaneous/Timed Pressure Support (S/T)
- Pressure Control Pressure Support (PC)
- Timed Pressure Support (T)
- Averaged Volume Assured Pressure Support (AVAPS) in conjunction with the modes listed above (S, S/T, PC, T)
- Volume Control Ventilation (CV)
- Volume Assist Control (AC)
- Synchronous Intermittent Mandatory Ventilation (SIMV)
- Pressure Control SIMV (PC SIMV)
- Pressure Regulated Volume Control (PRVC)

Target Patient Population

The patient population is extremely varied. The patient's age will vary from infant (≥ 5kg) to adult. The medical condition of the patient population ranges from critically ill acute respiratory conditions to pre-existing or developing chronic conditions. Patients treated with the Helix ventilator may suffer from diseases or injuries requiring invasive or non-invasive ventilation. Many of these diseases result in respiratory failure, which can be classified as acute or chronic. Acute respiratory failure is typically treated in a hospital ICU or sub-acute hospital, while chronic respiratory failure is treated at home or in a long term care facility. Specific examples of respiratory failure include, but are not limited to:

- Neuromuscular diseases leading to respiratory failure: Amyotrophic Lateral Sclerosis (ALS), Spinal Muscular Atrophy (SMA), Duchenne Muscular Dystrophy (DMD)

- Chronic Obstructive Pulmonary Disease (COPD)
- Asthma
- Spinal cord injuries
- Thoracic cage deformities
- Pneumonia originating from infectious disease such as influenza
- Pulmonary edema (symptom of congestive heart failure)
- Trauma leading to Acute Lung Injury (ALI)
- Acute Respiratory Distress Syndrome (ARDS)

II. Study Objective

The objective of this Engineering study is to verify the overall performance and controls of the Helix Ventilator.

Specific Aims

1. To collect and compare pressure and flow data between the participant's current therapy device and the Helix ventilator in either invasive or non-invasive ventilation. Pressure and flow waveform data will be evaluated to assess ventilator performance such as delivered pressure such as volume control accuracy, patient synchrony (triggering/cycling), and measured/calculated parameter accuracy.
2. To evaluate the therapy delivery using alternate circuit types, such as mouthpiece ventilation (MPV) or passive dual limb
3. To obtain participant feedback regarding the comfort of the therapy delivery.
4. To obtain caregiver feedback related to the usability of the study device
5. To evaluate the alarm functionality of the study device.
6. To compare the device's Spirometry measurement while it is operating on standard and alternative circuits, (Tidal Volume, breath rate, Peak flows) against a control measurement device

III. Subject Selection

Participants will be recruited from Boston Children's Healthl Physician's Group. Initial contact will be made by the participant's physician, or by his/her designee

Inclusion Criteria
Participants who are currently using mechanical ventilation (> 1 month at time of study participation) as part of medical care and have demonstrated a clinically acceptable response to this therapy and meet the following inclusion criteria:

1. Weight ≥ 5Kg;
2. Any medical condition requiring mechanical ventilation through nasal/facial mask, mouthpiece or tracheostomy
3. Any medical condition requiring mechanical ventilation for > 1 month

Exclusion Criteria

1.Participants intubated with an endotracheal tube
2.Clinically unstable, i.e.,
   a. Acute Respiratory Failure
   b. Participants with refractory hypotension (defined as systolic blood pressure less than 90 mm Hg despite inotropic agents)
   c. Uncontrolled cardiac ischemia or arrhythmias
   d. Any participant determined as inappropriate for the study by the Principal Investigator
3.Patients suffering from metastatic or terminal cancer
4.Currently employed by a manufacturer of respiratory products or family member employed by a manufacturer of respiratory products
Patient of surrogate is unable to provide informed consent

IV. Study Design

This clinical study is a non-randomized, single site, single-arm engineering clinical comparison study. The study is designed to collect and compare device parameters from the patient's current ventilator compared to the Helix ventilator.

V. Participant Enrollment

Following initial contact by their physician or his/her surrogate, participants/surrogate will be informed that their participation is entirely voluntary and the decision to participate or not, will in no way affect their further evaluation or therapy. Subsequently, the participant or surrogate will be given a complete and thorough explanation of the benefits and risks or discomforts that may be anticipated with this study. Informed consent will be obtained prior to enrollment in the study.

Sample Size:
Up to thirty (30) participants will be recruited for this study.

VI. Study Procedures

Following the completion of the informed consent, participants enrolled in this study will be asked to use their existing ventilator for up to 1 hour to collect pressure and flow data for comparison purposes against the Helix ventilator.

Participants will then be set up on the Helix Ventilatory System using the same mode of therapy as their current ventilator. Participants may receive mechanical ventilation using any patient circuit currently being designed for the Helix Ventilator (Passive, Active with PAP, Active with Flow, or dual limb). Patients currently using non-invasive ventilation may be asked to use a mouth piece in lieu of a mask interface. While using the study device, therapy setting may be altered by the physician or his/her surrogate while maintaining the ventilator needs of the patient. For e.g.,a patient currently prescribed an SIMV mode may temporarily be switched to a pressure control mode to assess patient synchrony and ventilator performance.

Once the participant is set-up, he/she will be asked to use the ventilator for up to 4 hours. During this time, Philips Respironics engineers will be collecting data through several mechanisms: 1) Helix SD Card, 2) NICO Monitoring System, and / or 3) External data collection device (ex. laptop). The study staff may ask the participant's opinions on the comfort of the therapy delivery. There will be no invasive monitoring as part of this study.

The engineering evaluations will take place at the Boston Children's Health Physician offices. The study investigators, respiratory therapist, and/or other qualified clinical staff, will be supervising and present for all study visits. Philips Respironics engineers will be present for observational purposes only. All study staff working on this trial will be trained to the protocol and device prior to beginning work.

Participants may be asked to participate in this data collection study up to six (6) times.

Study data collected for this study will be collected on paper or electronic source records. These records will include information regarding inclusion/exclusion, performed study procedures and questions regarding device use. Only those staff that have been delegated by the Principal Investigator will be able to enter or make changes to the data in the Case Report Forms.

VII. Statistical Analysis

The purpose of this Engineering study is to collect engineering and subjective data on the Helix Ventilatory System and the patient's existing ventilator device for comparison purposes. Therefore, no formal analysis of the data is planned.

Determination of Sample Size
Up to 30 participants will be enrolled in the study. Since this is an engineering study to address issues which arise, no sample-size calculation was performed.

General Considerations
The primary analysis will be performed including all completed participants. Descriptive data tables will be provided for all variables of interest. Continuous data will be presented by mean, standard deviation, median, minimum, and maximum observation. Data will be presented in the untransformed and transformed format (if applicable) for each continuous variable. Categorical data will be presented as frequencies and percentages. All analyses will be conducted using either SAS® or SPSS® software.

Participant Disposition
Participant disposition, including the total number of participant's enrolled, completed, early terminations and withdrawals, will be presented overall and by software version. A listing will be provided with the reasons for discontinuation.

Demographics and Baseline Characteristics
Standard subject demographics (e.g., age and gender) and baseline characteristics will be summarized for all participants enrolled and for evaluable participants.

Trends Analysis
The aim of this Engineering study is to verify the performance and controls of the Helix Ventilator. If formal significance testing is required, the endpoints will be compared between the device versions, including device hardware, software,

For continuous data, within-subject comparisons between two iterations will be performed using paired t-tests or the non-parametric Wilcoxon Signed-Ranks test, depending on the distribution of the data. Within-subject comparisons across three or more iterations will be done using Repeated-Measures Analysis of Variance (RMANOVA) or the non-parametric Friedman Test. For participants who only try one iteration throughout the trial, between-subjects comparisons across two iterations will be done using independent-samples t-tests or the Mann Whitney test. If between-subjects comparisons are made across

three or more iterations, ANOVA or the Kruskal-Wallis test will be employed. Post-hoc pairwise comparisons will include an appropriate alpha adjustment.

If formal analysis of categorical data is required, methods such as the Fisher's Exact or Chi Squared Test will be used for between-subjects comparisons, and the McNemar Test or Cochran's Q will be used for within-subject comparisons.

All tests will be conducted at a significance level of $p < 0.05$.

Treatment Compliance
It is expected that the drop-out rate will be low as the study is an engineering trial.

Safety Analysis
Safety evaluations will be performed by recording clinical adverse events at the time originally reported, and they will be followed at each visit thereafter until resolution. Adverse events will be provided in data listings.

Interim Analysis
There is no interim analysis planned for this study.

VIII. Risks and Discomforts

The risks of providing ventilatory support with the study device are no greater than the risks encountered with other ventilatory support devices.

The devices that will be used by the subject have been tested to ensure safety. Should the device not perform as designed, ventilation could increase and decrease more than desired. This effect could be uncomfortable. Should any problems be identified, the respiratory therapist will remove the study device and resume ventilatory support with the participant's current device.

The Helix ventilator has similar modalities to the Trilogy ventilator, which has FDA clearance. The key differences between the Helix Ventilator (study device) and previously cleared Trilogy devices are that the Helix device has improved algorithms, controls, and features to enhance the therapy delivery. Additionally Helix has an updated hardware platform which has been adequately tested to ensure that the device specifications are met. The improved algorithms and controls have been adequately tested to ensure that the delivery of therapy meets the device specifications.

Respironics believes that this patient study is a low risk study that does not require an IDE because of the following:

- The predicate devices, Trilogy Family of Ventilators, have been cleared by FDA:

- K083526 Trilogy 100 Ventilator
- K093416 Trilogy 200 Ventilator
- K093905 Trilogy 202 Ventilator

- The study device uses existing modes of therapy, therapy features and algorithms that have been previously cleared by FDA
- This patient study is recruiting stable, mechanically ventilated participants and will be conducted in a controlled, monitored environment
- The study will be supervised at all times by a respiratory therapist and/or other qualified site clinical staff.

Confidentiality:
Participants will be instructed to contact Philips staff with any questions and concerns related to the device use or the study in general. All information recorded by the study team will be study ID number.

Privacy rules and requirements according to federal and state governing regulations will be implemented. All the information collected as part of this study will be kept confidential. All information collected for this study will be kept in a secured area or stored in a password protected computer if digital. Confidentiality of data shall be observed by all parties involved at all times throughout the clinical study. All data shall be secured against unauthorized access.
The privacy of each subject and confidentiality of his/her information shall be preserved in reports and when publishing any data. Except when required by law, participants will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records. For records disclosed outside the Philips Respironics, participants will be assigned a unique code number.

Results of the study related data, medical history, and information obtained from the questionnaires and device data will be reported and received by Philips Respironics. Philips Respironics will use participant study data for research purposes to support scientific and marketing objectives described in this protocol.

In addition, participant records may be reviewed in order to meet federal and state regulations. Reviewers may include representatives from the FDA or similar government authorities in other countries where the device is being used, and Philips Respironics for the purposes of the following side effects, and to gather additional information related to the study, and the Institutional Review Board (IRB). Participant permission for review of confidential information is granted by signing the associated informed consent. Philips Respironics will ensure that it follows all applicable state and federal data protection regulations.

Withdrawal Criteria:
The term “discontinuation” refers to the participant’s premature withdrawal from the study prior to completing all procedures. Participants may be discontinued from the study for any of the following reasons:

- If in the investigator's judgement, continuation in the study may prove harmful to the participant. Such a decision may be precipitated by adverse events, including fever, nausea, rash, changes in vital signs, or the development of a new medical condition. The investigator will be solely responsible for making medical/safety decisions regarding the participant's continued participation in the study.
- Noncompliance;
- At the request of the participant.

The study team will document whether or not each participant completed the study. If, for any participant, study treatment or assessments were discontinued, the reason will be recorded.

The study goal is to have 30 participants to complete throughout the study. If a subject withdraws from the study, they will not be replaced. All data collected from participants will be used in the data analysis unless the participant has stated they do not want their data to be used.

Hard copies of the study will be kept on site for at 2 years after study completion. The sponsor will maintain study records indefinitely.

IX. Potential Benefits

Although participation in this trial will not result in any direct benefit to the participant, they will be contributing to generalizable data that will help improve device design and function. The advancements with the Helix platform may ultimately improve patient outcomes by allowing the ventilator to provide better ventilation for the patient.

X. Monitoring and Quality Assurance

All adverse events, serious and non-serious, occurring during the course of the study will be collected, fully documented, and reported to the Institutional Internal Review Board by the Principal Investigator or study staff. Serious adverse events will be reviewed by the Sponsor within 24 hours of the study team being aware of the event. For each adverse event, the investigator will provide the onset, duration, intensity and treatment required, outcome and action taken. We anticipate that adverse events during this study would be minimum. Participants will only be using the therapy for 4 hours under the supervision of clinicians. All reasonable care will be taken to avoid these complications. In addition to adverse event reporting, the investigators will report a summary of the protocol findings, participant recruitment, drop-outs, and events to the IRB annually.

All device deficiencies, use or user errors, and equipment failures will be documented. Use or User errors will be captured as part of the source documentation. Device deficiencies and equipment failures will be kept on a separate log. The serial numbers and type of deficiency/failure will be captured.

This clinical study will be monitored by Philips Respironics Inc. (Sponsor) in compliance with the Code of Federal Regulations (CFR) for clinical research; namely, 21 CFR Parts 50, 54, 56 and 812 and others as applicable. The purpose of such monitoring is to assure that the study remains in compliance with the approved protocol, investigator agreement and regulatory requirements, to verify the completeness, reliability and accuracy of study data and to resolve any issues that arise during the conduction of the study. The Sponsor will scheduled monitoring visits periodically as specified by the monitoring plan that will be conduct by trained clinical research professionals. A unique source record will be created for each study participant. This record will include documentation of the informed consent form review process, HIPAA completion according to site policies, concomitant medications and applicable medical history. The Sponsor will have access to these source records. It has been determined that this study does not require a Data Safety Monitoring Board (DSMB).

XI. Registration on ClinicalTrials.gov or other applicable registry

This engineering study is evaluating the Helix ventilator. It will be registered on ClinicalTrials.gov.

XII. References

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2. Byrd, Ryland and Roy Thomas. Ventilation, Mechanical. emedicine. 2004.

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4. AARC Clinical Practice Guidelines. Long-Term Invasive Mechanical Ventilation in the Home. Respir Care; Vol 40 (12): 1313-1320, 1995.