[redacted]

Hill-Rom

PROTOCOL TITLE

Evaluation of Oscillation and Lung Expansion (OLE) using The Volara® System for treatment of respiratory complications in patients with neuromuscular disease in the home setting

Final Protocol

Protocol Number: CR-RR-2020-005

Date: 11May2022

Protocol Number: CR-RR-2020 - 005
Status: Rev. D

Device(s): The Volara® System

Sponsor:
Hill-Rom Company, Inc.
Two Prudential Plaza, Suite 4100
180 N. Stetson Avenue
Chicago, IL 60601

Sponsor Contact(s):
[redacted]
Hillrom Company, Inc.
1020 West County Road F
Saint Paul, MN 55126
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Protocol Revision History

Amendment Number	Revision	Date	Rationale	Details
Not Applicable	Rev. A	25May2021	First release of Protocol	NA
1	Rev. B	28Jul2021	Clarify exclusion criteria and include minor verbiage clarifications throughout	See Summary of Changes Table below
2	Rev. C	02December2021	Add exclusion criteria for patients requiring continuous home mechanical ventilation Clarify exclusion for anticipated hospitalization to "respiratory related hospitalization" Clarify exclusion for Use of OLE therapy in the past 12	See Summary of Changes Table below

			months to "Home use of OLE therapy" Clarify Sponsor's responsibility for devices – Omit language suggesting delivery to investigators Minor verbiage clarification in Section 3.2.2	
3	Rev. D	11May2022	Clarify inclusion criteria to specify that study patients are patients with neurological disorders or neuromuscular disease Clarify requirements for completing pulmonary function testing – allow for patients that cannot complete all pulmonary function tests to participate in the study. Require documentation of tests not completed	See Summary of Changes Table below

[redacted]

[redacted]

Summary of Changes Table

[redacted]

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Evaluation of Oscillation and Lung Expansion (OLE) using The Volara® System for treatment of respiratory complications in patients with neuromuscular disease in the home setting

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Protocol Number: CR-RR-2020-005

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Amendment 2 (02 December 2021)

Section Number and Name	Description of Change	Brief Rationale
Protocol Synopsis & 3.2.2 Exclusion Criteria	In the Exclusion Section, add "Requirement for continuous mechanical ventilation"	Sponsor has decided to limit this initial study to application of therapy in non-ventilated patients due to the complexity of device interaction with mechanical ventilators.
Protocol Synopsis & 3.2.2 Exclusion Criteria	In the Exclusion Section, clarify exclusion for anticipated hospitalization to "respiratory related hospitalization"	Clarify exclusion and not exclude patients who may have planned hospitalizations for non-respiratory procedures
Protocol Synopsis & 3.2.2 Exclusion Criteria	In the Exclusion Section, clarify exclusion for Use of OLE therapy in the past 12 months to "Home use of OLE therapy"	Clarify exclusion and not exclude patients who may have used OLE in the hospital
6.2 Sponsor's Responsibilities	Clarify Sponsor's responsibility for devices – Omit language suggesting delivery to investigators	Devices will not be delivered to investigators in this study

Section 3.2.2 Exclusion Criteria	In the Exclusion Section, clarify language for exclusion "Diagnosed with rapidly progressing NMD such as certain types of Motor Neuron Disease (MND)"	Provide consistent language between Synopsis and Section 3.2.2 Exclusion Criteria

Amendment 3 (11May2022)

Section Number and Name	Description of Change	Brief Rationale
Protocol Synopsis & 3.2 Study Population	Study Population is revised, defined as: Patients with neurological disorders or neuromuscular disease (NMD)	Neurological disorders and neuromuscular disease often have similar pulmonary disease. "Neurological Disorders" was added to expand eligibility of patients that have neurologically related pulmonary complications and may not have neuromuscular weakness disorders.
Protocol Synopsis & 3.2.1 Inclusion Criteria	In the Inclusion Criteria Sections, define Inclusion Criteria as: Documented diagnosis of neurological disorder or neuromuscular disease (NMD)	Neurological disorders and neuromuscular disease often have similar pulmonary disease. "Neurological Disorders" was added to expand eligibility of patients that have neurologically related pulmonary complications and may not have neuromuscular weakness disorders.

1.3 Rationale for Proposed Study	Include language that describes the population as patients with neurological disorders or neuromuscular disease (NMD)	Clarify the population being enrolled and the rationale for including both "Neurological disorders and neuromuscular disease."
3.3.3.3	Under description of pulmonary function testing, add language that allows for participation in cases where subjects (because of their disorder or disease) cannot complete all of the pulmonary function tests.	Many patients with neurological disorders or neuromuscular disease do not have the strength or may not have the coordination to complete some pulmonary function tests

Investigator Signature Page

Investigator Agreement

I agree to conduct this study in accordance with the design and specific provisions of this protocol. Modifications to the study are acceptable only with a mutually agreed upon protocol amendment.

I agree to await Institutional Review Board approval for the protocol before initiating the study, to obtain consent from subjects (unless waived) prior to their enrollment (if required) in the study, to collect and record data as required by this protocol and case report forms, to prepare adverse event and study reports as required by this protocol and to maintain study documentation for the period of time required.

I acknowledge that I am responsible for overall study conduct. I agree to personally conduct or supervise the described study.
I agree to ensure all associates, colleagues and employees assisting in the conduct of the study are informed about their obligations. Mechanisms are in place to ensure that site staff receive the appropriate information throughout the study.

Printed Name:	Investigator Signature:	Date:

[redacted]

Hill-Rom

PROTOCOL TITLE

Evaluation of Oscillation and Lung Expansion (OLE) using The Volara® System for treatment of respiratory complications in patients with neuromuscular disease in the home setting

Final Protocol

Protocol Number: CR-RR-2020-005

Date: 11May2022

Protocol Synopsis

Protocol Title:	Evaluation of Oscillation and Lung Expansion (OLE) using The Volara® System for treatment of respiratory complications in patients with neuromuscular disease in the home setting
Protocol Number:	CR-RR-2020-005

[redacted]

Hill-Rom

PROTOCOL TITLE

Evaluation of Oscillation and Lung Expansion (OLE) using The Volara® System for treatment of respiratory complications in patients with neuromuscular disease in the home setting

Final Protocol

Protocol Number: CR-RR-2020-005

Date: 11May2022

Device Name(s):	The Volara® System
Sponsor:	Hill-Rom Company, Inc. Two Prudential Plaza, Suite 4100 180 N. Stetson Avenue Chicago, IL 60601
Objective(s):	Evaluation of the impact of Oscillation and Lung Expansion (OLE) therapy to treat respiratory complications of neuromuscular disease patients
Endpoints:	**Primary Endpoint:** ● Frequency of exacerbations of pulmonary disease requiring medical intervention (e. g. one or more of the following):[1] ○ Hospitalization ○ ED Visit ○ Unscheduled Antibiotics for Respiratory Infection ○ Unscheduled outpatient visit **Secondary Endpoints:** ● Pulmonary function tests ○ Slow Vital Capacity (SVC) ○ Peak Cough Flow (PCF) ○ Resting Oxygen Saturation (SPO2) ○ Maximal Inspiratory Pressure (MIP) ● Number of individual hospitalizations ● Number of inpatient hospital days ● Number of ICU admissions ● Number of ICU days ● Number of outpatient visits for pulmonary complication (Unscheduled Physician's office, Urgent Care Visits, ED visits) ● Number of antibiotic use days during episodes of pneumonia ○ IV antibiotic days ○ Oral antibiotic days

	○ Nebulized antibiotic days ● Mean adherence to prescribed treatment regimen ● Quality of Life (QOL) Assessment ● Patient/caregiver satisfaction with therapy
Study Design:	The study will be a non-blinded pre-post intervention study with all subjects receiving OLE therapy with The Volara® System
Study Conduct:	The study will be conducted as a decentralized, home-based study recruiting patients from six to ten (6-10) sites in the US.
Treatment of Subjects:	Enrolled subjects will receive OLE therapy with The Volara® System, following the labeled instructions for the device. The prescribed airway clearance therapy regimen including duration of therapy will be documented. A retrospective chart review will be done for each enrolled subject to document incidence of pulmonary exacerbations in the 12 months prior to OLE therapy initiation.
Duration of Subject Participation:	Each study subject will be treated with OLE therapy as their primary airway clearance modality and will remain in the study for a period of approximately seven (7) months.
Number of Subjects:	A total of approximately 70 subjects will be enrolled.
Study Population:	Patients with neurological disorders or neuromuscular disease (NMD) will be enrolled in the study including (but not limited to): ● Quadriplegia/Spinal Cord Injury (SCI) ● Slow Progressing, Bulbar Onset, Amyotrophic Lateral Sclerosis (ALS) ● Muscular Dystrophy (MD) ● Myotonic Dystrophy

	• Spinal Muscular Atrophy (SMA) • Polio • Multiple Sclerosis • Diaphragm Disorders • Cerebral Palsy
Inclusion Criteria	Patients who meet all the following inclusion criteria will be included in the study: • Documented diagnosis of neurological disorder or NMD • Age 5-80 years • History of one or more respiratory exacerbations in the past 6 months or two or more respiratory exacerbations in the past 12 months, which required unplanned or unscheduled medical intervention. • Ability to perform OLE therapy as directed • Signed informed consent (and assent if minor subject)
Exclusion Criteria:	Patients who meet one or more of the following exclusion criteria will not be eligible for the study: • Diagnosis with rapidly progressing NMD such as certain types of Motor Neuron Disease (MND) • Requirement for continuous mechanical ventilation • Anticipated requirement for respiratory related hospitalization within the next six months • History of pneumothorax within past 6 months • History of hemoptysis requiring embolization within past 12 months • Pregnancy • Home use of OLE therapy within the past 12 months • Inability or unwillingness to perform OLE therapy or study procedures as required

Methods:	After enrollment, baseline data including demographics, pulmonary related medical history including acute respiratory-related hospitalizations, ED visits and unscheduled physician office visits, that occurred during the 12 months prior to OLE therapy initiation, will be documented. Pulmonary function tests (PFTs) will be performed. Quality of Life measures, adherence to therapy and satisfaction with therapy data will be collected. Enrolled patients will be started on OLE therapy with The Volara® System. The device will be used within the approved product labeling. This will be the primary airway clearance devices for these patients during the 6 months of the active-treatment study period. Cough therapy such as mechanical insufflation exsufflation (MIE) therapy will be continued if currently prescribed. Other treatments such as high-frequency chest wall oscillation (HFCWO) or chest physiotherapy (CPT) will not be performed during the active treatment period. Following enrollment, completion of a baseline visit, and initiation of OLE therapy, subjects will be seen for 3 follow-up visits. Medical records will be reviewed for the 6-month active treatment study period to document the occurrence of acute respiratory events, documentation will include respiratory related interventions including: number of hospitalizations and hospitalization days, time to first hospitalization, number of courses of antibiotics for respiratory complications, number of ICU admissions and ICU days, and number of outpatient visits (unscheduled Physician's office visit, Urgent Care Visits, ED visits). Respiratory support requirements during the active treatment period will also be documented. The following tests/procedures will be performed/assessed during the active treatment period: ● Pulmonary function will be assessed to obtain SVC, PCF, SPO2, and MIP. ● A quality-of-life measure will be administered ● Adherence to the prescribed therapy regimen will be assessed using the internal therapy log in The Volara® System.

	• Airway Clearance Satisfaction surveys will be conducted. Results from the active treatment period will be compared to the baseline period, during which the subject received his/her regular airway clearance regimen. Any device related adverse events which occur after initial therapy with The Volara® System will be recorded. Any equipment related complaints which occur after initial therapy with The Volara® System will be recorded.
Subject Withdrawal:	Subjects may withdraw consent to participate in the study at any time. The subject may also be withdrawn from the study according to investigator judgement regarding the continued health or safety of the subject or related to inability or unwillingness to perform study therapy or procedures. Removal of subjects may occur for any of the following reasons: • Subject enrolled in violation of inclusion/exclusion criteria • Inability to tolerate OLE therapy • Adverse event or adverse device effect that occurs during therapy • Physician judgement that the patient is not a good candidate for the study • Inability or unwillingness to perform OLE therapy and data collection maneuvers as directed
Statistical Methods:	Descriptive summary statistics will be provided for demographics, the primary and secondary endpoints. Continuous data will be summarized with N, mean, median, standard deviation, min, and max. Categorical data will be summarized with the number and percent of patients in each category. Incidence of adverse device effects (ADEs) will be tabulated.

	Incidence of device-related complaints will be tabulated.

1.0 Introduction

1.1 Background and Significance

Airway clearance therapy is a key component of the care of many patients with chronic respiratory disease including patients with neuromuscular weakness disorders such as muscular dystrophy, spinal muscular atrophy or spinal cord injury. With limited respiratory muscle strength and weak expiratory muscles these patients often develop pulmonary complications as a result of low lung volume and inability to cough effectively. Airway clearance along with lung expansion and cough therapy are often prescribed in these patients to help maintain lung volume and avoid respiratory infections.

The Volara® System provides Oscillation and Lung Expansion (OLE) which consists of continuous positive expiratory pressure (CPEP) and continuous high frequency oscillation (CHFO). The therapy is often referred to in earlier studies as "CPEP" and "CHFO". The Volara® device has an internal blower system that allows for use of the device in the home as well as the hospital setting. The therapy is designed to assist patients that have acute or chronic respiratory disease and require regular airway clearance and/or lung expansion therapy. The Volara® System has recently become available for use in the home. However, limited data is available evaluating effectiveness of the therapy in this setting.

1.2 Research Rationale and Supporting Evidence

Though there have been no formal clinical studies of The Volara® System device, evidence from previous studies involving earlier OLE devices suggest that this therapy provides effective airway clearance and lung expansion in hospitalized patients. Huynh et al. found that post-operative patients treated with OLE had fewer pulmonary complications, shorter hospital stay and less required time on mechanical ventilation compared to those treated with standard therapy [2]. Patel et al. reported on a randomized parallel study comparing outcomes in 32 adult cystic fibrosis (CF) patients with severe pulmonary exacerbations and admitted for intravenous (IV) therapy. Patients were randomized to treatment with either The MetaNeb® System or The Vest® System for up to 14 days. In this setting, results were positive

but comparable to the alternative therapy [3]. Hsieh, et al. evaluated the impact of OLE using The MetaNeb® System in a group of anatomic lung resection patients. OLE therapy was compared to respiratory therapist driven protocol administered positive airway pressure (PAP) and positive expiratory pressure (PEP), the current standard of care. Results showed that OLE therapy resulted in significant improvement in vital capacity (VC) over time compared to standard positive pressure devices [4]. Morgan, et al. investigated the feasibility, safety and efficacy of CHFO administered via The MetaNeb® System to 59 invasively ventilated pediatric patients, between 2007-2012. A total of 528 treatments were evaluated. Results support safety and feasibility and suggest that CHFO may be beneficial by improving lung compliance in patients with secretion-induced atelectasis [5].

More recently, a study of OLE was completed evaluating use of the therapy in a small group of patients, including patients with NMD, in the home setting. This study. suggests the therapy was easy to do, patients were able to adhere to the treatment regimen and based on patient and caregiver reports, the therapy may be effective when used consistently as a primary therapy [6].

1.3 Rationale for the Proposed Study

Many patients with chronic respiratory disease require regular airway clearance therapy to mobilize secretions and to decrease the risk of pulmonary infections. Additionally, some patients (e.g. patients with neurological and neuromuscular disease) are prone to developing atelectasis and require therapy to maintain lung volume. OLE therapy has been shown in clinical studies and anecdotal reports to provide effective airway clearance and lung expansion therapy in a variety of patients in the acute care setting. The Volara® System is now available to provide this therapy in the homecare environment. The proposed study is intended to evaluate the impact of this therapy in treating patients with a need for daily airway clearance and/or lung expansion therapy in the home setting.

1.4 Study Device and Therapy

The intervention device use in this study is The Volara® System (Hill-Rom; St. Paul, MN). It is an FDA 510k cleared device (k192143), powered by an internal blower, that delivers oscillation and lung expansion (OLE) therapy using both continuous high-frequency oscillation (CHFO) and continuous positive expiratory pressure (CPEP). The therapy is indicated for mobilization of secretions, lung expansion therapy and the treatment and prevention of pulmonary atelectasis. The device can also provide supplemental oxygen when used with an oxygen supply.

OLE therapy in the current study may be delivered using aerosolized medications, if ordered by the subject's treating physician as part of his/her routine care. .Aerosolized medications may include, but are not limited to: Albuterol Sulfate, Ipratropium Bromide and Cromolyn Sodium. If no aerosolized medications are ordered and/or if the schedule for ordered medications does not align with the schedule for OLE therapy, the therapy should be delivered using 0.9% normal saline. OLE therapy should be delivered two times per day (e.g. morning and afternoon treatments). Therapy should be delivered using a pre-set (10-minute) therapy regimen that includes both CPEP and CHFO therapy.

Cough therapy such as mechanical insufflation exsufflation (MIE) therapy will be continued if currently prescribed. Other treatments such as high-frequency chest wall oscillation (HFCWO) or chest physiotherapy (CPT) will not be performed during the active treatment period.

2.0 Study Objectives

The primary objective of the study is to evaluate the impact of OLE to treat respiratory complications of neuromuscular disease patients. The frequency of pulmonary exacerbations and other clinical outcome measures will be assessed to determine the effect of consistent OLE therapy.

3.0 Study Design

3.1 Overview of Study Design

3.1.1 Design:

The study will be a non-randomized open label pilot study. It is a decentralized study using an observational design comparing a retrospective control period to an active treatment period. Approximately seventy (70) patients will be enrolled from identified clinics that currently treat NMD patients. All enrolled subjects will receive OLE treatment during the active treatment period. Subjects will be recruited from six to ten (6-10) sites in the US.

Study subjects will serve as their own control. Medical records will be reviewed for each study subject for the twelve-month period prior to initiation of OLE therapy. The study will compare the frequency of exacerbations experienced prior to treatment with OLE to the frequency of exacerbations experienced in the active treatment period, during which study subjects receive treatment with The Volara® System. In addition, specific healthcare utilization indicators including

hospitalizations, antibiotic use, and emergency department (ED) visits for pulmonary complications will be documented for each study period.

Pulmonary function measures, a quality of life (QOL) assessment and a satisfaction survey will be assessed at baseline and compared to results collected during the active treatment period. Adherence to OLE therapy will be collected throughout the active treatment period.

3.2 Study Population

The study population consists of adult and pediatric patients ages 5 to 80 with neurological disorder or NMD diagnoses who have a history of respiratory complications associated with their neurological disorder or NMD.

3.2.1 Inclusion Criteria

Patients who meet all the following inclusion criteria will be included in the study:

- Documented diagnosis of neurological disorder or NMD
- Age 5-80 years
- one or more respiratory exacerbations in the past 6 months or two or more respiratory exacerbations in the past 12 months, which require unplanned or unscheduled medical intervention.
- Ability to perform OLE therapy as directed
- Signed informed consent (and assent if minor subject)

3.2.2 Exclusion Criteria

Patients who meet one or more of the following criteria will be excluded (or will be exited) from the study:

- Diagnosis with rapidly progressing NMD such as certain types of Motor Neuron Disease (NMD)
- Requirement for continuous mechanical ventilation
- Anticipated requirement for respiratory related hospitalization within the next six months
- History of pneumothorax within past 6 months
- History of hemoptysis requiring embolization within past 12 months
- Pregnancy

- Home use of OLE therapy within the past 12 months
- Inability or unwillingness to perform OLE therapy or study procedures as required

3.2.3 Stipend for Study Participation

Patients who participate in the study will receive a stipend for participation. Patients will be paid up to $200 in the form of prepaid debit cards worth $50 after each study visit (Baseline, 1-month, 3-month, and 6-month).

3.3 Study Observations, Procedures and Evaluation Criteria

The study is a decentralized trial. All study visits required for the completion of the trial will occur in the home or will be done virtually. Eligible subjects will be pediatric and adult patients ages 5 – 80 who are able to perform OLE therapy using a mouthpiece, mask, or trach adaptor and who meet all inclusion and none of the exclusion criteria. Informed consent (and assent if minor subject) will be obtained prior to enrollment in the study. Demographic and medical history data will be collected from the medical record of each subject at the time of enrollment.

3.3.1 Informed Consent:

Informed consent (and assent if minor subject) will be obtained from the patient or legally authorized representative prior to enrollment in the study. Informed consent will be obtained by the principal investigator or his/her representative.

3.3.2 Selection Criteria:

Inclusion and exclusion criteria will be reviewed and documented for all study subjects (criteria are described in section 3.2 above).

3.3.3 Study Visits and Data Collection Procedures:

All study subjects will complete a virtual home baseline study visit for initiation of the trial and enrollment into the study. Following the baseline visit, each study subject will complete three follow-up visits. The first follow-up visit will be approximately one month after initiating therapy

and will occur virtually or by phone. Follow-up visits two and three will be done virtually and will occur approximately three months and six months after initiation of OLE therapy. Pulmonary function measures will be collected at baseline and at the end of each month of therapy during the active treatment period. Study Visits and procedures for data collection is described below.

3.3.3.1 Baseline Study Visit: During the baseline visit, study staff will review the informed consent form (and assent form if minor subject) with the study subject and/or caregiver(s). If the patient/caregiver agrees to participate in the study, the informed consent form (and assent form, if applicable) will be signed. A pregnancy test will be administered to female subjects of childbearing age. Inclusion and exclusion criteria will then be assessed and documented and (if eligible) the subject will be enrolled in the study. The study schedule and subject responsibilities will then be reviewed with the subject/caregiver. During the Baseline Visit, the subject's current respiratory therapy regimen and required respiratory support will be documented. A quality of life (QOL) assessment using the Severe Respiratory Insufficiency (SRI) questionnaire will be completed for each subject to assess QOL rating during the pre-treatment period and a Satisfaction Survey questionnaire will be completed by the subject and/or caregiver as an assessment of the current therapy regimen.

3.3.3.2 Documentation of Demographics, Medical History and Pulmonary Exacerbations: Demographic data will be collected for patients enrolled in the study. Medical records for each enrolled subject will be obtained and reviewed to obtain relevant patient medical history and to document pulmonary comorbidities and history at the time of enrollment. Current respiratory related medications and treatments will be documented. Pulmonary exacerbations (as defined in the study endpoints) that occurred in the 12-month period prior to enrollment in the study will be documented. Subsequent medical records will be obtained during the active treatment period and will be used to determine and to document the occurrence of pulmonary exacerbations during that period.

- **Demographic Data**
  The following demographic data will be collected: Age, Height, Weight, Race, Ethnicity and Gender.

- **Pulmonary Related Medical History**
  History of asthma, cystic fibrosis, bronchiectasis, COPD, obstructive sleep apnea, documented obesity (BMI $\geq$ 30 kg m^2), other pulmonary condition(s) will be documented.

- **Medications**
  Respiratory related medications such as bronchodilators, or mucolytics that are prescribed for each study subject during the 12-month pre-treatment period, as well as respiratory medications that are prescribed during the active treatment period will be documented.

- **Respiratory Status**
  Respiratory status including required respiratory support (e.g., invasive mechanical ventilation, noninvasive ventilation, requirement for tracheostomy, O_2 level, etc.) will be documented from the patient medical record for each subject.

- **Respiratory Treatments**
  Respiratory treatments, including mechanical insufflation/exsufflation or other lung expansion or airway clearance therapy, or other therapies to improve respiratory status will be documented from the patient medical record.

- **Pulmonary Exacerbations**
  Pulmonary exacerbations (as defined in the study endpoints) which occurred during the 12-month pre-treatment period or during the active treatment period will be documented.

3.3.3.3 Pulmonary Function Testing: Pulmonary function testing will be completed virtually by an external research organization which specializes in home pulmonary function testing (Zephyrx). This testing will be scheduled separately following enrollment into the study. Baseline parameters will be assessed, including slow vital capacity (SVC), Peak Cough Flow (PCF), Resting SpO_2, and Maximal Inspiratory Pressure (MIP). With this study population, certain subjects may not be able to complete a valid test for all pulmonary function procedures. If unable to complete, a procedure, the inability to complete that procedure will be documented.

3.3.3.4 Run-in Period: Following the Baseline Study Visit, a run-in period of two to four weeks will be completed by the subject prior to initiation of OLE therapy. During this period, the subject/caregiver will document use of MIE and other current airway clearance and lung expansion therapy/maneuvers for each day in the run-in period.

3.3.3.5 Home Training on The Volara® System: A Hillrom designated trainer will set up the device and review operation and treatment protocol at the time the device is delivered. Study subjects and caregivers will be instructed to use the device as their primary airway clearance and lung expansion therapy for a period of six months. Hillrom training staff will follow up with each Volara user according to the standard device placement and follow-up program.

3.3.3.6 Adherence Documentation: During the six-month follow-up period, adherence to the daily prescribed therapy regimen will be assessed. The Volara® System logs therapy details for each therapy completed, including the total time of therapy, the number of stages completed, the total time in CPEP mode, total time in CHFO mode and peak pressures achieved in each mode. Adherence data logs will be downloaded on a regular basis during the active treatment period.

3.3.3.8 One-month Virtual Study Visit: A one-month study visit with each study subject will be conducted virtually. Visits will be completed +/- 3 days from the one-month scheduled visit date. During this visit, the following procedures and assessments will be conducted:

- Review of study procedures with subject/caregiver
- Review of current respiratory status, respiratory treatments, and medications
- Documentation of patient/caregiver reported exacerbations and medical interventions for the prior period (run-in and first month of Volara therapy)
- Documentation of any Adverse Device Effects that the subject experienced during the follow-up period
- Completion of QOL questionnaire
- Completion of Patient/Caregiver Satisfaction survey

3.3.3.9 Three-month and Six-month Virtual Study Visits: Three-month and six-month study visits with each study subject will be conducted virtually by study staff. Visits will be completed

+/- 3 days from the one-month scheduled visit date. During these visits, the following procedures and assessments will be conducted:

- Review of study procedures with subject/caregiver
- Review of current respiratory status, respiratory treatments, and medications
- Documentation of patient/caregiver reported exacerbations and medical interventions for the prior period (three-months of Volara therapy)
- Completion of QOL questionnaire
- Completion of Patient/Caregiver Satisfaction survey

3.3.3.10 Monthly Pulmonary Function Measure Visit: Monthly virtual visits with each study subject will be conducted virtually in the subject's home by the pulmonary function specialists. Visits will be completed +/- 3 days from the one-month scheduled visit date. During these visits, the following procedures and assessments will be conducted:

- Slow Vital Capacity (SVC)
- Peak Cough Flow (PCF)
- Resting O2 Saturation (SpO2)
- Maximal Inspiratory Pressure (MIP)

3.3.4 Evaluation Criteria

The active treatment therapy regimen (which includes OLE therapy with The Volara® System) will be evaluated to determine the effect on the frequency of pulmonary exacerbation and/or change in other clinical endpoints during the active treatment (OLE therapy) period. Endpoints are described below:

3.3.4.1 Primary Endpoint(s):

- **Frequency of exacerbations of pulmonary disease**

  Exacerbations of pulmonary disease are defined as changes in respiratory status requiring intervention. Documentation of pneumonia or respiratory infection, change in chest x-ray, changes in requirement for respiratory support necessitating any of the interventions below will be considered an exacerbation of pulmonary disease:
  - Hospitalization
  - Emergency Department (ED) Visit

- Antibiotics (oral, intravenous, or nebulized)
- Unscheduled Outpatient Clinic Visit

3.3.4.2 Secondary Endpoint(s):

- **Hospital Admissions**

  Total number of Hospital Admissions will be determined for each study subject by review of the medical record for pre-treatment period and for the active treatment period. Total Hospital Admissions will be determined for each subject and for the study group (Mean ± SD) for each study period.

- **Hospital Length of Stay**

  Total Hospital Length of Stay will be determined for each study subject by calculating the number of days spent in the hospital for each admission, from time of admission to time of discharge. The sum of all hospital days for each subject will be calculated for the pre-treatment period and for the active treatment period. Total Hospital Days will be determined for each subject and for the study group (Mean ± SD) for each study period.

- **ICU Admissions**

  Total number of ICU Admissions will be determined for each study subject by review of the medical record during the pre-treatment period and for the active treatment period. Total ICU Admissions will be determined for each subject and for the study group (Mean ± SD) for each study period.

- **ICU Length of Stay**

  Total ICU Length of Stay will be determined for each study subject by calculating the number of days spent in the ICU for each admission, from time of admission to time of discharge. The sum of all ICU days for each subject will be calculated for the pre-treatment period and for the active treatment period. Total ICU Days will be determined for each subject and for the study group (Mean ± SD) for each study period.

- **Number of Outpatient Visits**

Total number of Outpatient Visits will be determined for each study subject by review of the medical record and identifying all visits defined as 1) physician office visits, 2) urgent care visits or 3) emergency department (ED) visits for pulmonary complications that occur during the pre-treatment period and during the active treatment period. Total Outpatient Visits will be determined for each subject and for the study group (Mean ± SD) for each study period.

- **Number of Antibiotic Use Days**

  Total number of Antibiotic Use Days for pulmonary exacerbation will be determined for each study subject by review of the medical record and by calculating the number of days of antibiotic use for each episode, from time of initiation to time of discontinuation. Antibiotic use will be further categorized and individual totals provided for 1) oral, 2) intravenous, and 3) nebulized antibiotic use for pulmonary complications that occur during the pre-treatment period and during the active treatment period. Total antibiotic days and totals for sub-categories will be determined for each subject and for the study group (Mean ± SD) for each study period.

- **Pulmonary Function Testing: Spirometry Measures, Oxygen Saturation and Maximal Inspiratory Pressure**

  Subject Pulmonary Function will be assessed at baseline and monthly during the active treatment period. Virtual visits will be conducted by pulmonary function specialists, as described above. The following measures will be collected:

  - Slow Vital Capacity (SVC)
  - Peak Cough Flow
  - Resting SpO_2
  - Maximal Inspiratory Pressure (MIP)

  Baseline measures will be compared to measures obtained during the active treatment period.

- **Quality of Life (QOL) Assessment**

  The Severe Respiratory Insufficiency (SRI) questionnaire will be administered to all study subjects by the study staff at baseline (reflecting pre-treatment therapy regimen) and during one-month, thee-month and six-month study visits. Results will be determined for each subject and for the study group for each time period and will then be compared to determine any differences in QOL scores between the pre-treatment and active treatment time periods.

- **Adherence to OLE Treatment Regimen**

  Adherence to the OLE treatment regimen will be determined by downloading device therapy log data during the active treatment period. Total adherence to the OLE treatment regimen will be determined for each subject and for the study group (Mean ± SD) for the active treatment period.

- **Patient/Caregiver Satisfaction with Therapy**

  A satisfaction questionnaire will be administered to all study subjects/caregivers by the study staff at baseline (reflecting the patient's pre-treatment therapy regimen) and at each subsequent study visit to assess satisfaction with OLE therapy. Results will be determined for each subject and for the study group for each time period and will then be compared to determine any differences in satisfaction scores between the pre-treatment and active treatment time periods.

3.3.4 Study Exit Documentation

Study exit data is collected to document the reason participation in the study ended. Reasons for exit from the study include:

- **Completion of the study**
- **Subject inability to tolerate therapy**
- **Subject withdrawal**
  This may be voluntary withdrawal on the part of the subject or subject caregiver or withdrawal by investigator for subjects deemed unfit for or unsafe to continue the trial
- **Subject death**

3.3.5 Study Observations/Procedures Table

The study observations and documentation timeline are outlined in Table 1.

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PROTOCOL TITLE

Evaluation of Oscillation and Lung Expansion (OLE) using The Volara® System for treatment of respiratory complications in patients with neuromuscular disease in the home setting

Final Protocol

Protocol Number: CR-RR-2020-005

Date: 11May2022

TABLE 1

Study Observations/Procedures

Procedures	Baseline	Run-in	1 month	3 months	6 months
Inclusion/Exclusion Criteria	X				
Pregnancy test (women of childbearing age)	X				
Informed consent (and assent if minor subject)	X[1]				
Demographics	X				
Medical History	X				
Baseline Pulmonary Medications	X				

Documentation of acute pulmonary exacerbations:
• Hospital admission and discharge (including ICU admission and discharge)
• Antibiotic use (IV/Oral/inhaled) *start and stop dates*
• Outpatient Visits for Pulmonary Complication
  ○ Physician Office Visits
  ○ Urgent Care Visits
  ○ ED Visits
Documented from the medical record
	X
	Retrospective (past 12 mo)
			X
			Active Treatment Period		

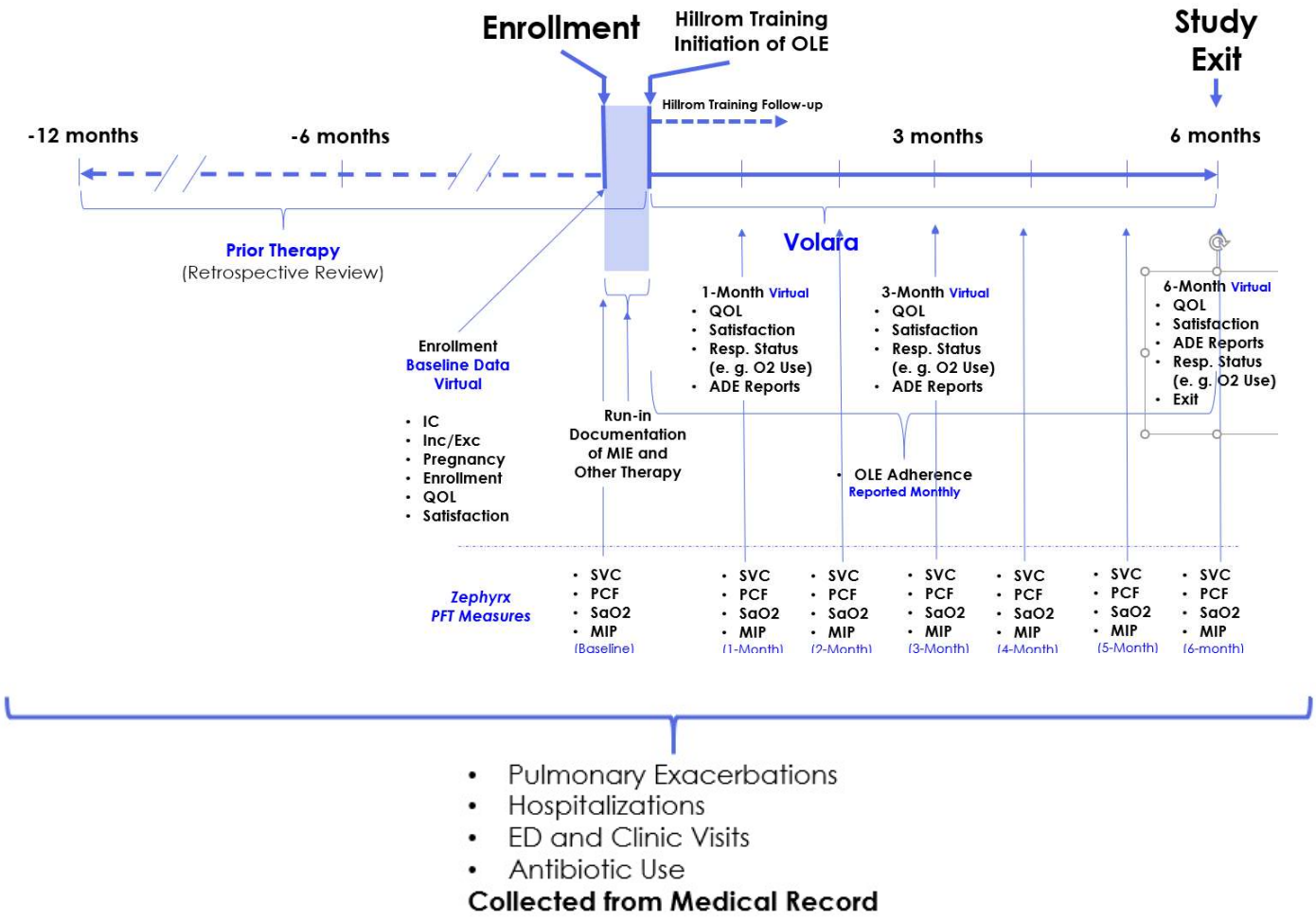
QOL Questionnaire	X		X	X	X
Patient/Caregiver satisfaction with Therapy	X		X	X	X
Basic Pulmonary Function Measures • SVC • PCF • Resting SpO2 • Maximal Inspiratory Pressure (MIP)	X		**Monthly**		
Adherence to prescribed regimen (OLE)			Ongoing		
Documentation of use of MIE or other airway clearance/lung expansion therapy/maneuvers		X			
Adverse device effects			Each Occurrence		
Study Exit Form					X

[1]Obtained prior to any study-specific procedures

3.3.6 Study Flow and Timeline

The study flow and timeline of events and data collection periods is shown below in and Figure 1.

FIGURE 1



3.5 Statistical Methods and Analysis

3.5.1 Sample Size Estimation

The sample size for this study is a convenience sample. Resulting data on the outcomes associated with the OLE may provide preliminary data on effectiveness of therapy and help to provide definition of the effect size and variability and the number of subjects required for subsequent studies.

3.5.2 Statistical Analysis

- Summary statistics and data listings will be provided.

- Demographic data will be summarized. For continuous type data (e. g. Age), descriptive summary statistics (N, mean, median, standard deviation, min, and max) will be presented. For categorical variables (gender, race, etc.) the number and percent of subjects in each category will be provided.

- Endpoints will be documented and compared as described below:

  Primary Endpoints:
  Frequency of Exacerbation of Pulmonary Disease (as defined in section 3.3.4.1) along with 95% confidence interval will be generated. A detailed description of the analysis plan along with specific subsets to be summarized will be described in a separate document (the statistical analysis plan).

  Secondary Endpoints:
  The secondary endpoints (listed in section 3.3.4.2) will be summarized with descriptive summary statistics appropriate for continuous or categorical data, depending on the outcome being summarized:

  1. Hospital Admissions
  2. Hospital LOS
  3. ICU Admissions

4. ICU LOS
5. Number of Outpatient Visits
6. Antibiotic Use Days
7. Pulmonary Function Testing
   - SVC
   - PCF
   - Resting SpO_2
   - MIP
8. QOL Assessment
9. Adherence to OLE Therapy Regimen
10. Patient/Caregiver Satisfaction

Comparison of Pre-treatment and Active Treatment Periods

Rate of exacerbation and heath care utilization will be evaluated to compare the active treatment period and the control periods (six-month period immediately prior to active treatment and six-month seasonally equivalent time-period). Remaining endpoints will compare baseline assessments to assessments obtained during the active treatment period. Comparisons will be conducted for the purpose of identifying any statistical associations that can be attributed to use of OLE treatment with The Volara® System.

General Study Information

4.1 Technical Support for Device(s)

Technical support will be performed by Hillrom following routine service practices (contact details will be provided).

4.2 Record Retention

Records must be maintained for a period of up to three years after the latter of the following dates: the date the study is completed/terminated, or the date of the last regulatory approval. The Investigators or Institutions shall notify the Sponsor at least thirty (30) days prior to any planned destruction of records from this study.

All records will be kept confidential and the patient's name will not be released at any time. Code numbers will be used to de-identify patient information on the CRFs and other study-related documents.

5.0 Safety and Device Complaint Definitions and Reporting Requirements

Safety surveillance within this study and the safety reporting both performed by the investigator, starts as soon as the subject signs informed consent (and assent if minor subject) and receives the first study-specific treatment. The safety surveillance and the safety reporting will continue until the last study-specific test has been performed, the subject/investigator concludes his participation into the study or the subject/investigator withdraws the subject from the study, except as otherwise specified in the protocol.

Reportable events:

(1) Adverse Device Effects (adverse event related to the device) associated with the use of The Volara® System

(2) Device Complaints associated with The Volara® System

During the study, safety events and device complaints must be reported to the Sponsor within 24 hours of becoming aware of the event. Please contact [redacted] by phone: [redacted] or email: [redacted].

A complaint is defined as any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of the device after its release for distribution (21 CFR 820.3(b)).

Any device Complaint and/or reported safety event be reviewed, evaluated, and investigated by Hillrom and reported to the appropriate Health Authority per current regulations.

Additional information may be requested, when required, by the Sponsor in order to support the reporting of safety events to regulatory authorities.

The investigator must notify the IRB/EC, if appropriate, in accordance with national and local laws and regulations, of the safety and/or complaint events reported to the Sponsor.

5.1 Foreseeable Risks and Benefits of the Clinical Study

5.1.1 Anticipated risks associated with study participation include, but are not limited to:

- Hyperventilation
- Decreased cardiac output
- Headache
- Increased air trapping
- Pulmonary air leak
- Pneumothorax
- Pulmonary hemorrhage

There may be other risks or discomforts associated with receiving this therapy which are currently unforeseen.

5.1.2 Possible benefits of study participation include, but are not limited to:

- Information learned about use of OLE therapy in patients with NMD in this study may help doctors learn more about treating patients with the same condition in the future.
- Study participation may contribute to improving the health of patients with NMD.
- It is possible that there will be no benefit from study participation.

5.2 Adverse Event (AE) Definition

Any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device under study.

This definition includes events related to the investigational medical device.

This definition includes events related to the procedures involved.

5.3 Serious Adverse Event (SAE) Definition

An adverse event that led to:

- Death
- A serious deterioration in the health of the subject, that either resulted in:
  - A life-threatening illness or injury OR

- A permanent impairment to a body structure or a body function OR
- An in-patient or prolonged hospitalization OR
- A medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body OR
- A malignant tumor

- Fetal distress, fetal death or a congenital abnormality or birth defect
- A planned hospitalization for a pre-existing condition, or a procedure required by the protocol is not considered a serious adverse event.

5.4 Adverse Device Effect (ADE) Definition

An adverse event related to the use of an investigational medical device.

This definition includes adverse events resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation, or any malfunction of the investigational medical device.

This definition includes any event resulting from the use error or from intentional misuse of the investigational medical device.

5.5 Serious Adverse Device Effect (SADE) Definition

Adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.

5.5.1 Unanticipated Serious Adverse Device Effect (USADE) Definition

A serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report.

1. UADE [applicable to investigational studies following FDA regulations]

As defined in 21 CFR §812.3, unanticipated adverse device effects (UADE) are defined as any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the clinical investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

If an unanticipated adverse device effect occurs, the investigator must notify Hillrom and the IRB/EC immediately, but no later than 10 working days of the investigator's knowledge of the event, as required by 21 CFR §812.150. Hillrom will take any steps necessary to investigate the event and will be responsible for notifying FDA and all other participating IRBs/ECs and investigators.

5.5.2 Anticipated Serious Adverse Device Effect (ASADE) Definition

A serious adverse device effect which by its nature, incidence, severity or outcome has been previously identified in the risk analysis report.

5.6 Subject Death

All subject deaths are to be documented and reported to the sponsor within 72 hours after becoming aware of the event.

5.7 Complaint or Device Deficiency Definition

A complaint is defined as any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of the device after its release for distribution (21 CFR 820.3(b)).

Any device complaint and/or allegation of injury shall be reviewed, evaluated, and investigated by Hillrom Post Market Surveillance and reported to the appropriate Health Authority per current regulations. The Investigators are responsible for informing the Institutional Review Boards, as per their guidelines.

6.0 Investigator, Sponsor, and IRB/EC Responsibilities

6.1 Investigator's Responsibilities

The Investigator will comply with Good Clinical Practices (GCPs) and applicable regulatory requirements, as itemized below.

- The Investigator shall be familiar with the appropriate use of The Volara® System and any other information provided by the Sponsor.
- The Investigator shall provide adequate staff to conduct and complete the study within the agreed study time period. The Investigator shall ensure that all persons assisting with the study are adequately informed about the protocol, The Volara® System and their study related duties.
- A qualified physician delegated as the Investigator will be responsible for all study related duties and functions. During a subject's participation, the

Investigator/Institution shall ensure that adequate medical care is provided to the patient for any adverse event.

- The Investigator shall have written and dated approval from the IRB/EC for the protocol, informed consent and assent forms or waiver of informed consent, HIPAA authorization, patient recruitment procedures and any other written information for the conduct of the study and/or to be provided to patients.

- The Investigator/Institution shall conduct the study in compliance with the protocol agreed to by the Sponsor. The Investigator shall sign the protocol or alternative contract to confirm agreement. The Investigator shall not implement any deviation or changes to the protocol without agreement with the Sponsor and prior review and agreement from the IRB/EC, unless the deviation or change is to eliminate an immediate hazard to study patients.

- The Investigator/Institution shall maintain subject confidentiality.

- In obtaining and documenting informed consent (and assent if minor subject), the Investigator must comply with the applicable regulatory requirements and shall adhere to GCP and the ethical principles that have their origin in the Declaration of Helsinki.

- The Investigator, per Title 21 Code of Federal Regulations Part 54, shall disclose any financial interests that could affect the reliability of the data.

- The Investigator shall ensure the accuracy, completeness, legibility and timeliness of the data reported to the Sponsor in the CRFs and required reports.

- The Investigator shall maintain the study documents as required by the applicable regulatory requirements. Records must be maintained for a period of three years after the latter of the following dates: the date the study is completed/terminated or the date of the last regulatory approval based on the study data. The

Investigator or Institution shall notify the Sponsor at least thirty (30) days prior to any planned destruction of records from this study.

- The Investigator shall submit written summaries of the status of the study to the IRB/EC annually, or as requested by the IRB/EC, and upon completion of the Study.

- All serious adverse device effects (SADE) and unanticipated adverse device effects (UADE) shall be reported immediately to the Sponsor and per the local IRB/EC's reporting policy at that site. The initial reports shall be followed by more detailed reports if more information becomes available. If the study is terminated prematurely or suspended for any reason, the Investigator shall promptly inform the study patients and ensure appropriate therapy and follow-up is scheduled or documented for each patient.

6.2 Sponsor's Responsibilities

The Sponsor of the program is Hillrom Company, Inc. The Sponsor's, responsibilities are itemized below.

- The Sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written standard operating procedures (SOPs) to ensure that studies are conducted and that the data are generated, documented, and reported in compliance with the protocol, GCPs and applicable regulatory requirements. The Sponsor is responsible for securing an agreement from all involved parties to ensure direct access to all study-related sites, source documents, and reports for the purpose of monitoring and auditing.

- The Sponsor may transfer any or all of the study-related duties and functions to a Contract Research Organization (CRO), but the ultimate responsibility for the quality and integrity of the data resides with the Sponsor.

- The Sponsor shall use an unambiguous patient identification code that allows for de-identification of all the data reported for each patient.

- The Sponsor shall retain the essential documents as required by the applicable regulatory requirements. Records must be maintained for a period of three years after the latter of the following dates: the date the study is completed/terminated or the date of the last regulatory approval.

- The Sponsor shall ensure the Investigator(s) selected for the study have the proper qualifications, training, and resources to perform the study adequately.

- The Sponsor shall provide the Investigator(s) with a protocol and an Investigator Brochure (or equivalent documentation) and allow sufficient time for the Investigator to review the information provided.

- The Sponsor shall ensure timely delivery of the Device(s); maintain records that document shipment, receipt, disposition, return and destruction (if applicable) of the Devices; maintain a system for retrieving Devices and documenting this retrieval; maintain a system for the disposition of unused Device(s) and for the documentation of this disposition.

- The Sponsor shall ensure that it is specified in the protocol or other written agreement that the Investigator(s)/Institution(s) provide direct access to source documents for study-related monitoring, audits, IRB/EC review, and regulatory inspection. The Sponsor shall verify that each patient has consented in writing, to direct access to his/her original medical records for study-related monitoring, audit, IRB/EC review and regulatory inspection, or that informed consent has been waived.

- The Sponsor is responsible for submitting reports of all recalls and device disposition to the IRB/EC and the FDA, as applicable.

6.3 Institutional Review Board (21 CFR Part 56) / Ethics Committee

- Prior to study initiation, the appropriate IRB/EC must review and give written approval for the study and provide the approved informed consent form. It is the responsibility of the Investigators, in collaboration with the Sponsor, to provide the IRB/EC with all necessary information to satisfy the individual Institution's requirements.

- Informed consent must be obtained from all subjects, or legally authorized representative, prior to participation as per Federal Regulations and/or the qualifying Institutional Review Board (IRB) or Ethics Committee (EC). A blank copy of the IRB/EC-approved form must be kept on-site site and by the sponsor. The signed original for each subject must be kept in the subjects will be given a copy of their signed informed consent.

7.0 Administrative Study Information

7.1 Pre-Study Site Visits (Qualification and Site Initiation Visits)

The Sponsor will confirm the site's ability to perform the study, store study equipment, and recruit patients. This is typically done during a visit to the site to meet with the Investigator(s), but may be done remotely in certain circumstances.

7.2 Investigator Records and Reports

Where required by applicable regulatory requirements, an investigator signatory will be obtained for the acceptance of the clinical study report. The Investigator(s) will be provided reasonable access to statistical results and tables and will be provided a summary of the study results.

7.3 Interim Monitoring and Closeout Visit(s)

In-person and/or remote interim monitoring and close-out visits may be conducted by the Sponsor for quality assurance.

7.4 Materials Provided by the Sponsor

The Sponsor will supply The Volara® System devices (as required) and as agreed upon in the study agreement.

8.0 Changes Necessary after Study Initiation

If there are changes to the study plan or protocol, these changes will be agreed upon by the Sponsor, its acting representative (if appropriate), the Investigator(s), and the IRB/EC before the changes are implemented. All changes must be documented.

9.0 Study Completion

See section 3.3 for study visit details. Upon completion of the study, a study exit form will be completed for each patient.

10.0 Confidentiality/Publication of the Study

Any information shared by the Sponsor regarding this clinical study is the property of the Sponsor. This protocol is considered proprietary information and should be kept confidential.

Ownership and guidelines for use of the data generated by this clinical study will be in compliance with the terms specified in the Clinical Research Agreement.

A Publication Plan and Policy will be developed based on the guiding principles of the International Committee of Medical Journal Editors (ICMJE) Guidelines.

A 'Publication Agreement' will be signed between the Principal Investigator and the Sponsor either as a separate Publication Agreement or within the Clinical Trial Agreement.

For more information on publication guidelines, please refer to the International Committee of Medical Journal Editors (ICMJE) on www.icmje.org.

11.0 References:

1. Rodriguez-Roisin R. Toward a Consensus Definition for COPD Exacerbations. Chest. 2000;117: 398s-401s.

2. Huynh TT, Liesching TN, Cereda M, Lei Y, Frazer MJ, Nahouraii MR, Diette GB. Efficacy of Oscillation and Lung Expansion in Reducing Postoperative Pulmonary Complications. J Am Coll Surg. 2019 Nov;229(5): 458-466.

3. Patel P, Fukushima L, Balekian A, Chou W, Lu A, Gali V, et al. Is MetaNeb comparable to high frequency chest compression in the setting of a severe pulmonary exacerbation in adults with cystic fibrosis? Pediatr Pulmonol 2013;48(Suppl 36):359.

4. Hsieh J, Prickett M, Willis N, DeCamp M, de Hoyos A. A comparison of positive pressure modalities in a respiratory therapist driven protocol for patients post anatomic lung resection. Respir Care. 2014;59(10):2017931.

5. Morgan S, Hornik CP, Patel N, Williford WL, Turner DA, Cheifetz IM. Continuous high-frequency oscillation therapy in invasively ventilated pediatric subjects in the critical care setting. Respir Care. 2016 Nov 1; 61(11): 1451-5.

6. Sharma R, Prickett M, Coleman JM, Hixon J, Wolfe LF. Adherence to therapy and patient reported satisfaction using a novel airway clearance and lung expansion treatment in motor neuron disease (MND) and cystic fibrosis (CF) patients in the home setting [abstract]. Am J Respir Crit Care Med. 2018;197:A6271.

12.0 List of Abbreviations

ADE	Adverse Device Effect
BMI	Body Mass Index
CHFO	Continuous High Frequency Oscillation
CPEP	Continuous Positive Expiratory Pressure
EC	Ethics Committee
ED	Emergency Department
GCP	Good Clinical Practice
IRB	Institutional Review Board
IV	Intravenous
MIP	Maximal Inspiratory Pressure
NMD	Neuromuscular Disease
OLE	Oscillation and Lung Expansion
PCF	Peak Cough Flow
QOL	Quality of Life
SpO2	Oxygen Saturation – obtained by pulse oximetry
SVC	Slow Vital Capacity
VC	Vital Capacity