Clinical Protocol

Amara View Minimal Contact Mask

An assessment of patient preference for the Amara View Full Face Mask compared to the ResMed AirFit F40 – a benchmark protocol

Protocol ID: SRC-300401-Amara View Benchmark Study

Version 1.0

June 24, 2024

Sponsored By

Philips RS North America LLC f/k/a Respironics, Inc.
6501 Living Place
Pittsburgh, PA 15206, USA

Sponsor Approval

Sarah Bass, PhD Senior Clinical Development Scientist	Date
Carolyn Newkirk, MEd Senior Clinical Research Associate	Date
Jeff Jasko, MS Associate Director, Data Analytics	Date

Investigator Agreement

As Investigator of the study entitled “An assessment of patient preference for the Amara View Full Face Mask compared to the ResMed AirFit F40 – a benchmark protocol”; Protocol ID SRC-300401-Amara View Benchmark Study, 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 Philips (the “Sponsor”), without first obtaining the written approval of the Sponsor;

(v) provide the Sponsor with accurate financial information as required by FDA regulations;

(vi) supervise all testing of study devices that involves any subject;

(vii) maintain Study documentation for the period of time as required by FDA regulations;

(viii) will supply to the Sponsor, as part of this Investigator Agreement, my curriculum vitae.

Investigator Signature: _____ **Date**:_____

Printed Name: _____

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Protocol Title: An assessment of patient preference for the Amara View Full Face Mask compared to the ResMed AirFit F40 – a benchmark protocol

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Background Information

Sleep disordered breathing (SDB) is characterized by an abnormal respiratory pattern during sleep and is highly prevalent in the general population. Obstructive sleep apnea (OSA) accounts for 80-90% of SDB cases.[1] OSA is a chronic condition characterized by repetitive and partial or complete pharyngeal collapse during sleep leading to temporary partial (hypopnea) or total obstruction (apnea) of the airway. The American Academy of Sleep Medicine (AASM) defines OSA as the occurrence of daytime sleepiness, loud snoring, witnessed breathing interruptions, or awakenings due to gasping or choking in the presence of at least 5 obstructive respiratory events (apneas, hypopneas or respiratory effort related arousals) per hour of sleep.[2] Data on the prevalence of OSA may vary depending on population and measurement criteria (e.g., diagnosis test used, scoring criteria, AHI threshold, etc.). A review of 24 epidemiological studies published between 1987 and 2016 found that the prevalence of OSA (apnea-hypopnea index [AHI] ≥5) in the general population ranged from 9% to 38%.[3] Obstructive Sleep Apnea has been associated with cardiovascular diseases,[4–8] high blood pressure,[9] clinical depression,[10] cognitive impairment,[11] voice disorders,[12] keratoconus,[13] metabolic syndrome,[14] preterm delivery,[15] and increased risk of motor vehicle accidents.[16]

A broad range of therapy options exist today to treat OSA including surgical interventions, oral appliances, positional trainers, and positive airway pressure devices. However, positive airway pressure is considered the standard treatment for OSA[17], and has been used since the early 1980's[18]. A large systematic review and meta-analysis involving 18 different interventions reported PAP therapy to be the most effective in reducing AHI and excessive daytime sleepiness compared to no treatment.[19] PAP therapy includes continuous (CPAP) and bi-level (BiPAP) therapy. Continuous Positive Airway Pressure (CPAP) is the most common form of PAP administration for OSA, in which the pressure of the air breathed is continuous and constant[20]. Bi-Level Positive Airway Pressure (BiPAP) is an alternative to CPAP and provides a higher pressure during inhalation and a lower pressure during exhalation[21]. By keeping the airway open, adequate breathing is maintained and the individual does not experience oxygen desaturation and arousal from sleep, leading to overall improved sleep quality and quality of life. Bi-Level PAP for OSA is provided in two modes of therapy, BiPAP-S where a fixed IPAP and EPAP setting is prescribed, and autoBiPAP, where the device auto titrates IPAP and EPAP levels based on the patient's airway state throughout the night. PAP therapy has been shown to decrease daytime sleepiness, and improve overall quality of life.[22,23]

In addition to the type of therapy administered, the patient interface system is an important component of PAP therapy delivery and is critical to adherence and compliance to treatment.[24] Patient interface systems (i.e., nasal masks, full-face masks, and nasal prongs or "pillows") connect the patient to the therapy device. Although there are many mask designs that use a wide variety of materials, these systems have typically been associated with side effects, limiting patients' acceptance with PAP. Common critiques of the masks include a lack of comfort, difficulty applying and adjusting the mask, mask movement requiring readjustments, noise, aesthetics of the mask and the tubing, skin irritation or trauma, obstruction of vision, and eye irritation from leaks.[25]

The Philips Respironics Amara View Full-face Mask was designed to be a minimal contact full-face mask to address limitations with traditional full-face masks and improve patient comfort.

The Amara View mask, although already cleared for marketing by the US FDA, is undergoing considerations for design changes. A new competitor minimal contact full-face mask (ResMed AirFit F40) has been recently cleared for marketing by the US FDA and released to the market. Prior to making design updates, this study will evaluate patient preference of the Amara View mask compared to the AirFit F40 to provide feedback to the design team.

Description of the Intervention Studied

Investigational Products

There are no investigational products in this benchmark clinical study.

Products Cleared for Marketing by the US FDA

- Amara View Minimal Contact Full Face Mask (MCFFM)

The Amara View Full-Face Mask is a minimal contact full face mask manufactured by Philips Respironics (Murrysville, PA) that covers the mouth and seals under the nose compared to traditional full-face masks which seal over the nose. The Amara View mask is intended to reduce discomfort on the bridge of the nose. There is no forehead arm, offering patients an enhanced design to keep the field of vision clear. The mask consists of a cushion assembly with three cushion sizes, and a modular frame assembly connected to an entrainment elbow and headgear with two size options. The silicone cushion seals under the nose and around the outer perimeter of the patient's mouth and contains a cutout that allows the nostrils to inhale and exhale through when the mask is under pressure. The cushion assembly can be removed from the frame assembly for cleaning or for replacement of the cushion assembly. This allows for one frame size to attach to all three cushion sizes. A quick release tube with a built-in swivel provides a means for connecting the mask to the breathing circuit. The mask can be secured to the patient via headgear, which attaches to the frame with either magnetic clips or non-magnetic talon clips. Amara View uses a traditional tube in front of the mask with a pig tail tube.

The Amara View MCFFM is for single-patient use in the home or multi-patient use in the hospital/institutional environment. The mask is intended to be used on patients (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed.

- AirFit F40 Minimal Contact Full Face Mask

The AirFit F40 is a minimal contact FFM manufactured by ResMed (San Diego, CA) that rests softly and securely under the patients nose and is designed to let patients sleep in any position and move freely throughout the night. The mask consists of three cushion sizes and three headgear sizes. Headgear adjustments can be made with magnetic clips that easily snap on and off.

The AirFit F40 MCFFM is for single-patient reuse in the home environment. The mask is intended to be used on patients weighing more than 66lbs (30kg), who have been prescribed non-invasive CPAP or Bi-level positive airway pressure therapy.

Study Objectives

The primary objective of the study is to assess patient preference for the Philips Respironics Amara View MCFFM compared to the competitor ResMed AirFit F40 MCFFM. The secondary

aim of the study is to compare PAP therapy device data between the two masks. A detailed description of the aims is presented in the following table.

Objectives	Hypothesis	Endpoints
To determine patient preference for the Amara View compared to the AirFit F40 as determined by ratings of mask attributes.	Subjective ratings on mask attributes will tend to be higher for the Amara View mask compared to the ratings for the AirFit F40 mask.	Comparison in satisfaction ratings between the Amara View and the AirFit F40 will be measured for the following attributes: • Bed partner satisfaction (overall) • Fit (cushion, headgear, frame, mask overall) • Comfort (cushion, headgear, frame, mask overall) • Ability to maintain a seal during use (seal satisfaction, leak location) • Stability of the mask • Noise level (self, bed partner) • Air venting (self, bed partner) • Comfort of breathing • Sleep quality • Visual appeal • Patient Satisfaction overall (headgear, cushion, frame, mask) Difference in NPS between the Amara View and the AirFit F40 Differences in ease of use and satisfaction ratings between the Amara View and the AirFit F40 • Mask clips • Mask overall • Assembly (elbow, cushion, frame, tubing quick disconnect, mask clips) • Disassembly (elbow, cushion, frame, tubing quick disconnect, mask clips)

		Proportion of patients who prefer the Amara View compared to the AirFit F40 for the following: • Seal • Comfort • Stability • Noise level • Headgear • Mask cushion attachment ease of use • Less disruptive air venting • Overall preference
Secondary Objective: compare residual AHI values between the Amara View and AirFit F40 masks during PAP therapy.	Residual AHI values will tend not to differ between the Amara View and AirFit F40 masks.	Residual AHI recorded by the participants PAP device while using the Amara View and AirFit F40 masks
Secondary Objective: compare the recorded leak values between the Amara View and ResMed AirFit F40 masks during PAP therapy.	Leak values will tend to be lower for the Amara View mask compared to the AirFit F40 masks.	Leak recorded by the participants PAP device while using the Amara View and AirFit F40 masks.
Secondary Objective: compare the air pressure used during PAP therapy between the Amara View and AirFit F40 masks	Air pressure values will tend not to differ between the Amara View and AirFit F40 masks	Air pressure (cmH20) used during PAP therapy recorded by the participants 'PAP device while using the Amara View and AirFit F40 masks
Secondary Objective: compare the adherence to PAP therapy while using the Amara View and AirFit F40 masks	Adherence to PAP will tend not to differ when using the Amara View mask compared to the AirFit F40 mask	Daily hours of use of PAP therapy recorded by the participants' PAP device while using the Amara View and AirFit F40 masks

Data obtained as part of the secondary objectives from this protocol will be used as part of a Post Market Clinical Follow-up Activity.

Study Design

This is an open-label, randomized cross over trial, comparing patient feedback between the Amara View MCFFM and the AirFit F40 MCFFM. This study will recruit approximately 40 adult patients who are established on PAP or Bi-Level therapy at the time of enrollment.

Adults who are currently adherent to PAP or Bi-Level therapy will be recruited through sleep clinics. Willing and eligible participants will undertake baseline data collection before using either the Amara View or AirFit F40 masks. Therapy will be delivered using their clinically prescribed PAP or Bi-Level device with no modification to settings.

The study will be completed according to applicable Good Clinical Practices and the Declaration of Helsinki. The study will be monitored onsite and/or remotely, as described below.

Randomization

The order in which participants will use the two masks will be randomized. A fixed allocation permuted-block randomization strategy will be used. Randomization will be administered through the electronic data capture system.

Blinding

There will be no blinding in this trial.

Study Procedures

Recruitment

Participants will be recruited via sleep clinics contracted to recruit participants within the United States. Recruitment may involve a combination of in-person recruitment during clinical appointments, phone calls, and emails. Study staff will be responsible for assessment of inclusion and exclusion criteria (listed below).

Scheduling will be conducted by the site. Participants who are willing to enroll will be scheduled for an in-person visit to provide informed consent and complete study procedures.

Baseline Visit (Visit 1)

<u>Consent, Eligibility and Baseline Information</u>

During the baseline visit, the study site coordinator will review the Informed Consent Form (ICF) with the participant explaining the details of the study and answering any questions the participant may have about the study. If the participant is willing to take part in the study, the ICF will be signed and dated by the participant and the site study representative obtaining consent. A copy of each participant's signed ICF will be given to them for their records.

Those who provide consent will then complete the Demographics Questionnaire (see Appendix I), which collects information about age, gender, sex, race, and ethnicity. Next, they will complete the Baseline Survey (see Appendix II) to collect information about the make and model of their prescribed mask and PAP device. The participants will then complete the Eligibility Questionnaire (see Appendix III) to confirm entry criteria.

Participants will be asked to bring their prescribed mask and PAP device to Visit 1.

The enrolled population will consist of all participants who provide informed consent and meet eligibility requirements.

Mask Fitting and Use

At the initial visit, participants will undergo a fitting of the mask they are randomized to start the study with; either the Amara View or the AirFit F40 mask. Participants will be fit with mask sizes recommended by the clinician. The clinician will use the provided sizing gauges for the Amara View and AirFit F40 masks respectively. Once a mask size is selected for the first study mask, the participant will have pressure applied for up to 15 minutes using his or her own PAP machine at therapeutic pressure, and an assessment of mask fit will be performed. If the participant's PAP device is not available, they will be fitted with the mask and will have a pressure of up to 10 cm H_2O applied (if participants do not know their therapy pressure) for up to 15 minutes using a PAP device provided by the site. A new bacteria filter and tubing will be used and a disinfection log will be maintained when/if study equipment is used by multiple participants. Participants may be fitted with up to three mask sizes for the mask. A Mask Fitting Survey (Appendix IV) will be used to capture the participant's prescribed pressure, mask (cushion/frame) sizes and fitting observations for the first study mask.

After the mask fitting, participants will be given the first study mask to take home and provided with the Instructions for Use. They will be encouraged to use the mask for the full 15-days of the first trial period. Participants will be instructed to contact the site if they have issues with the recommended cushion and/or headgear sizes. Participants may be provided with additional mask components/sizes as needed. Any change to cushion or headgear sizing during the trial will be documented in EDC.

It is anticipated that the consent, eligibility, baseline/demographic data collection, and mask fitting will take approximately 60 minutes to complete.

Follow-Up Data Collection

There will be two follow-up data collections occurring on 15 and 30-days after the baseline visit.

Visit 2

After the first 15-day trial period with the first study mask, participants will return to the site for their second study visit. Participants will be instructed to bring their PAP device and return the first study mask to the visit.

Participants will complete a mask attributes survey on the first study mask and then they will be fitted with the second study mask. Fitting procedures will follow the same procedure as described above in the baseline visit. After the mask fitting, participants will be given the second study mask to take home and provided with the Instructions for Use. They will be encouraged to use the mask for the full 15 days of the second trial period. Participants will be instructed to contact the site if they have issues with the recommended cushion and/or headgear size as needed.

If participants did not return the first study mask at the second study visit, they will be asked to bring it to the third study visit.

It is anticipated the survey completion and mask fitting will take approximately 60 minutes to complete.

Visit 3
After the second 15-day trial period with the second study mask, participants will return to the site for the third and final study visit. During this visit, participants will complete a mask-attributes survey on the second study mask and return all study product.

It is anticipated the survey completion and study product return will take approximately 30 minutes to complete.

After participants have completed both study arms, deidentified data from participants' PAP devices will be extracted from the connected device software Care Orchestrator (CO) for Philips device users only. The site coordinator will confirm the data has been uploaded into CO at visits 2 and 3.

Unscheduled Phone Calls

Documentation of unscheduled phone calls will be captured within the EDC.

Conclusion of Participation

Once the participant returns the study mask(s) and completes the survey, their participation in the study will be complete. Participants will be active in the study for approximately 30 days but no more than 60 days after receipt of the first study mask.

Participant Reimbursement

Participants who complete Visit 3 and return both of their study masks will be compensated $250.00 for their time and participation in the study. Pro-rated compensation will be provided to participants who voluntarily drop out of the study or are withdrawn from the study by the investigators or their designee (e.g., due to an AE). In that scenario, participants will be reimbursed based on the following schedule:

Visit	Activity	Timing	Payment Amount
Visit 1	Consent/Eligibility/Surveys	~30 minutes	$50
	Mask Fitting	~30 minutes	$50
Visit 2	Follow-up Survey	~30 minutes	$50
Day 15 (± 5 days)	Mask Fitting	~30 minutes	$50
Visit 3	Follow-up Survey	~30 minutes	$50
Day 30 (± 5 days)			

Total paid after Visit 3	$250

Participants will be asked to return study products at visits 2 and 3. They will not be compensated for study participation until all study products have been returned. Should participants not bring all study products for return at visit 3, they will be compensated at a later date upon return of all study products.

Standard Clinical Care

Each patient's health care provider will be responsible for the ongoing clinical care of each participant. Philips will not make any adjustments or recommendations regarding PAP device settings, beyond troubleshooting aspects of mask fit if necessary.

Stopping Rules

No stopping rules (for the trial) or discontinuation rules (for individual participants) are specified. Participants may choose to withdraw voluntarily or may be withdrawn by investigators on a case-by-case basis (see below).

Schedule of Events

Procedures	Performed/ supervised by	Pre-Screen	Visit 1	Visit 2 Day 15±5 days	Visit 3 Day 30±5 days
Preliminary eligibility assessment	Investigator/ Designee	X			
Consent (enrollment)	Investigator/ Designee		X		
Eligibility questionnaire	Study Coordinator		X		
Demographic & Baseline questionnaires	Study Coordinator		X		
Mask Fitting Survey	Clinician		X	X	
Dispense Study Mask	Clinician/Study Coordinator		X	X	
Mask Survey	Clinician/Study Coordinator			X	X
Inventory check to ensure product return	Clinician/Study Coordinator				X
Compensation	Study Coordinator	X	X	X	X

Selection and Withdrawal of Participants

Number of Subjects

Approximately 40 participants will be enrolled. It is anticipated that approximately 30 participants will complete all study procedures.

Recruitment considerations

As indicated below, eligibility is based on participants being established PAP users, and currently not using a Philips Amara View or ResMed AirFit F40 full face mask. Eligibility criteria will be collected via self-report by the participant.

Inclusion Criteria

- Aged 21-85 years (inclusive)
- Weight >66 pounds/30 kg
- Established on PAP for ≥90 days at the time of consent
- Currently prescribed and using fixed pressure, Auto CPAP, or Bi-Level therapy on a regular basis (average PAP usage of ≥4 hours/night, ≥ 4 days per week for ≥3 months)
- Currently using a Full-Face mask
- Able to read, write, speak and understand English
- Willing and able to provide informed consent
- Willing and able to follow instructions and complete all activities required by the study
- Able to remove a sleep apnea mask without assistance

Exclusion Criteria

- Currently using a Philips Respironics Amara View FFM or ResMed AirFit F40 FFM
- Allergy to silicone
- Allergy to latex
- Unique facial features (i.e., deformities of the face and/or head, piercings, etc.) that could interfere with the therapeutic use of this type of mask
- Employee or living with a family member who works for Philips or any company that designs, sells, or manufactures sleep-related products.
- Prescribed oxygen at night or continuously
- Recent eye surgery or dry eyes
- Hiatal hernia
- Excessive reflux
- Impaired cough reflux

- Impaired cardiac sphincter function
- Using prescription drugs that induce vomiting
- Currently participating in another interventional research study or planned participation in another interventional clinical research study during the trial period
- Prescribed an ASV (adaptive servo-ventilation) device
- Prescribed mechanical ventilation
- Pre-existing conditions such as bullous lung disease, pathologically low blood pressure, bypassed upper airway, pneumothorax, pneumocephalus, cerebral spinal fluid (CSF) leaks, or cribriform plate abnormalities
- Any unstable medical condition (e.g., uncontrolled cardiac, lung, or neurological disease) or limitation that would affect the participant's ability to complete trial activities
- Experiencing any acute illness (e.g., acute sinusitis, ear or eye infections, upper respiratory infections, pharyngitis, bronchitis, pleurisy, pneumonia, or facial dermatitis) that would impact their ability to use the mask and/or PAP therapy during the trial
- Surgical procedures involving the head, neck, face (eyes, ears, nose), or lungs in the previous 90 days or taking place any time during the trial period
- Pregnant
- Advised by a health care provider to avoid magnets
- Patient or patient's household member, caregiver or bed partner in close vicinity currently using medical implants or medical devices that would be affected by magnets, including but not limited to:
  - Pacemakers
  - Implantable cardioverter defibrillators (ICD)
  - Neurostimulators
  - Magnetic metallic implants/electrodes/valves placed in upper limbs, torso, or higher (i.e., neck and head)
  - Cerebral spinal fluid (CSF) shunts (e.g., ventriculo peritoneal (VP) shunt)
  - Aneurysm clips
  - Embolic coils
  - Intracranial aneurysm intravascular flow disruption devices
  - Metallic cranial plates, screws, burr hole covers, and bone substitute devices
  - Metallic splinters in the eye
  - Ocular implants (e.g., glaucoma implants, retinal implants)
  - Certain contact lenses with metal

- Implants to restore hearing or balance that have an implanted magnet (such as cochlear implants, implanted bone conduction hearing devices, and auditory brainstem implants)
- Magnetic denture attachments
- Metallic gastrointestinal clips
- Metallic stents (e.g., aneurysm, coronary, tracheobronchial, biliary)
- Implantable ports and pumps (e.g., insulin/infusion pumps)
- Hypoglossal nerve stimulators
- Devices labeled as MR (Magnetic Resonance) unsafe
- Magnetic metallic implants not labeled for MR or not evaluated for safety in a magnetic field

- PAP device is unknown, or they are using a recalled device that has not yet been remediated. Recalled devices include:
  - DreamStation CPAP, Auto CPAP, or BiPAP
  - DreamStation BiPAP, autoSV (ASV)
  - DreamStation ST, AVAPS (Also known as DreamStation BiPAP AVAPS or DreamStation BiPAP S/T)
  - DreamStation Go CPAP, APAP or Auto CPAP
  - Dorma 400 or 500 CPAP or Auto CPAP
  - System One ASV4
  - System One (Q-Series) 50 series CPAP, Auto CPAP, or BiPAP
  - System One (Q-Series) 60 series CPAP, Auto CPAP, or BiPAP
  - C Series ASV, S/T, or AVAPS
  - REMStar SE Auto CPAP

Withdrawal

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:

- At the discretion of the PI or his designee, if he believes that continuing with the protocol is not in the best interest or 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 responsible for making medical/safety decisions regarding the participants continuing in the study.
- At the request of the participant for any reason (or none)
- At the request of the sponsor

- Non-compliance, as defined by failure to respond to phone and/or email contact after three attempts made by a study representative or failure to attend study appointment(s) (lost to follow-up), or being unwilling/unable to consistently use PAP (at least 4 days per week) along with the provided mask
- If the study mask/s provided is/are found to be inadequate for use (e.g., seal, stability, comfort, air flow, etc.)
- If eligibility status changes during the study and the participant no longer meets inclusion or exclusion criteria

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. No further data will be collected following study withdrawal. Each patient's health care provider will be responsible for follow-up care following study withdrawal with communication from research staff.

Participants may withdraw from the study at any time. Withdrawal from the study will not affect their medical treatment or future participation in a research study.

Treatment of Subjects

PAP therapy will be managed and continue throughout the entire trial duration, using participants' clinically prescribed devices and settings. All participants will remain under the care of their sleep health care provider.

Assessment of Efficacy and/or Performance

This study will assess the effectiveness and performance of the Amara View mask as measured by residual AHI, leak, air pressure values, and adherence. Performance of the Amara View mask will be compared to the AirFit F40 mask for participants using a Philips PAP device.

Assessment of Safety

Overall, Philips has determined the risks in this study are minimal. Both masks being used in the trial are cleared for marketing by the US FDA; therefore, it was determined participation in this study will not expose the participant to anything greater than normal risks associated with these and similar marketed patient interface systems. This study presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context with a Class II medical device.

Trial surveys will include an assessment of breathing comfort. Data will be reviewed after each interval. A 'critical to quality' (CTQ) meeting will be prompted if an incidence of at least 20% of any breathing issue is reported and/or at least 10% incidence of one or more of the following breathing issues is reported: difficulty inhaling, difficulty exhaling, feeling a lack of pressure, feeling too much pressure, feeling of air restriction, feeling of shortness of breath (see Appendix V and Appendix VI). A "critical to quality" meeting will involve a review of safety data with the clinical and project teams and may prompt further discussion on the course of the trial overall.

Safety Monitoring

Adverse event (AE) means any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention related. An AE or suspected adverse reaction is considered “serious” if, in the view of either the investigator or sponsor, it results in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

An Unanticipated Adverse Device Event (UADE) is 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 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. Other important medical events which may not result in any of the outcomes above, but which may require intervention to prevent one of the outcomes above, may in the opinion of the investigator, be considered a UADE.

Adverse Event Classification and Reporting

The severity of all AEs will be assessed by the PI or designee as mild, moderate, or severe using the following guidelines:

- Mild – Events require minimal or no treatment and do not interfere with the subject’s daily activities.
- Moderate – Events result in a low level of inconvenience or concern with therapeutic measures. Moderate events may cause some interference with functioning.
- Severe – Events interrupt a subject’s usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term “severe” does not necessarily equate to “serious”.)

All AEs must have their relationship to study intervention assessed by the PI or designee who examines and evaluates the subject based on temporal relationship and his/her clinical judgment. The degree of certainty about causality will be classified using the categories below. In a clinical trial, the study product must always be suspect.

- *Not Related:* The event is not known to be an effect of the study product/study activity. There is no temporal relationship between the study product/study activity and the event onset. An alternate etiology has been established. The subject never received the study product/study activity.

- *Possibly Related:* The event is a lesser known or possible effect of the study product/study activity. There is some evidence to suggest a causal relationship and a reasonable temporal relationship between the study product/study activity and the event onset. However, other factors may have contributed to the event.
- *Causally Related:* The event is a known effect of the study product/study activity (e.g., listed in the protocol). There is a temporal relationship between the study product/study activity and the event onset. The event stops with discontinuation of the study product/study activity (and reoccurs on restarting).

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during study visits and interviews of a study subject presenting for medical care, or upon review by a study monitor.

All AEs will be captured on the appropriate (e)CRF. Information to be collected includes event description, time of onset, clinician's assessment of severity, relationship to study product (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event. All AEs occurring while on study must be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

Changes in the severity of an AE will be documented to allow an assessment of the duration of the event at each level of severity to be performed. AEs characterized as intermittent require documentation of onset and duration of each episode.

PI or designee will record all reportable events with start dates occurring any time after informed consent is obtained until the last day of study participation. At each study visit, the investigator will inquire about the occurrence of AE/SAEs since the last visit.

If an SAE or UADE occurs, the PI or designee shall complete a Serious Adverse Event or Unanticipated Adverse Device Effect Report and submit to the study sponsor for review as soon as possible (e.g., within 24 hours of awareness) and no later than 3 calendar days after site's awareness of event. As the site gains more information (i.e., admission records, hospital discharge summaries) a new report with the new information should be submitted to the Sponsor. The study sponsor is responsible for conducting an evaluation of the SAE or UADE and shall report the results of such evaluation to the reviewing IRB and other agencies as applicable.

Device Deficiencies

A device deficiency refers to the inadequacy in the identity, quality, durability, reliability, safety, or performance of an investigational device, including malfunction, use errors or inadequacy in information supplied by the manufacturer. All device deficiencies will be documented on the device deficiency tracking form. If the device deficiency led to a UADE, the SAE or UADE Report should be completed as noted above.

If a device deficiency had the potential to lead to a UADE but did not result in one, it should be documented on the device deficiency tracking form and submitted to the study sponsor for review

as soon as possible (e.g., within 24 hours of awareness) and no later than 3 calendar days after site personnel's awareness of event.

Statistical Methods

Determination of Sample Size

This study is not statistically powered. The sample size of approximately 30 trial completers is considered sufficient to gauge directional trends comparing the two mask designs.

General Considerations

All variables will be summarized by descriptive statistics. The statistics for continuous variables will include mean, median, standard deviation, minimum, maximum, 95% confidence interval (CI) for the mean, and number of observations. For categorical variables, frequencies and percentages will be presented. All formal analyses will be conducted using SAS®, and statistical comparisons will be considered significant at an alpha of 0.05, with adjustments for multiple comparisons, as applicable. There are no statistical criteria for terminating the study, and any deviations from the original statistical plan will be noted in the analysis report.

Participant Disposition

Participant disposition, including the total number of participants enrolled, randomized, completed and early terminations, will be presented. In addition, a listing will be provided with the reasons for early termination.

Statistical Analyses

Mask attribute ratings, scaled 0-10, will be collected on both the AirFit F40 and the Amara View Full Face masks. Since the study is not statistically powered, the analysis will focus on the effect sizes and confidence intervals of the paired differences between the masks [Amara View – AirFit F40]. The paired t-test and nonparametric Wilcoxon Signed-Ranks test will further evaluate the trends. In cases where one test calculates a p-value below 0.05 and the other indicates a p-value ≥0.05, the distributions of the paired differences will be inspected to determine which method better models the data. Participants will be excluded from the analysis of a given endpoint if they do not contribute a rating for both study masks.

Residual AHI, leak, air pressure, and average adherence will be extracted from the patients' PAP device data, and the paired differences [Amara View – AirFit F40] will be evaluated as described above.

Percentages and exact binomial confidence intervals will be calculated for categorical questions. The McNemar test will compare binary responses where the same questions are answered after the participants try both masks.

Net Promoter Scores (NPS) will be calculated for the question "Would you recommend this (Amara View FFM or AirFit F40) mask to others?" where the percentage of detractors (ratings 0-6) is subtracted from the percentage promoters (ratings of 9 or 10). Ratings of 7-8 will be considered neutral. Relative NPS will be calculated as [Amara View NPS] – [AirFit F40 NPS].

Participant Accountability and Missing Data

Participants who withdraw from the study will be tabulated with the reasons for the withdrawal. A participant will only be included in the formal statistical analysis if they contribute data for both study masks.

Safety Analysis

Safety evaluations will be performed by recording adverse events at the time originally reported, and they will be followed at regular intervals until resolution or study completion, whichever comes first. Adverse events will be provided in data listings, but no statistical comparisons will be undertaken.

Interim Analysis

No formal interim analysis is planned for this study.

Exploratory Analyses

Various exploratory analyses may be performed, including subgrouping, correlation, regression, and text analytics, in order to investigate the relation between baseline factors and study endpoints. These analyses could support algorithm development or aid in future study design, but they are not required for the final study report.

Case Report Forms

Study-related case report forms (CRFs) and source documentation will be collected and maintained by the sponsor. All such documentation will be kept confidential and stored on a secure server or protected device. Only staff delegated by the PI will have the ability to enter or make changes to the CRFs and source documents.

Quality Control and Quality Assurance

The PI and study personnel will be trained to the study protocol, study product, TMF documents, monitoring plan, CRFs and/or eCRFs, direct data reporting, and all Sponsor expectations, as applicable. Once complete, training and delegations will be documented for PI and study personnel.

Data queries will be addressed by delegated study personnel, and CRF/ eCRFs will be reviewed and signed off by PI prior to study closure. Monitoring will be completed in accordance with US CFR, ICH-E6 GCP Section 6, and ISO 14155:2011 as applicable and as outlined in the monitoring plan.

Monitoring and Monitoring Plan

Onsite and/or remote monitoring will be conducted for this study. Monitoring details will be outlined in the monitoring plan.

This clinical study will be monitored by Philips (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 conduct monitoring visits as specified by the monitoring plan. Monitoring will be conducted by trained clinical research professionals.

It has been determined that this study does not require a Data Safety Monitoring Board (DSMB).

Data Management System

All data will be entered into a 21 CFR Part 11-compliant electronic data capture system (EDC) provided by the Sponsor. The data will be housed within a secure server and accessible only to the sponsor, study personnel, and investigators. Access to the EDC system will be secured through logins managed by a system administrator and appropriate training will be provided. The EDC system provides the capability to perform data management activities within a consistent, auditable, and integrated electronic environment (data security, data entry, data validation). Data entries and modifications will be recorded via an audit trail. If the data manager or study monitors identify data errors or inconsistencies, they will generate queries that will be sent to the Principal Investigators and study staff. After queries are resolved, the database will be locked, and the data will be imported into statistical software and analyzed by biostatisticians.

Deidentified patient data will be retrieved from Care Orchestrator after participants have completed both study arms. Raw data files will be provided to the study team and housed within a server where they will be accessible by the sponsor, study personnel, and investigators.

Protocol Deviations

A protocol deviation is defined as the instance of failure to follow, intentionally or unintentionally, the requirements of the protocol. The noncompliance may be either on the part of the participant, the investigator, or research staff. The PI or designee shall document and explain any deviation from the approved protocol that occurs during the course of the study. These deviations may be major or minor/administrative in nature. Please see the table below for description and reporting requirements for each type. Protocol deviations will be reported to IRB per their policy, by the site or Sponsor, as applicable.

Type	Description	Reporting Requirements
Minor Deviation	Deviation does not have a significant effect on subject safety/rights or the scientific soundness of the study plan	Document on appropriate CRF

Major Deviation	Deviation does have a significant effect on subject safety/rights and/or the scientific soundness of the study plan, or significantly impact the integrity of research data	Document on appropriate CRF and report to sponsor within 7 calendar days from site awareness.

Ethics

The IRB for this study is the Allendale Institutional Review Board, 30 Neck Road, Old Lyme CT 06371; 860-434-5872.

Privacy rules and requirements according to 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. Except when required by law, participants will not be identified by name, address, telephone number, or any other direct personal identifier in study records. For records disclosed outside Sponsor, participants will be assigned a unique code number. The key to the code will be kept by the investigator. Data will be managed by study number and analyzed anonymously.

A unique source record will be created for each study participant. Privacy rules and requirements according to federal and state governing regulations will be implemented. The study record will include documentation of the informed consent form review process, HIPAA completion according to site policies, and applicable medical history. The Sponsor will have access to these source records.

Study data and source will be made available for study related monitoring or audits by the IRB/IEC, sponsor, or regulatory inspection(s).

The data collected during this study may be reanalyzed at a later date and may be combined with the results of other studies. Philips and third parties approved by Philips may use the results of this study for other research and commercial purposes, including:

- Reviewing the safety or effectiveness of the study device and other products or therapies
- Evaluating other products or therapies for patients
- Developing a better understanding of disease
- Identifying trends within the data

Results of the study related data, medical and sleep history, information obtained from surveys and device data will be reported and received by Philips. Philips 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, other government authorities, Philips, and the Institutional Review Board (IRB) to gather information related to the study. By signing the associated informed consent, participants grant permission for these parties to review their

confidential information. Philips will ensure that it follows all applicable state and federal data protection regulations.

Data Handling and Recordkeeping

Hard copies of study documents, if required, will be kept on site for at least two years after study completion. Only approved study staff will be granted access to the data directly entered into the EDC. The sponsor will maintain study records until the study product's end of life (EOL) + 15 years and biometric data for 15 years. Records will be stored at Iron Mountain, a secure information management services company.

Risk and Benefit Analysis

Philips has determined that participation in this study poses minimal risk. It is the opinion of the Sponsor and the PI that the benefits of this protocol outweigh the risks. Both masks being used in the study have been cleared for marketing by the US FDA.

Anticipated Clinical Benefits

Participation in this trial will not result in direct benefit to the participant.

Anticipated Adverse Device Effects

Overall, the risks in this study are minimal and not expected to be different from those encountered by patients prescribed PAP therapy outside of research; however, potential risks are listed below, and they will be described in the ICF and will be repeated verbally to the participants during the consenting process.

Possible risks or effects from use of the products in this research study include, but are not limited to:

- The presence of redness, marks, indentations and/or pressure wherever the mask or headgear touches the face.
- Skin irritation, skin breakdown, bruising or blisters where the mask or headgear comes in contact with the face.
- Discomfort or irritation (itchiness, excessive tearing, burning, dryness, puffiness, infection, blurred vision) of the eyes.
- Eye pain.
- Dry mouth or upper airway.
- Nasal irritation, a feeling of a dry nose, nose bleeds or excessive running of the nose.
- Stomach distension, belching.
- Claustrophobia.
- The study mask may deliver airflow differently from what the participant is accustomed to, and as such, breathing may feel more difficult than what they would experience with a different mask.
- Unusual chest discomfort, breathing discomfort, or shortness of breath.
- Headaches or increased drowsiness.
- In rare cases, the mask may cause tooth, gum, or jaw soreness or aggravate an existing dental condition.
- Pressure or pain in the ears.

- The participant's condition may not improve or may worsen while participating in this study.

Careful mask application, sizing, and adjustment should address or correct mask-related issues. Participants should be instructed to avoid overtightening the headgear and to only use the mask when the device is on and blowing air to avoid rebreathing exhaled air and potential suffocation. Note that some rebreathing may occur at low pressures. Breathing discomfort should be transient or can be addressed with counseling. However, all of these complications are normally encountered while using PAP therapies, and there should be no additional risk from participating in this study given that participants will be recruited on the basis of being established on therapy.

If a participant reports they have experienced an adverse event, they will be directed to contact the site study staff and instructed to discontinue therapy if appropriate.

Participation Risk:

- The loss of confidentiality is a potential risk of being in the study, but the site and sponsor will do everything to make sure that participant information is protected.
- Participants may experience frustration, fatigue, and anxiety while completing the study activities.

There may be a possibility of unanticipated or unknown risks; however, for this activity Philips has determined that this risk is low.

Publication and Registration

This study will be registered on ClinicalTrials.gov. There may be plans to publish the results of this trial, beyond the use of the data in marketing materials.

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Appendices

Appendix I Demographics captures participant's age, gender, sex, race, and ethnicity.

Appendix II Baseline Survey captures prescribed mask and PAP device characteristics

Appendix III Eligibility Assessment captures self-reported inclusion and exclusion information. The participant will sign and date the consent form attesting that all information noted on the Eligibility Assessment was reported by the participant and true.

Appendix IV Mask Fitting Survey captures the mask (cushion/frame) sizes and fitting observations.

Appendix V Mask Survey – Day 15 is to be administered at 15 days to capture preference, aesthetic appeal, and redness, marks and indentations, etc. for the study mask(s).

Appendix VI Mask Survey –Day 30 is to be administered at 30 days to capture preference, aesthetic appeal, and redness, marks and indentations, etc., and study mask comparisons.

Document Revision History

Version	Date	Author	Description of Change	Reason for Change
1.0	24-Jun-2024	S.Bass	Initial Release	N/A