

PAP Masks

Selection, Fitting, Assembly, Disassembly, Use, and Cleaning

For people who use Positive Airway Pressure (PAP), the most common challenge is the mask, or the interface that connects the machine and air tubing to the face. A good effort to match the best mask for each individual user can make all the difference in success or failure with PAP treatment for sleep apnea. The goal of mask selection and fitting is to find a mask that is comfortable while at the same time not allowing substantial leak at the edges where the mask seals with the face. If the headgear that holds a mask in place must be made too tight, to avoid leaks, then it will not be comfortable. The mask should seem snug but comfortable and hopefully relatively leak proof.

Some specific questions for the individual along with other observations at the bedside can make it more likely that an initial mask choice will work well. Usually the first, default mask to consider is a nasal mask, the traditional design that covers the nose but not the mouth. This type of mask or another type of nasal mask is usually considered before a full face mask, which covers the nose and the mouth. This is because full face masks are more likely to leak at the edges. However, for a subject who reports obligate mouth breathing on most nights, a full face mask may be the best initial choice. For a subject who feels like the nasal mask is bothersome, or makes him or her feel “claustrophobic”, a nasal pillow interface – which seal at the nares and do not cover the nose – may be the best choice. These two options are often good, comfortable, and well-liked options for subjects who do not need high PAP settings (high pressures).

Often, but not always, the prospective new PAP user will benefit from being able to try, and compare, more than one type of mask. In Sleep SMART, sites are not assumed to have necessary mask cleaning facilities to allow re-use of a new mask that a subject has tried on, just for fitting. Therefore, a mask that is tried on, but not used, must be discarded. (Sites may decide based on local policies and logistics whether these discarded masks may be cleaned and recycled for use by future Sleep SMART subjects who need to try out sample masks; by the local sleep laboratory; or by the hospital.) Also, if an initial mask selection and sizing can be successful without need for trial of all three available starter masks, mask fitting will be a greener experience for the planet, and Sleep SMART will be less costly. However, the primary consideration should be assuring that a comfortable, well-fitting, and non-leaking mask is found for each Sleep SMART participant, even when it means having to try all three initial mask types in order to select the one with the best fit.

This manual describes considerations that will help in the selection of an effective mask for each participant. This manual also describes how to put on, assemble, and disassemble the three main masks and interfaces that will be used, initially, at each site for Sleep SMART participants. Additional options will be available to Sleep SMART participants through FusionHealth after discharge. If the participant uses the best mask at the site, and still has difficulty during subsequent nights, then FusionHealth can work with the participant to find a different mask,

among the many other makes and models in existence and available for the study. FusionHealth will also serve as a resource for the participant, during the six months assigned to PAP use in the Sleep SMART trial, when it comes to replacement supplies, or subsequent problems with the use of the equipment. For example, PAP machine filters often need to be replaced every 2 to 12 weeks, depending on the environment. The rubber/silicone inner lining of a nasal or full face mask, or the rubber/silicone nasal pillows themselves, sometimes change in consistency with time and may need to be replaced every 1 to 6 months.

Initial Mask Selection Questions

Before you start, determine for each subject:

1. Does he or she have chronic sinus congestion (suggest that use of a chinstrap or full face mask may be needed)
2. Are facial features smaller or larger, ie: nose and mouth (helps determine mask size)
3. Is patient claustrophobic (argues for nasal pillow interfaces)
4. Is patient's face easily irritated (argues for nasal pillow interface, where less facial surface area makes contact with the mask)
5. Seasonal or year round facial hair (suggests that full face mask will not seal ideally over the facial hair, so other mask options may work better)
6. Does patient have dentures, which generally are not worn during sleep (suggests that nasal pillows may work better than nasal mask or full face mask, each of which has a ridge that depends on support from natural teeth and gums to make an effective seal)

Nasal Pillows Interface

Pros

- Smallest of all masks
- Fits directly into the nares
- Good for sensitive skin
- Good for facial hair
- Good for patients with dentures

Cons

- Only works well with lower or moderate pressures
- Direct flow of air into the nares
- Nasal dryness occasionally arises
- Mouth leaks may occur (in which case a chinstrap can be tried)
- May not work well for patients who often have severe nasal or sinus congestion. (Other subjects, with mild or only occasional congestion, may report that PAP through nasal pillows helps to maintain patency of their nasal airway).

Nasal Mask

Pros

- Mask that fits over the nose
- Subject may tolerate better than full face mask due to claustrophobia with larger masks
- Can accommodate higher pressures

Cons

- Potential irritation of the bridge of the nose
- Subjects may experience air leaks from the mouth, or air leaks up towards the eyes
- Not good for subjects who have frequent nasal or sinus congestion that leads to mouth breathing

Full Face Mask

Pros

- Mouth breathing and mouth leaks are not a concern: subject can breathe through nose or mouth
- Ideal for frequent or obligate mouth breathers who have frequent nasal or sinus congestion
- Works well with high pressures

Cons

- Can seal poorly over facial hair, especially stubble
- Claustrophobic patients may feel less comfortable
- Bridge of nose may become irritated
- Full face mask seals over more surface area, which can mean increased risk for air leaks at the interface

	Nasal Pillows	Nasal Mask	Full Face Mask
Facial Hair	Good	Less Good	Less Good
Dentures	Good	Less Good	Less Good
Low to Moderate Pressures	Good	Good	Good
Higher Pressures	Less Good	Good	Good
Mouth Leak	Less Good	Less Good	Best
Claustrophobia	Less Good	Next Best	Best
Nasal Congestion	Less Good	Less Good	Best

Special Considerations after Stroke

Subjects with decreased mental status, on tube feeds, or unable to remove the mask without assistance should not be given a full face mask because vomiting could create risk of aspiration. A nasal mask and nasal pillows are all options for these subjects. A chin strap may be used for a subject who would otherwise require a full face mask but is ineligible. A chin strap generally should be considered for subjects who mouth breathe before consideration of a full face mask.

Some patients after stroke do not have use, or full use, of both hands. Subjects in Sleep SMART who have hemiparesis may have to learn to put on a PAP mask with only one hand. They should be taught how to do this, and they should practice initially with assistance of a respiratory therapist (RT) or Sleep SMART coordinator. One useful strategy is to assemble the mask and headgear, and then “hook” the headgear onto the back of the head, in the approximate position where it should rest once the mask is in its final position. Then, with one hand, pull the mask down over the forehead and eyes, until it rests where it should on the nose or nose and mouth, all while trying to keep the headgear in place at the back of the head. This maneuver may be easier than trying to place the mask on the face first, and then trying to pull the headgear onto the back of the head. Practice taking the mask on and off by the participant prior to PAP use is very helpful and is therefore part of the Sleep SMART protocol.

ResMed P10 Nasal Pillows

Sizing is based on a visual assessment of the subject's nares. The outer diameter of the nasal pillow should not exceed the inner diameter of the nares.



Fitting

When fitting for appropriate size, use the largest size pillow for which the opening does not exceed the inner diameter of the nares. This is to prevent undersizing but also avoid excessive leaks.

1. Hold the pillows away from the nose ensuring that the pillow size (for example, M) with the left (L) and right (R) indicators are correctly facing towards the patient, then guide the nasal pillow onto the nostrils (L at the left nostril, R at the right nostril).
2. Pull the headgear over the head by holding the bottom strap and stretching it around the back of the head. The top strap should sit comfortably on top of the head.
3. Move the mask away from the face then place it back to get a comfortable fit. Ensure the nasal pillows fit securely at the entrance of the nostrils, with both pillows positioned upright.
4. Finally, connect the end of the mask tubing into the device air tubing. The mask is now fitted and ready to use. When the device is running, a light breeze should be felt through the vent at the front of the mask. To inspect the vent place a finger close but not over the entire vent area. The vent area is on the front of the nasal pillow frame, on either side of the tube.



Adjustment

1. To achieve a comfortable fit, adjust the split straps by spreading them apart to loosen or draw them closer together to tighten.



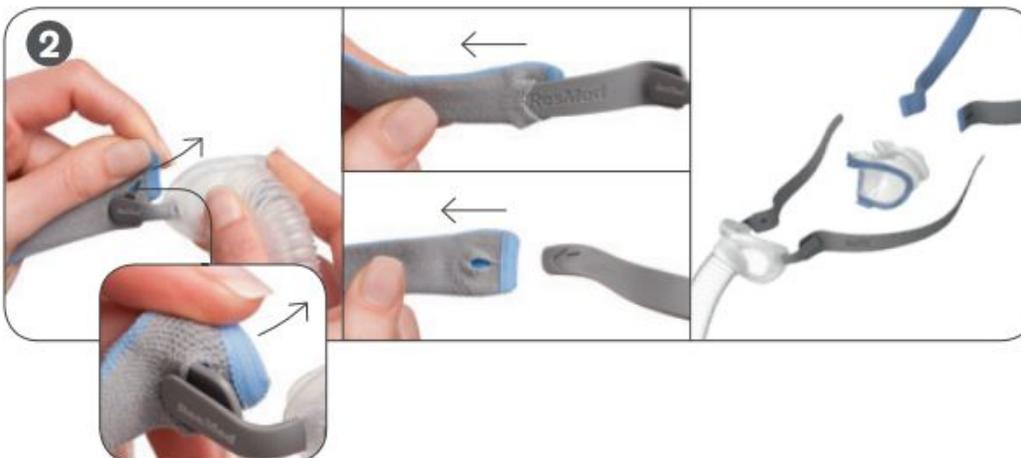
Removal

1. To take off the mask system, pull the mask and headgear by the split-strap, up and over the head.



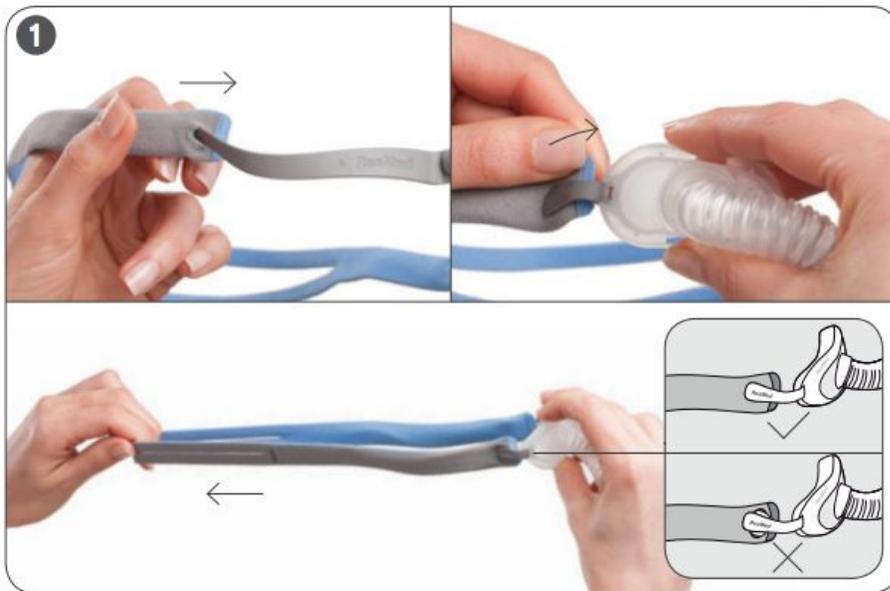
Disassembly

1. Holding the top of the mask tubing, squeeze and pull the pillows away from the mask frame.
2. Remove the headgear from the stabilizers by holding the fabric end of each strap and pulling out to reveal the buttonhole, then sliding over the node and off the end of each stabilizer. The mask is now disassembled.



Reassembly

1. With the gray side facing out, insert each end of the headgear strap over the stabilizers through the buttonholes. Secure in place by wrapping each strap end up and around the nodes. Holding the split straps, pull the headgear from the stabilizer to ensure it is tightly secure around the nodes. Ensure the headgear strap is not twisted.
2. Attach the pillows to the mask frame by inserting the top and bottom clips into the correct slots (shorter clip into top slot, longer clip into bottom slot) on the mask frame. The mask is now reassembled.
3. Ensure the inner walls of the nasal pillows are not compressed or collapsed. If they are, squeeze each nasal pillow so they return to the correct shape.



ResMed N20 Nasal Mask

Important note about the ResMed N20 Nasal Mask

The N20 Nasal Mask used in Sleep SMART includes magnets. Per the manufacturer's specifications, the magnets used in the mask are within ICNIRP guidelines for general public use. However, please ensure the headgear and frame are kept at least 2" (50 mm) away from any active medical implant (eg, pacemaker or defibrillator) to avoid possible effects from localized magnetic fields. The magnetic field strength is less than 400 mT. Do not use these masks if the subject has a metallic hemostatic clip implanted in the subject's head to repair an aneurysm, or has metallic splinters in one or both eyes following a penetrating eye injury. (During the Sleep SMART aCPAP run-in night, the nasal pillows mask (ResMed P10) can be used as it has no magnets). Alternative nasal and full face masks without magnets will be available from FusionHealth after discharge to subjects randomized to the aCPAP group. As noted elsewhere, additionally do not use a full face mask if: decreased mental status; is on tube feeds; or is unable to remove the mask without assistance.

Do not use N20 Nasal Mask if:

1. A metallic hemostatic clip implanted in subject's head to repair an aneurysm
2. Metallic splinters in one or both eyes following a penetrating eye injury

Sizing the N20 Nasal Mask

1. Use the N20 Sizing Template
2. Align the three template sizes to the patient's face
 - a. Small, Medium, Large
3. Following instructions on the sizing template, choose the correct size
4. The most comfortable sizing option will provide the best fit



Actual Size: 5 1/2" (Width)
x 6 7/8" (Height)

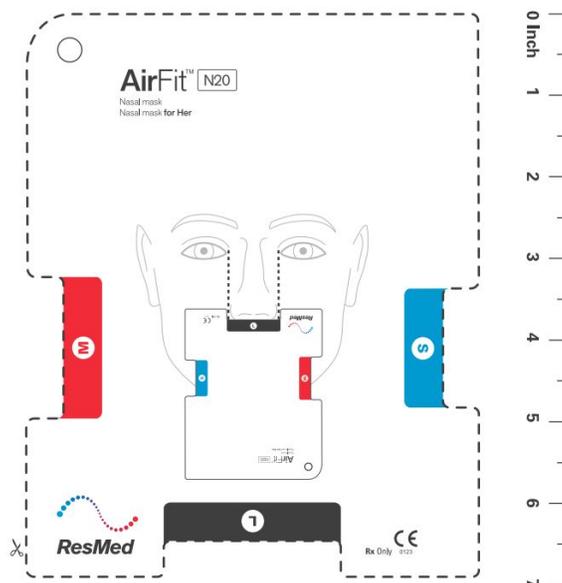
Ruler is for scaling purposes.

How to use the fitting template:

1. Please ensure the template is printed to scale
2. Cut out along dotted line
3. Refer to diagram on template to determine appropriate cushion size

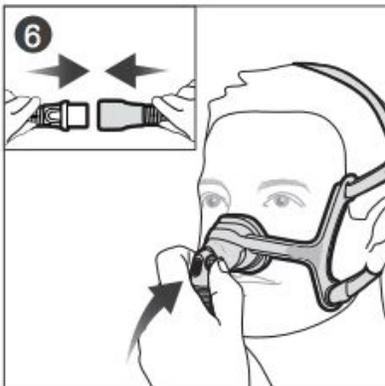
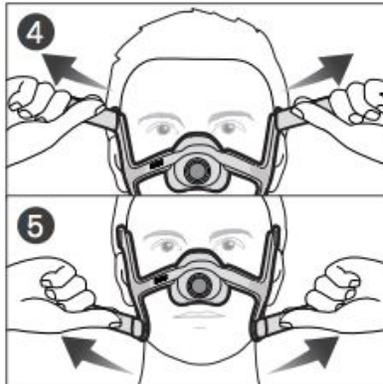
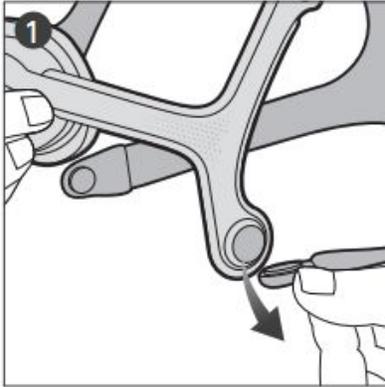


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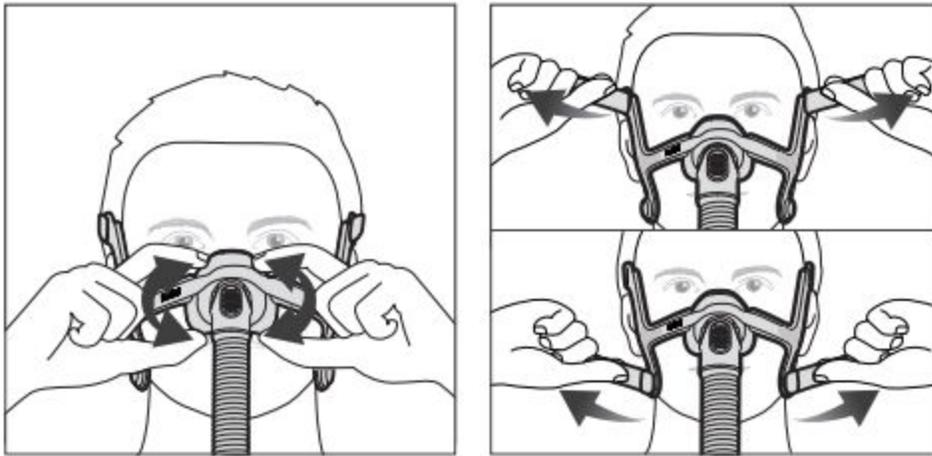
Fitting the N20 Nasal Mask

1. Unclip the magnetic clips.
2. With the mask held against the face, pull the headgear over the head.
3. Bring each of the magnets up to meet their corresponding clips on the frame.
4. Adjust the tabs on the upper headgear.
5. Adjust the tabs on the lower headgear.
6. Connect the device tubing to the mask elbow.
7. Connect the elbow to the mask.
8. Switch on the therapy device.



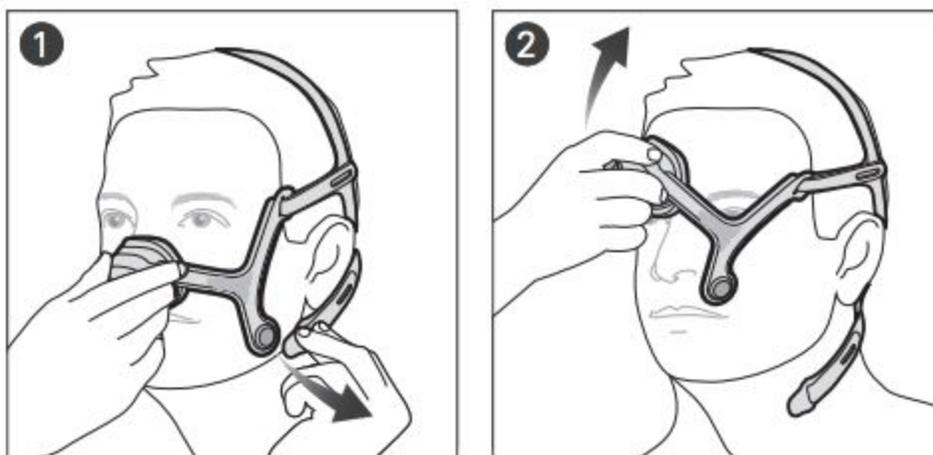
Adjustment

1. If necessary, slightly adjust the position of the mask for the most comfortable fit. Ensure that the cushion is not creased and the headgear is not twisted.
2. Turn on the device so that it is blowing air.
3. To resolve any leaks at the upper part of the mask, adjust the upper headgear straps. For the lower part, adjust the lower headgear straps. Adjust only enough for a comfortable seal.
4. The upper strap adjustment is the key to seal and comfort.
5. Do not overtighten the lower straps because they mainly serve to keep the cushion in position.



Removal

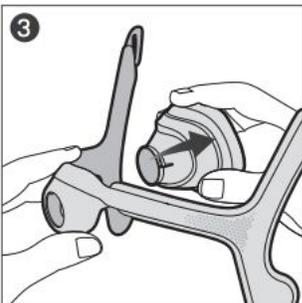
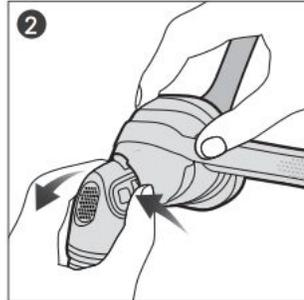
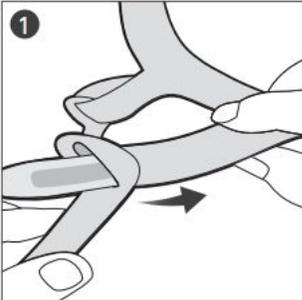
1. Twist and pull both magnetic clips away from the frame.
2. Pull the mask away from the face and back over the head.



Disassembly

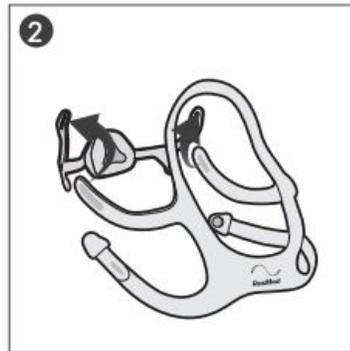
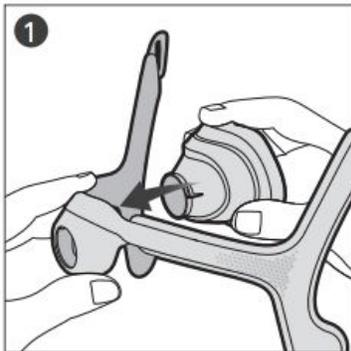
If the mask is connected to the device, disconnect the device air tubing from the short tube.

1. Undo the fastening tabs on the upper headgear straps. Pull the straps out of the frame. Keep the magnetic clips attached to the lower headgear straps to easily distinguish the upper and lower straps when reassembling.
2. Remove the elbow from the mask by pressing the side button and pulling the elbow away.
3. Hold the frame by placing the thumb over the side slot. Pull the cushion away from the frame.



Reassembly

1. Push the cushion into the frame. The frame has a shape that allows the user to insert the cushion only one way.
2. With the ResMed logo on the headgear facing outside and upright, thread the upper headgear straps into the frame slots from the inside. Fold them over to secure.



ResMed AirFit F20 Full Face Mask

Important note about the ResMed F20 Full Face Mask

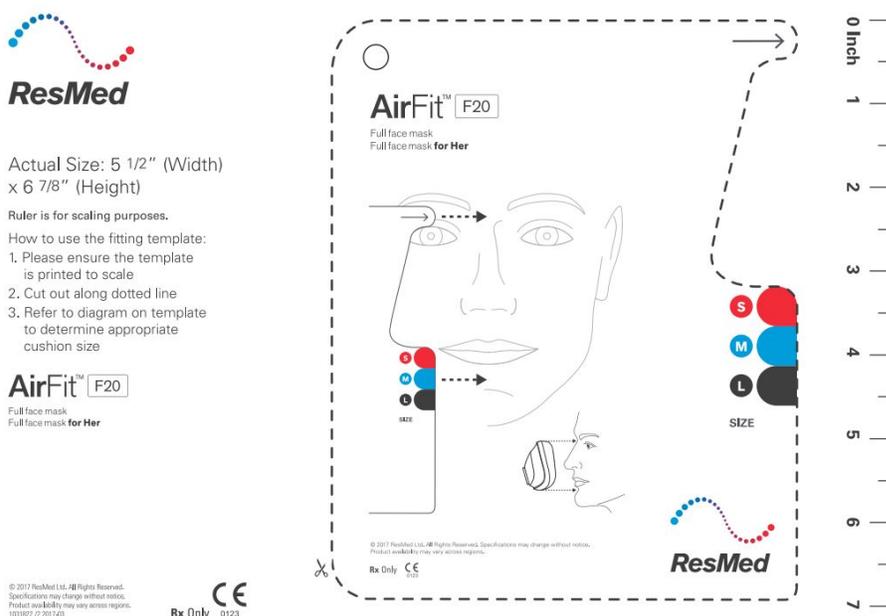
The F20 Full Face Mask used in Sleep SMART includes magnets. Per the manufacturer's specifications, the magnets used in the mask are within ICNIRP guidelines for general public use. However, please ensure the headgear and frame are kept at least 2" (50 mm) away from any active medical implant (eg, pacemaker or defibrillator) to avoid possible effects from localized magnetic fields. The magnetic field strength is less than 400 mT. Do not use these masks if the subject has a metallic hemostatic clip implanted in the subject's head to repair an aneurysm, or has metallic splinters in one or both eyes following a penetrating eye injury. (During the Sleep SMART aCPAP run-in night, the nasal pillows mask (ResMed P10) can be used as it has no magnets). Alternative nasal and full face masks without magnets will be available from FusionHealth after discharge to subjects randomized to the aCPAP group. As noted elsewhere, additionally do not use a full face mask if: decreased mental status; is on tube feeds; or is unable to remove the mask without assistance.

Do not use F20 Full Face Mask if:

1. A metallic hemostatic clip implanted in subject's head to repair an aneurysm
2. Metallic splinters in one or both eyes following a penetrating eye injury

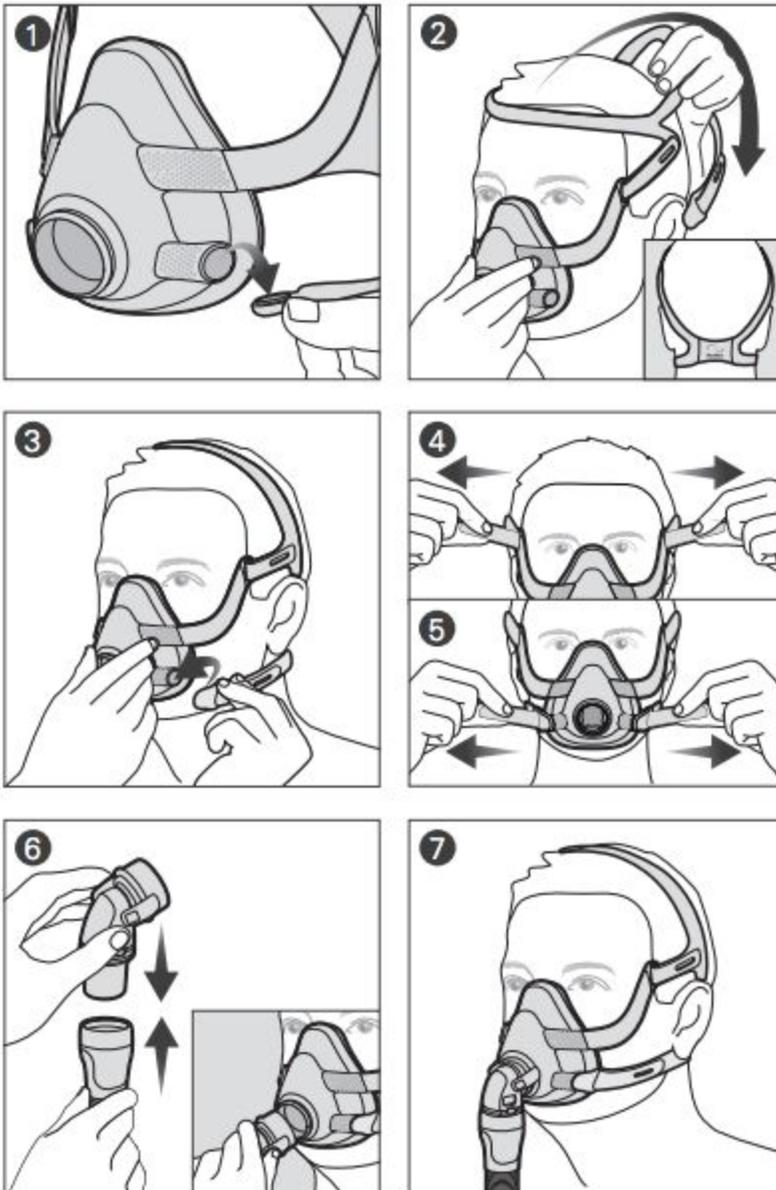
Sizing the AirFit F20

1. Use the F20 Sizing Template.
2. The top of the Sizing Template should correspond to the top of the nasal bridge.
3. The lower part of the Sizing Template indicates which mask size is the best fit to the face. The size that aligns with the crease below the lower lip will be the best fit.
4. If the size aligns between sizes, it is recommended to select the larger option for greater comfort.



Fitting the AirFit F20

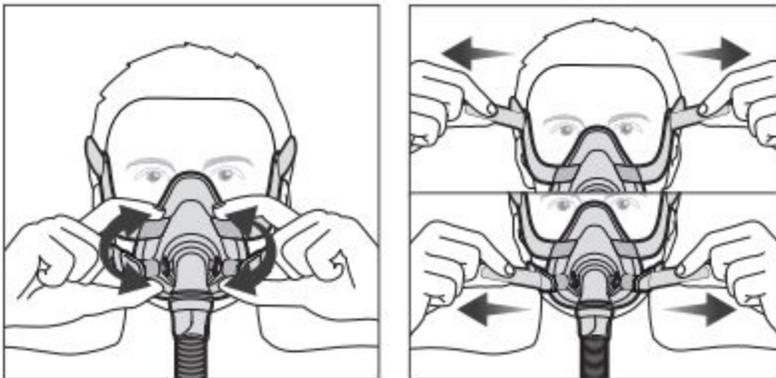
1. Unclip the magnetic clips
2. With the mask held against the face, pull the headgear over the head. Ensure the top of the mask cushion is sitting comfortably at the top of the nasal bridge. The bottom of the headgear should settle comfortably at the top of the neck while the top of the headgear should sit on the crown of the head.
3. Bring each of the magnets up to meet their corresponding clips on the frame.
4. Adjust the tabs on the upper headgear.
5. Adjust the tabs on the lower headgear.
6. With the device still switched off, connect the device tubing to the mask elbow.
7. Connect the elbow to the mask



Adjustment

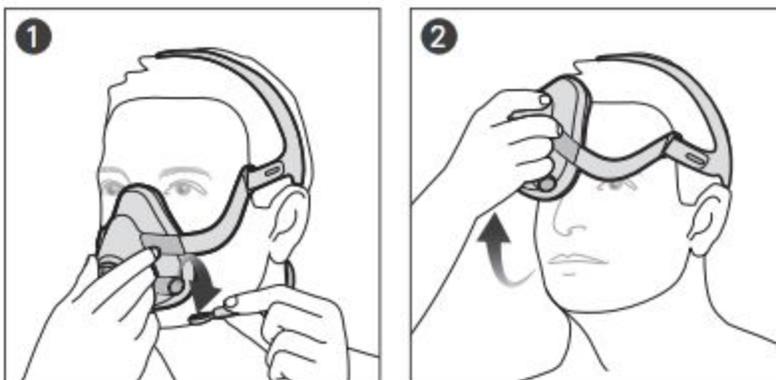
To ensure the fit will work with the therapy, do the following:

1. Switch on the device and position the patient as if they are about to begin therapy - that is lying down in bed.
2. Adjust the upper straps.
3. Adjust the lower straps.
4. Practice reseating the cushion
 - a. Pull the mask away from the face.
 - b. Allow the cushion to reinflate.
 - c. Resettle the inflated cushion so the cushion membrane is sitting at the top of the nasal bridge.



Removal

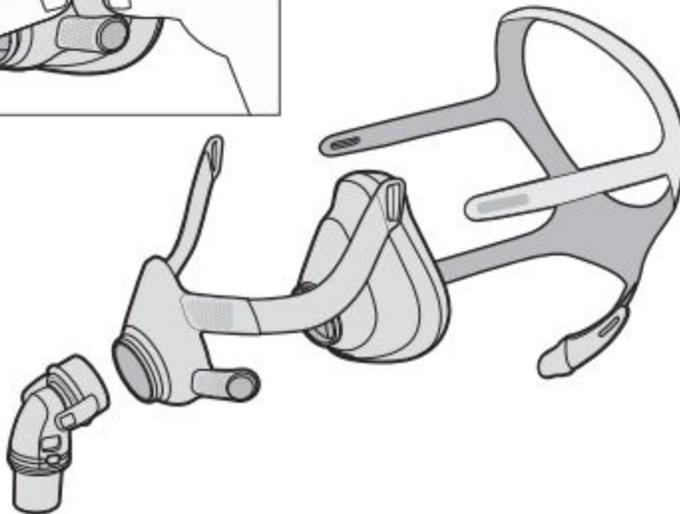
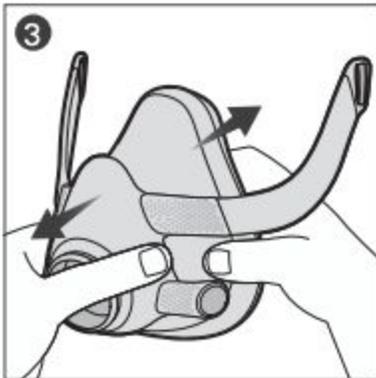
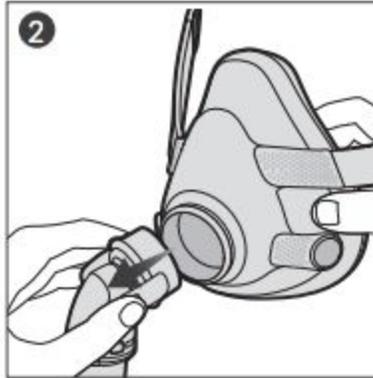
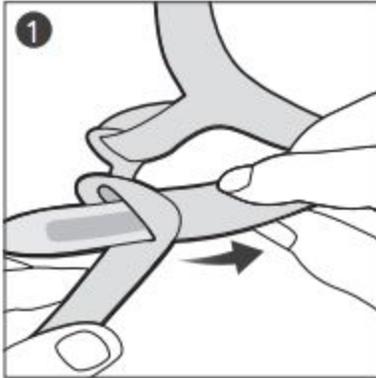
1. Twist and pull both magnetic clips away from the frame.
2. Pull the mask away from the face and back over the head



Disassembly

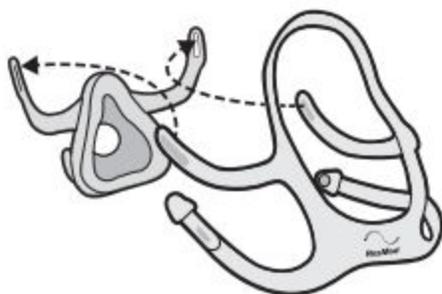
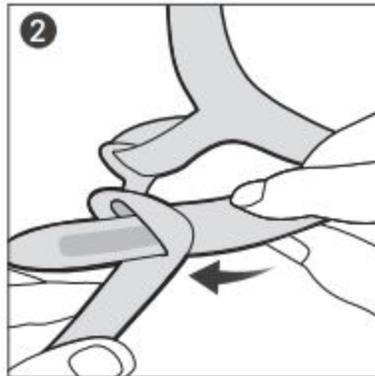
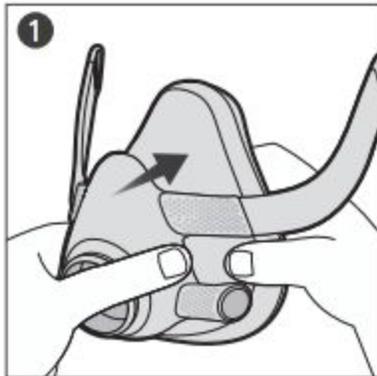
If the mask is connected to the device, disconnect the device air tubing from the elbow.

1. Undo the fastening tabs on the upper headgear straps. Pull the straps out of the frame. Keep the magnetic clips attached to the lower headgear straps to easily distinguish the upper and lower straps when reassembling.
2. Remove the elbow from the mask by pressing the side buttons and pulling the elbow away.
3. Hold the side of the frame between the upper and lower arms. Gently pull the cushion away from the frame.



Reassembly

1. Attach the cushion to the frame by aligning the circular openings and pushing together until retained.
2. With the ResMed logo on the headgear facing outside and upright, thread the upper headgear straps into the frame slots from the inside. Fold them over to secure.



Mask Fit Function

The Mask Fit function is designed to help clinicians assess and identify possible air leaks around the subject's mask.

To check mask fit:



1. Fit the mask as described in the mask user guide and this manual.
2. In **My Options**, turn the dial to highlight **Run Mask Fit** and then press the dial
3. This will activate the Mask Fit Function. The aCPAP will temporarily deliver 10cm water pressure.
4. Note the Green Smiley Face or Red Frowny face on the display of the aCPAP.
5. Adjust the mask, mask cushion and headgear until you get a Good result (Green Smiley Face).
6. To stop Mask Fit, press the dial or Start/Stop button.
7. If you are unable to get a good mask seal, consider changing to a different mask and repeat the Mask Fit function.

Use of PAP Masks

Once subjects start to use their masks, Sleep SMART Care Team will in most but not all cases be able to monitor their progress remotely. The PAP machines automatically transmit data on a daily basis through any of several commercial wireless data networks. These data summarize machine settings, pressures delivered, leaks, estimated frequency of residual apneas or hypopneas, and hours of machine use. However, if the Sleep SMART Care Team identifies a problem – for example, excessive air leak when the machine is used – they may not be able to reach out to assist until the subject has left the hospital and returned home. This is because local hospital rules may not permit FusionHealth to assist with something that might be considered inpatient care. FusionHealth may be limited to other options, such as contacting the patient or a family caregiver personally, or contacting the enrolling site research coordinator.

For these reasons, when and where possible, a research study team member should ask each Sleep SMART subject assigned to use PAP (or his or her legally authorized representative), on each morning ideally, how things went on the previous night with respect to PAP use. Examples of the types of issues to explore might include:

1. Quality of previous night's sleep
2. Length of use of PAP on the previous night
3. Awareness of any air leaks at seal between mask and face
4. Awareness of any air leaks from the mouth
5. Dry parched mouth in the morning (may suggest mouth leak, if a full face mask is not being used), or headache, which may indicate need to increase humidity
6. Acceptable comfort of mask
7. Any difficulty breathing comfortably or experience of claustrophobia using PAP
8. Any difficulty in putting the mask on, keeping it on, or replacing it on the face when necessary
9. Any nasal congestion
10. Any difficulty cleaning and drying the mask and tubing

When problems are reported and have no obvious solution, either the subject, the subject's legally authorized representative, or a Sleep SMART investigator can phone FusionHealth at **470-655-6688** and ask to speak to a member of the Sleep SMART care team. They may be able to advise and assist, if within rules and regulations of the local hospital site.

If FusionHealth is not able to assist, the local site may be able to intervene along the lines outlined in the following table, and take advantage wherever possible of local on-site, duly credentialed expertise. The table is designed to give the study team an idea of possible responses, but not to cover all particular subject situations and not to list all possible logical responses.

Issue	Possible Solution
Frequent Awakenings	Try to determine cause, and respond as listed below if any of these more specific problems are identified. Contact Sleep SMART Care Team.
Air leak from mask seal with nose or face	Tighten headgear that holds mask, within tolerated range; change from nasal pillows or full face mask (which tend to leak more especially with high pressures) to nasal mask. Contact Sleep SMART Care Team.
Air leak through mouth	Add chin strap; if chin strap does not eliminate mouth leak, replace mask with a full face mask that covers the mouth (if no contraindication to full face mask).
Dry mouth / Nasal dryness	Add chin strap as these could suggest mouth leak; consider increase in humidifier setting. Contact Sleep SMART Care Team.
Mask uncomfortable	Adjust headgear to improve fit; loosen headgear just short of allowing leaks at edges of mask; change to different mask type or model. Contact Sleep SMART Care Team.
Nose stuffiness	Increase humidification; consider chinstrap as congestion can occur with mouth leak; consider full face mask (if no contraindication). Contact Sleep SMART Care Team.
Too much pressure	Determine if leak is a factor. Verify that Ramp is in Auto Mode. Contact Sleep SMART Care Team.
Not getting enough air with PAP	Turn Ramp off. Turn EPR off, if it has been on (on is the Sleep SMART default position). Contact Sleep SMART Care Team.
Difficulty exhaling	Verify EPR is ON and set to 3. Verify Ramp is ON. Contact Sleep SMART Care Team.
Air swallowing / Bloating (Aerophagia)	Verify EPR is ON and set to 3. Elevate the head by adding pillows. Contact Sleep SMART Care Team.
Facial sensitivity / Desensitization	Consider switching to less obtrusive mask (e.g., nasal mask instead of a full face mask, or nasal pillows instead of nasal mask). Contact Sleep SMART Care Team for desensitization techniques.
Condensation in mask/tubing	Increase tube temperature setting by 1-2 degrees; can consider lowering the humidifier setting; and contact Sleep SMART Care Team.

Sleep SMART Care Team is able to make adjustments remotely to the following features:

- Device mode (auto-adjusting PAP levels vs one selected, fixed CPAP setting).
- Minimum and maximum pressures
- Expiratory Pressure Relief - EPR - [Fulltime, Ramp Only, OFF]
- EPR Level [1, 2, 3]
- Ramp Enable [Auto, On, OFF]
- Ramp Time [5 min increments to up to 45 mins]
- Start Pressure

Sleep SMART Care Team is unable to make adjustments remotely to the humidification level (humidifier and tubing), but they can help walk the study team through these adjustments if needed (also outlined in the aCPAP MOP instructions).

Cleaning of PAP Masks

Hospitalized subjects, attendant family members, or legally authorized representatives should receive instruction on how to clean and maintain masks, tubing, and humidifier Chambers. They also need to know how and when to ask for new supplies. The following sections demonstrate the type of instructions that the local site's Sleep SMART team should teach enrolled subjects who are randomized to the PAP arm.

Mask Cleaning (Daily)

Your mask should only be gently hand washed.

1. Remove headgear from mask.
2. Thoroughly clean the mask cushion in warm water using mild soap. Soap should be free of antibacterial agent, moisturizers or added scents. Recommended - plain Ivory® bar soap or baby shampoo.
3. The soap will help dissolve the facial oils.
4. Rinse thoroughly with warm water and allow to air dry during the day.

Headgear Cleaning (Weekly)

1. Hand wash the headgear with instructions stated above for the mask.

Climateline Air Tubing (Daily)

1. Disconnect the tubing from the PAP device. Hang tubing over the towel rack of shower rod to air dry.

Climateline Air Tubing (Weekly)

1. Disconnect the tubing from the PAP device.
2. Hold both ends of the tube with one hand, pour approximately a quarter of a cup of 50/50 white distilled vinegar and water solution into the tubing.
3. Move the tubing around as to make sure the solution contacts the inside of the tube.
4. Pour solution into the sink.
5. Rinse with warm water.

6. Hang tubing over the towel rack of shower rod to air dry during the day.

Filling the Water Tub (Daily)

1. Remove the water tub prior to bedtime.
2. Fill the water tub with distilled water just below the maximum water line.
3. Close the water tub and insert it into the side of the PAP device.

Cleaning the Water Tub (Weekly)

1. Remove the water tub.
2. Empty remaining water.
3. Pour 1 cup of 50/50 white distilled vinegar and water solution into the tub.
4. Let it sit for at least 30 seconds.
5. Swish the solution around.
6. Pour out solution.
7. Rinse thoroughly with warm water. Allow to air dry during the day.

How and When to Ask for New Supplies

1. Machine filters need to be replaced every month.
2. The rubber/silicone inner lining of a nasal or full face mask, or the rubber/silicone nasal pillows themselves, sometimes change in consistency with time. Typically they need to be replaced every 3 months, but sometimes they last for shorter or longer periods.
3. Masks, headgear, and tubing typically need to be replaced every 6 months.

When the subject need any of the above equipment, while he or she participates in Sleep SMART, the subject should contact the Sleep SMART Care Team at **470-655-6688**. They will mail appropriate supplies to the subject's home.