## Run-in night (AirSense 10)

## Introduction

This instruction manual explains how to complete a Run-In Night with automatically-titrating continuous positive airway pressure (aCPAP) in Sleep SMART.

## KOEO/FusionHealth Support E-mail

## sleepsmarttechsupport@noxhealth.com

## **KOEO/FusionHealth Support Phone Number**

## 404-480-5149 extension 4006 (8am-7pm M-F only)

# KOEO Login

## app.noxhealth.com (Please Use Google Chrome)

#### \*\*Important note about the ResMed full face mask and nasal mask\*\*

The ResMed full face mask (F20) and nasal mask (N20) include magnets. <u>Do not use these masks if</u> the subject, bedpartner, or anyone in close physical contact with the subject while using the mask has an active medical implant that interact with magnets (i.e., pacemakers, implantable cardioverter defibrillators (ICD), neurostimulators, cerebrospinal fluid (CSF) shunts, insulin/infusion pumps) or a metallic implant/object containing ferromagnetic material (i.e., aneurysm clips/flow disruption devices, embolic coils, stents, valves, electrodes, implants to restore hearing or balance with implanted magnets, ocular implants, metallic splinters in the eye). Keep the mask magnets at a safe distance of at least 6 inches (150 mm) away from implants or medical devices that may be adversely affected by magnetic interference. This warning applies to you or anyone in close physical contact with your mask. The magnets are in the frame and lower headgear clips, with a magnetic field strength of up to 400mT. When worn, they connect to secure the mask but may inadvertently detach while asleep.

Implants/medical devices, including those listed within contraindications, may be adversely affected if they change function under external magnetic fields or contain ferromagnetic materials that attract/repel to magnetic fields (some metallic implants, e.g., contact lenses with metal, dental implants, metallic cranial plates, screws, burr hole covers, and bone substitute devices). Consult your physician and manufacturer of your implant / other medical device for information on the potential adverse effects of magnetic fields. During the Sleep SMART aCPAP run-in night, the ResMed P10 nasal pillows mask, ResMed N30i nasal cushion mask, or Fisher & Paykel Evora full face mask can be used as they have no magnets. If needed, 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 the participant has decreased

mental status; is on tube feeds; or is unable to remove the mask without assistance.

# Do not use the ResMed full face (F20) or nasal mask (N20) if the subject, bedpartner, or anyone in close contact with the subject while using the mask has:

- 1. an active medical implant that interacts with magnets (i.e., pacemakers, implantable cardioverter defibrillators (ICD), neurostimulators, cerebrospinal fluid (CSF) shunts, insulin/infusion pumps), or
- 2. a metallic implant/object containing ferromagnetic material (i.e., aneurysm clips/flow disruption devices, embolic coils, stents, valves, electrodes, implants to restore hearing or balance with implanted magnets, ocular implants, metallic splinters in the eye).

#### Warning

Keep the mask magnets at a safe distance of at least 6 inches (150 mm) away from implants or medical devices that may be adversely affected by magnetic interference. This warning applies to the subject and anyone in close physical contact with the mask.

Brief overview of mask selection procedures (see Mask Fitting MOP for more details):

- 1. Show the participant the three mask types (nasal, nasal pillow, and full face) while the masks are still in the packaging and ask if the patient has a preference.
- 2. If the participant has a preference, select that mask.
- 3. If the participant has no preference, select the nasal/nasal cushion mask.
- 4. Identify the appropriate size, adjust the fit, and test the fit using the mask fit function on the aCPAP device. Adjust the mask accordingly.
- 5. If a good fit cannot be achieved, select an alternative mask and repeat these procedures.
- 6. Help participant practice placing and removing mask many times until participant facile with it.
- 7. Use the fitted mask for the 15-20-minute daytime trial prior to the run-in night. (To conduct the daytime trial, start the CPAP from the off setting. Do not use the mask fit function setting for the daytime trial.) Make adjustments to optimize comfort.

If the "Subject Eligible" task appears in KOEO, this means the subject is eligible for the Run-In Night in Sleep SMART. The Subject Eligible task is the first step in the Sleep SMART KOEO Process that applies to the Run-In Night.

	<b>(</b> )	~	Task Name 😂	Pat 🔶	Patient Name	Substatus	Best Time To ⇔	Created On	Tenant	Acti	
		۲	Subject Eligible	MR	102, Sleep SMART			2022-04-01	SleepSMART	$\equiv$	-
			Gender:	M	Home:						
= 9	M (20 8	<u>A</u> I	≪ ⊈  ⊎ ₽~	] Task: Subject I	Eligible						

95%

## The T3 study showed OSA that qualifies the subject to continue. Please perform mask fit and answer mask questions.

#### Evora Full Face Mask Extra Small Small/Medium Large Evora Full Face Mask Fit Poor Best Good N30i Nasal Mask Small Medium Wide Small-Wide N30i Nasal Mask Fit Best Good Poor AirFit F20 Full Face Mask Small Medium Large AirFit F20 Full Face Mask Fit Best Good Poor AirFit N20 Nasal Mask Small Medium Large AirFit N20 Nasal Mask Fit Best Good Poor AirFit P10 Nasal Pillows Small Medium Large AirFit P10 Nasal Pillows Fit Best Good Poor DreamWear Mask Small Medium Large DreamWear Mask Fit

Good

Best

Submit 🗸

Poor

#### 1. Subject Eligible Task

Click on the **Subject Eligible** task in KOEO, and the following appears:

Once the mask fitting is complete, indicate the *Mask Size* and *Mask Fit* for the mask selected as noted above in the **Subject Eligible Task**.

Click submit when done.

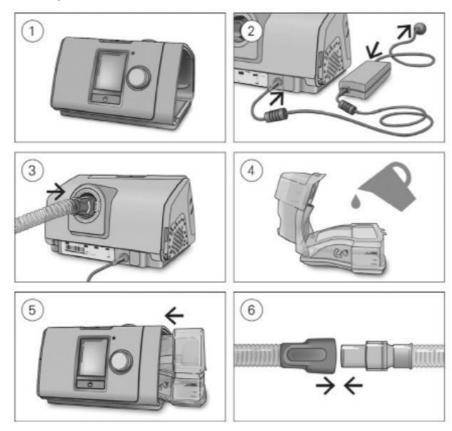
This will record the mask or masks that were selected for the Run-In Night.

The next Task to appear in KOEO is **APAP Night 1**. NO FURTHER ACTION is required in KOEO for the Run-In Night.

0	<b>~</b>	Task Name 🜲	Patient MR 🔷	Patient Name	Substatus 🖨	Best Time To Call	Created On 🗘	Tenant 🜲
	۲	APAP Night 1	MR043526	202, Sleep SMART			2019-02-19	SleepSMART

The **APAP Night 1** task is to be completed after the Run-In Night is finished.

#### 2. Setting Up the aCPAP Unit



## A CAUTION

Do not overfill the water tub as water may enter the device and air tubing.

- 1. Place the device on a stable level surface.
- 2. Plug the power connector into the rear of the device. Connect one end of the power cord into the power supply unit and the other end into the power outlet.
- 3. Connect the air tubing firmly to the air outlet located on the rear of the device.
- 4. Open the water tub and fill it with distilled water up to the maximum water level mark. Do not fill the water tub with hot water.
- 5. Close the water tub and insert it into the side of the device.
- 6. Connect the free end of the air tubing firmly onto the assembled mask. See the mask user guide for detailed information.

Recommended masks are available on www.resmed.com.



## 3. Filling the Water Tub

1. Remove the water tub.

2. Fill the water tub with distilled or deionized water up to the maximum water level.

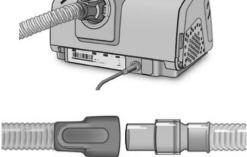
3. Close the water tub and insert it into the side of the device.

- 4. Setting Up the ClimateLine Air Tubing
  - 1. Align the ClimateLine Air tubing with the ClimateLine Air connection port. Push the ClimateLine tubing firmly onto the air outlet.
  - 2. Connect the assembled mask system to the end of the ClimateLine air tubing.









free

## Now that supplies are set:

#### 1. Make sure the power is connected.

- Adjust the humidification level, if required.
- Fit the mask as described in the mask user guide.
- Press the Start/Stop button or simply have the subject breathe into the mask. The Smart Start function will turn on the device. The green light indicates the device is off, and the blue light indicates it is on.
- Have the subject lie down and arrange the air tubing so that it is free to move if he or she turns during their sleep.
- To stop treatment at any time, press the Start/Stop button and remove the mask, or simply remove the mask. The SmartStop function will turn off the device.

#### 2. Have the participant try to use CPAP for 15-20 minutes prior to the run-in night.

- Have the participant use CPAP sometime before bed. If possible, the participant should be lying down in his/her usual sleeping position and doing a relaxing activity such as reading or watching TV.
- This gives the participant the opportunity to acclimate a bit to CPAP
- It also allows an opportunity for mask adjustments before the participant is trying to sleep at night.

#### 3. Using PAP at Bedtime

- Fill the water tub with distilled water only.
- Put on the mask and start the device. Remember that the device will increase flow if it senses a leak.
- Place the tubing above the headboard or between the pillow and the wall. Bringing it over the pillow in this manner may help keep it out of the way during sleep.

## 4. The SmartStart Feature

The aCPAP S10 device has a comfort feature called SmartStart / SmartStop that is enabled. This feature will start the device automatically when the subject breathes into the mask and then stop the device automatically when the subject removes the mask. If a subject does not like the SmartStart feature, it can be disabled by contacting the Sleep SMART Care Team. Please note that if the device is turned on via the SmartStart (the subject starts to breathe through the mask), and study staff then push the start/stop button, the device will then be in the off mode.

## 5. Restarting PAP during the Sleep Cycle

- If it is necessary to interrupt use of PAP (to use the restroom, for example), stop the device as noted above.
- Subjects can either disconnect the tubing at the mask, and keep just the mask on, or take the mask off and then put it back on when they come back to bed.
- When they return to bed, they should reassemble the connection or reapply the mask and push Start/Stop again or simply breathe into the mask. As before, the machine will gradually ramp up the pressure until it reaches the targeted range.

• If subjects wake up in the middle of the night and the mask is to the side of the face, off of their face, or off the bed, just put it back on and encourage them to return to sleep. People sometimes remove their PAP masks while they are asleep during the first few weeks of acclimation to treatment.

#### 6. When They Wake Up

- Turn off the aCPAP unit by pushing the Start/Stop button on the device or by simply removing the mask. This will also turn off the humidifier.
- Disconnect the hose and take the water out. Be careful with the humidifier because the heating element may be hot.
- Clean the hose and water tub if the subject is randomized to the CPAP intervention arm of Sleep SMART.
- For those who are not randomized to aCPAP intervention arm, discard the tub and hose.
- If they notice a small amount of flow coming from the device after turning it off, this is the system cooling off the humidifier. This is normal and automatically stops after 20 minutes.

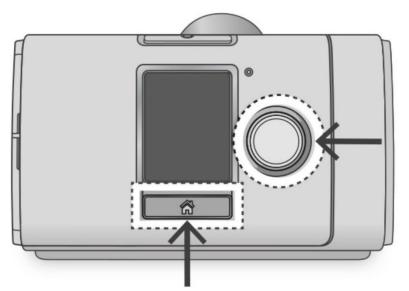
#### 7. Run-In Night Considerations

Per the Sleep SMART Protocol, aCPAP will be used on one night to determine tolerability. Subjects who use the device ≥4 hours on that night, who do not have excessive treatment-emergent Central Sleep Apnea (CSA), and are willing to continue to randomization will be randomized to receive either 6 months of aCPAP (intervention group), or 6 months of standard clinical practice (non-intervention group). Absence of excessive treatment-emergent CSA for Sleep SMART is defined by a Central Apnea Index less than 10 events/hr, based on aCPAP device-generated data from the Run-In Night.

After the Run-In Night, the device is interrogated manually in order to read the aCPAP devicegenerated data on hours of usage, the Central Apnea Index, and other variables (see below).

An aCPAP run-in night may be repeated up to two times if the subject is unable to qualify initially based on clinical care demands or other external interruptions, or if the run-in night was thought to have been poorly tolerated because of a specific situation that is not likely to recur (e.g. failure to use the humidifier). If the CAI was <10 but usage hours were <4.0 for any reason, and the subject would like to repeat the run-in night, it may be repeated once.

## 8. Determining if Subject is Eligible from the AirSense 10



- To check the usage and efficacy data on the aCPAP, click on the "Home Icon" button at the bottom of the display.
- Using the dial to the right of the display, scroll to Sleep Report.
- Press the dial button.
- Use the dial to scroll through the Usage and Efficacy Data visible in the Sleep Report.

#### 9. Viewing the Sleep Report

The Sleep Report screen shows sleep quality and mask seal status for the most recent therapy session. To view additional usage data, use the dial to scroll down in the Sleep Report.

Sleep Report	Sleep Report 🔐 🖬	Sleep Report
< Home	Humidifier	Avg. Usage 6.0hrs
Usage 7:15	Period 1 Month	Used Hrs 132.0hrs
hours	Days Used 22/30	Pressure 14.0
Events (AHI) per hour <b>10</b>	Days 4hrs+ 18/30	Leak 5L/min
Mask	Avg. Usage 6.0hrs	AHI 15
Seal	Used Hrs 132.0hrs	Total Al 8
Humidifier 🙆	Pressure 14.0	Central Al 3

**Prior to each run-in night**, the run-in night CPAP device will need to be configured to display **1 Day** in the "Period." The middle image above displays 1 Month (the default setting). These values may be edited, but for the Run-In Night in SleepSMART the device must be set to **1 Day** as this represents the data that were just acquired for this individual subject during the Run-In Night.

To do this, you will access the Sleep Report (from the home screen, use the dial to highlight and then select Sleep Report).

- Rotate the dial until "Period" is highlighted
- Press the dial to select "Period."
- Rotate the dial to highlight "1 Day"
- Press the dial to select "1 Day"

#### \*\* Again, remember to reset the "Period" to 1 day prior to each run-in night. \*\*

Note: For this reason, an aCPAP unit should never be used for more than one subject's Run-In Night within any 24-hour period. The 24-hour period starts at noon and ends at 11:59 AM the next day. Therefore, do not start a daytime study before noon because there will not be enough time to conduct the Run-In session.

#### 10. Outcome of Run-In Night

Following the Run-In Night, the site coordinator must determine the next step for the subject. Upon interrogating the Sleep Report on the aCPAP, the following criteria must be assessed:

- Were the Usage Hours ≥ 4.0 hours?
- Was the **Central AI below 10/hr** on aCPAP device-generated data?
- Repeat run-in night: If Usage Hours were < 4 hours, and CAI was <10, and the subject would like to repeat the run-in night, it may be repeated. If 4 hours were not achieved due to an external interruption, then it can be repeated twice.
- To be eligible for randomization, the subject must be willing to continue with randomization knowing that he/she has a 50% chance of being assigned to use CPAP and 50% chance of being assigned to no CPAP for the next 6 months.

#### 11. Equipment after Run-In Night

If the subject fails the run-in night and it will not be repeated, or is randomized to the Control (no CPAP) group, remove the tubing and humidifier basin from the aCPAP device and discard them along with any masks that have been tried or used. (If the subject will repeat the run-in night please use the same supplies for the second run-in night.)

If the subject is randomized to the treatment (CPAP) group, remove the tubing and humidifier basin and, along with the mask tried, provide to the subjects.

# Each NEW subject's run-in night should involve a brand new mask, tubing, and humidifier basin.

#### 12. WebDCU:

After the final Run-in Night, the following data (except for date) are read off the aCPAP display, and entered into WebDCU

- Date (date the run-in night was started)
- Used hrs (usage hours)
- Pressure
- Leak
- AHI
- Central Al

#### 13. APAP Night 1 Task in KOEO

Yes No	75% Co	mplete
ndicate subject's run-in night outcome wibjects "pass" the run-in night if: (1) usage hours are ≥ 4.0, AND (2) the aCPAP derived CAI is < 10. Subjects who pass the run-in night and agree to continue with Sleep SMART are eligible for randomization.	Retry Run-In Night?	
ndicate subject's run-in night outcome wibjects "pass" the run-in night if: (1) usage hours are ≥ 4.0, AND (2) the aCPAP derived CAI is < 10. Subjects who pass the run-in night and agree to continue with Sleep SMART are eligible for randomization.		
ubjects "pass" the run-in night if: (1) usage hours are ≥ 4,0, AND (2) the aCPAP derived CAI is < 10. Subjects who pass the run-in night and agree to continue with Sleep SMART are eligible for randomization.	Yes	No
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Submit	ubjects "pass" the run-in night if; (1) usage hours are ≥ 4,0, AND (2) the aCPAP derived CAI is <10. Subjects wi	

Upon completion of the Run-In Night, the site coordinator must answer the question in the **APAP Night** 1 task, about whether to **Retry the Run-In Night**: "Yes" or "No".

If NO, then the site coordinator must also select whether the subject is *Eligible for randomization* or *Not eligible for randomization*. The determination at this point is based upon the usage hours (must be  $\geq$  4 hours) and the aCPAP device-generated Central Apnea Index (Central AI must be <10), and the subject's willingness to continue (as the subject is comfortable being assigned to CPAP for 6 months), as previously discussed.

#### 14. APAP Tasks: if YES is Selected to "Retry Run-In Night"

Retry Run-I	In Night?	75% Com	plete
		Yes	No
	۲	APAP Night 2	Submit
	۲	APAP Night 3	

- If the Run-In Night is to be repeated, click "YES"
- Click Submit in the right hand corner

Next, the **APAP Night 2** task will appear in the KOEO Task List. It will NOT be necessary to repeat the **Subject Eligible** task in KOEO.

#### 15. APAP Tasks: if Outcome is "Not Eligible"

If the Run-In Night does NOT have to be repeated, but the subject could not utilize the aCPAP device for  $\geq$  4 hours, the CAI was  $\geq$  10, or the subject is unwilling to continue with Sleep SMART, the subject is Not eligible for randomization

75% Col	nplete
Retry Run-In Night?	
Yes	No
	pass the run-in night and agree to continue with Sleep SMART are eligible for randomization. Not eligible for randomization
Indicate subject's run-in night outcome Subjects "pass" the run-in night If: (1) usage hours are 2-4.0, AND (2) the aCPAP derived CAI is <10. Subjects wh Eligible for randomization	

- Click on **Not eligible for randomization**
- Click Submit

#### 16. APAP Tasks: Outcome is "Eligible"

If the Run-In Night does NOT have to be repeated, and the subject used PAP  $\geq$ 4 hours, central AI was <10, and the subject is willing to be randomized, the subject is eligible for randomization.

Yes	No
cate subject's run-in night outcome	
licate subject's run-in night outcome ijects "pass" the run-in night if: (1) usage hours are ≥ 4.0, AND (2) ee to continue with Sleep SMART are eligible for randomization.	the aCPAP derived CAI is <10. Subjects who pass the run-in night

- Click on *Eligible for randomization*
- Click Submit

#### 17. Treatment Assignment Task in KOEO

Following the aCPAP Run-In Night, subjects deemed *Eligible* are randomized centrally on the WebDCU website (https://webdcu.musc.edu/login.asp) to either the Intervention Group or Control Group (non-intervention group) in a 1:1 ratio with an algorithm developed by the National Data Management Center (NDMC).

Site coordinators must access information from WebDCU regarding treatment assignment of the subjects to either the Intervention Group or to the Control Group.

Once randomization is completed by WebDCU, the site coordinators must complete the **Treatment Assignment** task in KOEO by first clicking on the *Treatment Assignment* task:

0	~	Task Name	Patient 🖨	Patient Name	Substatus	Best Time To Call	Created On	Tenant 🔶
	۲	Treatment Assignment	MR043526	202, Sleep SMART			2019-02-19	SleepSMART

#### 18. Intervention Group

If a subject is randomized to the Intervention Group (aCPAP), he or she will receive aCPAP equipment and will be enrolled into Sleep SMART Care Management. (Remember to show the care management video, introduce myAir and Tess the chatbot, and offer to assist the subject with myAir registration and initial chatbot texting.) Select the appropriate Treatment Group for the subject and click Submit:

asks	🖥 🔊 🕍 🛔 🔒 🛛 🥰 🗍 🌄 🎮 Task: Treatment Assignment	
	Indicate subject's treatment assignment	
	Intervention group (CPAP)	Control group (No CPAP)
		Submit ✔
No CPAP omplete.	- select Control Group (No CPAP) and click St	ubmit. No more tasks and the process is

If CPAP - select Intervention group (CPAP) and click Submit. Next Task will be Enter Patient Info.

If randomized to the control (no CPAP) group: No further information needs to be entered into KOEO and the subject has no contact with FusionHealth.

If randomized to the intervention (CPAP) group: After submitting the subject's treatment assignment in KOEO, the next task is to **Enter Patient Info**:

0	~	Task Name	Patient 🖨	Patient Name	Substatus	Best Time To Call	Created On	Tenant 🖨
11111	۲	Enter Patient Info	MR043526	202, Sleep SMART			2019-02-19	SleepSMART

The following subject demographics are entered into KOEO:

- Name
- Date of Birth
- Address
- Telephone Number
- Best Call Times
- Patient Time Zone
- Gender
- Marital Status
- Special Instructions, if any

This information is critical for subsequent Care Management by the Sleep SMART sleep coaches. <u>Please be sure that this information is valid and entered accurately in the appropriate fields</u>. If you have any doubts regarding the information requested, please double check before entering the erroneous data.

	📰 🦄 🖿 🛔 🖷 🛛 ≼   🌌 🍋	Task: Enter Patient Info				Actions:
	Patient Name	First	MI Last		Suffi	
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	bject has left-sided paralysis and is being transferred to rehab		Special Instructions			
Patient Name	ep SMART 202 0% Compliance 0% Compliance	None / None Sieep5MART / Site2 Date of Sim: 1900-01-01 Mobile: Gender: U Home:	Special Instructions			Å

• Enter Demographic Information. PLEASE PROVIDE AS MUCH CONTACT INFORMATION AS YOU HAVE AVAILABLE IN THE CONSENT. You can use the Special Instructions section to add in additional contact info.

• Click the Save Icon in right hand corner when complete

#### 19. Dispensing aCPAP Equipment

After the demographic information has been entered in the **Edit Patient Info** task, the **Dispensing Questions** task will appear. Click on the *Dispensing Questions* task:

0	~	Task Name	Patient MR	Patient Name	Substatus	Best Time To Call	Created On	Tenant 🖨
	۲	Dispensing Questions	MR043526	Doe, John		16:00 - 17:00 (EST)	2019-02-19	SleepSMART

Subjects randomized to the Intervention Group in Sleep SMART will be issued new aCPAP equipment that has been provided by FusionHealth and kept in stock on site. PLEASE DO NOT SEND A SUBJECT HOME WITH THE RUN-IN NIGHT DEVICE. The site coordinators must enter both the *11-digit serial number* and the *3-digit device number* of the aCPAP into KOEO for the successful transmission of treatment usage and efficacy data throughout Sleep SMART. <u>Please double check to make sure you accurately entered these data</u>.

The serial number and device number are located on the outside of the aCPAP box, as well as on the back of the aCPAP device itself (as highlighted by the "red boxes" on the images below).

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			Ry Only Sectors	DN DOTA



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- Enter the 11-digit serial number of the aCPAP device at the top
- On the next line, enter the 3-digit device number of the aCPAP device

Subjects in Sleep SMART are eligible to receive the best fitting mask from the Run-In Night. Based on the best mask TYPE and FIT from the Mask fitting session prior to the Run-In Night, and based on the subject's preference, enter the details about the mask that worked best on the Run-In Night, the same mask that the subject will keep to continue using with aCPAP. Record the following as noted above:

- Enter first mask detail:
  - Select the type
  - Select the size
- When finished, Click Submit

Enter mask details:					
Туре					
Evora Full Face Mask	N30i Nasal Mask	AirFit F20 Full Face	AirFit N20 Nasal Mask	AirFit P10 Nasal Pillows	DreamWear M
Size					
O Extra SmallEvora Onl	ly				
O Small					
O Medium					
O Large					
O WideN30i Only					
O Small-WideN30i Only					

Next 🕨

Recording this information is important because it lets FusionHealth know what equipment the subject has and also what equipment needs to be resupplied to the site.

After clicking "submit", the Sleep SMART KOEO Process for the on-site team is complete.

For those subjects randomized to the aCPAP intervention arm, please note that the Sleep SMART Care Team will manage all sleep apnea care after discharge from the hospital. No additional data entry in KOEO will be required from the sites or the site coordinators following the **Dispensing Questions** task in KOEO.

## Cleaning the aCPAP Device for Use With Additional Run-In Subjects

After the Run-In night, the following components of the aCPAP Device should be discarded if the subject is **ineligible for randomization or randomization to the control group**, or given to the subject if the subject is **randomized to the aCPAP group**:

- Water basin
- Air Tubing
- Masks tried

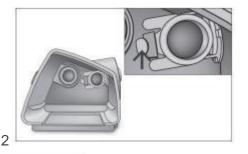
Before the Run-In Night aCPAP device can be reused with another subject, you should clean any soiled external surfaces of the aCPAP device with a disinfectant wipe or other routine disinfectant (Sleep SMART does not limit any other cleaning dictated by local policies). In the event of *possible contamination of the humidifier basin, mask or tubing*, and to minimize risk of contamination due to the COVID-19 virus, the **Air Outlet** should be removed, decontaminated, disinfected, and replaced into the aCPAP device.

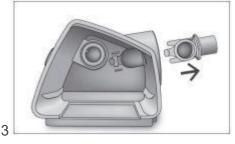
To minimize risk of contamination of COVID-19, it is suggested to remove, decontaminate, disinfect, and replace the Air Outlet of the aCPAP prior to next use.

#### Removing the Air Outlet

- 1: Locate the Air Outlet on the inside of the device
- 2: Release the Air Outlet by pressing the clip located inside the device
- 3: Remove the Air Outlet by pulling it out through the air outlet socket at the rear of the device (You may need to gently wiggle it while pulling it through the air outlet socket).







# Sleep SMART does not limit any other cleaning procedures dictated by local institutional policies

#### Decontaminating the Air Outlet

Before the disinfection process, clean and rinse the air outlet so that no visible contaminant is present as follows:

- Clean the Air Outlet with a soft bristle brush for 1 minute while soaking in a detergent solution (see table below for examples). Pay particular attention to all crevices and cavities.
- Thoroughly rinse the Air Outlet according to manufacturer's instructions

Detergent	Water Temperature
Alconox (1% dilution)	70-140° F
Gigazyme (1% dilution	113-140° F

## Disinfecting the Air Outlet

Using a chemical disinfectant (see table below), soak the Air Outlet for the indicated amount of time. Thoroughly rinse by immersing it completely in clean water for a minimum of 1 minute. Repeat the rinsing procedure a total of 3 times. Air dry away from direct sunlight and/or heat.

Disinfectant	Time in Bath
CIDEX OPA (0.55%)	12 minutes
Gigasept FF (5%)	15 minutes

## Reassembling the Air Outlet

- 1: Hold the Air Outlet with the seal pointing to the left and the clip pointing forward
- 2: Make sure that the Air Outlet is correctly aligned and insert the Air Outlet into the socket. It will click in place (You may need to gently wiggle it while pushing it through the air outlet socket).
- 3: Check if the Air Outlet is inserted correctly as shown

