

Run-in night (AirSense 11)

Introduction

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

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KOEO Login

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

The ResMed full face mask (F20) and nasal mask (N20) include magnets. Do not use these masks if 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 (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.

🕒	✓	Task Name	Pat...	Patient Name	Substatus	Best Time To ...	Created On	Tenant	Acti...
🟢🟢🟢	📍	Subject Eligible	MR	102, Sleep SMART			2022-04-01	SleepSMART	☰

1. Subject Eligible Task

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

Gender: M Home: Task: Subject 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
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Evora Full Face Mask Fit

Best	Good	Poor
------	------	------

N30i Nasal Mask

Small	Medium	Wide	Small-Wide
-------	--------	------	------------

N30i Nasal Mask Fit

Best	Good	Poor
------	------	------

AirFit F20 Full Face Mask

Small	Medium	Large
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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

Best	Good	Poor
------	------	------

Submit ✓

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**.

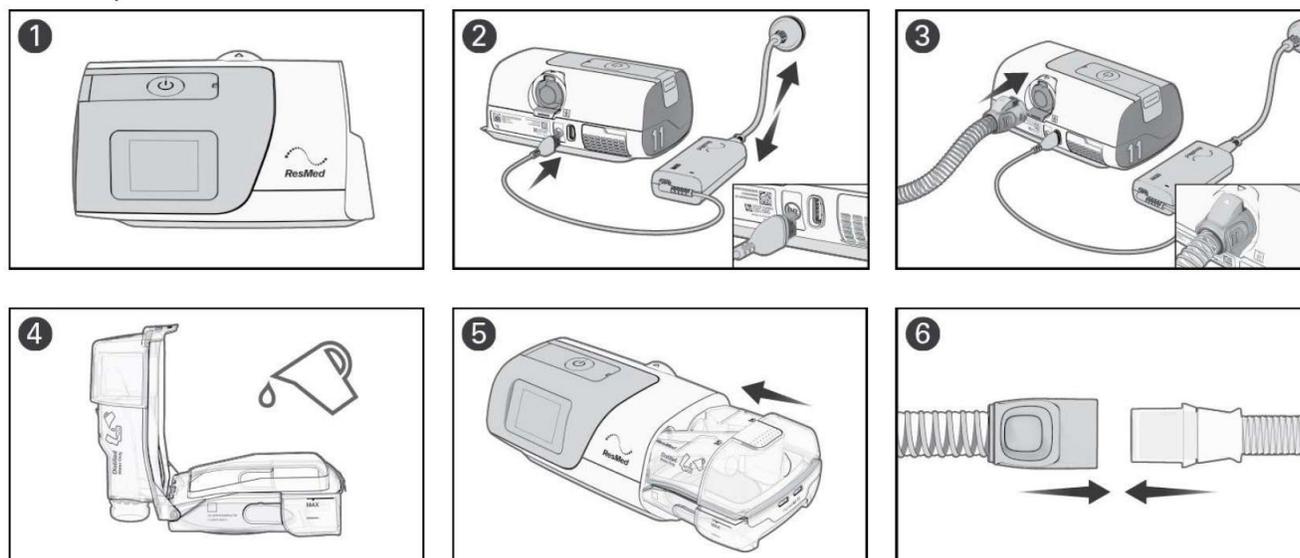
NO FURTHER ACTION is required in KOEO for the Run-In Night.

Task Name	Patient MR	Patient Name	Substatus	Best Time To Call	Created On	Tenant
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

To set up the device:



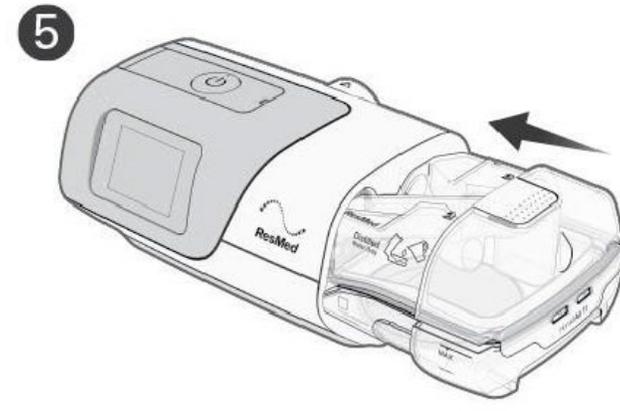
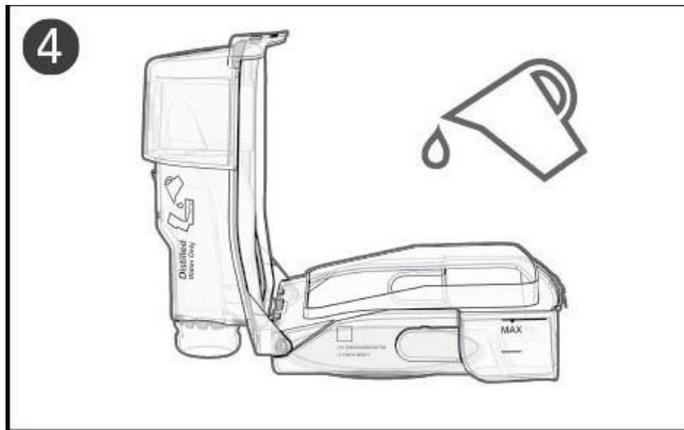
1. Place the device on a stable level surface
2. Connect the power cord into the power inlet at the rear of the device. Connect one end of the power cord into the AC adaptor and the other end into the power outlet. Ensure the device is set up and connected to power to enable settings to be applied wirelessly to the device if required.
3. Connect the air tubing firmly to the outlet connector at the rear of the device
4. Open the humidifier tub and fill it with water.
 - Note:** The humidifier tub must be removed from the device before adding water.
 - When using the HumidAir 11 Standard water tub, use distilled water only.
 Fill the water tub up to the maximum water level mark. The humidifier tub has a maximum capacity of 380 mL.
5. Close the humidifier 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.

Notes:

- Do not insert any USB cable into the AirSense 11 device or attempt to plug the AC adaptor into a USB device. This may cause damage to the AirSense 11 device or USB device.
- The electrical connector end of the heated air tubing is only compatible with the air outlet at the device end and should not be fitted to the mask.
- Do not use electrically conductive or anti-static air tubing.

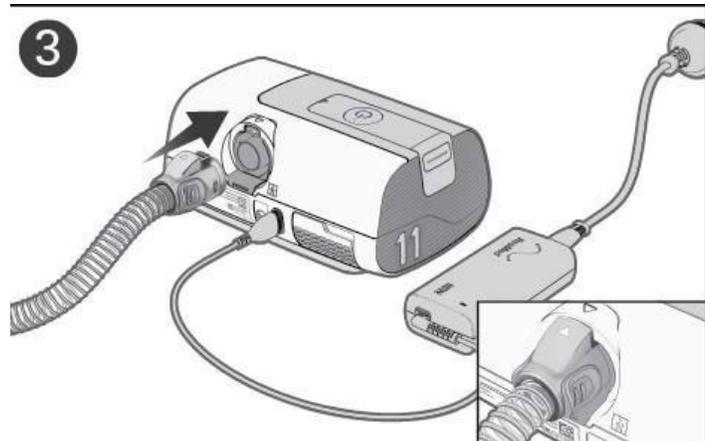
3. Filling the Water Tub

1. Hold the humidifier tub at the top and bottom, press it gently, and pull it away from the device.
2. Open the humidifier tub: one side of the tub has a locking latch. Lift the latch to open the tub, and discard any remaining water.
3. Use distilled water only and fill to the max fill line.
4. Close the lid and make sure it snaps back together to ensure a good seal.
5. Take the humidifier tub and slide it into the right side of the AirSense 11



4. Setting Up the ClimateLine Air Tubing

1. The purpose of the ClimateLineAir 11 tube is to help reduce the amount of condensation buildup and deliver optimal comfort
2. The ClimatelineAir 11 has two ends.
 - The soft rubber end attaches to the mask.
 - The more rigged end connects to the air outlet of the AirSense 11, located in the rear of the device.



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 SmartStart 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 sleep 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

- Always 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 and SmartStop Features

The aCPAP S11 device has two features that are enabled, SmartStart and SmartStop. SmartStart will start the device automatically when the subject breathes into the mask and SmartStop stops the device automatically when the subject removes the mask. If a subject does not like the SmartStart or SmartStop features, they can be disabled by contacting the Sleep SMART Care Team.

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.**

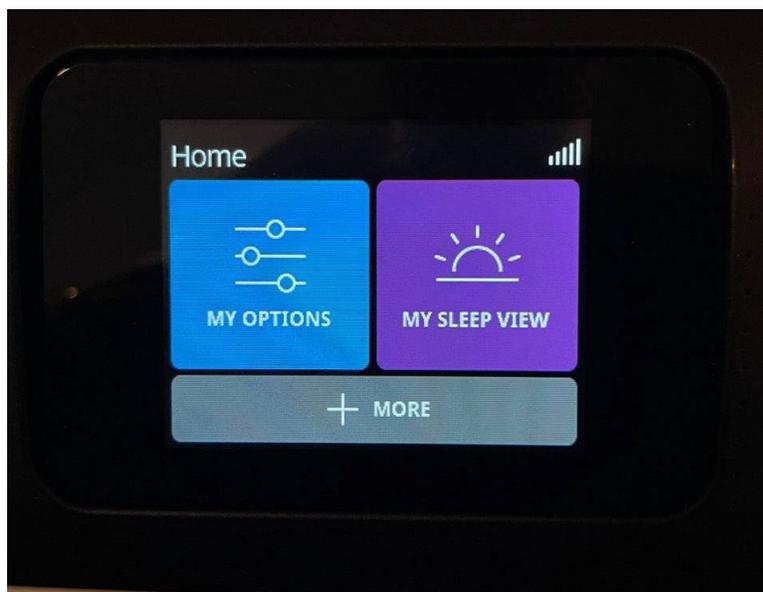
After the Run-In Night, the device is interrogated manually in order to read the aCPAP device-generated data on hours of usage, the Central Apnea Index, and other variables (see below).

Repeat Run-In Night: Subjects are welcome to retry the Run-In Night if use was <4.0 hours, CAI was <10, and they express interest in trying again. If the aCPAP Run-In Night was interrupted or otherwise limited by required clinical care, and for this reason did not meet the ≥ 4 hours criterion, testing should be repeated, if possible, and may be repeated twice.

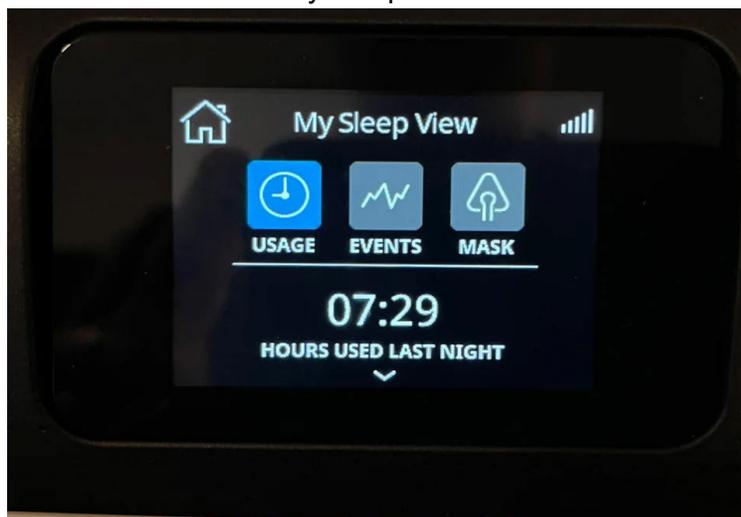
8. In the morning, determining if Subject is Eligible for randomization (AirSense 11: touch screen)

Viewing the Sleep Report

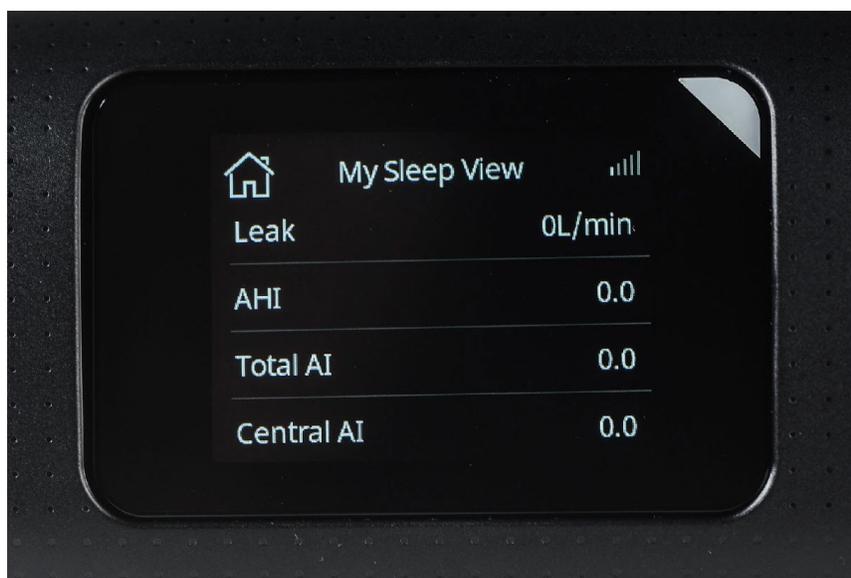
From the home screen, touch MY SLEEP VIEW.



You will then see the My Sleep View as below.



Scroll to see hours used, pressure (95th percentile), leak, residual AHI, and central AI (CAI).



Press the home icon to return back to the home screen.

The AirSense 11 is configured to display **1 Day**'s worth of data. 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.

9. 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.

10. 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.

11. 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 AI

12. APAP Night 1 Task in KOEO

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 ≥ 4 hours) and the aCPAP device-generated Central Apnea Index (Central AI must be <10), and the subject’s willingness to continue, as previously discussed.

13. APAP Tasks: if YES is Selected to “Retry Run-In Night”

- 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.

14. 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 ≥ 4 hours, the CAI was ≥ 10 , or the subject is unwilling to continue with Sleep SMART, the subject is Not eligible for randomization.

Task: APAP Night 1

75% Complete

Retry Run-In Night?

Yes No

Indicate subject's run-in night outcome

Subjects "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.

Eligible for randomization Not eligible for randomization

Submit ✓

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

15. APAP Tasks: Outcome is “Eligible”

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

75% Complete

Retry Run-In Night?

Yes No

Indicate subject's run-in night outcome

Subjects "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.

Eligible for randomization Not eligible for randomization

Submit ✓

- Click on ***Eligible for randomization***
- Click Submit

16. 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).

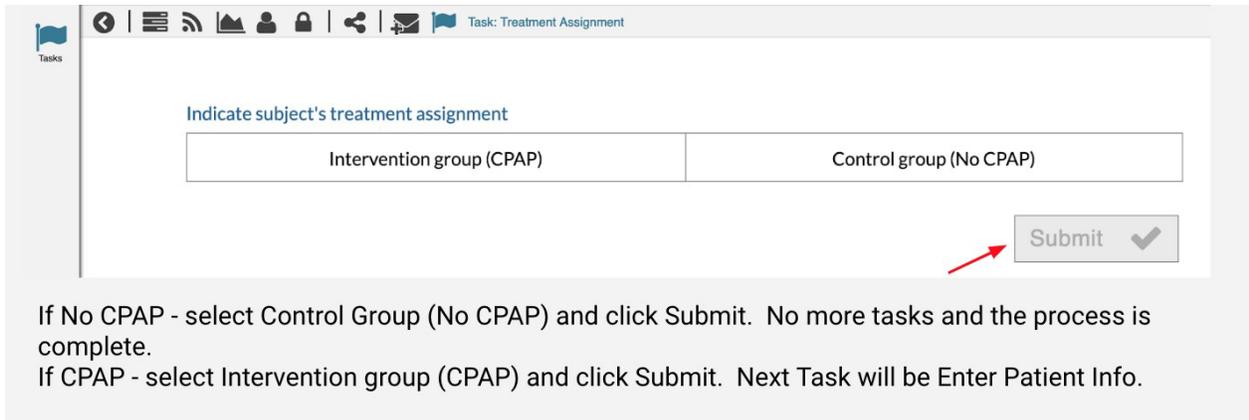
Site coordinators must access information from WebDCU regarding treatment assignment of the subjects to either the Intervention Group or to the Control Group.

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:

🕒	✓	Task Name	Patient ...	Patient Name	Substatus	Best Time To Call	Created On	Tenant
🟢🟢🟢	🌐	Treatment Assignment	MR043526	202, Sleep SMART			2019-02-19	SleepSMART

17. 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:



If No CPAP - select Control Group (No CPAP) and click Submit. No more tasks and the process is complete.
 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**:

🕒	✓	Task Name	Patient ...	Patient Name	Substatus	Best Time To Call	Created On	Tenant
🟢🟢🟢	🌐	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. Please be sure that this information is valid and entered accurately in the appropriate fields. If you have

any doubts regarding the information requested, please double check before entering the erroneous data.

The screenshot shows a web-based form for entering patient information. The form is titled "Task: Enter Patient Info" and includes an "Actions" button in the top right corner. The form is divided into several sections:

- Patient Name:** Fields for Title, First, MI, Last, and Suffix. The "First" and "Last" fields are highlighted with red boxes.
- Date of Birth:** Fields for Month, Day, and Year. The "Month", "Day", and "Year" fields are highlighted with a red box.
- Identification:** Fields for MRN, MR, and External MR. The "MRN" field contains the value "202".
- Payer Relationship:** A dropdown menu with "Subscriber" selected.
- Owner:** Fields for Tenant (SleepSMART), Location (Site2), Exception Group, and Default Exception Rule.
- Address:** Fields for Street, Street 2, City, State, Zip, and Country. The "City", "State", "Zip", and "Country" fields are highlighted with a red box.
- Shipping Address:** Fields for Street, Street 2, City, State, Zip, and Country. The "City", "State", "Zip", and "Country" fields are highlighted with a red box.
- Contact:** Fields for Mobile, Home, Work, Work Email, and Personal Email. The "Mobile" field is highlighted with a red box. There are also checkboxes for "Text Messages Enabled" (Yes/No) and "Best Time To Call" (16:00-17:00) and "Patient Time Zone" (Eastern Standard Time).
- Demographic Information:** Fields for Marital Status (Married), Sleep Schedule, Primary Language, Ethnicity, Gender (Male), Industry Type, and Industry Characteristic. The "Marital Status" and "Gender" fields are highlighted with red boxes.
- Regulatory Category:** A dropdown menu with "Non-Regulated" selected.
- Education Level:** A text input field.
- Special Instructions:** A text area containing the text "Subject has left-sided paralysis and is being transferred to rehab facility." This section is highlighted with a red box.

At the bottom of the form, there is a summary bar for "Sleep SMART 202" (MRN043526) with a "Compliance" indicator at 0%. Below this bar, there are icons for various services and a "Task: Enter Patient Info" label. A red arrow points to the "Actions" button in the bottom right corner.

- 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 additional contact info.

- Click the Save Icon in right hand corner when complete

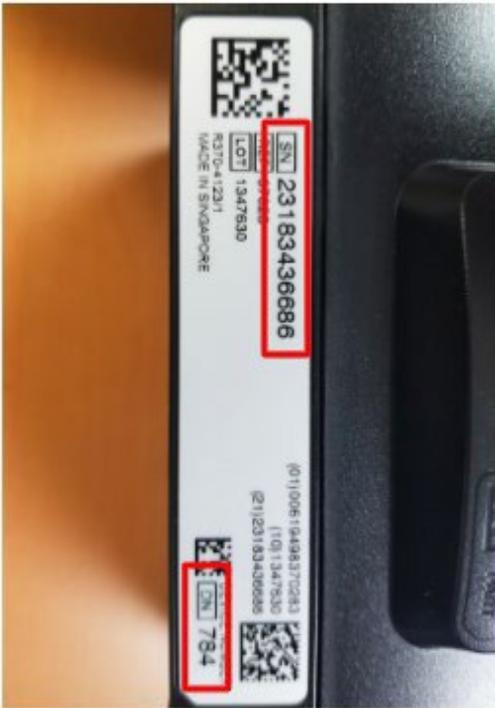
18. Dispensing aCPAP Equipment

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:

Task Name	Patient MR	Patient Name	Substatus	Best Time To Call	Created On	Tenant
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. Please double check to make sure you accurately entered these data.

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).



Task: Dispensing Questions

71%

APAP Device Serial Number

11 Digit Number

Device Number

S10 Device Number

3 Digit Number

- 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

Enter the details about the mask that was selected during 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

Task: Dispensing Questions

Enter mask details:

Type

Evora Full Face Mask	N30i Nasal Mask	AirFit F20 Full Face	AirFit N20 Nasal Mask	AirFit P10 Nasal Pillows	DreamWear Mask
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Size

Extra SmallEvora Only

Small

Medium

Large

WideN30i Only

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**:

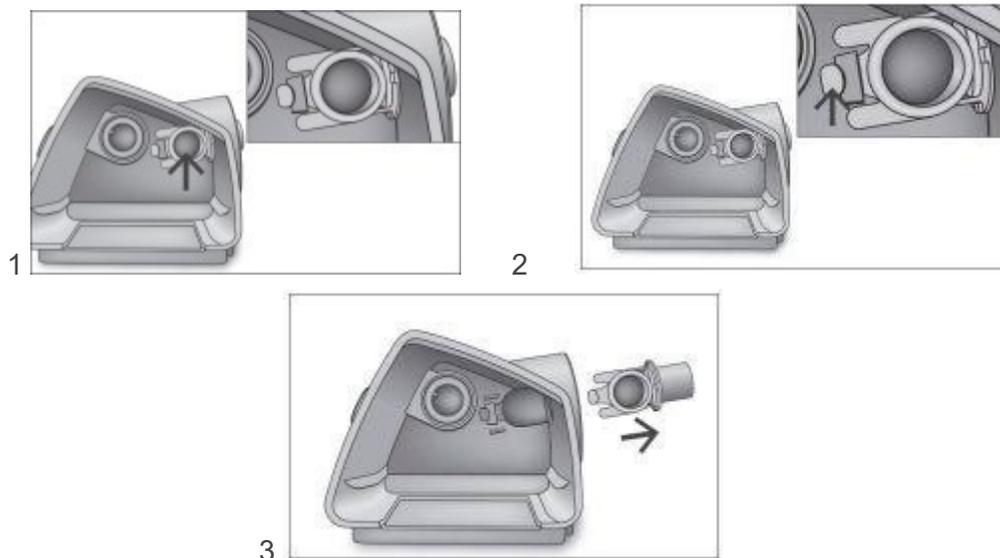
- Water basin
- Air Tubing
- Masks tried

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). Before cleaning, make sure the device is unplugged. 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. Pinch the cuff of the air tubing and gently pull it away from the device.
2. After the humidifier tub is removed, locate the Air Outlet on the inside of the device (image 1 below)
3. Release the Air Outlet by firmly pressing the clip located inside the device (image 2 below)
4. Remove the Air Outlet by pulling it out through the air outlet socket at the rear of the device (image 3 below) (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.

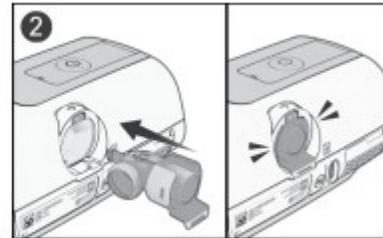
Disinfectant	Time in Bath
CIDEX OPA (0.55%)	12 minutes
Gigasept FF (5%)	15 minutes

Reassembling the Air Outlet

Reassembling

Once the components are dry, reassemble the device.

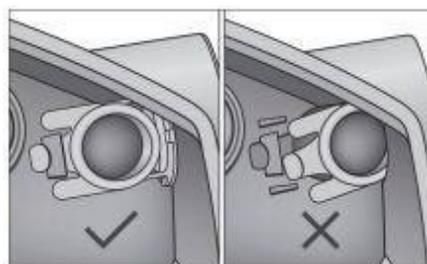
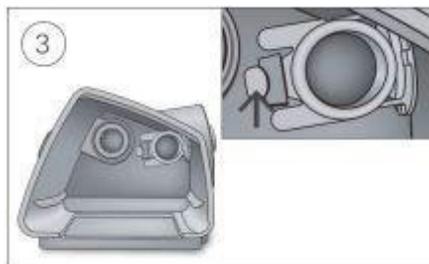
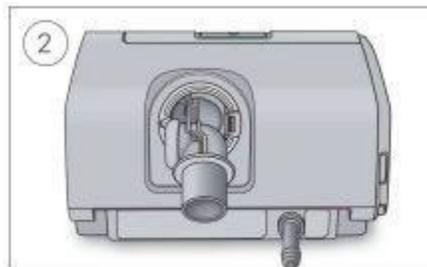
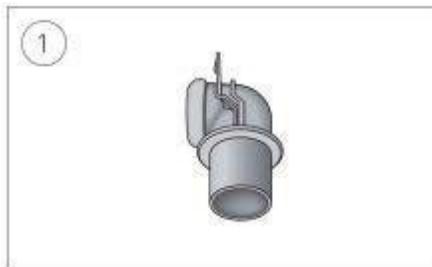
Outlet connector



1. Hold the outlet connector with the seal pointing to the left and the clip pointing forward.
2. Make sure the outlet connector is correctly aligned and insert the outlet connector into the socket. It will click in place.

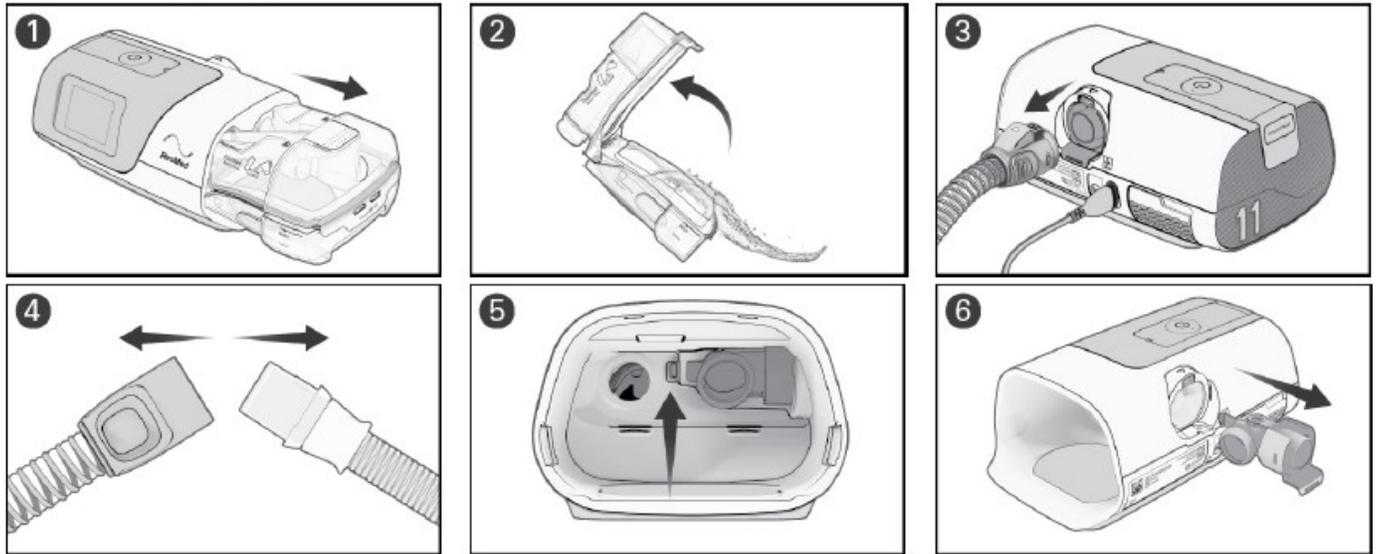
These images may also help:

1. image of the air outlet with the seal pointed to the left.
2. Insertion of air outlet with clip pointing forward.
3. Positioning of the clip from the inside
4. Correct vs incorrect positioning of the clip visualized from the inside of the unit (with humidifier tub removed).



Disassembling the device:

Disassembling



1. Hold the humidifier tub at the top and bottom, press it gently and pull it away from the device.
Note: take care when handling the humidifier tub as the humidifier tub may be hot. Allow 10 minutes for the heater plate and any excess water to cool.
2. Open the humidifier tub and discard any remaining water.
3. Pinch the cuff of the air tubing, and gently pull it away from the device.
4. Hold both the cuff of the air tubing and the swivel of the mask, then gently pull apart.
5. Locate the outlet connector on the inside of the device and release it by pressing the clip firmly.
6. Remove the outlet connector by pulling it out through the outlet connector socket at the rear of the device.