Re-opening Sleep Laboratories in the United States following COVID-19

Current industry-wide recommendations on the re-opening procedures for applications in the diagnosis and treatment of sleep disordered breathing

The information contained in this document is current as of June 24, 2020, and is based on currently available information that will continue to change over time. The information in this guide with respect to treatment is believed to have a reasonable basis. ResMed assumes no obligation to update the information in this presentation, whether as a result of new information or future events. **The information contained herein should NOT be used as a substitute for the advice of an appropriately qualified and licensed physician or other health care provider. This general guidance is based on publicly available information. It is the responsibility of the user to check any applicable state or local requirements.**

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Maintaining focus on Sleep Medicine in a COVID-19 world

The COVID-19 pandemic has touched every country in the world, causing an acute public health crisis that taxed our healthcare systems and resulted in halts to non-essential health services and new protocols for infection protection in healthcare facilities. As we now begin to understand the lingering impact of the pandemic and some countries move past their first acute wave of cases, ResMed understands the importance of supporting sleep labs as part of the whole care continuum in continuing to provide care to patients with sleep disordered breathing while still protecting personnel and patients from infection. This document is intended to collate the current guidance available for the re-opening of sleep labs/sleep clinics in the United States.

The importance of sleep testing

Sleep apnea is a major worldwide health issue and is highly prevalent in other chronic conditions including cardiovascular diseases[1,2], hypertension[3], diabetes[4], obesity[5], and stroke[6]. Several therapies currently exist to treat sleep apnea, but the current gold-standard is through postive airway pressure (PAP) therapy. Patients with sleep apnea that are treated with PAP therapy experience many benefits, including reduced mortality[7], a decrease in inpatient visits[8], and improved quality of life[9].

The global prevalence of sleep apnea is enormous and growing, with almost 1 billion people estimated to suffer from sleep apnea[10]. In the United States, sleep apnea is more than 80% undiagnosed[11,12], demonstrating that sleep testing is essential to identify undiagnosed patients that would benefit from treatment.

Re-starting and re-opening sleep clinics to sleep patients in the ‘new normal’

The healthcare world has changed to adapt to COVID-19; it may never be the same again.

As current restrictions and the delay of elective procedures are beginning to relax, sleep clinics are starting to consider their re-opening strategy. In an effort to gradually and safely reintroduce healthcare services, clinics should implement best practices for infection prevention and control, minimize patient, staff, and provider exposure to the virus, and promote public health and safety in order to maintain access and continuity of care.

Governmental Regulations

Most government agencies have not published guidance specific to sleep clinics, so they should observe local and state regulations for the re-opening of elective healthcare services.

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- Centers for Disease Control and Prevention: CDC Activities and Initiatives Supporting the COVID-19 Response and the President's Plan for Opening America Up Again [13]
- White House: Guidelines for Opening Up America Again[14]
- Centers for Medicare and Medicaid Services (CMS) Recommendations: Re-opening Facilities to Provide Non-emergent Non-COVID-19 Healthcare: Phase One[15]

Recommendations from Medical/Sleep Societies

Guidelines from sleep societies provide insight on the best way to implement regulations and determine proper risk management for the re-opening of sleep labs under variable community transmission conditions.

The American Medical Association (AMA) published a guide[16] for the re-opening of elective, non-COVID-19 care which includes guidance on topics such as step-wise facility opening, coordination of COVID-19 testing with local hospitals and clinics, legal considerations, and a pre-visit screening script.

The American Academy of Sleep Medicine (AASM) has published answers to frequently asked questions[17] and recommendations for sleep clinicians based upon the level of community transmission[18,19]. After previously recommending[18] sleep clinicians to delay all non-essential procedures starting March 19th, AASM released new guidance[19] for sleep clinicians starting May 1st with recommendations for varying levels of suggested re-opening based on community transmission.

Communities with substantial transmission (large-scale community transmission)

AASM continues to recommend postponing in-laboratory PAP therapy and diagnostic testing except in cases of emergency to patients that are properly screened. Home sleep testing is now encouraged under specific circumstances by AASM[19] (also, see below section on home sleep testing).

Communities with minimal to moderate transmission (multiple cases in community)

After recommending[1] a stop to all in-clinic PAP therapy and diagnostic testing, particularly for patients with a higher risk for severe illness from COVID-19, AASM continues to recommend[19] a postponement of all PAP therapy and diagnostic testing for higher risk patients. For patients at lower risk of severe illness from COVID-19, AASM now recommends[19] resuming both in-person clinic appointments and diagnostic testing.

Communities with no or minimal transmission

AASM did not specifically publish any previous recommendations for communities with no transmission, but they are now recommending[19] sleep clinicians to resume in-laboratory administration of PAP therapy and both in-person and at-home diagnostic protocols while continuing to monitor state and local public health communications.

Redesigning facility and treatment structure of in-person services

All healthcare facilities, including sleep clinics, will be motivated to protect their staff and patients in the event of a COVID-19 positive person entering their facility[19]. In addition to following local and state regulations and the above guidelines, clinicians must also rely on their expertise and clinical judgement during a time when evidence is still only slowly emerging. Decisions should also take into account the local transmission levels, availability of testing, and ability to protect the health and safety of patients, staff, and those at higher risk for severe illness through Personal Protective Equipment (PPE).

When possible, AASM recommends using telemedicine to limit non-urgent, in-person visits (see telemedicine section below). For communities that have existing transmission risk, sleep clinics should identify and only consider performing in-laboratory procedures on patients who have emergency needs. If an in-person visit is required, the following risk management plans should be considered to reduce risk of transmission from asymptomatic patients.

Intake methods

Prior to considering patients for in-person services, determine their COVID-19 status[22] based on recent contact, clinical symptoms[23], and any available diagnostic testing results. All patients, even those presumed to be negative for COVID-19, should undergo additional screening by the sleep clinic prior to their appointment through phone calls, patient portals, and online self-assessment tools. Clinicians should consider screening patients again just before entering the facility through temperature and symptom checks. Testing is recommended by many practitioners as the virus is most likely to be transmitted in asymptomatic individuals, just prior to symptom onset[24]. Even if a patient receives a negative test result, healthcare professionals should continue to abide by all safety regulations, as some testing procedures can have 15% false negative rate[25]. Of course, as the scientific knowledge surrounding COVID-19 increases, these guidelines should be revisited on an occasional basis.

Practitioners should consider eliminating penalties for patient cancellations so patients are not tempted to seek diagnosis and treatment despite respiratory symptoms[19].

Clinics should limit access of non-patient visitors (patients' family members) and consider remote-access translation services if necessary[19].

Facility modifications

For the foreseeable future sleep clinics should promote physical distancing throughout the in-person service. To minimize time in waiting rooms and check-in lines, patients and clinics should utilize telemedicine and/or electronic distribution of documents before and after the appointment to reduce face-to-face interaction. Clinics should space chairs six feet apart in waiting areas or ask patients to wait in their vehicles instead of waiting areas.

Clinics should provide supplies such as tissues, hand soap, waste receptacles, and alcohol-based hand sanitizer in readily accessible areas along with instructions[37] on hand hygiene, respiratory hygiene, and cough etiquette.

Equipment/supply considerations

Ventilation procedures have the potential to expose healthcare workers to infection risks due to aerosolized virus, which can remain viable for hours[26]. Healthcare professionals should be aware of the potential infection risks even when working with a patient presumed to be COVID-19 negative.

Evidence suggests that PAP procedures are more likely to produce large droplets (>10 µm) rather than aerosols as long as mask fit is optimized, and that these droplets are largely confined to within one meter due to their large mass[38]. This suggests that the risk of droplet dispersion as a result of use of PAP devices may not be that different to that of any COVID-19 patient in the hospital who is coughing or sneezing.

To further mitigate any possible risk of aerosolization, practitioners should ensure a good full face mask fit which will limit widespread dispersion of exhaled air[27,28] and aerosols[29] and create minimum room air contamination[30]. Particle dispersion is highest using nasal pillows at higher pressure (20 cmH_20) [264mm exhaled air dispersion] and may be the lowest with a well-fitting oronasal mask[31], although no specific data pertaining to COVID-19 is currently available.

ResMed's non-vented masks are currently not labelled for use in a passive-exhaust circuit configurations found in sleep labs. Based on the patient safety risk of carbon dioxide rebreathing[32], ResMed does not recommend the use of non-vented masks at this time.

Filters should be used in the circuit to minimize droplets in expelled air. As the COVID-19 virus is 0.125 microns in diameter[33], HEPA filters are able to capture almost 100% of particles at this size[34]. Note that antibacterial/antiviral filters increase resistance in the air circuit and may impact device performance and/or affect accuracy of displayed and delivered pressure, particularly at high flows[32]. ResMed has tested and recommends using an antibacterial filter (which also has antiviral capability) with a low impedance (eg, 2 cm H_2O at 60 L/min)[32].

The risk of aerosol dispersion can be mitigated by the use of PPE for healthcare workers (see PPE section below); the use of appropriate and compatible expiratory valve filters for single-limb non-invasive ventilators may also help to reduce the risk of virus spread in the open patient room.

Sufficient amounts of disposable supplies should be provided to accommodate patients (e.g. filters, AAIR or HEPA filters, leak valves) in anticipation of potential disposable shortages.

Infection control

Routine cleaning and disinfection procedures should be followed in healthcare settings, including patient-care settings in which aerosol generating procedures are performed. Specifically, the CDC recommends[39] using cleaners and water to pre-clean surfaces of frequently touched surfaces or objects prior to applying an EPA-registered[43], hospital-grade disinfectant.

Clean reusable medical equipment[35] according to manufacturer's instructions[36] (see appendix for cleaning ResMed devices) and follow CDC's recommendations for infection control[39] and environmental cleaning/disinfection[40].

Each sleep laboratory site should also develop a protocol to address how to protect high-risk patients and implementation of communication procedures and physical controls to encourage physical distancing[41].

Staff screening

In addition to the screening of patients described above, health care personnel and office staff should also be routinely screened through temperature checks twice per day. Implementation of sick leave policies that are non-punitive will allow ill personnel to stay home and not work when they are ill.

PPE

Clinicians and staff should strongly consider the use of surgical face masks at all times, and patients should wear a cloth face covering or surgical mask. All staff should be instructed on the appropriate use of PPE[44,45] .

During a procedure with a higher risk of aerosol transmission, such as PAP titration, staff should wear N95 respirators (requires fit testing), gloves, and face shields.

Anticipate potential PPE shortages as the worldwide need for these items rise.

Patient education

Untreated patients in communities with limited therapy due to transmission risk should receive risk-mitigation education on strategies to avoid adverse consequences of untreated sleep apnea[46,47,48]. To limit the risk of fall-asleep crashes, patients should be advised to limit the use of alcohol and sedating medications, control nasal congestion, and continue efforts at weight management.

Promoting off-site procedures

Home Sleep Testing

Home Sleep Testing has been recently encouraged by industry groups for its ability to continue health services while limiting infection risk[49,50].

Consider using single-use, fully disposable devices and/or components. Deliver these devices directly to patient's home and provide instructional brochures[51,52], video or telemedicine consultation to ensure proper set-up.

If using reusable devices, the units must be cleaned and sanitized according to manufacturer's instructions (see companion document) and CDC disinfection standards[53]. Individuals cleaning reusable devices must wear appropriate PPE[44].

Telemedicine

Whenever possible and allowable, patient education and evaluation via telemedicine should be pursued to protect the health of clinicians and staff.

Medicare[56] and some commercial providers are expanding coverage for telemedicine services and waiving requirements for in-person appointments through use of the appropriate billing codes[54]. For qualifying services, Medicare will make payment for telemedicine services furnished to patients in all areas of the country and in all settings, including the home. These virtual visits are considered the same as in-person visits and are paid under the Physician Fee Schedule at the same rate as regular, in-person visits. For clinics that need more information on how to start offering telemedicine services, AASM offers several resources, including a Sleep Telemedicine Implementation Guide[55]. Of course, it is the practitioners' responsibility to determine that appropriate billing guidance is followed.

During this public health emergency, Medicare will cover PAP devices[56] based on the clinician's assessment of the patient without requiring polysomnography (PSG) or a home sleep apnea test (HSAT). However, clinicians should consider that specific criteria to justify the prescription of PAP devices are unavailable, and CMS has not clarified what follow-up testing, if any, may be required after this public health emergency is over.

Conclusion

ResMed is continuing to support you to help improve the lives of patients while adapting your facility's operations and helping you protect your healthcare workers and staff.

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Appendix- Device cleaning procedures

Clean the external surfaces of the device using cleaners and water to pre-clean surfaces of frequently touched surfaces or objects prior to applying an EPA-registered[43], hospital-grade disinfectant, as per CDC recommendations[39]. Refer to the User Guide[57] for complete labelling instructions, including indications, contraindications, warnings and precautions.

S9 VPAP Tx

This disinfection guide[57] is intended for multi patient use of the air tubing in a sleep lab, clinic or hospital. This describes ResMed's recommended and validated procedures for cleaning and disinfection of the air tubing and humidifier. Each healthcare facility should consult its own procedure before carrying out those outlined below.

Tubing disinfection procedure

1. Disconnect the air tubing from your S9 device and mask system.
2. Clean the air tubing with a soft bristle brush for one minute while soaking it in the detergent solution. Pay particular attention to all crevices and cavities.
3. Run the detergent solution repeatedly through the air tubing until no contamination is visible.
4. Thoroughly rinse the air tubing according to the manufacturer's instructions.
5. Perform only one of the following disinfection and drying processes (see chart below to determine appropriate disinfection method:
    a. High level thermal
        i. Immerse the air tubing in a water bath. Take care that no air bubbles are trapped inside the air tubing.
        ii. Increase the water bath temperature to 167°F (75°C) for 30 minutes.
        iii. Air dry out of direct sunlight.
    b. High level chemical
        i. Soak the air tubing in a commercially available solution of a chemical sterilant. Take care that no air bubbles are trapped inside the air tubing.
        ii. Thoroughly rinse each component according to the manufacturer's instructions.
        iii. Air dry out of direct sunlight.
6. Perform a visual inspection of the air tubing. If any visible deterioration is apparent (cracking, tears etc), the air tubing should be discarded and replaced. Slight discoloration may occur and is acceptable.
7. Reconnect the air tubing to your S9 device and assembled mask system.
8. Store in a dry, dust-free environment away from direct sunlight. Storage temperature: -4°F to 140°F (-20°C to 60°C)

Part	Disinfection process				
	High level thermal	High level chemical			
	Hot water (approximately 75°C or 167°F) for 30 minutes	CIDEX™ OPA Ortho-phthalaldehyde 0.55% for 12 minutes	Anioxyde™ 1000 for 30 minutes	Sekusept aktiv 2.0% for 30 minutes	Validated number of cycles
SlimLine™	100	100	100	100	
Standard	20	100	20	100	
ClimateLine™	26	100	100	–	
ClimateLine™ MAX	20	20	20	–	
ClimateLine™ MAX Oxy	20	20	20	–	

Cleaning solutions

ResMed has tested the following detergents according to the manufacturer's instructions:

- Alconox Tergazyme (diluted at 1%) using hot water (approximately 60°C or 140°F) or warm water (approximately 50°C or 122°F)
- (SlimLine, Standard only) Aniosyme DDI (diluted at 0.5%) using room temperature water (approximately 20°C or 68°F)
- (SlimLine, Standard only) Neodisher MediZym (diluted at 2.0%) using warm water (approximately 45°C or 113°F)

Rinsing solutions

Thoroughly rinse the air tubing in drinking quality water (five litres per assembly) by immersing it completely for a minimum of one minute in duration. Repeat the rinse procedure two additional times using fresh water for a total of three rinses.

H5i water tub disinfection procedure

1. Disassemble the H5i according to the instructions.
2. Clean all components with a soft bristle brush for one minute while soaking them in the detergent solution. Pay particular attention to all crevices and cavities.
3. Thoroughly rinse each component according to the manufacturer's instructions.
4. Perform only one of the following disinfection and drying processes:
    a. High level thermal
        i. Soak the disassembled components in a hot water bath at pasteurising temperature. Take care that no air bubbles are trapped against the components.
        ii. Air dry out of direct sunlight.
    b. High level chemical
        i. Soak the disassembled components in a commercially available solution of a chemical sterilant. Take care that no air bubbles are trapped against components.

   ii. Thoroughly rinse each component according to the manufacturer's instructions.
   iii. Air dry out of direct sunlight.
5. Perform a visual inspection of all components. If any visible deterioration is apparent (cracking, crazing, tears etc), the water tub should be discarded and replaced. Slight discoloration of the silicone components may occur and is acceptable.
6. Reassemble the H5i according to the instructions on page 6.
7. Store in a dry, dust-free environment away from direct sunlight. Storage temperature: -4°F to 140°F (-20°C to 60°C).

Part	High level thermal or chemical disinfection
H5i cleanable water tub (including tub lid, plate and base)	✓
Air outlet	✓

Cleaning solutions

ResMed has tested the following detergents according to the manufacturer's instructions:

- Alconox Tergazyme (diluted at 1%) using hot water (approximately 60°C or 140°F) or warm water (approximately 50°C or 122°F)
- Aniosyme DDI (diluted at 0.5%) using room temperature water (approximately 20°C or 68°F)
- Neodisher MediZym (diluted at 2.0%) using warm water (approximately 45°C or 113°F)

High level thermal disinfection

Due to specific regional requirements, ResMed water tubs have been tested for disinfection for 100 cycles using hot water (approximately 93°C or 199°F) for 10 minutes.

High level chemical disinfection

ResMed cleanable water tubs have been validated for 100 cycles according to the manufacturer's instructions using solutions of:

- Ortho-phthalaldehyde 0.55% CIDEX OPA for 12 minutes
- Anioxyde 1000 for 30 minutes
- Sekusept aktiv 2.0% for 30 minutes

Rinsing solutions

Thoroughly rinse each component in drinking quality water (five litres per assembly) by immersing it completely for a minimum of one minute in duration. Repeat the rinse procedure two additional times using fresh water for a total of three rinses.

ApneaLink – US

Regular cleaning and maintenance should be carried out on the ApneaLink Air system as described here[52]. The cleaning shall be done by the physician or healthcare provider. Refer to the User Guide[48] for complete labelling instructions, including indications, contraindications, warnings and precautions.

- Never use abrasive agents, alcohol, chlorine-containing substances, acetone, or other solvents.
- Do not immerse the device, pulse oximeter, oximeter finger sensor or respiratory effort sensor in fluids, and ensure that no fluids penetrate into the products.
- Do not attempt to sterilize the device; this could cause unseen damage to the inside of the unit.

Cleaning procedure

1. Switch off the device.
2. If still attached, remove and dispose of the nasal cannula.
3. Remove the respiratory effort sensor.
4. Screw the protective caps onto the connectors for the nasal cannula and effort sensor.
5. Detach the pulse oximeter from the device.
6. Detach the oximeter finger sensor from the pulse oximeter. Note: Handle the pulse oximeter connection carefully. Do not twist the oximeter cable.
7. Press the protective cover for the USB cable in the housing opening.
8. Clean the following parts with a damp cloth and a mild liquid soap: device and pulse oximeter housing, pulse oximeter cable, clip fastener and respiratory effort sensor.
9. Leave the cleaned parts to dry.
10. Dispose of the single-use oximeter finger sensor. If you are using other approved oximeter finger sensors, follow the manufacturer's cleaning instructions.
11. Wash the belt by hand or in a regular washing machine at 86°F (30°C).
12. Allow the belt to drip dry. Do not tumble dry or dry clean.

Disinfection procedure

The following disinfectants can be used on the ApneaLink Air device: Mikrozid, Cavicide, Clorox, Lysol.

After cleaning the ApneaLink Air system as instructed, disinfect the ApneaLink Air device as follows:

1. Apply undiluted disinfectant to a clean non-dyed disposable cloth.
2. Wipe all surfaces of the device. Keep liquids away from any openings in the device.
3. Leave the disinfectant on the device for five minutes.
4. Wipe residual disinfectant from the device with a clean, dry, undyed disposable cloth.

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