Dental Practitioner Guide

Narval™ CC CAD/CAM Mandibular Repositioning Device
Join global leaders in sleep and respiratory medicine

ResMed is a global leader in the development, manufacturing and distribution of medical equipment to treat sleep-disordered breathing (SDB) and other respiratory disorders.

Formed in 1989, now with a global team of over 3000, ResMed operates in over 70 countries via subsidiaries and independent distributors with manufacturing sites in Australia, Europe, Singapore and the US.

The ResMed vision is not only to increase awareness of the inherent dangers of undiagnosed and untreated SDB, but also to improve the quality of life in people with SDB and other respiratory disorders. Studies have shown that poor sleep results in high health care expenditures and is often linked to obesity, cardiovascular risk and increased incidence of type 2 diabetes. With economic costs that include increased health care use, diminished workplace productivity and increased accidents, the global annual cost of sleeplessness is estimated to be between $30 and $107 billion per year. It is the goal of ResMed and its employees to bring attention to the severity, effects and impacts of SDB and engage the medical community with innovative products that offer resolution.

In 2004, Laboratories Narval developed an innovative mandibular repositioning device (MRD) based on patented ORM articulation and CAD/CAM technology. In line with its vision of providing state-of-the-art sleep therapy solutions, ResMed acquired the company in 2009 and initiated further product, clinical and commercial development. This high-precision customized device is much lighter, more flexible and more resilient than alternative offerings and has been embraced by dental practitioners worldwide.

Recent developments in sleep therapy solutions including MRDs have expanded the opportunity for dental practitioners to become members of multidisciplinary teams working to treat sleep apnea. Partnerships with sleep labs commonly run by specialists including sleep physicians, pulmonologists, neurologists and neuro-psychiatrists play a vital role in developing a sleep therapy network for any dental practice. While obstructive sleep apnea is a medical condition, MRD treatment requires dental expertise to ensure proper patient selection, diagnosis and treatment.

We hope you will become one of many practitioners around the globe offering Narval™ CC to your patients.
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What is sleep-disordered breathing (SDB)?

SDB describes a number of nocturnal breathing disorders, which include the following:

- Obstructive sleep apnea (OSA) is the most common form of SDB. The muscles at the back of the throat relax so much that they obstruct the upper airway, interrupt breathing and cause mini-awakenings called arousals.
- Central sleep apnea (CSA) occurs when the brain stops sending signals to the respiratory system; the airway remains open but breathing stops.
- Nocturnal hypoventilation (NH) is manifested by a reduced rate and depth of breathing, occurring due to the loss of muscle tone during sleep and especially during REM sleep. It occurs in patients with chronic obstructive pulmonary disease, neurological impairments, restrictive diseases (eg, scoliosis) and obesity.
- Cheyne–Stokes respiration (CSR) is characterized by crescendo and decrescendo periods of breathing accompanied either by five or more central apneas or hypopneas per hour of sleep or a cyclic crescendo and decrescendo change in breathing amplitude that lasts at least ten minutes.

What is obstructive sleep apnea (OSA)?

- OSA is a partial to complete collapse of the upper airway caused by relaxation of muscles controlling the soft palate and tongue.
- Person experiences apneas, hypopneas and flow limitation
  - Apnea: a cessation of airflow for ≥10 seconds
  - Hypopnea: decrease in airflow lasting ≥10 seconds with a 30% reduction in airflow and at least a 4% oxygen desaturation from baseline
  - Flow limitation: narrowing of the upper airway and an indication of an impending upper airway closure

OSA pathology: Apnea and hypopnea during sleep
Prevalence of sleep apnea

- 1 in 5 adults has mild OSA¹
- 1 in 15 has moderate to severe OSA²
- 9% of middle-aged women and 25% of middle-aged men suffer from OSA³
- Prevalence is similar to asthma and diabetes (20 million and 23.6 million respectively in US population)⁴
- 75% of severe SDB cases remain undiagnosed⁵

Classification of sleep apnea

Apnea–hypopnea index, or AHI, is an index used to assess the severity of sleep apnea based on the total number of complete cessations (apneas) and partial obstructions (hypopneas) of breathing occurring per hour of sleep.

Apnea–hypopnea index (AHI)

- \( \text{AHI} = 0–5 \) Normal range
- \( \text{AHI} = 5–15 \) Mild sleep apnea
- \( \text{AHI} = 15–30 \) Moderate sleep apnea
- \( \text{AHI} > 30 \) Severe sleep apnea
OSA comorbidities and associated risks

Sleep apnea is associated with several significant comorbidities. Researchers continue to develop an understanding of the risks created by and associated with sleep apnea.

Hypertension
- Studies have shown that sleep apnea is an independent risk factor for hypertension
- 30–83% of patients with hypertension have sleep apnea[^6,12]
- 43% of patients with mild OSA and 69% of patients with severe OSA have hypertension[^5]
- AHA guidelines on drug-resistant hypertension have shown treatment of sleep apnea with CPAP likely improves blood pressure control

Stroke
- 65% of stroke patients have SDB[^14]
- Moderate to severe sleep apnea triples stroke risk in men[^15]

Health care cost (economic consequences of untreated SDB)
- Undiagnosed patients used $200,000 more in the two-year period prior to diagnosis than matched controls[^16]
- Prior to sleep apnea diagnosis, patients utilized 23–50% more medical resources[^17]
- Total economic cost of sleepiness = approximately $43–56 billion[^18]
- Undiagnosed moderate to severe sleep apnea in middle-aged adults may cause $3.4 billion in additional medical costs in the US[^19]

Increased accidents
- People with moderate to severe sleep apnea have an up to 15-fold increase of being involved in a traffic accident[^20]
- Treating all US drivers suffering from sleep apnea would save $11.1 billion in collision costs and save 980 lives annually[^21]

Clinical signs and symptoms of OSA

<table>
<thead>
<tr>
<th>Daytime symptoms</th>
<th>Nighttime symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tired on waking</td>
<td>Chronic snoring</td>
</tr>
<tr>
<td>Excessive somnolence</td>
<td>Choking and breathing interruptions</td>
</tr>
<tr>
<td>Mood disturbance, depression</td>
<td>Waking up with a gasping sensation</td>
</tr>
<tr>
<td>Asthenia</td>
<td>Nocturia</td>
</tr>
<tr>
<td>Morning headache</td>
<td>Impotence</td>
</tr>
<tr>
<td>Difficulty concentrating, memory lapses</td>
<td>Nocturnal sweats</td>
</tr>
</tbody>
</table>

Effects of sleep deprivation are numerous, ranging from deficiency in alertness and attentiveness to physical symptoms like headaches, gastrointestinal problems and more. Fatigue resulting from insufficient sleep is a major cause of traffic accidents. Research shows that children who do not get the correct amount of sleep are more likely to be poor learners, overweight and have high blood pressure.
Validated SDB treatment options

Continuous positive airway pressure (CPAP) and custom mandibular repositioning devices (MRDs) are the two validated and most frequently prescribed treatments for OSA. CPAP prevents collapse of the airway by maintaining a positive airway pressure during inspiration. An MRD is an oral appliance that maintains the lower jaw in a forward and closed position during sleep, thus opening the airway. Oral appliance therapy treats OSA and snoring by preventing the airway from becoming obstructed during sleep, similarly to CPAP devices. However, MRDs accomplish this by protruding the lower jaw, which leads to:

- increased retrolingual space
- increased tension on the soft palate that, when relaxed, causes snoring

*Note: MRDs do not prevent breathing through the mouth*

Mandibular advancement has a double impact:

- Opens the upper airway at most levels, especially at the oro-pharynx
- Decrease in collapsibility of the upper airway
Mechanism of action of mandibular repositioning devices

MRDs maintain the lower jaw in a forward position during sleep. In doing so, MRDs generate the following effects:

- create an anterior movement of suprahyoid and genioglossus muscles
  - The suprahyoid muscle widens the esophagus during swallowing
  - The genioglossus muscle depresses and protrudes the tongue
- decrease the gravitational effect of the tongue
- stretch the soft palate
- stabilize the mandible to the hyoid bone.

The hyoid bone attaches to the muscles of the floor of the mouth and the tongue above, to the larynx below, and to the epiglottis and pharynx behind. This results in an increase in lateral pharyngeal cross-sectional area upper airway muscle activity, thus preventing snoring and obstructive apneas.

While most MRDs hold the lower jaw in a forward position, with the Narval CC the force of retention works along the occlusal plane, retaining the mandible in a protruded position rather than pushing it, thus relieving stress on the TMJ. The elevated articulation point, which allows the connectors to be parallel with the patient’s jawline, complements the physiological articulation.
American Academy of Sleep Medicine (AASM) guidelines for MRDs

1st Line Treatment
- For mild to moderate OSA (AHI 5-30) patients who:
  - prefer MRDs over CPAP
  - do not respond to CPAP
  - fail or are inappropriate candidates for CPAP
  - fail behavioral measures treatment.
- For patients who snore and do not respond or are not appropriate candidates for behavioral measures treatment

2nd Line Treatment
- For severe OSA (AHI>30) patients who lack compliance with CPAP

Narval CC contraindications
The Narval CC is a mandibular repositioning device, available under medical prescription and intended to treat mild to moderate OSA in adults.

In case of severe apnea, the Narval CC is recommended in second intention after CPAP refusal or failure or for patients who are noncompliant with CPAP. The device is contraindicated for patients who have:
- central sleep apnea
- severe respiratory disorder
- are less than 18 years of age
- loose teeth or advanced periodontal disease
- a completely edentulous lower arch
- complete removable dentures
- missing lower posterior molars on one or both sides of the mandible
- maximum mandibular advancement of less than 5 mm
- short teeth, insufficient teeth per arch and quadrant (eg, ~4 minimum per quadrant), or insufficient undercuts to retain the device.

Additional conditions should be considered; reference page 14 for detailed overview.
Narval CC features and benefits

The Narval CC offers a custom, individualized solution uniquely designed for each of your patients. As the first and only computer-aided design (CAD) and computer-aided manufacturing (CAM) solution on the market, the Narval CC ensures a precise fit and comfortable retention to meet each patient’s individual needs.

Protrusion by retaining—not pushing—the mandible into a forward position

No direct impact on the incisors

Discreet and comfortable splints

- Flexible, thin and light, ensuring more comfortable treatment and better patient compliance
- Engage the stronger posterior teeth, do not impinge on tissue or affect dental hygiene
- Easy to insert even on misaligned teeth and durable enough for heavy bruxers; strength tested to withstand over 100Ncm of force
**Narval CAD CAM Technology™**

- CAD enables a high degree of customization according to your prescription to accommodate the complex dental anatomy of individual patients
- CAM and selective laser sintering guarantees precision, accuracy and consistency for each patient
- Manufactured with durable biocompatible polymer material and is metal-free, ensuring no immune response
- Easy to reproduce, enabling quick response to lost or damaged appliance

**Strong and flexible connecting rods**

- Easily adjustable in 1-mm increments within a 15-mm protrusive range
- Ensure effective titration as treatment progresses

**Patented physiological articulation**

- Aligns splints along the occlusal plane, allowing for natural lateral and vertical movement
- Keeps mandible in a forward position by retaining rather than pushing it, minimizing stress on TMJ

Patent US 7,146,982
Narval CC clinical and patient benefits

Clinical benefits

High compliance

- 80% of patients wear the Narval device 7 nights a week 6 weeks into the treatment25
- Treatment compliance was high after 18 months with the MRD being worn on average 6.2 nights/week26
- Narval CC does not load incisors; this limits risk of incisor tilting and improves patient comfort

Proven efficacy

- Patients with moderate OSA exhibited an average decrease in AHI of 57%27
- AHI reduction even in severe OSA patients26
- Rapid improvement on sleepiness and quality of life parameters26

Patient benefits

Discreet and comfortable—yet effective

- Narval’s proprietary design combined with CAD/CAM technology offers one of the lightest solutions on the market
- Minimal bulk in the mouth ensures patient comfort and compliance
- Absence of contact with incisors reduces dental sensitivity post-wear
- Lateral flexibility eliminates “locked-in” sensation, offering freedom to talk and drink
- Patented ORM articulation promotes mouth closing and physiological breathing during sleep27

Treatment observance:

Excellent:
Patient wore MRD every night of the week, all night

Good:
Patient wore MRD for at least 4 nights per week and for at least 4 hrs per night

Unsatisfactory:
Patient wore the MRD for less than 4 nights per week for at least 4 hrs per night

“100% different. It’s very light, comfortable... very comfortable, no bulk... Very simple to use.”

Lilly—Narval CC patient at fitting
Narval CC treatment flow

As part of the multidisciplinary approach, you and your sleep network will monitor patient success. It is important to monitor treatment progress as a team to ensure efficacy.

Dental protocol of care for patient

Introducing Narval CC to your practice requires only a few appointments to identify, fit and monitor your patient.

1st appointment
- Validate absence of dental or TMJ contraindication
- Teeth impressions
- Record patient’s protrusion

2nd appointment
- Device fitting
- MRD adjustment for pre-set protrusion

Follow-up appointments
- Adjust mandibular advancement (titration) according to impact on symptoms (snoring, fatigue)
- Check side-effect improvements
Patient identification: Oral and prosthetics examination

It is necessary to perform a dental, periodontal, prosthetic and TMJ examination to establish whether a patient is suitable for MRD treatment. If there are no definitive or temporary contraindications, then proceed.

One or more of the following may make MRD treatment unsuitable:

**Dental Examination**
- Missing lower molars on one or both sides
- Missing two or more canine/premolar teeth in one quadrant on the maxilla unless they are replaced by a permanent bridge
- Maximum mandibular advancement of less than 5 mm
- Short teeth, insufficient teeth per arch and quadrant (e.g., ~4 minimum per quadrant)
- Insufficient undercuts to retain the device

**TMJ Examination**
- Temporomandibular joint pain needs to be further assessed by the patient’s treating physician
- Record of TMJ osteoarthritis: contraindicated for MRD treatment

**Periodontal Examination**
- Any periodontal disease must be treated by the patient’s regular dentist before MRD treatment
- Cysts and mouth ulcers should be treated by the patient’s regular dentist before MRD treatment
- If there are teeth to be extracted, or if there is any prosthodontic treatment pending, ask the patient to be treated by their usual dentist before MRD fabrication

It is essential to obtain valid informed consent before proceeding with the treatment. Once a patient has been identified as suitable for MRD treatment, then proceed to follow clinical protocol (next page).
Clinical protocol

Taking impressions

Fine detail impressions of both jaws to the full sulcal depth are required. Impressions must effectively depict the posterior molar region and 5 mm of tissue distal to the posterior molars.

• Accurate impressions—you may consider using Rim-Lock impression trays, thus allowing for full impression of gingival sulcus and posterior molar area.

• Suitable impression material—select impression material of your choice, ensuring it will not be affected by transport (silicone is recommended for 2-day/ground shipments and alginate for overnight shipments). Simply indicate which impression material you have selected.

• If you prefer to send stone models, please use grade 4 stone for the fabrication, paying particular attention to ensure bubbles are not present on the teeth surface or around the gingival margin.

• Finally, if you feel measurements and impressions will not be sufficient to exactly depict your prescription, please send any drawings or photos you may find useful. Please disinfect impression before shipping.

Bite record/registration

The preferred patient protrusion starting point is required to design and manufacture Narval CC. The George Gauge or similar device is recommended. The relationship of the jaws may be recorded using silicone putty. Please disinfect bite registration before shipping.

Lateral deviation

Please note and record on your prescription any lateral deviation of the mandible in protrusion (the direction and amount—measured at the incisors).

Complete the prescription order form

Simply complete the prescription order form, sign and date it, together with your patient’s name, your practice address and contact details.

Place the completed prescription in your shipper to be sent with the following elements:

• Impressions

• Protrusive bite registration and/or protrusion measurements

Your order information will be sent to a laboratory, where the molds will be produced and the Narval CC will be designed and manufactured with unique CAD/CAM technology to meet the needs of your patient.
Fitting Narval CC and instructing your patient

Fitting the device
• The device is supplied non-sterile. Clean it prior to fitting.
• Moisten the device and position it in the patient’s mouth with the upper splint against the upper teeth.
• Press firmly with your fingers on the splint until it is confidently in place. Do not pull or press on the connectors to adjust the position.
• Bring the patient’s lower jaw forward and proceed in a similar way to slide in the lower splint. In some cases, it may be easier to insert the lower splint first.
• Instruct the patient not to bite into the splint to insert it onto their teeth.

Validating proper fit
• Check the fit of each individual splint to ensure there is no tissue blanching or sore spots.
• Adjust and polish the inside surface of the splint as necessary using the burs provided at low revolutions.
• Ask the patient about any painful spots or excess pressure on the teeth or soft tissues.
• Check the contact surface areas for an even and balanced occlusion.

Validating proper retention
• In rare instances, when the patient opens their mouth, one or both splints may detach. In this case, remove the connectors and check retention individually. If both splints are retentive separately, then this is not a major concern. Advise the patient to sleep with the device and review at a follow-up appointment.

Removing the device
• First remove the lower splint by lifting the side of the device away from the gum with your fingers. Be careful never to pull or press on the connectors.
• Proceed in similar fashion to pull away the upper splint.
• Remove the device from the mouth.

General warning
• The Narval CC device is a comfortable and noninvasive MRD, but it still requires a few nights to get accustomed to its use.
• Use of any oral appliance may cause tooth movement or changes in dental occlusion, gingival or dental soreness, pain or soreness to the temporomandibular joint or obstruction of oral breathing.


**Titration and patient compliance**

**Titration**
Please explain to the patient that there is a need for patience while becoming accustomed to the device. Titration is the process by which you will adjust the protrusion of the device and the protrusion of the mandible for your patient, to find the best compromise between efficacy and comfort. There is a well-proven non-linear dose response to the level of protrusion until the efficacy plateau is reached. This means that the more you protrude, the more efficacious the MRD is going to be (up to a limit—the efficacy plateau), but the less comfortable it will be for the patient initially as pressure on the teeth and the TMJ articulation increases.

**To protrude more, a shorter connector is required**

Initial titration: Mandatory for all patients

Initial titration will enable you to find the right protrusion of the device based on symptoms reported by the patient and his/her partner such as:
- Snoring frequency and intensity
- Fatigue and tiredness
- Daytime somnolence and tendency to fall asleep
- Quality of sleep and nocturia

**STEP 1** The initial protrusion of the device is based on the bite registration in a comfortable protrusion (usually 60% of maximum protrusion). At the fitting appointment, there should not be a sensation of muscle/TMJ pain. If there is, please reduce the protrusion by replacing the connectors in place with longer connectors, until the discomfort resolves.

**STEP 2** At the follow-up appointment, once the patient is used to sleeping with the Narval CC, inquire about symptom improvements. If all symptoms are resolved, proceed to Step 4.

**STEP 3** If some symptoms persist and the patient can tolerate a 1 mm greater protrusion, replace the existing connectors with 1 mm shorter connectors to increase treatment efficacy. Set up a subsequent follow-up appointment one or two weeks later and repeat Step 3 until you reach resolution of symptoms or the tolerance limit of your patient, whichever happens first. Proceed to Step 4.

**STEP 4** For OSA patients, inform your sleep specialist partner of patient status and MRD titration. The patient should undertake a controlled sleep recording with the Narval CC in order to identify treatment efficacy on breathing parameters (apneas, oxygen desaturation, etc.) during sleep. A controlled sleep recording is usually not required for patients with simple snoring.

**IMPORTANT:** For OSA patients, if a satisfactory improvement in symptoms and an objective sleep recording validation cannot be achieved post titration(s), work with your sleep specialist partner to discuss alternate treatments.
To order a Narval CC mandibular repositioning device

1. Confirm that the patient is a good candidate for a mandibular repositioning device.
   • It is necessary to perform a dental, periodontal, prosthesis and TMJ examination.
   • It will be impossible to fit your patient if he/she has insufficient anatomy (see page 9 and 14) for contraindications.

2. Take impressions and bite registration, and provide required data for manufacturing the mandibular splint (for detailed instructions on taking impressions for Narval CC, see page 15).

3. Download an order form from www.resmed.com/narval or call 1-800-424-0737 and select #1 for customer service, then press #5 for Narval dental sleep solution.

ResMed works with several dental laboratories in the United States and Canada to support the sale of Narval CC. They will receive your impressions or plaster models and provide the scans and models to ResMed for design and manufacturing. For a list of these dental lab partners visit www.resmed.com/narval.