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 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 USA.

The ResMed vision is not only to increase awareness of the inherent dangers of undiagnosed and untreated sleep disordered breathing, but also to improve the quality of life in people with sleep disordered breathing and other respiratory disorders. Studies have shown that poor sleep results in poor quality of life, high health care expenditures and is often linked to obesity, cardiovascular risk and increased incidence of Type 2 diabetes. With the economic costs that include health care use, workplace effects and accidents and the global annual cost of sleep-related health problems is estimated to be between $35 and $107 billion per year. It is the goal of ResMed and its employees to bring attention to the severity, affects and impacts of sleep disordered breathing 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 O.R.M. 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 resilient than alternative offerings and has been embraced by dental practitioners worldwide.

Recent developments in sleep therapy solutions including Mandibular Repositioning Devices 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.
What is sleep-disordered breathing (SDB)?

SDB describes a number of nocturnal breathing disorders, which include

• 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 (e.g. 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 partial or complete collapse of the upper airway caused by relaxation of muscles controlling soft palate and tongue.

• Person experiences apneas, hypopneas and flow limitation.

• Apnea is a cessation of airflow for ≥10 seconds.

• Hypopnea: a decrease in airflow lasting ≥10 seconds with a 30% reduction in airflow with at least a 4% oxygen desaturation from baseline.

• Flow limitation: narrowing of the upper airway and an indication of an impending upper airway closure.

Prevalence of sleep apnea

• 1 in 5 adults has mild OSA.

• 1 in 15 has moderate to severe OSA.

• 9% of middle-aged women and 25% of middle-aged men suffer from OSA.

• Prevalence similar to asthma and diabetes (20 million and 23.6 million respectively in US population).

• 75% of severe SDB cases remain undiagnosed.

Classification of sleep apnea

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

AHI (Apnea-Hypopnea Index)

AHI = 0-4 Normal range  •  AHI = 5-14 Mild sleep apnea  •  AHI = 15-30 Moderate sleep apnea  •  AHI > 30 Severe sleep apnea

Reference:

OSA co-morbidities & 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 links**
- Studies have shown that sleep apnea is an independent risk factor for hypertension
- 30-63% of patients with hypertension have sleep apnea
- 43% of patients with mild OSA and 69% of patients with severe OSA have hypertension
- AHA guidelines on drug-resistant hypertension have shown treatment of sleep apnea with CPAP likely improves blood pressure control

**Stroke risk**
- 65% of stroke patients have SDB
- Moderate to severe sleep apnea triples stroke risk in men

**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
- Prior to sleep apnea diagnosis, patients utilized 23–50% more medical resources
- Total economic cost of sleepiness = approximately $43–56 billion
- Undiagnosed moderate to severe sleep apnea in middle-aged adults may cause $3.4 billion in additional medical costs in the US

**Traffic Accidents**
- Increased incidents of road accidents (falling asleep at the wheel)
- Workplace accidents
- People with moderate to severe sleep apnea have an up to 15-fold increase of being involved in a traffic accident
- Treating all US drivers suffering from sleep apnea would save $11.1 billion in collision costs and save 980 lives annually

**Clinical Signs and Symptoms of OSA**

<table>
<thead>
<tr>
<th>Day time symptoms</th>
<th>Night time 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>Concentration difficulties, 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. A mandibular repositioning device (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:
- opening up the space behind the tongue
- 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:**

- Increase in upper airway calibre at most levels, and especially at the oro-pharynx
- Decrease in collapsibility of the upper airway

**Reference:**
3. Young et al. Sleep Disorders Breathing and Mobility. Eighteen Year Follow-up of the Victoria Sleep Cohort. Sleep Vol. 21, No. 6, 2008
13. Youn et al. Sleep Disordered Breathing and Mobility. Eighteen Year Follow-up of the Victoria Sleep Cohort. Sleep Vol. 21, No. 6, 2008
15. Youn et al. Sleep Disordered Breathing and Mobility. Eighteen Year Follow-up of the Victoria Sleep Cohort. Sleep Vol. 21, No. 6, 2008
19. Youn et al. Sleep Disordered Breathing and Mobility. Eighteen Year Follow-up of the Victoria Sleep Cohort. Sleep Vol. 21, No. 6, 2008
**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.

**Indications and contra-indications for custom MRDs**

**American Academy of Sleep Medicine (AASM) • Guidelines for Custom MRDs**

1st Line Treatment

- Mild to Moderate OSAS (AHI 5-30) for patients who:
  - Prefer MRDs over CPAP
  - Do not respond to CPAP
  - Are inappropriate candidates for or fail CPAP
  - Fail behavioral measures treatment

2nd Line Treatment

- Severe OSAS (AHI>30) in case of lack of compliance with CPAP

Contraindications

- The device is contraindicated for patients who have
  - Central sleep apnea
  - Severe respiratory disorder
  - Loose teeth or advanced periodontal disease
  - Are less than 18 years of age
  - 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 (e.g. <4 minimum per quadrant), insufficient undercuts to retain the device

Additional conditions should be considered; reference page 14 for detailed overview.

Side effects when using MRDs are minor and transitory as cited in the Journal of Sleep Medicine 2008 Vecchierini study. Initial minor side effects of MRD appear to reduce with longer-term wear. Use of the device may cause tooth movement or changes in dental occlusion; gingival or dental soreness, pain or soreness to the TMJ, obstruction of oral breathing, excessive salivation. Dentists should consider the medical history of the patients, including history of asthma, breathing or respiratory disorders, or other relevant health problems, and refer the patient to the appropriate healthcare provider before prescribing the device.
Narval CC features & benefits

Narval CC keeps the mandible in a forward position in a comfortable way by retaining it rather than pushing it:
- Creates less stress on TMJ and allows for more flexible lateral movements.

Strong and flexible connecting rods are easy to change, allowing for a quick adjustment of MRD to patients’ individual needs as the treatment progresses:
- Allows dentists to provide an accurate customized solution much faster.

Patented physiological articulation allows for the splints to be as close to the occlusal plane as possible:
- Allows for a natural and free movement.

Comfortable and flexible Narval CC splints, easy to insert even in misaligned teeth, rest on the most solid teeth and do not touch gums, and do not affect dental hygiene:
- Minimizes the tissue irritation, overloading of the dentition or compromising of periodontal tissues.

Durable but very supple splints are thin and light; strong enough to be used in bruxers:
- Maximizes mechanical properties and allows for comfortable treatment.

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Narval CC features & benefits

Narval CC offers a custom, individualized solution uniquely designed for each of your patients and manufactured through a state-of-the-art CAD/CAM technology that meets individual needs of your patient and follows your prescription.

Unique CAD/CAM technology ensures precise fit and comfort retention for each patient – the first and only CAD/CAM solution on the market:
- Computer-aided design (CAD) enables a high degree of customization according to your prescription; this accommodates the complex dental anatomy of individual patients.
- Computer-aided manufacturing (CAM) and selective laser sintering guarantees precision, accuracy and consistency for each dental patient.
- Manufactured using durable biocompatible polymer material, to ensure no immune response; metal-free.
- Designed with patient compliance in mind, Narval CC is highly resilient, flexible and light.
- Easy to titrate – highly adjustable up to 15 mm protrusive range in 1mm increments.
- Easy to reproduce; enables quick response to lost or damaged appliance.

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 for 6 weeks into the treatment.
- Treatment compliance was high after 18 months with the MRD being worn on average 6.2 nights/week.
- Narval device does not load incisors; limits risk of incisor tilting and improves patient comfort.

Proven efficacy
- Patients with moderate OSA exhibited an average decrease in AHI of 57%.
- Significant AHI reduction even in severe OSAS patients.
- Rapid improvement on sleepiness and quality of life parameters.

Patient benefits
Discrete 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; offers freedom to talk and drink.
- Patented O.R.M. articulation promotes mouth closing and physiological breathing during sleep.

Reference:

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 steps to identify, fit and monitor your patient.

1st Appointment
- Validate absence of dental or TMJ contra-indication.
- 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 & clinical protocol

Patient Identification: Oral and Prosthetics Examination
Establish whether patient is suitable for MRD treatment:
It is necessary to perform a dental, periodontal, prosthetic and TMJ examination.

It will be impossible to equip your patient if they have:
• Missing lower molars on one or both sides
• Missing 2 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 is needs to be further assessed by 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 custom-made MRD fabrication.

If there are no definitive or temporary contraindications then proceed.
It is essential to obtain valid informed consent before proceeding with the treatment. Once a patient has been identified as a suitable for MRD treatment; the following clinical protocol should follow.

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.
• 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 (silicon would be preferred for long distance and weekend transportation and alginate should preferably be used for short distance transportation). Simply indicate which impression material you have selected.

If you prefer to send plaster/stone models, please use grade 4 plaster 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
A bite registration in full protrusion is required to design and manufacture Narval CC. The relationship of the jaws may be recorded using either wax or silicone putty. Alternatively, the George Gauge or similar device may be used. 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. 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. and move this sentence below the patient file section and bullets
Complete the patient file and place it in your shipper to be sent with the following elements:
• Impressions
• Protrusive Bite Registration and/or protrusion measurements.
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 when they do it at home not to bite into the splint to insert it on to 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 drills provided by ResMed Narval 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 other splint may get detached. 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 to establish if the patient uses the device at night.

To remove 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

Advice on first night usage
- The Narval device is a comfortable and non-invasive MRD, but it still requires a few nights to get accustomed to its use
- The first night with any oral appliance is likely to feel strange and foreign; advise the patient to persist with the device
- It is common for patients to experience some initial symptoms of tooth discomfort, jaw ache and hypersalivation. These mild symptoms generally resolve in time. If this discomfort persists recommend the patient to return to you. Check the occlusion and consider reducing the protrusion
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 his 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, replace the existing connectors with 1mm shorter connectors to increase treatment efficacy. Set up a subsequent follow-up appointment 1 or 2 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 to identify treatment efficacy on breathing parameters (apneas, oxygen desaturation, etc.) during sleep. A control 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 custom-made 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 equip your patient if he/she has insufficient anatomy (see page 13) for contraindications

2. Take impressions, bite registration and provide required data for manufacturing the mandibular splint (for detailed instructions on taking impressions for Narval CC, see page 14)

3. Send your completed order form, together with the above items, to your local ResMed Narval partner

Visit www.resmed.com/narval today or call 800-424-0737 to reach a dental specialist