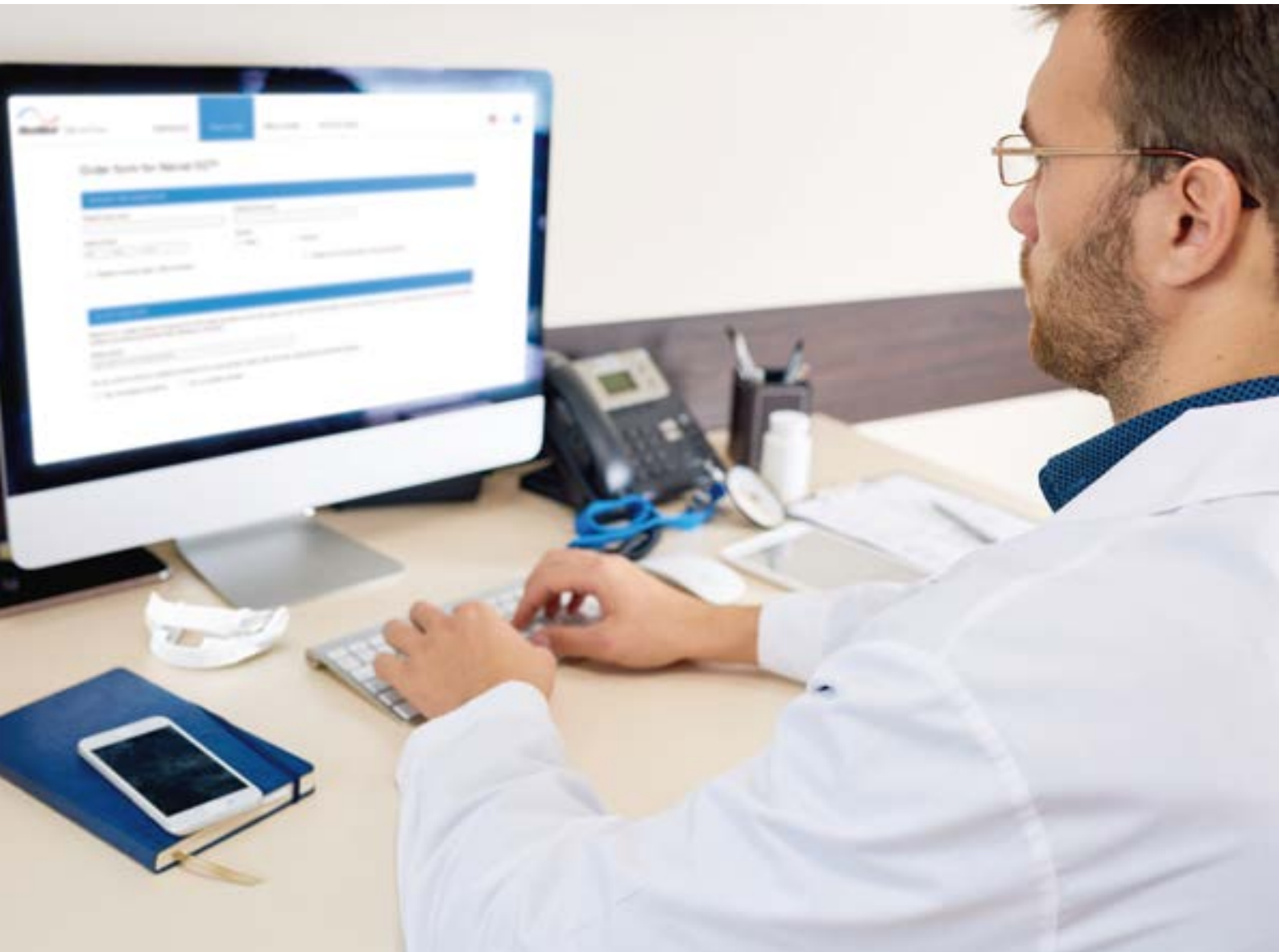




Narval CC™
Mandibular advancement device



Narval CC™ order guide

Step by step guide to order Narval CC Mandibular Advancement Device (MAD).

Introduction

Thank you for choosing the Narval CAD/CAM* oral appliance. This document provides qualified dental professionals with information about the care pathway for the Narval CC™ appliance. Please read it carefully before ordering the device.

Summary

Step 1: Device prescription

Step 2: Patient examination

Step 3: Dental impressions and ordering

3.1 Dental impressions

3.2 Protrusion setting specifications

3.3 Specific requirements for physical impressions

3.4 Specific requirements for digital impressions

3.5 Ordering

Step 4: Fitting and adjusting the device

Step 5: Device titration

Step 6: Sleep monitoring appointment

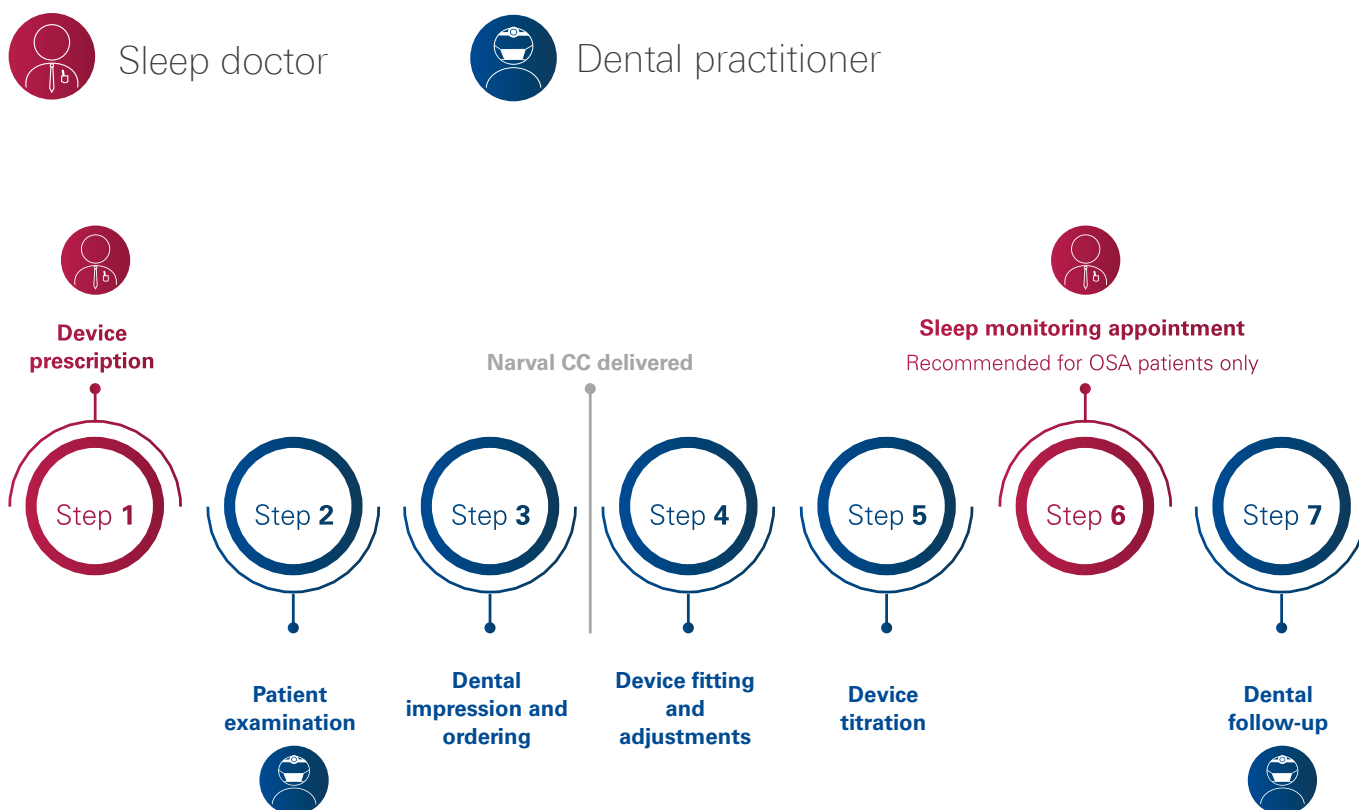
Step 7: Dental follow up



Care pathway with Narval CC

Treating a patient with the Narval CC appliance requires **pluridisciplinary cooperation between a sleep specialist and a dental practitioner**. The care pathway below summarises the main steps from prescription to device fitting and efficacy monitoring.

This guide details steps 1 to 3. For further details regarding steps 4 to 7, please refer to the professional instructions for use that are supplied with the Narval CC appliance.





Step 1 Device prescription

The Narval CC appliance is prescribed by a sleep specialist in accordance with the patient's diagnostic and treatment needs. The patient's diagnosis is conducted via a **polygraphy or a polysomnography that assesses obstructive sleep apnoea (OSA) severity according to OSA classification.**⁵

Pathologies	Primary snoring	Mild OSA	Moderate OSA	Severe OSA
AHI (Apnoea - Hypopnea Index)	< 5	5 to 15	15 to 30	> 30

The patient's AHI and daytime sleepiness are the two major indicators that help sleep doctors to choose the appropriate treatment. If the diagnostic result shows an AHI <5, a Narval CC appliance can be prescribed to treat snoring.

Indications

The Narval CC appliance is a custom-made mandibular advancement device (MAD), available under medical prescription and intended to treat adults with:

- mild to moderate obstructive sleep apnoea (OSA)
- severe obstructive sleep apnoea in the case of continuous positive airway pressure (CPAP) failure, non-compliance or refusal (second-line treatment)
- snoring.

General contraindications

The Narval CC appliance is contraindicated for patients who:

- Have central sleep apnoea
- Have severe respiratory disorders (other than OSA)
- Are under 18 years of age

AADSM recommendation statement¹

We recommend that sleep physicians consider prescription of oral appliances, rather than no treatment, for adult patients with obstructive sleep apnoea who are intolerant of CPAP therapy or prefer alternate therapy.

We recommend that sleep physicians prescribe oral appliances, rather than no therapy, for adult patients who request treatment of primary snoring (without obstructive sleep apnoea).



Step 2 Patient examination

Dental contraindications

The Narval CC appliance is contraindicated for patients who:

- Have loose teeth or advanced periodontal disease
- Have a completely edentulous lower arch unless a complete denture mechanically retained is present (e.g. retained by implants)
- Have a completely edentulous upper arch unless a complete upper denture is present
- Have short teeth and/or insufficient undercuts to retain the device.

Precautions

General examination

Prior to prescribing the Narval CC appliance to the patient, the dental practitioner shall check for relevant issues in the patient's medical history, such as respiratory disorders, asthma and breathing problems, allergies. Patients with any such problems should be referred to a qualified health professional before treatment.

It is necessary to perform a dental, periodontal, prosthetic and temporomandibular joint (TMJ) examination.

The following dental issues must be treated by a dental practitioner before MAD treatment:

- Periodontal disease
- Cysts and mouth ulcers
- Teeth that need to be extracted
- Prosthodontics - such as crown or bridge
- Orthodontics
- Temporomandibular joint pain needs to be further assessed by the patient's treating physician as well as any other TMJ disorder.

Anchoring value and retentive morphology

The dental practitioner shall check if the teeth (natural or dental implant) anchoring value and retentive morphology are sufficient to ensure the efficacy of the MAD without significant side effect of treatment.



Step 3 Dental impressions and ordering

Narval CC appliances can be ordered either using **physical impressions** (ResMed recommends using either silicone or alginate) or **digital impressions** (from an intra-oral scanner). In both cases, dental impressions and protrusion settings specifications must meet the requirements detailed below:

3.1 Dental impressions

The dental impressions must:

- Accurately depict both jaws.
- Include full sulcal depth (at least 5 mm to the margin).
- Include the most posterior tooth in each arch and, if possible, capture the distal surface, including third molars (if present).
- **Capture at least:**
 - For the upper arch**
 - 50% of the last present molars;
 - If all molars are missing, 100% of the second premolars AND 15 mm of soft tissue extension after distal.
 - For the lower arch**
 - 100% of the second molars AND 5 mm of soft tissue extension distal to them;
 - If second molars are missing, 100% of first molars AND 15 mm of soft tissue extension after distal.
- Capture details like occlusal surface textures, gingival margins, frenula and every bit of tooth shape, similar to a partial denture impression.
- Be taken with complete denture in place (if any), fully showing the limit of the denture in contact with the mucosa.
- If the patient has (a) partial denture(s):
 - If they wear it/them during the night, the impressions must be taken with the partial denture(s) in place. Please do not send the partial dentures to ResMed or authorised dental laboratory.
 - If they do not wear it/them during the night, the anchoring value of the remaining teeth must be sufficient. If the Narval CC appliance is not retentive enough, new impressions with the partial denture(s) in place could be requested, in which case the patient will need to wear the partial denture(s) every time the Narval CC appliance is used.

3.2 Protrusion setting specifications

ResMed also requires protrusion setting information to produce the Narval CC appliance. This information can be sent as a **bite registration in desired protrusion** or **measurements in maximum protrusion**.

Precaution:

According to the AADSM consensus report² for OSA management with MAD therapy, the minimum mandible advancement capability should be ≥ 5 mm in order to achieve optimal MAD efficacy. The patient's ability to advance the mandible can evolve over time, especially under MAD treatment. Additionally some patients with limited mandibular advancement before treatment initiation may benefit from MAD therapy. In any case, the dental specialist should assess the efficacy and safety of the treatment during follow-up appointments.

You may find it beneficial to have the patient move the jaw to maximum protrusion a number of times before taking your final measurements or bite recording.

If you have a doubt about maximum protrusion ability, you can ask the patient to open their mouth to the maximum. A rule of thumb indicates that:

maximum opening (in cm) $\times 2 \approx$ maximum advancement (in mm)

Option 1: Bite registration in desired protrusion

The initial mandibular protrusion of the Narval CC appliance will be set according to the bite registration provided.

- ResMed default option is to reduce the vertical dimension as much as possible, leaving a minimum of ~4 mm to allow proper design of the splints. If you would like this option, please tick **“Reduce the vertical dimension to the maximum (ResMed default option)”** on the order form.
- If you would like ResMed to reproduce the vertical dimension recorded by your bite registration, tick **“Reproduce the vertical dimension recorded by the bite registration”** on the order form. In this case, the bite registration must be at least ~4 mm thick to allow proper design of the splints. Remember to check posterior clearance and be careful of a deep curve of Spee or angled third molars as this may create clearance problems in protrusion
- Consider starting your patient’s therapy at approximately 60% of the maximum protrusive range, as long as it is comfortable for the patient. Narval CC has a wide range of adjustment so you do not need to begin with an aggressively protruded posture.

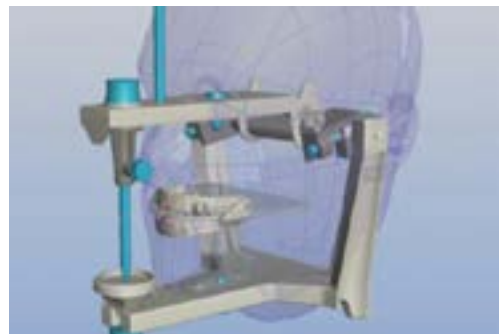
Option 2: Measurements in maximum protrusion

The initial mandibular protrusion of the Narval CC appliance will be set at approximately 60% of maximum advancement.

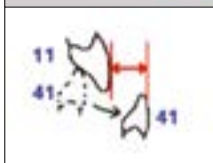
ResMed's CAD software includes a simplified model that simulates relevant mandibular movements based on the Quick Master B2 from Fag (France).

The vertical dimension will be minimised while ensuring no posterior contact during advancement.

Consider providing a bite in centric occlusion in case of special condition (prognathia, retrognathia) and/or unstable occlusion.



→ Measurements of maximum mandibular advancement

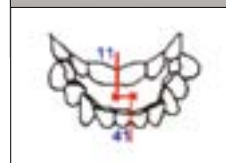
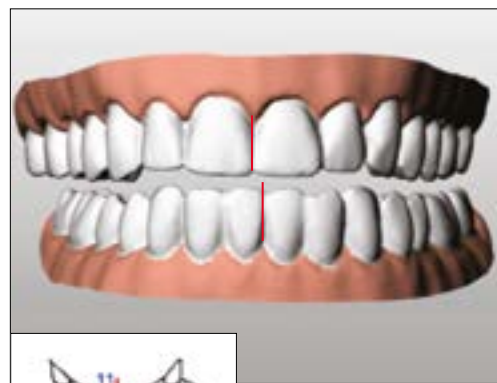


Maximum mandibular advancement as depicted on the order form.

Measure with a ruler and indicate your patient's maximum mandibular advancement from the middle of the facial surface of tooth 11 to the middle of the facial surface of tooth 41.

To do this, ask the patient to move the lower jaw as far forward as possible.

→ Measurements of lateral deviation



Lateral deviation to the patient's left as depicted on the order form.

Measure and indicate any lateral deviation of the mandible in maximum protrusion on the order form (midline deviation, in mm).

3.3 Specific requirements for physical impressions

The more precise the impressions, the more comfortable the appliance will be for your patient. If an impression is damaged, inadequate or inaccurate, the appliance will not provide proper fit and retention.

The packaging for every Narval CC appliance made from physical impressions includes a transportation box specifically designed to help protect the impressions of your next order. The cardboard transportation box and plastic bags help to protect the shape and precision of the impressions during transit and reduce the risk of damage caused by variations in humidity levels.

If you use alginate for your analog impressions, you shall send them out within 24 hours and no later than Thursday to prevent damage during transportation in the week-end.

Please disinfect your impressions and bite registration(s) before shipment.

Note: Impressions may be discarded following the production process.



Tips and tricks:

- Consider using Rim-Lock® impression trays which allow for full impression of the gingival sulcus and posterior molar area.
- Consider using the double-mix impression technique with two impression materials of PolyVinyl Siloxane (PVS) with different viscosity (low and high).
- Ask the patient to rinse their mouth with water to remove excess saliva.
- Dry occlusal surfaces.
- Choose the most appropriate impression material. ResMed recommends silicone for long distance and/or weekend transportation. Consider using a high quality silicone impression material, as you would for making a crown or bridge impression, allowing for multiple pours.
- Alginate should only be used for short distance transportation. If using alginate impression material, please use a tray adhesive and/or a specific impression tray intended for use with alginate.

Examples of good impressions



Upper

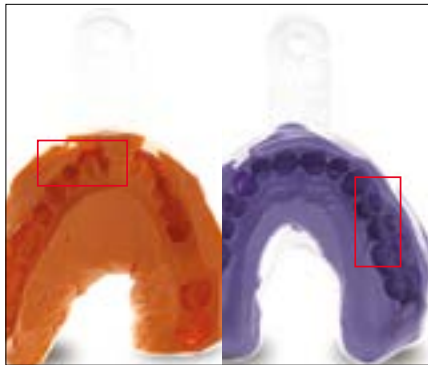


Lower

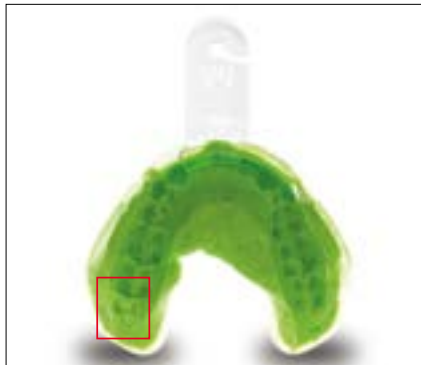
A complete, well defined upper and lower impression of all visible teeth, especially the molars. Each tooth is well defined with at least 5 mm of material beyond the gingival margin. A good homogeneous mixture of the material:

- no powder, bubbles or colour differences
- no deformation, pulls or tears
- no delamination from the tray

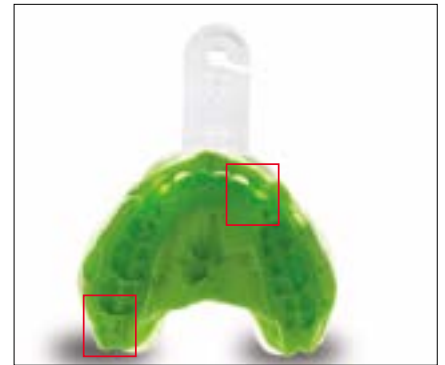
Examples of unusable impressions ✘



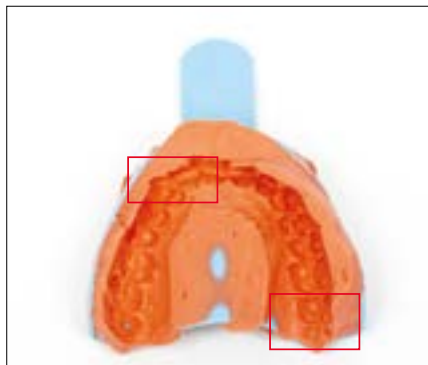
Deformation of the impression due to insufficient setting time of the material.



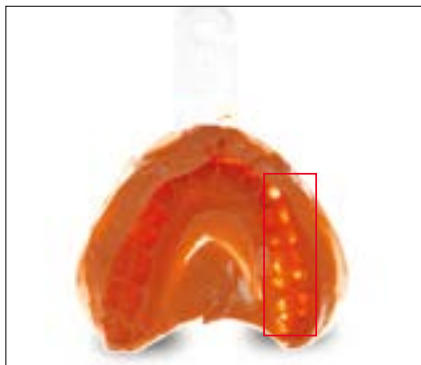
The gingival margins are not visible and a portion of a tooth is missing.



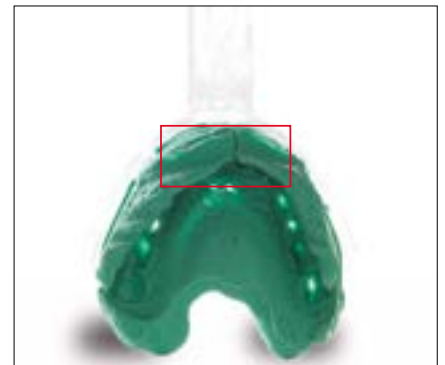
The impression was moved before the material had time to set, causing significant deformation in the anterior region.



The impression shows a lack of depth and width of material and the impression failed to capture the posterior molar.



The impression material was not mixed properly and shows evidence of bubbles and lack of material in the tray.



The impression material is delaminating from the tray.

Plaster models

Plaster models must comply with the requirements laid out in this Narval CC order guide. In case of renewal, ResMed will be able to use the previous models as long as they are less than 2 years old and no dental modifications (new crowns, restorations, missing teeth, etc.) have occurred in the meantime. In all other cases, you should send new impressions or models.

If you send plaster/stone models, please:

- Only use a Type IV high strength material, low expansion crown and bridge die stone that produces smooth, hard and accurate surfaces.
- Use light-coloured matt plaster that can be scanned by CAD/CAM systems.
- Prepare the plaster model in order to:
 - ensure that all the teeth can be read by the scanner used by our production facility
 - provide accurate details (e.g. remove bubbles).

Bite registration in desired protrusion

- The patient's bite registration in the desired protrusion can be supplied in a material of your choice. Consider using a positioning device, like a ProGauge or George Gauge, with a heavy body or fast-setting silicone (PVS) bite registration material. ResMed does not recommend using wax as it distorts easily.
- Please disinfect bite registrations before sending them to ResMed or your dental laboratory.



A plaster model in centric occlusion



The same model with the bite recorded with a George Gauge in desired protrusion

3.4 Specific requirements for digital impressions

If you have an intra oral scanner and you want to use the fully digital Narval CC ordering process, please contact your local ResMed representative or ResMed customer service to check that your scanner is compatible. We will provide you with information for ordering a Narval CC appliance from digital impressions through the Narval Easy platform.



3.5 Ordering

Narval CC appliances can be ordered using a traditional ResMed paper order form or digitally through the Narval Easy platform (except if ordering via an authorized dental laboratory).

You will be asked to enter all necessary information on the prescription order form, including your patient's identification, the desired protrusion settings, dental particularities and any other relevant design option, your practice address and contact details. Comments and additional information should be provided in English or French only. Please ensure that you sign and date the order form.

Please make sure that you inform your patient, and he/she agrees, that his/her personal data will be processed by ResMed. You'll be asked to report his/her consent on the order form.

→ If you order online through Narval Easy



Create your personal account on our Narval Easy registration page available from ResMed.com/NarvalEasy.

Once you've created your account, you will be able to:

- Place your Narval CC orders online
- Track your Narval CC orders and follow their status in real time
- Store your patients' data in a secure platform*
- Record your notes related to each appointment with your patient
- Record your clinical evaluations at each step of the titration process
- Share your patients records and related documents with your patients' sleep doctors

You can use the online ordering process whether you use an intra-oral scanner** or traditional physical impressions. Before placing your first order you will be asked to sign a data processing agreement to comply with the European General Data Protection Regulation.

If you use an intra-oral scanner that's compatible with Narval CC ordering**

- Send your scan via your scanner and then place your order on Narval Easy with your scan ID reference. For detailed information about how to use your IOS to order Narval CC, please refer to the Narval CC IOS guide available at ResMed.com/NarvalEasy.

If you use traditional, physical impressions or plaster models:

- Place your order on Narval Easy and print the generated confirmation PDF with a QR code on it. Send your disinfected physical impressions (and bite registration, if applicable) or models together with the order confirmation to ResMed SAS, Parc Technologique de Lyon, 292 allée Jacques Monod, 69791 Saint-Priest, FRANCE.

→ If you order using a traditional paper order form

Always use the latest order form to ensure that the most up-to-date information is recorded and sent to the production facility. Ask your Narval representative for it.

Send your paper order form with the disinfected impressions (and bite registration, if applicable) or models to the address provided on the back of the order form.

Important

The Narval CC appliance will be designed on the basis of your expert input and the specific needs of your patient. In order to optimise the design of your patient's appliance, please ensure you provide all relevant information on the Narval CC order form.









*Narval Easy was built to be secure and is hosted by a third-party company that holds the stringent French ASIP Santé certification as well as the ISO 27001 certification to host medical data.

**For a list of compatible scanners, please see the Narval CC IOS user guide available at ResMed.com/NarvalEasy

Focus on design preferences

This section on the order form allows you to select specific design variations according to your patient's morphology. The variations cover a broad range of patient needs and anatomical constraints as band design plays an important role in the fit, comfort and retention of the device.

The following Narval CC design guide will help you select the appropriate design for your patients:

		Morphology						Objective		
		Low retentive canines & molars (short or no undercut)	Proclined or highly retentive incisors	Retroclined incisors	Significant overbite	Significant overlap of the incisors	Frenulum close to gingival margins	Reduce tongue pressure on incisors	Maximise tongue space	Encourage anterior teeth alignment ³
WITHOUT ANTERIOR CONTACT	Facial band 			●	●	●			●	
	Facial band with cap 	●		●					●	
	Incisor full coverage 	●						●		
	Palatal/lingual band with cap 	●	●				●	●		
	Palatal/lingual band 		●		●	●	●			
WITH ANTERIOR CONTACT	Facial band with cap 	●	N/A	●					●	●
	Incisor full coverage 	●	N/A	N/A				●		●
	Palatal/lingual band with cap 	●	●	N/A				●		●

Important

Without any design specification, ResMed will select the design for you, prioritizing a non-contact facial band design or a non-contact full coverage design in case of low retention.

If you choose a specific design, ResMed will try to comply with your preference but might need to switch to a full coverage design in case of low retention.

Focus on anterior contact option

Three of the designs are also available with contact on the facial and lingual surfaces of the incisors. This option can be used in case of low retention, as it increases surface contact with the teeth. It can also be used to help maintain anterior teeth alignment into the splints (see above table).³ Whatever design you choose, the appliance does not take retention from the anterior teeth.

If you choose a design with anterior contact and we are not able to comply with your request, our technical support team will contact you and propose alternative design options.

Focus on vertical dimension and molar coverage

Following the AADSM report, the Narval CC appliance default design will prioritise comfort for the patient by minimising the vertical dimension and bulk of the device.

For this reason, the Narval CC appliance default design will not cover all of the molars, especially if canines and premolars are retentive enough to decrease the vertical dimension and bulk of the device. By default, the splints will be designed as follows:

- On the upper, we will cover up to tooth #6
- On the lower, we will cover up to tooth #7

In case of low retentive morphology it may be necessary to cover more posterior teeth in order to increase retention.

If this default choice does not fit your needs, you can request that we cover all of the molars by ticking the relevant box on the order form.

AADSM report⁴

*Vertical adjustability has been a controversial subject in the design of oral appliances. Despite anecdotal reports of patients benefiting from an increased vertical dimension, **several studies suggested that increased vertical dimension, measured as inter-incisal distance, resulted in decreased patient acceptance and had no consistent impact on efficacy.***

Focus on patient-specific dental particularities

If your examination shows that your patient has any of the following dental conditions, please specify this on the order form:

Teeth to protect:

ResMed will design the splint such that it does not take retention on the specified tooth / teeth. Please note that protecting too many teeth can affect the device's retention capacity.

Complete lower denture mechanically retained (e.g. by implants):

A complete lower denture is not a contraindication if it is mechanically retained (e.g. by implants). Please record the impression of the arch with the denture in place.

Complete upper denture:

A complete upper denture is not a contraindication. Please record the impression of the arch with the denture in place.

Presence of removable partial denture(s):

If the patient wears a removable partial denture during the night, dental impressions must be recorded with the removable partial denture in place. In that case, a specific design shape will be created to use the retention provided by the partial denture and allow the device to be clipped on to the edges of the denture. Please do not send the partial dentures to ResMed or authorized dental laboratory.

If the patient does not wear the removable partial denture during the night, please ensure that the anchoring value and morphology of the remaining teeth are sufficient.

Receiving the Narval CC device

When you receive your patient's Narval CC appliance, make sure to remove the professional instructions for use from the packaging as this document is intended for you only. The professional instructions for use must be carefully read as they contain important warnings and precautions and provide you with information about fitting and adjustment, titration, follow-up, cleaning, and the warranty.

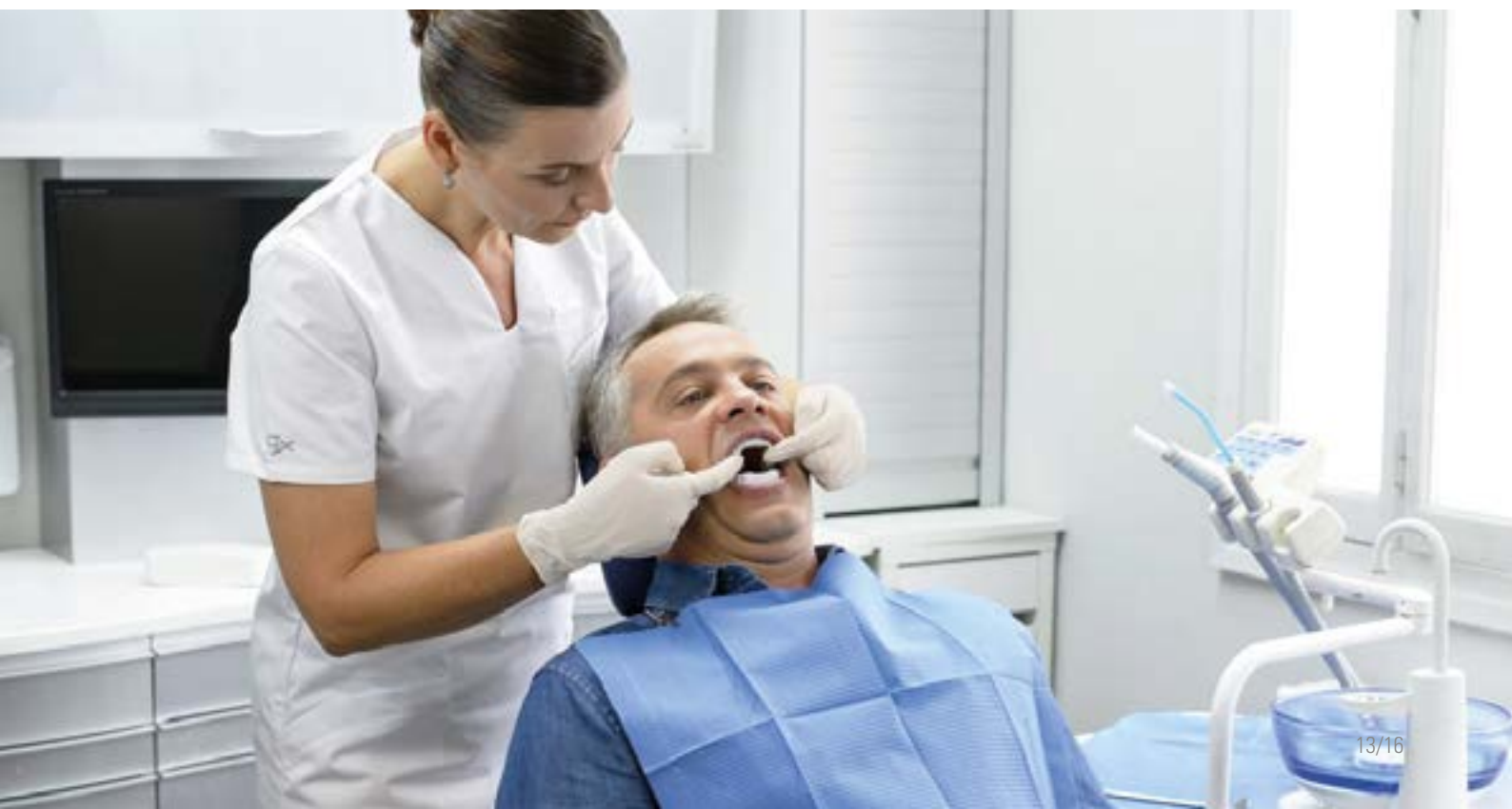
The following pages provide an overview of the next steps of the care pathway. Detailed information on these steps is available in the professional instructions for use, which are delivered with each device.

Step 4 Fitting and adjusting the device

The first fitting in mouth must take place under the supervision of a dental practitioner.

If necessary, you can add or remove some retention from the Narval CC appliance by making small incremental adjustments to the device. You can also adjust lateral deviation, adjust the balance of the slip plane or add elastic bands. It is also necessary to verify the initial protrusion of the Narval CC.

For detailed instructions on the fitting, adjustment process and the verification of the initial protrusion please refer to the professional instructions for use.





Step 5 Device titration

Titration is the process of adjusting the protrusion of the device and the mandible to find the best balance between efficacy and comfort. MAD therapy has a well proven non-linear dose response to the level of protrusion until the efficacy plateau is reached. This means that the greater the protrusion, the more efficient the Narval CC appliance will be (up to a limit - the efficacy plateau). However, as the protrusion increases, the pressure on the teeth and TMJ also increases, making the MAD less comfortable for the patient.

For detailed instructions on the titration process, please refer to the professional instructions for use.

A European Respiratory Society Task Force recommend

that the device should be custom made, evaluated and advance the mandible at least 50% of maximum protrusion. A titration procedure is essential⁴.



→ Follow-up your patient's titration on Narval Easy

If you order online via the Narval Easy platform, you will be able to record your clinical evaluations after each appointment with your patient all along the titration process:



When fitting the device

You can record your notes from the device fitting appointment:

- Patient symptoms: snoring, morning tiredness, daytime sleepiness, number of awakenings and discomfort evaluation
- Device's initial protrusion settings for easier follow up
- Connecting rod size at treatment initiation

At the various device titration appointments

You can create as many titration appointments as necessary until you consider that patient's titration is optimised and at each step:

- Evaluate patient symptoms and comfort in order to compare with previous results
- Record new protrusion settings and connecting rods size

→ Choose to communicate with your patient' sleep doctor when device titration is optimised.

Once you consider that the titration is optimized based on your clinical evaluation you can tick the 'Titration over' box in order to notify your patient's sleep doctor. You can also add a note for him to be informed whether there is potential to perform additional titration in case the objective sleep test performed by the sleep doctors shows insufficient efficacy of the device on AHI.





Step 6 Sleep monitoring appointment

- For OSA patients, objective monitoring from a sleep doctor is recommended to ensure that they keep being efficiently treated from their MAD therapy.
- The evaluation of the efficacy of their Narval CC appliance will be monitored via an objective sleep test (PG or PSG).
- The results might lead to a new titration follow-up appointment with the dental practitioner if treatment efficacy is not sufficient.

If you chose to order online via Narval Easy, you will be able to share data with your patients' sleep doctors. Sleep doctors will also be able to share their patient's monitoring results with you. To do so, connect with your patient' sleep doctor when placing your order on Narval Easy and you will have a common view on your patient's records.

AADSM recommend

that sleep physicians conduct follow-up sleep testing to improve or confirm treatment efficacy, rather than conducting follow-up without sleep testing, for patients fitted with oral appliances¹.



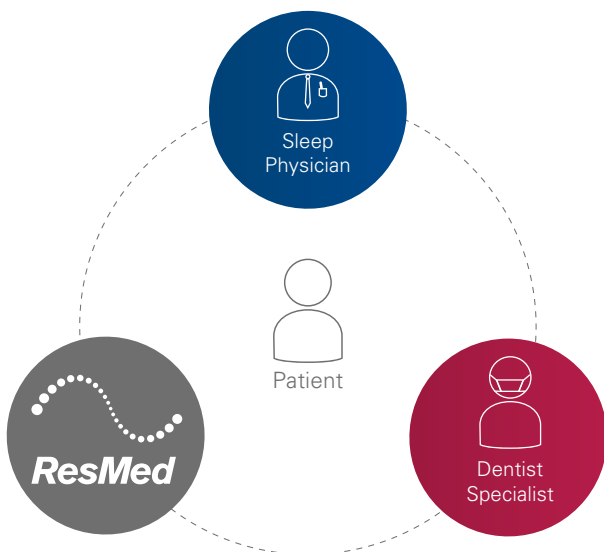
Step 7 Dental follow up

- Once the titration process is complete, it is important to schedule regular follow-ups with the patient to assess potential side effects and ensure treatment efficacy and safety in the long term.
- For OSA patients, if a satisfactory improvement in symptoms and an objective sleep recording validation cannot be achieved after titration, discuss about alternative treatments with your sleep specialist partner.

If you have Narval Easy account allows you will be able to record your notes and clinical evaluations at each follow up appointment in order to compare your results and MAD fittings from previous years.

AADSM recommend

that dental follow-up must be carried out under the supervision of a qualified dentist. Follow-up of oral appliance therapy in adult patients with obstructive sleep apnoea is required to survey for dental-related side effects and occlusal changes and reduce their incidence¹. We suggest that sleep physicians and qualified dentists instruct adult patients treated with oral appliances for obstructive sleep apnea to return for periodic office visits—as opposed to no follow-up—with a qualified dentist and a sleep physician.





Contact your local ResMed representative or Narval customer service

For more information, visit ResMed.com/Narval

References

- 1 Ramar K et al. Clinical Practice Guideline for the Treatment of Obstructive Sleep Apnoea and Snoring with Oral Appliance Therapy. An Update for 2015: An American Academy of Sleep Medicine and American Academy of Dental Sleep Medicine Clinical Practice Guideline. *Journal of Clinical Sleep Medicine (JCSM)* Official Publication of the American Academy of Sleep Medicine. 2015;11(7):773-827.
- 2 Scherr SC et al. Definition of an effective oral appliance for the treatment of obstructive sleep apnoea and snoring: a report of the American Academy of Dental Sleep Medicine. *Journal of Dental Sleep Medicine* 2014;1(1):39-50.
- 3 Anterior contact European Controlled Product Launch (CPL). ResMed Internal Report C247130 – September 2017 – 86% of the dental sleep experts chose the anterior contact option with the intent of preventing MAD-related tooth movements.
- 4 Marie Marklund et al. Non-CPAP therapies in obstructive sleep apnoea: mandibular advancement device therapy. *European Respiratory Journal* 2012 39: 1241-1247; DOI: 10.1183/09031936.00144711 (ERS Task-force report)
- 5 Sleep-related breathing disorders in adults: recommendations for syndrome definition and measurement techniques in clinical research. The Report of an American Academy of Sleep Medicine Task Force. *Sleep*. 1999;22(5):667-689.