



RESPIRE
breathe easy again

Sleep Devices

by **DynaFlex®**

Doctor

Instructions & Information

Package Contents

- a. Snoring / Sleep Apnea Device**
- b. Protective Case**
- c. Bite Repositioner**
- d. Patient Instructions Handbook**
- e. Upper and Lower Patient Molds**
- f. Bite Registration**
- g. Titration Screw Key (Blue / Pink)**
- h. Allen Key (Pink)**
- i. AT Titration Key (Pink AT)**
- j. Doctor Instructions Handbook**
- k. (A-d for Patient Use)**

Put your office information on the back of

- d. Patient Instructions Handbook**

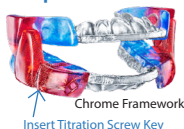
Give the Package Content **a. - d.**
to the patient, explaining **d.**

Respire Blue Series

Respire Blue+



Respire Blue EF+



Insertion

1. Place upper component gently onto the upper teeth by hand. Press up to ensure plate is seated securely and fits comfortably.
2. Place lower component gently onto the lower teeth by hand. Guide the lower jaw forward to ensure the plate is seated securely and fits comfortably.
3. Gently close the patient's mouth once the upper and lower components are seated fairly in place. Make sure the devices occlusal planes are in even contact throughout the arch.

Titration

Insert the titration screw key into the hole of the screw. Turn in the direction of the arrow. One quarter (1/4) turn is equal to the 0.2mm. Maximum advancement is 6mm = 30 quarter turns. Do not titrate over 6mm. **Titrating the device to the maximum may cause the wing to become loose.*

Fitting Surfaces

Two (2) types of fitting surfaces for Respire Blue+

1. **Hard/Soft Device** - Dual laminate layer that provides a soft layer on the tooth surface.

Adj. (mm)	0.2	0.4	0.8	1.2	1.6	2.0	2.4	2.8
Turns: 90°	1	2	4	6	8	10	12	14
Adj. (mm)	3.2	3.6	4.0	4.4	4.8	5.2	5.6	6.0
Turns: 90°	16	18	20	22	24	26	28	30

**1 Turn
=
0.2mm**

2. Hard Device - All acrylic and retained with ball clasps; allows the device to be tightened if it becomes loose.

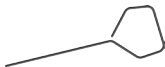
One (1) type of fitting surface for Respire Blue EF+

Hard EF Device - The EF is retained with "C" clasps. The tip of the clasp can be curved towards the tooth for greater retention.

Fitting surface adjustment

When adjusting the acrylic material it is recommended that a heat resistant bur is used. For the major adjustments the device may have to be remade. *Please contact DynaFlex for more details.*

*Titration Screw
Key (Blue/Pink)*



Allen Key (Pink)



*AT Titration Key
(Pink AT)*



Respire Pink AT Series

Respire Pink AT

Insert Titration
Screw Key



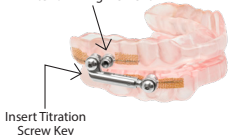
Respire Pink AT EF

Insert Titration
Screw Key



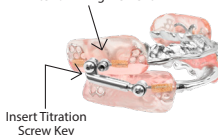
Respire Pink AT Micro

Anterior Fixing Element



Respire Pink AT EF Micro

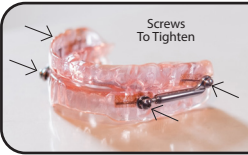
Anterior Fixing Element



Insertion

- 1. Place upper component* gently onto upper teeth by hand. Press up to ensure plate is seated securely and fits comfortably.
**Before giving the device to the patient, please double-check to ensure that the screws are tight.*
- 2. Place lower component* gently onto lower teeth by hand. Press down on both sides to ensure plate is seated securely and fits comfortably.
- 3. Gently close the patient's mouth once the upper and lower components are seated firmly in place. Make sure the device's occlusal planes are in even contact throughout the arch.

**Serial number indicates the lower component of the device.*



****The screws should be tightened periodically, using the Allen key / AT titration key provided.***

When tightening a screw, **stop turning the Allen key / AT titration key as soon as you feel resistance. The screws should be checked for tightness during every doctor visit.** Please follow these instructions carefully to avoid stripping the screw, and having them become loose.

AT Turns (360°)		1	2	4	6	8	10
Adjustment (mm)	0.0625	0.25	0.5	1.0	1.5	2.0	2.5
Turns (90°)	1	4	8	16	24	32	40
1 Turn = 0.0625mm	Micro Screw Change						

How to Replace Arms

1. Using the Allen key, unscrew all four (4) screws in order to remove the old arms from the device. In the case of the lower portion of the device does not slide forward in a smooth manner (excluding Pink AT / Pink AT EF). *Using a pair of pliers, slightly bend all four (4) eyelets of the new arms inwards towards the direction of the fixing elements. Creating this curvature of the eyelet allows the upper and lower trays of the device to smoothly move protrusively past each other.*
2. Using the Allen key, screw all four (4) screws of the new arms onto the device.
3. Slide the upper and lower trays of the device protrusively past each other to confirm smooth movement of the arm stroke mechanism.
4. If the movement is not smooth enough, repeat steps 2 & 3.

Titration

To titrate the device, place the titration screw key into hole. Turn in the direction of the plus (+) sign. A 90 degree (quarter) turn is equal to 0.0625mm. Four (4) quarter turns are equal to 0.25mm and 16 quarter turns are equal to 1mm. Maximum advancement is 5mm = 80 quarter turns. Do not titrate over 5mm.

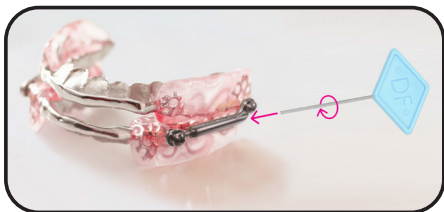
Pink Micro Titration

The micro arm will advance up to 3mm. For further titration once fully advanced, unscrew the arm from the fixing element on the upper device using the Allen key. Then turn the adjustable component on the arm back to the starting point (zero turns). Finally, using the Allen key, connect the arm to the anterior fixing element on the upper device. An additional 3mm of advancement can be made from this point. Maximum advancement per arm is 3mm = 48 quarter turns. Do not titrate over 3mm.

12	14	16	18	20	22	24	26	28
3.0	3.5	4.0	4.5	5.0	5.5	6.0	6.5	7.0
48	56	64	72	80				
0	8	16	24	32	40	48		

Pink AT Titration

Insert the AT titration key into the rear of the hinge attached to the device to adjust the mandibular advancement. Turning counterclockwise once, 360 degrees, extends the length by .025mm. Turning 4 times extends by 1mm. The maximum advancement is 7mm. *Do not titrate over 7mm.*



*Titrating the device to the maximum may cause arm to bend when the patient bruxes.

Fitting Surfaces

Two (2) types of fitting surfaces for Respire Pink AT and the Respire Pink AT Micro

- 1. Hard/Soft Device** - Dual laminate layer that provides a soft layer on the tooth surface.
- 2. Hard Device** - All acrylic and retained with ball clasps; allows device to be tightened if it becomes loose.

One (1) type of fitting surface for Respire Pink AT EF and the Respire Pink AT EF Micro

Hard EF Device - The EF is retained with "C" clasps. The tip of the clasp can be curved toward the tooth for greater retention

Fitting Surface Adjustment

When adjusting the acrylic material it is recommended that a heat resistant bur is used. For major adjustments the device may have to be remade. Please contact Respire Medical for more details.

Device Description

Each device is custom-made and consists of two (2) acrylic dental plates, or in the case of the EF device, two (2) acrylic and chrome dental plates (upper and lower). The attachments on the devices enable advancement of the device. EF Stands for “Endurance Framework”, which is chrome - made for extra durability.

Indications For Use

Our devices are indicated to treat mild to moderate Obstructive Sleep Apnea (OSA) in patients 18 years of age or older.

Contraindications

Device is contraindicated for patients who:

- Have Central Sleep Apnea
- Have severe respiratory disorders
- Have advanced periodontal disease
- Are under 18 years of age
- Are allergic to Acrylic (Methyl Methacrylate)
- Are allergic to metal, such as Nickel and Chrome (Wironit; EF devices only)

Precautions

The dentists should consider the medical history of the patient, including history of asthma, allergies, breathing or respiratory disorders, or other relevant health problems. Please refer the patient to the appropriate healthcare provider before prescribing the oral device. During the first few weeks some of the following discomforts may be experienced, but will dissipate after consistent usage: Slight tooth discomfort, jaw muscle pain, and excessive salivation may occur.

Warnings

We recommend the patient have a check-up after 10-14 days of using the device, and every 6 months to ensure a proper fit of the device. The patient should stop using the device if she is experiencing any of the below conditions.

Use of these devices may cause:

- Tooth movement or changes in dental occlusion
- Gingival or dental soreness
- Pain or soreness to the temporomandibular joint
- Obstruction of oral breathing
- Excessive salivation

Prescribing The Oral Device

CAUTION: Federal law restricts this device to sale by or on the order of a dentist licensed by the State law in which he/she practices to use or order the use of the device.

Special Notes:

1. Patients should inspect the device for signs of wear, and any concerns should be brought to the attention of the prescribing practitioner.
2. Device should not be soaked in any liquid for longer than five (5) minutes.
3. For Respire Pink Series devices, the attachment screws should be tightened at each patient follow up visit to avoid the screw becoming loose.

WE DO NOT RECOMMEND GIVING THE ALLEN KEY, TITRATION SCREW KEY, OR AT TITRATION KEY TO THE PATIENT.



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