MATRx™
Titration Tray Manual

Caution: Federal law restricts this device to sale or on the order of a licensed dentist or practitioner.

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1.877.341.8814 | www.zephyrsleep.com

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MATRx™ Titration Trays | For Use with OATRx™ Software
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SYMBOLS

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Name</th>
<th>Symbol Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>⚠️</td>
<td>Warning</td>
<td>The Warning symbol indicates the possibility for patient injury or harm.</td>
</tr>
<tr>
<td>🚫</td>
<td>Caution</td>
<td>The Caution symbol indicates the need to consult accompanying documents. Attention, see instructions for use.</td>
</tr>
<tr>
<td>💡</td>
<td>Consult Instructions</td>
<td>The Consult Instructions symbol indicates information that may require further instructions.</td>
</tr>
<tr>
<td>📜</td>
<td>Information</td>
<td>The Information symbol indicates important information to help the operator/technician complete a procedure or task correctly.</td>
</tr>
<tr>
<td>🔴</td>
<td>Do Not Reuse</td>
<td>The Do Not Reuse symbol indicates the accessories that are single patient multi-use for one study only.</td>
</tr>
<tr>
<td>🟢</td>
<td>Type B</td>
<td>Type B APPLIED PART.</td>
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</tbody>
</table>
INTENDED USE

Overnight use of a temporary oral appliance to determine in which patients with obstructive sleep apnea mandibular advancement by an oral appliance will reduce obstruction of airflow and thereby to identify patients suitable for oral appliance therapy. The device is also used to recommend a target mandibular position that will reduce obstruction of airflow in patients determined to be suitable for oral appliance therapy.

CONTRAINdications

This device is for diagnostic purposes only and is not to be used as an apnea monitor or in a life supporting or life sustaining situation. This device is contraindicated for use in patients who:

• Have central sleep apnea
• Have severe respiratory disorders
• Have loose teeth or advanced periodontal disease
• Have full dentures or dental implants
• Are under the age of 18

WARNINGS

1. Federal law restricts this device to sale by or on the order of a licensed practitioner.

2. Healthcare professionals (i.e., sleep physicians and 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. Use of the device 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

3. Titration Trays are disposable and are single patient multi-use for one study only. Do not re-use, re-process or sterilize. Re-use may result in injury to the patient and inaccurate assessment results.

4. Titration Trays are specialized impression trays for use with the Titration System and are not to be used for any other purpose.

CAUTIONS

Only use with Zephyr Sleep Technologies Inc. approved parts and accessories. Failure to use Zephyr approved parts and accessories will void the warranty.

SPECIFICATIONS

Impression Material

Titration Trays are only to be used with Henry Schein® Blu-Bite HP Fast Set with vinyl polysiloxane (P/N 102-3597). See manufacturer’s instructions for use and product specifications.
Titrination Trays

Dimensions:

<table>
<thead>
<tr>
<th>Components</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attachment Point</td>
<td>For attaching the Lower Tray to the Mandibular Positioner</td>
</tr>
<tr>
<td>Scale Indicators</td>
<td>For determining measurements when used in conjunction with the Upper Tray OATRx Scale</td>
</tr>
<tr>
<td>Guide Rails</td>
<td>For connecting the Lower Tray to the Upper Tray</td>
</tr>
<tr>
<td>Incisal Groove</td>
<td>To aid in positioning the lower incisors in the center of the Lower Tray</td>
</tr>
<tr>
<td>Impression Material Cavity</td>
<td>Cavity for holding impression material</td>
</tr>
<tr>
<td>Tray Label</td>
<td>To indicate the size and orientation of the Lower Tray</td>
</tr>
<tr>
<td>Trim Lines</td>
<td>To guide trimming of the Lower Tray</td>
</tr>
<tr>
<td>Tray Attachment Pin</td>
<td>For securing the Lower Tray to the Mandibular Positioner</td>
</tr>
</tbody>
</table>

Tray Materials: Trays are made from virgin polypropylene, an FDA-approved material.

Conforms to 21 CFR 178.2010, 21 CFR 177.1520

PACKAGE CONTENTS

<table>
<thead>
<tr>
<th>Part</th>
<th>Catalog #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Titrination Tray Kit (Medium)</td>
<td>CTR-0000002-00</td>
</tr>
<tr>
<td>Titrination Tray Kit (Large)</td>
<td>CTR-0000002-01</td>
</tr>
<tr>
<td>Tray Attachment Pins</td>
<td>CTR-0000001-00</td>
</tr>
<tr>
<td>Titrination Tray Manual</td>
<td>CDC-0000004-00</td>
</tr>
<tr>
<td>Patient Brochure</td>
<td>CDC-0000005-00</td>
</tr>
<tr>
<td>Patient Assessment Card</td>
<td>CDC-0000006-00</td>
</tr>
</tbody>
</table>
TRAY SETUP AND FITTING

MATRx Titration Trays can be set-up and fit by a dentist or a healthcare/dental professional that has been trained by a dentist to perform tray fitting. When a trained professional is fitting the trays, the patient must complete the MATRx Titration Tray Fitting Pre-Screening Questionnaire.

Tray Cleaning: Prior to Use
1. Upon removal of the tray packaging, rinse the trays under cold tap water.
2. Inspect the trays; if any tray appears damaged or is not visibly clean, quarantine the tray and contact Zephyr at 1.877.341.8814.

Tray Selection
Tray selection should be based on the smallest tray that fits well around the teeth, without binding or fitting loosely, and minimizes encroachment within the lingual space. If either tray is too long, tray trimming will be required prior to taking impressions.

Tray Labels
On each tray, a label can be found in the impression material cavity that denotes the size and orientation of the trays.

### Components

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<tr>
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<tbody>
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<td>OATRx Scale</td>
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Taking an Impression

1. The Upper Tray impression should always be taken first. Fill the Upper Tray with impression material and place onto the maxilla. Ensure the upper incisors are positioned midline and deep within the tray’s Incisal Groove and push the tray firmly around the teeth.

2. Allow the impression material to set (i.e. 30 seconds) and then slowly remove the Upper Tray.

3. Trim excess impression material from the Upper Tray (see next section).

4. After trimming is complete, connect the Upper Tray, with trimmed impressions, to the Lower Tray. Ensure both trays slide back and forth easily and all surfaces are smooth.

5. Before taking impressions of the Lower Tray, place the trimmed Upper Tray back into the patient’s mouth and confirm tray fit and patient comfort. Remove the trays, verifying adequate retention.

6. Fill the Lower Tray with impression material and place both trays into the patient’s mouth. Fit the Upper Tray onto the maxilla and instruct the patient to bite down gently into the Lower Tray. Check for adequate bite depth and midline positioning of the lower incisors within the tray’s Incisal Groove, and confirm patient comfort.

7. Allow the impression material to set and then slowly remove the trays.

8. Disconnect the trays and trim excess impression material from the Lower Tray (see next section). After trimming is complete, connect the Upper Tray to the Lower Tray and ensure both trays slide back and forth easily and all surfaces are smooth.

Recording the Reference Number

The reference number represents the tray’s edge-to-edge position and is determined by positioning the Incisal Grooves from the Upper and Lower Trays directly over one another and taking the OATRx Scale reading at this position. Record this number in the patient’s record to assist with fabrication of a custom oral appliance.

Trimming the Trays

Prior to taking impressions, trim the molar ends of each tray to ensure the trays do not extend beyond the last half of the most posterior tooth, in each quadrant. A series of Trim Lines are positioned on the molar ends of each tray to guide this trimming procedure. Correct tray trimming should prevent tissue impingement and allow the patient to comfortably achieve maximum protrusion.

Filling the Trays

Trays have been designed specifically for use only with Henry Schein® Blu-Bite HP Fast Set impression material.

For directions and guidance on making impressions with Henry Schein® Blu-Bite HP Fast Set please see manufacturer’s guidelines.
Signs of a good impression and proper tray size:

• Maximum bite into each tray
• Minimal areas of show through
• Minimum amount of impression material left in the tray
• Patient’s midline is aligned with the tray midline

Trimming the Impressions

The trays will be used in a supervised dental titration and assessment study, which can be up to 8 hours in length, therefore optimal tray comfort and fit is important. Trimming excess impression material from each aspect of the trays should result in the following:

• Lingual aspect of the tray: Maximizes space for the tongue.
• Bottom surfaces of the trays: Ensures the trays will slide back and forth easily.
• Side surfaces of the trays: Maximizes tray comfort, however be careful not to over-trim the material from the retention grooves.
• Distal ends of the trays: Prevents tissue impingement and ensures maximum retrusion and protrusion. Ensure material is flush with the ends of each tray.

Trimming of the vestibular edges is not required since this excess impression material should make the trays more comfortable.

Once trimming is complete, ensure all surfaces are smooth.

Ensure the Lower Tray Guide Rails and surface of the Upper Tray’s OATRx Scale are completely clear of impression material and slide smoothly back and forth parallel to each other before determining the patient’s mandibular measurements.

Verifying Tray Comfort and Fit

Place the trimmed trays back into the patient’s mouth to check patient comfort, tray fit, ease of tray movement and retention.

If the trays do not fit properly or the patient complains of discomfort, check for the following:

Excess impression material on the trays: this may prevent a tight or comfortable fit therefore remove any material that may be creating problems.

Sharp tray surfaces from tray trimming: remove material that may be creating problems and ensure all trimmed surfaces are smooth.

Teeth undercuts that may be in the way: if necessary remove undercuts but ensure adequate retention before proceeding.

Measurement and Assessment

Once the impression has been completed and the comfort and fit has been confirmed, the trays may now be used to determine key measurements needed to conduct the titration study. With the trays connected to each other via the Upper Tray OATRx Scale and Lower Tray Guide Rails, insert the trays back into the patient’s mouth.

Before using the trays for measurement and assessment it is recommended that the patient relax their jaw muscles by performing range of motion exercises with the lower mandible.
Measurement 1: Habitual Bite Position
With the trays in place, ask the patient to establish their most comfortable bite position. Once comfortable, the Habitual Bite Position can be read from the OATRx Scale identified by the points where the Lower Tray Scale Indicators cross the Upper Tray OATRx Scale.

Measurement 2: Maximal Voluntary Protrusion
With the trays in place, ask the patient to protrude their mandible as far as possible. Once Maximal Voluntary Protrusion has been achieved the position can be read from the OATRx Scale identified by the point where the Lower Tray Scale Indicators cross the Upper Tray OATRx Scale. Repeat this procedure 3 times and record the largest number.

Measurement 3: Full Retrusion
With the trays in place, ask the patient to relax their mandible. Using gentle pressure on the chin and mandible, manually retrude the mandible until Full (anatomical) Retrusion has been achieved. The position can be read from the OATRx Scale identified by the point where the Lower Tray Scale Indicators cross the Upper Tray OATRx Scale. Repeat this procedure 3 times and record the smallest number.

The patient’s range of motion (Maximal Voluntary Protrusion - Full Retrusion) should be roughly the same as the range of motion measured with the device used for bite registration. If there is a difference, it is likely that the trays have not been trimmed adequately and the extra material is interfering with the patient’s ability to maximally protrude and/or retrude. Therefore, check the trays, refit and repeat the patient’s measurements.

Recording Data
Record the Habitual Bite, Maximal Voluntary Protrusion and Full Retrusion positions in the patient’s record.

In the event that Maximal Voluntary Protrusion or Full Retrusion values exceed the OATRx Scale’s range of motion, record the Habitual Bite and those measurements that are within the OATRx Scale range. If a measurement lies outside the OATRx Scale range, record the last number on the OATRx Scale. For example, for Maximal Voluntary Protrusion this number would be 20; for Full Retrusion this number would be 2. The study can still be conducted but please contact Customer Support for assistance.
Tray Cleaning: After Impressions

1. Immediately following the impression procedure, rinse each tray under cold tap water for 30 seconds.

2. Once clean, the trays can be placed in the Tray Case and transported to the site of the titration study.

PRODUCT DISPOSAL

Disposal of the device or its accessories and disposables does not require any special precautions. Follow local waste disposal regulations.

CUSTOMER SUPPORT

Technical Support: 1.877.227.9832
E-mail: support@zephyrsleep.com
Customer Sales: 1.877.341.8814
E-mail: sales@zephyrsleep.com