

EMA DENTAL PROFESSIONAL AGREEMENT

1. This EMA Dental Professional Agreement (the “Agreement”) is between Myerson LLC and the undersigned Dental Professional (dental laboratory, dentist or denturist).
2. Recitals
 - a. Myerson is the exclusive owner or licensee under an agreement with Frantz Design Incorporated (“Frantz”) of patents (“Patents”), trademarks (“Trademarks”) and other intellectual property (including trade dress) related to the EMA Appliance (collectively, the “Intellectual Property;” see Exhibit A).
 - b. The “EMA Appliance” is an oral appliance useful for the treatment of apnea, snoring and similar sleep disordered breathing.
 - c. Dental Professional is skilled in the manufacture and assembly of oral appliances and desires to obtain the non-exclusive right to make the EMA Appliance on and subject to the terms of this Agreement.
3. Grant of License; Payment
 - a. Myerson grants to Dental Professional the non-exclusive, non-transferable right and license to use the Intellectual Property to make/assemble EMA Appliances according to the Specifications (Exhibit B) and the prescription issued by a licensed dentist.
 - b. This license is limited to the United States; and is non-exclusive and does not convey any right, title or interest in and to the Intellectual Property (including by implication, estoppel or otherwise) other than the limited license granted above. All goodwill associated with the Trademarks inures to the benefit of the owner thereof; and Myerson and Frantz, as applicable, reserve all rights not expressly granted hereunder.
 - c. Dental Professional will purchase all of its requirements of components and parts for EMA Appliances exclusively from Myerson or, if Myerson cannot supply sufficient quantities, only from Myerson-approved suppliers.

- d. Dental Professional agrees to pay Myerson for each EMA Appliance (including all parts or kits) Dental Professional makes or assembles during the term of this Agreement in the amounts shown on the most current published price list. Myerson may revise the pricing with 30 days' written notice to Dental Professional. Dental Professional's payments to Myerson are net 30 days.
4. Quality Control
- a. As a condition to the effectiveness of Dental Professional's license under this Agreement, to insure quality control Dental Professional must make one EMA Appliance for Myerson; and must make one EMA Appliance at Myerson's request, but no more than once per year. Dental Professional will provide each sample to Myerson at no cost but Myerson will supply the parts for the sample.
 - b. All EMA Appliances must be made to conform at a minimum to the standards of workmanship and quality in Exhibit B, as they may be revised from time to time ("Quality Standards"). Dental Professional will not apply the Trademarks to any appliance that does not meet the Quality Standards and utilize the Patents. Myerson will provide Dental Professional 30 days' prior written notice of any changes in Quality Standards.
 - c. Dental Professional will not use, promote the use of, or induce the use of the EMA Appliance (whether in whole or in part, including, for example, thermoforming discs, bite pads, buttons, straps) or any Trademarks in connection or combination with any non-EMA goods (including any appliance) or services, or any component of any non-EMA goods (including any appliance) or services.
 - d. Dental Professional will not (i) reverse engineer or analyze any EMA Appliance or other device furnished by Myerson, (ii) create improvements, enhancements or derivatives of any EMA Appliance or such samples, including for commercial purposes, or (iii) file any application for patent or any other intellectual property right or protection containing a claim to any of the Intellectual Property, including any subject matter either embodied by an EMA Appliance or other device furnished by Myerson or derived from any confidential or proprietary information related to the EMA Appliance.
 - e. Dental Professional will permit Myerson's representatives to inspect Dental Professional's EMA Appliance production facilities and techniques.

- f. During the term of this Agreement, and subject to all applicable laws and regulations, Dental Professional may use the Trademarks in advertising or promotional materials (regardless of the media) for the EMA Appliances, except that Myerson, in its sole discretion, may require Dental Professional to modify, correct, or cease any use of the Trademarks on whatever terms and/or notice Myerson deems appropriate in the given instance. Dental Professional further agrees that Myerson may require Dental Professional's use of the Trademarks to comply with any trademark and brand use guidelines or policies Myerson or Frantz may issue during the term of this Agreement.
 - g. Dental Professional will comply with all applicable laws and regulations in its assembly, offers for sale, and sales of EMA Appliances and use of the Intellectual Property.
 - h. Myerson or Frantz, as the applicable owner of the Intellectual Property subject to this Agreement, has the sole right and discretion to bring an infringement or misappropriation action concerning any such Intellectual Property, defend any declaratory judgment action concerning any such Intellectual Property, and take any other lawful action reasonably necessary to protect, enforce, or defend any such Intellectual Property, and control the conduct thereof and attempt to resolve any claims relating to any such Intellectual Property.
- 5. Confidentiality. Each party will maintain the confidentiality of non-public information of the other party and will use that information only for purposes of this Agreement. The provisions of Exhibits A, B and C are confidential.
- 6. Indemnity
 - a. Myerson and Dental Professional will indemnify and hold the other harmless from liability, loss or expense reasonably incurred as a result of any breach by that party of this Agreement or caused by any act or omission of that party.
 - b. Each party will maintain insurance, including products liability/completed operations coverage. Dental Professional agrees that it is solely responsible for (and assumes all liabilities related to) (i) the quality of and any defect in the EMA Appliances that Dental Professional makes, (ii) conformance of any EMA Appliance that Dental Professional makes with the applicable prescription and other specifications for the intended end-user of such EMA Appliance, and (iii) the promotion, sale and documentation of the EMA Appliance and its activities hereunder.

- c. MYERSON AND FRANTZ EACH DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES, WHETHER WRITTEN, ORAL, EXPRESS, IMPLIED, STATUTORY, OR OTHERWISE, CONCERNING THE VALIDITY, ENFORCEABILITY, AND SCOPE OF THE INTELLECTUAL PROPERTY, THE ACCURACY, COMPLETENESS, SAFETY, USEFULNESS FOR ANY PURPOSE, OR LIKELIHOOD OF SUCCESS (COMMERCIAL, REGULATORY OR OTHER) OF THE EMA APPLIANCE, AND ANY TECHNICAL INFORMATION, TECHNIQUES, MATERIALS, METHODS, PRODUCTS, PROCESSES, OR PRACTICES AT ANY TIME MADE AVAILABLE IN CONNECTION WITH THIS AGREEMENT, INCLUDING ALL IMPLIED WARRANTIES OF MERCHANTABILITY, QUALITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, AND WARRANTIES ARISING FROM A COURSE OF DEALING, COURSE OF PERFORMANCE, USAGE, OR TRADE PRACTICE.

- d. TO THE FULLEST EXTENT PERMITTED BY LAW, NEITHER MYERSON NOR FRANTZ WILL BE LIABLE TO DENTAL PROFESSIONAL OR ANY OTHER PERSON FOR ANY INJURY TO OR LOSS OF GOODWILL, REPUTATION, BUSINESS, PRODUCTION, REVENUES, PROFITS, ANTICIPATED PROFITS, CONTRACTS, OR OPPORTUNITIES (REGARDLESS OF HOW THESE ARE CLASSIFIED AS DAMAGES), OR FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, EXEMPLARY, SPECIAL, PUNITIVE, OR ENHANCED DAMAGES WHETHER ARISING OUT OF BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY, PRODUCT LIABILITY, OR OTHERWISE (INCLUDING THE ENTRY INTO, PERFORMANCE, OR BREACH OF THIS AGREEMENT), REGARDLESS OF WHETHER SUCH LOSS OR DAMAGE WAS FORESEEABLE OR THE PARTY AGAINST WHOM SUCH LIABILITY IS CLAIMED HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS OR DAMAGE, AND NOTWITHSTANDING THE FAILURE OF ANY AGREED OR OTHER REMEDY OF ITS ESSENTIAL PURPOSE.

7. Term

- a. This Agreement will remain in effect for a period of two years. It may be extended only by written agreement of the parties for additional periods of two years.
- b. This Agreement may be terminated at any time if any of the following occurs:
 - i. On 90 days' prior written notice of termination for any reason by either party to the other; or
 - ii. Automatically if Dental Professional fails to pay Myerson any amount due under this Agreement within 14 days after written notice to Dental Professional; or
 - iii. Upon written notice to Dental Professional if Dental Professional breaches a material provision of this Agreement (including any Quality Control obligation of Dental Professional under this Agreement), though Myerson, may in its sole discretion permit Dental Professional to cure such breach within a time period determined to be reasonable by Myerson in its sole discretion.
- c. On termination:
 - i. Dental Professional's right and license terminates and Dental Professional will stop using the Intellectual Property;
 - ii. All amounts due Myerson will become immediately due and payable; and
 - iii. Myerson will have the option of repurchasing from Dental Professional, at Dental Professional's cost, all parts and components for EMA Appliances that are in new and salable condition.

8. Miscellaneous

- a. This Agreement is governed by Illinois law. All disputes related to this Agreement will be subject to resolution by arbitration under the AAA commercial arbitration rules in an arbitration to be held in Chicago, Illinois.
- b. This Agreement can only be amended in writing; no oral amendments are legally effective. Any provision of this Agreement found in a final ruling to be invalid or unenforceable will be reformed to the extent necessary to be valid and will be enforced as modified.
- c. This Agreement is complete with respect to its subject matter; the parties are not relying on any agreement or representations concerning that subject matter not expressly set out herein. Dental Professional acknowledges that Myerson does not control Dental Professional's marketing of EMA Appliances and Myerson has not made any representations about Dental Professional's possible sales or profit from EMA Appliances.
- d. The parties are not partners and do not have the authority to bind or create obligations for the other.
- e. All notices must be in writing and sent to the address of the party to be notified beneath its signature.
- f. No failure by Myerson at any time to give notice of any breach by Dental Professional of, or to require compliance with, any condition or provision of this Agreement shall be deemed a waiver of Myerson's rights with respect to such breach or to similar or dissimilar breaches, provisions, or conditions at the same or at any prior or subsequent time.
- g. Dental Professional agrees that Frantz is an intended third party beneficiary of the obligations of Dental Professional under this Agreement without any imposition of obligation or liability on the part of Frantz with respect to Dental Professional. Dental Professional further agrees that Frantz, as third party beneficiary, may fully enforce Dental Professional's applicable obligations under this Agreement directly against Dental Professional without joinder of Myerson.
- h. The following provisions shall survive termination of this Agreement: 4(d); 5; 6(a); 7; and 8.

- i. This Agreement is personal to Dental Professional and may not be assigned or delegated; but Myerson may assign it. A change of control at Dental Professional constitutes an assignment.
- j. Dental Professional will not actively participate as an adverse party in, or otherwise provide material support to, any legal action or administrative proceeding to invalidate or limit the scope of any of the Intellectual Property or obtain a ruling that any of the Intellectual Property is unenforceable or not patentable, or that any EMA Appliance does not infringe one or more claims of any Patent (an "IP Challenge") until the expiration of forty-five (45) business days after Dental Professional serves on Myerson written notice of Dental Professional's intention to bring or participate in an IP Challenge together with a complete written disclosure of each and every basis then known to Dental Professional for the IP Challenge and will provide Myerson with a copy of any document or publication that Dental Professional intends to use in connection with the IP Challenge.

Exhibits

- A. Product Description, Patents, Trademarks and Other Intellectual Property
- B. Quality Standards

Signature page follows.

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the date first set forth above.

MYERSON, LLC

Address for notices:

5106 North Ravenswood Avenue

Chicago, IL 60640

USA

EXHIBIT A

DESCRIPTION OF PRODUCT

There are disclosed two embodiments of a mandibular advancement or positioning device which uses elastic bands to pull the jaw forward. The appliance has an upper plastic tray conforming to the patient's upper teeth including maxillary dentition soft tissue and palate, and including a set of plastic retention hooks, one on the right and one on the left anterior buccal portion of the upper plastic base, with each extending outwardly from the tray. The appliance also has a lower plastic tray conforming to the patient's lower teeth including mandibular dentition and soft tissues, and including having a bite plane which opens the bite vertically. The lower tray also has a set of plastic retention hooks extending outwardly from the teeth, one on the right and one on the left of the posterior buccal portion of the lower plastic base. Specially formed elastic bands, are releasably attached to both the top and bottom retention hooks on both sides of the trays to pull the mandible forward for treatment of snoring and sleep apnea.

US PATENTS

#5,947,724

#5,794,627

#6,109,265

D/328,620

and patents pending

TRADEMARKS

EMA®, EMA FIRST STEP®, and FIRST STEP® are registered trademarks of Frantz Design, Inc.

Dental Professional will comply with the patent marking provisions of 35 USC § 287(a) by marking all EMA Appliances with the word "patent" or the abbreviation "pat." and either the numbers of the relevant Patents or a web address that is freely accessible to the public and that associates the EMA Appliance with the relevant Patents. Dental Professional will also comply with the patent marking laws applicable to any jurisdiction in which EMA Appliances made by the Dental Professional are sold.



Myerson EMA custom oral appliance: laboratory processing instructions

PURPOSE:

The purpose of this document is to outline the process for fabricating a Myerson EMA custom oral appliance in the dental laboratory.

INTENDED USE:

The EMA parts are for making a device for the treatment of nasal respiratory dysfunction of obstructive sleep apnea and snoring in those patients where advancement of the mandible and opening the bite can increase the patient's air space.

SCOPE:

This document applies to current and prospective authorized Myerson EMA laboratories. Do not store / use product if the package is damaged.



Please store in a low humidity area. High humidity may cause the discs to collect moisture. If bubbles occur during thermoforming, please heat or bake unused discs for 4 hours at 100°-105°F

PROCEDURE:

1. Materials Required

- 2 Myerson EMA thermoforming discs (thickness: 1.5 mm, 2.0 mm or 2.5 mm; diameter: 120 mm or 125 mm)
- 2 Myerson EMA bite pads
- 4 Myerson EMA buttons
- Myerson EMA elastic straps (assorted)
- Clear orthodontic resin--cold cure, powder and liquid

2. Equipment

- 2.1. Thermoforming unit of choice
 - 2.1.1.1. Biostar
 - 2.1.1.2. Erkopress ES 200E
 - 2.1.1.3. Druformat
- 2.2. Assortment of carbide burs, hand piece, and lathe

3. Preparation

- 3.1. Pour duplicate models and mount one set of models employing the doctor's bite registration.
- 3.2. Save duplicate models for final delivery of appliances.
- 3.3. With case articulated, the anterior teeth should be open 5 mm to 7 mm from the incisal edges.

4. Examination of Models

- 4.1. Check for adequate undercuts.
- 4.2. Short clinical crowns may lead to subsequent failure because of lack of retention of the appliances. Alert your doctor to this being a problem before proceeding with case.

5. Blocking out undercuts (upper and lower models)

- 5.1. Remove Models from Articulator.
- 5.2. Block out with gray modeling clay, wax, or other suitable material. 5.3. Areas of missing Dentition or fixed crown and bridgework require EXTRA CARE.
- 5.4. Always block out buccal and lingual of all anteriors regardless of lack of any visual undercut.
- 5.5. If the model is blocked out too much, the appliance will be loose; too little and the appliance will be tight.

6. Thermoforming the Trays

- 6.1. For the Biostar unit, set the code at 745 and adjust pressure to 6.0 bar (knob on back) for the 2.0 mm disc. 6.2. The heating element should heat at 355 degrees Fahrenheit (177 degrees Celsius), with a heating time for the Biostar of 70 seconds for the 2 mm disc and 120 seconds for the 2.5mm disc; the heating time for the Erkopress is 120 seconds for either disc thickness.
- 6.3. We recommend running the press through at least one cycle before starting, which will preheat the coils to avoid unevenly or inadequately heated discs.
- 6.4. The discs are pre-dried and packaged with a desiccant packet. Moisture formation can lead to the formation of bubbles during thermoforming, so DO NOT open package until shortly before they are to be used.
- 6.5. Start thermoforming the discs once the material sags approximately 1.5 inches.
- 6.6. **DO NOT OVERHEAT DISC: THE APPLIANCE WILL BE BRITTLE**

7. Trimming Custom Trays

- 7.1. The margin of the finished product should lie a few millimeters below the gingiva all the way around buccal and lingual.
- 7.2. Start by cutting all the way around the outline of the tray with a 2" "econo" cutter. Cut right through to the stone cast (remember a duplicate cast is available). Preliminary cut should be overextended to accommodate final contouring with carbide burs once appliances are removed from the casts.
- 7.3. On the lower arch, extend a little further down on the lingual. Feather the border to maximize room and comfort for the tongue.
- 7.4. Lingual on the upper should be a semi-horseshoe design or scalloped to fully expose the palate.
- 7.5. If anteriors are flared to where insertion is compromised, reduce the length of buccal aspect towards the incisal edge.

8. Placement of maxillary Buttons

- 8.1. Buttons are shaped like blunt arrowheads. On the upper, the arrow faces forward.
- 8.2. Place the button between the distal of the cuspid and the mesial of the first bicuspid and towards the occlusal surface.
- 8.3. Slant downhill toward lower posteriors.
- 8.4. Attach with clear orthodontic cold cure powder and liquid method and cure in a pressure pot.
- 8.5. If time allows, attach the left and right side at the same time.
- 8.6. After curing, contour rough areas with a carbide bur.

9. Placement of the Bite Pads

- 9.1. Return models to the articulator.
- 9.2. With rope wax, position the left and right pads on the upper tray covering the mesial cusps of the second molars to the distal cusps of the second bicusps.
- 9.3. The pads should be located slightly buccal of the center of the ridge so when attached to the lower tray, the tongue is not crowded.
- 9.4. Add cold cure orthodontic resin to the exposed surface of the tray and close in centric. Continue to add material to completely fill the gap between lower tray and bite pads. Make sure that the material does not flow onto the upper tray.
- 9.5. Place articulator in curing pot.
- 9.6. Finish and contour acrylic that flowed beyond desired area.
- 9.7. At this point the pads are attached to the lower trays making contact with the posterior occlusal right and left surfaces of the upper tray, which will maintain the vertical opening.

10. Placement of mandibular Buttons

- 10.1. In the posterior region of the bite pads near the occlusal surface, attach the buttons with clear orthodontic resin.
- 10.2. Locate the buttons on the right and left sides approximately 25mm to 27mm posterior to the center of the maxillary buttons, as measured from center to center of the buttons using a boley gauge or millimeter ruler.
- 10.3. The button should be orient with a slight uphill tilt with the arrow facing back. The tilting is important so when the straps are placed, the lower jaw is being pulled forward
- 10.4. Cure in pressure pot.

11. Finish and Polish

- 11.1. Borders smooth and rounded.
- 11.2. Pumice in usual manner and Hi-Shine.

12. Insertion

- 12.1. These appliances will be inserted in the patient's mouth AFTER the straps are installed. They are inserted together with the upper being placed first and then the patient slides into the lower tray.

ROnly The product is solely for use by or on the order of a dental professional. They are not for over-the-counter use.

Once the buttons, bite pads and discs are assembled to make an appliance, they should not be re-used to make another appliance. Bonding of the components will be affected and can lead to safety or efficiency limitations.

13. Technical Support

- 13.1. Call Myerson at **800-423-2683** (US & Canada only) or **312-432-8200**, or email us at orders@myersontooth.com.

EMA® is a trademark of frantz design inc.

US Patent Numbers; 6,109,265;

D611,153 & Patent Pending



Español, Francés, Alemán, Italiano,



312-432-8200

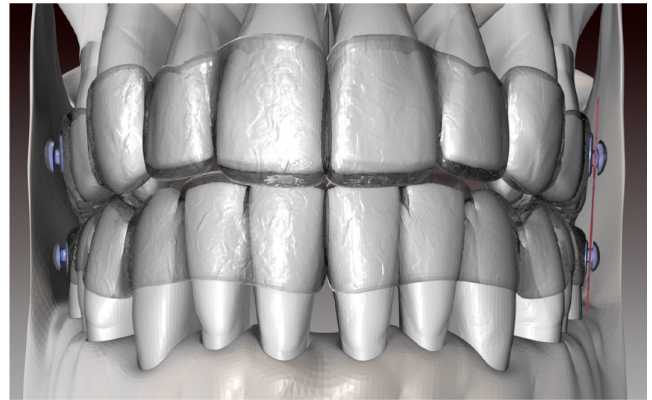


Exhibit A:
Illustration of properly fabricated Myerson EMA custom oral appliance



Manufactured By
Myerson Company Limited
3 Trinity Avenue
Laventille, Trinidad & Tobago

Distributed By
Myerson LLC
5106 N. Ravenswood
Chicago IL 60640 USA



***Authorized
Laboratory
Application:***

Laboratory Name:

Street Address:

City, State, Zip or Postal Code & Country:

Phone:

Contact:

Date Shipped:

Email:

Criteria	Acceptable	Unacceptable	Comment
adaptation of thermoformed ema trays to model			
maxillary tray fits securely	☐	☐	
mandibular tray fits securely	☐	☐	
trimming of maxillary tray			
labial/buccal portion trimmed at height of contour of gingiva	☐	☐	
lingual portion trimmed to tooth/gingival margin (i.e. scalloped)	☐	☐	
trimming of mandibular tray			
labial/buccal portion trimmed at height of contour of gingiva	☐	☐	
lingual portion trimmed at or 1 mm above height of contour of gingiva	☐	☐	
lingual portion is feather-edged	☐	☐	

Criteria	Acceptable	Unacceptable	Comment
placement of ema buttons			
maxillary buttons placed over interproximal space between cuspid and 1st bicuspid <u>near incisal edge</u>	☐	☐	
mandibular buttons placed 27 mm from maxillary buttons just below occlusal surface of bite pads	☐	☐	
buttons parallel to each other and perpendicular to plane of occlusion	☐	☐	
pointed ends of buttons are diametrically opposed	☐	☐	

placement of ema bite pads

distal edge of bite pads placed directly over distal edge of first molars (#19 and #30) when both bicuspid are present	☐	☐	
pads placed to buccal allowing 1 to 2 mm tongue space over lingual cusps of molars	☐	☐	
wider, thinner end points toward posterior and narrower, thicker end points toward anterior	☐	☐	

	Approved	Not Approved	Comment
overall	☐	☐	

Evaluator: James H Swartout Date Evaluated:

QM 2 Form #9, Rev A, 2021-03-16.

