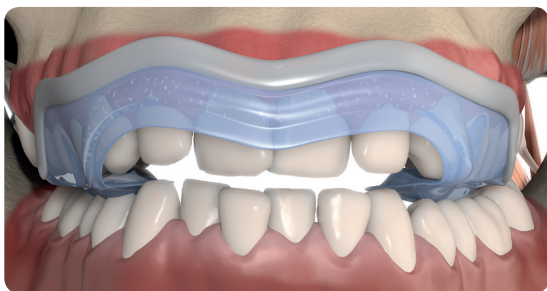
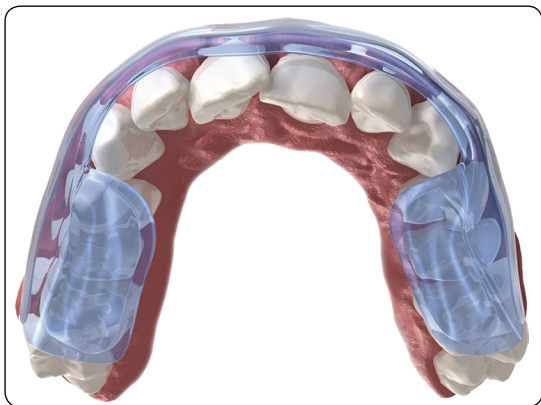


AQUALIZER



**Instant
Hydrostatic Splint**

**The First Aid Bite-Splint
for TMD Disorders**

Instruction for Use - Patient Information

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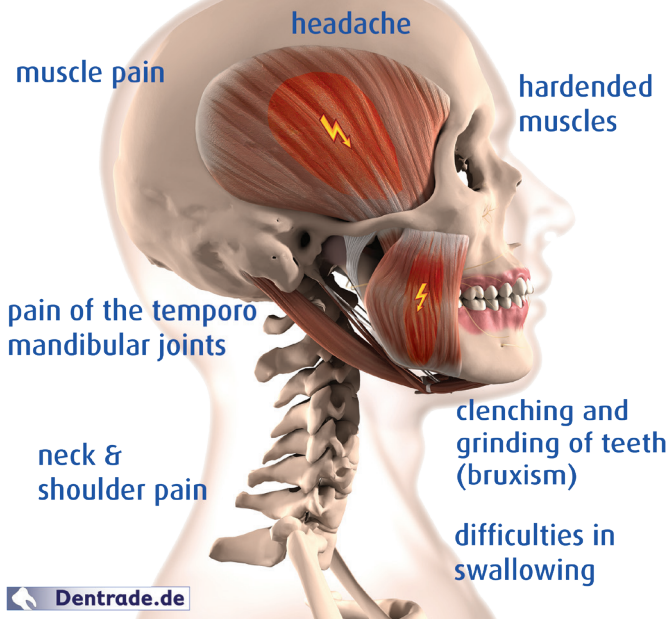
www.AQUALIZER.de

CMD Syndrome (TMD Syndrome)

The neuromuscular system of the head is extremely sensitive to all kinds of environmental influences. Stress and anger have to be compensated daily. The patient starts clenching and grinding teeth unconsciously. In the morning the patient wakes up with a serious headache especially in the temples and forehead. This tension headache is a sign of muscle tension of the major muscles of the head, neck, jaw and back. In many cases clenching or grinding of teeth can be caused by an occlusal high spot. The patient has the feeling that the new filling, crown or bridge is interfering with his bite. Automatically the patient is shifting the position of his jaw to a new habitual position, which can also interfere with the position of the mandible. Usually the patient is treated with a customized splint (occlusal bite guard) made from various materials.

The Aqualizer is the first instant emergency and temporary self-adjusting oral splint filled with water. It is made of a non toxic durable plastic material which can even compensate high pressure forces. The Aqualizer's smooth, flexible surface permits the teeth to easily slide across it. The flexible fluid pads, positioned between the upper and lower occlusal surfaces, eliminate all occlusal contacts. Proprioceptive guidance is neutralized as the dominant factor in functional mandibular placement. The muscles respond instantly by moving the mandible into its most comfortable, least accommodated position. The Aqualizer's fluid system relieves pain by taking the pressure off the painful joints and muscles without any side effect .

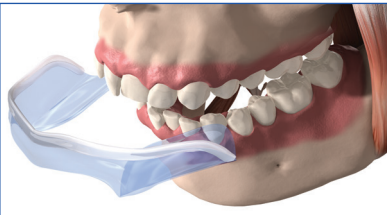
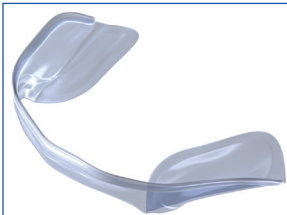
Typical TMD-Symptoms



Indikation: The AQUALIZER® is indicated for the following applications:

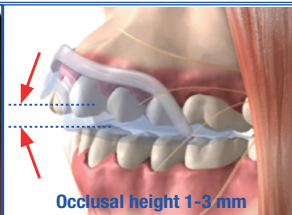
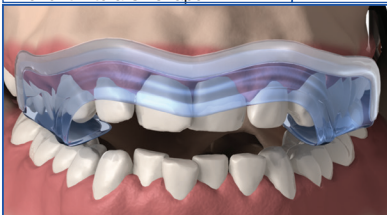
- **Treatment of pain in CMD/TMD complaints**
- **Neuromuscular relaxation also for the preparation of bite registrations in the physiological position of the condyles**
- **Therapy of muscular imbalances**
- **Pain therapy, pain diagnostics, tension headache**

AQUALIZER® Instruction for Use



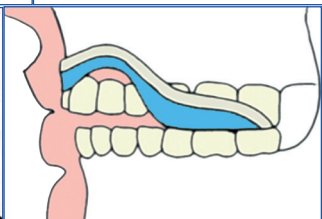
1) Take AQUALIZER® out of the package and hold it in both hands with the padded side up. Bend it into a U- shape.

2) Insert the AQUALIZER® into the mouth. The AQUALIZER® should be worn in the maxilla



3) Place the water cushions between the teeth of the upper and lower jaws. Bite gently on the pads to mold them slightly then just relax on the water bed system.

4) Checking the occlusal height, incisors have not to touch each other



5) If this "feel" is lost, one or both of the pads may have slipped out from between the teeth. Reposition your AQUALIZER® by pressing both sides of the face at the same time, gently, at tooth level. Do this whenever necessary.

6) When you are wearing the AQUALIZER®, it should fit as shown above. In order to receive full benefit, it is important to remember that both fluid-filled pads MUST ALWAYS stay between the back teeth.

How is AQUALIZER® fixed in the mouth?

The AQUALIZER® is worn in the oris vestibulum (oral forecourt). Due to its anatomically adapted shape, it is fixed in the oral vestibule by the cheek and lip muscles and thus cannot slip out. In addition, the AQUALIZER® is fixed to the water cushions between the teeth by lightly closing them. Therefore, the AQUALIZER® can also be used temporarily as a temporary splint during sleep.

General description and intended use of the AQUALIZER®

The AQUALIZER® is a water-filled self-adjusting occlusal splint based on the hydrostatic principle. The patient bites with the premolars and the molars onto the two water cushions, which are connected by a thin capillary. Thus the chewing pressure is evenly distributed. The thin polyamide film easily adapts to the shape of the tooth. Occlusal interferences are compensated. Adapted resting positions of the mandible will be dissolved.

Contraindication

If the patient has an impaired swallowing or choking reflex, AQUALIZER® should not be used under any circumstances or only under medical supervision.

The AQUALIZER® has been used for over 30 years. Based on many years of experience and feedback from the market, no documented event has been reported so far. With a normal gag reflex there is no danger of swallowing an AQUALIZER®. The AQUALIZER® cannot be used if there are missing teeth in the dentition. The AQUALIZER® is only intended for temporary use and cannot replace the bite correction by a dentist. On the water cushions, teeth are not stabilized as in the natural occlusion, so that excessive use over long periods of time may lead to tooth displacement.

Side effects

Side effects can be allergic reactions to the materials used in AQUALIZER®. The AQUALIZER® consists of a stable polyamide film. The welding edges that come into contact with the vestibulum are additionally provided with a protective edge made of foamed polyethylene. The materials comply with the requirements of the Medical Device Directive 93/42/EEC. The AQUALIZER® is filled with distilled water. If the AQUALIZER® bursts, only water escapes. AQUALIZER® may cause irritation of the gums in some patients. If worn for a longer period of time, the plastic film can easily rub against the gums in the oral cavity and on the inside of the cheeks, or it can cause pressure points on the mucous membrane. In this case, treatment with AQUALIZER® should be interrupted.

Remove AQUALIZER® immediately if there are sore spots on the gums and consult your doctor. In case of upper jaw irritation, AQUALIZER® can also be worn in the lower jaw. Your dentist may be able to cover the sharp edges on the underside of the AQUALIZER® with wax or other suitable material, e. g. soft silicones or relining materials for prostheses.

Application / Effectiveness

The AQUALIZER® is worn invisible under the upper lip and fixed by the lower and upper premolars and molars. Wearing an AQUALIZER® may increase the salivation for a short time. When swallowing the saliva, the patient should take care to relax his jaw muscles as much as possible and bite evenly onto the water cushions with his teeth. Care should be taken to ensure that the AQUALIZER® is worn as close to the center as possible and not moved too far to the left or right. It is not necessary to chew. When the AQUALIZER® is correctly inserted, the jaw muscles move the jaw by themselves into the most comfortable bite position. Relief of the symptoms indicates muscular relaxation, which can be easily treated with a splint or a RehaBite®. If the symptoms are the same or even worse, joint structures may be impaired. In both cases, a dentist or a suitably trained physiotherapist or osteopath should always be consulted.

Diagnosis / Efficacy

The AQUALIZER® can cause the following symptoms or changes in the condition:

Pain reduction in muscular pain due to overloading or tension due to gentle postures, change in bite position, relief of the temporomandibular joints.

Nightly grinding or clenching, also known as bruxism. Grinding or clenching are natural reactions to compensate stress. Involved structures may be overloaded which can cause damage on the dentition and joints. The AQUALIZER® can be used for a short time as a temporary splint to relieve muscular structures and teeth.

Tinnitus and dizziness: Some patients have reported a significant improvement in these symptoms. Dizziness and tinnitus can be associated with CMD/TMD if the condyles of the temporomandibular joints press too hard on the bilaminar zone.

Muscular relaxation of the head, neck, shoulder and upper back.

The Aqualizer® is not a replacement for proper dental treatment, or permanent splints. It is a short term temporary diagnostic splint.

The Aqualizer® is not indicated for heavy bruxers or clenchers.

Orthodontic treatments

Orthodontic treatments always implies a change of the occlusion.

Occlusal interferences are adapted by the neuromuscular system as a natural reaction avoiding an overloaded of occlusal forces. These relieving postures can have a significant destructive effect on muscles, joints and teeth and all other structures involved. The AQUALIZER® is a possibility to compensate the static influence of the occlusion during the treatment phase. During the orthodontic treatment no individual splints can be made because the treatment creates a new tooth position every day.

Cleaning instructions

The AQUALIZER® is intended for single use per patient. The AQUALIZER® should be cleaned daily with appropriate cleaning agents (water, soap and/or suitable disinfectant wipes). Storage in the protective box is recommended. For hygienic reasons the AQUALIZER® should be changed after 2 weeks.

Storage instructions

AQUALIZER® can be stored at room temperature for 12 months from the date of purchase. AQUALIZER® should be frozen when stored for longer than 12 months. The AQUALIZER® contains distilled water which can diffuse through the polyamide film. When the water is deep-frozen, no water molecules can escape through the film. Frozen Aqualizers have an unlimited shelf life.

Duration of use - Durability of AQUALIZER®

The durability of an AQUALIZER® depends on the individual load and force applied by the tooth rows. As a rule, an AQUALIZER® lasts 1-2 weeks with normal use of about 8 hours per day. Patients with pronounced parafunction/bruxism (strong presser or cruncher) can also bite through an AQUALIZER® in much shorter time. Therefore, the AQUALIZER® is only suitable to a limited extent for heavy presses or crunches. If the AQUALIZER® is bitten through in less than 2 days, this can be a sign of parafunction.

The Aqualizer® should be worn twice as long as it takes for pain relief, and then removed until symptoms begin reappearing. Repeat as necessary. Do not exceed eight hours of wear per twenty-four hours. Remove the Aqualizer® and discontinue use if irritation or other problems develop. Aqualizer® use life is between a few days and sometimes out to a week or so depending on the user's bruxing or clenching habits. The unphysiological occlusion is compensated by the water cushions and the lower jaw is guided into a relaxed physiological position. The dentist can fix this physiological position with a bite registration and then transfer this position of the mandible into a hard splint. Unlike other available dental splints, the Aqualizer® self-adjusting oral splint is a TMJ treatment which allows the body to unravel bite distortions and establish optimal systemic function and balance.

AQUALIZER® Vertical Dimension - high, medium, low

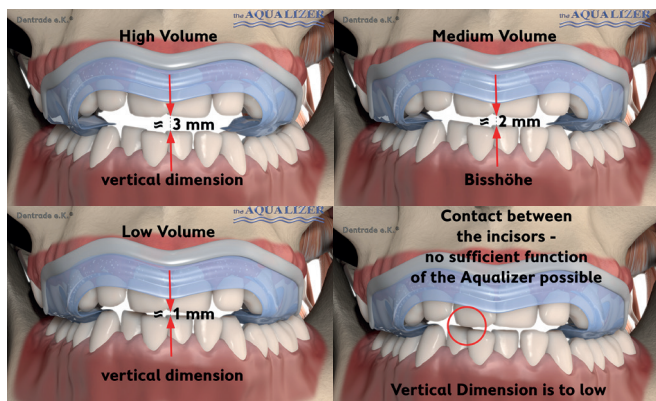
All models of the Aqualizer are available in three different vertical dimensions.

The vertical dimension (thickness) is controlled by the amount of fluid in the Aqualizer. All sizes have the same arch length, except the Aqualizer Mini. The vertical dimension is an approximate indication. It is dependent on the anatomy of the patient. The gap between the front incisors can be measured with Bausch Fleximeter Strips. A new Aqualizer should induce a distance of 0.5 - 2.0 mm between the incisors. Using an Aqualizer for a week, the vertical occlusion dimension can decrease. The water can diffuse through the plastic membrane. Therefore, always choose an AQUALIZER® with an adequate vertical dimension (high or medium). AQUALIZER® low are only suitable for patients with a limitation of mouth opening. For patients with a deep or covering bite, an AQUALIZER® with the bite height high should always be selected.

An AQUALIZER® can provoke a temporary relief by, distracting the joint capsule.

The occlusal vertical dimension medium is usually sufficient for 90% of all patients.

At the beginning of the therapy it is recommended to start with an AQUALIZER® medium (≈ 2 mm vertical dimension), if the patient does not have a pronounced deep bite.



AQUALIZER® high volume ≈ 3 mm Vertical Dimension

High volume Aqualizers ≈ 3 mm vertical occlusion dimension are used when a patient has excessive freeway space or needs a greater vertical dimension to fill the space between the upper and lower occlusal surfaces. The higher volume causes a firmer feeling on some patients which can provoke some discomfort. Based on clinical experience with parafunctional clenched/bruxers, the higher volume induces a better neuromuscular relaxation by increasing the vertical space.

AQUALIZER® medium volume ≈ 2 mm Vertical Dimension

Medium volume Aqualizers ≈ 2 mm vertical occlusion dimension are used by most patients (90 percent). Almost all patients can use medium volume.

AQUALIZER® low volume ≈ 1 mm Vertical Dimension

Low volume Aqualizers ≈ 1 mm are for patients with inadequate freeway space (or those sensitive to anything in their mouths) who may find the minimal vertical dimension more comfortable. The Low volume Aqualizer is also indicated when using the neuromuscular bite registration technique.

A higher Aqualizer always causes a slight rotation of the condyle. An Aqualizer with less vertical dimension causes minimal rotation. In determining a physiological position of the condyles as a possible reference position for a hard rigid bite splint or a possible therapeutic position for a restorative care, this effect should be considered.

AQUALIZER® Models and Sizes

The AQUALIZER® is available in 3 different versions. All models are also available in 3 bite heights (high, medium and low). This allows the practitioner to select the AQUALIZER® according to the physiological and therapeutic conditions of the patient.

AQUALIZER Modell Slim



This model has a good anatomical shape and 10mm wide bite block (AP) for a good occlusal force distribution. The only 10mm high side wings (SF) have are comfortable to wear. Irritations on the tongue and gums are thus reduced.

This AQUALIZER® is relatively durable under normal conditions. All AQUALIZER® Slim models have a splint length (SL) of 116 mm and are therefore suitable for all normal jaw sizes.

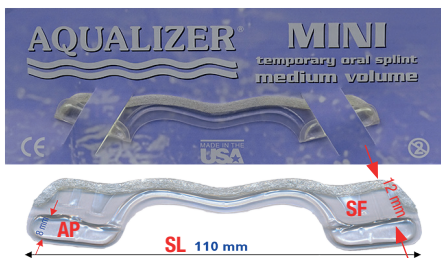
AQUALIZER Modell Ultra



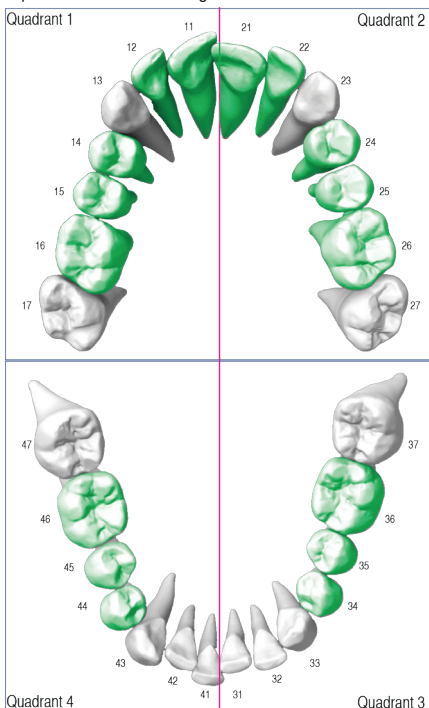
This model has slightly wider side wings (SF) than the slim model. Due to the wide wings and the linear shape, this model can also be worn in combination with brackets during orthodontic treatment. All AQUALIZER® Ultra models have a splint length (SL) of 116 mm and are therefore suitable for all normal jaw sizes.

AQUALIZER® Models and Sizes

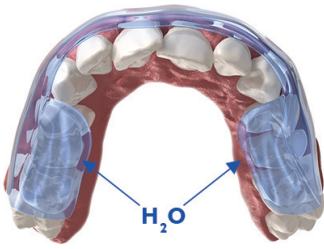
AQUALIZER Modell Ultra Mini



This model is a special version for small jaw sizes. But this model can also be used for patients with normal jaw size and missing molars (teeth 17, 47, 27, 37 according to FDI tooth scheme). The splint length (SL) is 110 mm and is 6 mm shorter than the models Slim and Ultra. The bite pads (AP) are only 8 mm wide and therefore suitable for patients with small teeth or frequent irritations of the tongue.



The Aqualizer can only be used if there are enough premolar and molar teeth to create an hydrostatic occlusal balance. Missing antagonists (molar teeth 17, 47, 27, 37), will interrupt the floating action of the hydrostatic splint. A gap ≥ 5 mm can disturb the physical function and cause a blister in the Aqualizer. Existing gaps can be closed with a temporary prosthesis. For missing molars, for example tooth 36, an Aqualizer Ultra Mini can also be used.



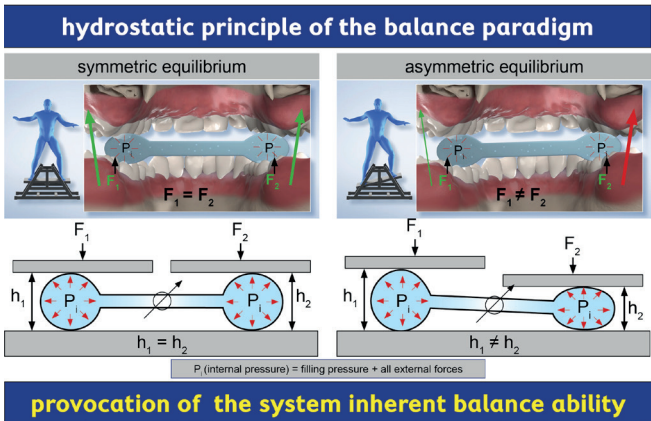
Product Description

The Aqualizer's fluid system creates perfect bite balance and stability through a minimally invasive approach to TMJ treatment. It works by allowing the muscles themselves to automatically reposition the jaw to where it naturally works best. For TMJ pain relief, restoring this balance is essential.

Unlike other available dental splints, the Aqualizer self-adjusting oral splint is a TMJ treatment which allows the body to unravel bite distortions and establish optimal systemic function and balance. The Aqualizer takes the uncertainty out of TMJ diagnosis and treatment. While other dental splints and TMJ treatment options can distort the jaw, causing TMJ pain, the Aqualizer facilitates relief through ideal occlusion automatically and naturally. The Aqualizer is also a perfect supplement in other medical disciplines besides dentistry. Today this device is integrated into physical therapy, osteopathy, orthodontic treatment, orthopedics and many other medical disciplines.

How the Aqualizer works

The Aqualizer is an application of a basic physical law of nature called Pascal's Law, which states that an enclosed fluid will apply equalized fluid pressure regardless of where pressure is applied to the fluid. In other words, biting down on the Aqualizer causes the fluid to distribute bite forces evenly across the bite, reducing TMJ pressure and pain and ensuring relief. Aqualizer dental splints impose no preset changes. By contrast, they enable the body to naturally balance itself, resulting in TMJ pain relief and improved function.



provocation of the system inherent balance ability

AQUALIZER® - Models:

AQUALIZER®	Design	Vertical Dimension	Order-No. REF-No.
AQUALIZER	slim	high ≈ 3 mm	AQ 300
AQUALIZER	slim	medium ≈ 2 mm	AQ 301
AQUALIZER	slim	low ≈ 1 mm	AQ 304
AQUALIZER	ultra	high ≈ 3 mm	AQ 305
AQUALIZER	ultra	medium ≈ 2 mm	AQ 306
AQUALIZER	ultra	low ≈ 1 mm	AQ 307
AQUALIZER	mini	high ≈ 3 mm	AQ 308
AQUALIZER	mini	medium ≈ 2 mm	AQ 309
AQUALIZER	mini	low ≈ 1 mm	AQ 310

All AQUALIZER® models are available separately. In our shop under www.dentrade.com you can order all models. On our shop page you will find attractive quantity discounts as well as further information and videos on how to use them. Of course we are also available for questions (0+49-221-9742834) during our office hours. If you have special medical questions, please ask your attending physician or therapist.

New for CMD/TMD therapy:



- **physiotherapeutic training device**
- **Coordinative jaw muscle training**
- **helps to reduce pain**
- **activates self-healing powers**



CMD Therapie Trainer

EC REP

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