

**FORM 2**

THE PATENTS ACT, 1970  
(39 of 1970)  
AND  
THE PATENTS RULES, 2003

**COMPLETE  
SPECIFICATION**

(See Section 10; rule 13)

TITLE OF THE INVENTION

“ORAL APPARATUS FOR OPTIMISING USER PERFORMANCE”

**APPLICANT**

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The following specification particularly describes  
the invention and the manner in which  
it is to be performed

  
AMENDED CLAIMS

received by the International Bureau on 04 April 2013 (04.04.2013)

1. A kit to optimise user performance in an activity comprising:  
oral apparatus including at least one bite portion configured to receive a pad;  
and  
a plurality of pads, each pad being configured to attach to the at least one bite portion wherein at least two of the plurality of pads have different depths each pad increasing the depth of the base of the mouthguard by a consistent amount along the pad's length; such that, in use, an optimal separation distance between the teeth of the upper and lower jaws of the user is maintained.
2. The kit as recited in claim 1 wherein the oral apparatus is configured such that, when inserted into a user's mouth, the bite pad is situated between the teeth of the upper and lower jaw of the user.
3. The kit as recited in claim 1 or claim 2 wherein the bite portion is removably connectable to a pad.
4. The kit as recited in any one of the preceding claims wherein the depth of a pad is between 1 and 12mm.
5. The kit as recited in any one of the preceding claims wherein the bite portion is provided with an attachment means and each of the pads is provided with complementary attachment means.
6. The kit as recited in claim 5 wherein one of the attachment means and complementary attachments means comprises a female member and the other of the attachment means and complementary attachments means comprises a male member.
7. The kit as recited in claim 6 wherein the female and male member are held in frictional engagement or comprise a complementary thread attachment or the male member includes an enlarged head receivable within a chamber of the female member.
8. The kit as recited in any preceding claim wherein the oral apparatus further comprises a restriction means situated, such that, when inserted into the user's mouth the restriction means is situated between the user's teeth and buccal mucosa,

the restriction means extending past the depth of a pad when attached to the bite portion.

9. The kit as recited in any one of claims 1 to 7 wherein the oral apparatus comprises a mouthguard and the bite portion forms part of the base of the mouthguard.

10. The kit as recited in any one of claims 1 to 7 wherein the oral apparatus comprises a mouthguard and the bite portion forms part of a side wall of the mouthguard.

11. The kit as recited in claim 10 wherein the pads have an L-shaped cross-section.

12. The kit as recited in any one of the preceding claims wherein the oral apparatus and bite pads are made from one or more of the group comprising silicon, TPE or EVA.

13. A kit comprising a plurality of pads, each pad being configured to attach to a bite portion of an oral apparatus wherein at least two of the plurality of pads have different depths, each pad increasing the depth of the base of the mouthguard by a consistent amount along the pad's length; such that, in use, an optimal separation distance between the teeth of the upper and lower jaws of the user is maintained.

14. The kit as recited in any one of the preceding claims wherein the oral apparatuses are made from one or more of the group comprising silicon, TPE or EVA.

15. A method of selecting an oral apparatus from a kit as claimed in any one of claims 1 to 13 comprising the steps of:

- a) inserting oral apparatus having pads of an initial depth into a user's mouth;
- c) measuring the user's performance at an activity;
- d) inserting the oral apparatus with pads of a second depth into the user's mouth;
- e) measuring the user's performance at an activity with the pads of a second depth; and



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f) determining the oral apparatus causing the optimal performance.

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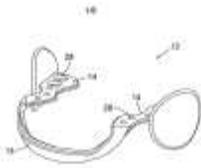


Fig. 1

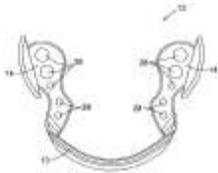


Fig. 2

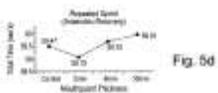
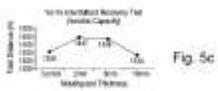
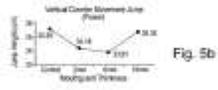
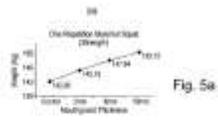
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Fig. 3



Fig. 4



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Fig. 6

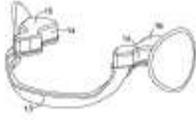


Fig. 7

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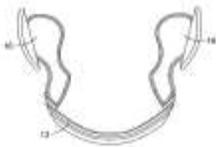


Fig. 8

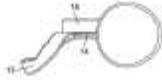


Fig. 9

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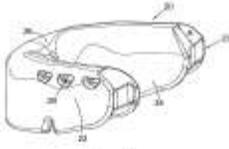


Fig. 10

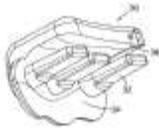


Fig. 11

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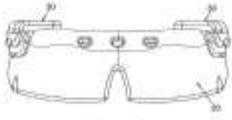


Fig. 12

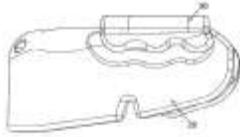


Fig. 13

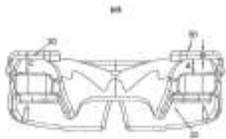


Fig. 14

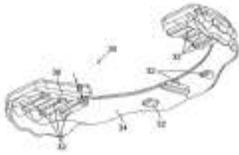


Fig. 15

## ORAL APPARATUS FOR OPTIMISING USER PERFORMANCE

### Field of the Invention

The present invention relates to oral apparatus and in particular, though not necessarily, oral apparatus for use during sporting activities.

### Background to the Invention

Mouthguards are commonly used in sports to protect a user's teeth and associated structures (such as the dental arches, and upper and lower jaws) from injury as a result of a force being applied to the mouth.

Mouthguards commonly available today fall within one of three categories: the stock mouthguard which is supplied to the user in the form in which it is to be used; self-mouldable mouthguards which can be moulded by the user so that the inside of the mouthguard adapts to the shape of the user's teeth; and custom mouthguards which are moulded by a professional to suit the characteristics of the user.

In more recent years the physiological effect of a mouthguard has been recognised and designs have been adapted so that a physiological benefit is provided to the user through the use of a mouthguard or even an oral apparatus which has minimal protective features. For example, WO 2009/012243 describes a mouthguard which reduces the pressure at the temporomandibular joint as the user bites onto the mouthguard thereby reducing the amount of a stress hormone released by a user using the apparatus.

### Summary of the Invention

In accordance with a first aspect of the present invention there is provided a kit comprising oral apparatus including at least one bite portion configured to receive a pad and a plurality of pads, each pad being configured to attach to the at least one bite portion wherein at least two of the plurality of pads have different depths. By providing interchangeable pads the distance that the pads maintain between the teeth of the upper and lower jaw of a user may be varied by changing the depth of the pads attached to the bite portion enabling an optimal depth to be selected for the user.

Optionally, the oral apparatus is configured such that, when inserted into a user's mouth, the bite pad is sited between the teeth of the upper and lower jaw of the user.

Preferably, the bite portion is removably connectable to a pad. By having removable pads different pads may be selected depending on the activity to be undertaken by a user. Also it enables experimentation to determine the optimal depth of pad to be used for an activity.

The depth of a pad may be between 1 and 12mm.

The bite portion may be provided with an attachment means and each of the pads is provided with complementary attachment means. Optionally, one of the attachment means and complementary attachment means comprises a female member and the other of the attachment means and complementary attachment means comprises a male member. The female and male member may be held in frictional engagement or comprise a complementary thread attachment or the male member includes an enlarged head receivable within a chamber of the female member.

Preferably the oral apparatus further comprises a restriction means situated, such that, when inserted into the user's mouth the restriction means is situated between the user's teeth and buccal mucosa, the restriction means extending past the depth of a pad when attached to the bite portion. The presence of this restriction means reduces the spread or lateral movement of the pad when it is depressed by a user's teeth by forming a physical barrier to the spread. This means that the depth of the pad is not significantly altered in use and/or stops the pad moving from between the teeth into the space between the teeth and the buccal mucosa.

The oral apparatus may be a mouthguard and the bite portion may form part of the base or part of a side wall of the mouthguard. Where the bite portion forms part of a side wall of the mouthguard the pads may have an L-shaped cross-section.

The oral apparatus and bite pads may be made from one or more of the group comprising silicon, TPE or EVA.

In accordance with a second aspect of the present invention there is provided a kit comprising a plurality of pads, each pad being configured to attach to a bite portion of an oral apparatus wherein at least two of the plurality of pads have different depths.

In accordance with a third embodiment of the present invention there is provided a kit comprising two or more oral apparatuses each apparatus including at least one bite pad the bite pad of each apparatus having a different depth to the bite pad of the other apparatuses. This enables a user to determine an optimal depth of bite pad for an activity and select an oral apparatus for future use in the activity.

Each oral apparatus may be configured such that, when inserted into a user's mouth, the bite pad is situated between the molar teeth of the upper and lower jaw of the user.

The depth of a bite pad is preferably between 1 and 12mm.

Advantageously, the oral apparatus further comprises a restriction means situated, such that, when inserted into the user's mouth the restriction means is situated between the user's teeth and buccal mucosa, the restriction means extending past the depth of a pad when attached to the bite portion. The presence of this restriction means reduces the spread or lateral movement of the pad when it is depressed by a user's teeth by forming a physical barrier to the spread. This means that the depth of the pad is not significantly altered in use and/or stops the pad moving from between the teeth into the space between the teeth and the buccal mucosa.

The oral apparatus may comprise a mouthguard and the bite pad forms part of the base of the mouthguard.

The oral apparatuses may be made from one or more of the group comprising silicon, TPE or EVA.

In accordance with a fourth aspect of the present invention there is provided a method of selecting an oral apparatus from a kit in accordance with the first aspect of the present invention comprising the steps of:

- a) inserting oral apparatus having pads of an initial depth into a user's mouth; c) measuring the user's performance at an activity;
- d) inserting the oral apparatus with pads of a second depth into the user's mouth;
- e) measuring the user's performance at an activity with the pads of a second depth; and
- f) determining the oral apparatus causing the optimal performance.

As will be understood by the skilled person this method may be performed multiple times with any number of pads having differing depths.

In accordance with a fifth aspect of the present invention there is provided a method of selecting an oral apparatus from a kit in accordance with the third aspect of the present invention comprising the steps of:

- a) selecting an oral apparatus;
- b) inserting the oral apparatus into a user's mouth;
- c) measuring the user's performance at an activity;
- d) inserting the other oral apparatus into the user's mouth;
- e) measuring the user's performance at an activity with the other oral apparatus in the user's mouth; and
- f) determining the oral apparatus causing the optimal performance.

As will be understood by the skilled person this method may be performed multiple times with any number of oral apparatuses having differing depths.

#### Brief Description of the Figures

Figures 1 to 4 illustrate oral apparatus in accordance with an embodiment of the present invention;

Figure 5a to 5d illustrate how a user's performance at an activity might vary with a depth of a mouthguard;

Figures 6 to 9 illustrate oral apparatus in accordance with another embodiment of the present invention;

Figure 10 illustrates a mouthguard in accordance with an embodiment of the present invention;

Figure 11 illustrates a pad in accordance with an embodiment of the present invention; Figure 12 is a front view of the mouthguard of an embodiment of the present invention engaged with the pad of an embodiment of the present invention;

Figure 13 is a side view of the mouthguard of an embodiment of the present invention engaged with the pad of an embodiment of the present invention; and

Figure 14 is a rear view of the mouthguard of an embodiment of the present invention engaged with an embodiment of the pad of the present invention; and

Figure 15 illustrates a pad for attachment to a mouthguard in accordance with a further embodiment of the present invention.

#### Detailed Description of the Figures

Figures 1 to 4 illustrate a support member 12 of an apparatus in accordance with the present invention.

The support member 12 has two plates 14 connected by an integral connecting portion 13. The plates 14 are positioned relative to each other so that when the oral apparatus is inserted into a mouth they sit between molars in the mouth. The connecting portion maintains the relative positioning of the two plates 14.

The connecting portion 13 has a substantially semi-circular shape. The connecting portion 13 is also on a substantially lower plane than the receiving portions 14 when the device 10 is oriented for use. Thus, the connecting portion 13 includes sloping parts. This enables the connecting portion to run around the gumline of the user when the oral apparatus is inserted into a mouth and provide minimal interference to the user. The skilled person will understand, however, that the connecting portion may take any suitable form. For example, the connecting portion may be a plate configured to be substantially in contact with the roof of a mouth when the oral apparatus is inserted into the mouth.

The one or more apertures 28 are present through the plates 14 of the apparatus.

The apparatus is further provided with removable pads (not shown). An upper and lower pad is provided for each plate 14. The upper and lower pads are configured to connect to each other through one or more of the apertures 28 present through the plates 14. The pads may connect to each other in any suitable way. For example, the upper pad may be provided with one or more

male members and the lower pad may be provided with one or more complementary female members such that the upper and lower pads are held in communication with one either side of the plate. Alternatively the upper pad may be provided with one or more female members and the lower pad may be provided with one or more complementary male members. In this way pads can be attached to be present above and below the receiving portion 14.

The support member 12 may be made from any suitable material. Examples of materials include silicon, a thermoplastic elastomer (TPE) or Ethylene vinyl acetate (EVA). It is advantageous for the plates 14 to be more resilient than the pads in order to help the pads maintain their shape and additionally help the distance between the teeth of the upper and lower jaw to be maintained.

It has been found that the performance of a user in an activity is related correlated to the distance that is maintained between the teeth of the upper and lower jaws of a user hereinafter referred to as separation distance. Figures 5a to 5d show how the performance of a user performing four different activities differs with separation distance. As can be seen, the same separation distance may result in different performance effects in same user depending on the activity that is being undertaken. Additionally, it has been noticed that the optimal separation distance may be different for different users performing the same activity. Namely, the optimal separation distance is dependent on the user and the activity.

Thus, it is desirable to determine the separation distance which is optimal for a user performing a particular activity. This is achieved using the above device by the user measuring their performance at an activity. For example, if the user is a weightlifter the measure of their performance may be the amount of weight they can lift in their chosen competitive discipline, the more weight they can lift the better their performance. The apparatus with a first set of upper and lower pads attached to each plate is then inserted into the user's mouth and the user's performance at the activity remeasured. The separation distance maintained by the oral apparatus may be further varied using pads of different depths and measuring the user's performance at the activity at each separation distance.

Once the user has the results they can compare their performance at different separation distances. The user can then determine the depth of pads required to provide them with optimal performance and will know to use this depth when performing this activity in future. If the user wishes to carry out more than one activity then they can vary the depth of the pads attached to the plates according to the activity. This allows a user to achieve optimal performance in both activities whilst only requiring one apparatus.

Thus, by enabling the pads to be removeably attached to the plates 14 of the device pads of different depth sizes may be selected. This allows the separation distance to be optimised for each user without requiring separate custom devices to be manufactured for each user.

In another embodiment illustrated in Figures 6 to 9 the plates 14 do not include apertures but are provided with integral pads 16 having a depth equal to the separation distance. The pads 16 may be provided above or below the plate surface when the apparatus is in use. Alternatively the plate may form the pad and have a depth  $d$ . The user is provided with multiple apparatus each having a different depth  $d$ . The user can then perform the same method to determine the optimal

separation distance for an activity as described above. However, rather than alternating the pads they can measure the performance achieved with each apparatus and determine the apparatus which provides them with the optimal performance.

In a further embodiment illustrated in Figures 10 to 15 the oral apparatus is a mouthguard. A mouthguard 20 in accordance with the present invention is illustrated in Figure 9. The mouthguard 20 has an outer wall 22 which, in use, is adjacent to the buccal surfaces of at least one of the user's teeth; an inner wall 24 which, in use, is adjacent to the lingual or palatal surface of at least one of the user's teeth and a base 26 joining the inner and outer walls and adjacent to the occlusal surface of at least one of the user's teeth when in use. The outer wall 22, inner wall 24 and base 26 all have at least an external surface and an internal surface. The internal surface is the surface of the mouthguard 20 closest to the user's teeth when the mouthguard 20 is in use and the external surface is the surface of the mouthguard 20 opposite to the internal surface.

The base 26 of the mouthguard 20 has a depth A which is the distance between its internal surface (adjacent to the occlusal surface of at least one of the user's teeth when in use) and its external surface (opposite the external surface).

The mouthguard 20 is provided with cavities 28 in the rear region of the external surface of the outer wall 22 of the mouthguard 20. The rear region of the mouthguard 20 being the region that is no further forward than the position of premolar teeth within a user's mouth. This may be, for example, 5mm from the rear end 23 of the mouthguard. Each cavity 28 is configured to receive, and hold in frictional engagement, a projection from a pad as described below with reference to Figures 11 and 12.

A pad 30 suitable for attachment to the mouthguard 20 of Figure 9 is illustrated in Figure 10. The pad 30 has a body with an L-shaped cross-section and a first inner face 34 and a second inner face 36. The first inner face 34 of the body has projections 32 which extend out of a surface of the pad 30. The projections 32 are situated such that, when the mouthguard 20 and pad 30 are in engagement the pad's first inner face 34 is brought into contact with the external surface of the outer wall 22 of the mouthguard 20 and the pad's second inner surface 36 is brought into contact with the external surface of the base 26 of the mouthguard 20 as illustrated in Figures 11 to 13.

The projections 32 are shaped such that they can be held in frictional engagement with the cavities 28 of the mouthguard 20.

The depth of the pad 30 is considered the distance between the surface of the pad 30 adjacent the base 26 of the mouthguard 20 (i.e. the second inner face) and the opposite surface. This distance is marked B in Figure 10.

As can be seen from Figures 11 to 13 when the pads 30 are attached to the mouthguard 20 the effective depth of the base 26 of the mouthguard 20 i.e. the distance that teeth from the upper and lower jaw are separated when the mouthguard 20 is inserted into a mouth is increased so that it is equal to the combined depth of the base 26 of the mouthguard 20 and the pad 30.

Although the pads have been described as having an L-shaped cross-section it will be understood that they may have any suitable cross-section. For example, they may have a rectangular cross-section. If the pads are provided with a rectangular cross section the projections will protrude from the face of the pad to be in contact with the external surface of the base of the mouthguard. Additionally, the cavities in the

mouthguard to receive the projections will be present in the base of the mouthguard rather than the outer wall of the mouthguard.

Optionally, rather than the first inner surface of a pad having an L-shaped cross-section being brought into contact with the outer wall of the mouthguard the pad and mouthguard cavities may be positioned so that the first inner surface of the pad is brought into contact with the external surface of the inner wall of the mouthguard.

The mouthguard is illustrated as being configured to receive two individual pads one on either side of the rear of the mouthguard. However, pads may be placed in any suitable configuration along the base of the mouthguard. For example, the mouthguard may be configured to receive a pad, such as that illustrated in Figure 14, which extends around the entire length of the base of the mouthguard. In such a configuration the mouthguard and pad may be provided with further receiving means and projections respectively. For example, the mouthguard may be provided with receiving means in the base at the front of the mouthguard. Alternatively, the mouthguard may be configured so that one or more pads may be received at the front of the mouthguard. As will be understood by the skilled person, any number of pads of any number of sizes may be used.

The pads may be of any suitable depth to provide the optimal effective depth for the base of the mouthguard. Preferably the pads have a depth of between 1 mm and 12mm and the base of the mouthguard has a depth of between 2mm and 4mm.

The pads may be made from any suitable resilient material for example they may be made from silicon, a thermoplastic elastomer (TPE) or Ethylene vinyl acetate (EVA).

Although the pads have been described as being held in frictional engagement with the mouthguard it should be understood that the projections and receiving means might be any suitable complementary shape which allows the pad and mouthguard to be removeably connectable. For example, the each projection may be provided with a portion having a widened cross-section at the end furthest from the body of the pad, for example a spherical shape may be placed at the end of the projection. Each cavity may comprise a neck whose diameter is less than the diameter of the widened cross-section and an enlarged receiving chamber to receive the portion of the projection with a widened cross-section, the enlarged receiving chamber being distant from the external surface of the mouthguard.

In another example, the pad may be connected to the base of the mouthguard by a ball and socket joint having the female member on the mouthguard and the male member on the pad. The pad may then be connected to the mouthguard and rotated into position. In an alternative embodiment the pad may be connected to the mouthguard using a sliding joint.

Any other suitable fastening means may be used which enables the pads to be removably connected to the mouthguard.

Preferably plastic inserts are provided and placed within any cavity present in the mouthguard during shaping of the mouthguard. The plastic inserts have a shape corresponding to the shape of the cavity and are made from any material which does not undergo deformation at the temperature at which the mouthguard is shaped to a user's teeth. In this way the shape of the cavity is maintained whilst the material of the mouthguard is deformable enabling the pads to be retained by the mouthguard after shaping has occurred.

Although the invention has been described with the mouthguard being provided with receiving means and one or more pads being provided with projections to be received by the receiving means the skilled person will understand that one or more projections may be present on the external surface of the mouthguard and received by a corresponding cavity or cavities in a pad to hold the pad in contact with the external surface of the mouthguard in any configuration described above.

In a further embodiment the user is provided with multiple mouthguards having bases with differing depths  $d$ . As with the second embodiment the user may alternate between the mouthguards in order to determine the mouthguard which provides the desired performance.