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(54) **Title:** INSTRUMENTED MOUTHGUARD DEVICES AND COMPONENTS CONFIGURED FOR USE IN INSTRUMENTED MOUTHGUARD DEVICES

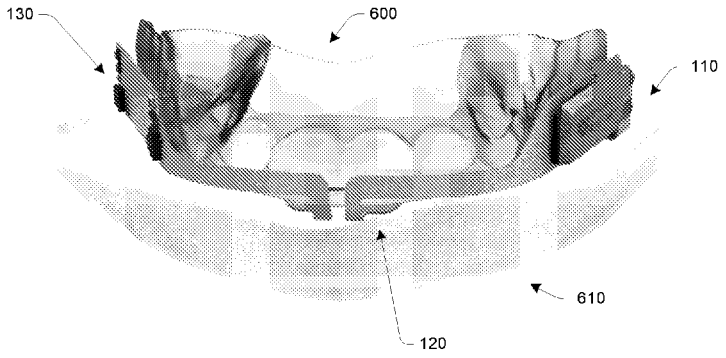


FIG. 6B

(57) **Abstract:** Described herein is technology relating to instrumented mouthguard devices, for example, instrumented mouthguards which include components such as accelerometer modules which enable monitoring of head movements of a mouthguard wearer. Various embodiments that provide instrumented mouthguard devices and components configured for use in instrumented mouthguard devices, including flexible circuit board substrates. In some embodiments the flexible circuit board substrate is configured to allow sizing irregularities resultant from customisation of the mouthguard body to a specific wearer.

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INSTRUMENTED MOUTHGUARD DEVICES AND COMPONENTS CONFIGURED FOR USE IN INSTRUMENTED MOUTHGUARD DEVICES

FIELD OF THE INVENTION

The present invention relates, in various embodiments, to instrumented mouthguard devices and components configured for use in instrumented mouthguard devices. For example, this includes instrumented mouthguards which include components such as accelerometer modules which enable monitoring of head movements of a mouthguard wearer. While some embodiments will be described herein with particular reference to those applications, it will be appreciated that the invention is not limited to such a field of use, and is applicable in broader contexts.

BACKGROUND

[0001] Any discussion of the background art throughout the specification should in no way be considered as an admission that such art is widely known or forms part of common general knowledge in the field.

[0002] In recent years, there has been an increasing focus on the effects of concussions and other traumatic brain injuries on participants in contact sports, such as football/rugby disciplines, martial arts, and the like. In response, various parties have explored the possibility of embedding instrumentation into mouthguards, including the likes of accelerometers and gyroscopes, thereby to collect data representative of head movements. However, as these instrumented mouthguards transition from research instruments to broader usage (for example as consumer devices), there are challenges to be addressed in the context of device/component design and configuration.

SUMMARY OF THE INVENTION

[0003] It is an object of the present invention to overcome or ameliorate at least one of the disadvantages of the prior art, or to provide a useful alternative.

[0004] One embodiment provides an instrumented mouthguard device including:

[0005] a mouthguard body that is configured to be worn in a user's mouth;

[0006] a flexible circuit board substrate mounted to the mouthguard body, wherein the flexible circuit board substrate includes:

[0007] at least a first and second component zone, wherein the first and second component zones are positioned at spaced apart locations on the mouthguard body;

[0008] one or more interconnective regions of the flexible circuit board substrate configured for enabling electronically coupling of the component zones, wherein a given one of the interconnective regions follows a meandering path having a length greater than the separation between those of the component zones connected by that interconnective region on a direct path along or within the mouthguard body.

[0009] One embodiment provides an instrumented mouthguard device wherein the meandering path allows for mounting of the flexible surface board substrate to the mouthguard body independent of sizing irregularities resultant from customisation of the mouthguard body to a specific wearer.

[0010] One embodiment provides an instrumented mouthguard device wherein the meandering path allows for mounting of the flexible surface board substrate to the mouthguard body such that, for a first component zone, second component zone, and third component zone:

(i) the component zones are located in:

a frontal region of the mouthguard body;

a side region of the mouthguard body; and

an opposite side region of the mouthguard body from the second component zone; and

(ii) the frontal region is located on an opposite side of a teeth-receiving channel to the side region and opposite side region.

[0011] One embodiment provides an instrumented mouthguard device wherein the frontal region is located on an inner side of the body relative to the protective channel, and the side region and opposite side regions are located on an outer side of the body relative to the protective channel.

[0012] One embodiment provides an instrumented mouthguard device wherein a sealing cover is mounted to the body thereby to seal components mounted on both the outer side of the body relative to the protective channel thereby to cover and the inner side of the body relative to the protective channel.

[0013] One embodiment provides an instrumented mouthguard device wherein at least one of the interconnective regions has a length that is at least 50% greater than the separation between the connected component zones on a direct path along or within the mouthguard body.

[0014] One embodiment provides an instrumented mouthguard device wherein the first and second component zones are respectively located in a frontal region and a side region of the mouthguard body.

[0015] One embodiment provides an instrumented mouthguard device wherein the first and second component zones are respectively located in opposed side regions of the mouthguard body.

[0016] One embodiment provides an instrumented mouthguard device including a third component zone, such that component zones are located in:

[0017] a frontal region of the mouthguard body;

[0018] a side region of the mouthguard body; and

[0019] an opposite side region of the mouthguard body from the second component zone;

[0020] wherein the conductive member has a first segment that electronically couples the first and second component zones, and a second segment that electronically couples the second and third component zones.

[0021] One embodiment provides an instrumented mouthguard device wherein at least one of the interconnective regions of the flexible circuit board substrate has a length that is at least 50% greater than the separation between the zones it couples on a direct path along or within the mouthguard body.

[0022] One embodiment provides an instrumented mouthguard device wherein at each interconnective region of the flexible circuit board substrate has a length that is at least 50% greater than the separation between the zones it couples on a direct path along or within the mouthguard body.

[0023] One embodiment provides an instrumented mouthguard device wherein the first component zone is located in the mouthguard body at a frontal region and the second component zone is located in the mouthguard body at a frontal region, and wherein the interconnective region coupling those zones is shaped thereby to provide an expandable region to enable adjustment of overall detention width thereby to accommodate varying sizes and/or shapes of mouthguard bodies.

[0024] One embodiment provides an instrumented mouthguard device wherein the expandable region has slack taken in or proximal a palette region of the mouthguard body.

[0025] One embodiment provides an instrumented mouthguard device wherein the first component zone is located in the mouthguard body at a frontal region and the second component zone is located in the mouthguard body at a frontal region, and wherein the conductive member coupling those zones is shaped thereby to provide an expandable region in a cuspid region to enable adjustment of component fit in the mouthguard body.

[0026] One embodiment provides an instrumented mouthguard device wherein each of the component zones includes at least one accelerometer device.

[0027] One embodiment provides an instrumented mouthguard device wherein at least one of the component zones includes a coupling to a battery module.

[0028] One embodiment provides an instrumented mouthguard device wherein at least one of the component zones includes a charging coil.

[0029] One embodiment provides an instrumented mouthguard device wherein at least one of the component zones includes a wireless communications module.

[0030] One embodiment provides an instrumented mouthguard device wherein at least one of the component zones includes a coupling to an antenna for the wireless communications module.

[0031] One embodiment provides an instrumented mouthguard device wherein at least one of the component zones includes a memory module and microprocessor.

[0032] One embodiment provides an instrumented mouthguard device wherein at least one of the component zones is formed from a plurality of rigid PCB segments interconnected by flexible regions.

[0033] One embodiment provides an instrumented mouthguard device wherein a common substrate in part defines the conductive member and the first and second component zones.

[0034] One embodiment provides an instrumented mouthguard device wherein the mouthguard is formed from a process including:

[0035] (i) measuring a subject;

[0036] (ii) forming an inner mouthguard body member based on the measuring of the subject;

[0037] (iii) mounting the component zones and conductive member to an outer face of the inner mouthguard body; and

[0038] (iv) sealing an outer mouthguard body member to the inner mouthguard body member thereby to encapsulate the component zones and conductive member.

[0039] One embodiment provides an instrumented mouthguard device wherein the step of measuring the subject includes a three-dimensional scanning process.

[0040] One embodiment provides an instrumented mouthguard device wherein the inner mouthguard body is formed using a mould generated from the three-dimensional scanning process.

[0041] One embodiment provides an instrumented mouthguard device wherein, wherein the component includes:

[0042] at least a first and second component zone, wherein the first and second primary component zones are configured to be positioned at spaced apart locations in a mouthguard body;

[0043] a flexible substrate that supports a conductive member electronically coupling the first and second component zones, wherein upon mounting in the mouthguard body the conductive member has a length that is at least 50% greater than the separation between the zones on a direct path along or within the mouthguard body.

[0044] One embodiment provides a method of forming a mouthguard device including:

[0045] (i) scanning an interior of a subject's mouth;

[0046] (ii) forming an inner mouthguard body member based on the scanning of the subject;

[0047] (iii) mounting a plurality of component zones and conductive member to an outer face of the inner mouthguard body, wherein the conductive member is irregularly shaped such that it is configured to enable fitting of the component zones at desired locations on inner mouthguard bodies of varied shapes and sizes; and

[0048] (iv) sealing an outer mouthguard body member to the inner mouthguard body member thereby to encapsulate the component zones and conductive member.

[0049] One embodiment provides a component for an instrumented mouthguard, wherein the component includes:

[0050] at least a first and second component zone, wherein the first and second primary component zones are configured to be positioned at spaced apart locations in a mouthguard body;

[0051] a conductive member electronically coupling the first and second component zones, wherein the conductive member is irregularly shaped such that it is configured to enable fitting of the component zones at desired locations on mouthguard bodies of varied shapes and sizes.

[0052] Reference throughout this specification to “one embodiment”, “some embodiments” or “an embodiment” means that a particular feature, structure or characteristic described in connection with the embodiment is included in at least one embodiment of the present invention. Thus, appearances of the phrases “in one embodiment”, “in some embodiments” or “in an embodiment” in various places throughout this specification are not necessarily all referring to the same embodiment, but may. Furthermore, the particular features, structures or characteristics may be combined in any suitable manner, as would be apparent to one of ordinary skill in the art from this disclosure, in one or more embodiments.

[0053] As used herein, unless otherwise specified the use of the ordinal adjectives "first", "second", "third", etc., to describe a common object, merely indicate that different instances of like objects are being referred to, and are not intended to imply that the objects so described must be in a given sequence, either temporally, spatially, in ranking, or in any other manner.

[0054] In the claims below and the description herein, any one of the terms comprising, comprised of or which comprises is an open term that means including at least the elements/features that follow, but not excluding others. Thus, the term comprising, when used in the claims, should not be interpreted as being limitative to the means or elements or steps listed thereafter. For example, the scope of the expression a device comprising A and B should not be limited to devices consisting only of elements A and B. Any one of the terms including or which includes or that includes as used herein is also an open term that also means including at least the elements/features that follow the term, but not excluding others. Thus, including is synonymous with and means comprising.

[0055] As used herein, the term “exemplary” is used in the sense of providing examples, as opposed to indicating quality. That is, an “exemplary embodiment” is an embodiment provided as an example, as opposed to necessarily being an embodiment of exemplary quality.

BRIEF DESCRIPTION OF THE DRAWINGS

[0056] Embodiments of the invention will now be described, by way of example only, with reference to the accompanying drawings in which:

[0057] FIG. 1 illustrates a PCB component for an instrumented mouthguard.

[0058] FIG. 2 to FIG. 4 illustrate positioning of the component of FIG. 1 relative to a mouthguard upon construction.

[0059] FIG. 5A and FIG. 5B illustrate components for an instrumented mouthguard according to further embodiments.

[0060] FIG. 6A to FIG. 6D illustrate an instrumented mouthguard according to a further embodiment.

DETAILED DESCRIPTION

[0061] Described herein is technology relating to instrumented mouthguard devices, for example, instrumented mouthguards which include components such as accelerometer modules which enable monitoring of head movements of a mouthguard wearer (for example in the context of collecting date relevant to assessment of brain injuries and the like). Various embodiments that provide instrumented mouthguard devices and components configured for use in instrumented mouthguard devices. In some embodiments the flexible circuit board substrate is configured to allow sizing irregularities resultant from customisation of the mouthguard body to a specific wearer.

[0062] In overview, embodiments described below include internal componentry for instrumented mouthguards. It will be appreciated that the shapes and sizes of individuals’ mouths and teeth vary significantly across a population (for example jaw size/shape, teeth size and position, and so on). In this regard, an objective, at least in some cases, is to provide an instrumented unit that is adapted to be fitted into a range of mouthguard bodies

having varied shapes and sizes. This allows for a common instrumented unit to be manufactured, and be used with mouthguard bodies that are individually customised for wearers (for example based on a 3D scanning process). Embodiments described below achieve this goal in a manner which additionally enables the instrumented component to perform well in a flexible mouthguard body, and cope with various impacts and stresses experienced by a mouthguard in use.

[0063] Some embodiments provide an instrumented mouthguard device including:

- A mouthguard body that is configured to be worn in a user's mouth - for example a custom fitted mouthguard body formed using a known user scanning and moulding process, or a variation thereof as described below.

- A flexible substrate including least a first and second component zone, wherein the first and second component zones are positioned at spaced apart locations on the mouthguard body. Preferably there are three spaced apart component zones – a front zone and two opposite side zones. The component zones each include one or more PCBs.

- Interconnective regions of the flexible substrate for electronically coupling the component zones. This may include a first segment that interconnects a side and front mounted component zone, and a second segment that interconnects the front mounted component zone and opposite side component zone.

[0064] In some embodiments there may be short separations between the component zones and interconnective regions. However, it is preferable in some embodiments that the component zones and interconnective regions are integrally formed by a common substrate. In a preferred example the conductive member and PCBs are provided on a common flexible substrate, for example a polyimide substrate which operates as a PCB itself (and has rigid PCB regions mounted thereto and/or formed thereon).

[0065] Between at least one pair of the adjacent component zones (and preferably between both adjacent pairings side zones and a common frontal zone), the interconnective region has a length that is at least 50% greater than the separation between the zones on a direct path along or within the mouthguard body. In some embodiments the interconnective region has a length that is at least 100%, 150% or 200% greater than the

separation between the component zones on a direct path along or within the mouthguard body. This extended length provides for slack in the conductive member thereby to accommodate varied mouthguard sizes, and provide a robust instrumented device. In preferred embodiments, for at least one segment, the conductive member meanders thereby to provide a “S” shape or partial “S” shape. That is, the segment includes a portion defined by a doubling back of the segment to provide a pair of substantially parallel regions.

[0066] FIG 1 illustrates an instrumented component 100 according to one embodiment, this being configured for mounting in a mouthguard body thereby to provide an instrumented mouthguard. FIG. 2, FIG. 3 and FIG. 3 show substantially how component 100 is positioned relative to a mouthguard upon instrumented mouthguard construction. As discussed in detail further below, a interconnective region supporting a conductive member electronically couples component zones (e.g. printed circuit board regions), the interconnective region supporting the conductive member being irregularly shaped such that it is configured to enable fitting of the component zones at desired locations on mouthguard bodies of varied shapes and sizes. More particularly, a PCB is formed to meander between component zones in a manner that allows for slack. It will be appreciated that, although a number of zones are discussed, an embodiment of the invention disclosed herein provides an integrally formed PCB substrate that provides a fundamental body for component 100, onto which conductive materials and PCB components are mounted. The PCB substrate may be of variable thickness, and/or have rigidity supports applied, thereby to adjust rigidity on a special basis thereby to protect PCB components as required for robustness.

[0067] Component 100 includes three component zones:

- A right side component zone 110. In this example the right side component zone is configured to support PCB components including an accelerometer(3-axis), wireless communications unit, memory and microprocessor.

- A frontal component zone 120. In this example, component zone 120 is split into two separate sub-zones, with a battery-mounting zone configured to be positioned on the inside of the front teeth, and an accelerometer supporting zone configured to be positioned on the other side of the front teeth (for a 3-axis accelerometer).

- A left side component zone 130. In this example the left side component zone provides mounting locations for an accelerometer (3-axis) and battery charging unit.

[0068] Flexible connective regions of the substrate connect these zones, including a first segment 181 which electronically couples right size component zone 110 and frontal component zone 120, and a second segment 182 which electronically couples front component zone 120 and left side component zone 130. As shown in FIG. 1, segment 181 is over 150% the length of the separation of connection points with zones 110 and 120, and segment 182 is over 200% of the separation of connection points with zones 120 and 130.

[0069] The flexible connector member provides a flexible substrate onto which conductive strips and a plurality of PCB components are mounted (for example PCB components in zones 110, 120 and 130). In some embodiments the flexible substrate has an increased thickness in certain regions thereby to provide increased rigidity for PCB components that are susceptible to damage as a result of PCB flexion (for example see regions 111, 112 and 113 discussed below). In some embodiments additional materials are applied to the flexible substrate thereby to increase rigidity where required.

[0070] In the illustrated embodiment, zone 110 is defined by three substantially rigid PCB regions 111, 112 and 113, interconnected by comparatively flexible regions (flex connectors) 114 and 115. This enables a better fit of zone 110 to a curved surface; in the present embodiment it is configured to mounted in a right cheek region of the mouthguard body. Zone 110 includes a range of electronic components, including:

- A 3-axis accelerometer.
- A microprocessor (for example a Qualcomm CSR1012).
- A memory module (for example a Macronix MX25L3233).
- A wireless communications module, in this embodiment being a Bluetooth module coupled to a Bluetooth antenna 140, this antenna configured to be mounted such that it runs across a frontal region of the mouthguard forward of a wearer's teeth.
- A coupling port to a programming tab 160. Programming tab is shown in dashed lines to indicate that it is removed prior to mounting of component 100 into a mouthguard body.

- A Light-Emitting Diode configured to be visible through the mouthguard body, in order to provide a device state indication to a user. For example, this is configured to be positioned behind the wearer's top lip.

[0071] It should be appreciated that the variations in rigidity within zone 110 (and across the component generally) is selected based at least in part of PCB components that are to be mounted at the various locations. For example, in one embodiment one or more of regions 111, 112 and 113 is not rigid, thereby to allow improved curvature upon application to the mouthguard body, and PCB components mounted to the non-rigid region are selected and/or mounted in such a manner to remain robust in spite to flexion in the PCB substrate.

[0072] Zone 120 includes a first PCB region 121 to which a battery unit is connected (with the battery being mounted to the mouthguard body in a location that in use is positioned behind right hand teeth- for example battery would be seen to extend from 121 rightwards, covering the second bicuspid and a major portion of two molars based on the constructed example in FIG. 2), and a second PCB region 122 including a 3-axis accelerometer (which is configured to be mounted to the mouthguard body in a location that in use is positioned behind front teeth).

[0073] Zone 130 is configured to be mounted on a left cheek region of the mouthguard body, and includes a PCB that carries a 3-axis accelerometer, along with a charging coil to enable wireless charging of the battery unit.

[0074] Segment 181 of the conductive member is configured such that, upon mounting to the mouthguard body, it traverses across a bottom region of the mouthguard body at a region adjacent cuspid and first bicuspid (or, alternately, first and second teeth). This allows zone 120 to be provided on an internal region (behind teeth) and zone 110 provided on an external region (in front of teeth).

[0075] Segment 182 includes a dentition meander which is configured to position slack primarily on the mouthguard body adjacent inside of the left-hand teeth as much as possible (or alternately, but less preferably, in a palette region proximal the mouthguard body adjacent inside of the left-hand teeth).

[0076] Construction of an instrumented mouthguard including component 100 preferably includes:

(i) Measuring a subject. For example, this may include a three-dimensional scanning process which accurately measures the subject's mouth and teeth. The measurement process may alternately include taking a mould.

(ii) Forming an inner mouthguard body member based on the measuring of the subject. This may include forming a mould from the measurement step, and using that to shape resilient mouthguard body materials. In some embodiments alternate techniques (such as 3D printing) are used.

(iii) Mounting component 100 (i.e. the component zones and conductive member) to an outer face of the inner mouthguard body.

(iv) Sealing an outer mouthguard body member to the inner mouthguard body member thereby to encapsulate component 100.

[0077] As further context, a conventional mouthguard manufacture method include vacuum forming one or more (typically two) layers of material over a positive mould of a dentition (for example a subject's detention as measured from scanning, moulding, or the like). According to an embodiment, a process for manufacturing an instrumented a mouthguard is a variation on this. The first layer is vacuum formed to the mould, and then the circuit board defining component 100 is affixed (for example using adhesive) to the outside of that first layer. A stiff resin or adhesive is used to fill the resulting gaps between the inner layer (which will follow the shape of the teeth) rigid sections of the PCB (which are nominally flat); this supports the circuit board and prevents damage during the next step. That next step is to vacuum form a second layer over the combined first-layer/PCB pair. If the adhesive/resin has been applied correctly, the material should not deform or flex the PCB.

[0078] Optional steps include:

- Wrapping the circuit board in electro-compatible material, such as Polyimide (Kapton) tape to prevent the outer MG layer forming around the individual components and subsequently transferring lateral force to those components, which can damage them

- Encapsulating some or all of the PCB in a semi-rigid epoxy or resin. This performs the same task as the tape above but also more strongly adheres the components to the PCB to mitigate the effect of any residual lateral loading and/or flex of the circuit board

[0079] In preferred embodiments, material layers are not modified before vacuum-forming (e.g. to form a recess into which component 100 is positioned); this ensures a minimum thickness of impact-absorbing material throughout the mouthguard (and therefore its function as a mouthguard is not compromised by presence of instrumentation).

[0080] In a further embodiment, component 100 or a variant thereof is embedded into a post-manufacture customised (e.g. a "boil and bite") mouthguard. In such an embodiment, a standard generic form is injection moulded, and a user heats the mouthguard into a temporarily deformable state and bites firmly into it thereby to shape the resilient materials substantially to their teeth before it cools and becomes stable in the new customised shape.

[0081] FIG 5A and FIG. 5B illustrates an instrumented component 500 according to a further embodiment, this being configured for mounting in a mouthguard body thereby to provide an instrumented mouthguard.

[0082] As shown in FIG. 5A, component 500 is defined by a flexible circuit board substrate which is configured such that one or more conductive members electronically couples component zones (e.g. printed circuit board regions). The flexible circuit board in this manner defines a conductive member which is irregularly shaped such that it is configured to enable fitting of the component zones at desired locations on mouthguard bodies of varied shapes and sizes. More particularly, a PCB is formed to meander between component zones in a manner that allows for customisable fitting, whilst providing for added flexibility and robustness when the mouthguard is used. This presents a significant advantage over non-meandering PCBs, or the use of wires interconnecting distinct PCBs.

[0083] The PCB substrate illustrated in FIG. 5A may be of variable thickness, and/or have rigidity supports applied, thereby to adjust rigidity on a special basis thereby to protect PCB components as required for robustness.

[0084] Component 100 includes three component zones:

- A right side component zone 110. In some implementations the right side component zone is configured to support PCB components including an accelerometer(3-axis), wireless communications unit, memory and microprocessor.

- A frontal component zone 120. In some implementations, component zone 120 is split provides an accelerometer supporting zone configured to be positioned on the outer side of the front teeth (for a 3-axis accelerometer).

- A left side component zone 130. In some implementations the left side component zone provides mounting locations for an accelerometer (3-axis), battery charging unit, and a battery mounting location.

[0085] The positioning of components described above, and shown in FIG. 5B, is an example only, and in other embodiments alternate configurations of components are distributed between the component zones.

[0086] A flexible connector member, defined by part of the PCB substrate onto which conductors connects these zones, has a first segment 181 which electronically couples right size component zone 110 and frontal component zone 120, and a second segment 182 which electronically couples front component zone 120 and left side component zone 130. As shown in FIG. 5A and 5B, these segments are meandering. In this example, as with examples above, the meandering is such that, segment 181 is over 150% the length of the separation of connection points with zones 110 and 120, and segment 182 is over 200% of the separation of connection points with zones 120 and 130.

[0087] The flexible connector member provides a flexible substrate onto which conductive strips and a plurality of PCB components are mounted (for example PCB components in zones 110, 120 and 130). In some embodiments the flexible substrate has an increased thickness in certain regions thereby to provide increased rigidity for PCB components that are susceptible to damage as a result of PCB flexion (for example see regions 111, 112 and 113 discussed below). In some embodiments additional materials are applied to the flexible substrate thereby to increase rigidity where required.

[0088] In the embodiment of FIG. 5B, zone 110 is defined by three substantially rigid PCB regions 111, 112 and 113, interconnected by comparatively flexible regions (flex connectors) 114 and 115. This enables a better fit of zone 110 to a curved surface; in the

present embodiment it is configured to mounted in a right cheek region of the mouthguard body. Zone 110 includes a range of electronic components, including:

- A 3-axis accelerometer.
- A microprocessor (for example a Qualcomm CSR1012).
- A memory module (for example a Macronix MX25L3233).
- A wireless communications module, in this embodiment being a Bluetooth module coupled to a Bluetooth antenna (not shown), for example, an antenna configured to be mounted such that it runs across a frontal region of the mouthguard forward of a wearer's teeth.
- A coupling port to a programming tab (not shown).
- A Light-Emitting Diode configured to be visible through the mouthguard body (not shown), in order to provide a device state indication to a user. For example, this is configured to be positioned behind the wearer's top lip.

[0089] It should be appreciated that the variations in rigidity within zone 110 (and across the component generally) is selected based at least in part of PCB components that are to be mounted at the various locations. For example, in one embodiment one or more of regions 111, 112 and 113 is not rigid, thereby to allow improved curvature upon application to the mouthguard body, and PCB components mounted to the non-rigid region are selected and/or mounted in such a manner to remain robust in spite to flexion in the PCB substrate.

[0090] Zone 120 includes a PCB region 122 including a 3-axis accelerometer (which is configured to be mounted to the mouthguard body in a location that in use is positioned behind front teeth).

[0091] Zone 130 is configured to be mounted on a left cheek region of the mouthguard body, and includes a PCB that carries a 3-axis accelerometer 131, along with a charging coil 132 to enable wireless charging of a battery unit 151.

[0092] In other implementations the battery unit is located in zone 110 or zone 120. In further embodiments additional components including the likes of gyroscopes may also be present at one or more of the component zones (for example a gyroscope in combination with an accelerometer at each component zone.

[0093] Segment 181 of the conductive member is configured such that, upon mounting to the mouthguard body, it traverses across a bottom region of the mouthguard body at a region approximately adjacent cuspid and first bicuspid (or, alternately, first and second teeth). This allows zone 120 to be provided on an internal region (behind teeth) and zone 110 provided on an external region (in front of teeth). A sealing cover is mounted to the body thereby to seal components mounted on both the outer side of the body relative to the protective channel thereby to cover and the inner side of the body relative to the protective channel.

[0094] As shown in FIG. 6A to FIG. 6D, an instrumented mouthguard device is formed from a user-customised body 600, a PCB component having a configuration similar to that shown in FIG. 5A/FIG. 5B, and a sealing cover 610. The meandering path allows for mounting of the flexible surface board substrate to the mouthguard body such that the component zones are located in a frontal region of the mouthguard body (component zone 120); a side region of the mouthguard body (component zone 110); and an opposite side region of the mouthguard body from the second component zone (component zone 130). The frontal region is located on an opposite side of a teeth-receiving channel to the side region and opposite side region. In this example the frontal region is located on an inner side of the body relative to the protective channel, and the side region and opposite side regions are located on an outer side of the body relative to the protective channel. A sealing cover 610 is mounted to the body thereby to seal components mounted on both the outer side of the body relative to the protective channel thereby to cover and the inner side of the body relative to the protective channel.

[0095] It should be appreciated that in the above description of exemplary embodiments of the invention, various features of the invention are sometimes grouped together in a single embodiment, FIG., or description thereof for the purpose of streamlining the disclosure and aiding in the understanding of one or more of the various inventive aspects. This method of disclosure, however, is not to be interpreted as reflecting an intention that the claimed invention requires more features than are expressly recited in each claim. Rather, as the following claims reflect, inventive aspects lie in less than all features of a

single foregoing disclosed embodiment. Thus, the claims following the Detailed Description are hereby expressly incorporated into this Detailed Description, with each claim standing on its own as a separate embodiment of this invention.

[0096] Furthermore, while some embodiments described herein include some but not other features included in other embodiments, combinations of features of different embodiments are meant to be within the scope of the invention, and form different embodiments, as would be understood by those skilled in the art. For example, in the following claims, any of the claimed embodiments can be used in any combination.

[0097] In the description provided herein, numerous specific details are set forth. However, it is understood that embodiments of the invention may be practiced without these specific details. In other instances, well-known methods, structures and techniques have not been shown in detail in order not to obscure an understanding of this description.

[0098] Similarly, it is to be noticed that the term coupled, when used in the claims, should not be interpreted as being limited to direct connections only. The terms "coupled" and "connected," along with their derivatives, may be used. It should be understood that these terms are not intended as synonyms for each other. Thus, the scope of the expression a device A coupled to a device B should not be limited to devices or systems wherein an output of device A is directly connected to an input of device B. It means that there exists a path between an output of A and an input of B which may be a path including other devices or means. "Coupled" may mean that two or more elements are either in direct physical or electrical contact, or that two or more elements are not in direct contact with each other but yet still co-operate or interact with each other.

Thus, while there has been described what are believed to be the preferred embodiments of the invention, those skilled in the art will recognize that other and further modifications may be made thereto without departing from the spirit of the invention, and it is intended to claim all such changes and modifications as falling within the scope of the invention.

CLAIMS

1. An instrumented mouthguard device including:

a mouthguard body that is configured to be worn in a user's mouth, wherein the body includes a protective channel which is configured to receive and protect the user's upper and/or lower teeth;

a flexible circuit board substrate mounted to the mouthguard body, wherein the flexible circuit board substrate includes:

at least a first and second component zone, wherein the first and second component zones are positioned at spaced apart locations on the mouthguard body;

one or more interconnective regions of the flexible circuit board substrate configured for enabling electronically coupling of the component zones, wherein a given one of the interconnective regions follows a meandering path having a length greater than the separation between those of the component zones connected by that interconnective region on a direct path along or within the mouthguard body.

2. An instrumented mouthguard device according to claim 1 wherein the meandering path allows for mounting of the flexible circuit board substrate to the mouthguard body independent of sizing irregularities resultant from customisation of the mouthguard body to a specific wearer.

3. An instrumented mouthguard device according to claim 1 wherein the meandering path allows for mounting of the flexible surface board substrate to the mouthguard body such that, for a first component zone, second component zone, and third component zone:

(i) the component zones are located in:

a frontal region of the mouthguard body;

a side region of the mouthguard body; and

an opposite side region of the mouthguard body from the second component zone; and

(ii) the frontal region is located on an opposite side of the protective channel channel to the side region and opposite side region.

4. An instrumented mouthguard device according to claim 3 wherein the frontal region is located on an inner side of the body relative to the protective channel, and the side region and opposite side regions are located on an outer side of the body relative to the protective channel.

5. An instrumented mouthguard device according to claim 3 wherein a sealing cover is mounted to the body thereby to seal components mounted on both the outer side of the body relative to the protective channel thereby to cover and the inner side of the body relative to the protective channel.

6. An instrumented mouthguard device according to any preceding claim wherein at least one of the interconnective regions has a length that is at least 50% greater than the separation between the connected component zones on a direct path along or within the mouthguard body.

7. An instrumented mouthguard according to claim 1 wherein the first and second component zones are respectively located in a frontal region and a side region of the mouthguard body.

8. An instrumented mouthguard according to claim 1 wherein the first and second component zones are respectively located in opposed side regions of the mouthguard body.

9. An instrumented mouthguard according to claim 1 including a third component zone, such that component zones are located in:

a frontal region of the mouthguard body;

a side region of the mouthguard body; and

an opposite side region of the mouthguard body from the second component zone;

wherein the conductive member has a first segment that electronically couples the first and second component zones, and a second segment that electronically couples the second and third component zones.

10. An instrumented mouthguard according to claim 9 wherein at least one of the interconnective regions of the flexible circuit board substrate has a length that is at least 50% greater than the separation between the zones it couples on a direct path along or within the mouthguard body.

11. An instrumented mouthguard according to claim 9 wherein at each interconnective region of the flexible circuit board substrate has a length that is at least 50% greater than the separation between the zones it couples on a direct path along or within the mouthguard body.

12. An instrumented mouthguard device according to claim 1 wherein the first component zone is located in the mouthguard body at a frontal region and the second component zone is located in the mouthguard body at a frontal region, and wherein the interconnective region coupling those zones is shaped thereby to provide an expandable region to enable adjustment of overall detention width thereby to accommodate varying sizes and/or shapes of mouthguard bodies.

13. An instrumented mouthguard according to claim 12 wherein the expandable region has slack taken in or proximal a palette region of the mouthguard body.

14. An instrumented mouthguard device according to claim 1 wherein the first component zone is located in the mouthguard body at a frontal region and the second component zone is located in the mouthguard body at a frontal region, and wherein the conductive member coupling those zones is shaped thereby to provide an expandable region in a cuspid region to enable adjustment of component fit in the mouthguard body.

15. An instrumented mouthguard device according to any preceding claim wherein each of the component zones includes at least one accelerometer device.

16. An instrumented mouthguard device according to any preceding claim wherein at least one of the component zones includes a coupling to a battery module.

17. An instrumented mouthguard device according to any preceding claim wherein at least one of the component zones includes a charging coil.

18. An instrumented mouthguard device according to any preceding claim wherein at least one of the component zones includes a wireless communications module.

19. An instrumented mouthguard device according to any preceding claim wherein at least one of the component zones includes a coupling to an antenna for the wireless communications module.

20. An instrumented mouthguard device according to any preceding claim wherein at least one of the component zones includes a memory module and microprocessor.

21. An instrumented mouthguard device according to any preceding claim wherein at least one of the component zones is formed from a plurality of rigid PCB segments interconnected by flexible regions.

22. An instrumented mouthguard according to any preceding claim wherein a common substrate in part defines the conductive member and the first and second component zones.

23. An instrumented mouthguard according to any preceding claim wherein the mouthguard is formed from a process including:

(i) measuring a subject;

(ii) forming an inner mouthguard body member based on the measuring of the subject;

(iii) mounting the component zones and conductive member to an outer face of the inner mouthguard body; and

(iv) sealing an outer mouthguard body member to the inner mouthguard body member thereby to encapsulate the component zones and conductive member.

24. An instrumented mouthguard according to claim 23 wherein the step of measuring the subject includes a three-dimensional scanning process.

25. An instrumented mouthguard according to claim 24 wherein the inner mouthguard body is formed using a mould generated from the three-dimensional scanning process.

26. A component for an instrumented mouthguard, wherein the component includes:

at least a first and second component zone, wherein the first and second primary component zones are configured to be positioned at spaced apart locations in a mouthguard body;

a flexible substrate that supports a conductive member electronically coupling the first and second component zones, one or more interconnective regions of the

flexible substrate configured for enabling electronically coupling of the component zones, wherein a given one of the interconnective regions follows a meandering path having a length greater than the separation between those of the component zones connected by that interconnective region on a direct path along or within the mouthguard body.

27. A component according to claim 26 wherein the component is configured to form a mouthguard device according to any one of claims 1-25

28. A method of forming a mouthguard device including:

(i) scanning an interior of a subject's mouth;

(ii) forming an inner mouthguard body member based on the scanning of the subject;

(iii) mounting a plurality of component zones and conductive member to an outer face of the inner mouthguard body, wherein the conductive member is irregularly shaped such that it is configured to enable fitting of the component zones at desired locations on inner mouthguard bodies of varied shapes and sizes; and

(iv) sealing an outer mouthguard body member to the inner mouthguard body member thereby to encapsulate the component zones and conductive member.

29. A method according to claim 28 wherein the formed mouthguard is a mouthguard device according to any one of claims 1-25.

30. A component for an instrumented mouthguard, wherein the component includes:

at least a first and second component zone, wherein the first and second primary component zones are configured to be positioned at spaced apart locations in a mouthguard body;

a conductive member electronically coupling the first and second component zones, wherein the conductive member is irregularly shaped such that it is configured to enable fitting of the component zones at desired locations on mouthguard bodies of varied shapes and sizes.

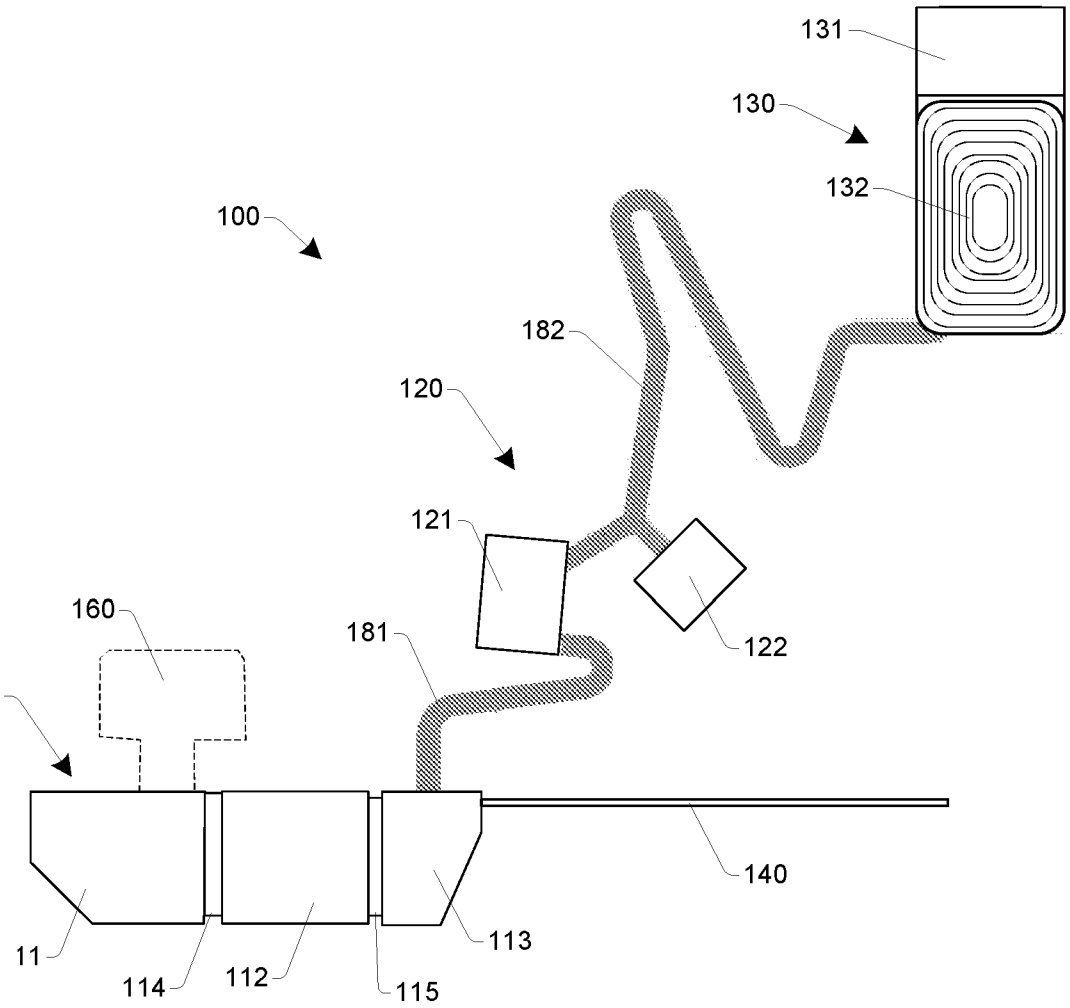


FIG. 1

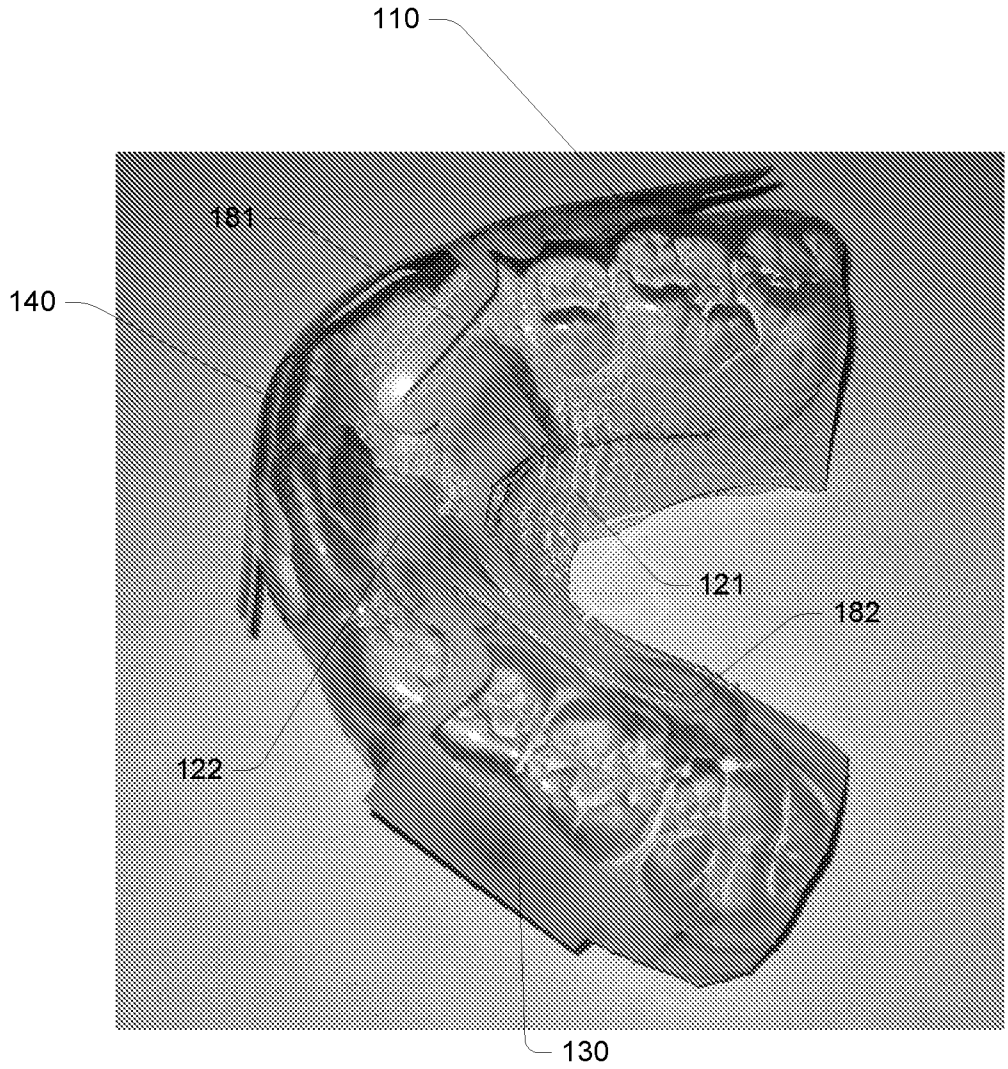


FIG. 2

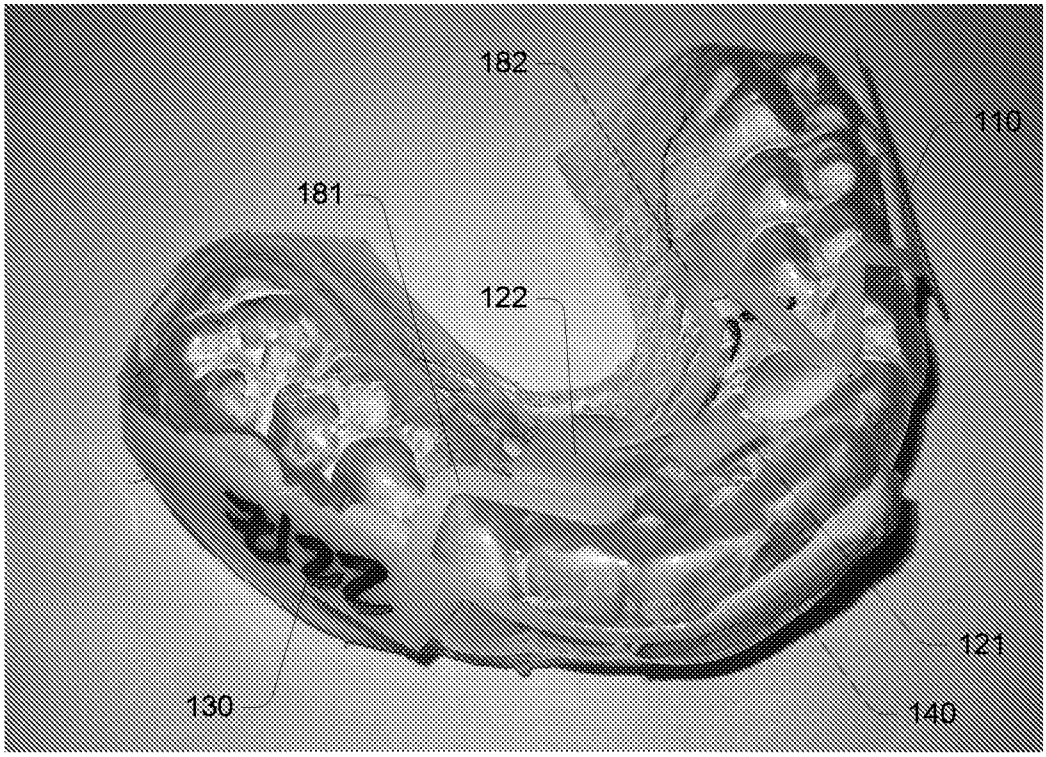


FIG. 3

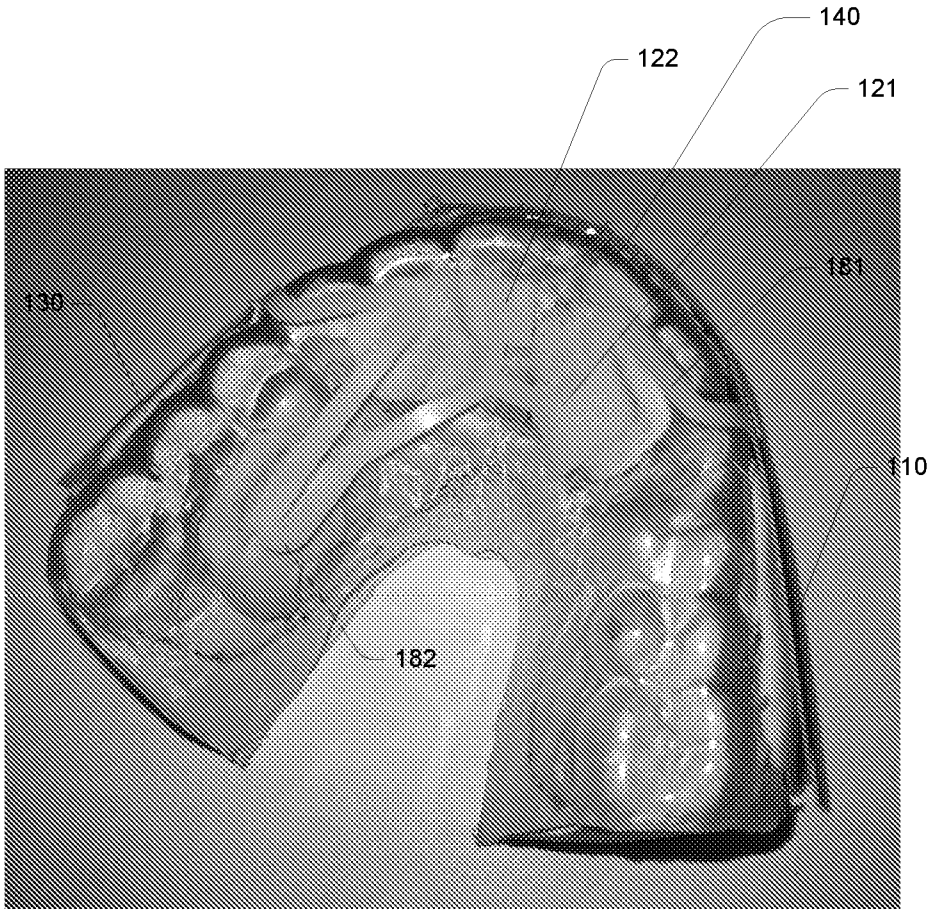


FIG. 4

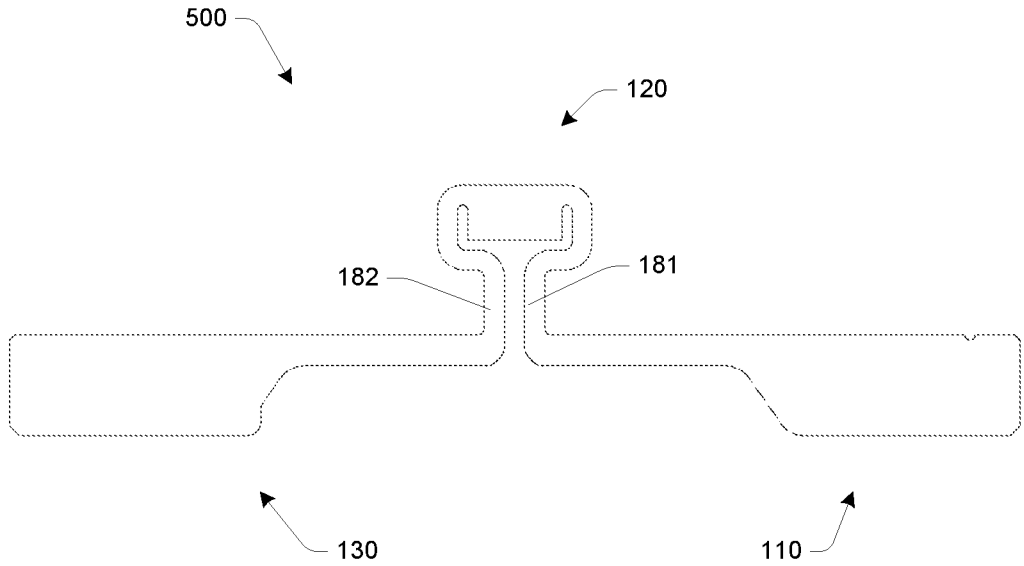


FIG. 5A

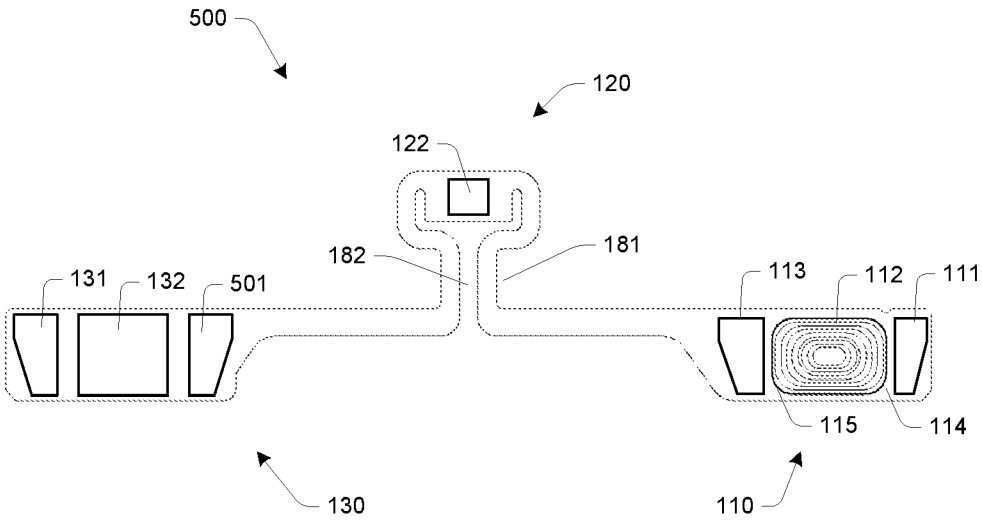


FIG. 5B

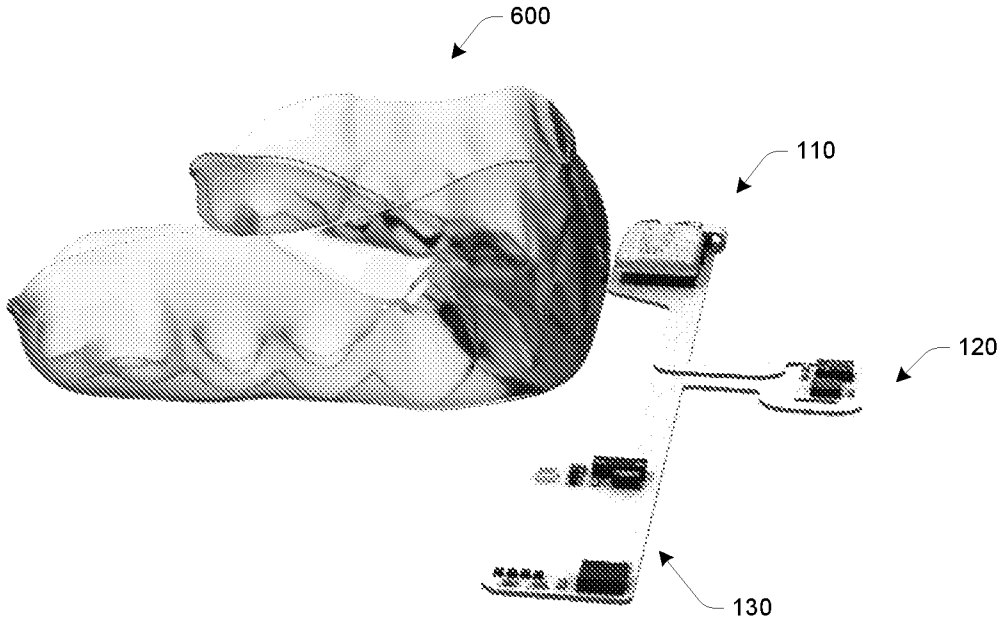


FIG. 6A

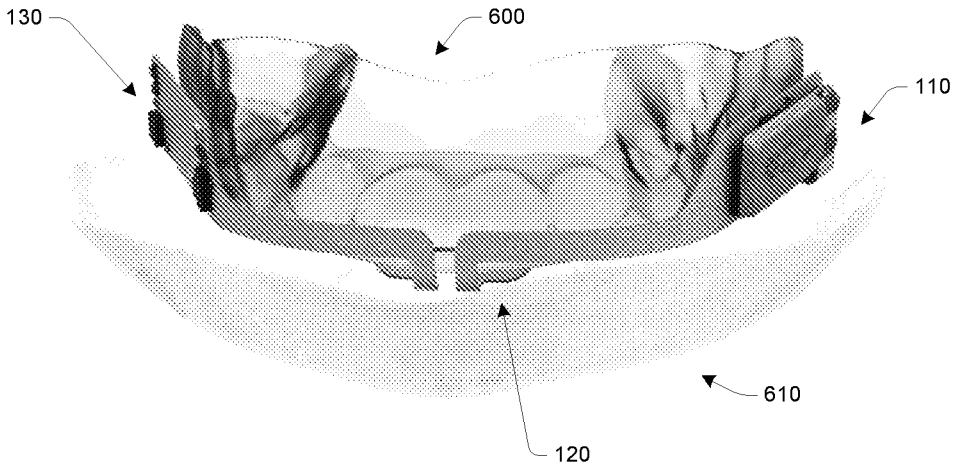


FIG. 6B

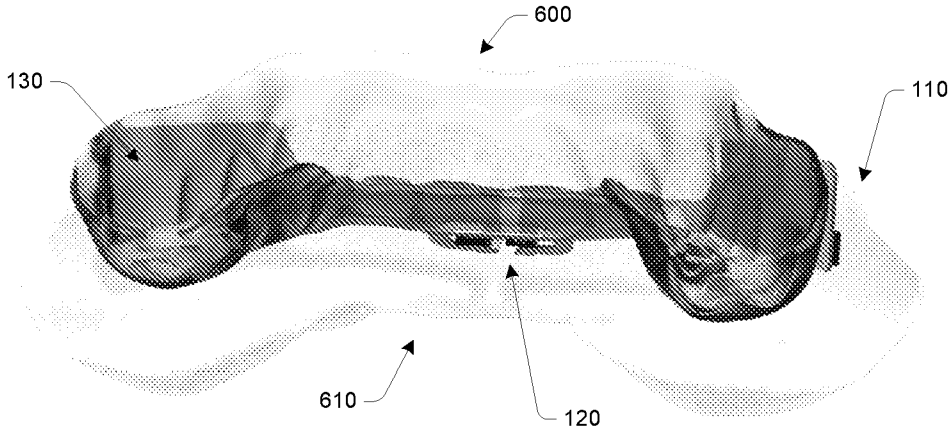


FIG. 6C

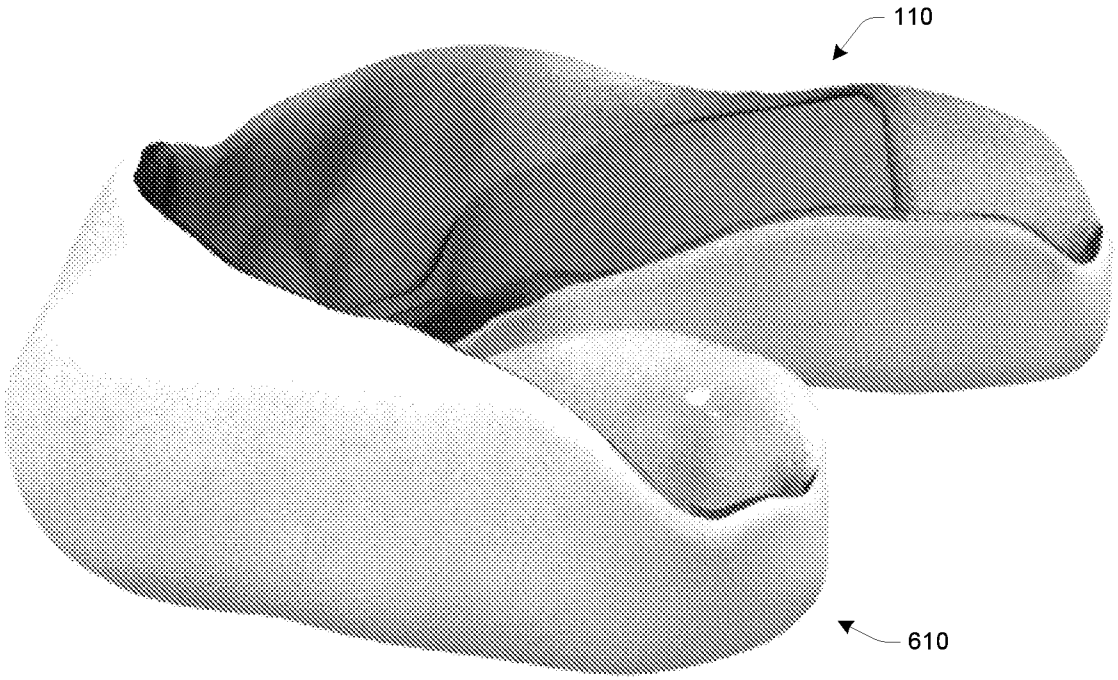


FIG. 6D

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2020/050096

A. CLASSIFICATION OF SUBJECT MATTER

A61B 5/11 (2006.01) A63B 71/08 (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Databases: PATENW, EPODOC, WPI; classification symbols: A61B5/4064, A61B5/4076, A61B5/11/LOW, A61C7/08, A61F2005/563, A61F5/566, A63B71/085/LOW, A63B71/10, A61B5/6803, A61B5/682, A61B5/6847, A61B2562/0219, A63B2220/836, A63B2220/40/LOW and A63B2220/803; keywords: detect, measure, acceleration, movements, meandering, irregular, interconnective, conductive, size, shape, customised, tailored and like terms; applicant name 'HITIQ LIMITED' searched; inventors name 'VEGAR Michael', 'NIZETTE Ben', 'LANG Lucas' and 'AUSTIN David' searched

Google Patents: mouthguard, gumshield, detect, measure, acceleration, movements, meandering, irregular, interconnective, conductive, size, shape, customised, tailored and like terms

Applicant/Inventors name searched in internal databases provided by IP Australia

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	Documents are listed in the continuation of Box C	

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"D" document cited by the applicant in the international application

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
7 May 2020	07 May 2020

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INTERNATIONAL SEARCH REPORT C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		International application No. **PCT/AU2020/050096**
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 3329844 A1 (IMPACT TECHNOLOGIES AUSTRALIA PTY LTD) 06 June 2018 Whole document	1-30
A	EP 3330971 A1 (IMPACT TECHNOLOGIES AUSTRALIA PTY LTD) 06 June 2018 Whole document	1-30
A	US 2017/0238850 A1 (MERRIGON, LLC) 24 August 2017 Whole document	1-30
A	US 2017/0156635 A1 (THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY) 08 June 2017 Whole document	1-30
A	US 2014/0188010 A1 (UNIVERSITY OF ALASKA ANCHORAGE) 03 July 2014 Whole document	1-30
A	US 2014/0187875 A1 (UNIVERSITY OF ALASKA ANCHORAGE) 03 July 2014 Whole document	1-30
A	US 2015/0305671 A1 (UNIVERSITY OF FLORIDA RESEARCH FOUNDATION, INC.) 29 October 2015 Whole document	1-30

INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/AU2020/050096**

This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document/s Cited in Search Report		**Patent Family Member/s**	
Publication Number	**Publication Date**	**Publication Number**	**Publication Date**
EP 3329844 A1	06 June 2018	EP 3329844 A1	06 Jun 2018
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		US 10517525 B2	31 Dec 2019
		WO 2014110548 A1	17 Jul 2014

End of Annex

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.