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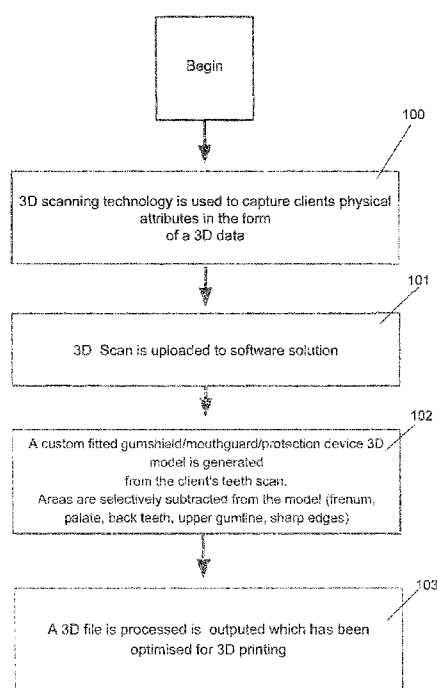


Figure 1

(57) Abstract: The present invention relates to a system and method of manufacturing a mouth piece by 3D printing a 3D printer readable file encoding the mouth piece, the method comprising steps of: obtaining a scan file comprising physical data representing a user's teeth and gum line using 3D scanner means (100); removing outlier data from physical data in the scan file; generating representative geometrical data of the curvature of the user's teeth and gum line from the physical data; generating a virtual base model representing a mouth piece from the physical data and the representative geometrical data, the virtual base model having customisable dimensions (101); removing selected regions from the mouth piece represented by the virtual base model (102); and from the virtual base model, generating the 3D printer readable file encoding the mouth piece for printing on 3D printing means (103). The present invention provides a computer implemented development environment adapted with user interface means providing an operator with the ability to customise the mouth piece as required.

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SYSTEM AND METHOD OF MANUFACTURING A MOUTH PIECE

The present invention provides a system and method of manufacturing a mouth piece, such as a protective gum shield, mouth guard or protection device worn in the mouth of a user.

5

A mouthpiece, also known as a protective gum shield or mouth guard, is a device fitted inside the mouth that offers personal protection to reduce the possibility of impact trauma to the arches, teeth, lips and gum line often associated with impact sports. Other uses also include; a protective mouthpiece which also offers corrective alignment, treatment for

10 Bruxism, mitigating or compensating for movement during medical procedures, an intraoral device to monitor athlete performance markers (temperature, heart rate, concussion, lactose levels, hydration etc.) to monitor sleep apnoea and Temporomandibular joint dysfunction.

15 There are several methods for producing mouth pieces and gum shields, including ready-made mouth guards, boil and bite, vacuum forming, pressure lamination, impressions, manual three dimensional (3D) modelling and 3D printed positive moulds.

With stock or ready-made mouth pieces and gum shields, devices are manufactured in a

20 pre-formed shape in various sizes but with nearly no adjustment to fit the user's mouth. The only adjustment possible is minor trimming with a knife or scissors. The approach results in a device that offers little protection of the teeth, nor any protection to the gum line. The devices are also extremely uncomfortable for the user to wear since they are ill fitting.

25 The "boil and bite" method involves a thermo-plastic material manufactured in a pre-formed shape in various sizes that is adapted to fit more closely to an individual's teeth and gum line. The method involves heating and moulding the pre-formed shaped thermo-plastic material, such as by boiling in water, then letting the pre-formed shape temporarily cool down before then placing in the wearers mouth. Such devices may incorporate fins within

30 fitting zones which increase retention and give an improved fit over traditional "boil and bite" mouth types. Such devices are usually made of ethylene-vinyl acetate, commonly known as EVA. Some of the newer technologies offer an alternative, stronger thermo-polymer that allows for lower moulding temperatures, below 140F, preventing burning by scolding hot water. "Boil and bite" devices are the most popular gum shield type used by amateur and

35 semi-professional sports people, and provide more protection than a ready-made gum

shield but still relatively low protection, comfort and fit in comparison to a custom-made mouth piece or gum shield.

Custom-made mouth pieces and gum shields require an impression of a user's teeth being
5 taken and then used by specialist manufacturers to create a best-fit mouth protector. The
impression may be obtained by using a specifically designed impression kit that uses dental
putty, or from a dentist who will take an impression in dental alginate material. The resulting
impression is sent to a lab that makes a device from the impression. The mouth pieces and
gum shields may then be made using vacuum form, pressure laminated or 3D scanning
10 techniques.

A custom-made mouth piece and gum shield is manufactured using a vacuum forming
machine and produces a single layer device. The fit is not as good as pressure laminated
but offers more protection than boil and bite. It is a slow, costly and labour intensive process.
15 A pressure laminated custom-made gum shield produces a multi-layer device which offers
superior fit, comfort and offers the most protection. Again it is a slow, costly and labour
intensive process.

Rather than using dental alginate to create a positive mould, a 3D scanner may also be
20 used to capture a user's dental profile. The dental profile of the person is then produced
through a high end 3D printing device. This dental profile can then be used to produce a
custom mouth piece or gum shield via the pressure laminated or vacuum forming methods.
This scan data can also be used to manually design a device using computer aided design
software, but is extremely time intensive and there are no available 3D plastic filaments on
25 the market that can be used via 3D printing methods.

The present invention provides a system and method for fabricating a mouth piece or
protective gum shield using 3D printing which alleviates the above problems or provides the
public or industry with a useful alternative.

30

Accordingly, there is provided a method of manufacturing a mouth piece by 3D printing a
3D printer readable file encoding the mouth piece, the method comprising steps of:

obtaining a scan file comprising physical data representing a user's teeth and gum
35 line using three dimensional (3D) scanner means;

removing outlier data from physical data in the scan file;

5 generating representative geometrical data of the curvature of the user's teeth and gum line from the physical data;

10 generating a virtual base model representing a mouth piece from the physical data and the representative geometrical data, the virtual base model having customisable dimensions;

removing selected regions from the mouth piece represented by the virtual base model, and

15 from the virtual base model, generating the 3D printer readable file encoding the mouth piece for printing on 3D printing means.

The present invention provides a method of manufacturing a mouth piece or gum shield, for the upper and/or lower teeth, in a computer implemented development environment adapted with user interface means providing an operator with the ability to customise the mouth piece as required. Using 3D scanned dental data obtained as input, an automated computer software enabled process generates a customisable, digital, three dimensional (3D) models and selectively removes specific areas of interference to create a device tailored for the individual in a range of sports and medical applications. The software process then outputs a file ready for digital manufacture using a 3D printer.

25 Alternatively, the scan file is generated using one or more photos of the user's teeth and gum line.

30 The step of selectively removing regions from the teeth and gum line in the virtual base model may be performed by a user interface provided as a slider or value shifter that when manipulated by a user shows a graphical representation of the regions that will be excluded when generating the mouthpiece.

35 Preferably, the method comprises a step of displaying the mouth piece represented in the virtual base model in a user interface, the user interface having adjustable value sliders or

value shifters which show a visual display of and are adapted for adjusting smoothness, thickness, scale, positioning and desired dimensions of the mouth piece.

5 Preferably, the method comprises a step of: operating sliders provided by a graphical user interface to outline outlier data in the virtual base model.

Preferably, the representative geometrical data is automatically generated according to a predetermined level of smoothness, thickness scale positioning and desired dimensions.

10 Alternatively, the representative geometrical data is generated according to an operator selected level of smoothness, thickness, scale, positioning and desired dimensions as specified by values in a settings file or as an input provided via a graphical user interface.

15 Preferably, the representative geometrical data comprises one or more of: spline data, point cloud data and/or other geometrical data for representing the curvature of the user's teeth and gum line.

20 Preferably, the mouth piece in the virtual base model has one or more regions comprising: a frenum region, palate region, one or more teeth regions, and the upper and/or lower gum line regions depending on whether the mouth piece is for one or both of the upper and/or lower teeth.

25 Preferably, the method comprises a step of selectively removing from the mouth piece in the virtual base model one or more of: the frenum region, palate region, back teeth region, upper and/or lower gum line region and sharp edges.

30 Preferably, the step of selectively removing regions from the mouth piece in the virtual base model is performed by an operator manually selecting regions for removal on user interface means.

Preferably, the method comprises a step of: exporting a collected set of rules or settings to process the virtual base model to achieve a desired thickness, scale positioning and desired dimensions for the mouth piece in the virtual base model.

Preferably, the method comprises a step of: batch processing a plurality of virtual base models in groups according to the model specific settings files exported from a graphical user interface. This step stores a set of rules to generate each mouth piece comprising of geometrical and positioning data, smoothing thickness, scale, desired dimensions and data to be added or removed.

5

Preferably, the step of removing one or more teeth regions from the mouth piece in the virtual base model is performed automatically.

10 Preferably, the method comprises a step of altering a thickness of walls of the mouth piece in the virtual base model. Such a feature offers varying levels of mass protection and shock absorption depending on the chosen sport or medical application.

15 Preferably, the method comprises a step of softening sharp edges of the mouth piece in the virtual base model.

20 Preferably, the method comprises a step of: automatically aligning and positioning the teeth and gum line shown in the scan file according to an origin or reference point on an X, Y, Z coordinate system such that teeth and gum line in the scan file are consistently positioned and pointing in the correct direction relative to the X, Y, Z coordinate system.

25 Alternatively, the method comprises a step of manually aligning teeth and gum line of the scan file using a graphical user interface. This step consists of the user choosing three or more points on the teeth and gum line in the scan file to align with three or more preset points to correctly orientate the scan file such that the teeth pointing in a consistent direction.

Preferably, the method comprises a step of removing a section of the top inner wall of the palate region from the virtual base model.

30 Preferably, the method comprises a step of automatically removing any overhanging or desired parts of the mouth piece in the virtual base model that may cause irritation to the gum line.

Preferably, dimensions of the top inner wall of the palate region removed from the virtual base model are computed according to physical data of the user's teeth and gum line in the scan file.

- 5 Preferably, the method comprises a step of using geometrical data to generate a shape which fills gaps between adjacent or missing teeth or area to avoid interconnected pieces on the finished mouth piece.

- 10 Preferably, the method comprises a step of tracking the location of all edges of the mouth piece in the virtual base model and softening the edges.

Preferably, the method comprises a step of printing the 3D printer readable file on a 3D printer or similar additive manufacturing machine to provide the mouth piece.

- 15 Alternatively, the method comprises a step of exporting a CNC readable file for subtractive manufacturing.

- 20 Preferably, the method comprises a further step of incorporating peripheral device attachment data into the virtual base model, the peripheral device attachment data representing a receiver or connection means for the attachment of peripheral devices to the mouth piece when 3D printed. The peripheral device attachment data provides the mouth piece, once printed, with the necessary receiving or connection means to facilitate attachment of peripheral devices to the mouth piece.

- 25 Preferably, the peripheral device is attached to the receiver or connection means using mechanical, interference, adhesive or other suitable attachment means.

- Preferably, the method comprises a step of: creating an internal void in the virtual base model for accommodating one or devices, such as electronic or other devices, therein.
30 Such devices may be positioned in the void created during and/or after 3D printing.

- Preferably, the method comprises a further step of incorporating internal components such as electronic or other device types in the mouth piece. Data representing the dimensions of the device is removed creating a void in the virtual base model in which the device will be
35 placed during or after the 3D printing process.

Preferably, the method comprises a step of adding symbols, lettering, numbers, images or logos onto the surface of the mouth piece either by creating cut outs in the virtual base model or applying colour mapped textures to the virtual base model.

5

Preferably, the method comprises a step of applying coloured logos, colours or images to the virtual base model for 3D colour printing.

10 This feature enables branding, product details, player or other information to be provided on the 3D printed mouth piece.

Preferably, the method comprises a step of: creating relief cuts to the outer surface of the virtual base model to facilitate fitting or removal with or without the presence of braces worn on the teeth of a user. This step which makes allowances for the presence of braces by
15 removing material and creating a void around the perimeter of the braces and placing relief cuts in the outer surface of the mouth piece to facilitate easier removal and to prevent irritation or damage to the brace.

The mouthpiece may thus also optionally be dimensioned and configured as required for
20 wearing over orthodontic teeth braces or other realignment devices worn by a user.

The invention also relates to a mouth piece manufactured according to the steps recited above.

25 The invention also provides a system for manufacturing a mouth piece by 3D printing a 3D printer readable file encoding the mouth piece, the system comprising:

means for obtaining a scan file comprising physical data representing a user's teeth and gum line using three dimensional (3D) scanner means;

30

means for removing outlier data from physical data in the scan file;

means for generating representative geometrical data of the curvature of the user's teeth and gum line from the physical data;

35

means for generating a virtual base model representing a mouth piece from the physical data and the representative geometrical data, the virtual base model having customisable dimensions;

5 means for removing selected regions from the mouth piece represented by the virtual base model, and

means for generating from the virtual base model the 3D printer readable file encoding the mouth piece for printing on 3D printing means.

10

Preferably, the system comprises means for incorporating peripheral device attachment data into the virtual base model, the peripheral device attachment data representing a receiver or connection means for attaching a peripheral device to the mouth piece when 3D printed.

15

The mouth piece in the virtual base model has one or more regions comprising: a frenum region, palate region, back teeth region and upper and/or lower gum line region, and the system comprises means for selectively removing from the mouth piece in the virtual base model one or more or portions of: the frenum region, palate region, back teeth region, upper
20 and/or lower gum line region and sharp edges.

Preferably, selectively removing regions from the mouth piece in the virtual base model is performed automatically or by an operator manually selecting regions for removal via user interface means.

25

Preferably, the system comprises means for altering a thickness of walls of the mouth piece in the virtual base model, softening sharp edges of the mouth piece in the virtual base model and/or removing a section of the top inner wall of the palate region from the virtual base model.

30

Preferably, the system comprises means for computing dimensions of the top inner wall of the palate region to be removed from the virtual base model according to physical data of the user's teeth and gum line in the scan file.

Preferably, the system comprises means for tracking the location of all edges of the mouth piece in the virtual base model and softening the edges.

5 Preferably, the system comprises for printing the 3D printer readable file on a 3D printer to provide the mouth piece.

Preferably, the system comprises means for incorporating an internal device during or after 3D printing of the mouth piece.

10 Preferably, the system comprises means for generating data representing the internal device and creating a void in the virtual base model into which the internal device can be placed pre, post or during 3D printing.

15 Preferably, the system comprises means for generating the scan file using one or photos of the user's teeth and gum line.

Preferably, the system comprises user interface means for selectively removing regions from the teeth and gum line in the virtual base model, the user interface means provided as a slider or value shifter that when manipulated by a user shows a graphical representation
20 of the regions of the teeth and gum line that will be excluded when generating the mouth piece.

Preferably, the system comprises user interface means for displaying the mouth piece represented in the virtual base model, the user interface having adjustable value sliders or
25 value shifters that show a visual display of and are adapted for adjusting smoothness, thickness, scale, positioning and desired dimensions of the mouth piece in the virtual base model.

Preferably, the system comprises means for exporting a collected set of rules or settings to
30 process the virtual base model to achieve a desired thickness, scale positioning and desired dimensions for the mouth piece in the virtual base model.

Preferably, the system comprises means for batch processing a plurality of virtual base models in groups according to the model specific settings files exported from a graphical
35 user interface by storing a set of rules to generate each mouth piece according to

geometrical and positioning data, smoothing thickness, scale, desired dimensions and data representing portions of the mouth piece to be added or removed.

5 Preferably, the system comprises means for automatically aligning and positioning the teeth and gum line shown in the scan file according to an origin or reference point on an X, Y, Z coordinate system such that teeth and gum line in the scan file are consistently positioned and pointing in the correct direction relative to the X, Y, Z coordinate system.

10 Preferably, the system comprises means for manually aligning teeth and gum line of the scan file using a graphical user interface, in which three or more points on the teeth and gum line in the scan file are chosen and configured to align with three or more preset points to correctly orientate the teeth and gum line in the scan file in a desired direction.

15 Preferably, the system comprises means for automatically removing any overhanging or desired parts of the mouth piece in the virtual base model.

20 Preferably, the system comprises means for using geometrical data to generate a shape which fills gaps between adjacent or missing teeth or area to avoid interconnected pieces on the printed mouth piece.

Preferably, the system comprises means for creating an internal void in the virtual base model for accommodating one or devices, such as electronic or other devices, therein.

25 Preferably, the system comprises means for using data representing the dimensions of the device to create the internal void in the virtual base model in which the device will be placed during or after the 3D printing process.

30 Preferably, the system comprises means for adding symbols, lettering, numbers, images or logos onto the surface of the mouth piece either by creating cut outs in the virtual base model or applying colour mapped textures to the virtual base model.

Preferably, the system comprises means for creating relief cuts in the outer surface of the virtual base model to facilitate fitting or removal with or without the presence of orthodontic braces worn on the teeth of a user.

The invention also provides a non-transitory machine-readable medium comprising instructions that, when executed by one or more processors, cause the one or more processors to perform the steps according to the method.

- 5 The invention will be more clearly understood from the following description of some embodiments thereof, given by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is a flow diagram showing the steps involved in a method of
10 manufacturing a mouth piece according to the invention, and

Figures 2 to 9 further illustrate the steps in the flow diagram of Figure 1

Figure 10 shows a manufactured 3D printed mouth piece with receiver or
15 connection means for attachment of a peripheral device;

Figure 11 shows a graphical user interface comprising an adjustable slider operable to reduce or increase the included height of a user's gum line as represented in a scan file of the users teeth and gum line;
20

Figure 12 shows a graphical user interface operable as adjustable sliders to position a cut line for removing sections of the users teeth and gum line as represented in a scan file of the users teeth and gum line;

25 Figure 13 shows a graphical user interface adapted for alignment and displaying teeth and gum line in a scan file;

Figure 14 shows the output of a step of filling gaps between adjacent or missing
teeth;
30

Figure 15 shows the output of a step of creating a void in the virtual base model to accommodate a device in a mouth piece;

Figure 16 shows the output of a step of applying colour textures to a mouth
35 piece in the virtual base model;

Figure 17 shows the output of a step of applying logos, letter and/or numerals to a mouth piece in the virtual base model, and

5 Figure 18 is a sectional view from above illustrating brace relief and voids created for use when a user wears teeth braces in the virtual base model;

Figure 18a is a front and a side sectional of Figure 18;

10 Figure 19 is a block diagram of a system configured according to the invention.

Accordingly, and referring to the drawings, there is shown a method of manufacturing a mouth piece by 3D printing a 3D printer readable file encoding the mouth piece.

15 As shown in Figures 1 and 2, the method comprises an initial step 100 of obtaining physical data representing a user's teeth and gum line 1 using 3D scanner means 2 and generating from such data a scan file. 3D scanning technology, as known in the art, and is used to capture a person's physical attributes in the form of the 3D data in the scan file for processing. The scan file is transmitted at step 101 to a computer device, such as
20 processing means 3, executing software operable to process the 3D data contained in the scan file. Alternatively, the scan file is generated by processing by suitable scanner means one or photos of the user's teeth and gum line. As shown, in Figures 3 the 3D scan file is displayed as image 4 of a user's teeth and gum line 1 by processing means 3 when uploaded.

25 Processing of the scan file is performed at step 102. As shown in Figures 4A and 4B, such processing includes selectively removing, ignoring or filtering outlier data 5 from the scan file. Such outlier data 5 includes gum line, cheek, tongue, scan anomalies, that when processed would result in invalid geometry, poor fit, discomfort or a poor aesthetic finish.

30 Using the scan 4 as a reference the software filters and removes such outlier data 5 to create representative geometrical data, such as smooth spline or point clouds representing curvature of the user's teeth and gum line from the physical data in the scan file 4. This process is performed on several cross sections over multiple axes, that is, by slicing the

model into sections and measuring the cross section of each and is repeated over the X, Y and Z axis.

Such a process of removing outlier data and generating representative geometrical data may be performed automatically or by manually defined settings gathered from user input via a graphical user interface according to a desired level of detail and smoothness, thickness, scale, positioning and desired dimensions as specified by values in a settings file or as an input provided via a graphical user interface..

Optionally, as shown in Figure 5, the back teeth region 6 may be removed from the data being processed since in most uses the back teeth do not need to be protected, and not removing the back teeth may add additional mass, affect speech in use and cause discomfort. Removal of the back teeth data 6 may be performed automatically according to predefined settings outlining how much of the scan 4 is to be removed and at what angle the cut removing the back teeth 6 should be made.

As shown in Figure 6, a virtual base model 7 representing a mouth piece 8 is generated from the physical data and the spline representative geometrical data. The virtual base model 7 has one or more defined regions, including a frenum region, palate region, back teeth region and upper gum line region. The virtual base model 7 closely represents the final mouth piece and is customisable to offer differing levels of protection according to the circumstances. Accordingly, selected regions may be removed from the mouth piece 8 represented by the virtual base model 7 as required or as desired, and such a step may be performed by an operator manually selecting regions for removal. The thickness of the walls of the mouth piece 8 in the virtual base model 7 may be adjusted as required according to the user.

As shown in Figure 7, to prevent interference with the palate or tongue, a section 9 of the top inner wall is removed from the mouth piece 8 shown by the virtual base model 7. The dimensions of the cut-out region 9 (such as length, breadth, and height) removed from the virtual base model 7 are computed according to physical data of the user's teeth and gum line in the scan file or may be defined manually by an operator. As shown in Figure 8, further regions 10 are removed from the mouth piece 8 shown by the virtual base model 7 to eliminate irritation between the mouth piece and the frenum glands.

According to Figure 9, sharp edges 11 of the mouth piece 8 in the virtual base model 7 are softened to prevent irritation between the gum line and the mouth piece. Such softening may be performed by a fillet, chamfer, point manipulation, or smoothing algorithm incorporated into the software of the present invention. To assist the location of all edges of the mouth piece in the virtual base model are tracked.

Optionally, a further step of incorporating peripheral device attachment data into the virtual base model is performed, whereby the peripheral device attachment data represents a receiver or connection means for the attachment of peripheral devices to the mouth piece when 3D printed.

As shown in Figure 10, the peripheral device attachment data represents a receiver or connection means, shown as a joint 14 at the front of the mouth piece 8, for attaching a peripheral device 12 to the mouth piece 8 when the mouth piece 8 is 3D printed. The device 12 may be attached or clipped to the joint 14 using mechanical, interference or adhesive means. It will be understood that the joint 14 may be provided at any desired location of the mouth piece 8 and reference to connection at the front of the mouth piece should not be seen as limiting.

Such a peripheral device 12 may be a helmet attachment used to attach the mouth piece 8 via a tether to a helmet to prevent the mouth piece 8 falling to the ground, or a camera attachment used to attach or mount a camera to the mouth piece 8 in order to free up a users hands while active. The peripheral device 12 may also be provided as an attachment to facilitate gripping and removal of the mouth piece 8 from the wearer's mouth, or may itself be an attachment to facilitate connection to additional mouthpieces, such as upper and lower mouth pieces used to treat conditions such as bruxism, sleep apnoea and other orthodontic or medical procedures and treatments.

Alternatively, the attachment data may represent a receiver or connection means 14 for attaching a peripheral device 12 used in neuro-imaging, MRI, body scan or X-ray procedures performed on the wearer of the mouth piece 8. A further connection means, provided as an aperture 13, may also be provided on the device 12 itself and be used to mount, retain or hold a further external device to facilitate such procedures as required.

Finally, at step 103, from the resulting processed virtual base model 7 a 3D printer readable file encoding the mouth piece 8 is generated and transmitted to a 3D printing means and printed.

- 5 Figure 11 shows a graphical user interface 20 comprising an adjustable slider 22 operable to reduce or increase the included height of a user's gum line 24 as represented in a scan file of the user's teeth and gum line 26.

10 Figure 12 shows a graphical user interface 28 operable as adjustable sliders 30 to position a cut line 32 for removing sections (shown as (R) right and L (left) sections) of the users teeth and gum line 26 as represented in a scan file. Selectively removing regions from the teeth and gum line 26 in the scan file may be performed by the user interface 28 provided as a slider 30 or value shifters that when manipulated by a user shows a graphical representation of the regions that will be excluded when generating the mouth piece.

15 The graphical interfaces 20, 28 may also be applied for use in displaying the mouth piece represented in the virtual base model, such user interfaces 20, 28 are provided with adjustable value sliders or value shifters adapted for adjusting the smoothness, thickness, scale, positioning and desired dimensions of the mouth piece in the virtual base model.

20 Figure 13 shows a graphical user interface 34 adapted for aligning and displaying teeth and gum line in a scan file. Such an interface 34 may be operable for automatically aligning and positioning the teeth and gum line shown in the scan file according to an origin or reference point on an X, Y, Z coordinate system 42 such that teeth and gum line in the scan file are consistently positioned and pointing in the correct direction relative to the X, Y, Z coordinate system. Shown in Figure 13 are the teeth and gum line 36 before alignment, and teeth and gum line 38 after alignment in the correct direction relative to the X, Y, and Z coordinate system. This step consists of the user choosing three or more points 40 on the teeth and gum line 36 in the scan file to align with three or more preset points to correctly orientate the teeth and gum line 36 so that the teeth point in a consistent direction.

35 Figure 14 shows the output of a step performed by a user interface to fill gaps 44 between adjacent or missing teeth 46. By using geometrical data the user interface is operable to generate a shape which selectively fills gaps 44 between adjacent or missing teeth 46 to avoid interconnected pieces on the finished 3D printed mouth piece. As shown, initially the

teeth and gum line 48 in the scan file representation has relatively large gaps 44 between adjacent teeth 46, and after filling the gaps 44 in the teeth and gum line 50 are significantly reduced. The graphical user interface may be further operable to outline or indicate outlier data in the virtual base model.

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Figure 15 shows the output of a step of creating a void or voids 54 in the mouth piece 52 of the virtual base model to accommodate a device 56, such as electronic or other devices. Such device or devices 56 may be positioned in the void 52 created during and/or after 3D printing of the mouth piece.

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Figure 16 shows the output of a step of applying colour textures 58 to a mouth piece 60 in the virtual base model. Figure 17 shows the output of a step of applying logos, letter and/or numerals 62 to a mouth piece 64 in the virtual base model. Accordingly, symbols, lettering, numbers, images or logos may be applied during processing onto the surface of the mouth piece either by creating cut outs in the virtual base model or applying colour mapped textures to the mouth piece displayed by the virtual base model.

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Figures 18 and 18a shows the creation of brace relief 67 and a channel or voids 66 in the mouth piece 68 displayed in the virtual base model for when a user wears teeth braces in the virtual base model. By creating relief cuts 67 to the outer surface of the mouth piece 68 of the virtual base model the fitting or removal with or without the presence of braces worn on the teeth of a user is facilitated. By removing material and creating a void or channel 66 around the perimeter of the mouth piece 68 and by placing relief cuts 66 in the outer surface of the mouth piece allowances for the presence of braces is provided and will facilitate easier removal and to prevent irritation or damage to the brace.

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Additionally, any overhanging or desired parts of the mouth piece in the virtual base model that may cause irritation to the gum line are automatically removed.

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Figure 19 is a block diagram of a system configured according to the invention. Shown is a system 200 for manufacturing a mouth piece by 3D printing a 3D printer readable file encoding the mouth piece. The system is implemented by software executing on one or more computer/processes and comprises means 210 for obtaining a scan file comprising physical data representing a user's teeth and gum line using three dimensional (3D) scanner means; means 220 for removing outlier data from physical data in the scan file;

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means 230 for generating representative geometrical data of the curvature of the user's teeth and gum line from the physical data; means 240 for generating a virtual base model representing a mouth piece from the physical data and the representative geometrical data, the virtual base model having customisable dimensions; means 250 for removing selected regions from the mouth piece represented by the virtual base model, and means 260 for generating from the virtual base model the 3D printer readable file encoding the mouth piece for printing on 3D printing means.

The system comprises means 270 for incorporating peripheral device attachment data into the virtual base model, the peripheral device attachment data representing a receiver or connection means for attaching a peripheral device to the mouth piece when 3D printed and means 280 for altering a thickness of walls of the mouth piece in the virtual base model, softening sharp edges of the mouth piece in the virtual base model and/or removing a section of the top inner wall of the palate region from the virtual base model.

Also shown is means 290 for computing dimensions of the top inner wall of the palate region to be removed from the virtual base model according to physical data of the user's teeth and gum line in the scan file; means 300 for tracking the location of all edges of the mouth piece in the virtual base model and softening the edges; means for printing the 3D printer readable file on a 3D printer to provide the mouth piece; means 310 for generating data representing an internal device and creating a void in the virtual base model into which the internal device can be placed pre, post or during 3D printing; and means for generating the scan file using one or photos of the user's teeth and gum line.

The system further comprises user interface means 320 for selectively removing regions from the teeth and gum line in the virtual base model, the user interface means provided as a slider or value shifter that when manipulated by a user shows a graphical representation of the regions of the teeth and gum line that will be excluded when generating the mouth piece. The user interface means 320 is adapted for displaying the mouth piece represented in the virtual base model, the user interface having adjustable value sliders or value shifters that show a visual display of and are adapted for adjusting smoothness, thickness, scale, positioning and desired dimensions of the mouth piece in the virtual base model.

Also shown, is means 330 for exporting a collected set of rules or settings to process the virtual base model to achieve a desired thickness, scale positioning and desired dimensions

for the mouth piece in the virtual base model; means 340 for batch processing a plurality of virtual base models in groups according to the model specific settings files exported from a graphical user interface by storing a set of rules to generate each mouth piece according to geometrical and positioning data, smoothing thickness, scale, desired dimensions and data representing portions of the mouth piece to be added or removed; means 350 for automatically aligning and positioning the teeth and gum line shown in the scan file according to an origin or reference point on an X, Y, Z coordinate system such that teeth and gum line in the scan file are consistently positioned and pointing in the correct direction relative to the X, Y, Z coordinate system; means 360 for manually aligning teeth and gum line of the scan file using a graphical user interface, in which three or more points on the teeth and gum line in the scan file are chosen and configured to align with three or more preset points to correctly orientate the teeth and gum line in the scan file in a desired direction; means 370 for automatically removing any overhanging or desired parts of the mouth piece in the virtual base model; means 380 for using geometrical data to generate a shape which fills gaps between adjacent or missing teeth or area to avoid interconnected pieces on the printed mouth piece, and means 390 for using data representing the dimensions of a device to create an internal void in the virtual base model in which the device will be placed during or after the 3D printing process.

The system further comprises means 400 for adding symbols, lettering, numbers, images or logos onto the surface of the mouth piece either by creating cut outs in the virtual base model or applying colour mapped textures to the virtual base model and means 410 for creating relief cuts in the outer surface of the virtual base model to facilitate fitting or removal with or without the presence of orthodontic braces worn on the teeth of a user.

It is to be understood that the invention is not limited to the specific details described herein which are given by way of example only and that various modifications and alternations are possible without departing from the scope of the invention as defined in the appended claims.

CLAIMS

1. A method of manufacturing a mouth piece by 3D printing a 3D printer readable file
5 encoding the mouth piece, the method comprising steps of:

obtaining a scan file comprising physical data representing a user's teeth and gum
line using three dimensional (3D) scanner means;

10 removing outlier data from physical data in the scan file;

generating representative geometrical data for the curvature of the user's teeth and
gum line from the physical data;

15 generating a virtual base model representing a mouth piece from the physical data
and the representative geometrical data, the virtual base model having customisable
dimensions;

20 removing selected regions from the mouth piece represented by the virtual base
model;

from the virtual base model, generating the 3D printer readable file encoding the
mouth piece for printing on 3D printing means.

25 2. A method of manufacturing a mouth piece as claimed in Claim 1, in which the
representative geometrical data is automatically generated according to a predetermined
level of smoothness or generated according to an operator selected level of smoothing.

30 3. A method of manufacturing a mouth piece as claimed in Claim 1 or Claim 2,
comprising a further step of incorporating peripheral device attachment data into the virtual
base model, the peripheral device attachment data representing a receiver or connection
means for attaching a peripheral device to the mouth piece when 3D printed.

35 4. A method of manufacturing a mouth piece as claimed in any one of the preceding
claims, in which the mouth piece in the virtual base model has one or more regions

comprising: a frenum region, palate region, back teeth region and upper and/or lower gum line region.

5. A method of manufacturing a mouth piece as claimed in any one of the preceding claims, comprising a step of: selectively removing from the mouth piece in the virtual base model one or more or portions of: the frenum region, palate region, back teeth region, upper and/or lower gum line region and sharp edges.

6. A method of manufacturing a mouth piece as claimed in any one of the preceding claims, in which a step of selectively removing regions from the mouth piece in the virtual base model is performed by an operator manually selecting regions for removal via user interface means.

7. A method of manufacturing a mouth piece as claimed in any one of the preceding claims, in which a step of removing one or more teeth regions from the mouth piece in the virtual base model is performed automatically.

8. A method of manufacturing a mouth piece as claimed in any one of the preceding claims, comprising a step of: altering a thickness of walls of the mouth piece in the virtual base model.

9. A method of manufacturing a mouth piece as claimed in any one of the preceding claims, comprising a step of: softening sharp edges of the mouth piece in the virtual base model.

10. A method of manufacturing a mouth piece as claimed in any one of the preceding claims, comprising a step of: removing a section of the top inner wall of the palate region from the virtual base model.

11. A method of manufacturing a mouth piece as claimed in Claim 10, in which dimensions of the top inner wall of the palate region removed from the virtual base model are computed according to physical data of the user's teeth and gum line in the scan file.

12. A method of manufacturing a mouth piece as claimed in any one of the preceding claims, comprising a step of: tracking the location of all edges of the mouth piece in the virtual base model and softening the edges.

5 13. A method of manufacturing a mouth piece as claimed in any one of the preceding claims, comprising a step of: printing the 3D printer readable file on a 3D printer to provide the mouth piece.

10 14. A method of manufacturing a mouth piece as claimed in any one of the preceding claims, comprising a step of: incorporating an internal device during or after 3D printing of the mouth piece.

15 15. A method of manufacturing a mouth piece as claimed in any one of the preceding claims, comprising a step of: generating data representing the internal device and creating a void in the virtual base model into which an internal device is placed during or after 3D printing the mouth piece.

20 16. A method of manufacturing a mouth piece as claimed in any one of the preceding claims, in which the scan file is generated using one or photos of the user's teeth and gum line.

25 17. A method of manufacturing a mouth piece as claimed in any one of the preceding claims, comprising a step of: selectively removing regions from the teeth and gum line in the virtual base model by operating a user interface provided as a slider or value shifter that when manipulated by a user shows a graphical representation of the regions of the teeth and gum line before and after removal.

30 18. A method of manufacturing a mouth piece as claimed in any one of the preceding claims, comprising a step of: displaying the mouth piece represented in the virtual base model in a user interface, the user interface having adjustable value sliders or value shifters that show a visual display of and are adapted for adjusting smoothness, thickness, scale, positioning and desired dimensions of the mouth piece in the virtual base model.

35 19. A method of manufacturing a mouth piece as claimed in any one of the preceding claims, comprising a step of: exporting a collected set of rules or settings to process the

virtual base model to achieve a desired thickness, scale positioning and desired dimensions for the mouth piece in the virtual base model.

20. A method of manufacturing a mouth piece as claimed in any one of the preceding claims, comprising a step of: batch processing a plurality of virtual base models in groups according to the model specific settings files exported from a graphical user interface by storing a set of rules to generate each mouth piece according to geometrical and positioning data, smoothing thickness, scale, desired dimensions and data representing portions of the mouth piece to be added or removed.

21. A method of manufacturing a mouth piece as claimed in any one of the preceding claims, comprising a step of: automatically aligning and positioning the teeth and gum line shown in the scan file according to an origin or reference point on an X, Y, Z coordinate system such that teeth and gum line in the scan file are consistently positioned and pointing in the correct direction relative to the X, Y, Z coordinate system.

22. A method of manufacturing a mouth piece as claimed in any one of the preceding claims, comprising a step of: manually aligning teeth and gum line of the scan file using a graphical user interface, in which three or more points on the teeth and gum line in the scan file are chosen and configured to align with three or more preset points to correctly orientate the teeth and gum line in the scan file in a desired direction.

23. A method of manufacturing a mouth piece as claimed in any one of the preceding claims, comprising a step of: a step of automatically removing any overhanging or desired parts of the mouth piece in the virtual base model.

24. A method of manufacturing a mouth piece as claimed in any one of the preceding claims, comprising a step of: using geometrical data to generate a shape which fills gaps between adjacent or missing teeth or area to avoid interconnected pieces on the printed mouth piece.

25. A method of manufacturing a mouth piece as claimed in any one of the preceding claims, comprising a step of: creating an internal void in the virtual base model for accommodating one or devices, such as electronic or other devices, therein.

26. A method of manufacturing a mouth piece as claimed in Claim 25, comprising a step of: using data representing the dimensions of the device to create the internal void in the virtual base model in which the device will be placed during or after the 3D printing process.

5 27. A method of manufacturing a mouth piece as claimed in any one of the preceding claims, comprising a step of: adding symbols, lettering, numbers, images or logos onto the surface of the mouth piece either by creating cut outs in the virtual base model or applying colour mapped textures to the virtual base model.

10 28. A method of manufacturing a mouth piece as claimed in any one of the preceding claims, comprising a step of: creating one or more relief cuts and/or voids in the outer surface of the mouth piece in the virtual base model to facilitate fitting or removal of the printed mouth piece with or without the presence of orthodontic braces worn on the teeth of a user.

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29. A non-transitory machine-readable medium comprising instructions that, when executed by one or more processors, cause the one or more processors to perform the steps according to any one of Claims 1 to 28.

20 30. A system for manufacturing a mouth piece by 3D printing a 3D printer readable file encoding the mouth piece, the system comprising:

means for obtaining a scan file comprising physical data representing a user's teeth and gum line using three dimensional (3D) scanner means;

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means for removing outlier data from physical data in the scan file;

means for generating representative geometrical data for the curvature of the user's teeth and gum line from the physical data;

30

means for generating a virtual base model representing a mouth piece from the physical data and the representative geometrical data, the virtual base model having customisable dimensions;

means for removing selected regions from the mouth piece represented by the virtual base model, and

means for generating the 3D printer readable file from the virtual base model
5 encoding the mouth piece, and 3D printing means for printing the 3D printer readable file.

31. A system for manufacturing a protective mouth piece as claimed in Claim 30, in which the representative geometrical data is automatically generated according to a predetermined level of smoothness or generated according to an operator selected level of
10 smoothing.

32. A system for manufacturing a mouth piece as claimed in Claim 30 or Claim 31, comprising means for incorporating peripheral device attachment data into the virtual base model, the peripheral device attachment data representing a receiver or connection means
15 for attaching a peripheral device to the mouth piece when 3D printed.

33. A system for manufacturing a mouth piece as claimed in any one of Claims 30 to 32, in which the mouth piece in the virtual base model has one or more regions comprising: a frenum region, palate region, back teeth region and upper and/or lower gum line region,
20 and the system comprises means for selectively removing from the mouth piece in the virtual base model one or more or portions of: the frenum region, palate region, back teeth region, upper and/or lower gum line region and sharp edges.

34. A system for manufacturing a mouth piece as claimed in Claim 33, in which
25 selectively removing regions from the mouth piece in the virtual base model is performed automatically or by an operator manually selecting regions for removal via user interface means.

35. A system for manufacturing a mouth piece as claimed in any one of the preceding
30 claims 30 to 34, comprising means for altering a thickness of walls of the mouth piece in the virtual base model, softening sharp edges of the mouth piece in the virtual base model and/or removing a section of the top inner wall of the palate region from the virtual base model.

36. A system for manufacturing a mouth piece as claimed in any one of Claims 30 to 35, comprising means for computing dimensions of the top inner wall of the palate region to be removed from the virtual base model according to physical data of the user's teeth and gum line in the scan file.

5

37. A system for manufacturing a mouth piece as claimed in any one of Claims 30 to 36, comprising means for tracking the location of all edges of the mouth piece in the virtual base model and softening the edges.

10

38. A system for manufacturing a mouth piece as claimed in any one of Claims 30 to 37, comprising means for printing the 3D printer readable file on a 3D printer to provide the mouth piece.

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39. A system for manufacturing a mouth piece as claimed in any one of Claims 30 to 38, comprising means for incorporating an internal device during or after 3D printing of the in the mouth piece.

20

40. A system for manufacturing a mouth piece as claimed in any one of Claims 30 to 39, comprising means for generating data representing the internal device and creating a void in the virtual base model into which the internal device can be placed pre, post or during 3D printing.

25

41. A system for manufacturing a mouth piece as claimed in any one of Claims 30 to 40, comprising means for generating the scan file using one or photos of the user's teeth and gum line.

30

42. A system for manufacturing a mouth piece as claimed in any one of Claims 30 to 41, comprising user interface means for selectively removing regions from the teeth and gum line in the virtual base model, the user interface means provided as a slider or value shifter that when manipulated by a user shows a graphical representation of the regions of the teeth and gum line before and after removal.

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43. A system for manufacturing a mouth piece as claimed in any one of Claims 30 to 42, comprising user interface means for displaying the mouth piece represented in the virtual base model, the user interface having adjustable value sliders or value shifters that

show a visual display of and are adapted for adjusting smoothness, thickness, scale, positioning and desired dimensions of the mouth piece in the virtual base model.

44. A system for manufacturing a mouth piece as claimed in any one of Claims 30 to 43, comprising means for exporting a collected set of rules or settings to process the virtual base model to achieve a desired thickness, scale positioning and desired dimensions for the mouth piece in the virtual base model.

45. A system for manufacturing a mouth piece as claimed in any one of Claims 30 to 44, comprising means for batch processing a plurality of virtual base models in groups according to the model specific settings files exported from a graphical user interface by storing a set of rules to generate each mouth piece according to geometrical and positioning data, smoothing thickness, scale, desired dimensions and data representing portions of the mouth piece to be added or removed.

46. A system for manufacturing a mouth piece as claimed in any one of Claims 30 to 45, comprising means for automatically aligning and positioning the teeth and gum line shown in the scan file according to an origin or reference point on an X, Y, Z coordinate system such that teeth and gum line in the scan file are consistently positioned and pointing in the correct direction relative to the X, Y, Z coordinate system.

47. A system for manufacturing a mouth piece as claimed in any one of Claims 30 to 46, comprising means for manually aligning teeth and gum line of the scan file using a graphical user interface, in which three or more points on the teeth and gum line in the scan file are chosen and configured to align with three or more preset points to correctly orientate the teeth and gum line in the scan file in a desired direction.

48. A system for manufacturing a mouth piece as claimed in any one of Claims 30 to 47, comprising means for automatically removing any overhanging or desired parts of the mouth piece in the virtual base model.

49. A system for manufacturing a mouth piece as claimed in any one of Claims 30 to 48, comprising means for using geometrical data to generate a shape which fills gaps between adjacent or missing teeth or area to avoid interconnected pieces on the printed mouth piece.

50. A system for manufacturing a mouth piece as claimed in any one of Claims 30 to 49, comprising means for creating an internal void in the virtual base model for accommodating one or devices, such as electronic or other devices, therein.

5

51. A system for manufacturing a mouth piece as claimed in any one of Claims 30 to 50, comprising means for using data representing the dimensions of the device to create the internal void in the virtual base model in which the device will be placed during or after the 3D printing process.

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52. A system for manufacturing a mouth piece as claimed in any one of Claims 30 to 51, comprising means for adding symbols, lettering, numbers, images or logos onto the surface of the mouth piece either by creating cut outs in the virtual base model or applying colour mapped textures to the virtual base model.

15

53. A system for manufacturing a mouth piece as claimed in any one of Claims 30 to 52, comprising means for creating one or more relief cuts and/or voids in the outer surface of the mouth piece in the virtual base model to facilitate fitting or removal of the printed mouth piece with or without the presence of orthodontic braces worn on the teeth of a user.

20

54. A method of manufacturing a mouth piece by 3D printing a 3D printer readable file encoding the mouth piece substantially as herein described with reference to and as shown in the accompanying drawings and/or examples.

25

55. A system for manufacturing a mouth piece by 3D printing a 3D printer readable file encoding the mouth piece substantially as herein described with reference to and as shown in the accompanying drawings and/or examples.

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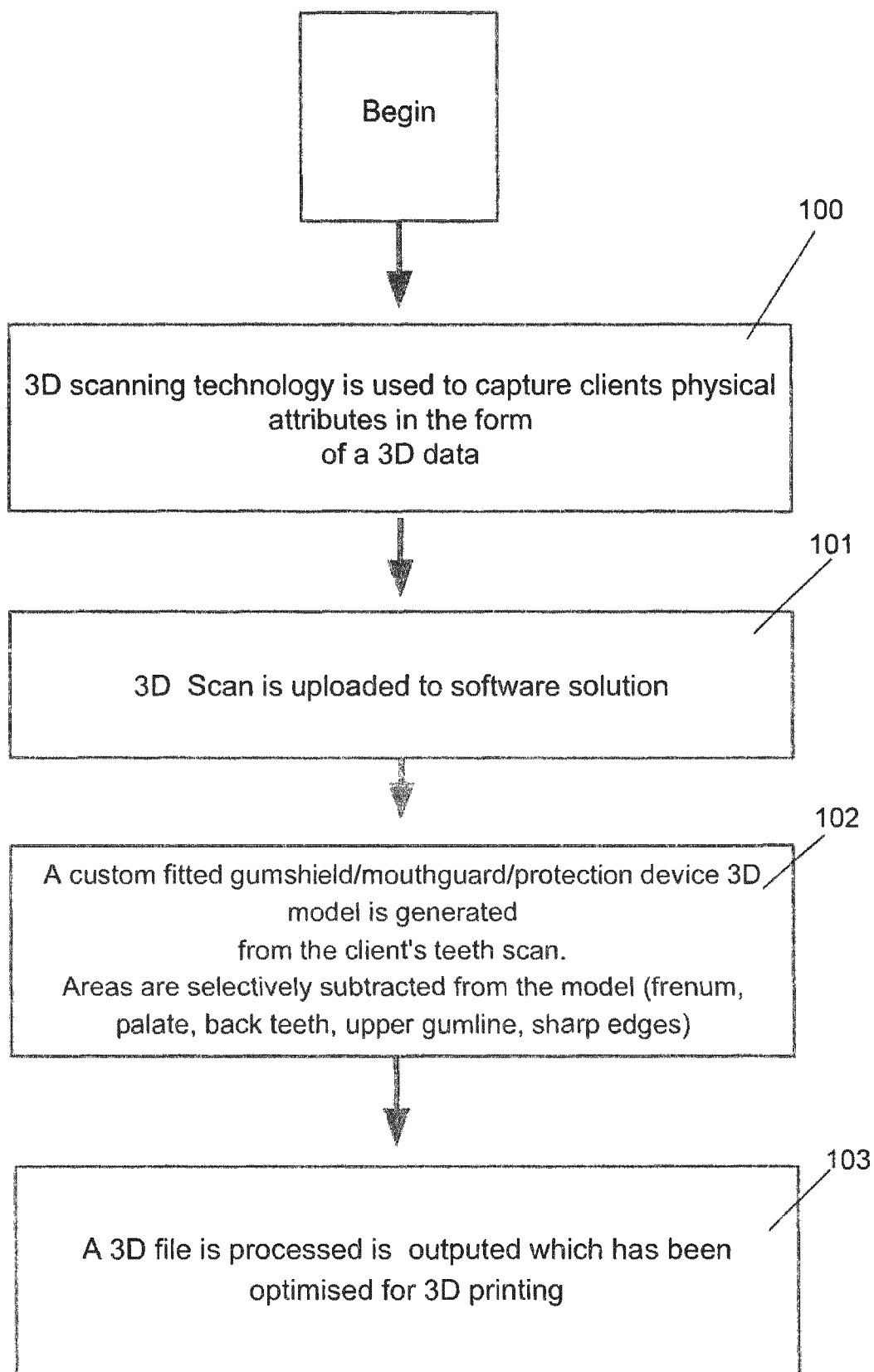


Figure 1

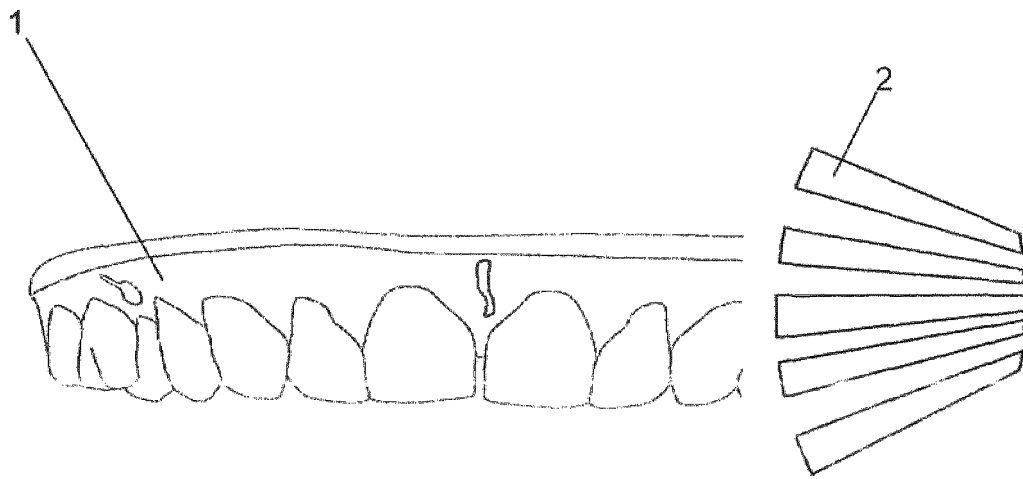


Figure 2

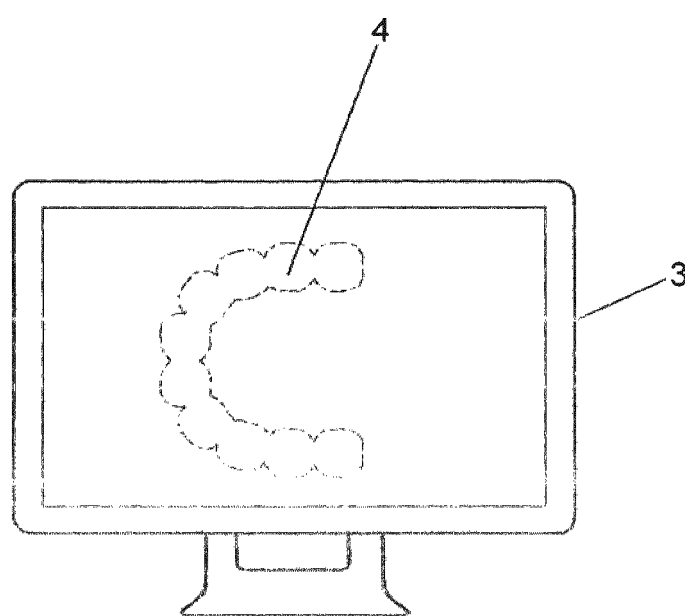


Figure 3

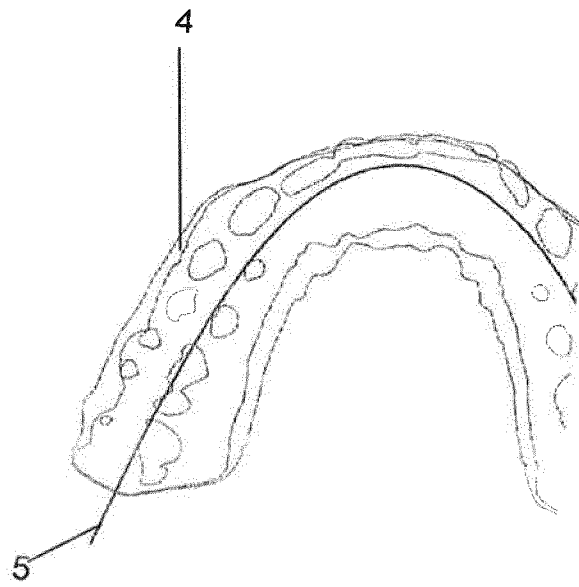


Figure 4A

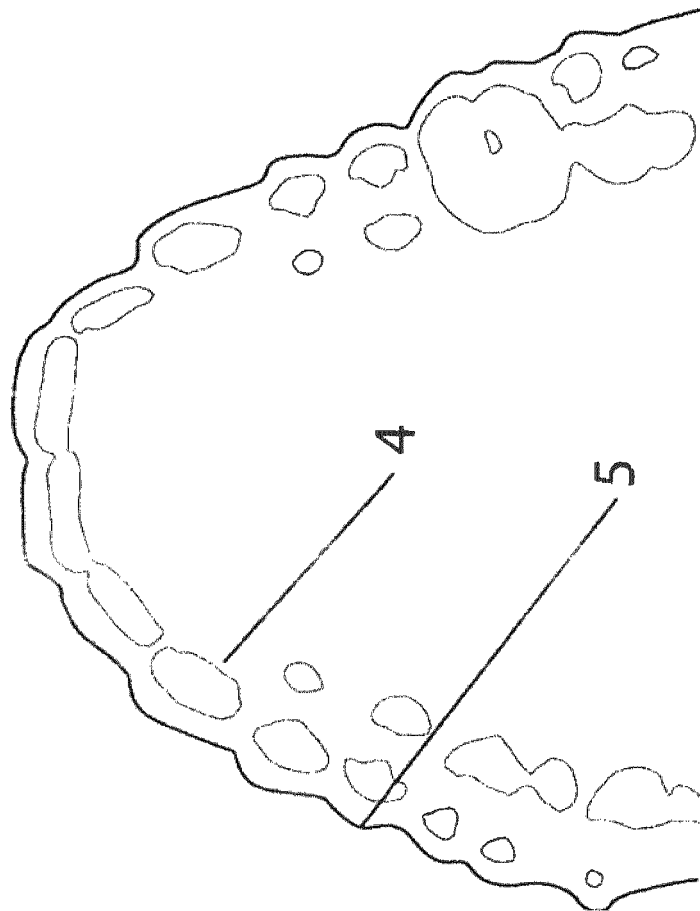


Figure 4B

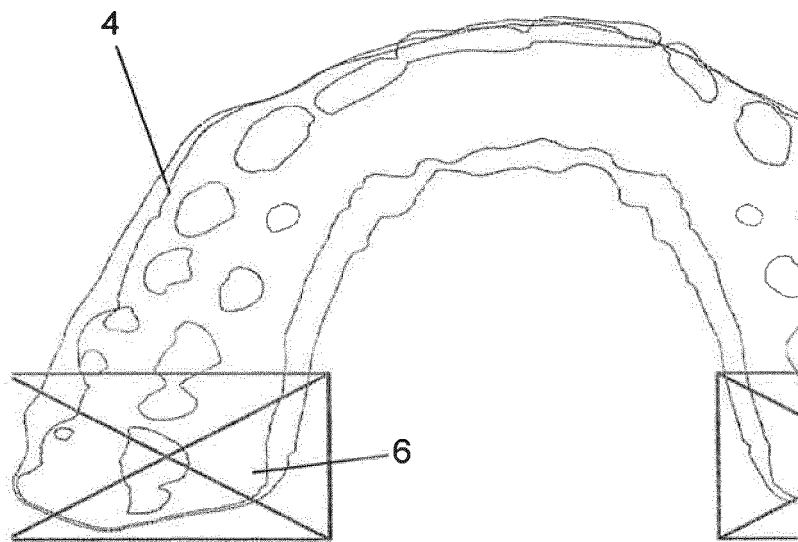


Figure 5

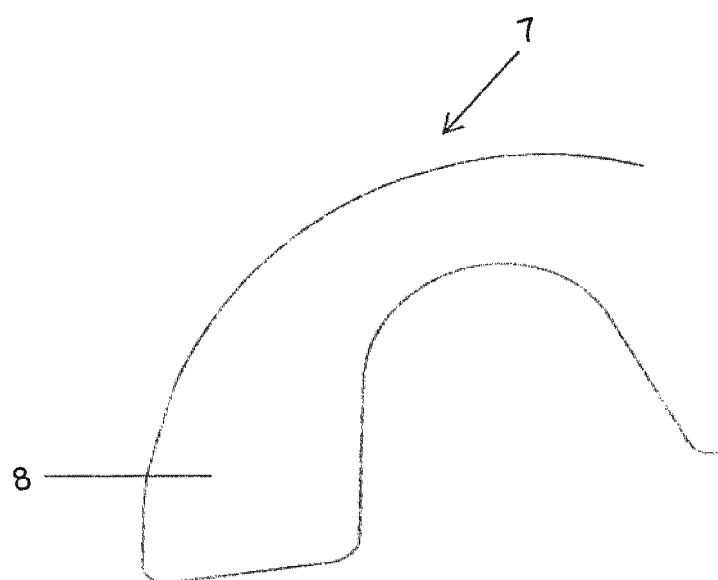


Figure 6

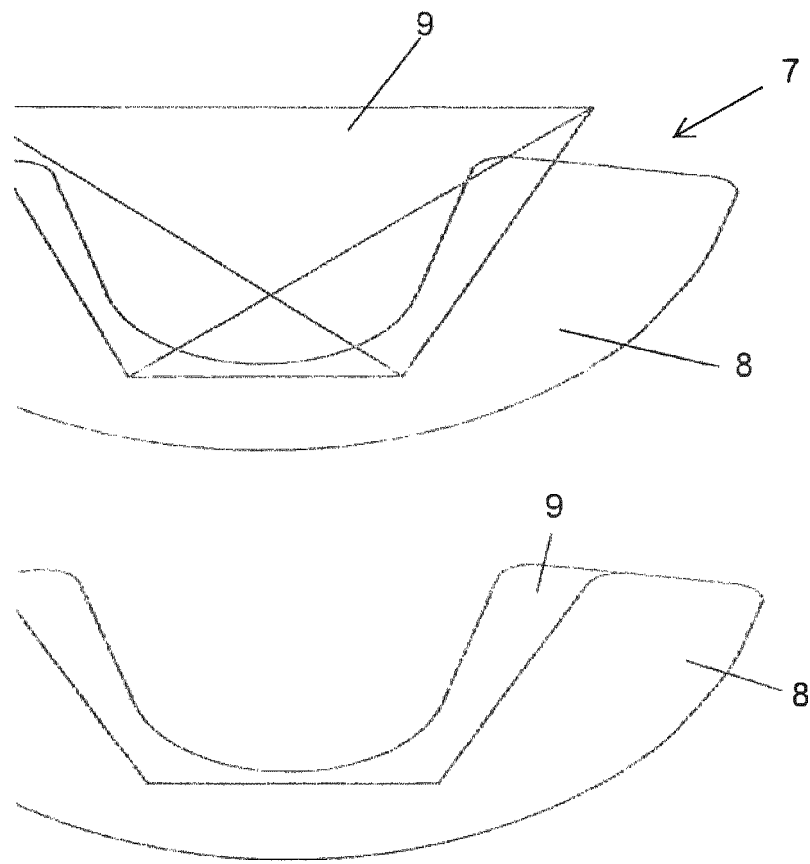


Figure 7

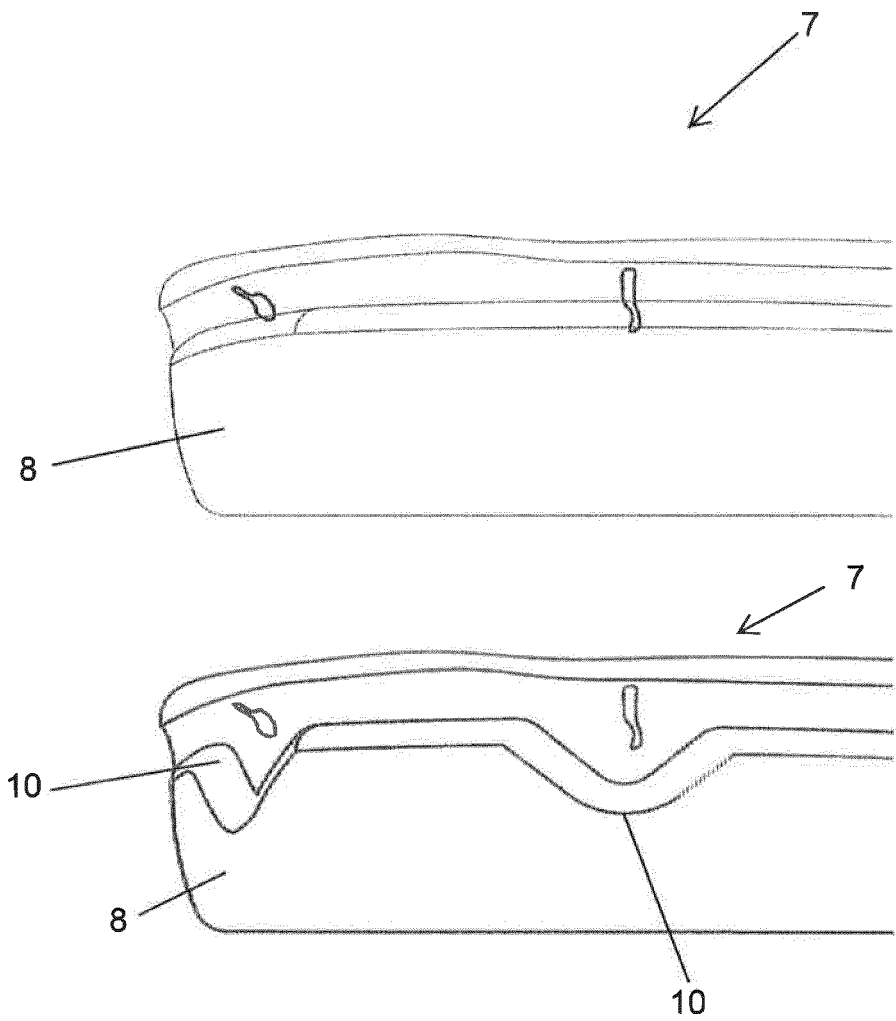


Figure 8

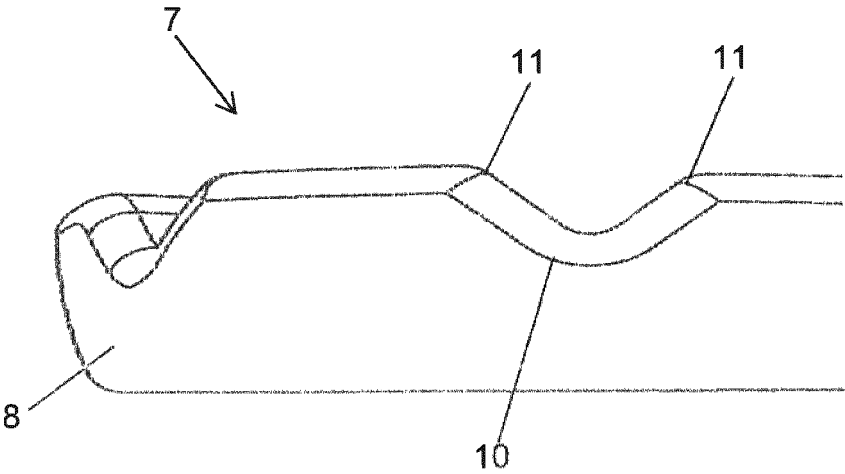


Figure 9

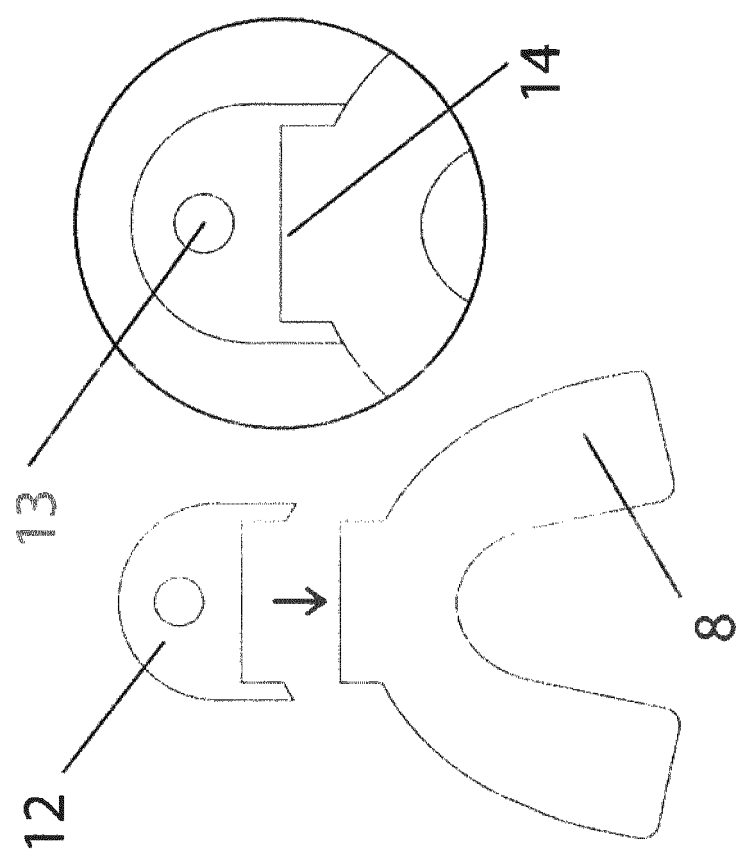


Figure 10

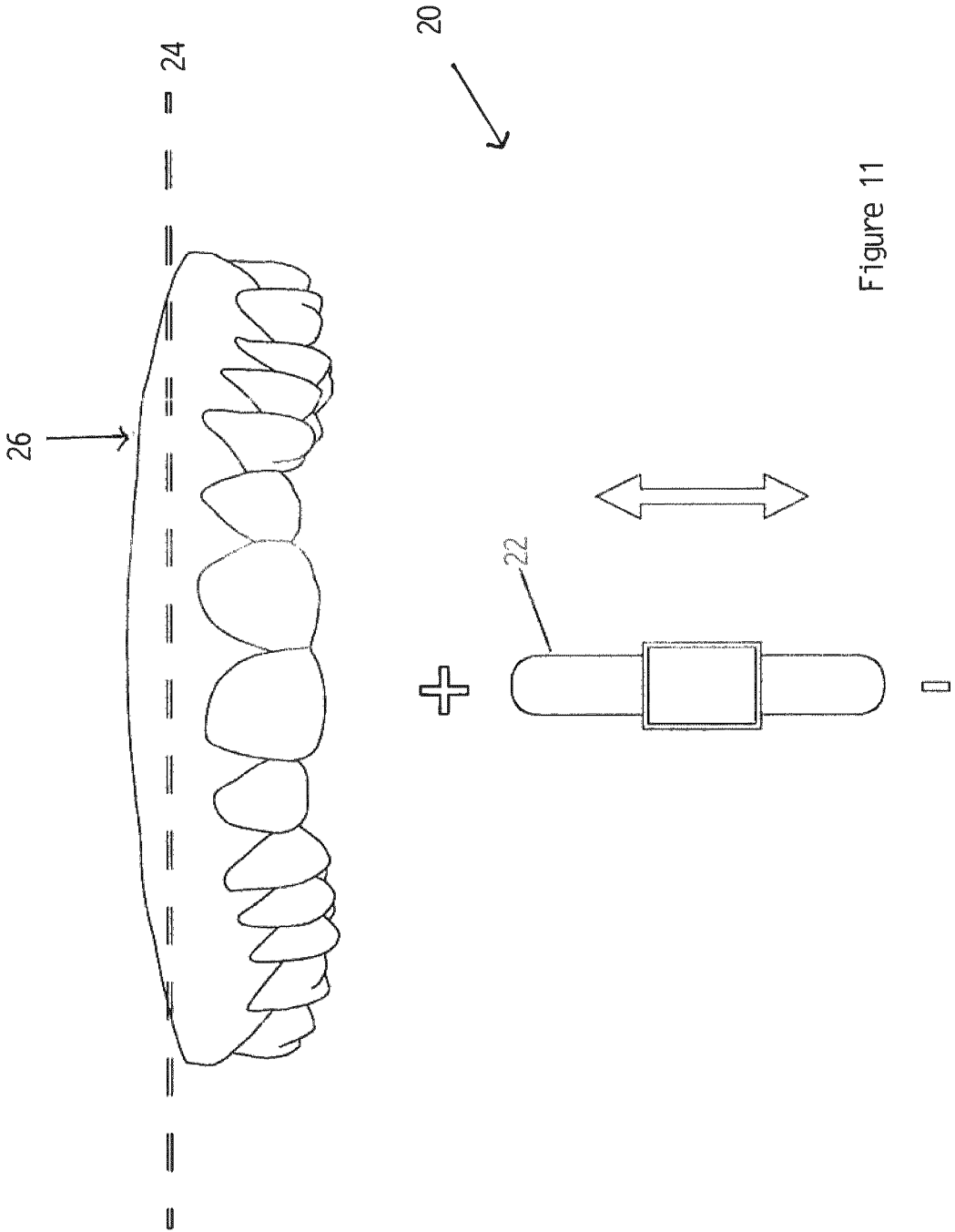


Figure 11

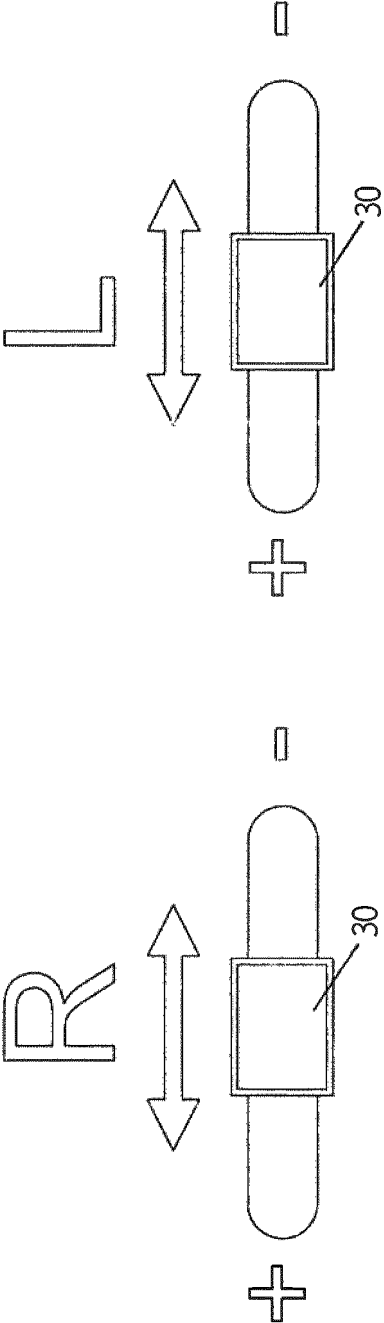
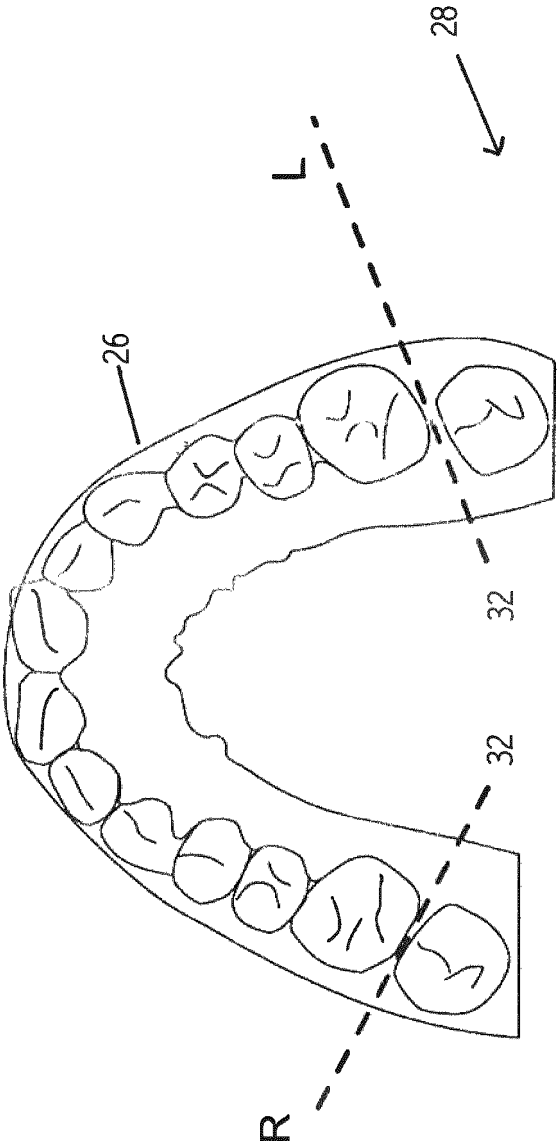


Figure 12

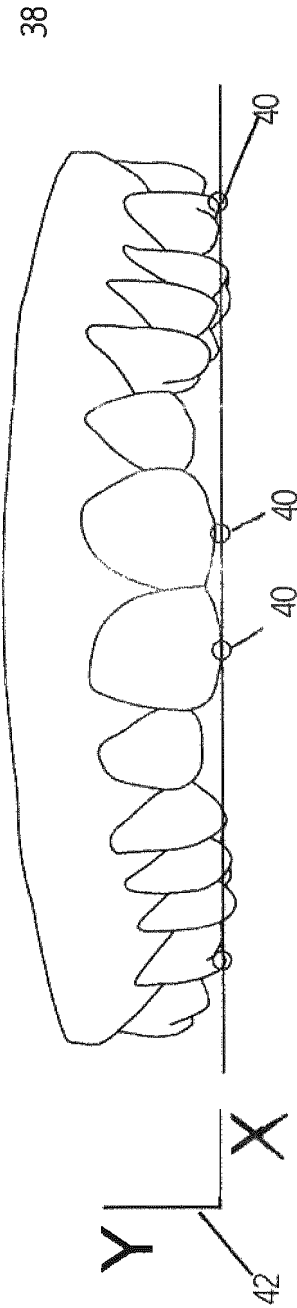
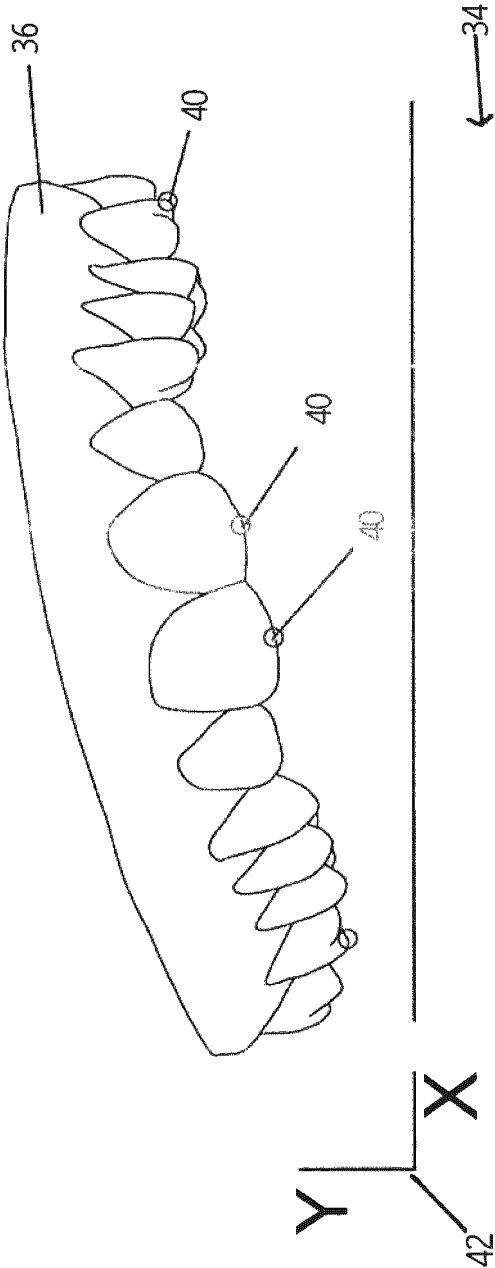


Figure 13

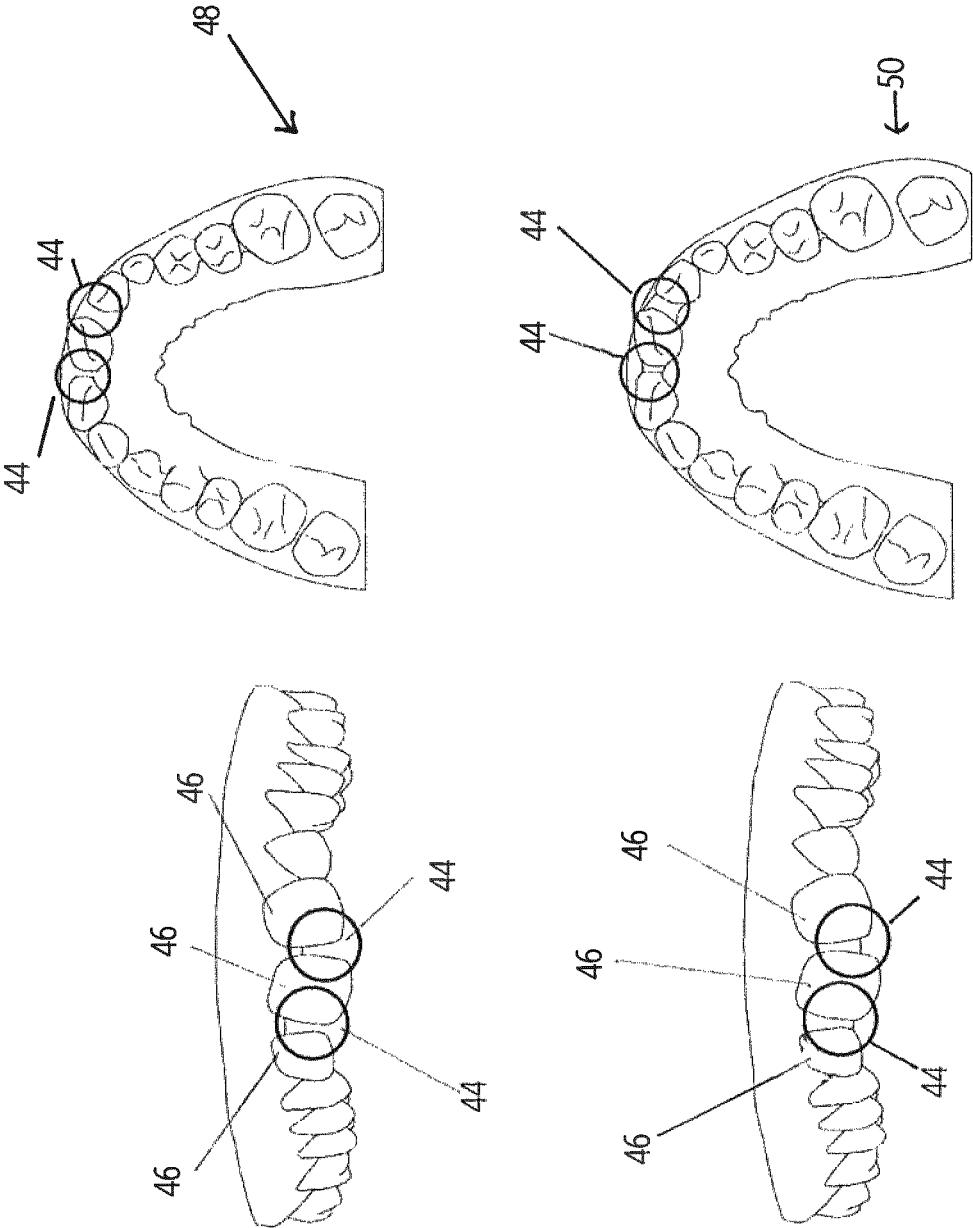


Figure 14

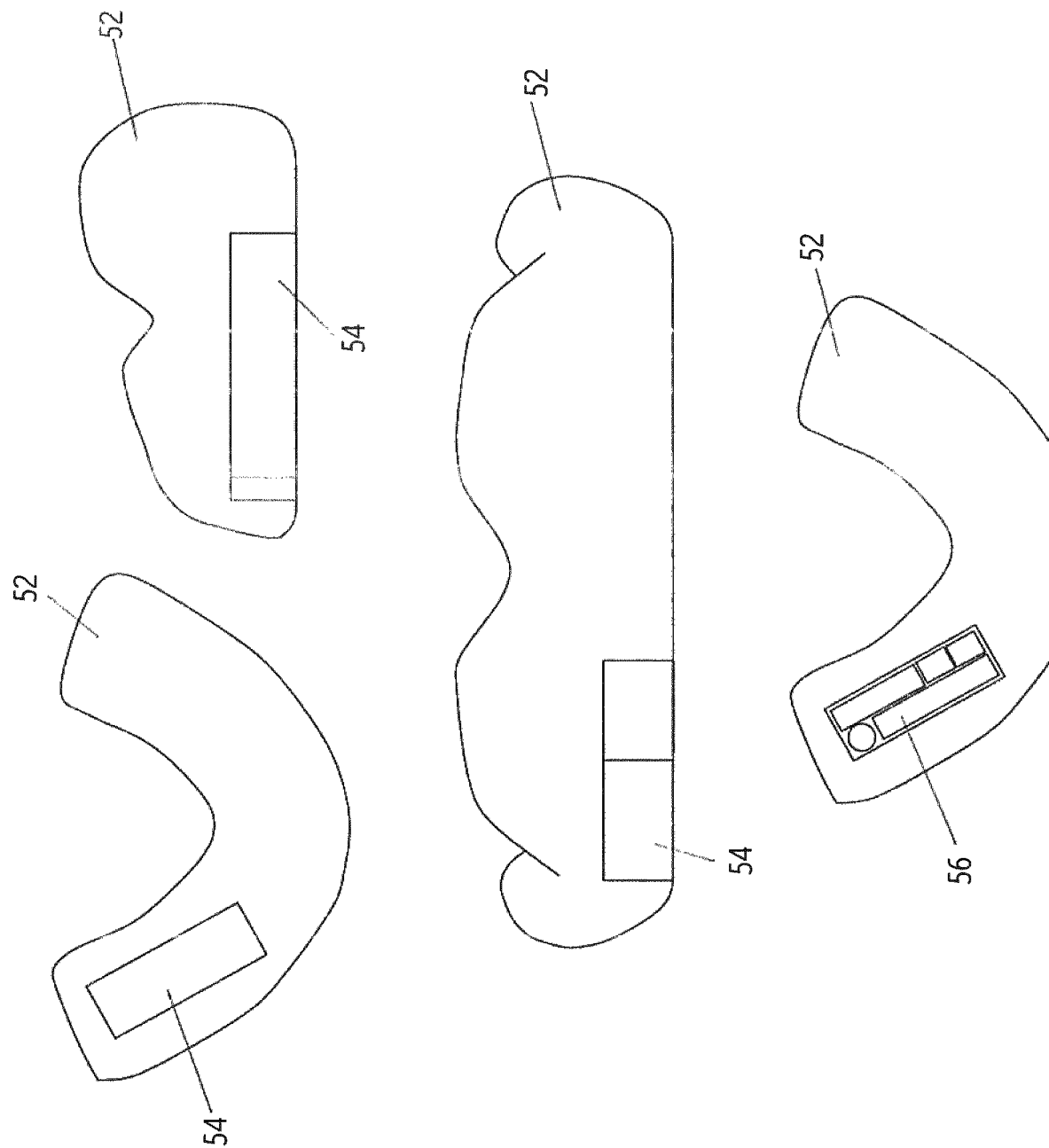


Figure 15

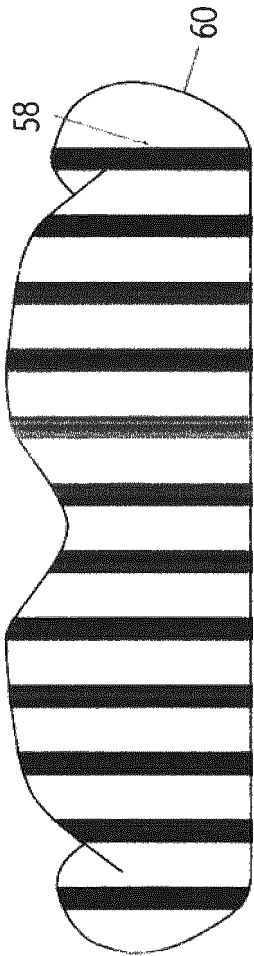
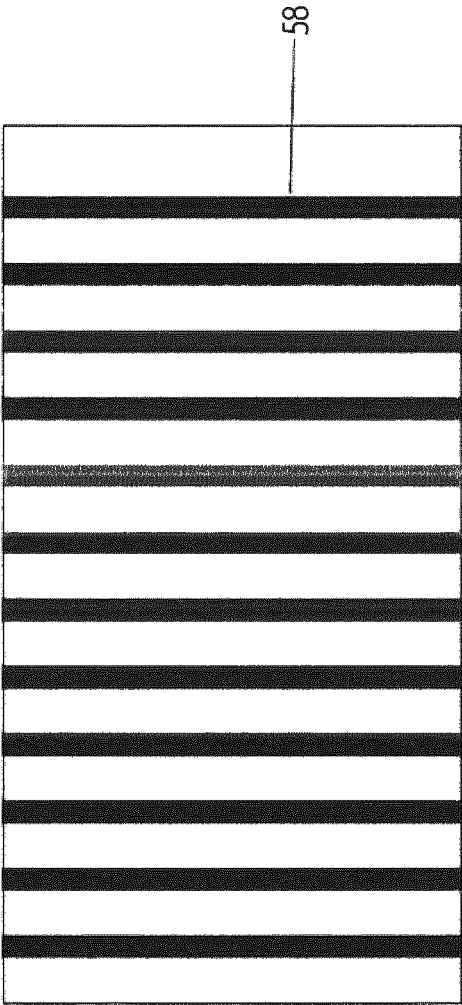


Figure 16

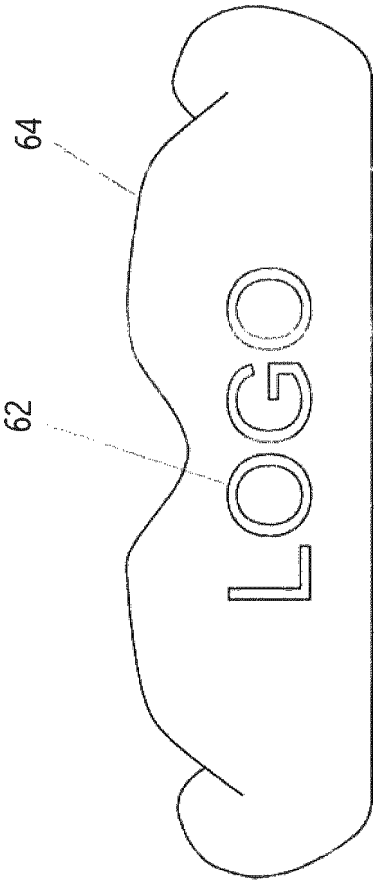
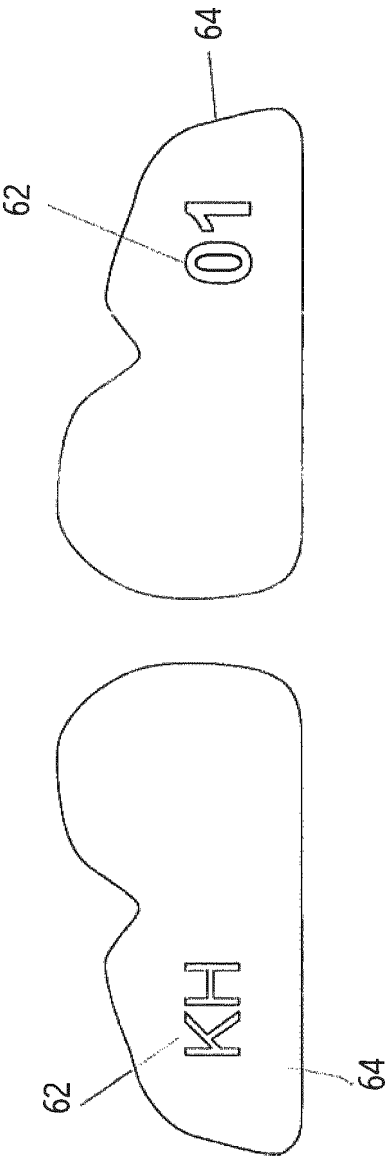


Figure 17

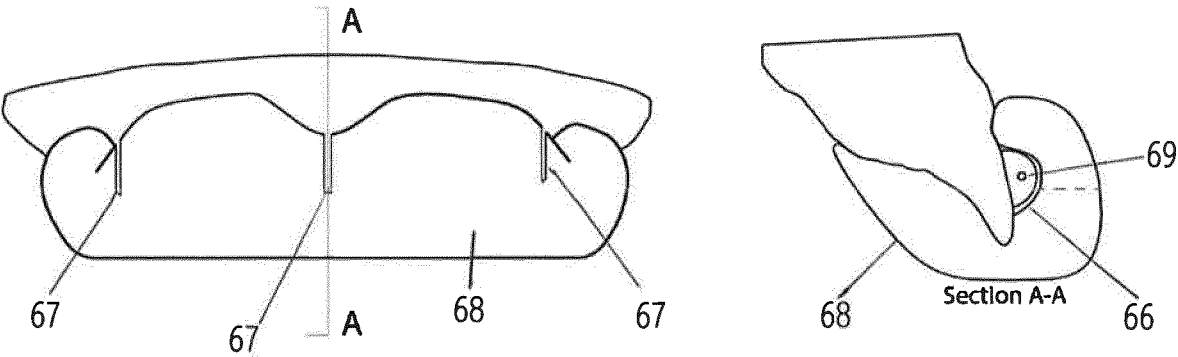


Figure 18a

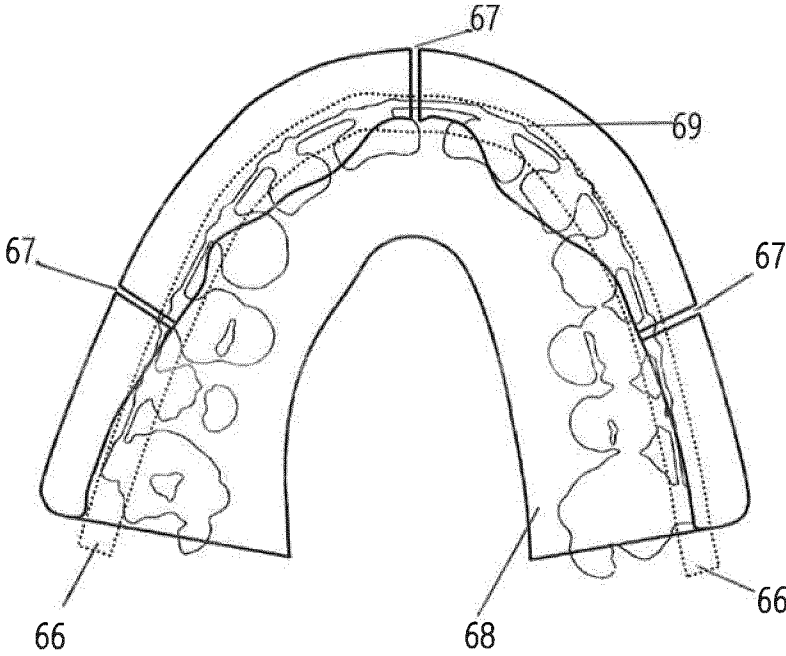


Figure 18

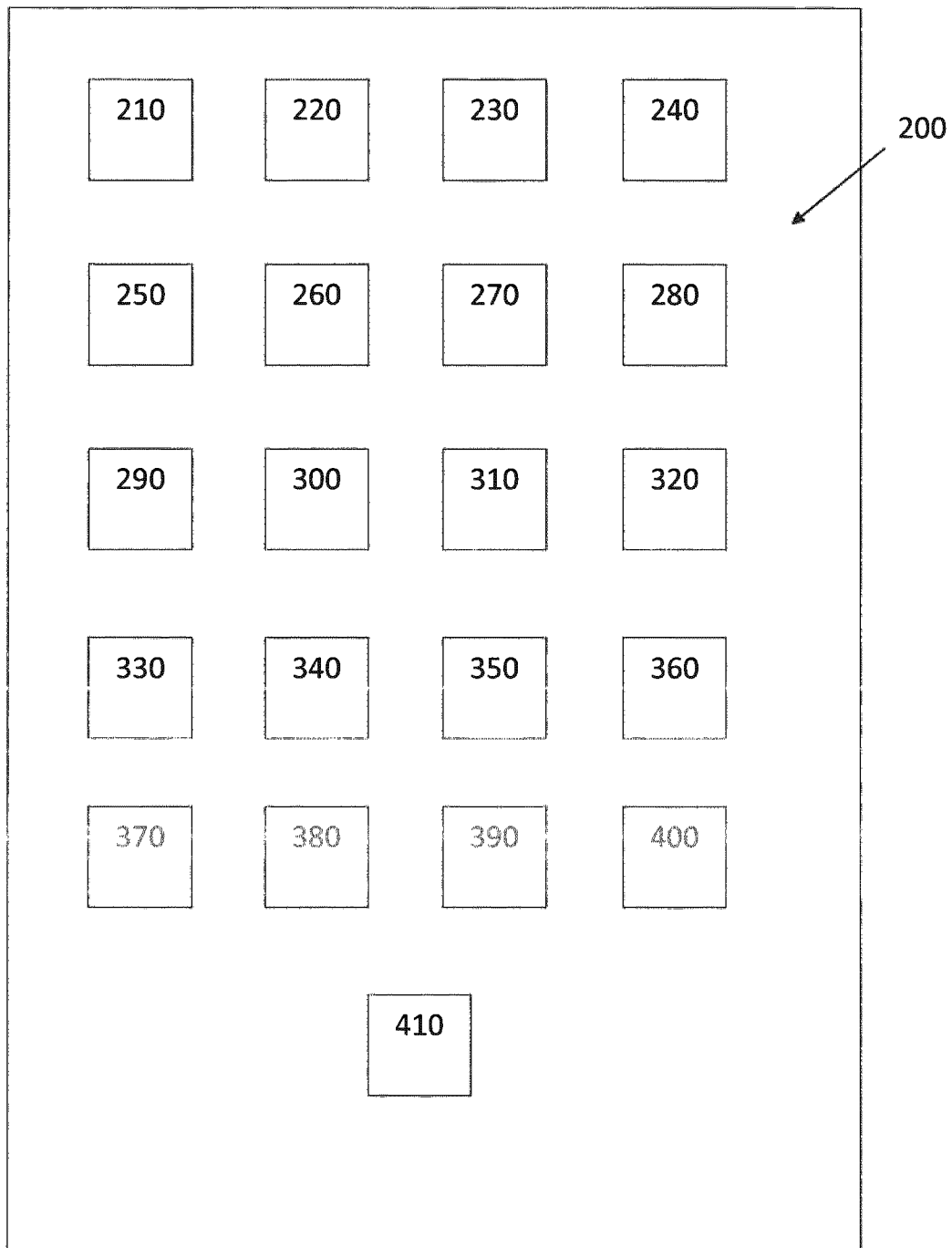


Figure 19