Muscle stimulating apparatus

Apparatus (60) for stimulating muscles which control the operation of the tongue (28) of a subject comprises a chin engaging member (62) which carries an external electrode (8) for locating externally beneath the floor (9) of the oral cavity of the subject. An oral electrode carrier (3) extends from the chin engaging member (62) for locating an oral electrode (64) in the oral cavity (4). A locating member (10) locates the oral electrode carrier (3) on the teeth of the lower jaw of the subject while a support member (65) extends from the locating member (10) for carrying the oral electrode (64) at a distal end thereof. The oral electrode (64) is provided by an electrically conductive silicon polymer for electrically engaging the tongue (28) on an underside thereof and for electrically engaging the floor (9) of the oral cavity (4). The oral electrode (64) is located within the oral cavity (4) spaced apart from the gum (12) of the oral cavity a sufficient distance for preventing stray currents entering the lower gum and teeth (11) of the subject. A pulse signal from a signal generator (34) is applied through a socket connector (71) to the oral and external electrodes (64, 8) for passing a current through the motor nerves of the muscles which control the operation of the tongue (28) for stimulating the muscles, and in turn toning and strengthening the muscles. By strengthening the muscles the tongue is retained in a more forward state in the mouth, thus alleviating sleep apnoea and snorin. The apparatus (1) by toning the muscles in the floor (9) of the oral cavity (4) cosmetically corrects a double chin condition.
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"Muscle stimulating apparatus"

The present invention relates to apparatus for stimulating muscles in the floor of the oral cavity of a subject, and in particular for stimulating at least some of the muscles which control the tongue, such as the genioglossus muscles, the mylohyoid and geniohyoid muscles, digastric muscles and the platysmus muscles.

The muscles in the floor of the mouth play an important role in maintaining an open airway. In sleep apnoea and in some types of obstructive snoring there is a tendency for the airway to collapse. Electrical stimulation, in general, tends to strengthen and/or tone these muscles making airway collapse less likely. Electrical stimulation may be carried out during sleep or while a subject is awake.

The muscles which control the tongue of a subject are the longitudinalis superficialis and profundus, transversus and verticalis linguae. These muscles form the body of the tongue, and together with the in-growing muscles genioglossus, hyoglossus, styloglossus and palatoglossus control the three-dimensional movement of the tongue. In particular, the muscles genioglossus and geniohyoideus, in general, are considered to be the muscles which are responsible for urging the tongue forward, and thus, in general, it is believed that by maintaining these muscles adequately toned, sleep apnoea in a subject can be significantly reduced, and in many cases eliminated.

Additionally, weakening of the muscles of the floor of the mouth may also result in a condition known as a double chin. This is also undesirable.

U.S. Patent Specification No. 5,190,053 of Meer discloses an intra-oral sublingual electrode device for the electrical stimulation of the genioglossus muscle to maintain the upper airway open in the treatment of sleep apnoea. The device of Meer comprises an arcuate tooth engaging member which engages the teeth of the lower jaw and which carries a pair of electrodes which when the carrier is engaged with the teeth of the lower jaw of the subject are located adjacent opposite side portions of
the gum of the lower jaw on respective opposite sides of the frenulum. A third electrode is located externally of the oral cavity beneath the floor of the oral cavity for co-operating with the two electrodes located in the oral cavity, so that when an EMF is developed across the external electrode and the electrodes in the oral cavity a current flows through the floor of the oral cavity for stimulating the genioglossus muscle. The device of Meer suffers from a number of disadvantages, in that firstly, due to the location of the electrodes in the oral cavity considerable discomfort is caused to the subject since stray currents are routed to the gums of the subject, which is undesirable. A second and more important disadvantage of the device of Meer is that it is limited in the muscles which can be stimulated, since the electrodes in the oral cavity are located adjacent the gums of the lower jaw of the subject.

A further disadvantage of the device of Meer is that there is a danger of the external electrode being located close to the carotid body, with the attendant risk of stimulating the carotid sinus.

A still further disadvantage of the device of Meer is that discomfort may be experienced by a subject, particularly in an area of the floor of the oral cavity adjacent the external electrode, and particularly on the outer side of the floor of the oral cavity.

There is therefore a need for apparatus for strengthening at least some of the muscles in the floor of the oral cavity of a subject which overcomes at least some of the disadvantages of the device of Meer.

The present invention is directed towards providing such apparatus. The invention is also directed towards providing use of the apparatus for strengthening at least some of the muscles in the floor of the oral cavity.

According to the invention there is provided apparatus for stimulating at least some of the muscles in the floor of the oral cavity of a subject, the apparatus comprising an oral electrode carrier for carrying and locating an oral electrode in the oral cavity of
the subject relative to an anatomical reference for applying an EMF for stimulating at least some of the muscles in the floor of the oral cavity, wherein the oral electrode carrier locates the oral electrode spaced apart from the gum of the lower jaw of the subject an effective distance from the gum for preventing stray electrical currents flowing to the gum.

In one embodiment of the invention the oral electrode carrier comprises an inner locating means engageable with the gum and/or teeth in the lower jaw of the subject for locating the oral electrode carrier in the oral cavity relative to the gum and/or teeth of the lower jaw of the subject.

In another embodiment of the invention the inner locating means comprises a locating member of arcuate shape for engaging front and side portions of the gum and/or teeth of the lower jaw of the subject. Preferably, the locating member comprises a front portion for engaging the front portion of the gum and/or teeth of the lower jaw of the subject, and a pair of side portions extending sidewardly rearwardly from the front portion for engaging respective opposite side portions of the gum and/or teeth of the lower jaw of the subject. Advantageously, the front portion of the locating member is of inverted U-shape cross-section defining a downwardly facing channel for engaging the front portion of the gum and/or teeth in the lower jaw of the subject. Ideally, the respective side portions of the locating member are formed by respective side wings for engaging the corresponding side portions of the gums and/or teeth of the lower jaw of the subject. Preferably, the side wings extend from the front portion of the locating member for engaging corresponding inner sides of the gums and/or teeth of the lower jaw of the subject.

In one embodiment of the invention a support means for supporting the oral electrode is connected to the front portion of the locating member and extends from the front portion of the locating member between but spaced apart from the side portions of the locating member.

In another embodiment of the invention the oral electrode carrier carries a tongue
engaging means for co-operating with the underside of the tongue of the subject for locating the oral electrode adjacent the motor nerves of the muscles to be stimulated for stimulating the muscles when an EMF is applied to the oral electrode.

5 In another embodiment of the invention the tongue engaging means is located on the upper side of the support means.

In a further embodiment of the invention the tongue engaging means defines a convex upper tongue engaging surface for engaging the underside of the tongue.

10 In one embodiment of the invention the oral electrode is formed on the tongue engaging means. Preferably, the tongue engaging means forms the oral electrode.

In another embodiment of the invention the oral electrode is located on the underside of the support means.

In a further embodiment of the invention the support means comprises an elongated support member extending to a distal end thereof.

20 Preferably, the oral electrode is located on the support member adjacent the distal end thereof.

In one embodiment of the invention the support member is inherently resilient for facilitating resilient urging of the oral electrode into electrically conductive engagement with the part of the oral cavity with which it is to be in electrically conductive engagement.

In another embodiment of the invention the support member is flexible.

30 In a further embodiment of the invention a pair of spaced apart oral electrodes are located on the support means spaced apart from each other. Preferably, the oral electrodes of the pair of spaced apart oral electrodes are electrically insulated from
each other.

In one embodiment of the invention the oral electrode carrier locates the oral electrode for co-operating with an external electrode located externally of the oral cavity beneath the floor of the oral cavity so that a stimulating current is driven by an EMF between the oral and the external electrodes through the motor nerves of the muscles to be stimulated.

In another embodiment of the invention the apparatus further comprises an external electrode carrier for carrying the external electrode and for locating the external electrode beneath and in contact with the floor of the oral cavity towards the chin of the subject.

In another embodiment of the invention an outer locating means is provided for locating the external electrode relative to the oral electrode and towards the chin of the subject. Preferably, a connecting means is provided for connecting the oral electrode carrier and the external electrode carrier so that the external electrode is located relative to the oral electrode. Advantageously, the connecting means locates the external electrode towards and relatively closely to the chin of the subject, and well spaced apart from the neck of the subject.

In one embodiment of the invention the outer locating means of the external electrode carrier comprises a chin engaging member for engaging the chin of the subject. Preferably, the chin engaging member is shaped for engaging the chin of the subject and opposite side portions of the lower jaw of the subject externally of the oral cavity.

In another embodiment of the invention a handle extends from the oral electrode carrier for facilitating insertion of the electrode carrier in the oral cavity of the subject. Preferably, the handle is adapted to extend from the oral cavity, in use, through the mouth of the subject. Ideally, a portion of the handle forms the connecting means for connecting the oral electrode carrier with the external electrode carrier. Preferably,
the connecting means is inherently resilient for facilitating relative movement of the oral and external electrode carriers.

In one embodiment of the invention an attachment means is provided for attaching the external electrode carrier to the subject.

In another embodiment of the invention the attachment means comprises an electrical conductive gel type adhesive.

Alternatively, the attachment means comprises a band extending from the chin engaging member for passing around the head of the subject for attaching the chin engaging member to the subject.

In another embodiment of the invention an electrical conductor is provided to each electrode for conducting a current to each electrode for developing the EMF on the electrode. Preferably, each electrical conductor terminates in an electrical connecting means remote from the corresponding electrode for connecting the electrical conductor to a signal generating source. Advantageously, the electrical connecting means comprises a jack plug socket for connecting the respective conductors to the signal generating means. Advantageously, each electrical conductor extends within and through the corresponding one of the oral and external electrode carriers.

In one embodiment of the invention the external electrode is a first external electrode, and a second external electrode is provided for locating externally beneath the floor of the oral cavity of the subject for co-operating with the first external electrode and the oral electrode for stimulating muscles in the floor of the oral cavity.

In another embodiment of the invention the first and second external electrodes are located on the external electrode carrier. Preferably, the first and second external electrodes are located adjacent but spaced apart from each other. Advantageously,
the first and second external electrodes are electrically insulated, one from the other. Ideally, the first and second external electrodes are co-planar with each other. Preferably, the second external electrode extends at least partly around the first external electrode.

In one embodiment of the invention the second external electrode extends around the first external electrode an angular distance of up to 270°.

In another embodiment of the invention the second external electrode extends around the first external electrode an angular distance of approximately 180°.

In a further embodiment of the invention the second external electrode extends around the first external electrode for an angular distance of less than 180°.

Preferably, the second external electrode is located between the first external electrode and the chin of the subject.

In one embodiment of the invention one of the first and second external electrodes is electrically connected to the oral electrode. Preferably, the second external electrode is electrically connected to the oral electrode.

Additionally the invention provides apparatus for stimulating at least some of the muscles of the floor of the oral cavity of a subject, the apparatus comprising an external electrode for locating externally beneath the floor of the oral cavity of the subject for co-operating with an oral electrode located in the oral cavity of the subject for applying an EMF for stimulating at least some of the muscles of the oral cavity wherein a first external electrode and a second external electrode are provided for locating externally beneath the floor of the oral cavity and for co-operating with the oral electrode for minimising discomfort to the subject when an EMF is applied to the respective external and oral electrodes for passing a current through the motor nerves of the muscles to be stimulated for stimulation thereof.
In one embodiment of the invention an external electrode carrier is provided for carrying the first and second external electrodes and for locating the first and second external electrodes beneath and in contact with the floor of the oral cavity of the subject. Preferably, the external electrode carrier locates the first and second external electrodes towards the chin of the subject. Advantageously, the external electrode carrier comprises an outer locating means for locating the first and second external electrodes relative to the oral electrode. Advantageously, an oral electrode carrier is provided for carrying and locating the oral electrode in the oral cavity of the subject relative to the first and second external electrodes.

In one embodiment of the invention a connecting means is provided for connecting the oral electrode carrier and the external electrode carrier. Preferably, the connecting means locates the external electrode towards and relatively closely to the chin of the subject, and well spaced apart from the neck of the subject.

In one embodiment of the invention the external electrode carrier comprises a chin engaging member for engaging the chin of the subject. Preferably, the chin engaging member is shaped for engaging the chin of the subject and side portions of the lower jaw of the subject externally of the oral cavity so that the chin engaging member forms the outer locating means for locating the first and second external electrodes.

Further the invention provides apparatus for stimulating at least some of the muscles in the floor of the oral cavity of a subject, the apparatus comprising an external electrode for locating externally beneath the floor of the oral cavity of the subject for applying an EMF for stimulating at least some of the muscles in the floor of the oral cavity, wherein a first external electrode and a second external electrode are provided for locating externally beneath the floor of the oral cavity, the second electrode extending at least partly around the first electrode and co-operating with the first electrode so that when an EMF is applied across the first and second electrodes a current is passed through the motor nerves of the muscles to be stimulated for stimulation thereof.
Further the invention provides apparatus for stimulating at least some of the muscles in the floor of the oral cavity of a subject, the apparatus comprising an oral electrode carrier for carrying and locating an oral electrode in the oral cavity of the subject relative to an anatomical reference for applying an EMF for stimulating at least some of the muscles in the floor of the oral cavity, wherein the oral electrode carrier carries a tongue engaging means for co-operating with the underside of the tongue of the subject for locating the oral electrode adjacent the motor nerves of the muscles to be stimulated for stimulating the muscles when an EMF is applied to the oral electrode.

The invention also provides for use of the apparatus according to the invention for stimulating at least some of the muscles in the floor of the oral cavity of a subject.

Additionally, the invention provides for use of the apparatus according to the invention for stimulating at least some of the muscles in the floor of the oral cavity of a subject for cosmetically correcting the condition of double chin in a subject.

Further the invention provides for use of the apparatus according to the invention for stimulating at least some of the muscles in the floor of the oral cavity of a subject for treating sleep apnoea.

The invention also provides for use of the apparatus according to the invention for stimulating at least some of the muscles in the floor of the oral cavity of a subject for correcting snoring during sleeping of the subject.

The advantages of the apparatus according to the invention are many. The apparatus is particularly suitable for the treatment of sleep apnoea and snoring. It is also particularly suitable for the cosmetic treatment of the condition of double chin. The apparatus according to the invention treats these conditions without any undue discomfort to the subject, and in particular, any discomfort which might otherwise be caused as a result of stray currents flowing into the gum and teeth of the lower jaw of the subject. By virtue of the fact that the oral electrode is located spaced apart from
the gum in the lower jaw of the subject, there is virtually no danger of stray currents flowing to the gum or teeth. Furthermore, by virtue of the fact that a tongue engaging means is provided for engaging the underside of the tongue, particularly good electrical contact is made between the oral electrode and the part of the oral cavity to be contacted by the electrode. When the oral electrode is located on the underside of the support means of the oral electrode carrier, the action of the tongue on the tongue engaging means urges the oral electrode into good electrical contact with the floor of the oral cavity. When the oral electrode is carried on the tongue engaging means the action of the tongue on the tongue engaging means also urges the oral electrode into good electrical contact with the tongue. A particularly important advantage of the invention is that not only does it provide for stimulation of the muscles in the floor of the oral cavity, but muscles in the tongue are also stimulated. This is achieved when the electrode is located on or forms part of the tongue engaging means such that the electrode engages the underside of the tongue for applying a current through the motor nerves of the relevant muscles in the tongue of the subject.

A further advantage of the invention is achieved when the apparatus according to the invention comprises both the oral electrode carrier and the external electrode carrier, and when the two electrode carriers are connected by a connecting means. In this embodiment of the invention the external electrode can be readily easily accurately aligned in the appropriate location without any guesswork being required. Thus, when the apparatus is provided with the external electrode carrier, there is no danger of the external electrode being mislocated whereby the external electrode could cause stimulation of the carotid sinus.

A further advantage of the invention is obtained when the external electrode is replaced by respective first and second external electrodes, in that it has been found that discomfort to the subject when the pulse train is being applied to the oral and external electrodes is minimised and effectively eliminated. This advantage is particularly achieved when one of the external electrodes is electrically connected to the oral electrode, and in particular, the advantage is achieved when the second
external electrode extends at least partly around the first external electrode, and the second external electrode is electrically connected to the oral electrode.

Additionally, the apparatus according to the invention provides a relatively simple and easily manufactured apparatus, and additionally, an apparatus which can readily easily be used by the subject, and which provides for ready and accurate location of each electrode for maximising the therapeutic and cosmetic effect while minimising any adverse side effects of the use of the apparatus.

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

Fig. 1 is a top perspective view of apparatus according to the invention for stimulating at least some of the muscles in the floor of the oral cavity of a subject,

Fig. 2 is an underneath perspective view of the apparatus of Fig. 1,

Fig. 3 is an upside down front elevational view of the apparatus of Fig. 1,

Fig. 4 is an upside down side elevational view of the apparatus of Fig. 1,

Fig. 5 is a top plan view of the apparatus of Fig. 1,

Fig. 6 is a transverse cross-sectional view illustrating the apparatus of Fig. 1 in use in a subject,

Fig. 7 is a front elevational view illustrating the apparatus of Fig. 1 in use in a subject,

Figs. 8 (a) to (c) are perspective views from different angles of apparatus
according to another embodiment of the invention also for stimulating at least some of the muscles on the floor of the oral cavity of a subject,

Fig. 9 is an underneath plan view of the apparatus of Fig. 8,

Fig. 10 is a side elevational view of the apparatus of Fig. 8,

Fig. 11 is an end elevational view of the apparatus of Fig. 8,

Fig. 12 is another end elevational view of the apparatus of Fig. 8 from the other end to that of Fig. 11,

Fig. 13 is a transverse cross-sectional side elevational view of the apparatus of Fig. 8 on the line XVI-XVI of Fig. 9,

Fig. 14 is a perspective view of apparatus according to a further embodiment of the invention,

Fig. 15 is a transverse cross-sectional side elevational view of the apparatus of Fig. 16,

Fig. 16 is a transverse cross-sectional side elevational view of the apparatus of Fig. 14, in use,

Fig. 17 is a perspective view of a portion of apparatus according to another embodiment of the invention for stimulating at least some of the muscles of the floor of the oral cavity of a subject,

Fig. 18 is a plan view of a detail of the apparatus of Fig. 17,

Fig. 19 is another plan view of the detail of Fig. 18 of the apparatus of Fig. 17,
Fig. 20 is a further plan view of a portion of the detail of Fig. 18 of the apparatus of Fig. 17,

Fig. 21 is a circuit diagram of the apparatus of Fig. 17,

Fig. 22 is a plan view of a detail of apparatus according to another embodiment of the invention for stimulating at least some of the muscles on the floor of the oral cavity of a subject,

Fig. 23 is a plan view of a detail of another apparatus according to another embodiment of the invention for stimulating at least some of the muscles on the floor of the oral cavity of a subject, and

Fig. 24 is a view similar to Fig. 6 of apparatus according to another embodiment of the invention.

Referring to the drawings and initially to Figs. 1 to 7 thereof, there is illustrated apparatus according to the invention indicated generally by the reference numeral 1 for stimulating the muscles in the floor of the oral cavity of a subject, and in particular, the genioglossus muscles, the mylohyoid and geniohyoid muscles as well as the digastric and platysmus muscles of the subject. By stimulating these muscles, they are strengthened and toned, thereby reducing the possibility of airway collapse and also tending to locate the tongue more forwardly in the oral cavity. Thus, the apparatus 1 according to the invention is particularly suitable for use in the treatment of sleep apnoea and snoring, and also for use in the cosmetic treatment of a condition known as double chin.

The apparatus 1 comprises an oral electrode carrier 3 for inserting into the oral cavity 4 of a subject for carrying and locating an oral electrode 5 in the oral cavity 4 for co-operating with an external electrode 8 located externally of the oral cavity 4 for applying an electrical current to motor nerves of the muscles in the floor 9 of the oral cavity 4 for stimulating and toning, and thus strengthening the muscles in the floor 9
of the oral cavity 4. The oral electrode carrier 3 is of plastics material and is integrally formed in one piece by injection moulding. The oral electrode carrier 3 comprises an inner locating means, namely, a locating member 10 for engaging the teeth 11 and gum 12 of the lower jaw 14 for locating the oral electrode carrier 3 relative to the teeth 11 and gum 12 of the lower jaw 14. The locating member 10 comprises a front portion 13 of inverted U-shape having an inner side wall 15 and a spaced apart outer side wall 16 which are joined by a web 17 for defining a downwardly facing channel 18 for engaging the front teeth 11 and front portion of the gum 12 of the subject. Two side portions 20 of the locating member 10 are formed by a pair of side wings 21 which extend rearwardly from the corresponding inner side wall 15 for engaging the inner sides of the corresponding side portions of the gum and the rear molar teeth of the subject. The side wings 21 are resiliently biased outwardly for facilitating engagement with the side portions of the gum 12 and the rear molar teeth 11 for centrally locating the oral electrode carrier 3 in the oral cavity 4 within the gum 12 of the lower jaw 14 of the subject.

A support means, namely, a support member formed by a support plate 24 is connected to the inner side wall 15 of the front portion 13 by a connecting piece 23 and extends rearwardly therefrom between but spaced apart from the side wings 21 for carrying the oral electrode 5. In this embodiment of the invention the oral electrode 5 is carried on the underside of the support plate 24, and as can be seen, by virtue of the fact that the support plate 24 is spaced apart from the side walls 21, and furthermore, by virtue of the fact that the oral electrode 5 is inwardly spaced from side edges 25 of the support plate 24, the oral electrode 5 is spaced apart an effective distance from the gum 12 of the lower jaw 14 sufficient for avoiding any danger of stray currents passing into the gum 12 and/or teeth 11 which would otherwise cause discomfort and irritation to the subject. The connecting piece 23 connects the support plate 24 to the inner side wall 15 at the lower edge thereof so that the support plate 24 is located adjacent the floor 9 of the oral cavity 4 of the subject. The connecting member 23 is resilient, as is the support plate 24 for resiliently urging the oral electrode 5 downwardly relative to the locating member 10 for urging the oral electrode 5 into engagement with the floor 9 of the oral cavity 4.
A tongue engaging means, in this embodiment of the invention provided by a pair of spaced apart tongue engaging members 27 are located on the upper side of the support plate 24 for engaging the underside of the tongue 28 of the subject. The tongue engaging members 27 define convex surfaces 29 which engage the underside of the tongue 28 so that the tongue acts to urge the support plate 24 downwardly when the oral electrode carrier 3 is inserted into the oral cavity beneath the tongue 28 for in turn urging the oral electrode 5 into engagement with the floor 9 of the oral cavity 4 for ensuring good electrical contact between the oral electrode 5 and the floor 9 of the oral cavity 4.

As well as being located on the support plate 24 to be spaced apart from the side portions of the gum 12, the oral electrode 5 is also located on the support plate 24 to be spaced apart from the front portion of the gum 12, likewise, for preventing stray currents passing into the forward portion of the gum 12. The support plate 24 locates the oral electrode 5 in the appropriate position on the floor 9 of the oral cavity 4 so that when an EMF is applied across the oral electrode 5 and the external electrode 8 the motor nerves of the genioglossus, mylohyoid, geniohyoid, digastric and platysmus muscles for stimulation thereof.

A rearwardly facing recess 30 formed in the support plate 24 accommodates the frenulum.

A handle 32 extends forwardly from the outer side wall 16 of the front portion 13 of the locating member 10 for facilitating insertion and removal of the oral electrode carrier 3 into and from the oral cavity 4 of the subject. The handle 32 is shaped and sized to extend outwardly of the oral cavity 4 through the mouth 36 of the subject.

A cable 33 which is insert moulded in the oral electrode carrier 3 connects the oral electrode 5 with a connecting means, namely, a socket connector 35 for connecting the oral electrode 5 to an externally located signal generator 34. The socket connector 35 is located in the distal end of the handle 32. The cable 33 extends
internally within and through the support plate 24, the inner side wall 15 of the forward portion 13 of the locating member 10, the top web 17, an upper portion of the outer side wall 16, and in turn through the handle 32 to the socket connector 35.

The plastics material from which the oral electrode carrier 3 is manufactured is preferably a food grade plastics material, or at the very least a non-toxic plastics material. Additionally, the plastics material of the oral electrode carrier 3 is selected to have an inherent resilience for providing the resilient urging action in the connecting piece 23 and the side wings 21. The oral electrode 5 is of metal, such as stainless steel, or may be of a conductive polymer, such as silicon carbon rubber, which are non-toxic.

The external electrode 8 is carried on an external electrode carrier 37 of plastics material, and a band 38 extends from the external electrode carrier 37 for securing the external electrode carrier 37, and in turn, the external electrode 8 externally to the underside of the floor 9 of the oral cavity 4 towards the chin 39 of the subject. The band 38 terminates at respective opposite ends 40 and 41 which overlap. A fastening means, which in this embodiment of the invention is provided by hooks and eyes of the type sold under the Trade Mark VELCRO, are provided on the overlapping ends 40 and 41, the hooks being provided on one end 40 and the eyes being provided on the other end 41 for securing the band over the head of the subject. By providing hooks and eyes on the respective ends 40 and 41 of the band 38, adjustment of the band 38 is provided for, for accommodating subjects of different face and head size.

A cable 42 which is connected to the external electrode 8 and extends from the external electrode carrier 37 terminates in a socket connector 43 for facilitating connecting the external electrode 8 to the signal generator 34. Cables 44 from the signal generator 34 terminate in plugs 45 for connecting the signal generator 34 to the socket connectors 35 and 43.

The signal generator 34, which is only illustrated in Figs. 6 and 7, is suitable for
outputting signals each comprising a pulse train, where the amplitude, polarity, EMF, current, pulse width and frequency of the pulses of each pulse train are variable. Appropriate controls (not shown) are provided on the signal generator 34 for controlling and varying these parameters of the pulse trains. Such controls will be well known to those skilled in the art. The signal generator 34 is portable, and is powered by a battery (not shown), and is suitable for carrying in the pocket of a subject.

In use, with the oral electrode carrier 3 located in the oral cavity 4 of the subject beneath the tongue 28 so that the oral electrode 5 is in good electrical contact with the floor 9 of the oral cavity 4, and with the external electrode carrier 37 secured to the subject by the band 38 and in good electrical contact with the outer skin of the floor 9 of the oral cavity 4 towards the chin 39 of the subject, the apparatus 1 is ready for use. The plugs 45 of the cables 44 from the signal generator 34 are connected to the appropriate socket connectors 35 and 43 for applying an EMF caused by the pulse train signal from the signal generator 34 to the oral electrode 5 and the external electrode 8 for in turn driving a pulsed current through the motor nerves of the relevant muscles in the floor 9 of the oral cavity 4. The pulsed current through the motor nerves of the muscles causes the muscles to contract, thus stimulating and toning, and in turn strengthening the muscles. With the muscles in the floor 9 of the oral cavity 4 toned and strengthened, the tongue 28 of the subject is retained in a more forward position, and thus, during sleep is retained in the forward position by the toned and strengthened muscles, thereby reducing and in many cases completely alleviating the condition of sleep apnoea. Additionally, by virtue of the fact that the muscles in the floor 9 of the oral cavity 4 are toned and strengthened for retaining the tongue in a more forward position, snoring is reduced, and in many cases eliminated. Furthermore, by strengthening the muscles in the floor 9 of the oral cavity 4 the condition of double chin is also significantly corrected.

The parameters of the pulse train signal from the signal generator 34 are selected depending on the subject and on the state of the muscles of the subject, and the condition to be treated. However, typically, it is envisaged that the frequency of the
pulse train will be in the order of 10Hz to 100Hz, and the duration of each pulse will be in the range of 100 microseconds to 300 microseconds, and typically of 200 microseconds. The EMF and the current induced in the nerves is suitable for providing adequate stimulation and exercise of the muscles. Typically, the EMF is in the range of 30 volts to 40 volts, and preferably in the range of 35 volts to 38 volts. The current which depends on the electrical resistance offered by the tissue and nerves between the oral and external electrodes 5 and 8, and also the contact resistance between the electrodes and the subject will typically be in the order of 35 mAmps when the voltage is set at a value of the order of 35 volts.

In general, it is envisaged that the subject will be subjected to a treatment regime, which will require a number of training sessions with the apparatus 1 over a period of time, for example, over a few months. In a typical treatment regime the subject would be subjected to two training sessions per day each lasting approximately twenty minutes while the subject is awake. It has been found that two training sessions of twenty minutes duration each in general is sufficient after a period of approximately two months for providing sufficient toning and strengthening of the muscles to correct for sleep apnoea, snoring and double chin. However, the subject may be subject to training sessions during sleeping periods. In which case, it is envisaged that the apparatus would be timed to provide training sessions to the subject of predetermined duration at predetermined intervals throughout the night while the subject is sleeping. It is also envisaged that the apparatus 1 may include a monitoring device for monitoring for non-breathing in the subject or excessive snoring, and the apparatus would be operated in response to the monitoring circuitry determining the absence of breathing or excessive snoring.

Referring now to Figs. 8 to 13, there is illustrated apparatus according to another embodiment of the invention, indicated generally by the reference numeral 50, also for stimulating muscles in the floor 9 of an oral cavity 4 of a subject. However, in this embodiment of the invention the apparatus 1 also stimulates muscles in the tongue of the subject. The apparatus 50 is substantially similar to the apparatus 1 and similar components are identified by the same reference numerals. The apparatus
50 is provided to be used in conjunction with an external electrode (not shown) but similar to the electrode 8 of the apparatus 1 of Figs. 1 to 7, and which would be located on an external electrode carrier 37, which would be secured to the subject by a band similar to the band 38. Additionally, the apparatus 50 also comprises a signal generator (not shown) similar to the signal generator 34 of the apparatus 1.

The main difference between the apparatus 50 and the apparatus 1 is in the construction of the support means for supporting the oral electrode, and also in the oral electrode. In this embodiment of the invention the support means comprises an elongated support member 52 extending from the front portion 13 of the locating member 10. The support member 52 extends rearwardly from the front portion 13 of the locating member 10 between but in this case well spaced apart from the side wings 21, and terminates in an oral electrode 53. In this embodiment of the invention the oral electrode 53 is of an electrically conductive plastics material, namely, a silicon polymer.

The oral electrode 53 also forms the tongue engaging member and is formed with an upper convex surface 54 for engaging the underside of the tongue 28. Since the oral electrode 53 is of electrically conductive silicon polymer material, the oral electrode 53 as well as making electrical contact with the floor 9 of the oral cavity 4 also makes electrical contact with the underside of the tongue 28 where it contacts the tongue 28. Thus, the oral electrode 53 applies an EMF to the underside of the tongue 28 which drives a current through the motor nerves of the muscles of the tongue 28 for in turn stimulating, and thus toning and strengthening these muscles, as well as the muscles in the floor 9 of the oral cavity 4.

In this embodiment of the invention the cable 33 is replaced by an electrically conducting member 55 which is also of electrically conductive silicon polymer, and is formed integrally with the oral electrode 53. The electrically conductive member 55 extends from the oral electrode 53 and terminates in a socket connector 56 also of silicon polymer. The socket connector 56 is located in a bore 57 in the distal end of the handle 32 for engaging a corresponding plug 45 of the signal generator 34. The
advantage of providing the socket 56 in a bore 57 is that the length of the bore 57 can be such as to prevent the ingress of saliva, which may dribble from the mouth of the subject onto the handle 32, to the socket connector 56.

The oral electrode carrier 3 is of plastics material and is integrally injection moulded in one piece, the oral electrode 53 and the electrically conductive member 55 being insert moulded with the oral electrode carrier 3 during moulding thereof. The electrically conductive member is located within the oral electrode carrier to avoid electrical contact with the subject.

Additionally, in this embodiment of the invention the inner and outer side walls 15 and 16 terminate towards the front portion 13 of the locating member 10, however, this has no particular significance, it is provided for facilitating ease of moulding of the oral electrode carrier 3.

Use of the apparatus 50 is similar to that of the apparatus 1, with the exception that as well as the muscles of the floor 9 of the oral cavity 4 being stimulated the tongue muscles are also stimulated by virtue of the fact that the oral electrode 53 is in electrically conductive engagement with the underside of the tongue 28 as well as with the floor 9 of the oral cavity.

Referring now to Figs. 14 to 16, apparatus according to another embodiment of the invention which is indicated generally by the reference numeral 60 is provided for stimulating muscles in the tongue 28 and floor 9 of the oral cavity 4 of a subject. The apparatus 60 is somewhat similar to the apparatus 1 and similar components where relevant are identified by the same reference numerals. However, in this embodiment of the invention the external electrode carrier comprises an external electrode carrier 61, which includes an outer locating means, namely, a chin engaging member 62 for locating the external electrode 8 on the subject. The chin engaging member 62 is shaped to engage the chin 39 and outer sides of the lower jaw 14 of the subject for locating the external electrode 8 beneath the floor 9 of the oral cavity 4 just rearwardly of the chin 39 and relatively close thereto.
The oral electrode carrier 3 is connected to the external electrode carrier 61 by a portion 63 of the handle 32, which extends from the oral electrode carrier 3. The portion 63 of the handle 32 is resilient for facilitating insertion and removal of the oral electrode carrier 3 into the mouth of the subject.

The oral electrode carrier 3 is substantially similar to that of the oral electrode carrier 3 of the apparatus 50 in that the oral electrode which is provided by an oral electrode 64 is similar to the oral electrode 53, and is formed of electrically conductive silicon polymer so that the oral electrode 63 is in electrical contact with the underside of the tongue 28 and also the floor 9 of the oral cavity 4. The oral electrode 64 is carried on a support member 65 which extends from the front portion 13 of the locating member 10. The support member 65 is cranked at 66 and 67 for ensuring good engagement of the oral electrode 63 with both the underside of the tongue 28 and the floor 9 of the oral cavity 4.

The chin engaging member 62 comprises a front wall 68 and a pair of side walls 69 extending rearwardly from the front wall 68. A base wall 70 extends rearwardly from the front wall 68 and joins the side walls 69. The front, side and base walls 68, 69 and 70 are shaped to substantially define the chin and forward side portions of the lower jaw of a subject so that when engaged with the chin of the subject the external electrode 8 is centrally located relative to the sides of the lower jaw 14 of the subject and slightly spaced from the forward portion of the chin 39 of the subject. The portion 63 of the handle 32 extends between the oral electrode carrier 3 and the front wall 68 adjacent the top thereof. The front wall 68, side walls 69 and base wall 70 of the chin engaging member 62 are formed to be relatively flexible and resilient for readily accommodating different chin and face shapes.

In this embodiment of the invention as well as the oral electrode 64 being of silicon polymer material, the external electrode 8 is also of electrically conductive silicon polymer material, and both are connected to a jack plug socket connector 71 located in a projection 72 which extends downwardly from the base wall 70 of the chin
engaging member 62. An electrically conductive member 73 of silicon polymer extends from the oral electrode 64 through the support member 65, and in turn through the portion 63 of the handle 32 and the front wall 68 to the socket connector 71, and an electrically conductive member 74 also of silicon polymer extends from the external electrode 8 to the socket connector 71 for facilitating connection of the respective electrodes 64 and 8 to the signal generator. A bore 75 extends into the projection 72 to the socket connector 71 for accommodating a jack plug to the socket connector 71. The bore 75 is of sufficient length for preventing the ingress of saliva to the socket connector 71.

A band 78 is connected to the respective side walls 69 of the chin engaging member 62 at 79 for securing the chin engaging member 62 to the subject. The band 78 terminates in ends (not shown) but similar to the ends 40 and 41 of the band 38 of the apparatus 1 of Figs. 1 to 7 which are provided with hooks and eyes of the type sold under the Trade Mark VELCRO for securing the band 78 over the head of the subject with the chin engaging member 62 tightly engaged with the chin.

In this embodiment of the invention the external electrode carrier 61 and the oral electrode carrier 3 are integrally injection moulded in one piece of plastics material. The oral electrode 64 and the external electrode 8 as well as their respective electrically conductive members 73 and 74 and the socket connector 71 are insert moulded during injection moulding of the apparatus 60.

In use, the apparatus 60 is offered up to the mouth and chin of the subject and initially the oral electrode carrier 3 is engaged in the oral cavity 4 of the subject with the support member 65 and the oral electrode 64 beneath the tongue 28 of the subject. The locating member 10 is engaged with the teeth of the subject, and the oral electrode carrier 3 is located in the oral cavity with the side wings 21 abutting the inner surfaces of the side portions of the gum of the lower jaw and the rear molar teeth of the lower jaw of the subject. The apparatus 60 is then pivoted in the direction of the arrow A, see Fig. 16, for engaging the chin engaging member 62 with the chin 39 of the subject. When the chin engaging member 62 is in tight
engagement with the chin of the subject the band 78 is secured around the head of
the subject. The apparatus 60 is then ready for use and is connected to the signal
generator 34 through the socket connector 71. Thereafter use of the apparatus 60 is
similar to that of the apparatus 1 and the apparatus 50.

A particularly important advantage of the apparatus 60 is that by virtue of the fact
that the apparatus 60 including the oral and external electrode carriers 3 and 61 are
formed as a single one piece unit, as well as accurately locating the oral electrode
64 in the oral cavity, the apparatus 60 also accurately locates the external electrode
8 so that the oral electrode 64 co-operates with the external electrode 8 for obtaining
optimum stimulation of the muscles. Additionally, by virtue of the fact that the
external electrode 8 is accurately located, there is no danger of the external
electrode being located adjacent to or close to, or indeed, on the carotid body which
would otherwise cause stimulation of the carotid sinus.

Referring now to Figs. 17 to 21, there is illustrated apparatus according to another
embodiment of the invention indicated generally by the reference numeral 90 for
stimulating muscles in the floor of the oral cavity of a subject, and also for stimulating
the muscles in the tongue of a subject. The apparatus 90 is substantially similar to
the apparatus 60, and similar components are identified by the same reference
numerals. Since the apparatus 90 is substantially similar to the apparatus 60, only
the external electrode carrier 61 is illustrated, since this is the only part of the
apparatus 90 which differs from the apparatus 60.

In this embodiment of the invention the single external electrode which is carried in
the external electrode carrier 61 is replaced by two electrodes, namely, a first
substantially circular disc external electrode 92 and a second arcuate disc external
electrode 93 both of electrically conductive metal foil. The second external electrode
93 extends partly around the first electrode 92 an angular distance of approximately
180°. The first and second external electrodes 92 and 93 are electrically insulated
from each other and are located on the base wall 70 of the chin engaging member
62 of the external electrode carrier 61, and are mounted on the base wall 70 to be
co-planar with each other. The first and second external electrodes 92 and 93 are bonded to and carried on a carrier disc 94 of electrically insulating material, namely, polyester. The carrier disc 94 is bonded to the base wall 70 of the chin engaging member 62 by a suitable adhesive for locating the first and second external electrodes spaced apart from the chin and in turn the front portion of the gum of the subject, but nonetheless relatively close to the chin of the subject. Additionally, the first and second external electrodes 92 and 93 are located on the external electrode carrier 61 so that the second external electrode 93 lies between the first external electrode 92 and the chin 39 of the subject when the chin engaging member 62 is secured to the subject. In other words, the open mouth defined by ends 97 of the second electrode 93 faces towards the neck of the subject.

Connecting terminals 95 and 96 extend from the first and second external electrodes 92 and 93, respectively, for connecting to corresponding cables (not shown) which extend through the chin engaging member 62 for connection to the signal generator 34.

Referring now in particular to Fig. 21, a circuit diagram of the connection of the first and second external electrodes 92 and 93 and the oral electrode 64 to the signal generator 34 is illustrated. In this embodiment of the invention the arcuate second external electrode 93 is electrically connected to the oral electrode 64, and both are connected to one of the terminals of the signal generator 34, while the first external electrode 92 is connected to the other terminal of the signal generator 34. Accordingly, the second external electrode 93 and the oral electrode 64 are held at the same potential, while the first external electrode 92 is held at a different potential when a pulse train signal is applied to the respective electrodes 64 and 92 and 93. Accordingly, an EMF is developed across the oral electrode 64 and the first external electrode 92, and the same EMF is developed across the first and second external electrodes 92 and 93.

It has been found that by electrically connecting the oral electrode 64 to the second external electrode 92 so that an EMF is developed across the first external electrode...
92 and the respective oral electrode 64 and the second external electrode 93, any
discomfort to the subject which may sometimes arise when the pulse signal is being
delivered between the oral electrode and a single external electrode is reduced. It is
believed that the reason for this is that the provision of the first and second external
electrodes connected as described with the oral electrode better directs current at
the superficial fibres of the genioglossus muscle in the floor of the oral cavity. This,
thus, permits a reduction in the current required for muscle stimulation, thus
minimising discomfort to the subject.

Otherwise, the apparatus 90 is similar to the apparatus 60 already described with
reference to Figs. 14 to 16. The oral electrode carrier 3 is identical to the oral
electrode carrier 3 of the apparatus 60, and is connected to the front wall 68 of the
chin engaging member 62 by the portion 63 of the handle 32.

Referring now to Fig. 22, there is illustrated an alternative arrangement of first and
second external electrodes 92 and 93 which is suitable for the apparatus 90. The
only difference between the first and second external electrodes 92 and 93 of Fig. 22
and those of the apparatus 90 is that the first electrode 92 is not quite circular, and
the second external electrode 93 extends around the first external electrode 92 an
angular distance of approximately 270°. Otherwise, the first and second electrodes
92 and 93 of Fig. 22 are similar to the first and second external electrodes 92 and 93
of the apparatus 90, and would be located on the base wall 70 of the chin engaging
member 62 with the second external electrode 93 located between the first external
electrode 92 and the chin of the subject, in other words, with the open mouth of the
second external electrode 93 defined by the free ends 97 facing towards the neck of
the subject.

Referring now to Fig. 23, there is illustrated another pair of first and second external
electrodes 92 and 93 which are also suitable for the apparatus 90. The first and
second external electrodes 92 and 93 are carried on a carrier disc 94 similar to the
carrier disc 94 of the apparatus 90. The first and second external electrodes 92 and
93 of Fig. 23 are substantially similar to those of the apparatus 90 with the exception
that the first external electrode 92 is of partly rectangular shape with one end terminating in a semicircular portion. The arcuate external electrode 93 extends around the first external electrode 92 an angular distance of between 180° and 270°. When mounted in the apparatus 90, the first and second electrodes 92 and 93 of Fig. 23 would be located on the base wall 90 with the second external electrode 93 located between the first external electrode 92 and the chin of the subject. In other words, the open mouth defined by the second external electrode 93 by the ends 97 would face rearwardly towards the neck of the subject.

Referring now to Fig. 24, there is illustrated apparatus according to another embodiment of the invention indicated generally by the reference numeral 100 also for stimulating the muscles in the floor of the oral cavity and in the tongue of a subject. The apparatus 100 is substantially similar to the apparatus 50 described with reference to Figs. 11 to 13, and similar components are identified by the same reference numerals. The main difference between the apparatus 100 and the apparatus 50 is in the arrangement of the external electrode. In this embodiment of the invention the external electrode 8 is carried on an external electrode carrier 37, both of which are similar to the external electrode 8 and the external electrode carrier 37, respectively, of the apparatus 50, however, instead of the external electrode 8 being secured to the subject by a band, the external electrode 8 and the external electrode carrier 37 are secured to the subject by an electrically conductive gel type adhesive. An outer locating means for locating the external electrode 8 and the external electrode carrier 37 relative to the oral electrode 53 in this embodiment of the invention is provided by an electrical connecting means, namely, an inextendable electrical cable 101 which extends from the handle 32. The cable 101 is of appropriate length so that the external electrode 8 and the external electrode carrier 37 are correctly located externally beneath the floor of the oral cavity close to but just spaced apart slightly rearwardly of the chin 39 of the subject. The cable 101 is an electrical cable and supplies the EMF to the external electrode 8. The cable 101 extends into the handle 32 and through the handle to the socket connector 43 which in this embodiment of the invention is a double contact jack socket. Cables 44 from the signal generator 34 terminate in a corresponding jack plug 102 for engaging
the socket connector 43, and for in turn delivering the pulsed signals from the signal
generator 34 to the oral electrode 53 and the external electrode 8. A particularly important advantage of the apparatus 100 according to this
embodiment of the invention is that by virtue of the fact that the external electrode 8
is secured to the subject by an adhesive, the requirement for the band of the
apparatus 50 is eliminated. Furthermore, by connecting the external electrode
carrier 37 to the handle 32 by the cable 101, the external electrode 8 is accurately
located beneath the floor of the oral cavity towards the chin of the subject, and well
away from the neck of the subject, thus avoiding any danger of stimulating the
carotid sinus. Thus, the apparatus 100 provides a relatively simple muscle
stimulating apparatus which in use can be worn with minimum discomfort by the
subject.

It will be appreciated that while the apparatus of Figs. 17 to 21 has been described
as having the external electrode provided by first and second external electrodes, it
will be appreciated that the apparatus of Figs. 1 to 7, 8 to 13, and 14 to 16 and 24
may also be provided with the external electrode replaced with first and second
external electrodes in the arrangement and configuration described with reference to
Figs. 17 to 21. While the outer locating means in the embodiment of the invention described with
reference to Fig. 24 has been described as being provided by an electrical cable
extending from the handle to the external electrode carrier, any other suitable
locating or connecting means may be used. It will of course be appreciated that
other outer locating means and connecting means besides a chin engaging member
and the cable described in Fig. 24 may be used. Indeed, it is envisaged that a
relatively narrow connecting member extending downwardly from the handle or
indeed from the oral electrode carrier to an external electrode carrier may be
provided. Such a connecting member would eliminate the need for a chin engaging
member of the type described with reference to Figs. 14 to 16.
While in the apparatus 90 described with reference to Figs. 17 to 21 the external electrode has been described as being provided by a pair of first and second electrodes 92 and 93, and while substantially similar first and second external electrodes 92 and 93 have been described with reference to Figs. 22 and 23, it is envisaged in certain cases that the oral electrode may also be provided by first and second electrodes of a substantially similar configuration to those described and illustrated with reference to Figs. 17 to 23.

While the second external electrode has been described as being electrically connected to the oral electrode, it is envisaged that instead of electrically connecting the second external electrode to the oral electrode, the first external electrode may be connected to the oral electrode, and the first and second electrodes would be insulated from each other. Although, as already discussed, it has been found that preferred results have been achieved by electrically connecting the second external electrode to the oral electrode.

It is also envisaged that in certain cases, the first and second electrodes may be electrically connected together.

It is also envisaged that the second external electrode may extend completely around the first external electrode, or may extend an angular distance around the first external electrode less than 180°.

While the oral electrode has been described as being provided by a single electrode, in certain cases, it is envisaged that the oral electrode may be provided as two separate mutually electrically insulated electrodes, which would be spaced apart on respective opposite sides of the frenulum. Where the oral electrode is provided as two separate electrodes, it is envisaged that the signals from the signal generator may be applied simultaneously to the respective oral electrodes, or alternatively, the signals from the signal generator may be provided alternately to the respective oral electrodes. It is also envisaged in certain cases that the signals from the signal generator may be applied to the two oral electrodes so that an EMF is established.
between the two oral electrodes for driving a current between the respective oral electrodes through the motor nerves of the muscles to be stimulated for stimulation thereof.

In certain cases, where two oral electrodes are provided, it is envisaged that the use of two oral electrodes may eliminate the need for an external electrode since under certain circumstances, it is envisaged that the two oral electrodes may be sufficient for establishing sufficient current through a sufficient number of the motor nerves for stimulating the relevant muscle. Where two oral electrodes are provided, the two oral electrodes may be arranged for engaging the underside of the tongue of the subject on the respective opposite sides of the frenulum, or for engaging the floor of the mouth on the respective opposite sides of the frenulum. It is also envisaged that where two oral electrodes are provided, they may each be provided for engaging both the underside of the tongue and the floor of the oral cavity on respective opposite sides of the frenulum. Furthermore, it is envisaged that where two oral electrodes are provided, one of the oral electrodes may be provided on the upper side of the support member, and the other would be provided on the underside of the support member.

While the oral and external electrodes have been described as being of specific shape and construction, electrodes of other shape and construction and indeed, other materials may be used. It will of course be appreciated that the oral electrode of the apparatus 50 and 60 may be used to replace the oral electrode of the apparatus 1, and vice versa. It will also of course be appreciated that while it is advantageous to provide the cable or other connections between the connector socket or sockets and the relevant electrode by wires or electrically conductive members which are internally located within the oral electrode carrier and/or the external electrode carrier, in certain cases, it is envisaged that the cables connecting the electrodes to the signal generator may be clipped onto the oral electrode carrier and the external electrode carrier. It will be appreciated that where the cables are exposed they will be insulated for avoiding electrical contact with the subject, both in the oral cavity and externally thereof.
It is also envisaged that the oral and external electrodes may be formed by printing onto the respective carriers.

The apparatus according to the invention may be used in the treatment of sleep apnoea, snoring and for the cosmetic correction of double chin condition.

While the apparatus has been described as being of a plastics material and being formed by injection moulding, the apparatus may be of any other suitable material and formed by any other suitable method.

In order to minimise discomfort to the subject, all corners and edges of the apparatus according to the invention, and in particular, all corners and edges of the oral electrode carrier are rounded.
Claims

1. Apparatus for stimulating at least some of the muscles in the floor of the oral cavity of a subject, the apparatus comprising an oral electrode carrier for carrying and locating an oral electrode in the oral cavity of the subject relative to an anatomical reference for applying an EMF for stimulating at least some of the muscles in the floor of the oral cavity, characterised in that the oral electrode carrier locates the oral electrode spaced apart from the gum of the lower jaw of the subject an effective distance from the gum for preventing stray electrical currents flowing to the gum.

2. Apparatus as claimed in Claim 1 characterised in that the oral electrode carrier comprises an inner locating means engageable with the gum and/or teeth in the lower jaw of the subject for locating the oral electrode carrier in the oral cavity relative to the gum and/or teeth of the lower jaw of the subject.

3. Apparatus as claimed in Claim 2 characterised in that the inner locating means comprises a locating member of arcuate shape for engaging front and side portions of the gum and/or teeth of the lower jaw of the subject.

4. Apparatus as claimed in Claim 3 characterised in that the locating member comprises a front portion for engaging the front portion of the gum and/or teeth of the lower jaw of the subject, and a pair of side portions extending sidewardly rearwardly from the front portion for engaging respective opposite side portions of the gum and/or teeth of the lower jaw of the subject.

5. Apparatus as claimed in Claim 4 characterised in that the front portion of the locating member is of inverted U-shape cross-section defining a downwardly facing channel for engaging the front portion of the gum and/or teeth in the lower jaw of the subject.

6. Apparatus as claimed in Claim 4 or 5 characterised in that the respective side portions of the locating member are formed by respective side wings for engaging
the corresponding side portions of the gums and/or teeth of the lower jaw of the subject.

7. Apparatus as claimed in Claim 6 characterised in that the side wings extend from the front portion of the locating member for engaging corresponding inner sides of the gums and/or teeth of the lower jaw of the subject.

8. Apparatus as claimed in any of Claims 4 to 7 characterised in that a support means for supporting the oral electrode is connected to the front portion of the locating member and extends from the front portion of the locating member between but spaced apart from the side portions of the locating member.

9. Apparatus as claimed in any preceding claim characterised in that the oral electrode carrier carries a tongue engaging means for co-operating with the underside of the tongue of the subject for locating the oral electrode adjacent the motor nerves of the muscles to be stimulated for stimulating the muscles when an EMF is applied to the oral electrode.

10. Apparatus as claimed in Claim 9 characterised in that the tongue engaging means is located on the upper side of the support means.

11. Apparatus as claimed in Claim 9 or 10 characterised in that the tongue engaging means defines a convex upper tongue engaging surface for engaging the underside of the tongue.

12. Apparatus as claimed in any of Claims 9 to 11 characterised in that the oral electrode is formed on the tongue engaging means.

13. Apparatus as claimed in any of Claims 9 to 12 characterised in that the tongue engaging means forms the oral electrode.

14. . Apparatus as claimed in any preceding claim characterised in that the oral
electrode is located on the underside of the support means.

15. Apparatus as claimed in any preceding claim characterised in that the support means comprises an elongated support member extending to a distal end thereof.

16. Apparatus as claimed in Claim 15 characterised in that the oral electrode is located on the support member adjacent the distal end thereof.

17. Apparatus as claimed in Claim 15 or 16 characterised in that the support member is inherently resilient for facilitating resilient urging of the oral electrode into electrically conductive engagement with the part of the oral cavity with which it is to be in electrically conductive engagement.

18. Apparatus as claimed in any of Claims 15 to 17 characterised in that the support member is flexible.

19. Apparatus as claimed in any preceding claim characterised in that a pair of spaced apart oral electrodes are located on the support means spaced apart from each other.

20. Apparatus as claimed in Claim 19 characterised in that the oral electrodes of the pair of spaced apart oral electrodes are electrically insulated from each other.

21. Apparatus as claimed in any preceding claim characterised in that the oral electrode carrier locates the oral electrode for co-operating with an external electrode located externally of the oral cavity beneath the floor of the oral cavity so that a stimulating current is driven by an EMF between the oral and the external electrodes through the motor nerves of the muscles to be stimulated.

22. Apparatus as claimed in Claim 21 characterised in that the apparatus further comprises an external electrode carrier for carrying the external electrode and for
locating the external electrode beneath and in contact with the floor of the oral cavity towards the chin of the subject.

23. Apparatus as claimed in Claim 22 characterised in that an outer locating means is provided for locating the external electrode relative to the oral electrode and towards the chin of the subject.

24. Apparatus as claimed in Claim 22 or 23 characterised in that a connecting means is provided for connecting the oral electrode carrier and the external electrode carrier so that the external electrode is located relative to the oral electrode.

25. Apparatus as claimed in Claim 24 characterised in that the connecting means locates the external electrode towards and relatively closely to the chin of the subject, and well spaced apart from the neck of the subject.

26. Apparatus as claimed in any of Claims 23 to 25 characterised in that the outer locating means of the external electrode carrier comprises a chin engaging member for engaging the chin of the subject.

27. Apparatus as claimed in Claim 26 characterised in that the chin engaging member is shaped for engaging the chin of the subject and opposite side portions of the lower jaw of the subject externally of the oral cavity.

28. Apparatus as claimed in any preceding claim characterised in that a handle extends from the oral electrode carrier for facilitating insertion of the electrode carrier in the oral cavity of the subject.

29. Apparatus as claimed in Claim 28 characterised in that the handle is adapted to extend from the oral cavity, in use, through the mouth of the subject.

30. Apparatus as claimed in Claim 28 or 29 characterised in that a portion of the
handle forms the connecting means for connecting the oral electrode carrier with the external electrode carrier.

31. Apparatus as claimed in any of Claims 24 to 30 characterised in that the connecting means is inherently resilient for facilitating relative movement of the oral and external electrode carriers.

32. Apparatus as claimed in any of Claims 22 to 31 characterised in that an attachment means is provided for attaching the external electrode carrier to the subject.

33. Apparatus as claimed in any of Claims 22 to 32 characterised in that the attachment means comprises an electrical conductive gel type adhesive.

34. Apparatus as claimed in Claim 32 characterised in that the attachment means comprises a band extending from the chin engaging member for passing around the head of the subject for attaching the chin engaging member to the subject.

35. Apparatus as claimed in any preceding claim characterised in that an electrical conductor is provided to each electrode for conducting a current to each electrode for developing the EMF on the electrode.

36. Apparatus as claimed in Claim 35 characterised in that each electrical conductor terminates in an electrical connecting means remote from the corresponding electrode for connecting the electrical conductor to a signal generating source.

37. Apparatus as claimed in Claim 36 characterised in that the electrical connecting means comprises a jack plug socket for connecting the respective conductors to the signal generating means.
38. Apparatus as claimed in any of Claims 35 to 37 characterised in that each electrical conductor extends within and through the corresponding one of the oral and external electrode carriers.

39. Apparatus as claimed in any of Claims 21 to 38 characterised in that the external electrode is a first external electrode, and a second external electrode is provided for locating externally beneath the floor of the oral cavity of the subject for co-operating with the first external electrode and the oral electrode for stimulating muscles in the floor of the oral cavity.

40. Apparatus as claimed in Claim 39 characterised in that the first and second external electrodes are located on the external electrode carrier.

41. Apparatus as claimed in Claim 39 or 40 characterised in that the first and second external electrodes are located adjacent but spaced apart from each other.

42. Apparatus as claimed in any of Claims 39 to 41 characterised in that the first and second external electrodes are electrically insulated, one from the other.

43. Apparatus as claimed in any of Claims 39 to 42 characterised in that the first and second external electrodes are co-planar with each other.

44. Apparatus as claimed in any of Claims 39 to 43 characterised in that the second external electrode extends at least partly around the first external electrode.

45. Apparatus as claimed in Claim 44 characterised in that the second external electrode extends around the first external electrode an angular distance of up to 270°.

46. Apparatus as claimed in Claim 44 or 45 characterised in that the second external electrode extends around the first external electrode an angular distance of approximately 180°.
47. Apparatus as claimed in Claim 44 or 45 characterised in that the second external electrode extends around the first external electrode for an angular distance of less than 180°.

48. Apparatus as claimed in any of Claims 39 to 47 characterised in that the second external electrode is located between the first external electrode and the chin of the subject.

49. Apparatus as claimed in any of Claims 39 to 48 characterised in that one of the first and second external electrodes is electrically connected to the oral electrode.

50. Apparatus as claimed in any of Claims 39 to 49 characterised in that the second external electrode is electrically connected to the oral electrode.

51. Apparatus for stimulating at least some of the muscles of the floor of the oral cavity of a subject, the apparatus comprising an external electrode for locating externally beneath the floor of the oral cavity of the subject for co-operating with an oral electrode located in the oral cavity of the subject for applying an EMF for stimulating at least some of the muscles of the oral cavity characterised in that a first external electrode and a second external electrode are provided for locating externally beneath the floor of the oral cavity and for co-operating with the oral electrode for minimising discomfort to the subject when an EMF is applied to the respective external and oral electrodes for passing a current through the motor nerves of the muscles to be stimulated for stimulation thereof.

52. Apparatus as claimed in Claim 51 characterised in that the first and second external electrodes are located adjacent but spaced apart from each other.

53. Apparatus as claimed in Claim 51 or 52 characterised in that the first and second external electrodes are electrically insulated, one from the other.
54. Apparatus as claimed in any of Claims 51 to 53 characterised in that the first and second external electrodes are co-planar with each other.

55. Apparatus as claimed in any of Claims 51 to 54 characterised in that the second external electrode extends at least partly around the first external electrode.

56. Apparatus as claimed in Claim 55 characterised in that the second external electrode extends around the first external electrode an angular distance of up to 270°.

57. Apparatus as claimed in Claim 55 or 56 characterised in that the second external electrode extends around the first external electrode an angular distance of approximately 180°.

58. Apparatus as claimed in Claim 55 or 56 characterised in that the second external electrode extends around the first external electrode for an angular distance of less than 180°.

59. Apparatus as claimed in any of Claims 51 to 58 characterised in that the second external electrode is located between the first external electrode and the chin of the subject.

60. Apparatus as claimed in any of Claims 51 to 59 characterised in that one of the first and second external electrodes is electrically connected to the oral electrode.

61. Apparatus as claimed in any of Claims 51 to 60 characterised in that the second external electrode is electrically connected to the oral electrode.

62. Apparatus as claimed in any of Claims 51 to 61 characterised in that an external electrode carrier is provided for carrying the first and second external
electrodes and for locating the first and second external electrodes beneath and in contact with the floor of the oral cavity of the subject.

63. Apparatus as claimed in Claim 62 characterised in that the external electrode carrier locates the first and second external electrodes towards the chin of the subject.

64. Apparatus as claimed in Claim 62 or 63 characterised in that the external electrode carrier comprises an outer locating means for locating the first and second external electrodes relative to the oral electrode.

65. Apparatus as claimed in any of Claims 62 to 64 characterised in that an oral electrode carrier is provided for carrying and locating the oral electrode in the oral cavity of the subject relative to the first and second external electrodes.

66. Apparatus as claimed in Claim 65 characterised in that a connecting means is provided for connecting the oral electrode carrier and the external electrode carrier.

67. Apparatus as claimed in Claim 66 characterised in that the connecting means locates the external electrode towards and relatively closely to the chin of the subject, and well spaced apart from the neck of the subject.

68. Apparatus as claimed in any of Claims 62 to 66 characterised in that the external electrode carrier comprises a chin engaging member for engaging the chin of the subject.

69. Apparatus as claimed in Claim 68 characterised in that the chin engaging member is shaped for engaging the chin of the subject and side portions of the lower jaw of the subject externally of the oral cavity so that the chin engaging member forms the outer locating means for locating the first and second external electrodes.
70. Apparatus as claimed in any of Claims 62 to 69 characterised in that a handle extends from the external electrode carrier for facilitating insertion of the oral electrode carrier in the oral cavity of the subject.

71. Apparatus as claimed in Claim 70 characterised in that the handle is adapted to extend from the oral cavity through the mouth of the subject, in use.

72. Apparatus as claimed in Claim 70 or 71 characterised in that a portion of the handle forms the connecting means for connecting the oral electrode carrier with the external electrode carrier.

73. Apparatus as claimed in Claim 72 characterised in that the connecting means is a resilient connecting means for facilitating relative movement of the oral and external electrode carriers.

74. Apparatus as claimed in any of Claims 62 to 73 characterised in that an attachment means is provided for attaching the external electrode carrier to the subject.

75. Apparatus as claimed in Claim 74 characterised in that the attachment means comprises a band extending from the chin engaging member for passing around the head of the subject for attaching the chin engaging member to the subject.

76. Apparatus as claimed in any of Claims 51 to 75 characterised in that an electrical conductor is provided to each electrode for conducting a current to each electrode for developing the EMF on the electrode.

77. Apparatus as claimed in Claim 76 characterised in that each electrical conductor terminates in an electrical connecting means remote from the corresponding electrode for connecting the electrical conductor to a signal generating means.
78. Apparatus as claimed in Claim 77 characterised in that the electrical connecting means comprises a jack plug for connecting the respective conductors to the signal generating means.

79. Apparatus as claimed in any of Claims 51 to 78 characterised in that each electrical conductor extends within and through the corresponding one of the oral and external electrode carriers.

80. Apparatus for stimulating at least some of the muscles in the floor of the oral cavity of a subject, the apparatus comprising an external electrode for locating externally beneath the floor of the oral cavity of the subject for applying an EMF for stimulating at least some of the muscles in the floor of the oral cavity, characterised in that a first external electrode and a second external electrode are provided for locating externally beneath the floor of the oral cavity, the second electrode extending at least partly around the first electrode and co-operating with the first electrode so that when an EMF is applied across the first and second electrodes a current is passed through the motor nerves of the muscles to be stimulated for stimulation thereof.

81. Apparatus as claimed in Claim 80 characterised in that the first and second external electrodes are located adjacent but spaced apart from each other.

82. Apparatus as claimed in Claim 80 or 81 characterised in that the first and second external electrodes are electrically insulated, one from the other.

83. Apparatus as claimed in any of Claims 80 to 82 characterised in that the first and second external electrodes are co-planar with each other.

84. Apparatus as claimed in any of Claims 80 to 83 characterised in that the second external electrode extends around the first external electrode an angular distance of up to 270°.
85. Apparatus as claimed in any of Claims 80 to 84 characterised in that the second external electrode extends around the first external electrode an angular distance of approximately 180°.

86. Apparatus as claimed in any of Claims 80 to 85 characterised in that the second external electrode extends around the first external electrode for an angular distance of less than 180°.

87. Apparatus as claimed in any of Claims 80 to 86 characterised in that the second external electrode is located between the first external electrode and the chin of the subject.

88. Apparatus as claimed in any of Claims 80 to 87 characterised in that one of the first and second external electrodes is electrically connected to the oral electrode.

89. Apparatus as claimed in any of Claims 80 to 88 characterised in that the second external electrode is electrically connected to the oral electrode.

90. Apparatus as claimed in any of Claims 80 to 89 characterised in that an external electrode carrier is provided for carrying the first and second external electrodes and for locating the first and second external electrodes beneath and in contact with the floor of the oral cavity of the subject.

91. Apparatus as claimed in Claim 90 characterised in that the external electrode carrier locates the first and second external electrode towards the chin of the subject.

92. Apparatus as claimed in Claim 90 or 91 characterised in that the external electrode carrier comprises an outer locating means for locating the first and second external electrodes relative to the oral electrode.
93. Apparatus as claimed in any of Claims 90 to 92 characterised in that an oral electrode carrier is provided for carrying and locating the oral electrode in the oral cavity of the subject relative to the first and second external electrodes.

94. Apparatus as claimed in Claim 93 characterised in that a connecting means is provided for connecting the oral electrode carrier and the external electrode carrier.

95. Apparatus as claimed in Claim 94 characterised in that the connecting means locates the external electrode towards and relatively closely to the chin of the subject, and well spaced apart from the neck of the subject.

96. Apparatus as claimed in any of Claims 90 to 95 characterised in that the external electrode carrier comprises a chin engaging member for engaging the chin of the subject.

97. Apparatus as claimed in Claim 96 characterised in that the chin engaging member is shaped for engaging the chin of the subject and side portions of the lower jaw of the subject externally of the oral cavity so that the chin engaging member forms the outer locating means for locating the first and second external electrodes.

98. Apparatus as claimed in any of Claims 90 to 97 characterised in that a handle extends from the external electrode carrier for facilitating insertion of the oral electrode carrier in the oral cavity of the subject.

99. Apparatus as claimed in Claim 98 characterised in that the handle is adapted to extend from the oral cavity through the mouth of the subject, in use.

100. Apparatus as claimed in Claim 98 or 99 characterised in that a portion of the handle forms the connecting means for connecting the oral electrode carrier with the external electrode carrier.
101. Apparatus as claimed in Claim 100 characterised in that the connecting means is a resilient connecting means for facilitating relative movement of the oral and external electrode carriers.

102. Apparatus as claimed in any of Claims 90 to 101 characterised in that an attachment means is provided for attaching the external electrode carrier to the subject.

103. Apparatus as claimed in Claim 102 characterised in that the attachment means comprises a band extending from the chin engaging member for passing around the head of the subject for attaching the chin engaging member to the subject.

104. Apparatus as claimed in any of Claims 80 to 103 characterised in that an electrical conductor is provided to each electrode for conducting a current to each electrode for developing the EMF on the electrode.

105. Apparatus as claimed in Claim 104 characterised in that each electrical conductor terminates in a connecting means remote from the corresponding electrode for connecting the electrical conductor to a signal generating means.

106. Apparatus as claimed in Claim 105 characterised in that the connecting means comprises a jack plug for connecting the respective conductors to the signal generating means.

107. Apparatus as claimed in any of Claims 104 to 106 characterised in that each electrical conductor extends within and through the corresponding one of the oral and external electrode carriers.

108. Apparatus for stimulating at least some of the muscles in the floor of the oral cavity of a subject, the apparatus comprising an oral electrode carrier for carrying
and locating an oral electrode in the oral cavity of the subject relative to an anatomical reference for applying an EMF for stimulating at least some of the muscles in the floor of the oral cavity, characterised in that the oral electrode carrier carries a tongue engaging means for co-operating with the underside of the tongue of the subject for locating the oral electrode adjacent the motor nerves of the muscles to be stimulated for stimulating the muscles when an EMF is applied to the oral electrode.

109. Use of the apparatus as claimed in any preceding claim for stimulating at least some of the muscles in the floor of the oral cavity of a subject.

110. Use of the apparatus as claimed in any of Claims 1 to 108 for stimulating at least some of the muscles in the floor of the oral cavity of a subject for cosmetically correcting the condition of double chin in a subject.

111. Use of the apparatus as claimed in any of Claims 1 to 108 for stimulating at least some of the muscles in the floor of the oral cavity of a subject for treating sleep apnoea.

112. Use of the apparatus as claimed in any of Claims 1 to 108 for stimulating at least some of the muscles in the floor of the oral cavity of a subject for correcting snoring during sleeping of the subject.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61N1/05

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)
IPC 7 A61N

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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
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Further documents are listed in the continuation of box C. Patent family members are listed in annex.

** Special categories of cited documents:
*A* document defining the general state of the art which is not considered to be of particular relevance
*E* earlier document 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)
*C* document referring to an oral disclosure, use, exhibition or other means
** document published prior to the international filing date but later than the priority date claimed

Date of completion of the international search 1 August 2002

Name and mailing address of the ISA
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-0200, Tx. 31 651 epo nl, Fac. (+31-70) 340-3019

Authorized officer
Ferrigno, A

Date of mailing of the international search report 9. 08. 2002

Form PCT/ISA/210 (second sheet) (July 1999)
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INTERNATIONAL SEARCH REPORT

Box I  Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 109, 111, 112
   because they relate to subject matter not required to be searched by this Authority, namely:
   Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2.  [ ] Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3.  [ ] Claims Nos.: because they are dependent claims and are not crafted in accordance with the second and third sentences of Rule 6.4(a).

Box II  Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1.  [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2.  [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3.  [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4.  [X] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

   1-50, 108, 110

Remark on Protest

[ ] The additional search fees were accompanied by the applicant’s protest.

[ ] No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (1)) (July 1996)
This International Searching Authority found multiple (groups of) inventions in this international application, as follows:


   Apparatus comprising a carrier for carrying stimulating electrodes, the carrier being engageable in the oral cavity, use of the apparatus for cosmetic treatment.

2. Claims: 51-107

   Apparatus comprising external electrodes for stimulating the floor of the oral cavity.