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Background

This invention relates to systems and methods related to promoting general oral hygiene or cosmetics, treating periodontal diseases such as gingivitis and periodontitis, killing or modifying oral microbes including cavity-causing bacteria, reducing oral biofilms, increasing blood flow in oral tissues, increasing salivation, promoting gingival tissue regeneration, fostering osteogenesis in the boney structures of the teeth, mouth and related areas, treating systemic diseases associated with oral bacteria, and/or treating other periodontal and oral maladies through the non-invasive application of direct current electricity to the surfaces in the oral cavity, and it also relates to an apparatus suitable for providing direct current electricity for these therapeutic, prophylactic, cosmetic, and regenerative

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effects.

Periodontal disease has been identified as a risk factor for various systemic diseases by both dentists and physicians. Included in these diseases are cardiovascular disease, adverse pregnancy outcomes, and diabetes with newfound evidence supporting its association with pancreatic diseases and arthritis. While many of the studies establish correlation between the presence of periodontal disease and these systemic conditions, causation, with most of these conditions, is still a subject of ongoing research. A few of the biological mechanisms which have been proposed as to how oral bacteria stemming from periodontal disease can cause systemic disease are as follows:

1. *Direct effect of oral infections:* Oral microbes and their byproducts can gain systemic access via the circulatory system through traveling through compromised tissue and inflamed periodontium in the oral cavity. In gaining systemic access, oral microbes have the potential to directly influence subclinical mediators of various systemic diseases.

2. *Inflammation:* People with periodontal disease have elevated levels of systemic inflammatory markers due to the burden of increased levels of oral bacteria. Treatment for periodontal disease has been reported to decrease systemic inflammation levels.

3. *Cross-reactivity:* The progression of systemic diseases can be accelerated by the immune response to bacterial heat-shock proteins creating antibodies that cross-react with innate heat shock proteins expressed on cells of the damaged tissues.

Cardiovascular Disease

Studies investigating the potential association

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between periodontal disease and cardiovascular diseases, including atherosclerosis, coronary heart disease, and stroke have found a significant positive correlation between poor oral health and the prevalence of cardiovascular disease. While both diseases share several common risk factors, recent studies suggest that periodontitis may precede and therefore contribute to atherosclerotic complications. In fact, meta-analyses show that subjects suffering from periodontitis experience an increased risk for developing cardiovascular diseases.

While it has not been definitively shown if these bacteria initiate atherosclerosis or rather invade an already compromised artery, antibodies to periodontal bacteria, including *Fuseobacterium nucleatum* and *Streptococcus oralis*, have been found in blood serum and are associated with an increased risk of coronary heart disease. A mouse study found that intravenous inoculation with *Porphyromonas gingivalis* accelerated atherosclerotic development. Further, following oral inoculation, *P. gingivalis* DNA was found in the aortic tissue of those infected mice that showed observable signs of accelerated early atherosclerosis. Another study has named *F. nucleatum* as a synergistic agent with *P. gingivalis*. *F. nucleatum* enhances the ability of *P. gingivalis* to invade host cells due to a coaggregating effect between the two organisms. This is significant as bacteria within the atheroma may lead to the development of atherosclerotic plaque. The evidence thus far supports the idea that periodontitis leads to systemic exposure to oral bacteria which serves as a potential source of systemic inflammatory mediators, cytokines produced in the infected periodontal tissues, capable of initiating

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or worsening atherosclerosis and coronary heart disease when they enter into the blood stream. Clinical studies on periodontal disease have also revealed a positive association with coronary disease and emphasis is now
5 being placed on understanding the exact relation between periodontal disease and atherosclerosis.

Pre-term Birth

Fusobacterium nucleatum, one of the most prevalent species of bacteria found in amniotic fluid and placental
10 infections that cause preterm birth, is also often named the sole infectious agent in preterm labor with intact fetal membranes. *F. nucleatum* is also highly associated with various types of periodontal disease. During periodontal infection, when the oral mucosa is injured
15 and inflamed and the quantities of periodontal pathogens increase dramatically, transient levels of bacteria can appear in the blood leading to selective colonization of undesired sites. One study demonstrated that pregnant mice injected hematogenously with *F. nucleatum* isolated
20 from either amniotic fluid infection or an oral source resulted in fetal death.

Recently, a human stillbirth case was analyzed and it was found that the *F. nucleatum* did indeed originate from the mother's oral cavity, a fact that had not yet
25 been proven. It is likely that the *F. nucleatum* translocated from the mother's mouth via the blood stream where it was then able to cross the endothelium to proliferate and colonize within the fetal membranes, amniotic fluid and fetus whereupon its presence lead to
30 fetal demise. In a mouse model, hematogenous injection of *F. nucleatum* into pregnant mice resulted in specific bacterial colonization in the placenta causing localized inflammation. *F. nucleatum* was completely cleared from

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the maternal circulation after 24 hours of injection. However, once colonized in the immune privileged placenta, the bacteria proliferated quickly and caused fetal death within 3 days. Chronic periodontal disease
5 could mediate infection through the translocation of periodontal bacteria/inflammatory markers to the fetoplacental unit.

Diabetes

Diabetes mellitus is an endocrine disease that
10 stems from genetic, environmental and behavioral risk factors. For the past several decades, diabetes has been considered a modifying factor for periodontal disease with recent years suggesting a bidirectional
15 relationship between the two. Further, presence of periodontal disease has been implicated as a risk for diabetic complications, namely poor glycemic control. Recent longitudinal and systemic studies have seen periodontal disease correlated to higher risks of death
20 from ischemic heart disease, diabetic nephropathy, end-stage renal disease and increased insulin resistance compared to patients with mild or no periodontal disease. In type II diabetes, insulin resistance is linked to the actions of pro-inflammatory cytokines. It is believed that periodontal disease leads to a significantly higher
25 amount of these serum markers of inflammation, thus conferring insulin resistance. A human study examining the bacterial content of adults with and without type II diabetes found diabetic patients had significantly more severe periodontitis and higher levels of many oral
30 bacteria, including *Streptococcus oralis*.

Pyogenic Liver Abscess

F. nucleatum has recently been implicated in pyogenic liver abscess (PLA). Normally caused by biliary

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tract pathology, diverticular disease and bowel malignancy, atrophic gastritis and cryptogenic liver disease, PLA caused by *F. nucleatum* is very rare with *Escherichia coli*, *Klebsiella* and *Enterobacter* being the most commonly isolated microorganisms in the drained abscesses. *F. nucleatum* was found in the liver abscess with no other infectious source being found, except for a dental extraction. It is hypothesized that due to the coaggregation properties of *F. nucleatum*, it is able to transport and breach the mucosa of the colon and lead to bacteremia which results in hepatic abscess.

Osteomyelitis

Osteomyelitis is a bone infection caused by bacteria, fungi or other germs. Commonly, bacteria spreads to the bone from infected skin, muscles or tendons and often time occur under a skin sore. The infection can also start in another part of the body and spread hematogenously. Occasionally *Fusobacterium* species have been isolated from bone/joint infections in the head and neck area and were associated with chronic periodontitis. A recent study has reported a case of osteomyelitis caused by *F. nucleatum* in conjunction with muscle abscess. The patient had no known predisposing factors and had no other infection sources except a history of periodontal disease. It is believed that due to the patient's poor oral hygiene, *F. nucleatum* bacteremia may have developed and lead to a hematogenous osteomyelitis of the lower leg.

Arthritis

Numerous clinical studies have suggested a potential association between rheumatoid arthritis (RA) and periodontal disease as several oral bacteria species, such as *P. gingivalis* and *Prevotella intermedia*, have

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been isolated from the synovial fluid of patients. Periodontal disease is thought to allow bacteria to penetrate through the permeable pocket epithelial in the oral cavity to reach the underlying gingival connection
5 tissue. From there, it may be transported out into the bloodstream with the ability to colonize elsewhere within the body. The oral bacteria found in the synovial fluid of patients suffering from RA has been attributed to synovial inflammation favorably trapping oral bacteria
10 DNA, which suggests periodontal disease may have a perpetuating effect on joint diseases. Therefore, periodontitis may in fact be a factor leading to the autoimmune inflammatory responses characteristic of RA. Patients suffering from RA may also be at a higher risk
15 of developing periodontal disease thus suggesting a bidirectional relationship between the two conditions. One particular study examined the presence of bacterial DNA in the synovial fluids of native and failed prosthetic joints of patients suffering from arthritis.
20 Out of the 5 patients where bacterial DNA was found, *F. nucleatum* was detected in 4 of these 5 patients. This suggests that this bacterium can translocate from the oral cavity to the synovial fluid, as *F. nucleatum* was also found in the patient's plaque sample.

25 **Oral Biofilm**

Periodontitis, gingivitis, and caries are infectious diseases of the oral cavity in which oral biofilm and bacteria plays a causative role. Biofilm formation is also involved in the pathogenesis of dental
30 implant failures such as peri-implantitis, denture stomatitis, and oral yeast infections such as candidiasis. Oral biofilms begin with dental pellicle formation on the teeth. This pellicle is composed of

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salivary proteins that coat the exposed surfaces of the teeth, primarily the supra-gingival ones, to which the planktonic bacteria begin to adhere. The aerobic bacteria, including gram-positive cocci, such as *S. oralis*, are the early colonizers that begin forming the initial biofilm colony, primarily through cellular division of the adherent bacteria.

Once the initial colony has been established, other co-aggregating bacteria species, such as *F. nucleatum*, *P. gingivalis*, and other gram-negative, anaerobic bacteria attach to the previously formed colonies. As these colonies mature, they grow to cover the sub-gingival surfaces of the teeth and begin to induce inflammation in the periodontium.

15 **Summary of the Invention**

The present invention relates to a method and apparatus for aiding overall oral health and/or cosmetic appearance, and more particularly to treating periodontal diseases such as gingivitis, periodontitis, and peri-implantitis; killing oral microbes including cavity-causing bacteria; reducing oral biofilms; increasing blood flow in oral tissues; increasing salivation; promoting gingival tissue regeneration; fostering osteogenesis in the boney structures of the teeth, mouth, and related areas; treating systemic diseases associated with oral bacteria; and treating other periodontal and oral maladies through the non-invasive application of weak electricity to the surfaces in the oral cavity. Alternatively or additionally, use of embodiments of systems and methods according to the present invention can lead to a reduction of periodontal pocket depth, a reduction of gingival bleeding, a reduction of gingival inflammation and/or a reduction in

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clinical attachment loss. Use of systems and methods according to the present invention has also been found to effectively tighten epithelial contact with one or more teeth (e.g., by the junctional epithelium and/or the sulcular epithelium) and/or cause a tightening of the oral epithelium, thereby improving an appearance of a person's smile.

These effects are accomplished by the delivery of electrical (preferably direct) current to the gingiva through a plurality of electrodes in direct physical (or at least electrical) contact with gingival tissue surfaces (e.g., lingual, buccal, palatal, and/or vestibular gingival tissue). The electrodes may be fashioned out of any electrically-conductive material, including but not limited to metals such as silver, stainless steel, copper, gold, platinum, palladium, aluminum, an alloy thereof, electrically-conductive nanotubes, carbonized rubber, electrically-conductive silicone, or electrically-conductive polymers. Each electrode may be composed of the same material as one or more of the other electrodes or it may be composed of a different material than one or more of the other electrodes. These electrodes fit snugly against, or proximate to, the lingual and buccal sides of the gingiva and make electrical (e.g., physical or spaced from but in electrical) contact with each side (i.e., lingual and buccal) or the same side (i.e., lingual or buccal) of the gingiva to pass electricity across or along the teeth and neighboring gingival tissues.

The electrodes on each side (lingual or buccal) of the gingiva along one or more teeth may be of the same polarity. Electrodes on opposite sides of the gingiva may be the opposite polarity, or adjacent

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electrodes on the same side of the gingiva may be opposite polarity. This allows the current to flow across and/or along the teeth and gums to the electrodes positioned on the transverse gingiva to complete the electrical circuit. Put another way, all electrodes on the lingual side of the gingiva may be completely anodic or completely cathodic. All electrodes on the buccal surfaces of the gingiva, transverse the lingual surfaces of the gingiva, may then have the opposite polarity of the lingual electrodes. The polarization of these electrodes may be reversed during an electrical stimulation session or in between sessions. Electrodes are preferably individually programmable to anode functionality, cathode functionality, or even disconnected or high impedance state. Alternatively, a group of electrodes (e.g., all lingual electrodes) may have fixed functionality as an anode or cathode.

The mandibular and maxillary gingiva each may receive a plurality of electrodes. This allows for stimulation of both the maxillary and mandibular periodontium either simultaneously or in isolation. The maxillary and mandibular sets of electrodes may be powered by two different adjustable power supplies or by the same adjustable power supply.

Electrical conductors (which may be wired or more preferably a conductive silicone) connect the electrodes to an adjustable power supply. All of the enabled anodic electrodes will connect to the negative pole of the power supply and all of the enabled cathodic electrodes will connect to the positive pole of the power supply, through a current regulator. The adjustable power supply is capable of delivering a stable, direct current in the approximate range of 1 to 500 microamperes. The

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preferred current setting for most stimulation sessions is in the approximate range of 50 to 250 microamperes. More preferably, the current setting is about 125-150 microamperes, controlled to $\pm 10\%$.

5 According to an aspect of an embodiment of a system according to the present invention, the system includes a controller and a mouthpiece. The controller has a housing containing a variable direct current power supply, the power supply capable of delivering
10 approximately 1 to 500 microamperes. The mouthpiece configured to be received in a human mouth, the mouthpiece comprising at least one U-shaped channel. A plurality of exposed electrodes may be supported by the mouthpiece and coupled to the direct current power
15 source. A neck portion preferably electrically couples the direct current power supply to the mouthpiece and physically couples the housing to the mouthpiece. The electrical coupling in the neck portion may be achieved by a plurality of electrically conductive pins inserted
20 into and substantially surrounded by traces of electrically conductive silicone.

 According to another aspect of an embodiment of a system according to the present invention, a first of the plurality of exposed electrodes is a cathode
25 electrode disposed on a first side of a first of the at least one U-shaped channel and a second of the plurality of exposed electrodes is an anode electrode disposed on a second side of the first channel.

 According to still another aspect of an
30 embodiment of a system according to the present invention, the mouthpiece comprises two U-shaped channels, wherein one channel is configured to receive one or more maxillary teeth of a human and the other

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channel is configured to receive one or more mandibular teeth of the human.

According to yet another aspect of an embodiment of a system according to the present invention, the controller comprises electronic circuitry disposed in the housing, the circuitry being configured to at least one of manipulate and monitor at least one of duration and intensity of current provided by the power source to each electrode. The controller may further include a user input interface and a user feedback interface. The controller also may be configured to store one or more counter values and an event log in non-volatile memory, the event log preferably capable of storing two thousand event occurrences, including a timestamp associated with each.

According to a further aspect of an embodiment of a system according to the present invention, the variable direct current power supply comprises a rechargeable lithium-ion battery. The system may include a charging station capable of physically supporting the controller housing and inductively recharging the rechargeable lithium-ion battery. The charging station may further include a hinged cover, which may contain the controller and mouthpiece, such as for storage and/or travel.

According to still a further aspect of an embodiment of a system according to the present invention, wherein the system further comprises a mobile wireless communication device capable of physical layer communication with the controller, the wireless device further including a software application capable of software layer communication with the controller. The controller is preferably capable of transmitting counter

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values and an event log to the wireless device the application, such transmission occurring upon at least one of an occurrence of a predetermined event, an expiration of a predetermined time period, and at a
5 predetermined time of day. The application is preferably configured to display simultaneously at least one transmitted counter value and event log and also configured to allow storage of the transmitted counter values and event log to non-volatile memory in the
10 wireless device. The application is also preferably configured to periodically or on-demand provide firmware updates to the controller.

According to yet a further aspect of an embodiment of a system according to the present
15 invention, the mouthpiece may be formed by a process comprising the steps of:

a first injection molding procedure using the conductive silicone material to form the traces and the electrodes to form a conductive skeleton; and

20 a second injection molding procedure using insulative silicone material to encapsulate at least a portion of each trace. The second injection molding procedure is preferably performed after the first injection molding procedure.

25 According to an aspect of an embodiment of a method according to the present invention, the method includes the steps of:

providing a mouthpiece supporting a plurality of electrodes coupled to a direct current power source;

30 positioning a first electrode of the plurality of electrodes between a cheek and exterior gumline of a human, and in physical contact with gingival tissue;

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positioning a second electrode of the plurality of electrodes medial to the first electrode, and in physical contact with gingival tissue;

delivering current from the power source to
5 the gingival tissue;

regulating the intensity of current delivery to the gingival tissues to approximately between 1 and 500 microamperes via a controller; and

regulating the duration of current delivery
10 to no more than 30 minutes via the controller.

According to another aspect of a method according to the present invention, the method further includes the steps of:

storing data metrics and an event log in non-
15 volatile memory in the controller;

providing a software application on an electronic wireless device capable of communicating with the controller;

pairing the wireless device to allow
20 communications with the controller;

transferring the data metrics and event log from the controller to the wireless device;

saving the data metrics and event log into non-volatile memory of the electronic device; and

25 reviewing at least some of the saved data metrics and event log using the software application.

Brief Description of the Drawings

Figure 1 is a perspective view of an intraoral electrical stimulation apparatus and associated storage and/or charging stand according to the present invention.
30

Figure 2 is a top plan view of a mouthpiece and controller according to the present invention.

Figure 3 is a bottom plan view of a mouthpiece

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and controller according to the present invention.

Figure 4 is a left side elevation view of a mouthpiece and controller according to the present invention.

5 Figure 5 is a rear elevation view of a mouthpiece and controller according to the present invention.

 Figure 6 is a diagrammatic representation of an electrical circuit of a controller according to the
10 present invention.

Figure 7 is a partial cross-section view of an embodiment of a controller according to the present invention, taken along lines 7-7 in Figure 3.

 Figure 8 includes schematic views of portions
15 of an electrical circuit in an embodiment of a controller according to the present invention.

Figure 9 is a front perspective view of the embodiment of Figure 1, showing the mouthpiece/controller supported by the stand.

20 Figure 10 is a front perspective view of a charging stand/case according to the present invention receiving a mouthpiece/controller according to the present invention.

 Figure 11 provides a table of user interface
25 feedback occurring at predetermined times in predetermined device or software states.

 Figures 12A-B provides a table of programmable parameters stored in memory in a controller according to the present invention.

30 Figures 13A-B provides a table of counters or metrics to be logged upon respective occurrence during operation of a controller according to the present invention.

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Figure 14 provides a table of events and associated event data recorded by software

Figures 15A-C provides a table of operating functions, associated operational user tasks, and responses of a controller according to the present invention.

Figure 16 is a flowchart depicting states of operation or non-operation of a controller according to the present invention.

Detailed Description

Although the disclosure hereof is detailed and exact to enable those skilled in the art to practice the invention, the physical embodiments herein disclosed merely exemplify the invention which may be embodied in other specific structures. While the preferred embodiment has been described, the details may be changed without departing from the invention.

It is known in the art that oral bacteria cannot survive when exposed to low-microampere direct current electricity. This method of killing oral bacteria and treating bacteria-caused conditions such as gingivitis has been demonstrated in Nachman, U.S. Pat. No. 4,244,373 of Jan. 13, 1981 and in Detsch, U.S. Patent 4,509,519 of Apr. 9, 1985. Killing oral bacteria has the added benefit of preventing tooth decay and dental caries, or cavities. Generally, tooth decay is attributed to aerobic acid-producing bacteria whose acid causes uncompensated demineralization of the teeth. However, Nachman does not instruct optimal approaches to reducing oral bacteria including aerobic and anaerobic bacteria on a species-by-species level and instead teaches a generic, untargeted treatment.

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While researching the effect of direct current electricity on the mouth, the applicants discovered that by increasing the current level to the approximate range of 50 to 250 microamperes (μA), a
5 direct current electrical stimulation was able to deliver new and unexpected therapeutic, prophylactic, cosmetic, and regenerative benefits previously unknown in the art.

Specifically, by utilizing a direct current in the aforementioned range, not only did such a
10 stimulation kill bacteria, but it was also found to kill or disable viruses and fungus as well. Studies from the podiatric field have shown that higher current levels than those used in existing oral electrical stimulations are necessary to effectively treat fungal infections
15 ("Low-Voltage Direct Current as a Fungicidal Agent for Treating Onychomycosis", Kalinowski, et al., Journal of the American Podiatric Medical Association Vol. 94 No.6: 565-572, 2004). By applying this knowledge of increased current levels from research outside the art, the
20 applicants were able to add fungicidal and viricidal benefits to a method already known to be bactericidal. The applicants' studies have shown that these microbicidal properties begin to take effect within approximately 5 and 15 minutes of stimulation, reducing
25 both supra- and sub-gingival microbes.

In addition, the applicants' clinical research unexpectedly demonstrated that a direct current in the approximate range of 50 to 250 microamperes was able to regenerate gingival tissues, providing a non-
30 surgical alternative for those with recessed gums. While the osteogenic properties of electricity have been known in the art, the connection between nonosseous tissue regeneration and electricity were not well known in the

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art prior to these experiments. The unique current range associated with the method and apparatus of this invention is one of a few effective methods in the dental field to accomplish effective gingival tissue
5 regeneration in a non-surgical manner.

In further research, the applicants conducted preclinical testing that examined the effects of direct current stimulation on three different oral bacteria (*F. nucleatum*, *S. oralis*, *P. gingivalis*) in both saline and
10 saliva solutions. This testing varied the current levels, inoculum size of bacteria, solution medium, and stimulation time to develop an optimal reduction in these three bacteria species associated with both periodontal and systemic diseases.

The results of this testing yielded unexpected results and showed that each different bacterium had a different dose response to DC stimulation. Through this testing, the applicants identified stimulation parameters that were able to kill
15 up to 100% of *S. oralis*, 99.1% of *F. nucleatum*, and 52.3% of *P. gingivalis* in a single stimulation session lasting thirty minutes or less. This research yielded specifications for DC-based stimulations of targeted pathogens that was previously unknown in the art. The
20 optimal stimulation parameters discovered in this research and described in this method can provide an innovative way to reduce these three species of bacteria, in both supra- and sub-gingival environments, and thus prevent and/or treat their associated complications
25 including periodontal disease, biofilm formation, as well as the systemic diseases correlated to these oral pathogens.
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In addition, scanning electron microscopy

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(SEM) was conducted on *F. nucleatum* colonies before and after a 30 minute stimulation, according to the method of this invention, to better understand the mechanism by which the method according to this invention is able to
5 reduce bacterial levels. The SEM imagery suggested that the method according to this invention interferes with bacterial cellular division and can weaken the outer envelope (cell membrane) resulting in fragile cellular structures that can easily break. It is contemplated that
10 this phenomenon is an example of electroporation, where the permeability of cellular membranes may be affected by electrical stimulation either temporarily or permanently. It is further contemplated that the electroporation caused by the method according to this
15 invention could play a role in developing new therapies in molecular biology which would take advantage of this cellular permeability and introduce new material into the cells of oral pathogens or oral tissues through mechanisms including, but not limited to, genetic
20 material (transfection) such as DNA, RNA, sRNA, siRNA, plasmids, etc. These effects would prove a new tool in targeted gene therapies for oral applications.

Specifically, the method according to the present invention has been shown to reduce viable colony
25 forming units (CFU) in various oral bacteria.

Table 1 below shows the efficacy of stimulation according to the present invention at current levels of 50 μ A or 500 μ A for 5-, 10-, 20-, and 30-minute durations for bacterial cultures ranging from 10^4 to 10^7
30 colony forming units (CFU) of *Streptococcus oralis* in a saline solution.

In Vitro Efficacy Against <i>Streptococcus oralis</i> in Saline
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CFU	μ A	0 Min	5 Min	10 Min	20 Min	30 Min
10e4	50 μ A	1120	1080	600	320	280
	500 μ A	1120	1200	800	240	0
10e5	50 μ A	10000	9600	8400	9200	7600
	500 μ A	11600	10400	11200	10800	8400
10e6	50 μ A	80000	63200	52800	32400	24800
	500 μ A	80800	70000	15200	14000	15600
10e7	50 μ A	1280000	1080000	1040000	800000	440000
	500 μ A	1080000	520000	160000	120000	320000

Table 1

Table 2 below shows the efficacy of stimulation according to the present invention at current levels of 50 μ A or 500 μ A for 5-, 10-, 20-, and 30-minute durations for bacterial cultures ranging from 10^4 to 10^7 CFU of *Streptococcus oralis* in a saliva solution.

In Vitro Efficacy Against <i>Streptococcus oralis</i> in Saliva						
CFU	μ A	0 Min	5 Min	10 Min	20 Min	30 Min
10e4	50 μ A	160	160	80	80	40
	500 μ A	200	80	80	80	80
10e5	50 μ A	5600	5600	6800	5600	4000
	500 μ A	8400	6800	7200	6400	2800
10e6	50 μ A	25600	25200	15200	17200	18400
	500 μ A	23600	16800	15600	17600	15200
10e7	50 μ A	316000	284000	300000	276000	220000
	500 μ A	324000	328000	300000	292000	252000

Table 2

Table 3 below shows the efficacy of stimulation according to the present invention at current levels of 50 μ A or 500 μ A for 5-, 10-, 20-, and 30-minute durations for bacterial cultures ranging for 10^4 and 10^6 CFU of *Fusobacterium nucleatum* in a saline solution.

In Vitro Efficacy of Device Against <i>Fusobacterium nucleatum</i> in Saline						
CFU	μA	0 Min	5 Min	10 Min	20 Min	30 Min
10e4	50μA	480	280	280	120	40
	500μA	560	440	400	200	120
10e6	50μA	94000	91600	85600	70400	84400
	500μA	46400	45600	27200	2000	400

Table 3

Table 4 below shows the efficacy of
5 stimulation according to the present invention at current
levels of 50 μ A or 500 μ A for 5-, 10-, 20-, and 30-minute
durations for bacterial cultures ranging from 10^4 to 10^6
CFU of *Fusobacterium nucleatum* in saliva.

In Vitro Efficacy of Device Against <i>Fusobacterium nucleatum</i> in Saliva						
CFU	μA	0 Min	5 Min	10 Min	20 Min	30 Min
10e4	50μA	1480	1480	1560	680	880
	500μA	2360	2360	1720	1240	1080
10e5	50μA	19600	19600	15200	14400	14000
	500μA	18000	17200	14400	11200	10800
10e6	50μA	348000	112000	120000	72000	68000
	500uA	156000	128000	124000	32000	28000

Table 4

Table 5 below shows the efficacy of stimulation to the present invention at current levels of 50 μ A or 500 μ A for 5-, 10-, 20-, and 30-minute durations for bacterial cultures ranging for 10^5 CFU of *Porphyromonas gingivalis* in a saline solution.

In Vitro Efficacy of Device Against
Porphyromonas gingivalis in Saline

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CFU	μ A	0 Min	5 Min	10 Min	20 Min	30 Min
10e4	50 μ A	3440	2040	2720	1640	1640
	500 μ A	2440	2120	2200	1880	1840

Table 5

Thus, this method and corresponding apparatus are able to achieve multiple prophylactic, therapeutic, cosmetic, and regenerative effects whose combination was not previously known or available in the art. Namely, these effects are: promotion of oral osteogenesis, destruction or disabling of oral microbes, gingival tissue regeneration, reduction and prevention of the formation of oral biofilms, caries prevention, increased oral vasodilation and oral blood flow, treatment of common oral conditions such as gingivitis and periodontitis, treatment of systemic diseases and conditions correlated with oral pathogens, and generally improved oral hygiene.

Turning now to the figures, Figure 1 shows one embodiment of a stimulation apparatus 10 according to this invention. The stimulation apparatus 10 is preferably a stand-alone device comprising a mouthpiece 100 and a controller 300 which may be physically supported by and operatively charged by a charging station or stand 400. Generally, the mouthpiece 100 is sized and configured to be received in a human mouth while positioning one or more electrodes at a desired location within the mouth. With reference also to Figures 2-5, the mouthpiece 100 includes at least one substantially U-shaped channel 110 configured to receive any maxillary or mandibular teeth of a human, and preferably includes a top U-shaped channel 110T and an opposing bottom U-shaped channel 110B, the channels 110

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configured to preferably contemporaneously receive any maxillary teeth and any mandibular teeth of the same human. The two U-shaped channels 110 are preferably separated from each other along at least a majority of their length 112 by a channel base 114. Forming the channels 110 in connection with the channel base 114 are opposing lingual 120 and buccal 130 sidewalls, extending preferably substantially perpendicular from the channel base 114. The lingual sidewalls 120 terminate in a lingual free edge 122, along a majority of which (and preferably along the entire lingual free edge 122) is provided one or more lingual electrodes 124. The lingual electrodes 124 are preferably formed from an electrically conductive silicone, and may be separated by one or more insulative gaps, such as a lingual wall air gap or notch 126 or other electrically insulative material. The buccal sidewalls 130 terminate in a buccal free edge 132, along a majority of which (and preferably along the entire buccal free edge 132) is provided one or more buccal electrodes 134. The buccal electrodes 134 are preferably formed from an electrically conductive silicone, and may be separated by one or more insulative gaps, such as a buccal wall air gap or notch 136 or other electrically insulative material, such as electrically insulative silicone. The mouthpiece 100 is preferably formed (e.g., molded) from tissue facing materials that are relatively comfortable, such as materials having a Shore A hardness of less than or equal to 80.

The connections made between the electrodes 124,134 and the circuitry in the controller 300 is made through a neck portion 200. The connection from electrodes 124,134 to the neck portion 200 may be achieved using flexible circuit technology, such as

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copper-clad polyimide, but a multi-shot injection mold including a first electrically insulative material and a second electrically conductive material to form electrical traces 140 may be more preferred. That is, 5 a first mold may be used to form electrically conductive silicone into a desired pattern, extending from a first connector end to and including one or more electrodes 124,134 to make an electrically conductive skeleton. The electrically conductive skeleton may then be overmolded 10 with electrically insulative silicone, so as to form a majority of the mouthpiece 100 and insulating the electrically conductive traces 140 that form the skeleton from each other. After insulation, the exposed electrically conductive areas are the electrodes 15 124,134, and a terminal surface within the neck portion 200.

The electrical traces 140 within the mouthpiece 100 are then electrically coupled to a header connector 210 mounted or to be mounted within the 20 controller housing 310, which is further described below. Specifically, the header connector includes pins 212, each pin preferably associated with and physically inserted into an electrically conductive silicone path (140 in Figure 7) to an electrode 124 or 134. The maximum 25 resistance of any conductive path from a terminal surface 142 of the trace 140 in the neck portion 200 to any portion of any respective electrode 124,134 is preferably less than 25 kΩ.

With reference also to Figure 7, the 30 controller 300 preferably comprises a housing 310 configured to be secured to the mouthpiece 100. The housing 310 contains a battery 302 and electronic circuitry to generally control the timing of connection

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(i.e., switching) of the electrodes 124,134 to deliver charge from the battery 302. The battery 302 is preferably a rechargeable lithium ion battery with a fully-charged capacity capable of performing at least
5 seven consecutive stimulation sessions, where such session durations are 20 minutes in length. The battery 302 is preferably rechargeable from a fully depleted state in less than 12 hours. The battery 302 is preferably rated for at least two hundred (200)
10 charge/discharge cycles. While the circuitry may be operatively mounted to one or more printed circuit boards 304, two circuit boards (a lower board 304L and an upper board 304U) are preferred to provide an improved packaging footprint. The housing 310 may comprise a
15 single or several housing pieces (e.g., housing top, bottom, sides, etc.) such as a molded polycarbonate plastic, a polycarbonate/ABS alloy (PC/ABS), which is preferably biocompatible. Regardless of the materials used to construct the mouthpiece 100 and the controller
20 300, the apparatus 10 preferably is capable of withstanding a gravitational drop ($\sim 9.81 \text{ m/s}^2$) onto a relatively hard surface (e.g., stone or ceramic tile, vinyl overlaid on wood substrate, or concrete) from a distance of about two meters (2m).

25 Figure 6 generally provides a diagram of the functional blocks of circuitry contained in the housing 310, including a programmable microprocessor (preferably in conjunction with a communications antenna), inductive charging circuitry to receive wireless inductive
30 charging for the battery 302, hardware overcurrent protection, current and voltage feedback for monitoring delivery parameters and open circuit conditions, and user interface components.

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The controller 300 preferably provides a user input interface in the form of a single pushbutton 306 (preferably debounced in hardware or software) and a user output or feedback interface, preferably including one or more of a battery indicator light 312, a status (or stimulation or treatment indicator) light 314, and an audible buzzer or speaker 316. The pushbutton 306 state (activated/deactivated) is monitored to control functionality. The battery indicator light 312 preferably is capable of displaying a plurality of colors (e.g., white and amber) preferably in either a consistently lit condition, flashing condition (which may be at different rates), or alternating colors, depending on the feedback to be provided. The treatment indicator 314 preferably is capable of displaying a plurality of colors (e.g., red, white and blue) preferably in either a consistently lit condition or flashing condition (which may be at different rates), or alternating colors, depending on the feedback to be provided. User feedback may additionally or alternatively be provided by touch, through the use of a haptic feedback generator, such as a vibratory motor. Preferred feedback is as shown in the table provided in Figure 11. Notes related to Figure 11 (indicated by superscript in the table, are as follows:

1. If the device has transitioned to LOW BATTERY from the COMPLETE state, the treatment LED 314 will continue Flashing-White and audible feedback will be Off.
2. Flashing-White when battery is charging, On-White when charging is complete.
3. If the device is placed on the charging stand while in the FAULT state, the device will continue

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to display the Flashing-Red treatment indicator light 314. The device will display the battery indicator light 312 according to the current battery charge (Flashing-White/On-White), but will not provide audible feedback when placed on the charger to avoid this being misinterpreted as clearing the fault.

4. The battery indicator light 312 will turn off if the device 10 is left on the charger 400 for greater than 10 minutes after charging is complete. The charger 400 will continue to charge during this time period if the battery voltage drops below the charging threshold, but the battery indicator 312 will remain off.

Generally, the electrical circuitry can be described as having multiple channels controlled and monitored by a microprocessor, where each channel is associated with the operation of one or more electrodes 124,134. The channels may be enabled or disabled independently of other channels, although each channel may control multiple electrodes. Additionally or alternatively, one or more electrodes may be permanently specified and operated as only a return electrode. A preferred embodiment includes eight channels, each capable of driving 125 μ A of direct electrical current across a resistance of up to 50 k Ω .

As can be seen in Figures 8A-8D, for each electrode channel, an enable signal 802 is received by a channel drive circuit 810. When activated, the enable signal 802 flips a switch (a MOSFET in this example) to provide voltage to a current source regulator, which then provides electrical current to the channel output 812. A sense resistor 814 is used to determine whether or not current is flowing and preferably how much current is flowing. CS_HIGH and CS_LOW signals are run through a

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comparative circuit to activate the CH_CURRENT signal to indicate that current is flowing. CH_VOLTAGE may be monitored to determine voltage and current levels delivered to a respective channel.

5 The operation of the controller 300 by a user (not shown) is preferably performed through the pressing of the push button 306. For example, the user can start or pause the delivery of current to the mouthpiece 100 by pressing the push button 306. To prevent
10 unintentional operation, the duration of the pressing of the push button 306 is sensed and debounced.

 The controller 300 is preferably configured by a clinician or other trained staff member prior to a user interfacing with the stimulation apparatus 10.
15 Additionally, or alternatively, the patient may configure the controller 300. Preferably configuration of the controller 300 is performed through attachment of an additional piece of hardware (not shown) connected to the controller 300, but may also take place through a
20 wireless connection (e.g. Bluetooth®, Wi-Fi, near field communications (NFC), infrared, magnetic). Finally, the controller 300 may be provided with a default stimulation regimen to reduce or eliminate initial configuration effort by a clinician or patient.

25 Configuration parameters preferably include: selection of electrode configurations to provide direct current for stimulation; selection of direct current output values, for example, 6µA, 12µA, 18µA, 25µA, 50µA, 62µA, 75µA, 100µA, 125µA, 150µA, and 200µA (preferably
30 not to exceed 1,000µA total current across all delivery electrodes at any one time); and selection of stimulation session duration (preferably from 1 minute through 30 minutes selectable in increments of 1 minute). Exemplary

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preferred configuration parameters can be seen in the table provided in Figures 12A and 12B.

The controller 300 is preferably capable of monitoring compliance of protocols and stimulation sessions performed by the stimulation apparatus 10 and recording a number of performance metrics in non-volatile memory (e.g., FLASH memory), such as counts of predetermined and monitored events and/or data associated with such events. The records may be utilized by a clinician (not shown) to evaluate and discuss stimulation response and efficacy. The controller 300 may also be configured to dynamically monitor the electrical characteristics (i.e., resistance, voltage, current) and adjust stimulation parameters or settings without clinician or user intervention. A real-time clock is preferably used and referenced to record the time and date at which the metrics and data are collected. Separate and apart from the real-time clock (which may be seeded by a wireless communication device or network), a real-time counter is maintained to track timing for automatic state changes and to track run time (up time).

For example, counters may be established to track the number of times a particular event occurs. Counters may be maintained in nonvolatile memory, such as those preferred counters shown in the table in Figure 13A and Figure 13B. Some metrics and data collected may include the following (along with the dates and times of such occurrences): the number of stimulation sessions (e.g., treatments) started; the number of successfully completed stimulation sessions (e.g., treatments); the number of open circuit faults; the number of stimulation sessions (e.g., treatments) with an open circuit; the

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number of stimulation sessions (e.g., treatments) with an open circuit that still completed successfully; the number of overcurrent faults; the number of low battery faults; the number of times the device was paused; the
5 number of stimulation sessions (e.g., treatments) that were paused but still completed successfully; the number of times the user turns the device on; the number of times the device is powered off by the user; the number of times the device is powered off by software; and the
10 total number of minutes the device has run since a memory reset. Recorded metrics and data may be stored only in non-volatile memory within the controller 300 and accessed through a physical connection (e.g., a serial UART connection if the housing 310 is removed, or through
15 a serial connector provided through the housing 310). Additionally or alternatively, recorded metrics and data may be accessed over a wireless connection (e.g. through a software application on a BLE-enabled wireless communication device) or even automatically pushed to a
20 wireless communication device over a wireless network to then be stored on the wireless communication device or remotely therefrom, such as on a remote data storage device networked with the wireless communication device (cloud storage or remote server, which may be associated
25 with the manufacturer and/or seller of the apparatus 10, a care provider (e.g., dentist, hygienist, administrative staff), an insurance company, or the user (or user's guardian).

The automatic data push could also be based
30 on a time interval or an event occurrence, such as transition from OFF to READY, entering the CHARGING state, entering the OFF state, etc. Pushed data may include user stimulation session data (e.g., patient

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compliance metrics), firmware version, device errors, and/or physical location of the apparatus 10 and/or charger 400 (if GPS or network location functionality provided).

5 The particular technology utilized for such data pushing may be assembled from generally known hardware technologies, heretofore not known to be used in conjunction with any oral appliances. The data push from the controller 300 may be directly to the charger
10 400 as an intermediary for forwarding over a wireless communication network (e.g., WAN, LAN, etc.), such as WiFi/LoRa/LoRaWAN/Helium or even a low-power wide-area network or mesh network.

Not only may a count of a particular event be
15 maintained, but data associated with a particular event occurrence may also be logged. Types of events to be recorded in an event log for the controller may also be stored in nonvolatile memory, including those shown in the table in Figure 14. Preferably, the events log can
20 store a minimum of 2,000 events. If the nonvolatile memory allocated to the events log is exceeded, then oldest events will be overwritten to store new data.

The nonvolatile memory will preferably store at least the following occurrences and related
25 information: how many minutes of stimulation (up to 30 minutes) the user completed; whether the mouthpiece was disconnected while running (e.g., OPEN state occurrence); whether an overcurrent fault occurred; total charge delivered per channel for a particular
30 stimulation duration (e.g., treatment), in units of coulombs (C) or microcoulombs (μC); and whether a low battery fault occurred.

The controller 300 may also be configured to

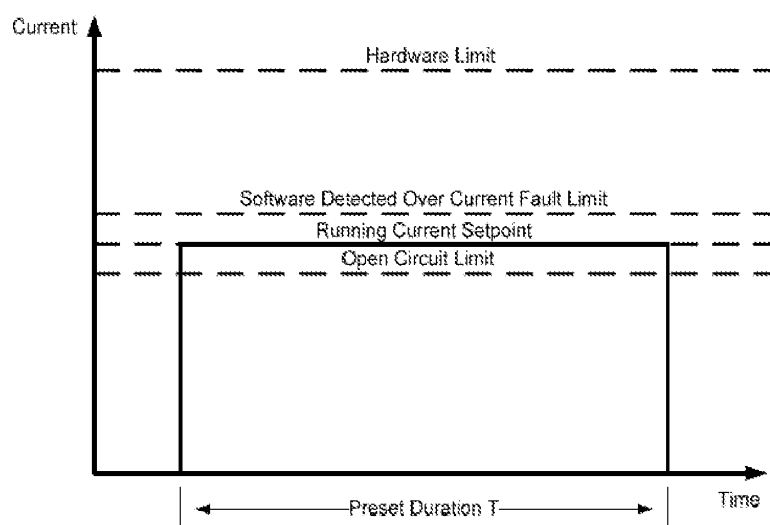
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detect when, the mouthpiece 100 is not located in the mouth of a user during a stimulation session, as discussed in connection with Figure 8. To do so, the controller 300 monitors the delivery of current and whether current is detected on any of the plurality of cathodic electrodes. If no current is detected, the controller 300 may pause stimulation and indicate a fault condition. For instance, the controller 300 monitors the stimulation circuits, including the anodic and cathodic electrodes. The controller 300 includes circuitry to measure or predict the amount of current to be delivered to the mouthpiece 100 (delivered current), and may also measure the amount of return current received from the mouthpiece 100 (return current). The circuitry then compares the return current to the delivery current, and if the difference is greater than a predetermined value (e.g., a percentage of the delivered current, such as 10% to about 50%), then stimulation is paused, preferably on all electrodes, and a fault message is displayed on the controller. Once the difference between delivered current and return current is less than the predetermined amount, then the stimulation program or regimen will resume from where it left off, preferably so no or little stimulation time is lost.

Graph 1 below provides parameters for monitoring the current delivered to a delivery electrode. As described above, the running current setpoint and also the duration "T" is determined and set during configuration prior to a patient using the stimulation apparatus 10, with the recommended setting for duration "T" at two seconds. The open circuit is preferably approximately 80% of the running current set point and

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the over current fault limit is preferably 120% of the running current set point. The hardware limit is preferably approximately 200 to 300 μA per stimulation channel (e.g., per anodic electrode).



5

Graph 1: Current Profile

The current is preferably polled eight times per second when the controller 300 is delivering current to any delivery electrode.

10

If the current detected is less than the open circuit limit for more than a preset duration, stimulation will pause and a notification will be indicated. If the current detected is more than an over current fault limit for more than the preset duration, stimulation will be stopped and a fault notification will be indicated.

15

It is further contemplated that the stimulation apparatus 10 be fully compatible with wireless technology such as Bluetooth® technology, near-field communication, and wi-fi to communicate with a user's electronic device (not shown), such as a cell

20

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phone, tablet, or personal computer. Preferably, a user may review usage history, the prescribed stimulation plan, and/or a comparison of usage history versus stimulation plan. The stimulation apparatus 10 may also
5 provide notifications regarding scheduled stimulation sessions to any of the user's electronic devices. This functionality is contemplated as operating through an application (not shown) downloadable to a user's electronic device. The application may also be configured
10 to share this data with a central server for storage, remote monitoring by the prescribing clinician, provide one-way or two-way communication between patient and clinician, and/or allow for a clinician to remotely adjust the stimulation parameters. Additionally,
15 firmware upgrades may be supplied to the controller 300 wirelessly.

The controller 300 preferably includes wireless communication technology, such as a Bluetooth Low Energy (BLE) module, which may be incorporated into
20 the microprocessor packaging. When the controller 300 is powered on (i.e., not in the OFF state), the controller preferably periodically transmits BLE advertisement packets, which preferably includes a device identifier such as a Unique Device Identifier
25 (UDI) as may be assigned by a regulatory authority, such as the U.S. FDA. The BLE communication channel is preferably used to transmit information about or contained in the controller 300, such as software version, programmable parameters, event log data,
30 counter data, and/or software state (e.g., READY, RUN, OPEN, etc.) and/or changes (since last transmission) in any of the foregoing. The BLE interface may also be used to exchange information with a software application (such

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as a user or physician service application) on a remote wireless communication device, such as a tablet computer, mobile phone, or other BLE enabled device, which preferably also includes a real-time clock. The real-time clock data may be received from the application by
5 the controller 300 and stored and referenced to start, maintain, and/or update its own real-time clock.

Specifically, an application (running on a wireless communication device) may scan (on demand or
10 periodically) for BLE advertisement packets transmitted by the controller 300. By manipulating a user interface on the device, the user may then pair the device to the stimulation apparatus 10 by selecting from a list of nearby advertising BLE enabled devices. Additionally, or
15 alternatively, the application is preferably capable of pairing the wireless device to the stimulation apparatus 10 via RSSI (Received Signal Strength Indicator), where the wireless device need only be brought into a predetermined proximity of the apparatus 10 to pair. The
20 user may manipulate the user interface of the application to engage or disengage the RSSI function.

Once the mobile device is paired to the apparatus 10, the present date and time (from a local time stored on the mobile device or from a network, such
25 as wifi or cellular) is preferably transmitted to the apparatus 10 to store in the event log. The application may confirm this connection and transmittance by displaying the contents of the event log for the user to see. Further, the application may display parameter
30 values and counters of the paired apparatus 10. Preferably, the application offers the option to highlight and notify the user to changes in the event log, parameter values, or counter values as they occur

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(or soon after) on the apparatus 10, to provide a real-time update.

The application may also preferably display the current software state of the apparatus 10 and information related to that state. For example, when the apparatus 10 is in the RUN or OPEN states (i.e. when stimulation is in progress or paused, respectively), the application may display a timer counting down the time remaining in the stimulation cycle as well as an electrical current and voltage measurement for each channel on the apparatus 10. While in these states, the application also preferably provides the option to save, from the apparatus 10, the event log, parameter values and counters, UDI of the apparatus 10, Bluetooth MAC address(es) of paired apparatus 10, and other information for future display within the wireless device application or as a log file saved into the memory of the wireless communication device, which may be retrievable without use of the application (e.g., a retrievable or moveable electronic file, such as an ASCII text file or formatted file, such as a comma separated variable (*.csv) file).

The application also preferably provides a user interface to transition the apparatus 10 between software states, allowing a remote control (e.g., through the use of a virtual button) of the apparatus 10 instead of requiring physical interaction with the button 306. For example, the apparatus 10 may transition from the READY, CHARGING, or FAULT states to the SERVICE state or vice versa. When in the SERVICE state, the application preferably allows the user to clear contents of the event log, reset counters, update parameter values, or perform a firmware update on the apparatus 10. The states are discussed in more detail below in.

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A charging station 400 according to the present invention preferably comprises a base 402 and a shell 410, as can be seen at least in Figures 1 and 10. The base 402 preferably comprises a power input (not shown), such as a USB-C receptacle. The power input is configured to receive input power from a power input source (not shown) (for example, a direct current transformer plugged into a standard electrical outlet providing alternating current). The input power is operatively coupled to a wireless charging coil (not shown) such as that defined by the Qi wireless charging standard.

The base 402 includes a controller support interface 420, including a cradle ridge 422 defining a cradle surface 422a. The cradle ridge 422 is configured to mate with the controller support ridge 322 to help support the controller 300 and to help register the relative positioning of the wireless charging circuitry components. Positioning and registration of the controller 300 relative to the base 402 is preferably further aided by one or more magnets (not shown) secured within the controller housing 310 and the base 402. In this way, when the controller 300 is supported by the controller support interface 420, the inductive charging coil (within the base 402) generates a magnetic field through the shell 410, which is used by a receiving coil (within the controller 300) to charge the battery 302.

The shell 410 is preferably hollow, defining a shell cavity 412 configured to receive the entire controller 300/mouthpiece 100 combination, such as for storage or travel. The shell cavity 412 can be accessed by changing the position of the shell 410, either by removing the shell 410 (if, e.g., a circumferential snap

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fit cooperation with the base 402 is used) or by pivoting the shell 410 about a hinged pivot point 414, such as a pinned hinge or living hinge. Within the shell cavity 412, and preferably formed integrally with a portion of the base 402, is an arcuate saddle surface 416 configured to receive the U-shaped mouthpiece 100.

To increase electrical conductivity in, across, or to oral tissues adjacent to the electrodes, an ionic or colloidal liquid or gel may be used as a conductive medium to decrease electrical resistance in the mouth. This medium may be placed along any desired areas of desired electrical contact, such as the teeth, gums, or surrounding oral tissues. Examples of such a medium include, but are not limited to, colloidal silver gel, liquid colloidal silver, colloidal copper gel, liquid colloidal copper, colloidal gold gel, liquid colloidal gold, saline gel, liquid saline or any combination thereof.

Colloidal silver, in whole or in combination, has great promise not only in increasing electrical current flow, but also in offering additional bactericidal benefits. Colloidal silver, in concentrations as little as five parts per million, is known to be bactericidal by inhibiting a bacterium's production of adenosine triphosphate.

This conductive medium may also contain dietary supplements including, but not limited to, oil of oregano. Oil of oregano is believed to have many health benefits and may also be microbicidal. Such microbicidal properties would be effective in treating common oral infections and diseases as well as aiding in preventative oral care.

This conductive medium may also contain teeth

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whitening agents. This would allow for the addition of teeth whitening to the list of cosmetic benefits offered by an embodiment of this invention. A whitening agent that is catalyzed by direct current electricity could be
5 included and may even offer reduced teeth whitening stimulation times when compared with nonelectrically-catalyzed whitening agents.

Artificial or natural flavorings may also be added to this conductive medium to offer a more appealing
10 taste to the user, similar to the method of flavoring dental fluoride treatments. This flavoring would mask any unpleasant tastes from the ingredients of the conductive medium or as well as any taste of the mouthpiece or electrodes themselves.

Thus, at least one embodiment addresses a
15 desired need in the oral hygiene and dental fields to concurrently treat common oral diseases and conditions in a more effective, less invasive, and less expensive manner. These embodiments promote general oral hygiene,
20 reduce oral biofilm, treat periodontal diseases such as gingivitis and periodontitis, kill oral microbes including bacteria and thus preventing cavities and tooth decay, increase vasodilation and blood flow in oral tissues, promote gingival tissue regeneration, foster
25 osteogenesis in the boney structures of the teeth, mouth, and related areas, treat systemic diseases related to oral pathogens, and treat other periodontal and oral maladies through the non-invasive application of weak direct current electricity to the surfaces in the oral
30 cavity.

In some cases, dental procedures can break up oral bacterial colonies found in biofilms and introduce bacteria into the bloodstream causing bacteremia and

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other infections. It is further contemplated that it may be desirable to utilize a mouthpiece according to the present invention immediately prior to performing a dental procedure. The stimulation apparatus 10 according to the invention may be used by the patient either at home or in the dental office. In this manner, the living bacteria in the patient's mouth, both supra- and sub-gingival, can be reduced prior to the procedure and the risk of bacteremia and other infections will be reduced.

For example, and not by way of limitation, the stimulation apparatus 10 may be utilized prior to a dental prophylaxis or a scaling and root planning procedure in a dental office to reduce the risks of introducing bacteria into the patient's blood stream.

The stimulation apparatus 10 may also be utilized following a clinical procedure as prevention for infections, for scenarios including but not limited to post-extraction or post-implantation infection prevention.

In operation, it may be preferable that the number of anodic electrodes is equal to the number of cathodic electrodes, but alternative arrangements are contemplated with different numbers of anodic and cathodic electrodes. It is to be understood that targeted stimulation may be selectively provided, such as may be desirable to treat predetermined gingival areas. To provide targeted stimulation, delivery of electrical current to other portions of the mouth is preferably prevented or reduced mechanically or electrically. As an example, mechanical prevention or reduction may be achieved by particularized arrangement of electrodes, such as providing an anodic or cathodic electrode on a mouthpiece at a first location of gingival

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tissue that at least partially surrounds (a) a tooth to be removed and replaced with an implant, or (b) an empty tooth socket from which a tooth has already been removed intentionally or by accident, or (c) a portion of a previously placed dental implant. The mechanical prevention or reduction may be further enhanced by providing a cathodic or anodic electrode on the mouthpiece at a second location of (preferably on the opposite side of teeth from first location) gingival tissue that at least partially surrounds (a) the tooth to be removed and replaced with an implant, or (b) an empty tooth socket from which a tooth has already been removed intentionally or by accident, or (c) a portion of a previously placed dental implant. If the two electrodes are provided as described, and no other electrodes are disposed on the mouthpiece, then mechanical reduction of electrical current stimulation is achieved. In this way, a mouthpiece may be customized for a particular user by mechanically arranging electrodes on the mouthpiece to target electrical stimulation towards a dental implant site.

As an example of electrical prevention or reduction of non-targeted electrical current is selective electrode control by the controller. That is, mechanically there may be provided on a mouthpiece a plurality of electrodes spaced about the mouthpiece, as shown and described herein. However, through electrical control of such electrodes, each electrode may have a selectable state to provide stimulation. The selectable electrode state may be anodic, cathodic, or off (e.g., tri-stated). Thus, where targeted electrical current is desired, a first electrode on the mouthpiece may be selected to be an anodic or cathodic electrode. The

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first electrode position on the mouthpiece may correspond to a first location of gingival tissue that at least partially surrounds (a) a tooth to be removed and replaced with an implant, or (b) an empty tooth socket from which a tooth has already been removed intentionally or by accident, or (c) a portion of a previously placed dental implant. The electrical prevention or reduction of non-targeted electrical stimulation may be further enhanced by a first electrode on the mouthpiece being selected to be a cathodic or anodic electrode (opposite the first electrode). The second electrode position on the mouthpiece may correspond to a second location of (opposite side of teeth from first location) gingival tissue that at least partially surrounds (a) the tooth to be removed and replaced with an implant, or (b) an empty tooth socket from which a tooth has already been removed intentionally or by accident, or (c) a portion of a previously placed dental implant. If the two electrodes are selected as described, and no other electrodes are activated on the mouthpiece (e.g., all other electrodes are turned off or sent into a high impedance, or tri-state, mode), then electrical reduction of electrical current stimulation is achieved. In this way, a mouthpiece may be mechanically standardized for multiple users, but electrically customized to target electrical stimulation towards a dental implant site.

While mechanical and electrical prevention or reduction of stray or non-targeted electrical current has been described with respect to targeting a single dental implant site, it is to be understood that such targeting may be accomplished at multiple implant sites simultaneously or in a time sequenced fashion (e.g., one

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target site is stimulated for a predetermined time and then a different target site is stimulated for a predetermined amount of time).

During operation, the controller 300
5 generally cycles through and/or between software states, some of which can be seen described in the table provided in Figure 15A, Figure 15B, and Figure 15C. Referring now to Figure 16, preferred states of the controller 300 can be seen. In an OFF state, there is either no power
10 supplied to the microprocessor or there is a minimal amount of power provided so as to place the microprocessor in a sleep or low-power mode and preferably maintain operation of only a real time clock and perhaps a visual indicator (constant or
15 intermittent). The OFF state can be entered from any other state of the controller if the pushbutton 306 is activated for a predetermined time, such as at least 3 seconds. The OFF state can also be entered from the following states based on a predetermined period of
20 inactivity: OPEN, READY, COMPLETE, LOW BATTERY, CRITICAL_BATTERY or FAULT. The predetermined period of inactivity is used to monitor user activity (i.e., depressing of pushbutton 306) or correction of an OPEN condition. If either of those things happen within an
25 inactivity period, then a different state, besides OFF will be entered from the respective state. The predetermined period of inactivity is preferably a programmable software variable, and is preferably separately programmable with respect to the inactivity
30 (i.e., in the READY, COMPLETE, LOW BATTERY, CRITICAL_BATTERY and/or FAULT states) and the OPEN correction (i.e., current begins flowing again before the expiry of this time). The OFF state is exited by

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activation of the pushbutton 306 for a predetermined time, such as at least 2 seconds.

The READY state is a state of the controller from which stimulation may be started. The READY state
5 may be entered from the OFF state by activation of the pushbutton 306 for a predetermined time, such as at least 2 seconds. The controller 300 will remain in the READY state until either the pushbutton 306 is activated by a user or a period of inactivity causes the controller to
10 exit the READY state and return to the OFF state.

The RUN state is a state in which delivery electrodes are activated and current is delivered therethrough for a predetermined, programmed time and at a predetermined, programmed current level. The RUN state
15 is entered from the READY state by an activation of the pushbutton 306, either intermittently or for a predetermined period of time. The software causes electrical current delivery (i.e., the controller software will transition to the RUN state) to electrode
20 channels that are activated (i.e., turned on) when the user presses the push button 306 (or a virtual button), preferably only from the READY state. The software monitors a stimulation (e.g., treatment) duration counter which increments at least once every second while
25 current is being delivered. The software compares the stimulation duration counter to the programmed TREATMENT_DURATION to determine when current delivery should end. Alternatively, upon entering the RUN state, the software may set an initial value of a decrementing
30 counter to TREATMENT_DURATION, and then monitor that counter to determine when reaches a value of zero, thereby indicating and preferably causing a cessation of current delivery.

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Presuming that current is delivered successfully and the stimulation duration counter has expired, the controller software will enter the COMPLETE state, in which electrical current delivery is stopped.
5 Generally, the software will then transition to the OFF state after a predetermined period of time from the COMPLETE state.

Once a stimulation session is complete, or the user otherwise is finished with the device, it may
10 be cleaned by the following process, or equivalent:

1) rinse mouthpiece 100 under cold water for approximately 30 seconds;

2) (occasionally, 2-4 times per month) use a toothbrush to gently scrub the mouthpiece 100 with a mild
15 soap (e.g. dish soap or hand soap) and then rinse the mouthpiece 100 under water to remove soap; and

3) Air dry (e.g., supported on the stand 400).

Additionally or alternatively, the mouthpiece may be occasionally or periodically placed in a solution
20 of denture cleaner for a duration of up to 30 minutes.

If during the RUN state, however, there is an interruption of current delivery (e.g., indicating that the apparatus 10 may have been removed from a user's mouth), as determined by monitoring channel current
25 and/or voltage of one or a combination of channels over a period of time (e.g., if no current is being delivered across all active channels for a period of two seconds), the software will enter the OPEN state, thereby pausing the stimulation duration timer. If electrical current
30 delivery resumes, as determined by monitoring channel current and/or voltage of one or a combination of channels, within a predetermined time period (e.g., prior to the expiration of a counter set to the programmed

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INACTIVITY_DURATION_OPEN parameter), then the software returns to the RUN state and resumes electrical current delivery to the activated channels and restarts (but does not reset) the paused the stimulation duration timer.

5 If electrical current delivery fails to resume, as determined by monitoring channel current and/or voltage of one or a combination of channels, within the predetermined time period (e.g., not prior to the expiration of a counter set to the programmed

10 INACTIVITY_DURATION_OPEN parameter), then the software returns to the OFF state.

Also during the RUN state, operational faults may occur, such as efficacy (undercurrent) faults and overcurrent faults, thereby transitioning the controller

15 software into a FAULT state, in which electrical current delivery is stopped and a visual and/or aural indication is provided by the controller 300. An efficacy fault may occur if the total current being delivered across all active electrode channels is less than a

20 predetermined, programmable percentage of a target value (MIN_CURRENT_PERCENT, e.g., 75 percent (75%)) for a predetermined, programmable time (MIN_CURRENT_TIME, e.g., 30 seconds). Accordingly, using the exemplary parameter values, if 4 channels are active, and a target

25 current delivery is 125 μ A per channel, then an efficacy fault will occur if the total current being delivered, as determined by monitoring channel current of all active channels, falls below 375 μ A (125 μ A/channel x 4 channels x 0.75) for more than 30 seconds. An overcurrent fault

30 may occur when current being delivered on any channel, as determined by monitoring each channel current level, exceeds a predetermined level, such as about 200 μ A, or a programmable percentage of a predetermined target

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current level, such as 110% of the predetermined target current level. The FAULT state preferably requires user intervention to exit and return to the OFF state, such as by requiring depression of the button 306 (or a virtual button) for a predetermined time, such as three seconds.

The CHARGING state is entered whenever the controller 300 is interfaced with a powered charging stand (electrical current delivery to electrode channels being preferably disabled) when the software is in any state except the FAULT state. When the controller 300 is placed on the charging stand 400 in the FAULT state, it preferably will remain in the FAULT state but will allow the battery to charge. The controller 300 preferably does not exit the FAULT state automatically when removed from the charging stand 400, if it was in the FAULT state when placed thereon. Rather, the FAULT state remains, thereby preferably requiring user intervention to exit and return to the OFF state, such as by requiring depression of the button 306 (or a virtual button) for a predetermined time, such as three seconds.

Other states than those shown in Figure 11 may be defined and utilized, such as a LOW BATTERY state, a CRITICAL BATTERY state, and a SERVICE state. The circuitry monitors available voltage at the battery 302. In LOW and CRITICAL BATTERY states, electrical current delivery is deactivated, and the user is informed, through visual and/or aural indicators of the battery state. A LOW BATTERY state may be entered if the voltage of the battery 302 is less than a first predetermined battery run value (e.g., 3.5 volts) when a user attempts to enter the RUN state. The LOW BATTERY state may also

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be entered upon transition between the RUN state and the COMPLETE state, if the voltage of the battery 302 is less than a second predetermined battery run value (e.g., 3.6 volts), which is preferably higher than the first
5 predetermined battery run value. A CRITICAL BATTERY state is preferably entered if the voltage of the battery 302 is less than a lower predetermined value than the low battery predetermined value (e.g., 3.1 volts) in any state, except in the FAULT state. This provides an
10 ability for event logging to non-volatile memory prior to a brownout of the microprocessor, thereby shutting the system down in a controlled fashion. If the controller 300 is powered down (e.g., by depressing the button 306 for a predetermined time) while in the
15 CRITICAL BATTERY state, it will preferably subsequently power on in that same state if it has not been placed on the charger 400 in the meantime.

The SERVICE state may be entered through the use of a wireless communication device application in
20 communication with the controller 300, thereby allowing parameters to be programmed through a user interface provided thereon. The SERVICE state may be entered from any of the READY, CHARGING, or FAULT states. The SERVICE state may provide the following functionality:

25 viewing and changing programmable parameters (e.g., those listed in Figures 12A-B);

 viewing counter values (e.g., of one or more counters listed in Figures 13A-B) as provided by the controller 300;

30 resetting one or more counter values on the controller 300 (and/or archiving counter labels and values on the paired wireless communication device, during or after pairing);

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viewing the event log (e.g., of one or more events listed in Figure 14) as provided by the controller 300;

clearing one or more events from the event
5 log on the controller 300 (and/or archiving the event log on the paired wireless communication device, during or after pairing); and/or

nondestructive, preferably authenticated, updates of firmware on the controller 300.

10 Once data is obtained from the controller 300, it may be forwarded by the wireless communication device manually or automatically over a wireless network to then be stored remotely therefrom, such as on a remote data storage device networked with the wireless communication
15 device (cloud storage or remote server, which may be associated with the manufacturer and/or seller of the apparatus 10, a care provider (e.g., dentist, hygienist, administrative staff), an insurance company, or the user (or user's guardian).

20 When a user has completed any of the above tasks (i.e., when the user wants to exit the SERVICE state), the user may do so through the use of the application on the mobile wireless device. From the SERVICE state, the controller transitions back to READY
25 if the apparatus 10 is not on an active charger 400, to CHARGING if on an active charger 400, or FAULT if the SERVICE state was entered from the FAULT state.

Prevention of Systemic Disease

30 It is contemplated that a mouthpiece according to the present invention may be used to prevent or treat systemic diseases as will be outlined in more detail below. The method according to the present

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invention has been shown to be effective in reducing the amount of oral bacteria, specifically *F. nucleatum*, *P. gingivalis*, and *S. oralis*.

1. Cardiovascular disease

5 It is contemplated that use of a mouthpiece according to the present invention may be used to reduce microbial burdens caused by the translocation of oral bacteria, including but not limited to *S. oralis*, *P. gingivalis*, and *F. nucleatum*, from the gingival tissues
10 to the rest of the body and also decrease the amount of inflammatory mediators produced by oral bacteria. Further, by reducing *F. nucleatum*, it is contemplated that the ability of *P. gingivalis* to invade host cells will be lessened and thus diminishing the development of
15 bacteremia that has been linked with the initiation/worsening of atherosclerosis and coronary heart disease.

 It is contemplated that a mouthpiece according to the present invention may be used according
20 to a predetermined stimulation regimen to prevent, treat and/or mitigate cardiovascular disease. In the predetermined stimulation regimen, the patient will wear a mouthpiece according to the present invention for a predetermined amount of time at a predetermined current
25 level and at predetermined time intervals. It is further contemplated that the specific stimulation regimen may be determined based on the bacterial levels present in a patient. According to one embodiment of the invention, the stimulation regimen would consist of a patient
30 wearing a mouthpiece according to the present invention for 20 minutes once per day at a current level of 500µA. For acute cardiovascular conditions, this stimulation may continue on a daily basis until the conditions is

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resolved. For chronic cardiovascular disease, this stimulation may be repeated a few times a week on a continuing basis.

2. Still Birth

5 It is further contemplated that stimulation sessions with a mouthpiece according to the present invention according to a predetermined stimulation protocol would reduce the oral population of *F. nucleatum* associated with periodontal disease and thus prevent, 10 treat and/or mitigate still birth. In turn, this reduction would lessen the likelihood of *F. nucleatum* translocating from the oral cavity into the bloodstream, where it could then migrate into the placenta and colonize. It is contemplated that a mouthpiece according 15 to the present invention may be used according to a predetermined stimulation regimen to prevent still birth. In the predetermined stimulation regimen, the patient will wear a mouthpiece according to the present invention for a predetermined amount of time at a 20 predetermined current level and at predetermined time intervals. It is further contemplated that the specific stimulation regimen may be determined based on the bacterial levels present in a patient. According to one embodiment of the invention, the stimulation regimen 25 would consist of a patient wearing a mouthpiece according to the present invention for 20 minutes once per day at a current level of 500 μ A for the duration of the pregnancy. The stimulation parameters outlined above have been demonstrated to be highly efficient at reducing 30 levels of *S. oralis* and *F. nucleatum* at inoculation sizes of 10^7 colony-forming units (CFU).

3. Diabetes

It is contemplated that a mouthpiece

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according to the present invention according to a predetermined stimulation protocol may be used to prevent, treat and/or mitigate diabetes by causing a reduction of *S. oralis* in the oral cavity and consequently reduce the amount of serum markers of inflammation produced by bacterial infections. In the predetermined stimulation regimen, the patient will wear a mouthpiece according to the present invention for a predetermined amount of time at a predetermined current level and at predetermined time intervals. It is further contemplated that the specific stimulation regimen may be determined based on the bacterial levels present in a patient. According to one embodiment of the invention, the stimulation regimen would consist of a patient wearing a mouthpiece according to the present invention for 20 minutes once per day at a current level of 500 μ A to effectively reduce oral levels of *S. oralis* that in turn will lower the amount of systemic inflammatory markers. This stimulation may be repeated multiple times a week on an ongoing basis to help reduce inflammatory markers.

4. Pyogenic Liver Abscess

It is contemplated that a mouthpiece according to the present invention according to a predetermined stimulation protocol may be used to prevent, treat and/or mitigate pyogenic liver abscess by causing a reduction of *F. nucleatum*. Specifically, it is contemplated that stimulation sessions with a mouthpiece according to the present invention would reduce bacterial levels and may stop *F. nucleatum* and other oral bacteria species from traveling to the liver and reduce overall bacteremia. In the predetermined stimulation regimen, the patient will wear a mouthpiece according to the

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present invention for a predetermined amount of time at a predetermined current level and at predetermined time intervals. It is further contemplated that the specific stimulation regimen may be determined based on the bacterial levels present in a patient. According to one embodiment of the invention, the stimulation regimen would consist of a patient wearing a mouthpiece according to the present invention for 20 minutes once per day at a current level of 500 μ A to effectively reduce oral levels of *F. nucleatum* which may prevent any bacteria from being transported from the oral cavity systemically. This stimulation may be repeated multiple times per week until the abscess is reduced.

5. Osteomyelitis

It is contemplated that a mouthpiece according to the present invention according to a predetermined stimulation protocol may be used to prevent, treat and/or mitigate osteomyelitis by causing a reduction of *F. nucleatum*. In the predetermined stimulation regimen, the patient will wear a mouthpiece according to the present invention for a predetermined amount of time at a predetermined current level and at predetermined time intervals. It is further contemplated that the specific stimulation regimen may be determined based on the bacterial levels present in a patient. According to one embodiment of the invention, the stimulation regimen would consist of a patient wearing a mouthpiece according to the present invention for 20 minutes per stimulation session at a current level of 500 μ A to effectively reduce oral levels of *F. nucleatum* bacteria and prevent any bacteria from being transported from the oral cavity systemically. This stimulation may be used in conjunction with or separate from standard

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antibiotic-based treatments for osteomyelitis. When used in conjunction with antibiotics, stimulation sessions will normally take place within a period of 29 to 42 days. When used separately from antibiotics, this stimulation may be used once a day for a few months for acute conditions, or a few times a week on a continuing basis for chronic conditions.

6. Arthritis

It is contemplated that a mouthpiece according to the present invention according to a predetermined stimulation protocol may be used to prevent, treat and/or mitigate arthritis by causing a reduction of *F. nucleatum*. In the predetermined stimulation regimen, the patient will wear a mouthpiece according to the present invention for a predetermined amount of time at a predetermined current level and at predetermined time intervals. It is further contemplated that the specific stimulation regimen may be determined based on the bacterial levels present in a patient. According to one embodiment of the invention, the stimulation regimen would consist of a patient wearing a mouthpiece according to the present invention for 20 minutes once per day at a current level of 500µA to effectively reduce oral levels of *F. nucleatum* bacteria and prevent any bacteria from being transported from the oral cavity and translocating to the synovial fluid and reducing the associated inflammation. This stimulation may be repeated multiple times per week on a continual basis for this type of chronic condition.

30 Reducing Biofilm and Preventing Biofilm Formation

It is contemplated that a mouthpiece according to the present invention according to a predetermined stimulation protocol may be used to

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prevent, treat and/or mitigate oral biofilm by causing a reduction of *F. nucleatum*, *P. gingivalis*, and/or *S. oralis*, all of which are involved in oral biofilm formation. In the predetermined stimulation regimen, the patient will wear a mouthpiece according to the present invention for a predetermined amount of time at a predetermined current level and at predetermined time intervals. It is further contemplated that the specific stimulation regimen may be determined based on the bacterial levels of specific bacterial species present in a patient. According to one embodiment of the invention, the stimulation regimen would consist of a patient wearing a mouthpiece according to the present invention for 20 minutes once per day at a current level of 500 μ A to effectively reduce oral levels of *F. nucleatum* bacteria to prevent further biofilm formation caused by *F. nucleatum* and to reduce the viability of existing biofilm colonies of *F. nucleatum*.

According to another embodiment of this invention, the stimulation regimen would consist of a patient wearing a mouthpiece according to the present invention for 20 minutes once per day at a current level of 50 μ A to effectively reduce oral levels of *P. gingivalis* bacteria to prevent further biofilm formation caused by *P. gingivalis* and to reduce the viability of existing biofilm colonies of *P. gingivalis*.

Furthermore, according to another embodiment of this invention, the stimulation regimen would consist of a patient wearing a mouthpiece according to the present invention for 20 minutes once per day at a current level of 500 μ A to effectively reduce oral levels of *S. oralis* bacteria to prevent further biofilm formation caused by *S. oralis* and to reduce the viability

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of existing biofilm colonies of *S. oralis*.

These stimulation sessions for biofilm reduction and prevention may be repeated on a daily basis for three to six weeks for acute biofilm-based issues or
5 may be repeated once or more per week on a continuing basis for chronic biofilm issues.

Treatment and/or Prevention of Peri-Implantitis

Peri-implantitis is generally inflammation of oral tissue in physical contact with, surrounding, or
10 otherwise in proximity to, and occurring after, placement of a dental implant. This inflammation may be reduced or prevented using methods according to the present invention. Methods may be performed before and/or after a dental implant surgical procedure of dental implant
15 placement or replacement.

A method of reducing a likelihood of peri-implantitis involves, prior to a dental implant being placed or replaced partially or in its entirety, applying or directing electrical current to gingiva tissue near
20 or at an oral site of future implantation. While electrical current may be distributed elsewhere throughout oral tissue, at least 6 μA and more preferably at least approximately 50 μA of electrical current (and preferably no more than 300 μA) is delivered to the
25 gingiva tissue near or at a predetermined oral site of future implantation. A pre-surgery stimulation regimen may consist of approximately twenty minutes of electrical stimulation per day for one to fourteen days prior to a dental implant surgical procedure.

30 A method of reducing a likelihood of peri-implantitis (if it has not yet begun) or reducing peri-implantitis (if it has already begun) involves, after a dental implant has been placed or replaced partially or

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in its entirety, applying or directing electrical current to gingiva tissue near or at an oral site of implantation. While electrical current may be distributed elsewhere throughout oral tissue, at least 6
5 μA and more preferably at least approximately 50 μA of electrical current (and preferably no more than 300 μA) is delivered to the gingiva tissue near or at a predetermined oral site of implantation. A post-surgery stimulation regimen may consist of approximately twenty
10 minutes of electrical stimulation per day for one to fourteen days after a dental implant surgical procedure, or until desired inflammation reduction has occurred.

While the pre-surgery and post-surgery methods have been separately described for clarity, it
15 is to be understood that either or (preferably) both methods may be utilized for a particular patient, or user of the mouthpiece.

The foregoing is considered as illustrative only of the principles of the invention. Furthermore,
20 since numerous modifications and changes will readily occur to those skilled in the art, it is not desired to limit the invention to the exact construction and operation shown and described. While the preferred embodiment has been described, the details may be changed
25 without departing from the invention.

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We Claim:

1. A system comprising:

a controller having a housing containing a variable direct current power supply, the power supply
5 capable of delivering approximately 1 to 500 microamperes;

a mouthpiece configured to be received in a human mouth, the mouthpiece comprising at least one U-shaped channel;

10 a plurality of exposed electrodes supported by the mouthpiece and coupled to the direct current power source; and

a neck portion electrically coupling the direct current power supply to the mouthpiece and
15 physically coupling the housing to the mouthpiece,

wherein the electrical coupling in the neck portion is achieved by a plurality of electrically conductive pins inserted into and substantially surrounded by traces of electrically conductive
20 silicone.

2. A system according to claim 1, wherein a first of the plurality of exposed electrodes is a cathode electrode disposed on a first side of a first of the at least one U-shaped channel and a second of the
25 plurality of exposed electrodes is an anode electrode disposed on a second side of the first channel.

3. A system according to claim 1, wherein the mouthpiece comprises two U-shaped channels, wherein one channel is configured to receive one or more
30 maxillary teeth of a human and the other channel is configured to receive one or more mandibular teeth of the human.

4. A system according to claim 3, wherein

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the controller comprises electronic circuitry disposed in the housing, the circuitry being configured to at least one of manipulate and monitor at least one of duration and intensity of current provided by the power source to each electrode.

5 5. A system according to claim 4, wherein the controller further comprises a user input interface and a user feedback interface.

10 6. A system according to claim 5, wherein the controller is configured to store one or more counter values and an event log in non-volatile memory.

 7. A system according to claim 6, wherein the event log can store a minimum of two thousand event occurrences, including a timestamp associated with each.

15 8. A system according to claim 1, wherein the variable direct current power supply comprises a rechargeable lithium-ion battery.

 9. A system according to claim 8, wherein the system further comprises a charging station capable of physically supporting the controller housing and inductively recharging the rechargeable lithium-ion battery.

20 10. A system according to claim 9, wherein the charging station comprises a hinged cover, which may contain the controller and mouthpiece.

 11. A system according to claim 6, wherein the system further comprises a mobile wireless communication device capable of physical layer communication with the controller, the wireless device further including a software application capable of software layer communication with the controller.

30 12. A system according to claim 11, wherein the controller is capable of transmitting the counter

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values and event log to the wireless device the application.

13. A system according to claim 12, wherein the controller transmits the counter values and event
5 log upon at least one of an occurrence of a predetermined event, an expiration of a predetermined time period, and at a predetermined time of day.

14. A system according to claim 12, wherein the application is configured to display simultaneously
10 at least one transmitted counter value and event log.

15. A system according to claim 12, wherein the application is configured to allow storage of the transmitted counter values and event log to non-volatile memory in the wireless device.

16. A system according to claim 11, wherein the application is configured to provide firmware updates to the controller.

17. A system according to claim 1, wherein the mouthpiece is formed by a process comprising the
20 steps of:

a first injection molding procedure using the conductive silicone material to form the traces and the electrodes to form a conductive skeleton; and

a second injection molding procedure using
25 insulative silicone material to encapsulate at least a portion of each trace.

18. A system according to claim 17, wherein the second injection molding procedure is performed after the first injection molding procedure.

19. A method comprising the steps of:
providing a mouthpiece supporting a plurality
of electrodes coupled to a direct current power source;
positioning a first electrode of the

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plurality of electrodes between a cheek and exterior gumline of a human, and in physical contact with gingival tissue;

5 positioning a second electrode of the plurality of electrodes medial to the first electrode, and in physical contact with gingival tissue;

 delivering current from the power source to the gingival tissue;

10 regulating the intensity of current delivery to the gingival tissues to approximately between 1 and 500 microamperes via a controller; and

 regulating the duration of current delivery to no more than 30 minutes via the controller.

20 20. A method according to claim 19, further comprising the steps of:

 storing data metrics and an event log in non-volatile memory in the controller;

25 providing a software application on an electronic wireless device capable of communicating with the controller;

 pairing the wireless device to allow communications with the controller;

 transferring the data metrics and event log from the controller to the wireless device;

30 saving the data metrics and event log into non-volatile memory of the electronic device; and

 reviewing at least some of the saved data metrics and event log using the software application.