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(54) **EXTRACORPOREAL DEVICES AND METHODS FOR FACILITATING CESSATION OF UNDESIRE BEHAVIORS**

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(76) Inventors: **David Scott Utley**, Redwood City, CA (US); **Jack Denton Utley**, Fairview, PA (US); **Kathryn Mary Utley**, Redwood City, CA (US); **Alek Denton Utley**, Redwood City, CA (US); **Haley Grace Utley**, Redwood City, CA (US); **MacKenzie Taylor Utley**, Redwood City, CA (US); **Emma Kathryn Utley**, Redwood City, CA (US)

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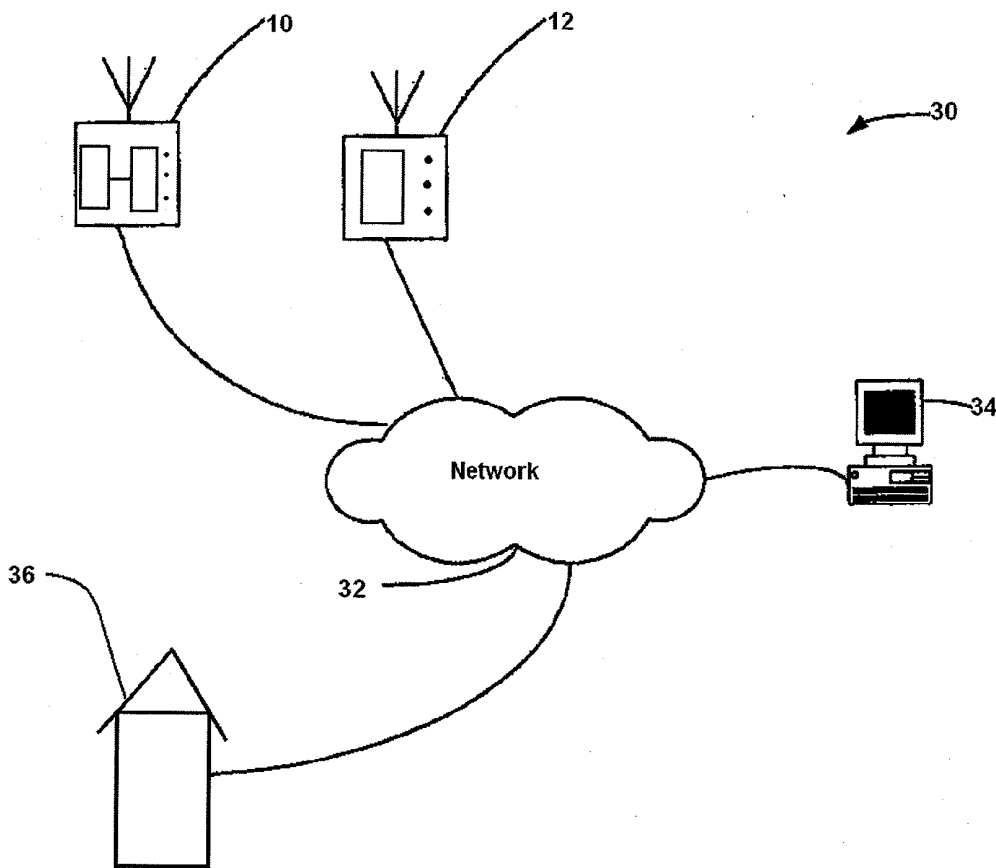
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(57) **ABSTRACT**

Devices, Methods and Systems are disclosed for assisting patients in behavioral modification and cessation programs aimed at terminating undesired behaviors such as smoking, alcohol use and others. Patient devices with automated patient prompting for self-testing, analysis of test results and data logging are included in a networked system with a specifically designed treatment modality.

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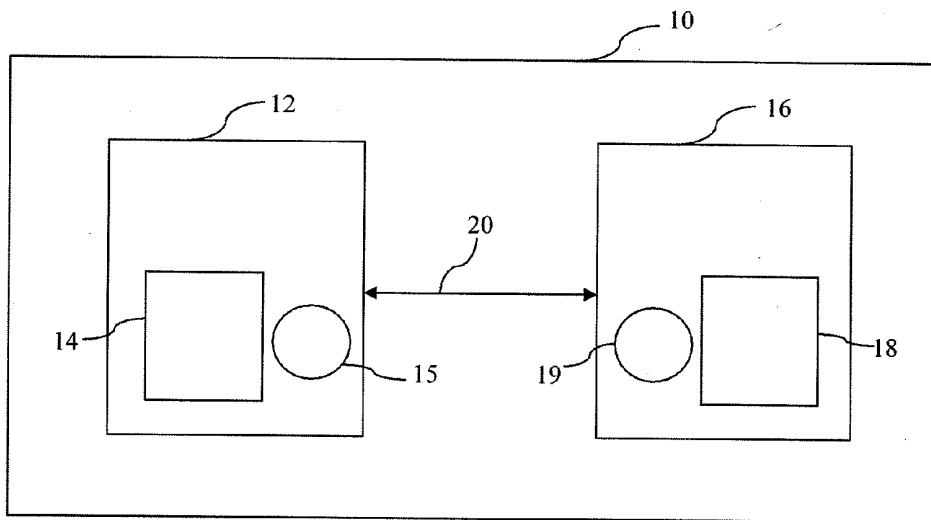


FIG. 1

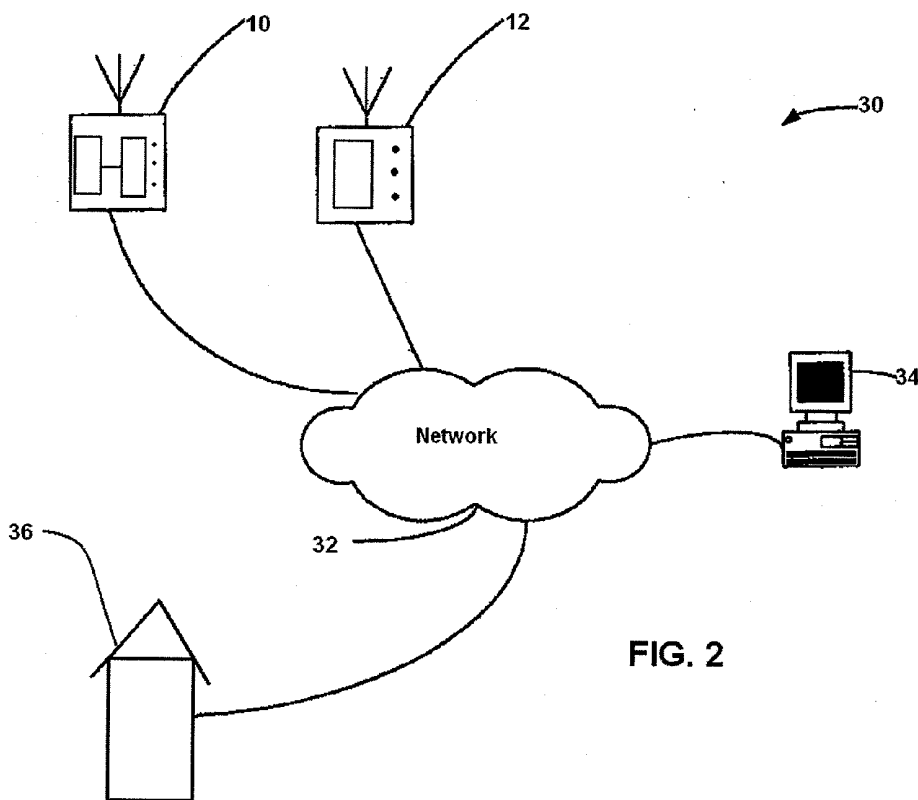


FIG. 2

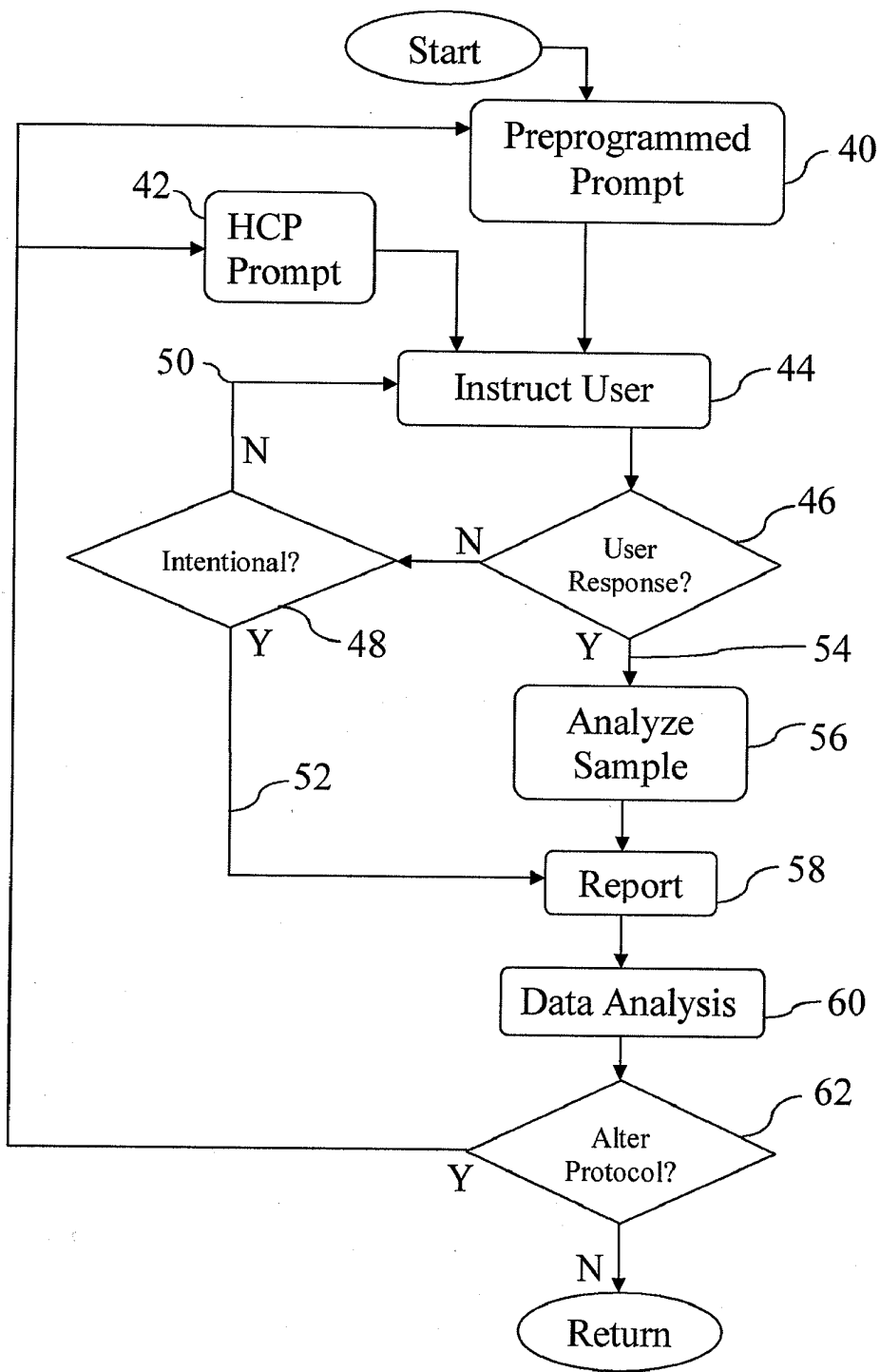


FIG. 3

EXTRACORPOREAL DEVICES AND METHODS FOR FACILITATING CESSATION OF UNDESIRE BEHAVIORS

RELATED APPLICATION DATA

[0001] This application claims the benefit of priority of U.S. Provisional Patent Application Ser. No. 61/254,685, filed Oct. 24, 2009, and titled Extracorporeal Devices and Method for Intermittent Signaling and Prompting of Patient Self-Testing for Substances, which is incorporated by reference herein in its entirety.

FIELD OF THE INVENTION

[0002] The present invention generally relates to the field of behavioral modification. In particular, exemplary embodiments of the present invention are directed to extracorporeal devices, systems and methods for facilitating cessation of undesired behaviors.

BACKGROUND

[0003] Certain persons may engage in certain undesirable activities that have significant negative acute and/or long-term health, social, and safety implications for the person and for other associated persons. In some cases, the person may wish to quit this behavior. Often, the person's family, friends, and/or healthcare providers are also engaging with the person in an attempt to have them quit the behavior. Associated persons may also be negatively impacted by the behavior, socially, financially, and from a health perspective. Such behavioral modification or cessation attempts to terminate the undesirable behavior may be formal and administered by healthcare professionals, or the person may take their own personalized approach to cessation.

[0004] An example of such a behavioral modification program is a formal multi-modality smoking cessation program that utilizes counseling and drug therapy to achieve the end goal of abstinence from smoking. Drug therapy typically includes one or more of: nicotine replacement therapy, varenicline, bupropion, and other drugs. Alcohol cessation programs, by comparison, may include similar approaches with counseling and drug interventions targeted specifically to achieve abstinence from alcohol use and abuse.

[0005] In a typical multi-modality smoking cessation program, participants are asked to voluntarily and honestly report on their smoking behavior before and during therapy. For example, the patient's baseline smoking behavior is measured according to the patient's own voluntary report and is based solely on their recall (i.e., patient states that they average forty cigarettes per day prior to entering program). The patient may also be asked to provide a blood sample at the clinic or hospital location to test for substances associated with smoking behavior, such as hemoglobin bound to carbon monoxide. Alternatively, the patient may be asked to exhale into a device at the clinic or hospital location to detect carbon monoxide levels in the exhaled gas from the lungs. Such tests would be performed on location and observed by the health care provider, and such tests may require processing by a professional laboratory. Based on the values of carbon monoxide or other substances at this specific point in time, a gross estimate of smoking behavior may be made by the health care professional. Limitations of such testing are that it is made at a single point in time and likely does not fully and accurately reflect the true behavior of the patient at multiple time points

before entering the program. The patient may alter their behavior, for example, for days prior to testing thus making the test result less relevant and accurate.

[0006] At each visit during a patient's cessation program participation, the patient's interval smoking behavior since the previous visit is quantified by patient voluntary reporting (recollection, diary, etc.). For example, if the patient is seen weekly, they will report on their smoking behavior for the prior seven days. Typically, the patient keeps a diary or smoking log during each interval in which daily entries are made regarding the number of cigarettes smoked and certain lifestyle events that occur in conjunction with smoking behavior. This methodology relies on compliance and full disclosure by the smoker, as well as a commitment to record the data every day.

[0007] Clinical trials have shown that patients often fail to disclose their true smoking behavior when queried in this manner, grossly under-reporting the amount of smoking that takes place or forgetting certain lifestyle events that are associated with smoking. These limitations in reporting impair the effectiveness of the program. Further, blood tests or exhaled carbon monoxide breath tests may be performed on the spot at these weekly or biweekly visits, to detect substances associated with smoking. Unfortunately, such predictable and infrequent testing gives the patient the opportunity to abstain for hours or longer prior to the visit to avoid detection of smoking behavior or to lessen the positivity of the test. Such behavior results in collecting physiological data that erroneously suggests that smoking has stopped or diminished. For example, if a patient has a bi-weekly 3 pm clinic visit on Mondays, they may abstain from smoking after 9 am on the day of the visit so that their blood and exhaled breath levels of carbon monoxide decline or normalize in time for the test. Further, such spot testing by the clinic is infrequent and does not accurately represent patient behavior during non-clinic days. Due to these significant limitations, counseling and drug therapy cannot be accurately and effectively tailored to optimize patient outcomes. If healthcare professionals do not have accurate information regarding true patient behavior, for example, the efficacy of the cessation program will be severely impaired. This is one reason why failures of smoking cessation programs, as well as other behavioral cessation programs, are so high and recidivism almost guaranteed. Given the currently limited options for objectively determining a patient's smoking behavior, (or other behaviors) a more objective and accurate means of determining a patient's behavior is needed.

SUMMARY OF THE DISCLOSURE

[0008] In one exemplary embodiment of the present invention, a method for facilitating cessation of undesired behavior in a patient includes steps such as configuring a patient device with a predetermined test protocol including patient test prompts, prompting the patient in accordance with the predetermined test protocol to provide at least one biological input to the patient device, the biological input being correlated to the undesired behavior, analyzing the patient biological input to the patient device, generating a machine readable data set representative of the patient input based on the analyzing, associating the data set with a specific patient biological input, evaluating the predetermined test protocol based on the data set, and altering or maintaining the predetermined test protocol based on the evaluation. In certain embodiments, such a method may also include steps of determining whether

the patient properly provided a biological input in response to the prompting, and re-prompting the patient to provide the at least one biological input when the determining result is negative.

[0009] Other aspects of exemplary embodiments may include remotely reconfiguring the test protocol in the patient device through a communications network, prompting the patient to input requested information to the patient device through a user interface, and associating the requested information with the data set associated with a specific patient's biological input. Additionally, the evaluating may be based on the requested information associated with the data set.

[0010] In further exemplary embodiments, methods according to the present invention may include transmitting the data set and associated requested information to a health care provider device. Other optional steps may include communicating with the patient device through a network, and prompting the patient to provide at least one biological input outside of the predetermined test protocol. In order to arrive at a test protocol, exemplary embodiments may also include collecting data related to the patient undesired behavior, and analyzing the patient behavior data to determine the predetermined test protocol.

[0011] In another exemplary embodiment of the present invention, system for facilitating cessation of undesired behavior in a patient includes a patient device or PD and a health care provider device or HCPD that are configured to communicate with one another through a network or other known means of data transfer. The PD may be configured and dimensioned to be carried by the patient, may include a PD user interface, a test element configured to receive a biological input from the patient and output information representative of the content of the biological input, a PD storage module containing instructions for various functions including for a predetermined test protocol, and a PD execution module communicating with the user interface, the test element and the storage module, the PD execution module configured to execute instructions contained in said PD storage module.

[0012] The predetermined test protocol instructions may, for example, include prompting the patient through the user interface to provide a biological input to the test element at selected intervals, determining the completeness of a biological input, and providing additional patient prompts based on the completeness determination.

[0013] In such exemplary embodiments, an HCPD may be configured to be accessed by a health care provider, and include an HCPD user interface, an HCPD storage module containing certain instructions and an HCPD execution module communicating with the user interface and storage module, the execution module configured to execute instructions contained in the HCPD storage module.

[0014] Instructions stored in the HCPD storage module may include instructions for displaying and manipulating information representative of the content of the biological input, and revising the predetermined test protocol based on at least one of user input and the information representative of the content of the biological input.

[0015] In certain other exemplary embodiments instructions for executing some functions may be stored in either the PD or HCPD storage modules and executed by the associated execution modules as appropriate. Examples of such instructions may include instructions for generating a machine readable data set based on the test element output information, and for associating the data set with a specific patient biological

input, or instructions for causing the patient device to prompt the patient to input requested information to the patient device through the PD user input and for associating the requested information with a data set associated with a specific patient biological input.

[0016] In further exemplary embodiments, the patient device may further include an identification device for acquiring patient identifying information correlated to a biological input. Such an identification device may communicate with the storage module and execution module for associating the acquired identifying information with the correlated biological input and storing the associated identifying information. The system may also permit receiving unprompted patient input through the PD user input and then associating the unprompted input with a biological input based on a predetermined algorithm.

[0017] In another exemplary embodiment of the present invention, an apparatus for use in connection with facilitating cessation of undesired behavior in a patient, may include at least one housing configured and dimensioned to be carried by the patient, a user interface disposed in the at least one housing, a test element disposed in the at least one housing, the test element being configured to receive a biological input from the patient and output information representative of the content of the biological input, a storage module containing instructions related to the operation of the apparatus, and an execution module communicating with the user interface, the test element and the storage module.

[0018] Exemplary instructions contained in the storage model, which may be executed by the execution module, may include instructions for executing a predetermined test protocol, b) generating user readable indicator based on the test element output and displaying the output on the user interface, associating the user readable indicator with a specific biological input, associating the requested information with a specific user readable indicator associated with a specific patient biological input, and storing test result information including the user readable indicator and associated requested information in the storage module. The predetermined test protocol instructions may include steps of prompting the patient through the user interface to provide a biological input to the test element at selected intervals, determining the completeness of a biological input, providing additional patient biological input prompts based on the completeness determination, and prompting the patient to input requested information through the user interface.

[0019] In some exemplary embodiments, the apparatus may be configured to communicate through a network for transfer of the test result information.

[0020] In yet another exemplary embodiment of the present invention, a method for collecting and confirming patient participation in select behaviors, may include steps such as configuring a patient device with a predetermined test protocol including patient test prompts, prompting the patient in accordance with the predetermined test protocol to provide at least one biological input to the patient device, the biological input being correlated to the select behavior, determining whether the patient properly provided a biological input in response to the prompting, re-prompting the patient to provide the at least one biological input when the determining result is negative, analyzing the patient biological input to the patient device, generating a machine readable data set representative of the patient input based on the analyzing, associating the data set with a specific patient biological input,

prompting the patient to input requested information to the patient device through a user interface, associating the requested information with the data set associated with a specific patient biological input, evaluating the predetermined test protocol based on the data set and the requested information associated with the data set.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] For the purpose of illustrating the invention, the drawings show aspects of one or more embodiments of the invention. However, it should be understood that the present invention is not limited to the precise arrangements and instrumentalities shown in the drawings, wherein:

[0022] FIG. 1 is a block diagram illustrating a patient monitoring device according to an exemplary embodiment of the present invention.

[0023] FIG. 2 is a diagram illustrating a system according to an exemplary embodiment of the present invention.

[0024] FIG. 3 is a flow chart illustrating a method according to an exemplary embodiment of the present invention.

DETAILED DESCRIPTION

[0025] Embodiments of the present invention provide devices, methods and systems capable of prompting a patient to perform self-testing for undesired behaviors, objectively analyzing the test results, logging the data to a local or central storage unit, and providing a comprehensive interface for the patient and healthcare professional to analyze and observe results and correlate these results with progress within a cessation program. Such self-testing may be according to a protocol that is monitored and altered in real time to adapt to specific circumstances of the patient's needs. While exemplary embodiments of the present invention are described in more detail in connection with smoking cessation, and to some extent alcohol cessation, it will be appreciated by those skilled in the art that the devices, methods and systems taught herein are generally applicable to facilitating behavior modification with respect to any number of undesired behaviors for which markers are present in the patient's breath or saliva.

[0026] A number of undesirable behaviors that involve smoking of one or more substances, oral ingestion of one or more substances, oral placement of one or more substances, transdermal absorption of one or more substances, nasal sniffing of one or more substances, and other methods of absorbing one or more substances result in the subsequent presence of one or more of the substances in the exhaled breath. The presence of a unique substance or substances in the exhaled breath can be used as a marker for the specific undesirable behavior and intermittent testing of the exhaled breath for this substance(s) can quantify the occurrence of the undesirable behavior.

[0027] Such substances may be detected in the exhaled breath due to one or more of the following mechanisms: 1) the substance was previously absorbed into the body and bloodstream and is then released from the bloodstream into the pulmonary airspace for exhalation, 2) the substance was very recently inhaled into the pulmonary dead space (non-absorbing portion of inhaled air) and is being exhaled acutely therefore not requiring a blood level of the substance to be present, 3) the substance is present in the oral cavity mucous and epithelial surface layers and certain portions volatilized into the exhaled breath, 4) the substance was previously absorbed into the body and bloodstream and is then released from

salivary glands into the oral cavity in the saliva and then volatilized into the exhaled breath, and/or 5) the substance was exhaled previously and a portion of the substance was retained within the oral cavity mucous and epithelial surface layers and certain portions subsequently volatilized into the exhaled breath.

[0028] One alternative to intermittently testing the exhaled breath to detect one or more substances associated with an undesirable behavior is to intermittently test saliva for one or more substances associated with an undesirable behavior, as these substances as disclosed above often reside in the oral cavity via secretion within the saliva from the bloodstream or accumulation within the oral cavity mucous, saliva, and epithelial lining due to ingestion or exhalation residues.

[0029] In the specific example of smoking cessation, high quality objective data collected in an improved manner could be used by the healthcare professional to adjust therapy (i.e., nicotine replacement therapy, other drug therapy, counseling, etc.) to achieve a better outcome, to provide real-time or delayed positive and negative feedback to the patient, to determine success or failure of the cessation program, and to provide long-term maintenance of cessation after successfully quitting the behavior (avoidance of relapse). For example, if smoking behavior remained unchanged after initiating counseling and a trial of nicotine replacement therapy (NRT), the dose of the NRT could be immediately increased and/or other therapies could be added with this approach. Likewise, as smoking behavior began to improve as evidenced by objective signs of decreased frequency of smoking, the various therapies could be titrated downward and ultimately discontinued.

[0030] An exemplary embodiment of a patient monitoring device according to the present invention is illustrated in FIG. 1. In this exemplary embodiment, patient device 10 includes two main components: extra-corporeal detector unit 12 containing at least one test element and signaling unit 16. The components may be combined into a single unit or may be separated physically. Other embodiments may include additional components and these components may be combined or separate as well.

[0031] Extra-corporeal detector unit 12 includes at least one test element that is capable of detecting a substance in a biological input from the patient that is indicative of recent targeted behavior. The detector analyzes the biological input from the patient, such as expired gas from the lungs or saliva, and in at least one embodiment logs the date and time of day, quantifies the presence of the targeted substance(s), and then stores the data for future analysis and/or sends the data to a remote location for analysis. Detector unit 12 thus may include a processor, memory and user interface 14 as appropriate for its specific functions. The user interface may include data inputs such as a touch screen, keyboard or pointer.

[0032] Detector units may be specifically configured by person of ordinary skill in the art for detection of specific marker substances related to targeted behaviors as described herein. Examples of substances detected related to smoking include but are not limited to carbon monoxide, nitrogen oxides, ammonia, arsenic, nicotine, acetone, acetaldehyde, formaldehyde, hydrogen cyanide, isoprene, methyl ethyl ketone, benzene, toluene, phenol, and acrylonitrile. Sensor technologies for detecting alcohol in the exhaled breath include infrared spectrophotometer technology, electrochemical fuel cell technology, or a combination of the two.

Smaller portable units well suited for use in embodiments of the invention may be based on electrochemical fuel cell analysis or “Taguchi cell” sensors.

[0033] One example of a suitable detector unit for determining the presence of alcohol in the breath is described in U.S. Pat. No. 7,797,982, entitled “Personal Breathalyzer Having Digital Circuitry.” Another example of detector units that may be configured to determine the presence of a variety of substances is disclosed in U.S. Pat. No. 7,421,882, entitled “Breath-based Sensors for Non-invasive Molecular Detection.” U.S. Pat. No. 7,525,093, entitled “Liquid or Gas Sensor and Method” discloses another sensor device that may be readily incorporated into embodiments of the present invention by persons of ordinary skill in the art. Each of the foregoing U.S. patents are incorporated by reference herein in their entirety.

[0034] Detector unit 12 may also be configured to recognize a unique characteristic of the patient, such as a fingerprint, retinal scan, voice label or other biometric identifier, in order to prevent, at least to a degree, having a surrogate respond to the signaling and test prompts to defeat the system. For this purpose, patient identification sub-unit 15 may be included in detector unit 12. Persons of ordinary skill in the art may configure identification sub-unit 15 as needed to include one or more of a fingerprint scanner, retinal scanner, voice analyzer, or face recognition as are known in the art. Examples of suitable identification sub-units are disclosed, for example in U.S. Pat. No. 7,716,383, entitled “Flash-interfaced Fingerprint Sensor,” and U.S. Patent Application Publication No. 2007/0005988, entitled “Multimodal Authentication,” each of which is incorporated by reference herein in their entirety.

[0035] Identification sub-unit 15 may also comprise a built in still or video camera, which would record a picture or video of the patient automatically as the biological input is provided to the test element. Regardless of the type of identification protocol used, the processor and memory in the detector unit will associate the identification with the specific biological input, for example by time reference, and may store that information along with other information regarding that specific biological input for later analysis.

[0036] A patient may also attempt to defeat the detector by blowing into the detector with a pump, bladder, billows, or other device, for example, when testing exhaled breath. In the embodiment of saliva testing, a patient may attempt to substitute a “clean” liquid such as water. While no means will absolutely prevent an uncooperative and determined patient from these attempts, some means to defeat these attempts can be incorporated in to the system. For example, the detector unit may incorporate the capability of discerning between real and simulated breath delivery. In one exemplary embodiment this functionality may be incorporated by configuring detector unit 12 to sense oxygen and carbon dioxide, as well as the maker substance (carbon monoxide, etc.). In this manner, the detector is able to confirm that the gas being analyzed is truly coming from expired breath, as expired breath has lower oxygen and much higher carbon dioxide than ambient air. In another embodiment, the detector unit may be additionally configured to detect enzymes naturally occurring in saliva so as to distinguish between saliva and other liquids. Basic biochemical tests are well known to persons skilled in the art for identifying such substances.

[0037] Signaling unit 16 may communicate with detector unit 12 through an appropriate communication link 20 (for

example, wired, WI-FI, Bluetooth, RF, or other means) as may be devised by a person of ordinary skill in the art based on the particular application. Signaling unit 16 may be integrated with detector unit 12 in patient device 10 or may separate from the detector unit, but the units are synchronized and able to communicate real-time or at various intervals in order to correlate signaling and detector results. Thus, when physically separate from detector unit 12, signaling unit 16 may include its own processor, memory and graphical user interface 18, but when integrated with detector unit 12 both units may share one of more of those subcomponents. Utilizing graphical user interface 18, signaling unit 16 prompts the patient to blow into the detector unit at various times of the day, and/or prompts the patient to test their saliva or other body fluid as appropriate for the specific detector unit input. Together, memory for detector unit 12 and signaling unit 16 will contain instructions appropriate for operation of the patient device in accordance with the various method embodiments described herein.

[0038] In some circumstances, a prompt to test may have to be ignored for reasons not considered noncompliant due to the patient being engaged in an activity that prevents testing, such as exercise, work, driving, etc. A means by which to delay testing in response to a prompt, such as “snooze button” 19 may be incorporated. For example, if a patient is driving a vehicle, they may push button 19 to activate a preset interval until the test is again requested. A certain number of delays may be permitted each day, with this number being set by the provider or patient in the program.

[0039] Signaling unit 16 may also include means permitting the patient to input information that the patient believes relevant to his or her condition without prompting. Such information may, for example, include information about the patient’s state of mind, that is feeling stressed or anxious. Such unprompted information could then be correlated to a biological input based on a predetermined algorithm, such as being associated with the biological input that is closest in time to the unprompted input, or associated with the first biological input occurring after the unprompted input.

[0040] In one exemplary embodiment of patient device 10, detector and signaling units 12, 16 are combined and exist in an entirely portable configuration with battery power. Such embodiments may also be provided with network connection capability (WI-FI, wireless cell, RF, etc.) as described in greater detail below. For example, a PDA-like device that is able to both signal the patient as well as perform the expired gas analysis could be carried in the patient’s pocket at all times and improve compliance by the patient by allowing them to respond immediately to notifications.

[0041] In yet another exemplary embodiment, wherein detector unit 12 and signaling unit 16 are physically separate units, the signaling unit may be configured to be worn as a wristwatch or carried like a PDA. Likewise, the detector would be worn or carried, but separately. In any separate unit embodiment, the units are time synchronized or linked via a wireless communication link 20 to allow analysis of the time dependent data (linking of the notification and exhalation events).

[0042] In the example of a combined unit or wirelessly (or wired) connected units, either the detector or the signaling unit could act as the storage entity for the data utilizing its own internal memory. Alternatively, either could act as the sending unit to upload the data to a remote source for live tracking of patient data as described in more detail below. Data could be

uploaded immediately, intermittently or not at all. The data could also be downloaded from the storage media either by the patient or health care professional

[0043] In a further exemplary embodiment, as illustrated in FIG. 2, system 30 includes mobile patient devices 10 (including integrated detector and signaling units) and/or stand alone detector units 12 that communicate through network 32 with healthcare provider base station 34. Network 32 may comprise the Internet, a land-based or cellular telephone network or any other communications networks or combination of networks as appropriate for the particular patients and cessation program. Healthcare provider base station 34 may comprise a specially programmed personal computer in a doctor's office linked to communication network 32 through an appropriate communications bus or a specialized device including its own memory, processor and graphical user interface. Persons of ordinary skill in the art may configure and program base station 34 based on the teachings contained herein.

[0044] System 30 also may include fixed patient devices 36. Fixed patient devices may comprise substantially the same components as mobile patient devices 10 except that they are configured to be fixed at a particular location such as a patient's home, office or automobile. In addition, system 30 permits remote programming by the healthcare provider as appropriate for the particular patient and/or cessation program. An exemplary method for implantation of a cessation program utilizing system 30 is described in greater detail with reference to the flow chart of FIG. 3.

[0045] As illustrated in FIG. 3, system 30 may be preprogrammed to prompt the patient at specific times (step 40) and/or the healthcare provider (HCP) may randomly prompt the patient (step 42) when there is a concern that behavior is timed to avoid preprogrammed prompts. Alternatively the programmed prompts 40 may occur at random intervals as described in more detail below. For example, patient devices 10 may be programmed to be operational during prescribed hours (typically waking hours, for example from 6 am to 11 pm), although sleep hour function can be activated. The patient is prompted at various times throughout the day to exhale into the detector. The patient is instructed (step 44) with each prompt regarding how to properly and consistency perform the requested test. In one example of an algorithm for breath testing, the patient will take several full breaths in and out into the detector, followed by a deep test exhalation for the detector to analyze. A determination is then made (step 46) as to whether the patient has complied. Circumstances of non-compliance may also be determined (step 48). For example if device 10 determines that there was simply no attempt at compliance the patient may be re-instructed a set number of times (branch 50). However, after a predetermined number of re-instructions without compliance, the device simply may report a non-compliant episode (branch 52). Alternatively, if it is determined that the patient attempted to comply but compliance was incomplete (for example, does not exhale fully) then the test may be rejected and the patient instructed to repeat the test (branch 50).

[0046] When compliance is determined (branch 54), the sample is analyzed (step 56) according to the predetermined detector unit protocol. Marker substances, if present, may be quantified at each test interval if such analysis is included in the protocol. Each event may be reported (step 58), either in real time through network communications or via periodic downloads. To facilitate reporting and data logging, data regarding the qualitative (yes/no) values as well as the quan-

titative substance level may be stored within the detector in a memory unit such as a flash drive or disk. Alternatively, as mentioned, the unit may upload the data live via a cell connection or local network. Such upload may occur intermittently or immediately. Disk space may be freed up upon confirmation of successful upload, as needed. Reported events are analyzed (step 60), for example by being categorized as either negative or positive for the substance of interest based on a pre-determined threshold for positivity, and therefore negative or positive for the smoking behavior. The threshold for positivity may be set at standard levels derived from the scientific literature or may be adjusted by the healthcare professional to the specific needs of the patient. Such adjustments may occur in real time 62 based on data analysis and may include changes in the testing as well as prompting protocols.

[0047] If the patient fails to respond (fails to blow into the unit) within a certain period of time after receiving the signal to respond (for example, within 3 minutes although the time interval allowable for testing may be set at any preferred value), the event is interpreted as a failure and flagged in the database. Data analysis can interpret failed tests as being positive for smoking behavior or may omit the value entirely. The analysis tool is capable of variably dealing with such failed signals for testing. If considered positive for a smoking behavior, a positive quantitative value may be assigned to that data point. Such a design prevents the patient from gaining a benefit (logging a negative data point) by ignoring a signal if they were engaging in smoking at the time of the signal to test.

[0048] Programming necessary to implement the exemplary methodology illustrated in FIG. 3 may exist entirely within software or firmware resident in patient device 10, divided between detector unit 12 and signaling unit 16 as appropriate for the particular configuration of the device. Alternatively, such programming may at least in part reside in a server or other source associated with base station 34, communicating with patient devices 10 and 36 and/or detector unit 12 through communications network 32.

[0049] Regardless of the exact embodiment of the invention as a single unit (combined and integrated) or multiple units, an advantage of the present invention is that it may be specifically configured for individual patients so that the detector and signaling unit can be with the patient at all times. The patient is thus able to respond to a signaling notification within the allotted and permitted time interval (i.e., within about 2-10 minutes) at all times and may not use lack of availability as an excuse for noncompliance.

[0050] In one exemplary embodiment, the patent prompts are programmed to be intermittent and of varying intervals, so as not to be predictable. The frequency of prompting can vary throughout the day, and the pattern can be unpredictable and non-repeating, thus preventing the patient from predicting when they will be notified to blow into the detector or test saliva. Alternatively, or additionally, the healthcare provider may initiate additional prompts through network 32 when in appropriate circumstances. This unpredictability and variability prevents the patient from modifying the timing of their smoking behavior in such a manner so as to avoid detection of the smoking behavior or to minimize the quantitative result of the test. Further, the number of signaling events per day can vary, for example on one day twenty signals may be delivered, while on the next day only twelve are delivered. Variability can be important, for example, if the signaling unit notified the patient every hour on the hour, the smoker could smoke

three cigarettes immediately after the hour then avoid smoking for the remainder of the hour until prompted next. Presumably, during that hour-long interval of no smoking, the substance detected in expired gas or saliva might return to lower or even undetectable levels. To prevent the patient from predicting when the notification will occur, the notification schedule will be unpredictable and can be programmed in an infinite number of permutations based on frequency, number of notifications per day, max/min time between notifications, time allowed to respond, etc. Further, the pattern of notifications will not repeat itself on subsequent days, further making the pattern unpredictable and undefeatable.

[0051] Patient devices **10, 36** according to embodiments of the invention may be programmed to be active during wake hours only or may include sleep hours as well. In the former, the hours of operation are programmable based on healthcare provider choice and patient need. One example would be to have the unit active from 6 am to 12 midnight every day. Another example would be to have the unit be normally active during the waking hours with frequent notifications at unpredictable times, and then revert to an alternative schedule during sleep hours where only one or two signals occur at night. This would provide a modicum of aversion to smoking at night by the patient in an attempt to defeat the system, yet would not dramatically disrupt sleep patterns. Another alternative would be to have the system active twenty-four hours per day, and night time failed test events (no response by patient) be considered as sleep events and not counted against the patient as positive for the undesirable behavior.

EXAMPLE

[0052] The following is one example of a practical application of one embodiment of the invention. A patient is enrolled in a smoking cessation program and self-reports a certain amount of smoking behavior (number of cigarettes smoked per day) upon entry into the program (baseline smoking behavior). The patient completes the enrollment process and initial counseling visit with a healthcare professional. The patient begins NRT and is provided with mobile patient device **10** programmed to function between 6 am and 12 midnight each day. During the active daily interval, the signaling unit prompts the patient approximately twenty times each day to follow the provided instructions for how to perform exhalation testing with the detector unit. The detector unit may also provide displayed or audio instructions through the graphical user interface. The patient must comply within a predetermined time period (for example, within 3 minutes of notification) or else the event is considered a failure to respond. In the analysis of the data, this failure to respond can be treated as a positive smoking behavior event or can be ignored. In the example of carbon monoxide as the test substance, the level of CO (ppm) is recorded at each test instance. All data is logged and stored in the detector or signaling unit (or uploaded real time or intermittently) until downloaded to a software analysis program. Further, the user interface may prompt the patient to enter additional information about lifestyle events that occur during the day (meals, activity, sex, alcohol consumption, stress, travel, etc.) that can then be temporally correlated with smoking behavior as detected by the exhaled gas to draw conclusions about trigger events for smoking behavior. For example, after a test the detector unit may scroll through a number of potential scenarios for selection by the patient (i.e., did you have a meal in the last thirty minutes, did you have a drink in the last thirty minutes). If not

uploaded automatically through a communications network, then at the one-week visit, the healthcare provider downloads the data and uses a software program to analyze the data. Alternatively, the data was uploaded in advance of the visit obviating the need for download. A print out is provided which shows the daily notification times and the associated CO levels, as well as the missed or possibly faked responses. The analysis program is described further below, but there are several summary metrics which could be tracked to estimate the number of cigarettes smoked and the timing of peak substance in the bloodstream. Correlations are made between program interventions versus trends in smoking behavior over time. Correlations are also made between recorded lifestyle events and smoking behavior to allow improved counseling and drug therapy interventions. The printed analysis is provided to the patient for positive/negative feedback regarding their progress and response to therapy. Each week, this process is repeated, progress towards the goal of smoking cessation is tracked and medical therapy is adjusted according to the objective data in an optimized manner.

[0053] Analysis of the data can be performed in many different ways in various alternative embodiments. Once the data is uploaded or downloaded, many different metrics can be summarized and analyzed. Each day of use may have, for example, twenty test points for analysis. The timing and number of test points is variable and can be preprogrammed according to healthcare professional recommendation and needs. Each test point will have a yes/no, binary value, as well as a quantitative value. The yes/no value may have a role in determining if the patient is smoking "at all" and, if any tests are "yes", may provide some insight into how often during the day the patient is smoking. The quantitative value for each test interval, if positive, may provide additional information about how often the patient is smoking and trends towards abstinence. Also these trends can provide information about peaks of smoking during each day and week. CO levels in expired gas, for example, peak immediately after smoking a cigarette or series of cigarettes, and then gradually decline over time. A time vs. CO level could be plotted and a predictive algorithm created to estimate the number of cigarettes and time of smoking per day for each patient. A time vs. CO level plot for each test period (day, week, month, year) provides significant information to the healthcare provider regarding patient progress in a longer term program and allows alteration of therapy in an objective manner. Further, on the time vs. CO plot, data regarding administration of medication, changes in medication regimens over time, counseling interventions, etc. can be annotated and used to track effect of each intervention and dose change. Such data analysis functionality may be incorporated into patient devices **10, 36**, or may reside in healthcare provider base station **34**.

[0054] Another software analysis feature involves an interactive program that the patient engages within the interval between cessation program visits (for example, between biweekly program visits). Such a patient-interface could be used by persons who independently utilize this cessation system outside of a smoking cessation program. While the devices would be similar to the previously disclosed detector and signaling units, such an embodiment may include means by which the patient can upload the data on a regular basis to a local or remote source (or both) and follow their data on a regular basis for trends and feedback. As the data is uploaded and analyzed, the data is added to previously uploaded data and can be viewed by the patient and healthcare provider and

other authorized persons. The data can be displayed for any party in the same manner as it is displayed for the healthcare professional. Alternatively, unique, patient-friendly interactive displays can be provided for the patient so that they can track and observe their smoking behavior in a number of ways, including total number of days in the program, baseline smoking behavior compared to current smoking behavior, number of cigarettes avoided in last period of time, number of hours, days, months, and years of lifetime saved, time to goal of smoking cessation, daily results, weekly results, progress towards goal displayed numerically or graphically. Other metrics can also be tracked and correlated with smoking behavior results, such as blood pressure, heart rate, body weight, quality of life testing, stress level questionnaire results, and others. If viewed simultaneously by the qualified health care professional, prompts can be provided to the patient that are positive reinforcement about good behavior and improvements, alterations that may be made to drug therapy, observations about lifestyle events that may be precipitating smoking behavior, etc. Additionally, the patient can observe within the analysis program which lifestyle events may be impacting daily smoking behavior. Avoidance of these situations can then ensue.

[0055] In such a patient-centric interactive program, a series of questions could be levied each day (or more or less frequently) to the patient, which could be standardized or could be prompted by certain changes (improvement or worsening) in smoking behavior. For example, a patient may be asked at the end of each day to log in the analysis program the number of cigarettes smoked, blood pressure measurement, heart rate, quality of life scale questions, significant life event, etc. Results of these queries can be tracked overtime with the smoking behavior objective readings from the CO monitoring data. Such linkage of patient volunteered data as well as objective data and therapeutic intervention data are helpful for the patient and healthcare professional to tailor therapy optimally.

[0056] While exemplary embodiments of the invention are described above with a focus on smoking behaviors, examples of which include but are not limited to smoking of tobacco via cigarettes, pipes, cigars, and water pipes, and smoking of illegal products such as marijuana, cocaine, heroin, and alcohol related behaviors, it will be immediately apparent to those skilled in the art that the teachings of the present invention are equally applicable to any number of other undesired behaviors for which markers are present in the breath and/or saliva. Such other examples include: oral placement of certain substances, with specific examples including but not limited to placing chewing tobacco and snuff in the oral cavity, transdermal absorption of certain substances, with specific examples including but not limited to application on the skin of certain creams, ointments, gels, patches or other products that contain drugs of abuse, such as narcotics, and LSD, and nasal sniffing of drugs or substances of abuse, which includes but is not limited to sniffing cocaine. In general, the basic configuration of patient devices **10**, **36**, as well as the prompting, self-testing, data logging, feedback and other steps and methods as disclosed herein will be similar as between the different behaviors that are being addressed. However, detector unit **12** may differ somewhat in design only to account for different marker substances that are required for testing or different testing methodology necessitated by the different markers associated with particular undesired behaviors.

[0057] It will also be appreciated by persons of ordinary skill in the art that a patient participating in a formal cessation program may take advantage of the assistive devices, methods and systems disclosed herein as adjuncts to the cessation program. However, in alternative embodiments, it will be equally appreciated that the patient may be independently self-motivated and thus beneficially utilize the assistive devices, methods and systems for quitting the undesired behavior unilaterally, outside of a formal cessation program.

[0058] In further exemplary embodiments of the present invention, devices, systems and methods disclosed herein may be readily adapted to data collection and in particular to collection of reliable and verifiable data for studies related to undesired behaviors for which the present invention is well suited to test. Such studies may be accomplished with virtually no modification to the underlying device or methods except that where treatment was not included there would not necessarily be a need for updating of the test protocol or treatment protocol based on user inputs.

[0059] Exemplary embodiments have been disclosed above and illustrated in the accompanying drawings. It will be understood by those skilled in the art that various changes, omissions and additions may be made to that which is specifically disclosed herein without departing from the spirit and scope of the present invention.

What is claimed is:

1. A method for facilitating cessation of undesired behavior in a patient, comprising:
 - configuring a patient device with a predetermined test protocol including patient test prompts;
 - prompting the patient in accordance with said predetermined test protocol to provide at least one biological input to said patient device, the biological input being correlated to the undesired behavior;
 - analyzing said patient biological input to said patient device;
 - generating a machine readable data set representative of the patient input based on said analyzing;
 - associating said data set with a specific patient biological input;
 - evaluating the predetermined test protocol based on said data set; and
 - altering or maintaining the predetermined test protocol based on said evaluation.
2. The method of claim 1, further comprising determining whether the patient properly provided a biological input in response to said prompting; and re-prompting the patient to provide said at least one biological input when said determining result is negative.
3. The method of claim 1, wherein said altering comprises remotely reconfiguring the test protocol in the patient device through a communications network.
4. The method of claim 1, further comprising:
 - prompting the patient to input requested information to said patient device through a user interface; and
 - associating the requested information with the data set associated with a specific patient biological input.
5. The method of claim 4, wherein said evaluating is additionally based on the requested information associated with said data set.
6. The method of claim 4, further comprising transmitting said data set and associated requested information to a health care provider device.

7. The method of claim 3, further comprising:
communicating with the patient device through a network;
and
prompting the patient to provide at least one biological input outside of the predetermined test protocol.
8. The method of claim 3, further comprising displaying said data set and associated requested information on a healthcare provider device.
9. The method of claim 1, further comprising:
collecting data related to the patient undesired behavior;
and
analyzing said patient behavior data to determine the predetermined test protocol.
10. The method as in claim 9, wherein the predetermined test protocol includes one at least one of the following parameters: active period during day, type of signal, number of prompts per day, variability of number of prompts each day, min/max prompts per day, characterization of night time prompts, ability to defer prompts due to other activities, manner in which deferred prompts are handled and grouping of prompts during the day.
11. The method of claim 1, further comprising:
determining patient compliance in response to said prompting; and
re-prompting the patient if non-compliance determined.
12. The method of claim 11, further comprising:
permitting the patient to delay a biological input in response to said prompting for a set time period; and
re-prompting the patient after said set time period
13. The method of claim 1, wherein:
the test protocol comprises a part of a patient treatment protocol;
said evaluating further comprises evaluating the treatment protocol; and
said altering or maintaining comprises altering or maintaining the treatment protocol.
14. The method of claim 11, wherein said treatment protocol comprises a course of therapy to facilitate cessation of the undesired behavior based at least in part on biological inputs from the patient device.
15. The method of claim 1, wherein said prompting comprises at least one of instructing the patient to place a disposable strip or a portion of the patient device in the oral cavity, and/or to blow into an inlet in the patient device.
16. The method of claim 15, wherein said prompting further comprises instructing the patient to place the test strip in a test receptacle in said patient device.
17. The method of claim 1, further comprising linking the patient device with a health care provider device comprises intermittently by direct connection or by intermittent network connection for synchronizing said devices.
18. The method of claim 1, further comprising providing communication between said patient device and a health care provider device through a network.
19. The method of claim 18, wherein said communication is provided in real time, wherein each biological input associated data set is uploaded to the healthcare provider device upon acquisition.
20. The method of claim 18, further comprising providing feedback to the patient through said health care provider device communication with the patient device.
21. The method of claim 4, wherein said requested information comprises information regarding patient life events temporally associated with select test protocol events.
22. The method of claim 4, wherein said requested information comprises at least one of blood pressure, quality of life scores, voluntary behavior reporting, quality of life survey questions, body weight, current drug therapy dosing, blood, and heart rate.
23. The method of claim 8, further comprising displaying trend data, including at least one of a total number of days in the program, baseline smoking behavior compared to current smoking behavior, number of cigarettes avoided in last period of time, number of hours, days, months, and years of lifetime saved, time to goal of smoking cessation, daily results, weekly results, progress towards goal displayed numerically or graphically.
24. A system for facilitating cessation of undesired behavior in a patient, comprising:
a patient device (PD) configured and dimensioned to be carried by the patient, the patient device comprising:
a PD user interface,
a test element configured to receive a biological input from the patient and output information representative of the content of the biological input,
PD storage module containing instructions for a predetermined test protocol, comprising:
prompting the patient through the user interface to provide a biological input to the test element at selected intervals,
determining the completeness of a biological input,
and
providing additional patient prompts based on said completeness determination, and
PD execution module communicating with the user interface, the test element and the storage module, the PD execution module configured to execute instructions contained in said PD storage module; and
a health care provider device (HCPD) configured to be accessed by a health care provider, comprising
an HCPD user interface,
HCPD storage module containing instructions for displaying and manipulating information representative of the content of the biological input, and
revising the predetermined test protocol based on at least one of user input and said information representative of the content of the biological input, and
HCPD execution module communicating with the user interface and storage module, the execution module configured to execute instructions contained in said HCPD storage module,
wherein said patient device and healthcare provider device are configured for communication there between.
25. The system of claim 24, wherein one of the PD or HCPD storage modules contains instructions for generating a machine readable data set based on said test element output information, and for associating said data set with a specific patient biological input.
26. The system of claim 25, wherein one of the PD or HCPD storage module contains instructions for causing the patient device to prompt the patient to input requested information to said patient device through the PD user input and for associating the requested information with a data set associated with a specific patient biological input.
27. The system of claim 24, wherein the test element comprises a detector configured to detect substances in exhaled breath.

28. The system of claim 1, wherein the test element comprises a detector configured to detect substances in saliva.

29. The system of claim 1, wherein the patient device and healthcare provider device are configured for communication through a network.

30. The system of claim 29, wherein the network is a telephone network.

31. The system of claim 29, wherein the network is a computer network.

32. The system of claim 29, wherein the network is the Internet.

33. The system of claim 24, wherein the patient device and health care provider device are configured for communication through a transferrable storage medium.

34. The system of claim 24, wherein the patient device and health care provider device are configured for communication through a direct wired connection.

35. The system of claim 24, further comprising plural said patient devices configured to communicate with at least one said health care provider device.

36. The system of claim 1, wherein the PD storage module further includes instructions for delaying said determining the completeness of biological input for a set period in response to a patient input through the PD user interface.

37. The system of claim 24, wherein:

the patient device further comprises an identification device for acquiring patient identifying information correlated to a biological input; and

said identification device communicating with said storage module and execution module for associating the acquired identifying information with the correlated biological input and storing said associated identifying information.

38. The system of claim 24, wherein the PD storage module further includes instructions for receiving unprompted patient input through the PD user input and for associating said unprompted input with a biological input based on a predetermined algorithm.

39. The system of claim 24, wherein said patient device is contained within a housing.

40. The system of claim 24, wherein said patient device comprises at least two housings, with the test element disposed in one housing and the user interface disposed in a separate housing, and wherein said test element and user interface are configured for wireless communication there between.

41. The system of claim 24, wherein said test element is configured for detecting one or more substances associated with smoking tobacco products.

42. The system of claim 24, wherein said test element is configured for detecting one or more substances associated with smoking of illegal drugs.

43. The system of claim 24, wherein said test element is configured for detecting alcohol.

44. The system of claim 24, wherein the test element is configured for detecting substances associated with oral ingestion or transdermal absorption of specified compounds.

45. The system of claim 44, wherein said specified compounds include one of molecules related to benzodiazepines, narcotics, LSD, GHB, Rohypnol, ketamine, methamphetamine, PCP/phencyclidine, anabolic steroids, and secreted or exhaled metabolites of said substances.

46. The system of claim 24, wherein the test element is configured for detecting one or more substances associated with oral placement of products.

47. The system of claim 24, wherein the test element is configured for detecting one or more substances associated with nasal sniffing of substances of abuse.

48. An apparatus for use in connection with facilitating cessation of undesired behavior in a patient, comprising:

at least one housing configured and dimensioned to be carried by the patient;

a user interface disposed in said at least one housing;

a test element disposed in said at least one housing, the test element being configured to receive a biological input from the patient and output information representative of the content of the biological input,

a storage module containing instructions comprising:

a) executing a predetermined test protocol including,

1) prompting the patient through the user interface to provide a biological input to the test element at selected intervals,

2) determining the completeness of a biological input,

3) providing additional patient biological input prompts based on said completeness determination,

4) prompting the patient to input requested information through said user interface,

b) generating user readable indicator based on said test element output and displaying said output on the user interface,

c) associating the user readable indicator with a specific biological input,

d) associating the requested information with a specific user readable indicator associated with a specific patient biological input, and

e) storing test result information including the user readable indicator and associated requested information in said storage module; and

an execution module communicating with the user interface, the test element and the storage module, the execution module configured to execute said instructions, wherein said apparatus is configured to communicate through a network for transfer of said test result information.

49. The apparatus of claim 48, wherein the storage module further includes instructions for delaying said determining the completeness of biological input for a set period in response to a patient input through the user interface.

50. The system of claim 49, further comprising an identification device for acquiring patient identifying information correlated to a biological input, said identification device communicating with said storage module and execution module for associating the acquired identifying information with the correlated biological input and storing said associated identifying information.

51. The apparatus of claim 48, wherein said apparatus comprises a single housing.

52. The apparatus of claim 48, wherein said apparatus comprises two housings with the test element disposed in a first housing and said user interface, storage module and execution module disposed in a second housing, said test element and execution module being configured for wireless communication there between.

53. A method for collecting and confirming patient participation in select behaviors, comprising:

configuring a patient device with a predetermined test protocol including patient test prompts;

prompting the patient in accordance with said predetermined test protocol to provide at least one biological input to said patient device, the biological input being correlated to the select behavior;

determining whether the patient properly provided a biological input in response to said prompting;

re-prompting the patient to provide said at least one biological input when said determining result is negative;

analyzing said patient biological input to said patient device;

generating a machine readable data set representative of the patient input based on said analyzing;

associating said data set with a specific patient biological input;

prompting the patient to input requested information to said patient device through a user interface;

associating the requested information with the data set associated with a specific patient biological input;

evaluating the predetermined test protocol based on said data set and the requested information associated with said data set.

54. The method of claim **53**, further comprising:

transmitting said data set and associated requested information to a health care provider device; and

displaying said data set and associated requested information on a healthcare provider device.

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专利名称(译)	用于促进停止不良行为的体外装置和方法		
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[标]申请(专利权)人(译)	厄特利DAVID SCOTT 厄特利JACK DENTON 厄特利KATHRYN MARY 阿列克厄特利DENTON 厄特利HALEY GRACE 厄特利MACKENZIE TAYLOR 厄特利EMMA KATHRYN		
申请(专利权)人(译)	厄特利, DAVID SCOTT 厄特利, JACK DENTON 厄特利凯瑟琳MARY 厄特利, 阿列克DENTON 厄特利海利GRACE 厄特利, MACKENZIE TAYLOR 厄特利, EMMA KATHRYN		
[标]发明人	UTLEY DAVID SCOTT UTLEY JACK DENTON UTLEY KATHRYN MARY UTLEY ALEK DENTON UTLEY HALEY GRACE UTLEY MACKENZIE TAYLOR UTLEY EMMA KATHRYN		
发明人	UTLEY, DAVID SCOTT UTLEY, JACK DENTON UTLEY, KATHRYN MARY UTLEY, ALEK DENTON UTLEY, HALEY GRACE UTLEY, MACKENZIE TAYLOR UTLEY, EMMA KATHRYN		
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摘要(译)

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