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(54) **PERSONAL COMPUTER BREATH ANALYZER FOR HEALTH-RELATED BEHAVIOR MODIFICATION AND METHOD**

Publication Classification

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(57) **ABSTRACT**

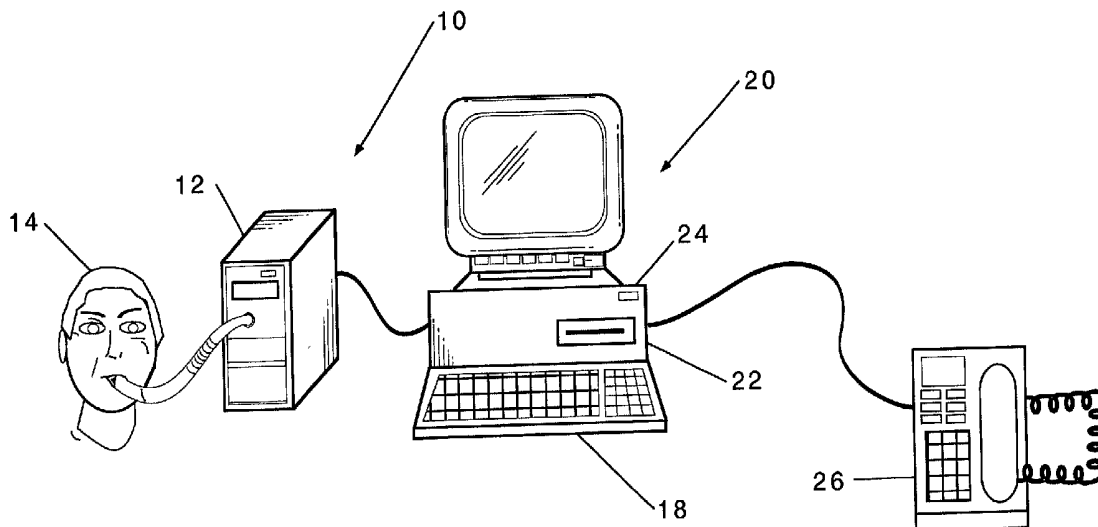
A medical breath component analyzer which maintains a data-base profile of a patient over time. The apparatus may be used chronically by a patient so that a baseline status for that patient may be determined. Acute variations from the baseline are identified as clinically significant. The acquired data can be reported to the patient using the device at home and transmitted electronically to a physician or health care provider. Multiple tests may be provided, ranging from quantitative tests to qualitative tests to quantitative approximations using qualitative devices. A set of tests is selected for a particular patient, and may be customized to the patient's condition. One of the tests may include passing multiple laser beams of differing wavelengths through a breath sample and using pattern recognition to correlate from spectral analysis of all the laser beams.

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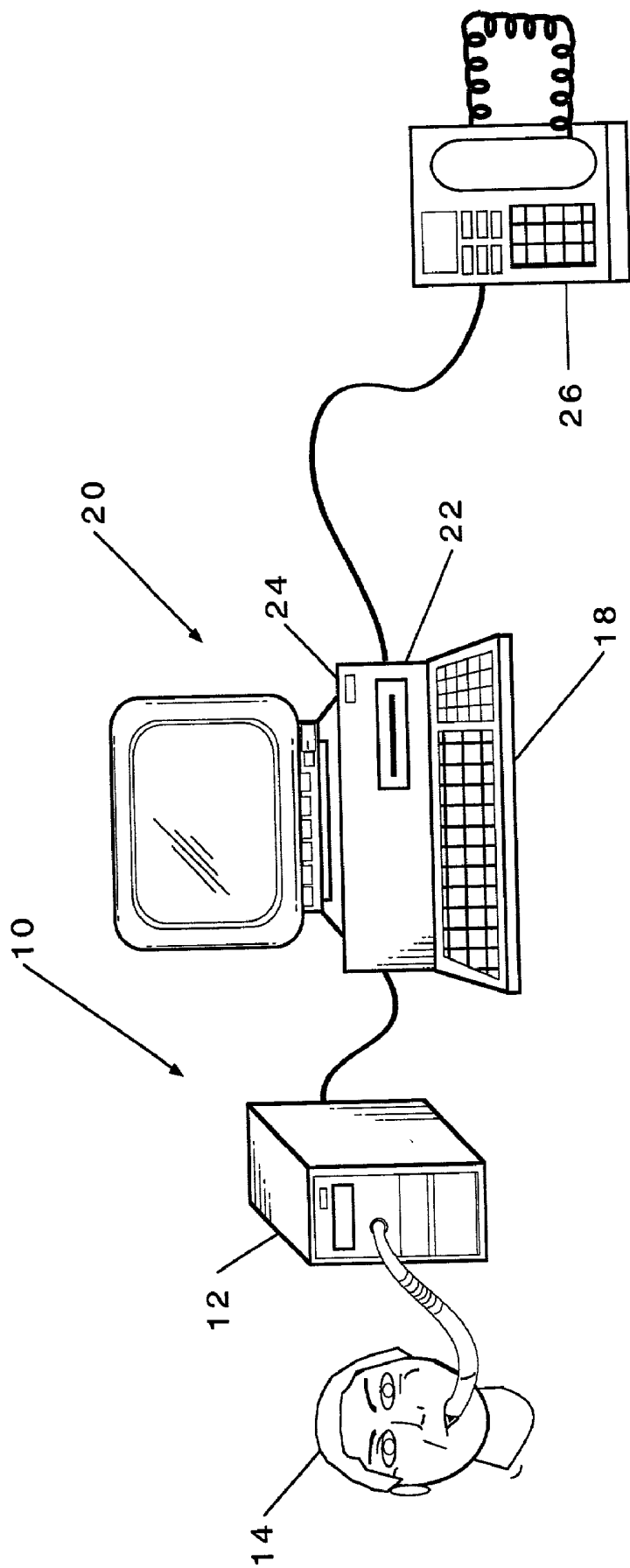


Fig. 1

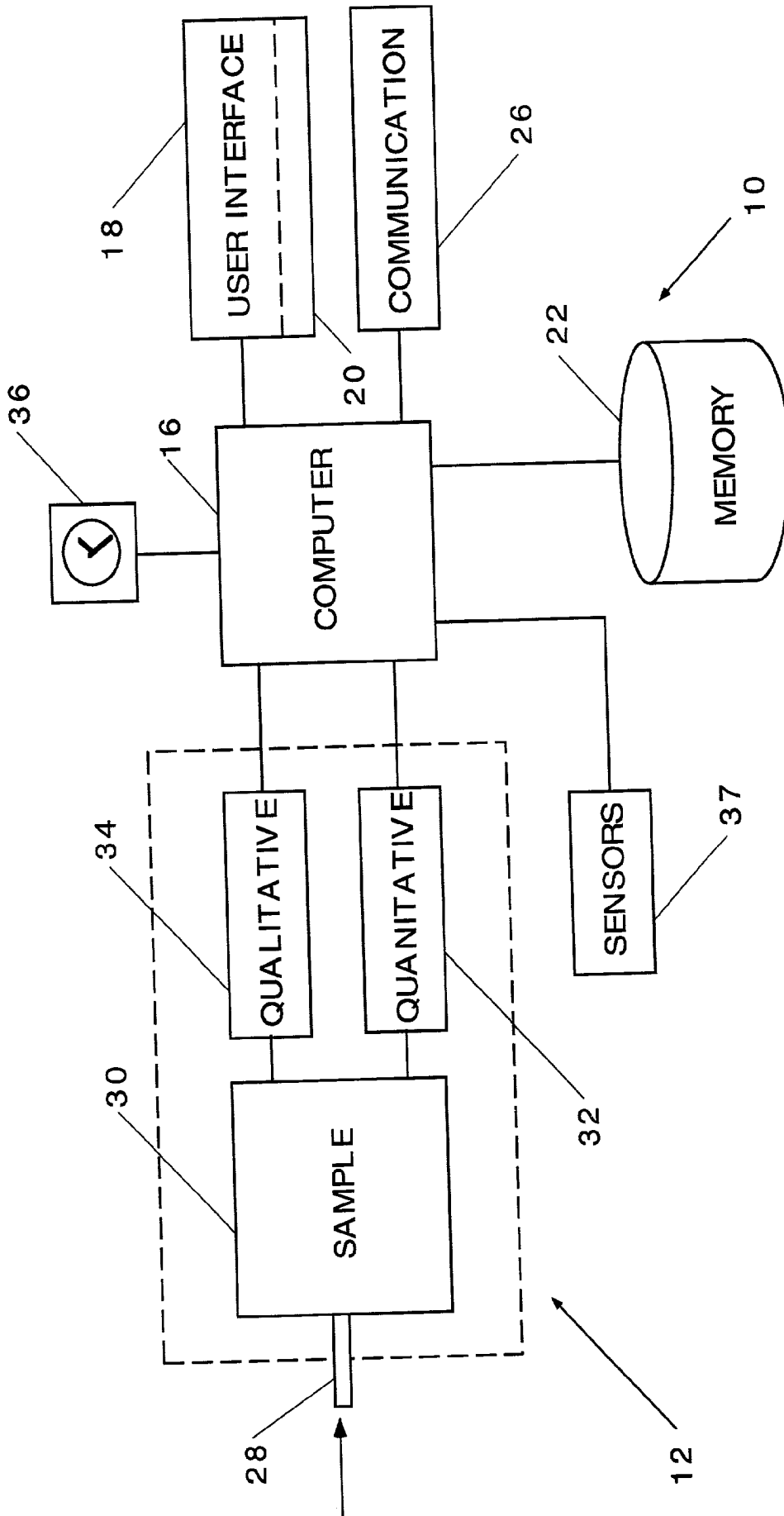


Fig. 2

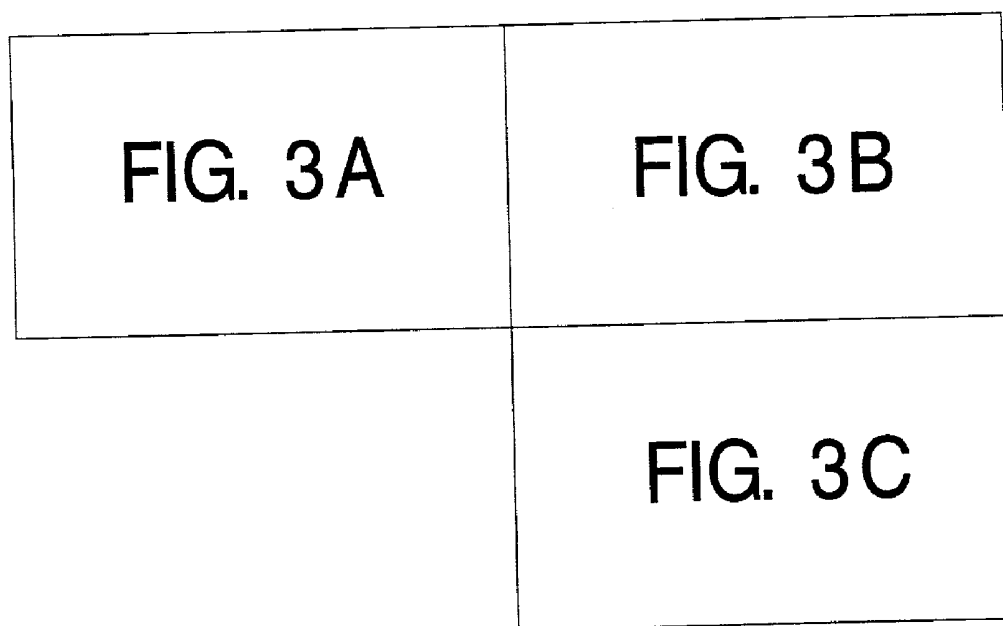
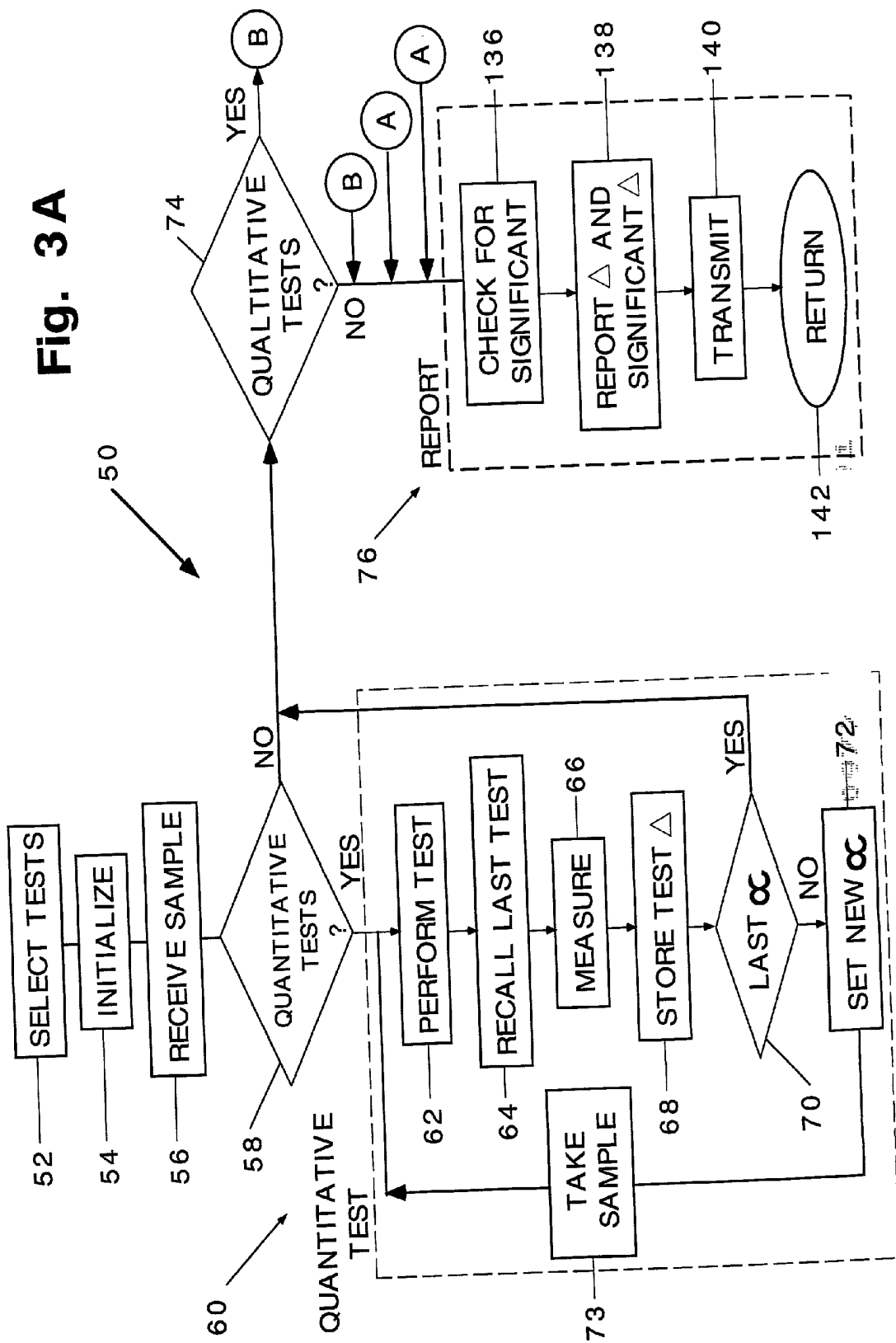


Fig. 3

Fig. 3A



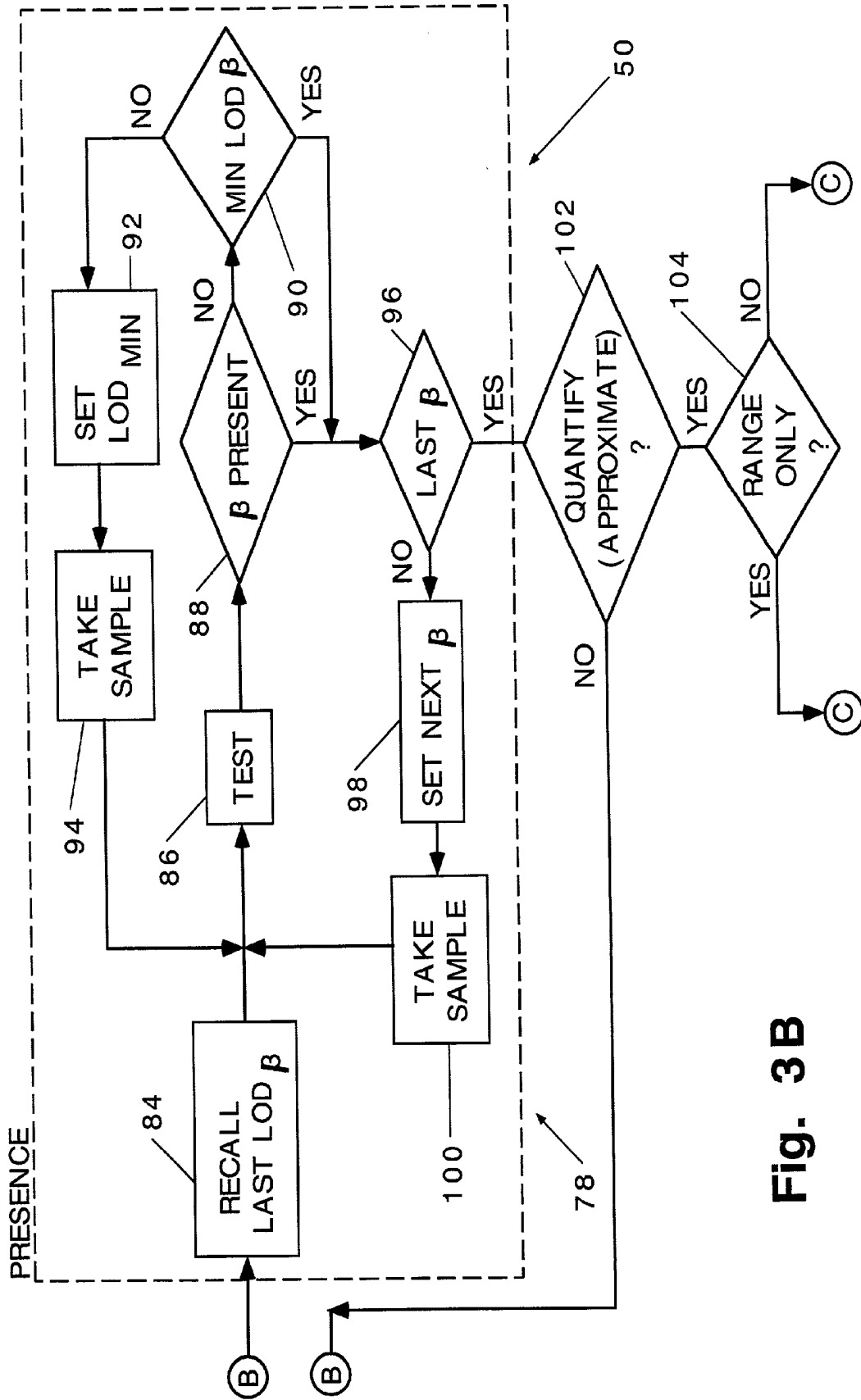
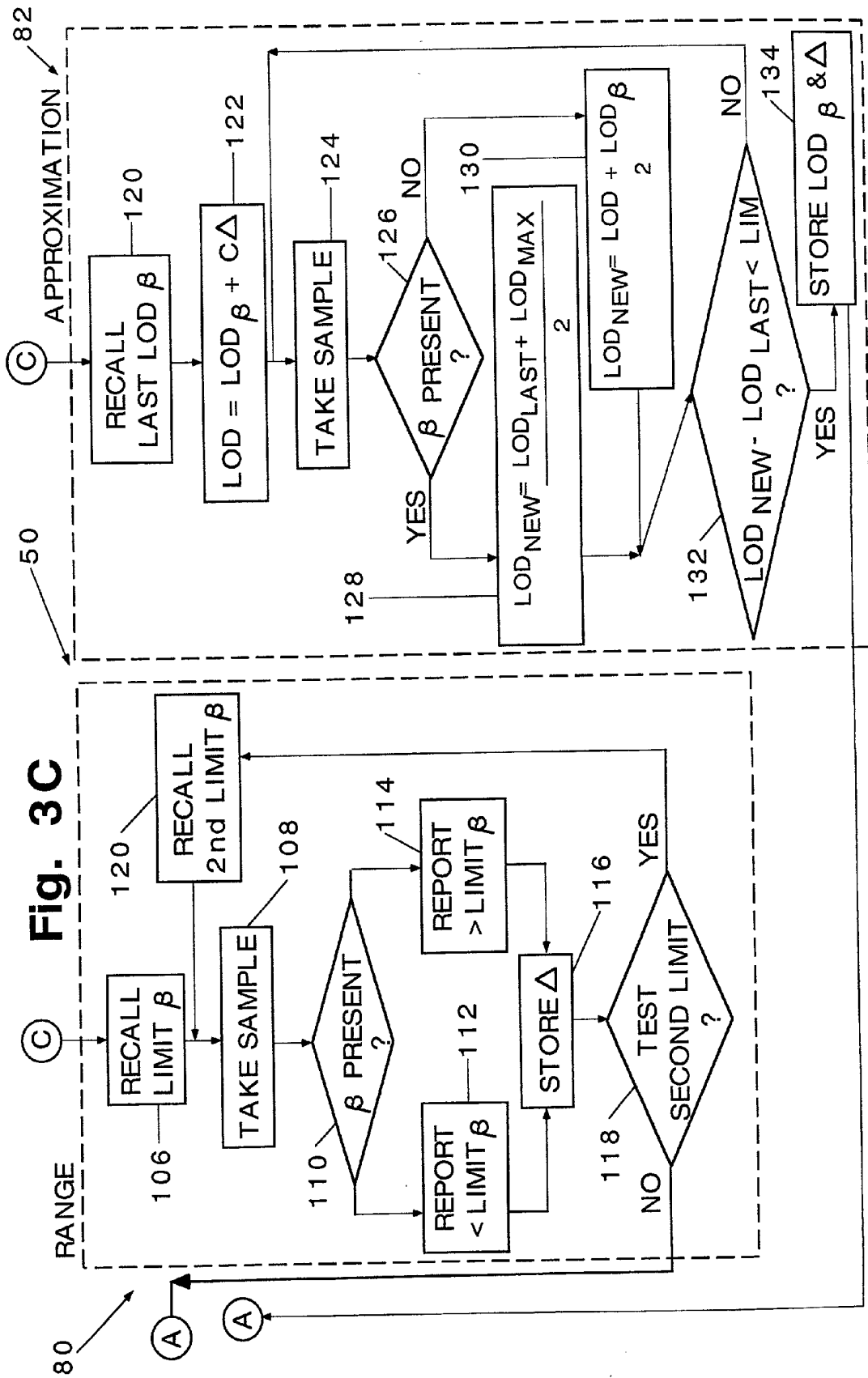


Fig. 3B



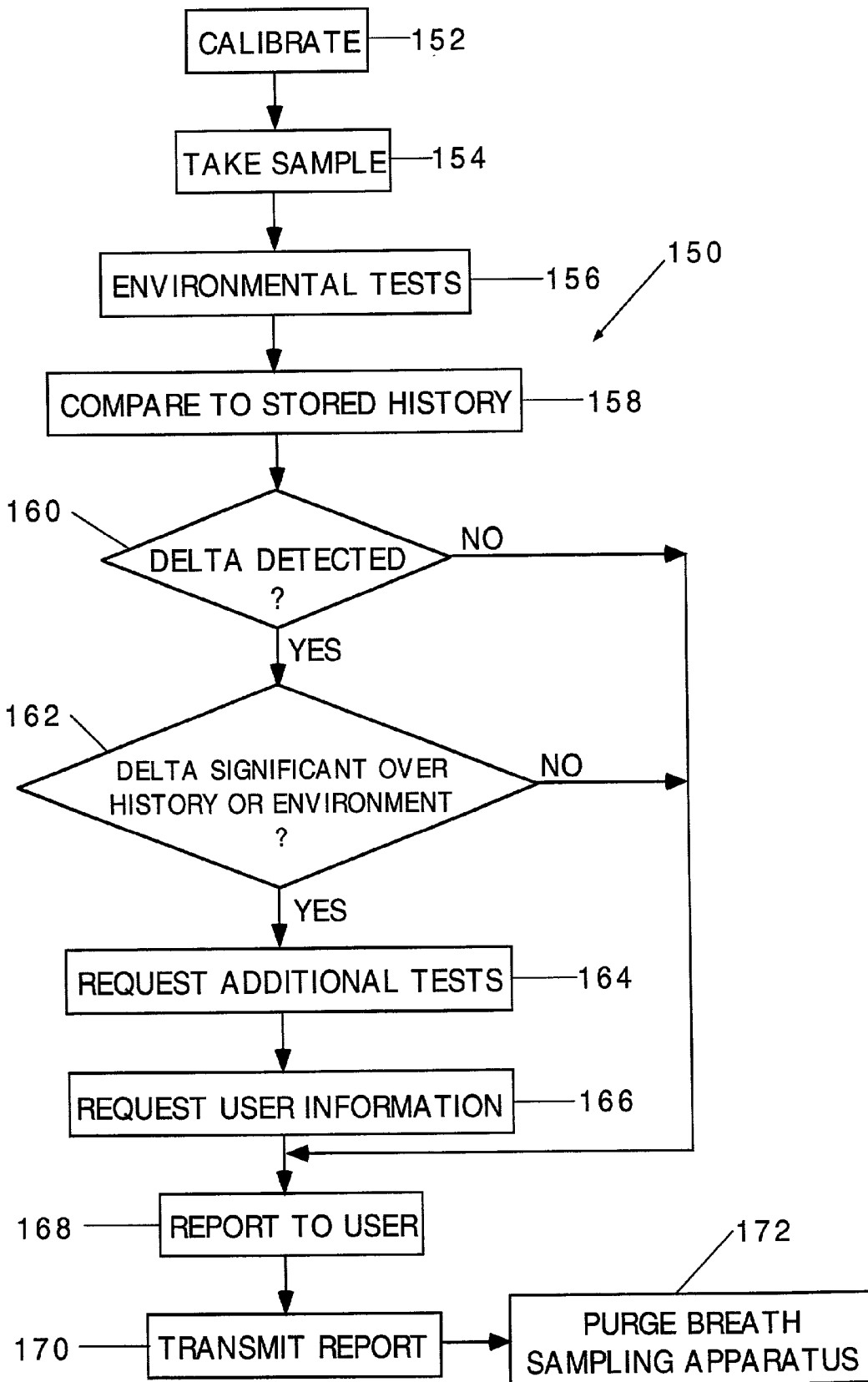


Fig. 4

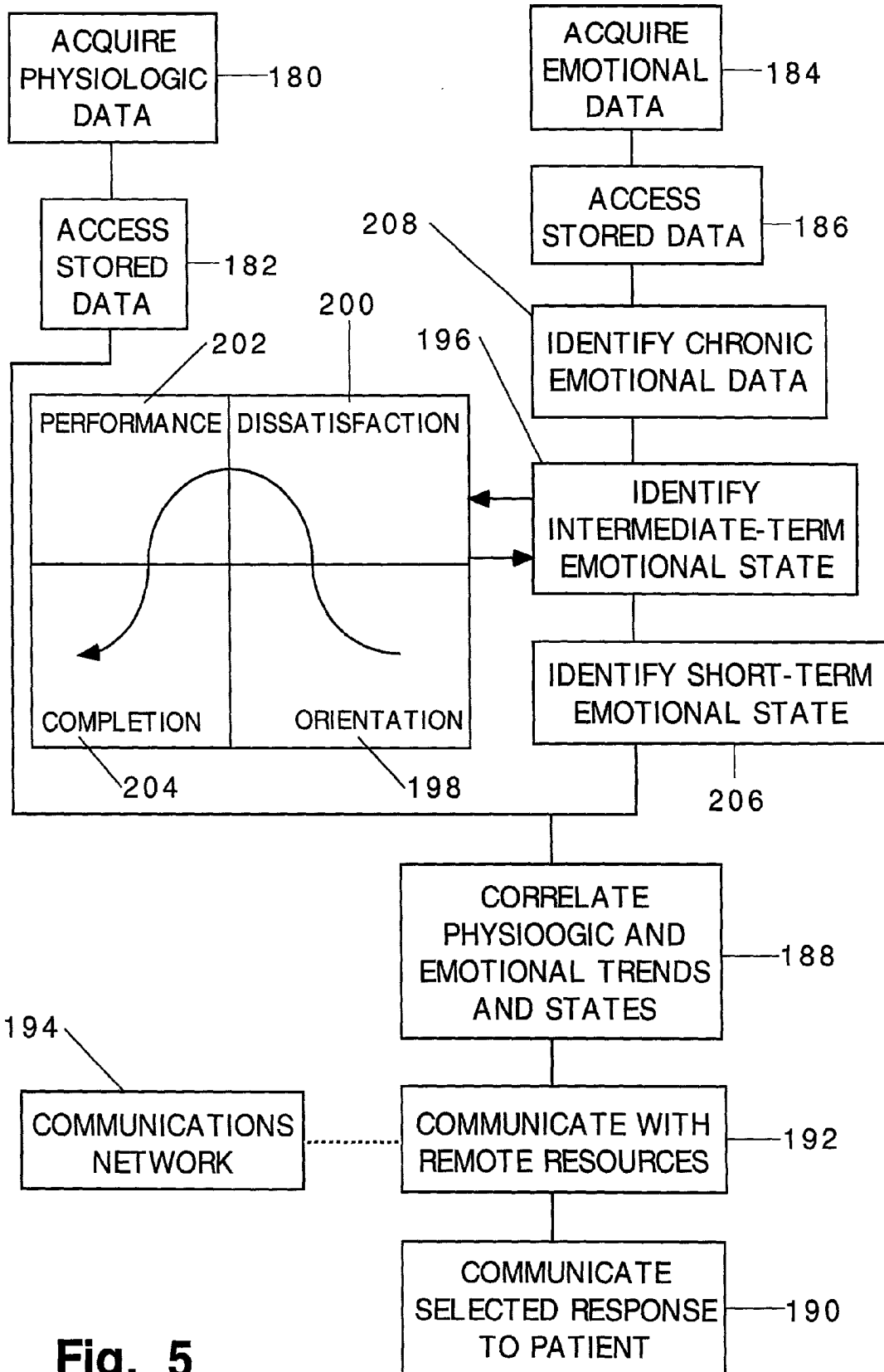


Fig. 5

**PERSONAL COMPUTER BREATH ANALYZER
FOR HEALTH-RELATED BEHAVIOR
MODIFICATION AND METHOD**

**CROSS REFERENCE TO RELATED
APPLICATION**

[0001] This Application dais the benefit of U.S. Provisional Application No. 60/184,039 filed Feb. 22, 2000

[0002] This invention relates generally to medical apparatus and in particular to apparatus for analyzing medically significant components in exhaled breath.

BACKGROUND OF THE INVENTION

[0003] The potential for the use of exhaled breath as a diagnostic tool has long been recognized. Hypocrites taught the physician to be aware of the smell of the patient's breath, as a clue to the patient's condition. In 1784 Antoine Lavoisier and Pierre Laplace analyzed breath of a guinea pig, finding that an animal inhales oxygen and expires carbon dioxide. This was the first direct evidence that the body uses a combustion process to obtain energy from food. Since that time, as many as 200 compounds have been detected in human breath, some of which have been correlated with various diseases.

[0004] Detection apparatus for breath components employ varying technologies. Infrared light has been used to measure breath alcohol content by Bowlds U.S. Pat. No. 5,422, 485 and Paz U.S. Pat. No. 5,515,859. Sauke et al. U.S. Pat. No. 5,543,621 used a laser diode spectrometer. Other types of lasers and absorption spectrosopes have been used including cavity-ringdown spectroscopy. See, for example, "Absorption Spectrosopes: From Early Beginnings to Cavity-Ringdown Spectroscopy" B. A. Paldus and R. N. Zare, American Chemical Society Symp. Ser. (1999), Number 720, pp. 49-70. Other techniques include direct head space analysis, gas-liquid chromatography, atmospheric pressure ionization mass spectrometry, tandem mass spectrometry and chemical methods. See, for example., "The Diagnostic Potential of Breath Analysis", Antony Manolis, Clinical Chemistry, 29/1 (1983) pp. 5-15. Among the chemical sensors are so-called electronic noses, which rely on patterns of physical or chemical characteristics to identify components. Such sensors are commercially available from Cyrano Sciences, Pasadena, Calif., for example, and their use in detecting medical conditions such as pneumonia, halitosis and malignant melanoma has been suggested.

[0005] Many of these technologies are complex, expensive and difficult to calibrate. They have not been economically adapted for individual health care use. It has been suggested, however, that self-administered breath alcohol tests could be used (See, Brown et al. U.S. Pat. No. 5,303, 575) by multiple individuals at bars or other locations where alcoholic beverages are served to detect a predetermined level of breath alcohol.

SUMMARY OF THE INVENTION

[0006] To overcome the difficulties of calibration, patient-to-patient variation, and other problems, we have invented a medical breath-component analyzer, which maintains a database profile of a patient over time. It is intended that our invention be used chronically by a patient so that a baseline

status for that patient may be determined. Acute variations from baseline are identified as clinically significant. The acquired data can be reported to the patient using the device at home and transmitted electronically to a physician or health care provider. Multiple tests may be provided, including quantitative tests, qualitative tests, and quantitative approximations using qualitative devices. In particular, laser spectroscopy with multiple lasers having different output characteristics may be used on a single breath sample. The merged output of the plurality of lasers can form a template or pattern, characteristic of a particular patient, whereby complex conditions may be more easily recognized. A set of tests is selected for a particular patient, and may be customized to the patient's condition. If a change in condition is detected, additional environmental and user-supplied information may be acquired to determine if a change is clinically significant.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] **FIG. 1** is a perspective drawing of a diagnostic breath analysis system according to the present invention.

[0008] **FIG. 2** is a block diagram of the system of **FIG. 1**.

[0009] **FIG. 3** is a drawing showing the relationship of **FIG. 3A**, **FIG. 3B** and **FIG. 3C**.

[0010] **FIG. 3A** is a portion of a flowchart for the system of **FIG. 1**.

[0011] **FIG. 3B** is an additional portion of the flowchart for the system of **FIG. 1**.

[0012] **FIG. 3C** is a final portion of the flowchart for the system of **FIG. 1**.

[0013] **FIG. 4** is an additional flowchart including use of the system of **FIG. 1**.

**DETAILED DESCRIPTION OF THE
INVENTION**

[0014] We will now describe our invention in connection with the accompanying figures, wherein like numerals are used to designate like parts in each drawing. **FIG. 1** illustrates a diagnostic breath analysis system **10** according to our invention. The system comprises an analysis unit **12**, which receives a breath sample from a patient **14** and provides quantitative and qualitative analysis of that sample as will be more fully explained below. Analysis of breath samples for diagnostic purposes has the advantage that the sample is collected non-invasively with a minimum of discomfort or inconvenience. The data resulting from the analysis is transferred to and stored in a computer **16**, preferably a microcomputer having an input device or devices **18**, such as a keyboard or mouse, an output device **20** such as a video monitor, printer, or other means of displaying data, memory **22** and an appropriate CPU **24**. The computer **16** is preferably connected to an information grid **26** such as a telephone system or the Internet.

[0015] The basic components of the breath analysis system **10** can be further understood with reference to **FIG. 2**. The breath analyzer **12** comprises a mouthpiece **28** connected to a sampling device **30**. The sampling device **30** captures a portion of the patient's exhaled breath, preferably alveolar breath from deep within the lungs. The first part of exhaled breath usually contains "dead space" air, that is, air

from the upper airways such as the trachea, mouth and nasal cavities. Dead space air does not contain many of the components that are of interest in making a diagnosis. In general, the first 150 ml of expiration is dead space air. About 500 ml is exhaled in each breath. About ninety percent of the breath is nitrogen and oxygen. The breath sample may be captured in a chamber or in a trap or both, depending on the apparatus employed for qualitative and quantitative analysis of the sample. Generally, traps fall into three categories: chemical, cryogenic, and adsorptive.

[0016] It is important that the sample be representative of the breath of the user, and not contaminated by other influences. The system **10** should be calibrated from time to time. This may be done by injecting a gas of known composition into the sampling device. A gas-filled canister may be provided for this purpose. It is also important to purge the sampling device after use to discharge excess moisture or other components. This can also be accomplished by the injection of a gas and the two functions of calibration and purging may be performed in a single step. Certain types of analyzers are more stable and require less calibration than others. Cavity ring-down spectroscopy, for example, may require reference or "zero" calibration, but will remain stable unless the associated laser or cavity is changed.

[0017] Although calibration is important, our invention reduces reliance on absolute standards by maintaining the patient profile or history. Thus a particular patient will usually be able to provide a consistent volume of breath for a sample. The volume will vary from patient to patient, but because records are maintained for the patient, the criticality of sample volume and other repetitive or consistent background factors (for example, air quality) is reduced or removed. Such features contribute to the usefulness of the apparatus in, for example, individual homes where each family member would develop their own profile by entering identifying information into the computer in connection with providing a sample.

[0018] Certain portions of the sample are processed in a quantitative analyzer **32**. Quantitative analyzers may include laser spectroscopic devices, cavity ring down spectrometers and even certain electronic nose sensor arrays capable of performing quantitative measurements. Electronic nose sensor systems may be based on several different types of solid state sensor elements, the most sensitive of which are polymer-coated surface acoustic wave ("SAW") oscillators that operate in the 100 megahertz range. Each element can easily sense as little as a femtogram (10^{-15} gram) of absorbed mass. Upon exposure to vapor-phase samples, patterns of change in the masses of these elements are then seen as frequency shifts and interpreted by signal processing networks. These "neural networks" are computational layers of signal processing that compare these patterns to known responses characteristic of the target vapors "learned" in prior exposures to known compounds. The system then reports the result, usually along with statistical significance, or probability of correctness. The advantages of the electronic nose sensor include compactness and low cost due to an absence of moving parts. Improvements in on-chip memory capacities and signal processing speeds contribute to the usefulness of electronic nose sensor arrays for tracking vapors.

[0019] A qualitative analyzer **34** may also be provided. Electronic nose sensor arrays may be also used in a qualitative configuration. Other possibilities include ion mobility spectrometer detectors, acoustic wave detectors, and fiber optic detectors. Processed data from both the quantitative analyzer **32** and the qualitative analyzer **34** are stored in memory **22** of the computer **16**. Preferably both quantitative and qualitative analyzers may be based on solid-state technology with consideration for reliability, accuracy and cost.

[0020] In our invention, data from a particular patient is stored so that multiple samples over an extended period of time may be taken. This permits a baseline to be established for a particular patient, and trend analysis can be performed on the resulting data. If there is an acute and significant change in the chronic condition of the patient's breath, indications of this change may be sent by communications **26** to a physician or healthcare provider. It is important, therefore, that the patient **14** be identified through the user interface such as the keyboard **18**. Moreover, a clock **36** should be provided and connected to the computer **16**. Quartz crystal-based real-time clocks are common features of personal computers. The computer **16** should distinguish between multiple samples taken during a single session of data acquisition and multiple sessions of data acquisition that occur over an extended period of time, for instance, days, weeks, or months. The rate of change of the components of the breath over time is important in determining if a change in the patient's health, diet, or other condition has occurred. Additional sensors **37** may also be provided. These sensors may include an environmental thermometer, a barometer, a hygrometer, or other sensors for determining the condition in which the sample is given. The sensors may also include additional patient sensors, such as a patient thermometer, heart rate or blood pressure sensors. The output from the sensors **37** would be stored with the data obtained from the breath analysis and might also be used to determine if a particular change in breath components were significant or not.

[0021] Processing of the sample by the analysis unit **12** and the computer **16** can be further understood in connection with the flowchart as illustrated in FIGS. **3A**, **3B**, and **3C**. FIG. **3** shows the relationship of FIGS. **3A**, **3B**, and **3C** to each other. The combined FIGS. illustrate a process system **50** for analyzing a patient's breath. Initially, the system **50** should be customized for the particular patient by selecting the tests **52** to be employed, as shown in FIG. **3A**. Tests may also be added to or removed from the profile for a particular patient at any time during the use of the apparatus, particularly in response to changes in the patient's condition or for other reasons. The types of tests that may be employed include carbon dioxide content, breath temperature, alcohol, lipid degradation products, aromatic compounds, thio compounds, ammonia and amines or halogenated compounds. As an example of the usefulness of detecting these components, lipid degradation products such as breath acetone are useful in monitoring diabetes. Thio compounds such as methanethiol, ethanethiol, or dimethyl sulfides have diagnostic significance in the detecting widely differing conditions, such as psoriasis and ovulation. Increased ammonia has been associated with hepatic disease. Halogenated compounds may be indicative of environmental or industrial pollutants.

[0022] Another set of tests may be based on analysis of certain breath components after the patient has taken a diagnostic reagent, in accordance with instructions from a physician. For example, urea, especially C^{13} labeled urea, or C^{13} labeled carbohydrates may be taken orally and the C^{13} -based CO_2 analyzed in the exhaled breath to determine if the patient has *heliobacter pylori* infection of the stomach lining (urea $\Rightarrow NH_3$ and CO_2) or carbohydrate malabsorption, glucose intolerance, lactase deficiency or small bowel bacterial overgrowth. Carbon 13 isotopes can be differentiated by laser spectroscopy. See, for example., G. B. U.S. Pat. No. 2,218,514. As explained hereafter (step 140), the resulting data would be transmitted to the attending physician for appropriate action.

[0023] With particular tests selected for the patient, the system would be initialized 54 to begin to build a baseline or chronic breath condition history for a particular patient. Both during initialization and thereafter, as tests are taken over an extended period of time, a sample would be received from the patient at step 56. The microprocessor 16 determines if quantitative tests 58 have been selected for this particular patient. If quantitative tests have been selected, a quantitative test segment 60 would be performed. Quantitative tests are performed for selected components α , either simultaneously or serially, depending on the capacity of the quantitative test device 32. The tests would be performed 62 using a suitable quantitative device 32, as mentioned above, including, for instance, laser spectroscopic devices, cavity ring down lasers, certain electronic nose sensor arrays, or other quantitative apparatus. The last stored or baseline test data 64 would then be recalled from memory and the change or delta information between the new test data and stored test data is determined 66. New test data and delta information 68 is stored in memory 22. It is determined at step 70 if the tested component α is the last component for which quantitative tests have been selected. If it is not the last component or α , a new α is set at step 72 and tests for the next component α are then performed. This may be done simultaneously or serially on a single sample if the quantitative device 32 is capable of multiple analysis or an additional sample may be requested of the patient at step 73. Cavity-ring-down spectroscopy, for example, is capable of measuring multiple components simultaneously. If the last quantitative test has been performed, control of the device inquires at step 74 whether any qualitative tests should be performed.

[0024] If no qualitative tests are to be performed, data would be reported through a report process 76, as will be more fully described below. If qualitative tests are to be performed, the tests may fall into three different types. First, the presence 78 of the breath component alone may be significant to the health of the patient. See FIG. 3B. This may particularly be important where the chronic monitoring of the breath components of the patient have indicated the absence of a component and that component appears in a new test. The converse change may also be significant, that is, if a component formerly present is absent in the new test. Both conditions can be detected by a device because of the maintenance of a patient's specific data history in memory 22.

[0025] Second, it may be significant that a newly detected component falls within a given range 80. See FIG. 3C. Although the components may be detected by a qualitative

device 34, estimates of the range may be obtained by certain manipulations of the qualitative device. This may be important where it is economically infeasible to employ a quantitative device with respect to a particular component but an approximation can be obtained which is sufficient to alert an attending physician of the need for a more detailed analysis or which is sufficient to allow the patient to follow a course of treatment, as in diet control, either for weight loss or for diabetes.

[0026] Third, a more specific approximation 82 may be obtained using the qualitative device as will be more particularly described below. See FIG. 3C. The results of both testing for presence, range and approximation, together with quantitative results would then be reported 76.

[0027] Referring now to FIG. 3B, the presence of 78 of a component β may be tested with a qualitative device, for example, an electronic nose sensor array, by recalling 84 the patient's last settings for detection of the desired components at a level of detection ("LOD β ") for that particular component. Qualitative tests would then be performed at 86. At step 88, it is determined if the component β is present. If the test for component β is negative, it should be determined 90 if the minimum or most sensitive setting for the LOD β has been used. If greater sensitivity can be employed, the sensitivity would be adjusted 92 to maximum or LOD min and, if necessary, an additional sample 94 requested of the patient before the test 86 is performed again. In a particular qualitative device it may not be necessary to take an additional sample 94. However, successive approximations using qualitative tests to acquire an approximate quantitative result may require that additional samples be taken from time to time. The computer 16 would alert the user 14 of the need to supply an additional sample. All such initial and additional samples would then be considered a single data acquisition event.

[0028] If the component is determined to be present at 88, or if the minimal setting LOD β has already been used, indicating that a component is not present within the limits of the detection device, it should be determined if this is the last component β for which a test is required. If it is not the last component, the test for the next component 98 would be initiated which may involve taking an additional sample 100. As with the quantitative test, however, it is also possible to simultaneously identify multiple components from a single sample or sample cycle. This is particularly the case for pattern recognition type technology, such as an electronic nose sensor array. Tunable diode lasers are also effective in identifying multiple components simultaneously. Thus, in addition to the diagnostic significance of a compound present in the breath, and the amount of compound present, the presence of the compound in a familiar pattern with other compounds may also be diagnostically significant.

[0029] After the qualitative components have been identified, it may be desirable to quantify certain of those components at step 102. Of course, only components determined to be present need be quantified. If no quantitative approximation is desired, the report 76 would again be generated. If a quantitative approximation is desired, it is determined whether a range 104 is requested or if a more narrow approximation is to be sought.

[0030] If a range is desired, a range test 80 is initiated, as shown in FIG. 3C. A first limit 106 for the particular patient

is recalled from memory **22**. This may involve setting the level of detection LOD to a particular level such that the component β will no longer be detected because the qualitative detector is no longer sensitive enough to recognize that component. This would indicate that the component is below a selected maximum. If necessary, a new sample is taken **108** and it is determined if the component β is present **110** at that level of detection LOD. If the component β is no longer detected, it would be reported **112** that the component falls below the selected limit. On the other hand, if the component continues to be detected, it would be reported that the component's concentration exceeds the selected limit **114**. The data would be stored **116** indicating that for the particular component met or did not meet the selected criteria. This may be sufficient to determine if the component is low enough for health or if it exceeds a healthy range. If it is desired to place the component within a maximum and minimum range, a test for a second limit **118** should be performed. If the second limit test is performed, a new setting for the LOD is provided **120** and the cycle is repeated at the second selected setting. Results of the test are then delivered to the report section **76**.

[0031] It may also be desired to obtain an approximation of the quantitative level for a particular component, employing a qualitative test device at subroutine **82**, as shown in **FIG. 3C**. This may also be accomplished by adjusting the level of detection of the qualitative device and performing iterative tests. Because the patient's data is maintained over a longer period of time, the last level of detection for the component β can be recalled from memory at step **120**. This provides a starting point for the search for the present level of the component. A new level of detection LOD_{NEW} is obtained from the last level of detection plus or minus a selected constant or "delta" **122**. The LOD_{NEW} must be lowered by taking new approximation **130** comprising LOD_{LAST} plus the minimum LOD_{MIN} divided by two. If it is determined **132** that the difference between LOD_{NEW} and LOD_{LAST} is less than a preselected limit, then the process should be halted as the desired degree of accuracy has been obtained. The information would then be stored **134** before. Otherwise, the microprocessor would repeat the process by applying LOD_{NEW} to either an existing sample or a new sample **124**.

[0032] We have described here one method for obtaining a quantitative approximation utilizing a qualitative device. Methods of numerical analysis known to persons skilled in the art will suggest other techniques that could be applied to obtain a similar result without departing from the teachings of our invention.

[0033] The results obtained from the quantitative tests **60**, the presence test **78**, range test **80** and qualitative approximation **82** are examined in the report algorithm **76** by the computer **16**. Computer **16** should check for significant changes **136** in the selected components either α (quantitative) or β (qualitative) as set in a profile for the particular patient selected by the physician or as part of the step of identifying the selected tests **52**. Significant deviations from the patient's chronic condition are reported both to the patient **138** and by the communications connection **26** through transmission **140** to the physician or healthcare provider. In addition significant components that exceed predetermined levels or are less than acceptable levels will be reported. Two-way communication across the informa-

tion grid **26** would also permit the remote care-giver to select additional tests, initiate apparatus self-diagnostics, or perform other functions associated with setting or testing the apparatus from a remote location.

[0034] Maintaining the patient's chronic history of breath analysis enables our device to identify acute changes of significance to the patient's treatment and health. Background influences and variation from patient to patient can be reduced or eliminated by establishing this baseline condition for the patient. The tests described herein will be terminated **142** and may be performed again at a subsequent time thus allowing the patient to monitor his condition over time.

[0035] Significant changes in a patient's condition may be identified by suitable statistical or analytical methods. One such method for determining significant changes in multivariate data is described by Beebe et al., U.S. Pat. No. 5,592,402, incorporated herein by reference. Components of breath identified by the selected tests represent a multivariate data set which can be analyzed to determine whether abnormal features are present. Variations can be identified by establishing a calibration set from which a set of average values and expected statistical deviation from those values may be determined. Variations of a predetermined magnitude, for example more than three standard deviations from the expected average value, may be declared statistically significant and reported as such. Average values and statistical deviations may be set by providing an initial test period or series of initial samples taken under controlled conditions, or they may be continually updated by the apparatus either by calculating a cumulative average and deviation or by maintaining a rolling average and deviation. Moreover, the complex set of data may be separated into various sub-parts to further identify significant variation. Such sub-parts may include peak or minimum values, noise, baseline offset or baseline shape. Each of the sub-parts can be monitored to see if it is within the normal range expected for analysis. This may help in identifying which type of feature is abnormal. For example, different patients may have the same absolute value for a particular breath component. In one patient, this value may be associated with a with a particularly high baseline level. In another patient, the baseline may be rising sharply. In another, it may be falling slowly. In another, the value may have been reached by an acute change, exceeding a peak value and statistically significant. Yet another patient may routinely have much wider variation in the selected component and the change in value may not be statistically significant. For each patient, a different report may be provided, based on the learned pattern for the particular patient. Of course, absolute maximum or minimum values for given components may also be set, and measurements exceeding those maximum or minimum values may be reported without regard to patient history.

[0036] The use of the breath analyzer **10** is further explained in connection with the flow chart **150** of **FIG. 4**. As shown in the flow chart **150**, use of the breath analyzer **10** begins with calibration **152**. This may be accomplished by injecting a gas of known composition into the device. A canister of such gas may be provided for this purpose. After calibration, a sample **154** is taken. This step includes the procedures described in greater detail above in connection with **FIG. 3**. The analyzer **10** may acquire environmental

data at step **156**, using the additional sensors **37** described above. The analyzer **10** would then compare **158** the stored history of the patient to present readings to determine **160** if a change has taken place. If there is a change, it is determined **162** if the change is significant in view of the patient's history and the environmental factors measured at step **156**. If the change is determined to be significant, the analyzer may request additional tests **164**. Such tests may include further breath tests for additional components not ordinarily in the set of tested components, repeat tests, or additional tests for which sensors **37** are provided, for example, blood pressure, blood oxygen (through, for example, an infrared sensor placed on the patient's finger), heart rate, or body temperature. A cardiac pacemaker programming and data transfer wand may be one such sensor **37**. Cardiac pacemakers often store historic data including numbers of pacing beats, number of ectopic beats, incidents of atrial fibrillation or tachyarrhythmia, or (for cardiovertor/defibrillators) ventricular fibrillation or tachyarrhythmia. Information on applied therapies, threshold levels, and even recorded electrocardiograms may be stored by a pacemaker or implantable cardiovertor/defibrillator. This information may be associated with the data records maintained by our device after transmission from the implanted cardiac stimulator. Techniques for such data transfer are well known.

[**0037**] The analyzer may also request the user or patient to enter certain data through the microcomputer user interface (for example., keyboard or mouse). The requested data might include diet information, perceived general state of health, amount and duration of recent exercise and similar factors which might either explain an acute change in breath components (that is, indicate that the change is not in fact significant) or provide important information for a health care provider.

[**0038**] After gathering additional information (steps **164** and **166**) or if there was no change (step **160**) or no significant change (step **162**), a report will be generated **168** for the user and the information stored as part of the patient's history. The report or data may be transmitted **170** to a remote health care provider, either immediately or in response to a request for data. Finally, the system would be purged **172** to prevent contaminants from building up in the sampling device. As mentioned above, this may be accomplished by providing a gas of known composition and may be combined with the calibration step **172**.

[**0039**] Multiple tests performed on a single sample may be independent or the results of several tests may be combined to produce a template or pattern representative of a patient's condition or representative of the presence of a particular compound or set of compounds. E-nose techniques have used pattern recognition to detect the presence of particular compounds. Multiple lasers could also be used on a single sample to extend the band width for detection and pattern recognition could then be applied to the combined output of the several lasers. A single laser is generally capable of emitting light at certain limited frequencies. Although some tuning or variation of frequencies is possible, the elements or compounds that can be effectively recognized by a single laser device are limited by the frequency characteristics of the selected laser. The detector **34** of our invention may include multiple lasers having different emission frequencies. The lasers may be directed into a single sample by being physically offset around the sample, by being fired at

slightly different times, or other techniques. Optical apparatus such as mirrors, lenses or prisms may be used to direct a beam from a selected laser along a path through the sample and into a detector. By adjusting the optical apparatus, beams from other lasers may be directed along the same or a similar path through the sample. By using lasers with different emission characteristics with the same sample, A wider set of data points may be obtained. Instead of three or four data points for a single laser, three lasers may obtain twelve or more data points from the same sample. This information may be expected to be both more selective and more quantitatively precise than similar information obtained by electronic nose technology. The resulting more accurate information from all the laser beams can nevertheless be processed together, using pattern recognition methods in similar to those used in connection with e-nose techniques. As a result, a wider range of conditions or compounds may be identified by correlating the data pattern or changes in the data pattern over time.

[**0040**] The foregoing examples of embodiments of our invention should be deemed exemplary only. Persons skilled in the art will recognize that changes and modifications could be made in the design or construction without departing from the scope or teachings of our invention. It is intended, therefore, that the scope of our invention should be defined by the accompanying claims.

What is claimed is:

1. A medical apparatus comprising
 - a breath-component analyzer; and
 - characterized by
 - a computer connected to said analyzer and receiving a breath-component signal from said analyzer;
 - memory connected to said computer;
 - a data structure stored in said memory representative of at least one breath-component signal; and
 - a computer program comparing said stored data structure to said breath component signal.
2. The medical apparatus of claim 1 further comprising a clock and wherein said data structure associates a time from said clock with said breath component signals.
3. The medical apparatus of claim 2 wherein said data structures stores a plurality of representations of breath content signals.
4. The medical apparatus of claim 3 wherein said computer program determines a rate of change of selected components of said breath component signal.
5. The medical apparatus of claim 1 wherein said breath-component analyzer is a quantitative analyzer.
6. The medical apparatus of claim 1 wherein said breath-component analyzer comprises a qualitative analyzer.
7. The medical apparatus of claim 6 further comprising a circuit iteratively measuring a component of breath to obtain an approximate quantitative measurement of said component.
8. The medical apparatus of claim 6 further comprising a circuit measuring a component of breath to obtain a range measurement of said component.
9. The medical apparatus of claim 1 further comprising a communications circuit for transmitting said comparison of said stored data structure and said breath component signal.

10. The medical apparatus of claim 1 wherein said computer program maintains a baseline representation of a chronic condition of a patient's breath components and identifies significant acute deviations from said baseline representation.

11. The medical apparatus of claim 1 wherein said computer program stores a plurality of data structures and associates said data structures with a single patient.

12. The medical apparatus of claim 1 further comprising at least one environmental sensor producing an output and wherein said data structure includes a representation of said output, said representation being associated with said breath-component signal.

13. The medical apparatus of claim 12 wherein said environmental sensor includes at least one of a thermometer, a hygrometer or a barometer.

14. The medical apparatus of claim 1 further comprising at least one patient condition sensor producing a patient condition output and wherein said data structure includes a representation of said patient condition output, said representation being associated with said breath-component signal.

15. The medical apparatus of claim 14 wherein said patient condition sensor comprises at least one of a thermometer, a blood-oxygen content sensor, a blood pressure sensor, a pulse sensor, or an implantable cardiac stimulator data transfer device.

16. The medical apparatus of claim 1 further comprising means for comparing said stored data structure with said breath-component signal, means for detecting a change between said stored data structure and said breath component signal, and means for requesting additional input in response to said detected change.

17. The medical apparatus of claim 16 wherein said means for requesting additional input comprises at least one patient condition sensor producing a patient condition output and wherein said data structure includes a representation of said patient condition output, said representation being associated with said breath-component signal.

18. The medical apparatus of claim 17 wherein said patient condition sensor comprises at least one of a thermometer, a blood pressure sensor, or a pulse sensor.

19. The medical apparatus of claim 17 wherein said means for requesting additional input includes a computer user interface.

20. The medical apparatus of claim 16 wherein said means for requesting additional input includes a computer user interface.

21. The medical apparatus of claim 1 wherein said breath component analyzer comprises at least one laser spectrometer having a plurality of lasers, at least one of said lasers emitting radiation at wavelengths different from wavelengths emitted by another of said lasers.

22. The medical apparatus of claim 21 further comprising pattern recognition apparatus in communication with said spectrometer having a plurality of lasers, said pattern recognition apparatus correlating data from said plurality of lasers.

23. A method for analyzing breath components of a patient comprising the steps of taking a breath sample from a patient;

analyzing components of said sample to produce a first breath component profile;

storing said first breath component profile in computer-accessible memory;

taking a second breath sample from said patient;

analyzing components of said sample to produce a second breath component profile; and

comparing said first and second breath component profiles.

24. The method of claim 23 further comprising associating a time from a clock with said breath component signals.

25. The method of claim 24 further comprising storing a plurality of representations of breath content signals acquired at a plurality of times.

26. The method of claim 25 further comprising determining a rate of change of selected components of said breath component signal between said plurality of representations.

27. The method of claim 23 further comprising quantitatively analyzing breath components.

28. The method of claim 23 further comprising qualitatively analyzing breath components.

29. The method of claim 28 further comprising iteratively quantitatively analyzing a component of breath at selected sensitivities to obtain an approximate quantitative measurement of said component.

30. The method of claim 28 further comprising measuring a component of breath to obtain a range measurement of said component.

31. The method of claim 23 further comprising transmitting said comparison of said stored data structure and said breath component signal.

32. The method of claim 23 further comprising maintaining a baseline representation of a chronic condition of a patient's breath components and identifying significant acute deviations from said baseline representation.

33. The method of claim 23 further comprising storing a plurality of data structures and associating said data structures with a single patient.

34. The method of claim 23 further comprising sensing at least one environmental condition at the time of taking a breath sample, storing a representation of said sensed condition in computer-accessible memory, and associating said representation with the breath-component profile produced from said breath sample.

35. The method of claim 34 wherein said sensing at least one environmental condition includes at least one of temperature, humidity or barometric pressure.

36. The method of claim 23 further comprising sensing at least one patient condition at the time of taking a breath sample, storing a representation of said sensed patient condition in computer-accessible memory, and associating said representation with the breath-component profile produced from said breath sample.

37. The method of claim 36 wherein said sensing at least one patient condition comprises at least one of body temperature, blood-oxygen content, blood pressure, pulse rate, or data recorded by an implantable cardiac stimulator.

38. The method of claim 23 further detecting a change between said stored breath component profile and said second breath component profile, and requesting additional input in response to said detected change.

39. The method of claim 38 wherein requesting additional input comprises sensing at least one patient condition, storing a representation of said sensed patient condition in

computer-accessible memory, and associating said representation with the breath-component profile produced from said breath sample.

40. The method of claim 39 wherein said sensing at least one patient condition comprises at least one of a body temperature, a blood pressure, or pulse rate.

41. The method of claim 39 wherein requesting additional input includes requesting and receiving information through a computer-user interface.

42. The method of claim 38 wherein requesting additional input includes requesting and receiving information through a computer-user interface.

43. The method of claim 23 wherein said steps of analyzing breath components comprise passing a plurality of lasers beams through said breath sample, at least one of said lasers beams having wavelengths different from wavelengths of another of said laser beams and spectrally analyzing said laser beams after said beams have passed through said sample.

44. The method of claim 43 wherein said step of spectrally analyzing said laser beams further comprises pattern recognition processing.

* * * * *

专利名称(译)	个人计算机呼吸分析仪用于健康相关的行为改变和方法		
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摘要(译)

一种医用呼吸成分分析仪，可以随时间维持患者的数据库分布。该装置可以由患者长期使用，以便可以确定该患者的基线状态。基线的急性变异被确定为具有临床意义。可以使用家中的设备向患者报告所获取的数据，并将其以电子方式传输给医生或医疗保健提供者。可以提供多种测试，范围从定量测试到定性测试，再到使用定性装置的定量近似。为特定患者选择一组测试，并且可以根据患者的状况进行定制。其中一项测试可包括使多个不同波长的激光束通过呼吸样本，并使用模式识别来关联所有激光束的光谱分析。

