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(54) Title: ELECTRONIC MONITORING SYSTEM FOR THE PRODUCTION OF DATA PACKAGES FOR ANALYTIC AND DIAGNOSTIC PURPOSES

(57) Abstract: A system providing at least one clinical data package obtained from a patient and transmission of said data recipient to enable identification and/or diagnosis and treatment of a patient pathology determined from the data package. The system includes an assembly comprising at least a sensor capable of sensing data from the patient. The at least one sensor detects data, over a predetermined period of time, and transmission of said at least one package of data to said data recipient. The data includes patient parameters including body movement and breathing sounds, ambient local sound, ausculatory sound, relating to a pathology of the patient. The system enables the recipients of said packages of data to re-play the data on a sound and /or video device to detect vibrational data thereby enabling the recipient to simulate a physical examination of the patient.

Electronic Monitoring System For the Production of Data packages for Analytic and Diagnostic Purposes

Background

[0001] The present invention relates to systems and methods associated with the acquisition, distribution and use of clinical data for diagnostic and other purposes. The invention further relates to a system in which data and information collected by sensing and monitoring apparatuses enables the preparation of a package of clinically relevant data for a particular patient condition for transfer to relevant professionals, patients and carers enabling one or more of those individuals to apply that package of data for diagnostic or other medical and/or non medical purposes. The invention also provides a system of distribution of collected data including data related to and perceptible by various senses such as, but not limited to, sound. The invention further provides a data package transfer system which distributes patient related packages of data to enable provisional diagnosis or assessment of clinical significance and consideration of data including data which is relevant but not observed by a practitioner.

PRIOR ART

[0002] The diagnosis of disease is made using a series of steps starting with the taking of a medical history, in which symptoms of disease are sought, followed by a physical examination in which clinical signs are detected. The symptoms and physical signs then determine the appropriate test procedures to be done (which may include for example, blood tests, X rays, electrocardiogram, CAT scans etc).

[0003] A patient's symptoms are obtained in several steps. In the first step the patient volunteers the information in response to the general question – "what is / are the problems?" (i.e. "I have chest pain"). In the second step, the medical examiner asks a series of well defined question that seek symptoms typical of a wide range of disease processes. These questions usually follow a systematic review of each organ system with set questions seeking symptoms of heart disease, lung disease, gut disease, neurological disease etc. Most symptoms cannot be verified by an external observer as they are the subjective experience of the patient. For example, patient complaints of chest pain, headache, breathlessness etc are symptoms impossible to measure by the

external observer. Finding physical signs that link those symptoms to a disease process is the next step in the process. A clinician examines a patient to identify physical signs using uses his/her human visual, tactile, auditory, and olfactory senses to identify abnormalities. For example, visual inspection can reveal a range of signs such as cyanosis, jaundice, or the presence of abnormal movements, or gait etc. Tactile examination may reveal the presence of localised pain, an enlarged body organ (e.g. liver or spleen), or the location of an abnormal mass (e.g. a breast lump, or an abdominal mass). Olfactory signs may reveal the typical smell of liver failure, for example. This sequence of evaluation is exemplified by way of an example; when a patient is found to complain of the symptom of breathlessness, finding the presence of wheezing on chest physical examination leads to the provisional diagnosis of asthma. In contrast, finding crackles on chest examination, points the physician in the direction of heart failure or lung infection.

[0004] One of the most important tools that a clinician uses to elicit physical signs is the stethoscope. This form of physical examination is called "auscultation". The stethoscope amplifies various vibrations generated by the body (e.g. breathing, cardiac and gut, blood flow in vessels etc) so that an ordinary clinician can hear them. The assessment is highly specific for pathology (for example, wheeze which indicates airways obstruction; or crackles (also called crepitations) in the lungs — indicating likely heart failure; or other sounds that indicate the presence of a heart murmur). The combination of palpation and auscultation typically give highly specific information — for example palpation of the thorax will demonstrate a bruit (a course continuous vibration) combined with a continuous murmur on auscultation) — typical of a patent ductus arteriosus. The occurrence of intestinal obstruction — for example as occurs in paralytic ileus — can be identified by the auscultation of a characteristic "tinkling" sound.

[0005] Palpation and auscultation are also used in assessing a fetus. The fetus normally makes a large number of various movements, including breathing movements, that are best palpated (as they are low frequency) as well as fetal heart sounds (which have higher frequency components that may be audible with some form of amplification). Similarly, other pregnancy related functions such as uterine and placental blood flow can be assessed with auscultation. The eliciting of physical

signs by means of a clinical physical examination still remains a cornerstone and starting point of medical diagnosis. However, technologies such as modern ultrasound can literally reveal the structural features and heart function of a fetus. Also heart monitors can provide a continuous measure of fetal and fetal heart movements over hours and days.

[0006] Diseases often have symptoms and signs that vary both in occurrence and in severity over time, so that a physical examination at a single point in time may miss the problem. Furthermore, both the symptoms, and associated signs, may be more pronounced with fluctuations in disease severity; and at times when it is less likely that patients will notice symptoms or when clinicians are not present to observe the signs. This is particularly the case when considering sleep, a time when the patient will be less likely to notice key symptoms, and when there is unlikely to be any clinical person present. Typically, patients are often totally unaware of sleep disorders such as snoring and apnea and may have no day time symptoms, or may have symptoms that are not recognized to be linked with what was occurring in sleep. Children with nocturnal asthma typically have increases in severity at night which often go unnoticed by parents (as they are also asleep), and the typical physical signs (such as wheezing) which would be obvious if assessed by a clinician during the night, are not present when evaluated by their clinician during the daytime.

[0007] Similarly patients with a range of common disorders and diseases, such as congestive heart failure, bruxism, COPD, gastrointestinal reflux, night time cough, heart arrhythmia etc often have increased disease severity at night time and are unaware of these changes while awake. Similarly, strokes which often occur during sleep, may be precipitated by unrecognised events such as arrhythmias, or snoring and sleep apnea. Typically, patients with heart failure have worsening of their cardiac function at night and improvement during the day, and this pattern is predictive a progression into complete cardiac decompensation over days or weeks.

[0008] Accurate diagnosis and treatment of diseases such as those mentioned above present a number of challenges for those involved in the consultation, diagnosis and treatment process. Diagnosis and treatment is largely dependent upon the patient,

their carers, general practitioners, specialist clinicians, diagnostic analysis technicians and other healthcare practitioners such as nurses and dentists. One problem for health professionals is that they are typically not present at the time the signs of the disease are occurring (especially at night), or are unaware of the occurrence of disease signs, in the case of patients — because they are asleep. This dissociation can be magnified if a number of interactive diseases are present which require diagnostic input from more than one clinician.

[0009] For diagnosis and treatment to be successful, healthcare providers have to be aware of the disease signs and symptoms and must be convinced of the disease's potential impact on their patient's health. They also have to be convinced that a patient has a significant form of the disease before they will feel compelled to additional diagnostic procedures and prescribe treatment, or refer them to other practitioners for treatment. Similarly patients and their carers will be most likely to respond to a disease seriously and comply with treatment if they are convinced that they have it in a serious form.

[0010] Practitioners involved in diagnosis need proof in a form that it understandable to them that the disease is present before they will recommend treatment, and then after diagnosis they need further proof that the treatment is actually working. Where serious disease signs are not directly evident and proven it is less likely that each patient will have an optimal outcome. In general patients with a particular disease will not be identified and treated as someone with a serious health problem. Healthcare providers will be less likely to send patients for review or appropriate treatment to other healthcare providers if there is not sufficient evidence of disease and evidence flow between the relevant professionals. Patients and their carers will be less likely to take the presence and treatment of a disease seriously if they don't experience compelling evidence of its incidence and severity. Finally, in most health care systems, the organisation that pays for the disease management will require robust evidence of the disease and the outcomes of treatment before agreeing to reimburse the various practitioners / and or insured patient.

[0011] The general problem can be illustrated with an example of the suspicion, diagnosis and treatment of the sleep apnea syndrome. General practitioners may

identify a patient who reports snoring which disturbs a partner. The GP may suspect the patient has sleep apnea and may send the patient to a sleep specialist who diagnoses the patient using polysomnography (PSG). Depending on the severity of the disease, and the presence of co-morbidities, the sleep physician will decide if the patient should receive positive airway pressure therapy, or an oral device. The specialist may send the patient to a dentist for fitting of a mandibular advancement splint (MAS) for instance if it is found that the patient snores without significant levels of sleep apnea. Decisions of this type should be based on accurate data and evidence of the conditions suspected. Typically, a patient, dentist, or GP will not have sufficient evidence of the snoring other than perhaps a report by the spouse and a PSG report which will only provide a written record that snoring was identified.

[0012] If a MAS is fitted, the only information about its efficacy will come from the patients partner who may or may not be able to accurately report on the patients response to MAS use. In this scenario only the patient's partner would have convincing evidence through hearing the snoring that the problem is severe and ongoing. The patient, GP, dentist and potentially the sleep specialist will not have definitive evidence convincing them of the snoring severity. In addition after treatment there will be uncertainty as to whether the MAS device has been effective. The lack of any objective evidence of the effectiveness of an MAS device is one major reason that many sleep physicians are reluctant to refer such patients to use such devices.

[0013] Ideally a team of practitioners with the right data and evidence can have an informed discussion about the patient's condition and best form of treatment. The problem is that the optimal data (including information that a clinician cannot witness) is not always available so the team approach although ideal is compromised by want of a full package of data. Due to the uncertainties this creates about disease presence and the quality of patient care, patients may be reticent to seek treatment and practitioners reticent to refer patients for treatment. Similarly in the case of nocturnal asthma neither the patient, spouse or carer, GP or specialist may have definitive evidence of its incidence and severity. Scenarios like this significantly reduce the likelihood of patients being identified, successfully diagnosed and treated in a timely manner. Presently, there are many disease signs which can easily be identified and

quantified by a clinician using a stethoscope and palpation if they are present with the patient when these signs exhibit. Diseases and signs include partial or total upper airway obstruction. central apnea. chronic obstructive pulmonary disease, asthma, congestive heart failure, cardiac and vascular murmurs and bruits, bruxism (teeth grinding), reflux and heart murmurs. The sounds and palpation events (vibrations) associated with these diseases and signs will be immediately recognizable by specialist and general clinicians as well as by many patients, carers and other healthcare professionals.

[0014] Electronic stethoscopes can be used to record sounds of interest for storage or playback following a consultation. to other clinicians who may not be present with the patient. Electronic stethoscopes can also be used to facilitate telemedicine enabling a clinician to consult in real time on a patient where they are at a site remote from the patient. However, these devices require a healthcare professional to be present with the patient in order to hold the stethoscope in place. Typically during this time the patient will also be awake. Electronic stethoscopes can't be used on an unattended patient. In addition these sound files are typically used by one clinician to diagnose a patient and not to provide evidence of disease severity to all the non-diagnosing professionals in the treatment chain. A disadvantage of the electronic stethoscope is that only the sound file and not the palpation related information can be recorded and replayed. Following diagnosis by one clinical professional he or she will typically communicate their findings to others including general practitioners, patients and carers through the use of a written or verbal diagnostic summary without provision of any disease sign evidence.

[0015] In the case of diagnosing upper airway breathing obstruction or central apnea the diagnosing clinician can study the patient within a clinic where they are attended by sleep technicians during the night or through use of take home sleep study equipment for use in an unattended study. In both cases typically a clinician specializing in sleep medicine undertakes the diagnosis and is rarely attendant at the clinic during the study period. The equipment used typically involves either thermocouple (or thermistor) and / or pressure sensors placed in or near the patient's nostrils to measure breathing flow. Neither of these sensors provides sound files. A minority of devices also may include a room sound microphone, or microphone or

accelerometer for attachment to the patient for recording breathing related sounds. Video may also be used to provide visual and sound recordings of the study period. These records are typically assessed by the sleep technicians to provide quantitative written metrics of the patient's status. The sleep physician will typically review the technicians report and may sample some of the record files including the microphone or video material if present and then make a diagnosis. The sleep physician will typically review their diagnosis with the patient verbally and send a written diagnostic summary to the patient's general practitioner. Although some method to record snoring is often used — the only component of this recording that is reported is an overall statement of the presence or absence of snoring. The commonest method is to use an accelerometer to record only the low frequency component of snoring, a signal that is not suitable to provide a replay of the actual sound. Sound files or palpation files indicative of the patient's condition such as snoring sounds or other sounds or vibrations related to partial or total obstruction are not provided as definitive evidence of the patient's condition to the patient, their carer, the patient's general practitioner or other healthcare professionals such as a dentist. In the case of asthma, wheezing is a sound that is instantly recognized by clinicians, other relevant health professionals as well as patients and their carers. More recently, sound sensors have been developed for use in diagnosing the presence and severity of asthma and cough particularly in young children who are unable to use other methods such as spirometry. Sensors have been developed for use when the clinician is present. These are held against the patient. Attachable sensors have been developed for use in unattended studies. These devices may also be used by a patient or carer at home in order to communicate the status of the homebound or remote patient to the clinician. The sound files generated by these devices are used for diagnosis of disease presence and severity. A disadvantage of the aforesaid sensor devices, such hand held devices, can only be used for brief periods and are not suitable for long term measurement or obtaining measurements from a sleeping subject. They were not developed for providing evidence of disease presence and severity to practitioners not involved directly in the diagnostic process

[0016] Alternative device versions have been developed where the sound sensors are attached to the patient and can be used to record sounds including wheeze and cough

sounds from patients who are unattended. The records from these devices have been developed for and are used for diagnosis by the clinician.

[0017] In the case of diagnosing patients with cardiac disorders that are identified by abnormal heart sounds these can be found using a stethoscope if these sounds are present when the patient is observed by the diagnosing clinician. However, if the abnormalities are only present intermittently or only at night, if associated with other disorders such as sleep apnea, then current technologies won't enable easy diagnosis. In this case abnormalities may only be diagnosed if the disease increases in severity and signs become evident during the day time. Vibration related information that would be evaluated by the clinician palpating the patient is not recorded other than as a written observation by the diagnosing clinician. A pulse or heartbeat may be felt by the clinician as well as heard via stethoscope. However currently there is no way of providing that touch sensory information to anyone not attending to the patient and additionally not involved directly in the diagnostic process. Prior art technologies used with sleeping or unconscious patients have been developed for use and interpretation by those persons directly involved in the diagnostic process. Once diagnosed, information provided to other non-diagnosing parties is provided in the form of written or verbal summaries which don't include direct record evidence of disease signs occurring within the patient at the time of the unattended recording.

[0018] A disadvantage of the known systems is that there are no systems available which enabled the sensing of easily identifiable disease signs from patients who may be unattended during the study period and the playing or replaying of those signs to all healthcare professionals and non medical practitioners.

[0019] In order to optimize the identification of patients with intermittent or night time symptoms and maximize the likelihood that they will be reviewed and treated by appropriate healthcare practitioners methods are required to enable simple and convenient collection of diagnostic information in a form which is suitable for understanding by all those in the treatment chain including clinical specialists, general clinicians, other healthcare providers (who are not specializing in the disease of interest), and importantly, the patients and their carers.

INVENTION

[0020] To ameliorate the aforesaid disadvantages the present invention provides a system in which data packages and clinical information are collected by suitable sensing and monitoring apparatuses. The system enables the preparation of at least one package of clinically relevant data for a particular patient condition for transfer to relevant persons such as butnot limited to parents of children, health professionals, diagnostic professionals enabling one or more of those persons or professionals to apply targeted packages of data for diagnostic or other medical or non medical purposes. The system also provides the package of information to enable and enhance remote case-conference meetings of all relevant carers, practitioners and specialist consultants to enable remote examination of the subject..

[0021] A system and method which can conveniently capture and provide the appropriate evidence for each data recipient including practitioners increases the likelihood with time that more patients can be identified, diagnosed and successfully treated. Such a system needs to be convenient and able to be easily and safely set-up and used over long periods when only the patient is present and in cases where the patient may be sleeping or unconscious, and in the case of an elderly person or invalid either in their own home or care facility.

[0022] For instance, systems which require young children to be assessed overnight in hospital may also require that their parents stay in order to reduce the level of their child's anxiety. This is very disruptive and inconvenient for the family and reduces the likelihood that a child will undergo monitoring and review. In addition the severity of some diseases such as asthma is affected by the environment, so that testing in the subject's normal environment is an important factor in gaining an accurate overview of disease status. A system which can be used simply at home due to its convenience will increase the likelihood that parents and other stakeholders will undertake the monitoring assessment.

[0023] In this way such a diagnostic and reporting system derives economic benefits by increasing the demand for its use. This is achieved through its convenience, ease of

use and its ability to provide appropriate, convincing evidence to all stakeholders of disease severity and status. This benefit can be captured in a number of ways including through sale of the system or sale of the diagnostic and reporting service. Practitioners using it also derive benefit where increased demand for the system, results in an increased demand for the therapeutic treatments provided by them. The system derives benefit for instance in a case where its use convinces a patient to proceed with a therapeutic treatment. Using current technologies, there was evidence that insufficient proof of disease presence inhibits optimal patient identification, diagnosis and treatment.

[0024] Although the invention is suited for use with human subjects, it will be appreciated that the invention described herein has veterinary applications. According to a preferred embodiment, the package of data includes sounds and/or palpation signals from patients with breathing obstruction, snoring, asthma, bruxing, cardiac related and other signs of disorders and diseases. The data may also include video records. The data packages created by the sensing and monitoring apparatuses provide practitioners and patients alike with evidence of particular conditions which would not previously have been included in patient data due to the difficulty in establishing patient monitoring and measuring regimes.

[0025] It was observed that in the case of child patients their parents were more easily convinced of the presence and significance of disorders and diseases such as snoring, or sleep apnea or asthma following their listening to sound records exemplifying relevant signs. Similarly, appropriate recordings of the child by a worried parent have been shown to also convince otherwise sceptical and disbelieving clinicians of the need to treat a child's breathing obstruction at night. Snorers were more easily convinced of the need for treatment after hearing their snoring than if they only had a partner's report of its incidence. A typical attitude of many snorers is that it is not their problem, as they don't hear it. Such problem snorers readily change their attitude when they are made to experience the true intensity and quality of their own snoring. Parents with children suffering significant nocturnal asthma incidence were more likely to seek appropriate treatment immediately if they heard and understood the significance of the asthma signs. In the case of specialist clinicians reviewing sleep studies it was observed that often amongst all the diagnostic information

provided by a PSG study including EEG, EMG, breathing flow and other signals regularly the most impactful data which would direct treatment prescription was video and sound records of the subjects sleep behaviour. Visual evidence of a subject struggling to or ceasing to breathe and sound record evidence of snoring, or wheezing or crepitations most often resulted in immediate recognition of a disorder or disease and its severity by the diagnosing specialists. It was noted by the inventors that practitioners involved in various aspects of a subject's healthcare could exhibit significant scepticism in the existence and severity of disorders and diseases where they were unable to directly observe evidence of actual signs or symptoms.

[0026] For instance, general practitioners whose infant patients on being reviewed by a paediatrician or respiratory specialist were recommended for a tonsillectomy to treat obstructed breathing or instigation of significant pharmaceutical regimens to treat nocturnal asthma were often sceptical of disease severity and treatment needed if no disease signs were discernable to them during their patient consultation and if parents couldn't accurately report night time signs. The general practitioner faced with infant patients being sent for surgery or prescribed pharmaceuticals with significant side effect risk in some cases let their scepticism dictate an approach resulting in fewer patients being sent for review by the specialist than would occur if they had better evidence of disease significance.

[0027] An advantage of the system of data acquisition, transfer and application provided by present invention, is that it increases (medical and/or non medical) practitioner confidence in treatments based on additional data and evidence of pathologies not previously part of clinical observations and when used in conjunction with previously obtainable data such as partner observations. As a result a practitioner will have increased confidence in referral of patients for specialist review and treatment.

[0028] The present invention also allows a recipient of the data packages to employ data so that touch can be used to contribute to assessment and diagnosis. More specifically in the case of palpation or vibrational information a disease indication can be determined by touching or feeling sound data through a speaker cone or

vibrating touch pad which is related to a particular patient. One example of a condition indication which can be obtained using this method is a bruit.

[0029] In one broad form the present invention comprises;

a system which provides clinical patient data to medical and non medical practitioners and patients and their carers to enable detection and treatment of a patient pathology determined from the data; the system including,

an apparatus comprising at least a sensor capable of sensing data from the patient and/or a video recording device; the at least one sensor and video recording device enabling over a predetermined period of time, detection and storage of at least one package of data including patient parameters, ambient local sound, ausculatory sound, and/or video recordings relating to a pathology of the patient;

providing the at least one data package to one or more practitioners or patients and their carers selected as authorised recipients of the data package;

allowing the recipients to re-play the data on a sound and /or video, and /or palpably detectable vibrational surface reproduction device, thereby enabling the authorised practitioner to determine/diagnose a pathology of the patient using the data to make the physical signs accessible to their normal senses of vision, hearing and manual feeling so enabling them to do a physical examination of the patient. Authorisation or eligibility criteria for use of the data packages includes but is not limited to payment for each data package, registration for use, entry into a License for use.

[0030] In another broad form of an apparatus aspect the present invention comprises:

an apparatus which over a predetermined period of time, detects and stores at least one package of data including patient parameters, ambient local sound, auscultatory sound, palpably detectable vibration, and/or video recordings relating to a pathology of the patient;

providing the at least one data package to one or more practitioners or patients or their carers selected as authorised recipients of the data;

enabling the one or more practitioners to use the package upon satisfaction of eligibility criteria for medical, diagnostic or other non medical purposes;

thereby enabling the authorised practitioner to determine/diagnose a pathology of the patient using the data.

[0031] According to one embodiment at least part of the data package is playable on a device which allows visual and/or ambient local sound and/or auscultatory sound signals or images of patient parameters to be used by the practitioner. According to another embodiment, the sound data is readable by touch and feel of vibrations in a sound emitting speaker or other surface such as a model of human thorax, abdomen etc.

[0032] According to one embodiment the present invention provides a system integrated with a medical diagnostic and record playing apparatus in which the apparatus includes sensors, readers, monitors, video recorders to allow continuous sensing and recording of patient sounds and/ or palpably detectable signals, video signals and/or olfactory signals to indicate the presence of disease or a condition including various respiratory, cardiac, gastrointestinal, dental and other disorders or diseases.

[0033] According to the apparatus aspects, there are provided sensors of a direct contact and/or remote (contactless) sensing type in which sensors are either attached to the patient or remotely located relative to a patient such that when sensors are not attached, the patient can freely move in relationship to the sensors. In this case microphones and or remote sensors can be used to monitor and record patient data.

[0034] According to one embodiment the data is collected from patients who are unattended by health professionals and the records can be obtained over selected time periods which may be many hours, days or weeks, according to the particular patient condition being evaluated. Patients may be asleep or unconscious. Alternatively they may be conscious and unattended, or invalid or elderly requiring constant supervision. The data records are either manually or automatically analysed for signs indicating the presence and severity of disorders or diseases, and may be evaluated in relation to long time series (i.e. the chronobiological timing and pattern of the physical signs can be identified).

[0035] In a further embodiment local ambient sound, auscultatory sound, palpable vibration data and video records are playable by an authorised practitioner or practitioners or patient or their carer on suitable players which enable the practitioner

to listen to sound, and feel vibrations created by sounds on speakers (or other surfaces) and see the related images either separately or concurrently on one apparatus or separately on dedicated separate players. Data such as ambient localsound, ausculatory sound, palpable vibration, video and olfactory data are provided as a package available to one or more practitioners using separate reproduction apparatuses. Individual practitioners involved in the care of the patient or, multiple practitioners may review the records using the same apparatus.

[0036] In a further embodiment, the "package" of --- ambient local sound, ausculatory sound, palpable vibration data and time synchronised video --- is available to enable all participants joining a case conference from remote locations to simultaneously undertake a physical examination of the patient, providing an efficient sharing of information to provide an efficient management outcome.

DETAILED DESCRIPTION OF EMBODIMENTS

[0037] The system allows data records that consist of a "data package" *(a "physical signs data package")* that include sounds (both ambient local and proximate to the patient and auscultatory) and palpable vibrations, video images and /or olfactory signals that indicate the presence of absence of, or incidence and or severity of a specific disorder or disease to be transmitted to groups or individuals involved in the treatment/diagnosis of a particular patient.

[0038] Practitioners who can receive and assess and analyse the data include; a patient carer (such as a parent of a child), the patient's general practitioner, non- diagnosing clinical specialists, and other healthcare practitioners such as dentists or nursing staff. A patient can also receive the patient data. The packages of data according to one embodiment, allow the practitioner or patient to hear the records sound, feel the palpation signals, watch video images or smell the olfactory records using appropriate apparatus such as speakers or earphones for the sounds and by touching appropriate speaker components or vibrating surfaces for the palpation records or video players or computer monitors for the video files. Chemical emitting apparatus can be used for olfactory data records. A data package therefore can contain tailored data drawn from

combinations of the above parameters including video, sound and data capable of analysis by touching a device which is capable of vibration.

[0039] To enable practitioners to make more accurate judgements on patient data, a package of control or comparative data (control or reference "physical signs packages") can be provided from a library of sounds, palpation, video image signal records or olfactory records. These records can be drawn from patients' earlier records or from a data reference package to enable a practitioner to assess a patient's data relative to the reference package. **In each case the reference package can be accompanied with written explanations and a guide to interpretation.**

[0040] This approach can also be used for parent monitoring to educate a parent as to normal and abnormal data. For instance, a parent may not be familiar with the sound of normal or abnormal snoring or significant upper airway breathing resistance in a young infant, or the difference in sound between a mild, moderate or severe asthmatic wheeze breathe sound. Library sounds and vibrations can be used to highlight differences in this data. For both the practitioner and parent, the reference package allows a better understanding of the actual measured data package and will result in more accurate diagnosis and treatments. This results in higher patient compliance with treatment, increased confidence in diagnosis for the practitioner and increased GP confidence in specialist treatment, disease screening, diagnosis, treatment and review. The availability of data and the creation of a data package provided by the system described herein increase the likelihood that diseases are identified earlier than previously without use of the system. Recorded information and data packages may be provided as **files sent via the internet** or using other methods to provide them to each user.

[0041] The ambient local sound, ausculatory sound, vibrations or video signals or olfactory signals and data referred to above may be simultaneously captured with one or more of a multiplicity of other records from other known sensor types including but not limited to oximeters, EEG, EMG, ECG, breathing effort sensors and ultrasound devices. Data from those sources can be included in the patient data package.

[0042] Records from the additional sensors are manually or automatically analysed and total or sample signals of interest including some or all of these signal records as well as sound, or vibration or video or olfactory records sent to one or more of the non-diagnosing practitioners as appropriate to their understanding of the additional signal record types.

[0043] **Example 1**

An example of this is as follows: a sleep specialist conducts a sleep study on a subject where the study includes the recording of an ECG signal as well as breathing and heart auscultatory sounds and heart related palpation records. The subject is diagnosed as having sleep apnoea and the sleep physician also notes signs of atrial fibrillation or other cardiac abnormalities identified from listening to the heart sound signal or studying the ECG signal. The sleep physician sends sample "physical signs data package" of the subject's obstructed breathing to the subject as well as sound files of their atrial fibrillation or other heart abnormalities and normal heart rhythm sounds.

[0044] These records are also sent to a cardiologist and the patient's general practitioner in addition to the ECG record. In addition, the vibrational records related to heart abnormalities are recorded and sent as data files for palpation by the cardiologist. Preferably the sleep physician includes a sleep apnoea diagnosis with the records and then relies on the cardiologist to diagnose the subjects cardiac abnormalities from the data package including heart sounds and /or ECG and palpation records as well as undertaking any further studies required.

Thus the package of data for a particular patient *(the "physical signs package")* could potentially include some or all available data drawn from various monitoring and detection apparatuses but a particular practitioner may only use that component of the data referable to one particular area of expertise, although taking into account the overall clinical picture of a patient. Thus, the cardiologise for instance, will be likely to use vibrational records related to heart abnormalities.

[0045] Both the subject and general practitioner are made aware of the subject's disease/pathology/condition through listening to the records (i.e by examining the "physical signs"). In this case if the heart abnormalities are interrelated to the presence of sleep apnea and currently only occurring at night, the cardiologist is presented with evidence of the abnormalities in the form of heart (auscultatory) sound and palpation information which they would not observe during a day time consultation with the patient. The use of a known Holter monitor during a night time evaluation would also not pick up many abnormalities most easily identified through abnormal heart sound signals. Without this transfer of information this patient's heart abnormalities would most likely go unnoticed until they became significant enough that they started to occur throughout the day. Accordingly, the data packages are prescriptive and predictive. They are prescriptive in that a set of parameters to be measured can be prescribed in advance for the purpose of analysing for a suspected condition. Alternatively, the data packages are predictive in that a complete subject profile can be measured to provide a series of data packages having various sets of parameters from which selections can be made for study.

[0046] Following treatment for both the sleep apnea and heart abnormalities a follow-up study may be recorded to determine whether both diseases have been successfully treated with the relevant sound and palpation records again being provided to each recipient of the data.

[0047] **Example 2**

Children with nocturnal asthma may also suffer from sleep apnea or upper airway flow restriction. A respiratory specialist or general practitioner may use the data packages provided by the system of the present invention to study a child suspected of having nocturnal asthma at night in bed at its home. On review of the records the specialist or GP can diagnose nocturnal asthma as well as noticing signs pointing to the presence of sleep apnea. After the study analysis, auscultatory sound records of asthma and apnea events can be sent to the child's parents and also to a sleep specialist for review of the suspected apnea. The sleep specialist can identify the presence of snoring or apnea and could require further studies to complete a diagnosis of severity.

[0048] In addition, the sleep specialist using a data package will be able to hear the obvious signs of nocturnal asthma and potentially its time relationship to apneic events which may be causally related. This data would then be sent to the Respiratory (Asthma) specialist to convince him/her that the child does have asthma as well as snoring and apnea. The treatment for apnea may involve need for a tonsillectomy in which case sound files from a patient data package ("physical signs package") can also be provided to an ear nose and throat surgeon in order to assess the need for surgery. Following treatment for apnea and asthma a follow-up study can be completed and both specialists and the surgeon can review the tailored data package sound records to assess the effectiveness of treatment. During this process the parents are made aware of the signs and severity of the asthma and apnea through review of the sound files in the data package. The parents may also be involved in the treatment process through cleaning the child's room of potential allergens if they are affecting asthma severity and then help them provide a more judicious and timely use or asthma drugs. The provision of the sound data files informs all relevant practitioners about disease severity, the urgency of the required treatment and the ability to easily understand and monitor the success of treatment or of cleaning the child's environment for both diseases. It therefore facilitates understanding, urgency for action and increases the likelihood that the clinicians involved will optimise the identification, diagnosis and treatment of similar patients in the future.

[0049] The problem of convincing a patient and or medical and non-medical recipients of data for the patient's care of the presence and status of disease incidence occurring in periods during which a patient may be unattended is solved by use of an apparatus and data package supply which records sounds and or other vibrations and or video and or olfactory signals from the patient then analyses and sends samples of these sound and or vibration and or video and or olfactory records to interested parties in a format which allows those parties by using an apparatus to accurately reproduce and sense the physical signs, thereby facilitating disorder or disease identification and evaluation by each party.

Presentation of Data Packages

[0050] Data packages are presented with content to suit particular subjects and for particular practitioners depending upon clinical objectives. For example a package or packages of data can be provided for detection of a pathology of a subject such as asthma or congestive heart failure or cystic fibrosis or obstructive pulmonary disease (COPD) potentially obtained with reference to a subject's sleep patterns.

[0051]]The reporting format for each medical or non medical practitioner and patient is according to one embodiment, in the form of written files, record signal trace files and sound files, touch files for feeling vibration related signs or video or olfactory signs or any combination of these file types as appropriate for understanding by the reviewer. Apparatus including software is designed to enable the simple identification, sampling and storage of relevant data records for presentation as part of a data package. Files of library signs exemplifying disorder or disease information may also be provided to stakeholders in order to further optimise understanding of the test record files.

[0052] One advantage of the system of the present invention is that some or all non diagnosing practitioners or non practitioners can experience the physical signs using their own senses including tactile and or auditory or visual or olfactory systems. For example a parent of a child can look and/or, hear and/or touch first hand a reproduced package of data referable to a state of behaviour such as occurs during the sleep cycle, breathing sounds, sound intensity generated by movement and breathing, heartbeat sounds, wheezing coughing and other behaviours. A further advantage is that in circumstances where patients have multiple disorders or diseases and require the involvement of multiple specialists (eg subjects with diabetes and sleep apnea, sleep apnea, heart diseases and heart failure or sleep apnea and chronic lung disease and sleep apnea and asthma), the availability of tailored or targeted packages of data enables efficient integration and sharing of information from a patient oriented data package from which various practitioners can draw data appropriate to their specialty and review other potentially relevant data not directly related to that specialty. Due to the integration of the data packages practitioners can collectively assess a subject related to each practitioners field of expertise, all of which can be effected remotely as

if the patient was physically present before each practitioner effectively allowing a simulated physical examination of each subject for known or unknown conditions..

The packages of data

[0053] The data packages made up of data such as sounds generated by a variety of patient sources (breathing, heartbeat etc), images, olfactory information, can be used in totality or broken up into specific sample record files or groups of files depending upon the information required on or for a particular patient and by a particular practitioner or group of practitioners. The data package can be transmitted by any form of data carrying device such as but not limited to via the internet, emails, discs or portable drives.

More Specific Examples

SNORING AND OBSTRUCTIVE APNEA:

[0054] Snoring is a loud, vibratory, annoying breathing sound made by someone sleeping. Despite this common problem, its medical significance and potential impact are very poorly understood by most. Snoring is typically regarded as a symptom. Thus, a patient will report to the clinician that he/she snores — and typically that the reason he/she knows about it is that a bed partner or someone who has been near the subject when they are asleep has told them about the noise. Snoring however, is a robust and characteristic physical sign of upper airway obstruction. It is not normally considered a physical sign because the clinician is not present when it is happening. It usually comes to light from a partner complaint. If a trained medical observer was present while the patient was asleep, he/she would identify the snoring as a physical sign. Because the sounds that are produced during snoring have "signature" characteristics, most untrained listeners can readily recognize mild snoring from snoring that is on the verge of choking, and then a period of apnea. Snoring is particularly obvious sign that can be heard and felt by partners, parents and practitioners. Further, the sound quality of the snoring can clearly separate extremely obstructed breathing- with almost no air flowing into the lungs -- from less severe mild vibratory snoring in which there is otherwise good air flow. An untrained parent (as well as the trained clinician) immediately recognises the characteristic sound of snoring that is on the verge of complete choking. The GP to whom the patient

describes a snoring problem is presented with a dilemma — is it dominated by the partner's complaint — or is it more serious? Because the potential treatment options are non-trivial — for example will the patient require upper airway surgery, the use of a CPAP machine or have to go through the dental work to have an oral MAS (maxillary advancement device) fitted -- the patient and the GP will often find it easier to minimise or ignore the problem.

FURTHER EXAMPLES

Examples of Clinical Scenarios and their related Data Packages

Example (1): Pediatric Subject with Asthma and Sleep Disordered Breathing.

[0055]**Clinical Vignette:** A Pediatric subject has asthma, sleep disordered breathing (SDB) and enlarged tonsils and adenoids. Nocturnal asthma is causing increased SDB severity. The subject presents to the general practitioner with symptoms of mild daytime wheezing and sleepiness. The GP sends the subject to the Asthma Specialist who suspects presence of nocturnal allergy related asthma. An overnight study is ordered. The Asthma Specialist diagnoses the presence and severity of Asthma and notes indications of sleep disordered breathing and enlarged tonsils and adenoids. They prescribe asthma treatment and also send the subject to the Sleep Specialist for a review of potential sleep disordered breathing. The Sleep Specialist diagnoses SDB and the enlarged tonsils, sending the subject to the Ear Nose and Throat Specialist (ENT) for review and possible tonsillectomy. The ENT reviews the subject and completes a tonsillectomy. Following surgery a follow-up overnight study is completed and records sent to all parties to assess Asthma and SDB efficacy.

Data Packages by Observer:

[0056] **Asthma Specialist**. This specialist receives a package containing full night sound records of all periods of wheezing and non-wheezing breathing sounds. Samples indicating examples of SDB such as snoring or apneas (breathing cessation) are included and highlighted. Samples of breath sound records showing the temporal relationship between wheezing and apnea would also be included. After tonsillectomy they receive the same data package from the follow-up study.

Sleep Specialist: This specialist receives a data package containing the full nights sound (SBD and non SBD breath sounds) and body movement records indication all periods where SDB is present or absent. Samples of wheezing sound records showing the temporal relationship between wheezing and apnea would also be included. After tonsillectomy they receive the same data package from the follow-up study.

ENT Specialist: This specialist receives sample sound records of SBD sounds indicating snoring or apnea as well as sample wheezing sounds in their data package. After tonsillectomy they receive the same data package from the follow-up study

General Practitioner and Patient and Carer: They receive Sample sound records of SBD sounds in their data package indicating snoring or apnea as well as sample wheezing sounds. After tonsillectomy they receive the same data package from the follow-up study. Thus, each package of data can be tailored to accommodate the requirements of the particular practitioner.

Example (2) Patient Heart Attack, Breathless at night time, OSA and mitral incompetence

[0057] Clinical Vignette: A 55 year old overweight male with a prior history of myocardial infarct reports waking during the early morning with breathlessness. He has had a prior diagnosis of mild sleep apnea and is using an MAS (Mandibular advancement device). The general practitioner refers the patient back to his cardiologist and also to his sleep physician. An overnight study is arranged and the study reveals snoring and sleep apnea despite the use of his oral device (MAS), and in addition during the night there is a change in pattern from obstructive to central apnea with the development of crackles and the onset of a loud mitral murmur (that was not present during the day). The study reveals that sleep apnea is not being treated with the MAS and is precipitating heart failure which in turn leads to heart dilatation during the night with the onset of a mitral murmur. Various packages of data sent to the sleep physician and the cardiologist leads to treatment of the sleep apnea with CPAP and the addition of diuretics for heart failure.

Data Packages by Observer:

[0058] **Sleep Specialist**: This specialist receives a data package containing the full nights sound (SBD and non SBD breath sounds) and body movement records indicating all periods where SDB is present or absent. The package would also include samples of lung crackles and heart murmur sound records showing their temporal relationship with apnea. After CPAP and diuretic implementation they receive the same data package from a follow-up study to enable review of treatment efficacy.

Cardiology Specialist: This specialist receives a full nights sound record of all the periods involving crackle and heart murmur sounds as well as periods where these sounds are absent. The specialist also receives sample sound records of SDB sounds indicating snoring or apnea. After CPAP and diuretic treatment they receive the same data package from a follow-up study.

General Practitioner and Patient and Carer: They receive sample sound records of SDB sounds indicating snoring or apnea as well as sample crackle and heart murmur sounds. After CPAP and diuretic treatment they receive the same data package of sample sounds from the follow-up study to show treatment efficacy.

Example (3): Pediatric hyperactivity is it Sleep apnea?

[0059] Clinical Vignette: A 5 year old male child has signs of attention deficit hyperactivity disorder and is placed on stimulant therapy. Although there is some improvement his mother remains concerned about his difficulty at pre-school. The child is referred back to a Pediatrician who enquires about the child's sleep. The mother reports that he sometimes snores. A sleep study reveals marked obstructed breathing but no apnea, and he is referred for adeno-tonsillectomy. A marked improvement occurs in his behavior after treatment however he continues to snore. A repeat sleep study shows marked improvement with a loss of obstructed breathing but a continuation of some snoring. He is referred for orthodontic assessment, and scheduled for follow up reviews of his snoring.

Data Packages by Observer:

[0060] **Sleep Specialist**: This specialist receives a data package containing the full nights sound (SBD and non SBD breath sounds) and body movement records

indicating all periods where SDB is present or absent. The specialist would review sleep sounds for signs of SDB and movement data for evidence of sleep quality (e.g. insomnia related to stimulant drug therapy). Follow–up studies would be completed using the same data package after adeno-tonsillectomy, during any orthodontic treatment if prescribed and dependent on circumstances if drug therapy was altered or ceased.

ENT Specialist: A data package of SBD sound samples such as snoring would be sent prior to and after adeno-tonsillectomy to indicate proof of SDB and evidence of treatment outcome.

Pediatric Specialist: A data package of SDB sound samples such as snoring would be sent prior to and after adeno-tonsillectomy to indicate proof of SDB and evidence of treatment outcome. Further follow-up SDB sound sample data would be sent as appropriate depending on treatment progression.

General Practitioner and Patient and Carer: They receive sample sound records of SDB sounds indicating presence of snoring or apnea before and after all treatments.

Example (4): Pregnant women query still birth

[0061] Clinical Vignette: 35 year old obese primipara in the last trimester (35 weeks) has not noticed any fetal movements. Her blood pressure is normal and there is no sign of any disease. An ultrasound is unremarkable. A sleep study is organized with fetal movement sensors. The study reveals normal sleep and demonstrates a normal high rate of fetal movement throughout the night. The results reassure the mother and carers that the fetus is alive. The mother is able to feel the replayed movements and hear the normal fetal heart sounds. Late gestation stillbirth is more common in obesity, but obesity (which occurs in about 30% of all current pregnancies) reduces the ability of the mother to feel normal fetal movements.

Data Packages by Observer:

[0062] **Sleep Specialist:** This specialist receives a data package containing the full nights sound (i.e. any SBD and non SBD breath sounds) and body movement records indicating all periods where SDB is present or absent. The specialist would review sleep sounds for signs of SDB and movement data for evidence of sleep quality. Samples from the fetus of palpable fetal movements and fetal heart sounds would be included in this package.

Obstetrician Specialist: A data package of sample breathing sounds would be sent to show that no SBD is present. A full night record of the studies fetal movements (palpable vibrations) and fetal heart sounds would be sent and reviewed by sound and touch.

General Practitioner and Patient and Carer: Samples of the normal night time breathing sounds would be send as well as fetal records. The patient would review the movement (by touch) and amplified heart sound records with the Obstetrician after which they would be reassured of their babies health.

Example (5): Pregnant women, hypertension, edema

[0063] Clinical Vignette: A 25 year old woman who is 29 weeks pregnant has noticed marked ankle swelling. She has gained more than expected weight. Her blood pressure is just below the upper limit of normal and she has no proteinuria. The high risk physician who sees her elicits a history of recent onset of an unusual form of snoring and refers her to a sleep physician. The sleep study shows long periods of obstructed snoring but no sleep apnea. On this night she has blood pressure recorded simultaneously with a portable oscillometric system that measures blood pressure every hour. During the night the blood pressure goes to very high levels during the periods of snoring, but returns to normal on waking. Fetal movements and heart sound are recorded. Although the heart rate is normal there is a marked reduction of fetal movement. She is put on nasal CPAP which controls both the obstructed snoring and the blood pressure and there is a very obvious and marked increase in fetal movements . This dramatic effect is shown to the mother who is thus very happy to use CPAP. Pregnancy is known to precipitate snoring in up to 50 % of women, and there is strong evidence that it precipitates hypertension. Early and timely recognition of this problem and early use of nasal CPAP is thought to be a potentially important new clinical management.

Data Packages by Observer:

[0064] **Sleep Specialist**: This specialist receives a data package containing the full nights sound (i.e. any SDB and non SDB breath sounds) and body movement records indicating all periods where SDB is present or absent. The specialist would review sleep sounds for signs of SDB and movement data for evidence of sleep quality. Samples records (not full night) from the fetus of palpable fetal movements and fetal

heart sounds would be included in this package as would a summary of the blood pressure information. Following implementation of CPAP this specialist would review the same post treatment data package.

Obstetrician Specialist (high risk patients): A data package of sample breathing sounds would be sent to show that SDB is present. A full night record of the studies fetal movements (palpable vibrations) and fetal heart sounds wound be sent and reviewed by sound and touch as would the full night blood pressure data. Following implementation of CPAP this specialist would review the same post treatment data package to review treatment effects on the babies health

General Practitioner and Patient and Carer: Samples of the pre CPAP SDB night time breathing sounds would be sent as well as fetal records. The patient would review (by touch) the movement and amplified heart sound records with the Obstetrician for both the pre and post CPAP implementation data. The patient would be convinced by the data package of the importance to her baby of continuing CPAP throughout the pregnancy.

Example (6): Adult bruxing and snoring

[0065] Clinical Vignette: A 35 year old male reports heavy snoring. He is referred to a sleep physician who orders a sleep study that reveals mild sleep apnea and then refers the patient for a MAS (oral splint). The mat study reveals both snoring and bruxing and indicates that CPAP is a more suitable option as well as a bruxing oral splint (that don't work for snoring and apnea). A repeat study shows that bruxing is greatly reduced when CPAP is used --- we now know that bruxing is induced with brief awakenings.

Data Packages by Observer:

[0066] **Sleep Specialist**: Following fitting of the MAS this specialist receives a data package containing the full nights sound (i.e. any SDB and non SDB breath sounds) and body movement records indicating all periods where SDB is present or absent. The specialist would review sleep sounds for signs of SDB and movement data for evidence of sleep quality. The package would also include all sound records of bruxing enabling the specialist to look at the temporal relationship of the bruxing to

the SDB. Following implementation of CPAP therapy this specialist would review the same post treatment data package to review treatment efficacy

Dentist: After MAS fitting a data package of sample breathing sound records would be sent to show that SDB is still present. A full night record of the bruxing sounds would also be included so the dentist could assess bruxing severity. Following implementation of CPAP the dentist would review the same post treatment data package to review treatment effects of the new splint on bruxing.

General Practitioner and Patient and Carer: Samples of the post MAS fitting SDB night time breathing and bruxing sounds would be sent to show that the MAS wasn't fully efficacious and that bruxing was present. Following implementation of CPAP and bruxing splint therapy the same post treatment data package would be provided to show treatment efficacy.

Example (7): Chronic Lung Disease: Cystic Fibrosis

[0067] Clinical Vignette: A 21 years thin woman with cystic fibrosis is on the lung transplant program. The major challenge is keeping her as well as possible and preventing her getting a Hospital acquired bacterial infection. She is managed at home using the system on her bed with all night recordings of her physical signs. Regular review of the lung sound records indentifies early change in lung signs so that antibiotic therapy is initiated early. She is trained to listen to her own records to recognize early lung signs of infection which help her take each minor episode more seriously

Data Packages by Observer:

[0068] **Pulmonary Specialist**: The specialist reviews a full night's sound record of lung sounds on nights when the patient (or automated analysis software) has identified that infection may be present. The specialist reviews the sound record's to identify wheeze and crackle sounds indicative of lung infection and contacts the patient to organize and monitor treatment. All subsequent night's records are sent as data packages and reviewed until lung sounds indicate that the infection has been successfully treated

Patient and Carer: The patient or carer reviews lung sound file data packages composed of the full nights records either manually or if an auto analysis software program indicates that infection related sounds may be present. If infection is

suspected then full sound records are sent to the specialist (manually or automatically) and discussed. Treatment is commenced as appropriate and similar data package records reviewed daily until infection is no longer present.

Example (8): Heart failure

[0069] Clinical Vignette: A 72 year old woman has long standing hypertension. Recently she has begun waking early in the morning with breathlessness. Her partner describes periods in which she is both snoring and stopping breathing. The primary care practitioner refers her to a cardiologist, who in turn refers her to a sleep physician because of the symptoms of sleep apnea. The sleep study shows central sleep apnea, and the snoring occurs during the breathing recovery. The central sleep apnea progressively worsens throughout the night and she develops lung crackles. The study reveals that the problem is not sleep apnea, but worsening heart failure and following more effective treatment of hypertension and diuretics she improves. A repeat study shows that both the central apnea and snoring have stopped as has the breathlessness at night

Data Packages by Observer:

[0070] **Sleep Specialist**: This specialist receives a data package containing the full nights sound (SBD and non SBD breath sounds) and body movement records indicating all periods where SDB is present or absent. The package would also include samples of lung crackles sound records showing their temporal relationship with apnea. After treatment implementation they receive the same data package from a follow-up study to show treatment efficacy.

Cardiology Specialist: This specialist receives a full nights sound records of all the periods involving crackle sounds as well as periods where these sounds are absent. This specialist receives samples sound records of SDB sounds indicating snoring or apnea and the temporal relationship to the onset of crackles. After treatment implementation they receive the same data package from a follow-up study

General Practitioner and Patient and Carer: They receive Sample sound records of SDB sounds indicating snoring or apnea as well as sample crackle sounds. After treatment they receive the same data package from the follow-up study to show treatment efficacy.

Example (9): Arythmia

[0071] Clinical Vignette: A 62 year old overweight man reports waking with breathlessness at night and has noted irregular heartbeats. He snores but has no other history of sleep apnea. He is referred to a cardiologist who does a Holter monitor study that shows extensive heart rate variability during the night, with periods of very slow heart rate. He arranged for him to have a cardiac pacemaker. During his stay in hospital the staff notice that he has apneic events. He is referred for a sleep study and there is clear repetitive obstructive apnea that are triggering marked slowing of the heart. The episodes of sleep apnea are triggering the heart block. He goes ahead with the pacemaker, but is also put on CPAP that greatly reduces the night time bradycardia events.

Data Packages by Observer:

[0072] **Sleep Specialist**: This specialist receives a data package containing the full nights sound (SDB This specialist receives a data package containing the full nights sound (SBD and non SBD breath sounds) and body movement records indicating all periods where SDB is present or absent and non SDB breath sounds) and body movement records indicating all periods where SDB is present or absent. The also receive the full nights heart sounds record enabling them to detect the relationship between onset of apnea and bradycardia. After treatment implementation they receive the same data package from a follow-up study to enable assessment of treatment efficacy.

Cardiology Specialist: This specialist receives a data package containing sample night sounds (SDB and non SDB breath sounds), heart sound and body movement records indicating periods where SDB is present or absent and exemplifying the temporal relationship of the apnea with the bradycardia.. After CPAP and pacemaker treatment implementation they receive the same data package from a follow-up study to show treatment efficacy.

General Practitioner and Patient and Carer: They receive a data package of sample sound records of SDB sounds indicating snoring or apnea as well as related sample bradycardia heart sounds. After treatment they receive the same data package from the follow-up study to show treatment efficacy.

Example (10): TIA

[0073] Clinical Vignette: A thin 58 year old woman wakes with transient right sided paralysis. She is admitted to hospital for observation. Assessment of her brain and carotid arteries show that she has marked carotid atheroma. The transient stroke is thought to be the result of carotid artery plaque rupture. The neurologist elicits a long history of heavy snoring. The woman has not previously revealed this problem out of embarrassment. A sleep physician is consulted and a sleep test is done. The test shows very obstructed snoring for most of the night, but only minor episodes of complete apnea. She is treated with nasal CPAP. There is now strong evidence that the vibration of snoring damages the carotid arteries and leads to atheroma and is a causative factor in many strokes. There is also evidence that the arterial damage can partially improve if the snoring is controlled.

Data Packages by Observer:

[0074] **Sleep Specialist**: This specialist receives a data package containing the full nights sound (SBD and non SBD breath sounds) and body movement records indicating all periods where SDB is present or absent. After CPAP treatment implementation they receive the same data package from a follow-up study

Neurologist Specialist: This specialist receives a data package containing sample night SDB sounds.. After CPAP treatment implementation they receive the same data package from a follow-up study to show treatment efficacy.

General Practitioner and Patient and Carer: They receive sample sound records of SBD sounds indicating snoring. After CPAP treatment they receive the same data package from the follow-up study to show treatment efficacy.

[0075] The present invention provides a solution to the above and other diagnostic and clinical problems by providing measured, prescriptive or predictive data packages relating to the patient condition including recorded sounds (e.g. snoring) which can be reproduced for any interested party. An advantage of the present invention is that the patient data package can encompass a variety of time periods such as hours or multiple days or nights and can capture varying physical signs that indicate fluctuations in disease severity. This is of particular advantage in providing long term

at home (or in hospital) surveillance of chronic diseases such as most forms of chronic lung disease (e.g. cystic fibrosis and asthma), and chronic heart disease (heart failure for example) where early changes indicative of deterioration can be identified and earlier treatment intervention initiated so to prevent deterioration.

[0080] Another unique aspect of the system according to the present invention is that it can record all night and for as many nights as needed to overcome the problem of inaccurate patient or partner reports of snoring which can be exaggerated due to the absence of a reference to what is acceptable, normal or abnormal or serious. The present invention ameliorates this problem. There are patient pathologies which can be treated in different ways. For example sleep apnea can be treated with various therapies including the use of the oral anti snoring /device (MAS). Many GPs and Sleep Physicians are reluctant to recommend this form of therapy because currently the patient must undergo expensive dental fitting of such a device (with costs in the AU$1500 vicinity) in order to find out if it works. Because MAS devices can be effective in treating both snoring and obstructive apnea, there is a pressing need to be able to assess the patient before and during treatment. However, there is a very variable response to such devices; about 30% of all patients with snoring and or sleep apnea have an excellent response to MAS treatment. However, about 25 to 30% either have no response or get worse on this therapy, and the rest have some improvement. The GP and Sleep Physician's reluctance is also caused by the fact that in general the only feedback that occurs on the effectiveness of the device comes from the patient reporting that their spouse thinks it works. The data on the effectiveness of the MAS device is variable, and it is not yet clear why it works well in some, and poorly in others. Thus there is a great need for a simple robust device that can provide accurate recordings of the snoring and apnea that can be used in both assessment of the problem and then the effectiveness of the treatment.

[0081] The present invention allows the dentist to provide the patient, the patient's partner and the sleep physician with the evidence of the physical signs by using the data packages.. In a research trial which included playing sounds back to patients following their recording during home studies, a dentist /orthodontist found that many of his referred patients took up the option of using an oral device (MAS) after hearing what they sounded like at night, whereas before these patients had refused to try the

therapy. Thus, by providing, the means to record data and then reproduce via tailored data packages the snoring and apnea sound to the patient, the partner, GP, sleep physician and the dentist/orthodontist are in a better position to treat a patient and allow the patient an informed choice in that treatment.

[0082] In the case of children, there is now strong evidence that many children who snore would benefit from appropriate orthodontic interventions that expand the upper airway as well as improving the dentition. However, this approach to treating upper airway obstruction is impeded by the lack of any means at present to study these children, at the beginning of assessment, and to measure the success of the orthodontic procedures. The cost of these orthodontic procedures is high and typically borne by the family without any re-imbursement. So there may be great but understandable reluctance to embark on such therapy unless the clinical evidence is available to enable an informed decision. The present invention provides the data packages which enable lay persons and practitioners to make appropriate judgement as to physical behaviours and treatments which in the past may have been speculative.

[0083] In another example the present invention provides advantage in the treatment of Asthma by enabling recording and collection of data at home over many nights related to a child's asthma. Currently, asthma is poorly managed and treated because the GP and physician have to rely almost entirely on the reports from parents. This leads to both under-treatment and over-treatment --- in the latter case with many children are being put on high doses of inhaled steroids unnecessarily. In many cases asthma may coexist with obstructed breathing which may further complicate identification and effective treatment. The measured data obtained from sensors and records of sounds from a subject who may have signs of asthma, increases the accuracy of diagnosis and treatment options by manually or automatically analysing and identifying sound signals which then indicate presence or absence of disease.

[0084] According to another embodiment, the data collected and used allows using data packages a method of analysis in which the energy of vibrational signals may be quantified for determination of various pathologies such as but not limited to stroke, carotid damage prediction or detection. More particularly the signals from the data packages may be standardised for the purpose of measuring a parameter. For instance

the practitioner can standardise a signal or set of signals to determine how energy in the signal is related to the pathology of a subject. A total amount of energy used in a snore for example can be used to create an index to compare over time a risk of a pathology in a given patient or group of patients. Using this methodology a reference signal or index can be set up for a patient to determine pathology such as tissue damage, eg vascular carotid artery, nerve damage. Deduction can be made based on the energy of the signal with the energy forming a baseline reference for patients. This baseline can be built up over time to quantify what implications a data package might have for diagnostic purposes. A relationship can be made between the energy of a signal and a particular pathology or severity of a condition or state of anatomy. This can allow the creation of indexes or bench marks for patients or groups of patients over time.

[0085] It will be recognised by persons skilled in the art that numerous variations and modifications may be made to the invention described herein without departing from the overall spirit and scope of the invention.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A system providing at least one clinical data package containing physical signs obtained from a subject and transmission of said at least one data recipients to enable identification and/or diagnosis of a patient pathology determined from the at least one data package; the system including;

an assembly comprising at least a sensor capable of sensing data from the subject which forms said package/s of data:

the at least one sensor providing a sensor field for detecting said data over a predetermined period of time, and transmission of said at least one package of data to said data recipient; thereby enabling the recipients of said packages of data to reproduce the data on a sound and /or video device and to remotely simulate a physical examination of the patient;

2. A system according to claim 1 wherein, the data packages obtained from the subject are tailored to suit clinical objectives for assessing a subject's condition.

3. A system according to claim 2 wherein, the data comprises behavioural parameters detected from the subject including body movement, breathing sounds, sound intensities and vibrations.

4. A system according to claim 3 wherein, at least part of the data package is playable on a device which allows visual and/or ambient local sound and/or auscultatory sound signals or images of patient parameters to be usable by the data recipient.

5. A system according to claim 4 wherein, the data is collected over selected time periods including hours, days or weeks, according to the data required for a particular subject's condition.

6. A system according to claim 5 wherein data collected in the data packages enables a data recipient to use sound, sight and touch to interpret breathing and/ or heart and/or gut function movement sounds, local ambient sounds, auscultatory sounds and palpable vibration data.

7. A system according to claim 6 wherein, the data is playable on separate receiving apparatuses including sound and video players.

8. A system according to claim 7 wherein, the sound player includes a surface capable of emitting vibrations alone or in conjunction with video data such that the recipient is able to use touch of said surface for simulated remote physical examination of the subject.

9. A system according to claim 8 wherein, the packages of patient data are transmissible to a plurality of a potentially unlimited number of diagnostic practitioners or other recipients for remote conference analysis of patient condition.

10. A system according to claim 9 wherein, the data packages include sound and breathing movement data relating to sleep activity or inactivity thereby enabling a determination of patient conditions from sleep quality and quantity.

11. A system according to claim 10 wherein the at least one data package is prepared to accommodate the clinical requirements of a particular subject.

12. A system according to claim 11 wherein the conditions capable of determination from the data packages include: sleep apnoea, crackles (crepitations), lung infection, asthma, bronchitis, bronchopneumonia, lobar collapse, pleural effusion, pleurisy, pulmonary infarction and embolus with awakenings, heart murmurs and arrhythmias, congestive heart failure or obstructive pulmonary disease (COPD), gut conditions such as irritable bowel and or bowel obstruction, disrupted sleep and or potential sleep loss.

13. A system according to claim 12 wherein there are a plurality of said sensors in either direct contact with a patient or remote from said patient.

14. A system according to claim 13 further comprising microphones near sensor fields to detect patient sounds.

15. A system for providing data packets of information related to detected movements and breath sounds for the purpose of identifying and optimizing quiescent period and movement measures in a subject as an indicator of sleep status and classifying and analysing pathological events;

evaluating a time distribution and longevity of periods of movement and quiescence to determine the presence of pathologies such as asthma or congestive heart failure or obstructive pulmonary disease (COPD) or other condition affected and indicated by a subject's sleep thereby enabling assessment of the subject's physical condition with reference to sleep quality sleep quality.

16. A system according to claim 15 comprising the further step of analysing the data packages to determine the effects of treatment or pathology of a subject.

17. A system according to claim 16 wherein the data packages are capable of analysis for indicating pathologies of a subject such as apnoea, crackles(crepitations), lung infection, asthma, bronchitis, bronchopneumonia, lobar collapse, pleural effusion, pleurisy, pulmonary infarction and embolus heart failure and heart arrhythmias, with awakenings, disrupted sleep and or potential sleep loss.

18. A system according to claim 17 wherein the patient conditions or pathologies are from data determined over a predetermined test period with reference to sleep time, distribution and longevity of periods of movement and quiescence.

19 A system according to claim 18 wherein, the data is provided to confirm a subject's known or suspected condition

20. A system according to claim 18 wherein the data is provided to enable analysis of a subject's unknown condition.

20 A medical diagnostic assembly comprising;

apparatus including sensors, readers, monitors, video recorders allowing continuous sensing and recording of patient sounds and/ or palpably detectable signals, sound intensity and breathing effort, video signals and/or olfactory signals to indicate the presence of disease or a condition including various respiratory, cardiac, gastrointestinal, dental and other disorders or diseases; the assembly allowing the production of data packages related to a physical condition of a subject; thereby enabling diagnosis of the condition remotely with reference to one or more data packages..

21. An apparatus according to claim 20 including means to enable detection and storage of at least one tailored package of data collected over a period of time wherein the data packages are created from subject parameters are detected including detects and stores including patient parameters, ambient local sound, sound intensity auscultatory sound, palpably detectable vibration, and/or video recordings relating to a pathology of a patient;

means to provide the at least one data package to one or more authorised recipients;

to enabling the one or more recipients to use the data packages upon satisfaction of eligibility criteria for medical, diagnostic or other non medical purposes;

22 An apparatus according to claim 21 wherein the apparatus includes sensor fields capable of detection of a combination of body movement and breath sound signals to enable assessment using data packages collected of sleep status of the patient and to identify events that affect sleep and are effected by sleep patterns and the interrelationship between both.

23. An apparatus according to claim 22 wherein, the data includes data detected from said detected movements and breath sounds for the purpose of identifying and optimizing quiescent period and movement measures as an indicator of sleep status and analysis of pathological events

24. An apparatus according to claim 23 wherein, the packages of data relate to a subject's sleep quality and quantity and the effects of pathological events or

treatments on the subject's sleep by evaluating the time distribution and longevity of periods of movement and quiescence.

25. An apparatus according to claim 24 wherein, the data relates to severity of air flow restriction or snoring or the severity of the frequency of snoring or the rise in amplitude of breath sounds and high frequency inspiratory or expiratory sounds.

26. An apparatus according to claim 25 wherein, a data package indicating severity, intensity of vibrational breathing data enables a determination of a pathology such as stroke damage, arterial disease snoring and sleep apnea.

27. An apparatus according to claim 26 wherein, the apparatus is used to assist in determining a site and cause of flow restriction being recorded and breath sounds both during sleep and the awake state.

28. An apparatus according to claim 27 wherein, the data package includes data related to parameters selected from one or more of wheeze sounds, , snoring or the frequency of snoring or the rise in amplitude of breath sounds and high frequency inspiratory or expiratory sounds.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2012/000606

A. CLASSIFICATION OF SUBJECT MATTER

A61B 5/00 (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPODOC and G06F 19/34C and keywords: audio and camera and sleep and apnea and replay and diagnose and similar terms.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	Documents are listed in the continuation of Box C	

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 August 2012	20 August 2012

Name and mailing address of the ISA/AU	**Authorized officer**
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2012/000606

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

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

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

See Supplemental Box for Details

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		International application No. **PCT/AU2012/000606**
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	US 2006/0074709 A1 (McALLISTER) 06 April 2006	
X	paragraphs 27, 36, 37 and 39 to 48	1 to 20, 20 to 28
Y	paragraphs 27, 36, 37 and 39 to 48	6 to 14
	US 2011/0087079 A1 (AARTS) 14 April 2011	
X	paragraphs 16 to 26	1 to 20, 20 to 28
Y	paragraphs 16 to 26	6 to 14
	US 2010/0152543 A1 (HENEGHAN et al.) 17 June 2010	
X	paragraphs 18, 31, 66 and 67	1 to 20, 20 to 28
Y	paragraphs 18, 31, 66 and 67	6 to 14
	US 2010/0121156 A1 (YOO) 13 May 2010	
X	paragraphs 304 and 312 to 326	1 to 9, 20, 21
Y	paragraphs 304 and 312 to 326	6 to 9
	US 6598084 B1 (EDWARDS et al.) 22 July 2003	
X	column 5 lines 32 to 57 and column 6 lines 39 to 65	1 to 9, 20, 21
Y	column 5 lines 32 to 57 and column 6 lines 39 to 65	6 to 9
	US 2008/0077435 A1 (MURADIA) 27 March 2008	
X	paragraphs 20, 25 and 49	1 to 9, 20, 21
Y	paragraphs 20, 25 and 49	6 to 9
	US 6416471 B1 (KUMAR et al.) 09 July 2002	
X	column 4 line 38 to column 6 line 16, column 9 lines 19 to 25, column 11 lines 41 to 43	1 to 9, 20 and 21
Y	column 4 line 38 to column 6 line 16, column 9 lines 19 to 25, column 11 lines 41 to 43	6 to 9
	EP 1582145 A2 (CEL-KOM LLC) 05 October 2005	
Y	paragraphs 2, 23 and 28	6 to 14

Supplemental Box

Continuation of: **Box III**

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

This Authority has found that there are different inventions based on the following features that separate the claims into distinct groups:

- Claims 1 to 14 and 20 to 28 are directed to a system for simulating a remote physical examination of a patient, the system including sensors which produce a package of data that is transmitted to a remote data recipient. The feature of the transmission of the data package to a remote data recipient is specific to this group of claims.

- Claims 15 to 20 are directed to a system of providing data packets relating to periods of movement and quiescence of a patient enabling assessment of a patient's physical condition with reference to sleep quality. The feature of data packets relating to periods of movement and quiescence is specific to this group of claims.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

When there is no special technical feature common to all the claimed inventions there is no unity of invention.

In the above groups of claims, the identified features may have the potential to make a contribution over the prior art but are not common to all the claimed inventions and therefore cannot provide the required technical relationship. Therefore there is no special technical feature common to all the claimed inventions and the requirements for unity of invention are consequently not satisfied *a priori*.

INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. PCT/AU2012/000606

This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document/s Cited in Search Report		Patent Family Member/s	
Publication Number	**Publication Date**	**Publication Number**	**Publication Date**
US 2006/0074709 A1	06 Apr 2006	US 2006074709 A1	06 Apr 2006
		WO 2006034588 A1	06 Apr 2006
US 2011/0087079 A1	14 Apr 2011	CN 102088911 A	08 Jun 2011
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		WO 2008035211 A2	27 Mar 2008
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		US 6416471 B1	09 Jul 2002

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. PCT/AU2012/000606

This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document/s Cited in Search Report		Patent Family Member/s	
Publication Number	**Publication Date**	**Publication Number**	**Publication Date**
		US 6454708 B1	24 Sep 2002
		WO 0062664 A1	26 Oct 2000
		WO 0193756 A2	13 Dec 2001
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		WO 2006088574 A2	24 Aug 2006

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INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. PCT/AU2012/000606

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Patent Document/s Cited in Search Report		Patent Family Member/s	
Publication Number	**Publication Date**	**Publication Number**	**Publication Date**

End of Annex

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