(12) UK Patent Application (19) GB (11) 2489704 (13) A

(43) Date of A Publication 10.10.2012

(21) Application No: 1105699.1

(22) Date of Filing: 04.04.2011

(71) Applicant(s):
Cardiocity Limited
Blackburn House, 32A Crouch Street, Colchester, Essex, CO3 3HH, United Kingdom

(72) Inventor(s):
Chris Crockford

(74) Agent and/or Address for Service:
Page White & Farrer
Bedford House, John Street, London, WC1N 2BF, United Kingdom

(51) INT CL:
A61B 5/0428 (2006.01) ***A61B 5/0408*** (2006.01)
A61B 5/0488 (2006.01)

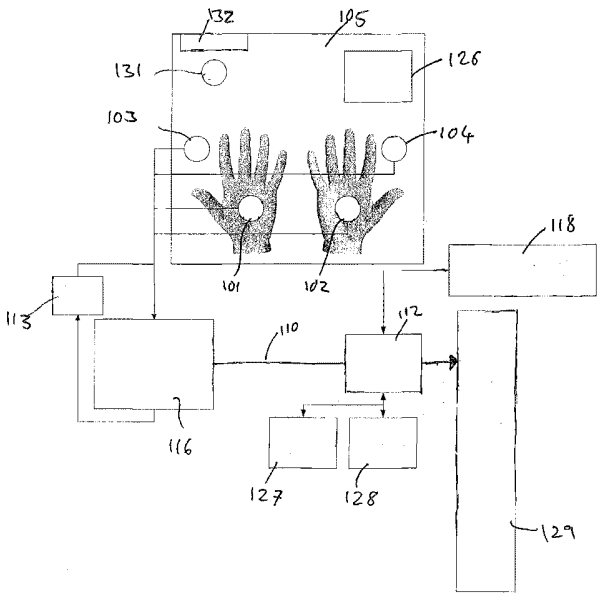
(56) Documents Cited:
EP 1627597 A1 **WO 2011/007292 A1**
WO 2009/074955 A1 **WO 2006/131855 A2**
DE 102005048496 A1 **US 20100049068 A1**
US 20070197925 A **US 20070149888 A1**

(58) Field of Search:
INT CL **A61B**
Other: **Online: EPODOC, WPI, TXTE**

(54) Title of the Invention: **ECG mat**
Abstract Title: **Electrocardiographic mat with multiple electric potential sensors**

(57) An electrocardiographic (ECG) device for sensing cardiac activity in a user comprises a set of electric potential (EP) sensors 101, 102 provided within an insulating mat 105 and a set of indicia on the surface of the mat indicating an optimal location and orientation of a user's hands. The hands of the user are placed so that the sensors 101, 102 lie under the ball of the thumb of each hand. The indicia may be an outline of a pair of hands or indentations in the surface of the mat. The mat may include further EP sensors 103, 104 and indicia indicating the position of a user's feet. A control unit 112 processes the data from the sensors and may determine whether the user is optionally engaged with the device and indicate how to improve the engagement. The invention may involve controlling the interaction of a user with an electromyographic device. A similar mat may be used for an infant to determine whether the infant is sleeping in a safe position. The control unit 112 may determine the most likely position in which the user is engaged with the sensors and analyze the data accordingly.

Figure 1



GB 2489704 A

Figure 1

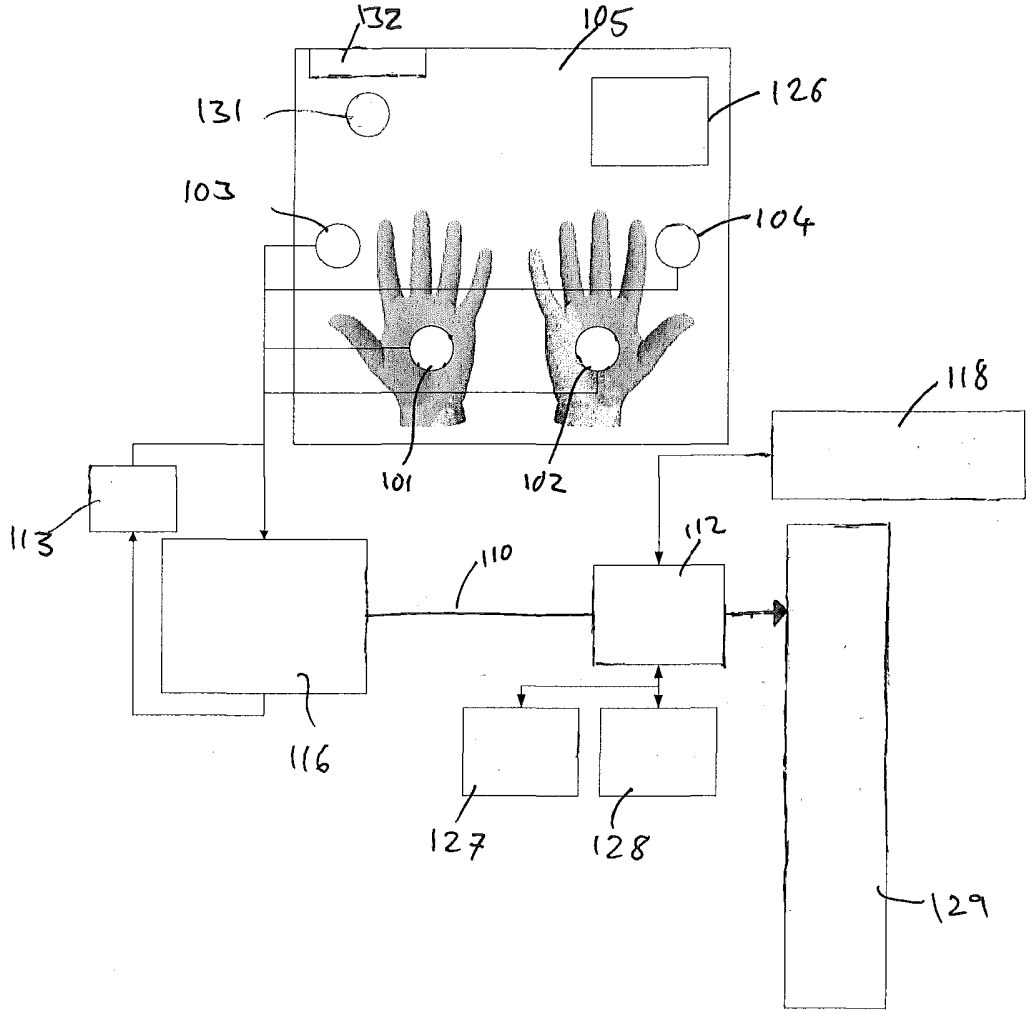
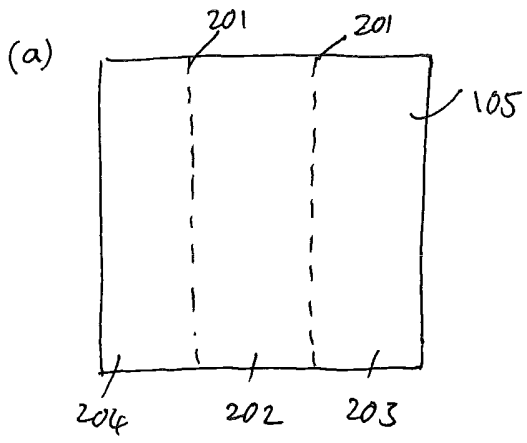
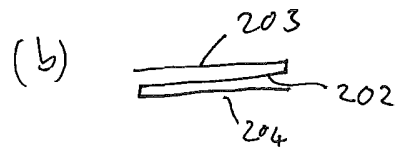
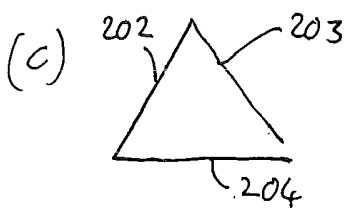


Figure 2







The following terms are registered trademarks and should be read as such wherever they occur in this document:

Bluetooth

ECG Mat

BACKGROUND OF THE INVENTION

The present invention relates to methods and apparatus for the acquisition and interpretation of ECG signals.

The use of electrocardiograph (ECG) detection and monitoring equipment has become pervasive, with ECGs being used to determine cardiac electrical activity of both animals and humans. ECG equipment is used for a variety of purposes: from measuring the cardiac performance of athletes, to observing basic heart function, through to the detailed monitoring of problems in specific sections of the cardiac system.

Long term ECG monitoring is an established practice, and the detection of the heart's rhythm when monitored over time can identify performance problems known as arrhythmias that can be classified according to the area of the cardiac system that has caused the rhythm to be disrupted. Short term monitoring can provide a means to understand momentary cardiac performance but will not provide a full insight into what may subsequently happen to the cardiac system.

Conventional ECG equipment monitors the electrical activity at the skin of a subject due to the beating of the heart and expresses the electrical activity as a waveform (an electrocardiograph). The electrical activity is detected by electrodes (typically Ag/AgCl electrodes) attached at specific points on a subject's anatomy and electrically coupled to the skin by a conductive gel. Modern ECG systems can make use of automated algorithms that analyse the structure, timing, and electrical characteristics of the cardiac systems various components.

The placement of the electrodes is conventionally determined in accordance with Einthoven's Triangular law, which allocates three electrodes as limb leads: Left Hand (LH), Right Hand (RH), and Left Foot (LF). The potential difference (typically millivolts) between LH and RH, being known as Lead 1, between LH and LF as Lead 2, and RH and LF as Lead 3. The term lead is used to refer to a conceptual investigative lead and not a physical electrode cable lead. By taking readings from the three limb leads it is possible to understand the electrical activity of the cardiac system from three angular perspectives. If the average of any two leads is then further compared against the third lead, it is possible to derive a further three investigative leads, known as the derived Leads 4-6.

A 6 lead systems allows an investigator to see a cardiac system's electrical activity from the centre of the source of the electrical signal along six different axes. To understand the effect of the electrical signal on specific muscle tissues of the cardiac system, further investigative leads (chest leads) must be attached to the body to look at the electrical signal passing through the regions of the heart. The deployment of chest leads (known as V1 through V6) in an arc from approximately the sternum to under the left hand side of the rib cage allows such a detailed reading of the electrical activity passing sequentially through the muscles of the heart. This allows various diseases, conditions and any damage to the heart to be determined.

Variations on the placement of leads has led to more derived leads being obtained through fewer electrodes, and various algorithms have been established to enable fewer electrodes to yield more information about the electrical activity of the cardiac system.

The algorithms used to identify different rhythm problems, or arrhythmias, use time based analysis of the outputs from the electrodes and care must be used to ensure that the correct time base is used when comparing one electrode's signal with another. The time stamping of individual signals can require a highly accurate and correlated time source.

The placement of conventional electrodes on the subject often causes issues, especially if the subject is hairy or has a skin condition that causes the subject's skin to react to the adhesive pad. Conductive gels can also cause irritation to the subject and also introduce the problem that the gel can provide low resistance paths between adjacent electrodes. The usage of conventional dry electrodes is limited since their signal to noise ratio is often very high.

Recently, "contactless" electrodes have been introduced that measure electrical potential at the skin without a direct electrical contact by means of capacitive coupling. These electrodes, commonly referred to as electric potential sensors, work by sensing the electric field created by displacement currents in the body of the subject. These electric potential sensors are discussed in International Patent Application Publication No. WO 01/16607, which describes an electric field sensor having a capacitive pick-up electrode for the detection of alternating electrical fields originating from within the human body. The electrode is connected to a high impedance sensing amplifier. In order to render the capacitance coupling relatively sensitive to variations in the separation between the body and the electrode, the electrode itself is separated from the body by a thin (preferably low dielectric) insulating layer, and a limiting capacitor is placed in series with the input to the sensing amplifier. Thus the sensor can be seen to be contactless.

Further relevant publications include European Patent No. 1451595, Japanese Patent Application NO. 2005511174, Taiwanese Patent Application No. 2003200664, US Patent Application No. 20060058694, and International Patent Application Publication No. WO 03/048789. These describe the operation of an electro-dynamic sensor, in which a number of different circuit techniques are combined to achieve several orders of magnitude improvement in sensitivity compared to previously known electro-dynamic sensors, whilst still maintaining sufficient stability to permit a measurement to be acquired in everyday conditions.

These publications describe an electrodynamic sensor comprising a high input impedance electrometer adapted to measure small electrical potentials originating from the subject under test and which employs at least one input probe having no direct electrical contact with the subject. In order to function, the circuit arrangement of the electrometer comprises an amplifier that includes a combination of ancillary circuits providing feedback from the output of the amplifier and arranged cumulatively to increase the sensitivity of the electrometer to the small electrical potentials whilst not affecting the electrical field being monitored. Such ancillary circuits typically provide at least two characteristics that can refine the signal, such as guarding, bootstrapping, neutralisation, supply rail drift correction, supply modulation and offset correction for the sensor.

However, the use of the output signal from the amplifier as the feedback signal has the disadvantage that such a signal is a broadband signal, which may have a poor signal to noise ratio. This noise is then fed back to the amplifier input by the feedback setup, causing further degradation of the signal to noise ratio.

In contrast, the feedback signal of an electric potential sensor is not a broadband signal derived directly from the output of the sensor, but is a generally a coherent signal. This has the effect of significantly improving the signal to noise ratio and makes electric potential sensors a better alternative to conventional wet electrodes for ECGs than electrodynamic sensors.

The use of electric potential (EP) sensors using capacitance coupling for data acquisition is not without its own inherent problems, including: how to standardise the time-base for wirelessly connected sensors, how to best couple the sensors to a subject, and how to isolate the highly sensitive sensors from external interference so as to allow the identification of the desired signal, which may be of relatively low value in comparison to environmental noise. However, the fact that EPS sensors allow capacitively coupled measurements to be taken through thin clothing, without the use of

conductive gels and whilst maintaining good electrical isolation from the subject means that this new class of sensors is very promising for use as an alternative to conventional dry ECG electrodes.

SUMMARY OF THE INVENTION

According to a first aspect of the present invention there is provided an electrocardiographic device for sensing cardiac activity in a user comprising: a first set of electric potential sensors provided within an insulating mat; and a first set of indicia on the surface of the mat indicating an optimal location and orientation of a user's hands; wherein the first set of sensors are arranged relative to the first set of indicia such that, in use, at least one sensor is located under the ball of the thumb of each of a user's hands.

Suitably the indicia are an outline of a pair of hands indicating the desired location of a user's hands relative to the sensors and/or indentations in the mat indicating the desired location of a user's hands relative to the sensors.

The electrocardiographic device may further comprise: a second set of electric potential sensors provided within an insulating mat; and a second set of indicia on the surface of the mat indicating an optimal location and orientation of a user's feet; wherein the second set of sensors are arranged relative to the second set of indicia such that, in use, at least one sensor is located under the ball of the foot of each of a user's feet.

Suitably the indicia are an outline of a pair of feet indicating the desired location of a user's feet relative to the sensors and/or indentations in the mat indicating the desired location of a user's feet relative to the sensors.

Preferably each electric potential sensor comprises an electrometer amplifier. Preferably each electric potential sensor is located within a shielded housing within the insulating mat. Preferably each electric potential sensor comprises

a conducting electrode coated with a thin insulating layer such that, in use, at least the thin insulating layer separates the user from the conducting electrode.

The electrocardiographic device could further comprise a control unit for processing signals acquired by the electric potential sensors of one or more insulating mats and forming an electrocardiograph of the user's cardiac electrical activity. The electrocardiographic device could further comprise a display screen operable to display said electrocardiograph.

Suitably the flat insulating mat is configured to be foldable along one or more folds such that, when folded and resting on a surface, the mat is operable to form a tube-like closed structure presenting at least some of the electric potential sensors to a user on its outward-facing surfaces.

The electrocardiographic device could further comprise a camera arranged to monitor the position of a user's hands or feet on the mat, and the control unit being configured to, on detecting a poor quality signal from one or more electric potential sensors, cause a user to reposition their hands or feet on the mat with respect to the electric potential sensors by displaying instructions on the display screen.

Suitably the control unit is configured to cause wideband noise to be allowed into the amplifier of an EP sensor so as to maintain a noise level such that information carried on signals that do not form part of an ECG waveform may be acquired by the EP sensor and passed to the control unit.

According to a second aspect of the present invention there is provided a method for controlling the interaction of a user with an electrocardiographic device having a plurality of electric potential sensors for contact with a user, the method comprising: a user engaging with at least some of the electric potential sensors of an electrocardiographic device; the electrocardiographic device sensing cardiac activity of the user by means of contact between the

sensors and the user; receiving at a control unit a representation of the cardiac activity sensed by the sensors; comparing the representation of the cardiac activity of the user with a set of predetermined characteristics of cardiac activity so as to determine whether the user is optimally engaged with the electrocardiographic device; and if the user is not optimally engaged with the electrocardiographic device, indicating how the user may improve their engagement with the device.

Preferably the set of predetermined characteristics of cardiac activity include characteristics of cardiac activity indicative of a poor coupling between a user and one or more electric potential sensors.

The contact between the sensors and user need not be skin contact and may be through one or more layers of clothing.

Preferably the control unit is provided at the electrocardiographic device. Preferably the sensors are provided in an insulating mat. Preferably the indication is by means of a display screen at the electrocardiographic device. Preferably the indication is arranged to cause the user to position the ball of the thumb of their hand, or the ball of their foot directly over one or more electric potential sensors.

According to a third aspect of the present invention there is provided a method for controlling the interaction of a user with an electromyographic device having a plurality of electric potential sensors for contact with a user, the method comprising: a user engaging with at least some of the electric potential sensors of an electromyographic device; the electromyographic device indicating to the user to contract a particular muscle or set of muscles; sensing electrical activity due to the contraction of the muscle or set of muscles by means of contact between the sensors and the user; receiving at a control unit a representation of the muscle electrical activity sensed by the sensors; comparing the representation of the muscle electrical activity of the user with a set of predetermined characteristics of muscle electrical activity so

as to determine whether the user is optimally engaged with the electromyographic device; and if the user is not optimally engaged with the electromyographic device, indicating how the user may improve their engagement with the device.

According to a fourth aspect of the present invention there is provided a method for monitoring the sleeping position of an infant with an electrocardiographic device having a plurality of electric potential sensors incorporated into a sleeping mat, the method comprising: an infant engaging with at least some of the electric potential sensors of an electrocardiographic device; the electrocardiographic device sensing cardiac activity of the infant by means of contact between the sensors and the infant; receiving at a control unit a representation of the cardiac activity sensed by the sensors; comparing the representation of the cardiac activity of the user with a set of predetermined characteristics of sensed infant cardiac activity in different sleeping positions, at least some of the predetermined characteristics being associated with unsafe sleeping positions; in dependence on the result of the comparing step, determining if the infant is likely to be in an unsafe sleeping position; and if the infant is determined to be likely to be in an unsafe sleeping position, indicating that the infant is in an unsafe sleeping position.

The control unit could be provided at the electrocardiographic device. Preferably the control unit comprises a wireless transmitter for operation with a baby monitor and the indication that the infant is in an unsafe sleeping position is transmitted as an alert over the wireless transmitter.

According to a fifth aspect of the present invention there is provided a method for analysing data representing cardiac activity of a user acquired by an electrocardiographic device having a plurality of electric potential sensors for contact with a user, a user being operable to engage with the electric potential sensors in a plurality of different positions, the method comprising: at an electrocardiographic device, acquiring data representing cardiac activity of a user by means of contact between at least some of the electric potential

sensors of the electrocardiographic device and the user; receiving at a control unit the data representing the cardiac activity of the user; and comparing the representation of the cardiac activity of the user with a set of predetermined representations of cardiac activity so as to determine the most likely position in which the user is engaged with the electric potential sensors; and analysing the data representing the cardiac activity of the user in accordance with a set of stored parameters provided for the analysis of cardiac activity data acquired from a user engaged with the electric potential sensors in the determined most likely position.

Preferably the control unit is provided at the electrocardiographic device.

DESCRIPTION OF THE DRAWINGS

The present invention will now be described by way of example with reference to the accompanying drawings, in which:

Figure 1 is a schematic diagram of an electrocardiographic device for sensing cardiac activity in a user in accordance with the present invention.

Figure 2 is a schematic diagram of a foldable ECG mat in accordance with the present invention.

DETAILED DESCRIPTION OF THE DRAWINGS

The following description is presented to enable any person skilled in the art to make and use the invention, and is provided in the context of a particular application. Various modifications to the disclosed embodiments will be readily apparent to those skilled in the art.

The general principles defined herein may be applied to other embodiments and applications without departing from the spirit and scope of the present invention. Thus, the present invention is not intended to be limited to the

embodiments shown, but is to be accorded the widest scope consistent with the principles and features disclosed herein.

Due to the low sensitivity of conventional electrodes and the nature of the electrical signals generated by cardiac activity, it has been necessary to accurately locate conventional ECG electrodes. The present invention recognizes that the spatial location of electric potential sensors can challenge the conventional locations for applications in which detailed monitoring of the electrical activity in the heart is not required (such applications are generally handled by 12 lead ECG machines). The present invention provides the performance of conventional 1 to 6 lead ECG machines, depending on the configuration of a device configured in accordance with the present invention.

The present invention further recognizes that the variation in an acquired electrocardiograph due to variations in the position of the EP sensors on the user's body has several novel uses.

A schematic diagram of an electrocardiographic device for sensing cardiac activity in a user is shown in figure 1. The two hands are shown by way of illustration only and are an example of one use of the mat. The electrocardiographic device includes EP sensors 101 and 102, and optionally EP sensors 103 and 104. The sensors are set into an insulating mat 105 which includes one or more sets of indicia indicating where on the mat the user is intended to place their hands and/or feet. Preferably a mat comprises sets of indicia for both hands and feet so as to allow a mat to be used to acquire ECG signals from either hands or feet. These indicia may be in the form of outline shapes showing where the hands/feet should be placed, and/or indentations in the surface of the mat showing where the hands/feet should be placed. Most advantageously, the mat is configured such that: (a) in the case of hands: the hands of a user are placed so that at least sensors 101 and 102 lie under the ball of the thumb of each hand when in use, with the palms face-down on the mat; and (b) in the case of feet: the feet of a user are placed so that at least sensors 103 and 104 lie under the ball of each foot

when in use, with the feet soles-down on the mat. This helps to shield the sensors from environmental noise.

Each sensor feeds its data to an analogue to digital converter 116, with each sensor typically being on a different channel. The analogue to digital convertor may incorporate a feedback loop 113 for controlling the signal to noise ratio and the background environmental signals being amplified. Preferably the AtoD and feedback loop include an amplifier for coherent amplification of EGC signals received from the EP sensors. Preferably data representing the output from the sensors is passed to a control unit 112 over link 110, which is typically a microcontroller or microprocessor. The link may be effected by any kind of connection, including by means of a packet based communications protocol.

Control unit 112 is configured to process the data representing the output from the sensors in the manner required by the application. Preferably the control unit is operable to process the data in accordance with a set of algorithms stored at data store 118 for identifying arrhythmias. The output 129 from the control unit may be in the form of a set of one or more rhythm strips of ECG data. The output could be stored the device, transmitted over optional wireless interfaces 127 or 128, and/or displayed at display screen 126. The screen may be presented in mat 105 or could be provided separately. Optional wireless interface 127 may provide telephonic interfaces such as GSM or 3G. Optional wireless interface 128 may provide other radio interfaces such as Bluetooth or Wifi. The control unit may alternatively or additionally output a statistical analysis of the ECG rhythm strips, indications of any arrhythmias detected by its processing, and instructions to the user.

The device optionally includes a camera 131. The output from the camera can be fed to the control unit so as to allow the control unit to interactively instruct the user as to the optimal placement of their hands. An optional mirror 132 may also be provided that can be configured to increase the camera's field of view.

The sensors 101 to 104 being EP sensors need not be in direct contact with the skin of a subject in order to sense an ECG signal. For example, a user may engage with the EP sensors through one or more layers of clothing. That part of the EP sensors with which a body part is engaged could be enclosed within the material of the mat such that engagement of a user with the EP sensors occurs through the insulating material of the mat. Such an arrangement can help to minimise the level of unwanted environmental noise leaking into the EP sensors.

In the example shown in figure 1, a mat or pad is provided onto which the subject under investigation can arranged their hands upon sensors 101 and 102 in order to allow a 1-lead ECG reading to be recorded as the potential difference between EP sensors 101 and 102. The mat or pad 105 could have additional sensors 103, 104 in order to capture ECG readings from additional body parts. For example, sensors 103, 104 could be adapted to take readings from feet placed in an advantageous orientation over the sensors. The mat could be configured so as to capture readings from all sensors simultaneously. The provision of multiple sets of sensors allows a mat to be used in multiple configurations – for example, to take 1-lead readings from either a pair of hands, a pair of feet, or a foot and a hand.

The provision of multiple sets of sensors in a mat allows multiple mats to be combined for the simultaneous capture of ECG data from both the feet and hands of a user – for example, a user could stand on one mat and engage one or more feet with feet sensors 103 and 104, whilst engaging their hands with sensors 101 and 102 of a second mat. Both mats would be coupled to control unit 112. This allows ECG leads 1 to 3 to be obtained, and hence the derived leads 4 to 6.

EP sensors configured in accordance with the present invention can be located at the limbs of a subject so as to capture multi-lead ECG signals in an equivalent manner to conventional multi-lead ECG systems having electrodes

located at the same positions, but with the benefit that no adhesives or conductive gels need to be used.

In the particular example of a mat having sensors configured to engage with a user's feet, it should be noted that the use of EP sensors allows the mat to pick up ECG signals through the thick skin of the soles of the user's feet, and possibly also through a layer of clothing, such as socks. This is to be contrasted with conventional electrodes that require a direct electrical connection to a user's body and would be unlikely to function well (if at all) connected to the thick skin of a user's feet. The provision of a mat comprising EP sensors conveniently allows the ECG signal of a user to be captured simply by stepping onto a mat configured in accordance with the present invention, and optionally placing their hands on another mat.

It is particularly advantageous that the parts of the user's anatomy that are placed on the mat are arranged such that the user's anatomy shields the EP sensors from environmental noise. This can improve the fidelity and speed of detection of an ECG system that uses EP sensors. For example, the positioning of the hand such that the ball of the thumb of the hand is located over an EP sensor provides a good ECG signal and allows the thick, fleshy part of the hand to shield the EP sensor from environmental noise. This speeds up ECG acquisition time by the EP sensor and lowers noise levels present in the signal. The positioning of a foot such that the ball of the foot (or base of the big toe) lies over an EP sensor is similarly advantageous.

It is advantageous if a feedback system is provided for use with the mat so as to ensure that the limbs of a user are placed in their optimal positions in order to best shield the EP sensors from environmental noise. When ECG signals are acquired by the mat but those signals are of poor quality, the control unit 112 is preferably configured to alert the user to the fact that their limbs may not be optimally placed on the mat. The control unit can determine whether a signal is poor quality by comparing an acquired ECG signal with sets of characteristics stored at data store 118, at least some of which indicate that

there is poor engagement between the user and the respective electric potential sensors. Preferably the control unit directs the user to adjust the placement of their limbs (e.g. hands or feet) on the mat and then determines whether the signal quality has improved. The control unit may direct the user to make multiple adjustments and then ask the user to adopt the position that was associated with the best signal quality. The control unit may be configured to present such directions to the user by means of screen 126, which may or may not form part of the mat 105.

Most preferably, mat 105 further comprises a camera 131 configured to monitor the position of the user's limbs on the mat relative to the EP sensors. The output of the camera is fed to control unit 112 which can be configured to direct the user to place their limbs in the optimal position. This may be in response to acquiring a poor quality signal. For example, the control unit may monitor by means of the camera the position of a user's hands on the mat. If the user's hands are not in the optimal position, the control unit could direct the user to improve their position by means of images or text on screen 126 that identifies to the user how their position might be improved.

The provision of a camera 131 may alternatively allow the control unit to adapt its processing of the acquired ECG signals in dependence on the position of the user's limbs as detected by the camera relative to the EP sensors. A mirror 132 may also be provided at the mat so as to allow the camera to identify the position of a user's limbs at points that are not visible by direct line of sight from the camera aperture. Alternatively or additionally the camera could have multiple apertures and sensors, or there could be multiple cameras 131.

The present invention is not limited to the detection of electrocardiographic (ECG) signals and could also be used for the detection of electromyographic (EMG) signals, i.e. the acquisition of electrical activity due to skeletal muscles. If camera 131 is present, it can be used to direct the user to place their limb in the optimal position for acquisition of the EMG signals of interest. For

example, the control unit 112 could be configured to monitor the position of a user's forearm relative to sensors of the mat and direct by means of screen 126 the optimal placement of the forearm over those sensors in order to acquire a wrist muscle EMG. This can be achieved by causing a user to contract the particular muscle of interest, acquiring the EMG of that muscle or muscle group and comparing the characteristics of the EMG with a set of characteristics stored at data store 118. If the characteristics of the EMG suggest that the user's body part is not optimally positioned, the device can indicate to the user to reposition their body part. The device preferably indicates to the user the optimal position they should adopt.

By the provision of multiple sensors, the mat could be configured to acquire both ECG and EMG signals simultaneously. A system that incorporates the EP Sensors with an active feedback loop may have benefits in systems not necessarily for medical usages, such as sports and gym equipment. Understanding the muscle EMG coupled with a cardiac ECG might allow an exercise programme to be controlled for the limited exercising of specific muscle groups as analysed by the EMG, and with positive feedback being given to the subject by means of the camera and screen.

EP sensors are typically much smaller than human hands or feet. Multiple EP sensors can therefore be allocated for each human limb. Through the use of statistical averaging over the sensors allocated to a limb (e.g. hand or foot) a cleaner signal can be acquired and in a shorted space of time.

Mat 105 may be configured to be foldable along folds 201 as illustrated in figure 2. This can have two benefits. Firstly, as shown in figure 2(b), the mat can then be stored more compactly. Secondly, as shown in figure 2(c), the mat can be folded into a three-dimensional object: for example, a tubular object of triangular cross-section as shown in figure (c), or a tubular object of rectangular cross-section if the mat were to have three folds 201. In figure 2(c), the folds of the mat are configured such that the surfaces of the mat comprising the EP sensors 202, 203 are presented to a user when the mat is

rested on a third surface 204. Such a folding arrangement might allow the mat to be used more comfortably when an ECG signal is acquired from a pair of hands or any other body part.

In an embodiment of the present invention, mat 105 could take the form of a sleeping mat for an infant. Placing an infant on the sleeping mat would allow an ECG to be acquired by means of the EP sensors embedded in the surface of the mat. Such a sleeping mat is advantageous for two reasons. Firstly, the ECG itself can be used to ensure the safety of the infant since problems with the infant's heartbeat can be immediately alerted to the parent or carer. Secondly, the ECG can be used in a novel manner to determine the position in which the infant is sleeping and hence determine whether the infant is sleeping in a safe position.

This second use of an infant ECG acquired by a mat configured in accordance with the present invention relies on the fact that an ECG acquired by EP sensors varies in dependence on the position of the EP sensors on the infant's body. Thus, the ECG acquired from an infant sleeping on its back will be different from the ECH acquired from an infant sleeping on its front. By configuring control unit 112 to process the ECG of a sleeping infant in dependence on a set of stored characteristics indicative of various sleeping positions of an infant, the system can be configured to determine which position the infant is sleeping in. The control unit may be configured to display and/or sound an alarm when the infant is found to be sleeping in an unsafe position, preferably by means of a baby monitor so as to avoid waking the infant.

The ECG signals acquired by the EP sensors of the mat are analysed at control unit 112 after digital encoding at analogue to digital converter 116 and transmission over link 110. By comparing the signal acquired at one EP sensor with that acquired at another EP sensor according to a common time base, the various leads of an ECG system can be determined and derived as is known in the art. The control unit 112 may be able to run any form of digital

analysis on the acquired ECG data, such as algorithms for arrhythmia detection.

The ECG signal could be cleaned up by analogue electronics at the input of AtoD converter 116 and/or its feedback loop 113, or by means of digital electronics at the output of the AtoD converter or at the control unit 112. The AtoD converter preferably samples at 5kHz.

During both the signal acquisition phase and during the continuously returned signal monitoring phase, owing to the high frequency and the ability of the EP sensors to positively feedback coherent signals into the stage amplifier (typically part of the AtoD 116 and feedback loop 113), it is likely that other bio-information may be detected, such as the respiration rate of the subject, or the electrical signal of a particular muscle group.

It may be beneficial to encode not only the ECG signal, but also additional signals from different muscle groups (or other anatomical entities) and encode these as well. If the control unit cannot itself process such additional signals, they can be stored by the control unit for later analysis.

There may also be benefit in being able to control through a duplex manner, the ability of the amount of wideband noise, being allowed back into the amplification sub process of the EP sensor, such that a microcontroller could in effect signal back to the EP sensor, to maintain a certain level of background noise, such that specific biomarkers that may be carried on another signal, perhaps an ECG waveform, may be established, identified, and analysed accordingly.

At the commencement of any ECG reading delivered through the utilisation of the EP sensors, there will be a period of time before the system locks onto the ECG signal when the level of background noise is relatively high. This inhibits for a short period the identification of a clean ECG signal trace, or a signal

trace that is of high enough quality to form the input data for a cleaning and refinement algorithm operating on the control unit.

There is therefore required a mechanism between an EP sensor and the control unit that allows the establishment of a clear to send/ready to send handshake. This may well be implemented in software such that the EP sensor output at analogue level may be encoded with a preceding marker bit that can be set such that, when the analogue side of the analogue to digital converter has found and isolated an ECG signal from the background noise, that it can set the marker bit as ready to send, thus allowing the analogue to digital converter to signal to the control unit that it is ready to send over link 110. This first marker bit may be acknowledged with a clear to send bit, which in turn is then acknowledged by the analogue to digital converter. Whereupon the streaming of data may commence. Such transmission mechanisms are known in the art from modems and connection orientated communications protocol such as TCP/IP.

The data from EP sensors may be transmitted over link 110 in a high level format such as XML or HL7. Preferably timestamps are encoded into such a high level stream format, along with optionally an indication of location of the parts of the anatomy being monitored/the location of EP sensors on a subject's body. This may prove beneficial in the production of body mapped electrical systems activity and subsequent multi dimensional imagery through the utilisation of a plurality of sensor, perhaps in the region of 120 EP sensors in a system to wrap and encompass the upper torso of the human body. Such a system could be incorporated into a shirt or other clothing offering.

Screen 126 may be used to give feedback to the subject with regards the duration that the subject should keep their limbs engaged with the surface. In such a manner if the control unit that received the data from the plurality of EP sensors and passed this to data to an algorithm to analyse, and subsequently the algorithm identified that the user had a known problem with their physiological data, then the system, through the screen could inform the

subject to extend their testing period for a known period of time, such that the condition identified may be verified by taking a longer reading of physiological data over a longer period of time, thus reducing the potential for false positive analysis.

The present system can be utilised to take a quick ECG reading through limb placement over a multitude of EP sensors and lends itself to being able to provide a quick ECG analysis of current cardiac performance. Even over a time period of perhaps only 90 seconds it may well be possible to not only run an algorithm on the system to detect arrhythmia and other well documented cardiac conditions, but also to export the statistics of each cardiac or physiological parameter recorded, and then to calculate the average or median performance of each physiological cycle. Such data can be used in the control inputs of a medical scoring system, such as the Karnofsky, Zubrod, Apache III, or Geneva scoring systems.

Where specific physiological monitoring scoring systems exist for say cardiology, it may be possible to identify a risk stratification for the subject based on the output performance characteristics of their sinus rhythm with regards the time span that they were monitored by the EP sensors. In such a manner it may well be possible to extrapolate a whole series of performance indices, such as average QRS complex time. Such indices can be provided with the ECG traces themselves at the output 129 of the control unit, and/or at screen 126. These indices, coupled with any artefacts identified by the unique to subject start up sequence acquired by each EP sensor, can yield artefacts for further analysis which can be output from the control unit.

The start up process and signal refinement stage of the present system may well yield some form of physiological signal detected by the EP sensors that would not be detected by conventional electrodes, and care should be taken to isolate this signal, identify it, and potentially pass it as an output from the system as part of a risk stratification process or algorithm.

The output of the source ECG signal that has been acquired from the limb placement upon the EP sensors, may well be output in a high level format such as HL7, XML, etc, in such a manner that the original source ECG trace may be available for analysis in conjunction with any events that caused arrhythmias to be identified already correlated to the source ECG trace. In a similar manner any identified other physiological parameters identified may also be included in the analysis.

The applicant hereby discloses in isolation each individual feature described herein and any combination of two or more such features, to the extent that such features or combinations are capable of being carried out based on the present specification as a whole in the light of the common general knowledge of a person skilled in the art, irrespective of whether such features or combinations of features solve any problems disclosed herein, and without limitation to the scope of the claims. The applicant indicates that aspects of the present invention may consist of any such individual feature or combination of features. In view of the foregoing description it will be evident to a person skilled in the art that various modifications may be made within the scope of the invention.

CLAIMS

1. An electrocardiographic device for sensing cardiac activity in a user comprising:

a first set of electric potential sensors provided within an insulating mat; and

a first set of indicia on the surface of the mat indicating an optimal location and orientation of a user's hands;

wherein the first set of sensors are arranged relative to the first set of indicia such that, in use, at least one sensor is located under the ball of the thumb of each of a user's hands.

2. An electrocardiographic device as claimed in claim 1, wherein the indicia are an outline of a pair of hands indicating the desired location of a user's hands relative to the sensors and/or indentations in the mat indicating the desired location of a user's hands relative to the sensors.

3. An electrocardiographic device as claimed in claim 1 or 2, further comprising:

a second set of electric potential sensors provided within an insulating mat; and

a second set of indicia on the surface of the mat indicating an optimal location and orientation of a user's feet;

wherein the second set of sensors are arranged relative to the second set of indicia such that, in use, at least one sensor is located under the ball of the foot of each of a user's feet.

4. An electrocardiographic device as claimed in claim 3, wherein the indicia are an outline of a pair of feet indicating the desired location of a user's feet relative to the sensors and/or indentations in the mat indicating the desired location of a user's feet relative to the sensors.

5. An electrocardiographic device as claimed in any preceding claim, wherein each electric potential sensor comprises an electrometer amplifier.

6. An electrocardiographic device as claimed in any preceding claim, wherein each electric potential sensor is located within a shielded housing within the insulating mat.

7. An electrocardiographic device as claimed in any preceding claim, wherein each electric potential sensor comprises a conducting electrode coated with a thin insulating layer such that, in use, at least the thin insulating layer separates the user from the conducting electrode.

8. An electrocardiographic device as claimed in any preceding claim, further comprising a control unit for processing signals acquired by the electric potential sensors of one or more insulating mats and forming an electrocardiograph of the user's cardiac electrical activity.

9. An electrocardiographic device as claimed in any preceding claim, further comprising a display screen operable to display said electrocardiograph.

10. An electrocardiographic device as claimed in any preceding claim, wherein the flat insulating mat is configured to be foldable along one or more folds such that, when folded and resting on a surface, the mat is operable to form a tube-like closed structure presenting at least some of the electric potential sensors to a user on its outward-facing surfaces.

11. An electrocardiographic device as claimed in claim 9 as dependent on claim 8, further comprising a camera arranged to monitor the position of a user's hands or feet on the mat, and the control unit being configured to, on detecting a poor quality signal from one or more electric potential sensors, cause a user to reposition their hands or feet on the mat with respect to the electric potential sensors by displaying instructions on the display screen.

12. An electrocardiographic device as claimed in claim 8, wherein the control unit is configured to cause wideband noise to be allowed into the amplifier of an EP sensor so as to maintain a noise level such that information carried on signals that do not form part of an ECG waveform may be acquired by the EP sensor and passed to the control unit.

13. A method for controlling the interaction of a user with an electrocardiographic device having a plurality of electric potential sensors for contact with a user, the method comprising:

a user engaging with at least some of the electric potential sensors of an electrocardiographic device;

the electrocardiographic device sensing cardiac activity of the user by means of contact between the sensors and the user;

receiving at a control unit a representation of the cardiac activity sensed by the sensors;

comparing the representation of the cardiac activity of the user with a set of predetermined characteristics of cardiac activity so as to determine whether the user is optimally engaged with the electrocardiographic device; and

if the user is not optimally engaged with the electrocardiographic device, indicating how the user may improve their engagement with the device.

14. A method as claimed in claim 13, wherein the set of predetermined characteristics of cardiac activity include characteristics of cardiac activity indicative of a poor coupling between a user and one or more electric potential sensors.

15. A method as claimed in claim 13 or 14, wherein the contact between the sensors and user need not be skin contact and may be through one or more layers of clothing.

16. A method as claimed in any of claims 13 to 15, wherein the control unit is provided at the electrocardiographic device.

17. A method as claimed in any of claims 13 to 16, wherein the sensors are provided in an insulating mat.

18. A method as claimed in any of claims 13 to 17, wherein the indication is by means of a display screen at the electrocardiographic device.

19. A method as claimed in any of claims 13 to 18, wherein the indication is arranged to cause the user to position the ball of the thumb of their hand, or the ball of their foot directly over one or more electric potential sensors.

20. A method for controlling the interaction of a user with an electromyographic device having a plurality of electric potential sensors for contact with a user, the method comprising:

a user engaging with at least some of the electric potential sensors of an electromyographic device;

the electromyographic device indicating to the user to contract a particular muscle or set of muscles;

sensing electrical activity due to the contraction of the muscle or set of muscles by means of contact between the sensors and the user;

receiving at a control unit a representation of the muscle electrical activity sensed by the sensors;

comparing the representation of the muscle electrical activity of the user with a set of predetermined characteristics of muscle electrical activity so as to determine whether the user is optimally engaged with the electromyographic device; and

if the user is not optimally engaged with the electromyographic device, indicating how the user may improve their engagement with the device.

21. A method for monitoring the sleeping position of an infant with an electrocardiographic device having a plurality of electric potential sensors incorporated into a sleeping mat, the method comprising:

an infant engaging with at least some of the electric potential sensors of an electrocardiographic device;

the electrocardiographic device sensing cardiac activity of the infant by means of contact between the sensors and the infant;

receiving at a control unit a representation of the cardiac activity sensed by the sensors;

comparing the representation of the cardiac activity of the user with a set of predetermined characteristics of sensed infant cardiac activity in different sleeping positions, at least some of the predetermined characteristics being associated with unsafe sleeping positions;

in dependence on the result of the comparing step, determining if the infant is likely to be in an unsafe sleeping position; and

if the infant is determined to be likely to be in an unsafe sleeping position, indicating that the infant is in an unsafe sleeping position.

22. A method as claimed in claim 21, wherein the control unit is provided at the electrocardiographic device.

23. A method as claimed in claim 21 or 22, wherein the control unit comprises a wireless transmitter for operation with a baby monitor and the indication that the infant is in an unsafe sleeping position is transmitted as an alert over the wireless transmitter.

24. A method for analysing data representing cardiac activity of a user acquired by an electrocardiographic device having a plurality of electric potential sensors for contact with a user, a user being operable to engage with the electric potential sensors in a plurality of different positions, the method comprising:

at an electrocardiographic device, acquiring data representing cardiac activity of a user by means of contact between at least some of the electric potential sensors of the electrocardiographic device and the user;

receiving at a control unit the data representing the cardiac activity of the user; and

comparing the representation of the cardiac activity of the user with a set of predetermined representations of cardiac activity so as to determine the most likely position in which the user is engaged with the electric potential sensors; and

analysing the data representing the cardiac activity of the user in accordance with a set of stored parameters provided for the analysis of cardiac activity data acquired from a user engaged with the electric potential sensors in the determined most likely position.

25. A method as claimed in claim 24, wherein the control unit is provided at the electrocardiographic device.

26. An electrocardiographic or electromyographic device substantially as described herein with reference to figures 1 or 2.

Amendments to the claims have been filed as follows

CLAIMS

1. An electrocardiographic device for sensing cardiac activity in a user comprising:

a first set of electric potential sensors set into an insulating mat; and

a first set of indicia on the surface of the mat indicating an intended location and orientation of a user's hands;

wherein the first set of sensors are arranged relative to the first set of indicia such that, in use with the user's hands engaged with the electrocardiographic device in the intended location and orientation, at least one sensor is located under the ball of the thumb of each of the user's hands.

2. An electrocardiographic device as claimed in claim 1, wherein the indicia are an outline of a pair of hands indicating the intended location of a user's hands relative to the sensors and/or indentations in the mat indicating the intended location of a user's hands relative to the sensors.

3. An electrocardiographic device as claimed in claim 1 or 2, further comprising:

a second set of electric potential sensors set into the insulating mat; and

a second set of indicia on the surface of the mat indicating an intended location and orientation of a user's feet;

wherein the second set of sensors are arranged relative to the second set of indicia such that, in use with the user's feet engaged with the electrocardiographic device in the intended location and orientation, at least one sensor is located under the ball of the foot of each of the user's feet.

4. An electrocardiographic device as claimed in claim 3, wherein the indicia are an outline of a pair of feet indicating the intended location of a user's feet relative to the sensors and/or indentations in the mat indicating the intended location of a user's feet relative to the sensors.

23 08 12

5. An electrocardiographic device as claimed in any preceding claim, wherein each electric potential sensor comprises an electrometer amplifier.

6. An electrocardiographic device as claimed in any preceding claim, wherein each electric potential sensor is located within a shielded housing set into the insulating mat.

7. An electrocardiographic device as claimed in any preceding claim, wherein each electric potential sensor comprises a conducting electrode coated with a thin insulating layer such that, in use, at least the thin insulating layer separates the user from the conducting electrode.

8. An electrocardiographic device as claimed in any preceding claim, further comprising a control unit for processing signals acquired by the electric potential sensors of one or more insulating mats and forming an electrocardiograph of the user's cardiac electrical activity.

9. An electrocardiographic device as claimed in claim 8, further comprising a display screen operable to display said electrocardiograph.

10. An electrocardiographic device as claimed in any preceding claim, wherein the insulating mat is foldable along two folds such that, when folded and resting on a surface, the mat forms a tubular object of triangular cross-section presenting the electric potential sensors to a user on its outward-facing surfaces.

11. An electrocardiographic device as claimed in claim 9, wherein the control unit is configured to, on detecting poor quality signals from the electric potential sensors, alert the user by means of the display screen that their limbs are not in the intended location and orientation on the mat, the control unit being configured to determine whether signals from the electric potential sensors are poor quality by comparing those signals with sets of characteristics stored at a data store of the electrocardiographic device, at

23 08 12

least some of those characteristics indicating poor engagement between the user and the electric potential sensors.

12. An electrocardiographic device substantially as described herein with reference to figures 1 or 2.

23 08 12

Application No:	GB1105699.1	**Examiner:**	Dr Susan Dewar
Claims searched:	1-12	**Date of search:**	20 October 2011

Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
A	-	DE 102005048496 A1 (INMEDITEC MEDIZINTECHNIK GMBH)
A	-	EP 1627597 A1 (QUANTUM APPLIED SCIENCE AND RESEARCH)
A	-	US 2010/0049068 A1 (FUWAMOTO et al)
A	-	US 2007/0197925 A (MOORE)
A	-	US 2007/0149888 A1 (KOHLS et al)

Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC^{X} :

Worldwide search of patent documents classified in the following areas of the IPC

A61B

The following online and other databases have been used in the preparation of this search report

Online: EPODOC, WPI, TXTE

International Classification:

Subclass	Subgroup	Valid From
A61B	0005/0428	01/01/2006
A61B	0005/0408	01/01/2006
A61B	0005/0488	01/01/2006

Application No: GB1105699.1 **Examiner:** Dr Susan Dewar

Claims searched: 13-19 **Date of search:** 8 November 2011

Patents Act 1977
Further Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
A	-	WO 2009/074955 A1 (KONINKLIJKE PHILIPS ELECTRONICS N.V.) Whole document relevant
A	-	WO 2006/131855 A2 (KONINKLIJKE PHILIPS ELECTRONICS N.V.)
A	-	WO 2011/007292 A1 (KONINKLIJKE PHILIPS ELECTRONICS N.V.)

Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC^{X} :

Worldwide search of patent documents classified in the following areas of the IPC

A61B

The following online and other databases have been used in the preparation of this search report

Online: EPODOC, WPI, TXTE

International Classification:

Subclass	Subgroup	Valid From
A61B	0005/0428	01/01/2006
A61B	0005/0408	01/01/2006
A61B	0005/0488	01/01/2006