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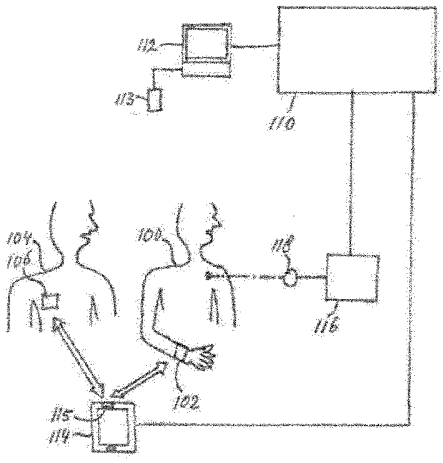
(54) **System and method for monitoring a condition of a plurality of patients.**

(57) A condition of a plurality of patients is monitored. Patients are identified by patient tags having a patient code. Healthcare staff members are identified by healthcare staff tags having a healthcare staff code. A patient data processing system stores assignments of specified healthcare staff codes to specified patient codes for each healthcare staff member monitoring a patient identified by the specified patient code. A user terminal reads a healthcare staff code from a healthcare staff tag and a patient code from a patient tag. The patient data processing system determines whether an assignment of the read healthcare staff code to the read patient code is recorded. If so, it provides access through the user terminal to patient condition data for the particular patient in the patient data processing system, for indicating a general patient condition, and a possibility a cardiac tamponade occurring in a patient.



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System and method for monitoring a condition of a plurality of patients

TECHNICAL FIELD

The present disclosure relates to a system and a method for monitoring a condition of a plurality of patients. The present disclosure further relates to such system and such method for monitoring and indicating a probability of cardiac tamponade occurring in a patient. The present disclosure further relates to such system and such method for monitoring and indicating an early warning score or early warning trend score for a patient.

BACKGROUND

In hospitals and clinics, or in any other institution where human or animal patients reside, there is a need to monitor the health condition of each individual patient, in particular if the patient is, or has been, under medical treatment. Such monitoring may be made by a member of a healthcare staff assigned to the patient, by checking one or more parameters of the patient in predetermined time intervals. A parameter, such as temperature, may be obtained by manual intervention using an appropriate instrument, or may be obtained by a measuring device measuring the parameter on a continuous basis. The measuring result provided by the instrument or the measuring device may be manually recorded on a list, or in an electronic patient data processing system, as patient condition data. Sometimes, patient condition data provided by measuring devices are directly acquired by an electronic patient data processing system.

Healthcare staff members need to have access to patient condition data over time to be able to judge a development of the patient condition when being with the patient. Specifically, if the patient condition data are stored in a patient data processing system, the healthcare staff member needs to have access to the patient data processing system at the location of the patient, such as the bedside. Furthermore, if the healthcare staff member has measured a patient parameter while being at the patient location, the healthcare staff member also needs to have access to the patient data processing system to input the patient parameter.

In processes of accessing the patient data processing system for data input, data retrieval, and other operations performed on patient data, security and integrity of patient data are important issues, while healthcare staff members should be properly authenticated to ensure that unauthorized persons cannot gain access to the relevant part of the patient data processing system in general, and the specific patient data in particular. At the same time, the routines and procedures performed by the healthcare staff members should not be impeded by tedious data access procedures which would lower their professional efficiency. Thus, there is a need for improvement in the accessing of a patient data processing system by healthcare staff members.

Patent application US2005/0086072 discloses a method and system for managing patient care in order to minimize caregiver error. The system includes caregiver machine readable identifiers and patient machine readable identifiers, as well as a caregiver portable computing device having a scanning device. The caregiver portable computing device allows the caregiver access according to varying access levels to a central database connected with a central information system. Application programs running in the central information system include components for matching patient data, caregiver data, and medication data in the central database with identifiers transmitted by the caregiver portable computing device.

In use of such patient data processing systems, a need for reliable patient condition indications exists. A patient condition indication is to be understood as a brief characterization of the condition of a patient. Such characterization may be a score figure, where different figures indicate different degrees of patient condition. Such characterization may also be in terms of colors, where different colors indicate different degrees of patient condition. Such characterization may also be in terms of words or phrases, where different words or phrases indicate different degrees of patient condition. The characterization may be specific for a particular health condition. In this disclosure, some patient condition indications, and monitoring a patient based on these patient condition indications, are explained. A first one relates to a patient condition after cardiac surgery, and a second one relates to a patient condition in a more general sense. The first one and the second on of the patient condition indications can be combined to provide a more complete characterization of the patient condition.

After cardiac surgery, it remains a problem as to how to monitor the cardiovascular situation of operated patients. An accumulation of fluid or clot in the

intra-pericardial space surrounding the heart may result in a pressure increase in this intra-pericardial space, indicating the occurrence of cardiac tamponade, which constitutes one of the possible complications following cardiac surgery. "Tamponade" means obstruction of blood flow due to a constriction of a blood channel caused by an outside force, in this case the overpressure acting on the heart wall. In this condition, blood is prevented from entering the heart from the veins due to increased pressure in the intra-pericardial space, resulting in a lowering of blood pressure and tachycardia, which if left untreated may result in cardiac death. It is known that cardiac tamponade may occur due to local accumulation of fluid or clot, for example due to bleeding from the pericardial wound bed into the intra-pericardial space, or due to mediastinal bleeding and effusion occurring around the pericardium, any of which being a possible consequence of surgery or trauma. Accumulation of fluid or clot inside a body compartment may be generically indicated as a "compartment syndrome".

Patent application US2005/0283092 discloses a compartment pressure-monitoring device for continuous monitoring of pressure in a localized compartment, with the pericardium presented as an example. The proposed compartment pressure monitoring device comprises a tube (catheter) connected at one end to a pressurizable balloon and a Trocar sleeve for insertion into the compartment, and connected at the other end to a pressure gauge. An alarm device is provided for indicating that the pressure inside the compartment as registered by the inserted tube and balloon exceeds a predetermined pressure, indicating an occurrence of compartment syndrome.

Unfortunately, the device in US2005/0283092 does not enable assessment of cardiac tamponade occurrence probability under various conditions.

In a general monitoring of a patient condition, a use of lists to record values of parameters of a patient is common. So-called Early Warning Systems, EWSs, or Modified Early Warning Systems, MEWSs, require healthcare staff members to record values of a predefined set of parameters on a standard list. Through predefined rules, the parameter values are converted into score points. Addition of score points resulting for the different parameter values provides an overall score leading to maintenance of the monitoring as it is, or changing the rate and intensity of monitoring, depending on the overall score. A need of direct medical intervention may also be indicated by the overall score.

In the early warning systems, the recording of parameter values, conversion of parameter values into score points, and addition of score points to obtain an overall score is done using a preprinted paper list. This makes the monitoring time-consuming, prone to errors, and difficult to add to the patient condition data that are recorded for the patient.

SUMMARY

It would be desirable to provide a system and method for improved monitoring of a condition of a plurality of patients. It would also be desirable to provide a system and a method that enable improved alerting of the possibility of cardiac tamponade occurring in a patient. It would further be desirable to provide a system and a method that enable improved early warning for a patient.

To better address one or more of these concerns, in a first aspect of the present disclosure, a system for monitoring a condition of a plurality of patients is provided. The monitoring system comprises: a plurality of patient tags provided to the patients, each patient tag having a unique patient code assigned to it identifying a unique patient; a plurality of healthcare staff tags provided to members of a healthcare staff, each healthcare staff tag having a unique healthcare staff code assigned to it identifying a unique healthcare staff member; a patient data processing system configured for storing and processing patient condition data for each patient; and a user terminal comprising a tag reader. The user terminal is configured for: reading a healthcare staff code from a healthcare staff tag; reading a patient code from a patient tag provided to a particular patient. The patient data processing system is configured for: recording an assignment of a specified healthcare staff code to a specified patient code for each healthcare staff member assigned to monitor a patient identified by the specified patient code; determining whether an assignment of the read healthcare staff code to the read patient code is recorded; and if said assignment is recorded, providing access through the user terminal to the patient condition data for the particular patient in the patient data processing system.

With the monitoring system of the present disclosure, a healthcare staff member utilizing a user terminal may quickly and easily gain access to patient condition data for a particular patient in the patient data processing system. Reading a unique patient tag and the healthcare staff member's own tag usually only requires to bring the tag reader

of the user terminal in the proximity of the tag concerned. A variety of tag types fulfils the proximity requirement, where the tag type preferably is an NFC type, an RFID type, or a one-dimensional or two-dimensional barcode type, and the tag reader is configured to read the respective tag type, such as by radio communication or by optical scanning, respectively. Use of these tags will uniquely and reliably identify the patient and the healthcare staff member seeking to access the patient data processing system. A further authentication of the healthcare staff member may be required in this process, e.g. input of a password. Furthermore, it may be required to read the healthcare staff tag and the patient tag one after the other within a predetermined brief time period, e.g. within at most 5 seconds, preferably within at most 3 seconds, to ensure that the healthcare staff member actually is located near the patient.

Thus, in a situation of a healthcare staff member visiting a patient, or vice versa, allowing the consecutive reading of the healthcare staff tag and the patient tag in either order, preferably within a time period having a predetermined short duration, e.g. 3 seconds, may allow the subsequent access through the user terminal to patient condition data, e.g. for inputting new patient condition data, updating or changing patient condition data, retrieving patient condition data stored previously, deleting patient condition data, etc.

Preferably, the user terminal is a portable type user terminal, such as a tablet type user terminal comprising a tag reader, a processor, a memory, a graphical user interface and a wireless communication module for communication with or within a patient data processing system.

The patient data processing system comprises a plurality of user terminals, at least one server, at least one administration workstation, and further may comprise at least one data collecting station locally collecting patient data. A data network is used for coupling the user terminals, server, administration workstation and data collecting station through wireless and possibly also wired communication. Patient condition data may be stored at the server and/or at the user terminal and/or at the data collecting station.

Before the user terminal can be used to access patient condition data for a particular patient in the patient data processing system, healthcare staff member data including a healthcare staff code associated with a healthcare staff tag provided to a healthcare staff member is input into the patient data processing system, preferably by

using the administration workstation. Similarly, patient data including a patient code associated with a patient tag provided to a patient is input into the patient data processing system, preferably by using the administration workstation. Then, an assignment of a specified healthcare staff code to a specified patient code is recorded for each healthcare staff member assigned to monitor a patient identified by the specified patient code. Subsequently, when a healthcare staff member seeks access to patient condition data in the patient data processing system, the healthcare staff code and the patient code are read from the respective healthcare staff tag and patient tag, and the patient data processing system first determines whether an assignment of the read healthcare staff code to the patient code has been recorded previously. If not, then no access through the user terminal to the patient condition data in the patient data processing system is granted. In case said assignment has been recorded, access is provided.

In some embodiments of the monitoring system, the patient data processing system and the user terminal are configured to manually input patient condition data for the particular patient into the patient data processing system.

Patient condition data, such as parameter values, can be input in various convenient ways, limiting or mitigating a risk of input errors. For example, a real or virtual keyboard of the user terminal may be used to input patient condition data, where a validity check can be performed on the input patient condition data by the patient data processing system, before it is accepted and stored. As another example, patient condition data may be input using a slide bar on a touch screen of the user terminal to define the range of data.

In some embodiments of the monitoring system, the patient data processing system is operatively connected to sensor devices for measuring patient condition data, and is configured for acquiring and storing the patient condition data, for example by a data collecting station or a server of the patient data processing system. In such embodiments, patient condition data may be acquired automatically, without intervention of healthcare staff members.

In some embodiments of the monitoring system, the user terminal is configured to display, in a user interface, patient condition data for the particular patient retrieved from the patient data processing system.

Patient condition data stored in the patient data processing system may be desired to be inspected by a healthcare staff member to support a decision on treatment of the patient. Specific patient condition data may be displayed in a user interface, such as a graphical user interface, of the user terminal, for example showing a graph of historical patient condition data.

In some embodiments of the monitoring system, the patient data processing system is configured for processing the patient condition data to provide patient condition indication data for the particular patient, wherein the user terminal is configured to display, in a user interface, the patient condition indication data.

In many situations, for a proper monitoring of a patient, it does not suffice to monitor one type of patient condition data. Instead, several types of patient condition data need to be examined in combination, and from this combination a patient condition indication may be derived. For a healthcare staff member, it takes time and experience to interpret a combination of different types of patient condition data. Using an automated patient condition data interpretation process, which may be a model of the human interpretation process, the patient data processing system may process the different types of patient condition data to present a patient condition indication which straightforwardly indicates the patient's condition.

In some embodiments of the monitoring system, the patient data processing system is configured for: processing the patient condition data to provide patient condition indication data for the particular patient; determining whether the patient condition indication data represent a critical patient condition, and if so, then sending a message to a user device of a healthcare staff member identified by a healthcare staff code assigned to the patient code of the particular patient.

In order to further facilitate the patient monitoring process, in some embodiments the system may automatically send out an alarm message if it is found that the patient condition is critical, without a need for a healthcare staff member to be in the vicinity of the patient. The system may autonomously monitor the patient condition data and patient condition indication data derived therefrom, and activate an alarm on a user device, such as a smartphone or any other personal communication device, by sending a message to the user device of a healthcare staff member. The message may, for example, be a short message sent through a telecommunication network.

In some embodiments of the monitoring system, the message comprises an access code for the user device of the healthcare staff member to gain access to the patient condition data and/or the patient condition indication data of the particular patient in the patient data processing system.

The access code allows the healthcare staff member to remotely inspect the patient condition data and/or the patient condition indication data to determine which further steps should be taken with the patient.

In an embodiment of the monitoring system to be used when the patient has undergone cardiac surgery, the monitoring system comprises: a right atrium pressure sensor, configured for measuring a right atrium pressure in a right atrium of the patient; an intra pericardial pressure sensor, configured for measuring an intra pericardial pressure in a portion of an intra-pericardial space of the patient. The patient data processing system is operatively connected to the pressure sensors, is provided with a predetermined statistical distribution of pressure versus tamponade probabilities, and is configured for: determining a trans-mural pressure difference between the right atrium pressure and the intra pericardial pressure; comparing the trans-mural pressure difference with the statistical distribution, and indicating the occurrence probability for cardiac tamponade, based on the trans-mural pressure difference comparison.

The described differential pressure sensor monitoring system allows for an improved method of indicating an occurrence probability for cardiac tamponade, for example after cardiac surgery. After a patient has undergone heart surgery, a right atrium access is often maintained in the post-operative period for administering fluids and medications. This access is commonly used to monitor the cardiac preload of the patient, by means of for example right atrium pressure measurements with a pressure sensor. By the addition of an intra pericardial pressure sensor to the pressure measurement system, measurements of fluid pressure within the intra pericardial space may be simultaneously obtained. Elevated pressure in the pericardial space is a unique feature indicating the occurrence of cardiac tamponade. In known methods, as described for example in US2005/0283092, this elevated pressure is directly measured. Instead of directly measuring the intra pericardial pressure, the system proposed herein above enables measurements of a trans-mural pressure difference between the right atrium pressure and the intra pericardial pressure, which provides information on an occurring imbalance between these two regions surrounding the cardiac wall. Due to

the differential measurement principle, the proposed system is able to detect cardiac tamponade under both normal and low cardiac preload, which is not possible on the basis of merely pressure readings in the pericardial space alone, i.e. by means of known direct intra pericardial pressure measurement systems. Consequently, also the low pressure tamponade can be detected, which was not possible up to now using known systems. The pressure difference between the right atrium pressure and the intra-pericardial pressure is compared by the processing device to a predefined statistical distribution of pressure versus tamponade probabilities, which may for example be based on results from earlier clinical studies. The probability of cardiac tamponade occurrence resulting from the comparison may be indicated to the healthcare staff member (e.g. the medical specialist), signalling an increased chance of an occurring intra pericardial tamponade. Based on such a possibility indication, the healthcare staff member may decide to investigate further. In an embodiment, the statistical distribution is in its most simplistic form represented by only a predefined trans-mural pressure threshold. Here, a measured drop below the predefined trans-mural pressure threshold may be indicated to the healthcare staff member by a binary indicator. In other embodiments, the statistical distribution and the patient condition indication may contain more detailed information in the form of likelihood graphs.

According to an embodiment, a right atrium pressure sensor and the intra pericardial pressure sensor are provided with a joint for fastening the sensors in a button configuration enclosing the inner and outer walls of the right atrium respectively. The right atrium pressure sensor, the intra pericardial pressure sensor, and the joint are then jointly configured for fluid tight enclosure of the right atrium wall, in order to prevent fluid leakage between intra pericardial space and right atrium.

Advantageously, the right atrium pressure sensor and the intra-pericardial pressure sensor can be retained at a mutually fixed configuration, in order to improve the reliability of the trans-mural pressure difference readings. In addition, the joint may be provided with a channel and valve combination configured for exchanging fluids between the right atrium and the intra-pericardial space. The opening and/or closing of the valve may for example be controllable by an actuator in the joint, which is operated based on the trans-mural pressure difference measurements obtained by the two sensors. The intra pericardial pressure sensor may for example be positioned in the pericardial space during an operation (e.g. during open heart surgery, or using a

catheter), be subsequently inserted through the right atrium wall into the right atrium, and then connected to an already present atrium pressure sensor, resulting in the sensor button configuration described herein above. Alternatively, a catheter with the right atrium pressure sensor may be configured for puncturing the right atrium wall on the inner right atrium wall using a catheter tip that is provided with a trans-luminal intra-pericardial pressure sensor (TIPPS). Such a catheter tip may comprise a fold-out joint for fastening the TIPPS on the outer right atrium wall inside the intra-pericardial space, resulting in the sensor button configuration described herein above.

According to an embodiment, the system comprises a reference pressure sensor, configured for measuring a reference pressure at a reference location outside the right atrium and the intra-pericardial space. The patient data processing system is operatively connected to the reference pressure sensor and is configured for: determining a right atrium pressure difference between the right atrium pressure and the reference pressure; and indicating the occurrence probability based on differentiating between an ordinary pressure tamponade in case the right atrium pressure difference is above a predetermined right atrium pressure threshold, and a low pressure tamponade in case the right atrium pressure difference is below the right atrium pressure threshold.

The occurrence of low pressure cardiac tamponade is notoriously difficult to register by known direct pressure measurement methods. Usually, low pressure tamponade will only manifest itself after administering additional fluid to the patient. Advantageously, the described monitoring system for indicating cardiac tamponade is improved by supplementing the differential cardiac pressure measurements with further pressure measurements in which the direct right atrium pressure is compared with a reference pressure measured outside of the intra pericardial space. The reference pressure sensor may for example be located outside the intra-pericardial space of the patient, and is configured for detecting the reference pressure. The reference pressure sensor may for example be located outside of the patient for determining atmospheric pressure, e.g. a sensor that is an integral part of the patient data processing system, or even positioned at a remote location.

According to a further embodiment, the monitoring system comprises a plurality of intra pericardial pressure sensors, configured for measuring a plurality of intra pericardial pressures at a set of distinct intra-pericardial portions. The patient data processing system is operatively connected to the plurality of intra pericardial pressure

sensors, and configured for: determining a plurality of intra pericardial pressure differences between each of the intra pericardial pressures and the reference pressure; registering an occurrence of a pressure deviation for any one of the plurality of pressure differences from a set of intra pericardial threshold values; and correlating the intra-pericardial space with the pressure deviation.

In general, the accumulation of clot, blood, or other fluids may occur locally, or throughout the pericardial space. Advantageously, in an embodiment of the monitoring system having multiple intra pericardial pressure sensors at distinct locations inside the pericardial space, cardiac tamponade occurring from local pressure build-up in a compartmentalized intra-pericardial space, for example resulting from local accumulation of fluid or clot, may be registered and localized quickly. The described monitoring system enables the study of yet unknown effects of intra-pericardial fluid or clot accumulation on the intra-pericardial pressure distribution, and ultimately on the development of cardiac tamponade. Furthermore, a plurality of pressure sensors assists in preventing a misreading of information due to an isolated measurement error by one of the pressure sensors. By monitoring a plurality of trans-mural pressure differences, with one difference reading for each intra pericardial pressure sensor, it becomes possible to detect compartmentalized tamponade even under low blood filling conditions.

According to another embodiment, the monitoring system comprises a cardiac performance detector for measuring an indication of cardiac output for the patient, wherein the patient data processing system is configured for: comparing the indication of cardiac output with a stored characteristic value of previous cardiac output measurements; and adapting the occurrence probability, based on a decrease of the cardiac output larger than a predefined cardiac output drop below the characteristic value.

Measurement of for example the cardiac output provides an indication of the performance of the heart muscle. A decrease of the cardiac output indicates a deterioration of cardiac performance, forming a further indication of the occurrence of cardiac tamponade. According to embodiments, the cardiac output may be intermittently or continuously measured. Due to inter subject differences (between patients) in the normal values for cardiac output, the currently measured cardiac output is preferably compared to a characteristic value of previous cardiac output

measurements for the same patient. This characteristic value may be only the latest previous measurement, or a desired statistical average of multiple previous measurements (e.g. obtained by Kalman filtering or similar time averaging techniques). In an embodiment, the occurrence probability used for indicating cardiac tamponade will be altered based on a decrease of the cardiac output that is larger than the allowed (i.e. noise estimate based) decrease, for example by comparison to a predefined output drop value. The cardiac output measurements may be supplemented by measurements of the patient's end tidal partial carbon dioxide pressure level in the respiratory gases (i.e. the carbon dioxide concentration released at the end of expiration). This concentration follows the cardiac output, and can be used as a first indicator for priming detailed cardiac output measurement, and/or as a mutual check.

According to another embodiment, the right atrium pressure sensor is on a distal end of a lead.

This lead may for example be a catheter configured for thermo dilution applications used in cardiac output measurements. The right atrium pressure sensor provided on the distal end of the lead or catheter yields a probe that is reliably insertable and repositionable into the right atrium, and suitable for reading pressures at any desired location in the right atrium. An indication of imminent cardiac tamponade can already be obtained by monitoring the right atrium pressure alone with this lead based right atrium pressure sensor, and by registering a disappearance of the so-called "y descent" deflection in the jugular venous pressure curve resulting from an pericardial pressure impeded filling of the ventricle after tricuspid valve opening.

According to a further embodiment, the lead is an intra cardiac echo catheter, comprising an ultrasound transducer for imaging of and measuring a blood flow in the aorta, and connectable to the patient data processing system. The patient data processing system is configured for determining the cardiac output from the measured blood flow and an imaged cross-section of the aorta.

The disadvantage of known thermo dilution methods for measuring cardiac output is that measurement can only be obtained intermittently. Consequently, the acute occurrence of (localized) intra pericardial tamponade may be overlooked in the interval between subsequent dilution based cardiac output measurements. A combination of ultrasound blood flow imaging (e.g. Doppler) and cardiac wall imaging (e.g. time resolved 2- or 3-dimensional echo) yields a relatively accurate method of cardiac

performance determination. The cardiac output may for example be derived by relating the imaged aorta diameter (i.e. the perimeter dimensions, for example near the aortic valve) to the time integral of measured blood flow through the aorta (i.e. the temporal flux). Alternatively or in addition, the venous blood inflow into the right atrium (via the superior and/or inferior vena cava) may be imaged by the intra cardiac echo catheter, and deviations in the flow velocities registered. Once the intra-cardiac echo catheter is positioned in the right atrium, the described ultrasound measurements may be executed continuously and at any desired moment. By providing the monitoring system with the catheter probe having the both capabilities of continuous pressure reading and ultrasound imaging, a decrease in cardiac output may be noticed with relatively high specificity, and directly related to occurring trans-mural pressure difference deviations. The addition of synchronously measurable cardiac output to the pressure measurements improves the reliability of indicating the occurrence probability of cardiac tamponade. Alternatively, the ultrasound imaging may be conducted intermittently, or be triggered in response to an abrupt change in pressure readings. For example, the imaging measurements may be started at the moment that a decrease in trans-mural pressure difference to below the predetermined trans-mural pressure threshold is detected, or inversely, a pressure drop may initiate ultrasound imaging for providing acknowledgement. Furthermore, the lead may also be configured for both thermo dilution measurements and intra cardiac echo measurements. Advantageously, the cardiac output may then be measured intermittently by either thermo dilution methods or continuously or intermittently by ultrasound measurements.

According to another further embodiment, the cardiac performance detector comprises a thoracic electric bio impedance measurement device that is connectable to the patient data processing system, wherein the patient data processing system is configured for determining the cardiac output from a thoracic electric bio impedance measurement between two impedance measurement locations on the patient.

Alternatively or in addition to ultrasound aortic wall and blood flow imaging, the cardiac performance may be (coarsely) monitored by means of thoracic electric bio-impedance (TEB) measurements, using a bio-impedance measurement device. Such a TEB device may for example comprise a plurality of electrodes suitable for attachment to the thorax according to a fixed scheme of electrode positions. The TEB device may for example operate based on determination of both atrial and ventricular filling status

as a function of time, by measurement of various potential difference pairs between the plurality of electrodes. The TEB device may be configured for monitoring only a trend in the cardiac output, as absolute measurement values are hard to obtain with contemporary TEB technology. Instead, any deviations in a trend as measured by the TEB device may serve as a trigger for or a mutual check with another cardiac performance assessment method, for instance ultrasound based cardiac performance assessment, in addition to or instead of exploiting the trans-mural pressure readings.

According to another embodiment, the plurality of intra pericardial pressure sensors is arranged in a sensor array and attached to a mesh support that is configured for deployment on and around a portion of an epicardial wall of the patient.

Insertion and proper positioning of the intra pericardial pressure sensor array with mesh support may be executed during cardiac surgery. The inserted array unambiguously defines the positional relationship of the pressure sensors surrounding the epicardium during measurements, for example by means of biomechanical modelling of the heart cycle. Use of the mesh support warrants the spatial integrity of the sensor array, the mesh serving to attach the array to the epicardium and to hold the pressure sensors in their initially planned positions.

According to further embodiments, each intra pericardial pressure sensor comprises a wireless transmission unit for transmitting a wireless signal representing the intra pericardial pressure measurement, and wherein the patient data processing system comprises a receiver unit for receiving the wireless signal.

The use of implantable wireless pressure sensors obviates the need for sensor cabling required for power and signal transmission. Without outward protruding cabling, the outer fibrous pericardium is allowed to heal after surgery, restoring the pericardial pressure balance. Furthermore, by wireless signal transmission, multiple processing devices may simultaneously receive and process the transmitted measurements, and the patient is not motionally impeded by any wiring. According to an embodiment, the pressure sensors are made from bio degradable or absorbable material. Alternatively or in addition, the pressure sensors may be powered by bioelectricity alone.

In an embodiment of the monitoring system to be used when the condition of the patient is such that monitoring should result in early warning on developments in the patient condition, the patient condition indication data may comprise an early

warning score for a patient based on a sum of score points attributed to measured values of at least two of the following parameters: respiratory rate, heart rate, systolic blood pressure, AVPU score, temperature, and urine production. Rate and intensity of monitoring the patient depends on the early warning score and its development. The early warning score may be expressed as a number, for example 0, 1, 2, 3, … where a higher number expresses a worse condition of a patient. The early warning score may also be expressed as a color, for example green, orange, red, …, or as an advice expressed in words or phrases. The early warning score may be linked to the parameter(s) causing the particular score, i.e. the deviation from a normal score, to allow a healthcare staff member to follow the link and better judge the patient condition.

Different early warning systems have been developed over time, some of which use all or less than all or more than all of said parameters to provide an early warning score. An early warning score of 1 already may lead to increased intensity of monitoring, whereas higher early warning scores may lead to specified actions of healthcare staff.

In some embodiments of the monitoring system, the patient condition indication data comprise an early warning trend score for a patient based on a combination of trends over time of measured values of at least two of the following parameters: respiratory rate, heart rate, systolic blood pressure, AVPU score, temperature, and urine production. Rate and intensity of monitoring the patient depends on the early warning trend score and its development. The early warning trend score may be expressed as a number, for example 0, 1, 2, 3, … where a higher number expresses a worse condition of a patient. The early warning trend score may also be expressed as a color, for example green, orange, red, …, or as an advice expressed in words. The early warning trend score may be linked to the parameter(s) causing the particular trend score, i.e. the deviation from a normal trend score, to allow a healthcare staff member to follow the link and better judge the patient condition.

Determining an early warning trend score, in particular in combination with determining an early warning score, provides important advantages in the monitoring of a patient. An early warning trend score may reveal a relevant deterioration of a condition of a patient even if an early warning score in itself would be such as not to lead to any change in rate and/or intensity of monitoring the patient. Thus, the patient

safety may be increased by the patient condition indication data comprising an early warning trend score.

The values of the parameters may be manually measured and input as patient condition data into the patient data processing system through the user terminal having access to patient data in the patient data processing system.

In some embodiments of the monitoring system, the patient data processing system is operatively connected to sensor devices for measuring the values of the at least two parameters, and is configured for indicating the early warning score, thereby providing a continuous, and automatic input of parameter values.

In some embodiments of the monitoring system, the respiratory rate is measured in breaths per minute, wherein: if the respiratory rate is 9-14 , then the score point is 0; if the respiratory rate is lower than 9 or 15-20, then the score point is 1; if the respiratory rate is 21-29, then the score point is 2; and if the respiratory rate is higher than 29, then the score point is 3.

In some embodiments of the monitoring system, the heart rate is measured in beats per minute, wherein: if the heart rate is 51-100, then the score point is 0; if the heart rate is 41-50 or 101-110, then the score point is 1; if the heart rate is lower than 41 or 111-129, then the score point is 2; and if the heart rate is higher than 129, then the score point is 3.

In some embodiments of the monitoring system, the systolic blood pressure is measured in mm Hg, wherein: if the systolic blood pressure is 101-199, then the score point is 0; if the systolic blood pressure is 81-100, then the score point is 1; if the systolic blood pressure is 71-80 or higher than 199, then the score point is 2; and if the systolic blood pressure is lower than 71, then the score point is 3.

In some embodiments of the monitoring system, the APVU score is determined on responsiveness of the patient, wherein: if the patient is alert, then the score point is 0; if the patient is not alert, and reacts to voice, then the score point is 1; if the patient is not alert and does not react to voice, and reacts to pain, then the score point is 2; and if the patient is not alert and does not react to voice or pain, then the score point is 3.

In some embodiments of the monitoring system, the temperature is measured in °C, wherein: if the temperature is 35-38.4, then the score point is 0; and if the temperature is lower than 35 or higher than 38.4, then the score point is 2.

In some embodiments of the monitoring system, the urine production is measured in ml per hour for two hours, wherein: if the urine production is 30-44, then the score point is 1; if the urine production is 10-29, then the score point is 2; and if the urine production is lower than 10, then the score point is 3.

In a second aspect of the present disclosure, a method of monitoring a condition of a plurality of patients is provided. The method comprises the steps of: providing the patients with a plurality of patient tags, each patient tag having a unique patient code assigned to it identifying a unique patient; providing members of a healthcare staff with a plurality of healthcare staff tags, each healthcare staff tag having a unique healthcare staff code assigned to it identifying a unique healthcare staff member; providing a patient data processing system for storing and processing patient condition data for each patient; providing a user terminal comprising a tag reader; reading, with the tag reader of the user terminal, a healthcare staff code from a healthcare staff tag; reading, with the tag reader of the user terminal, a patient code from a patient tag provided to a particular patient; recording, in the patient data processing system, an assignment of a specified healthcare staff code to a specified patient code for each healthcare staff member assigned to monitor a patient identified by the specified patient code; checking, with the patient data processing system, whether an assignment of the read healthcare staff code to the read patient code is recorded; and if said assignment is recorded, providing access, through the user terminal, to the patient condition data for the particular patient in the patient data processing system. Such method steps are explained in the context of a corresponding system herein above.

In another aspect of the present disclosure and in accordance with effects described herein above, a method is provided for indicating an occurrence probability for cardiac tamponade in a patient, comprising: determining a trans-mural pressure difference between a right atrium pressure measured in a right atrium of the patient, and an intra pericardial pressure measured in a portion of an intrapericardial space of the patient; comparing the trans-mural pressure difference with a predetermined statistical distribution of pressure versus tamponade probabilities; and indicating the occurrence probability, based on the trans-mural pressure difference comparison.

According to an embodiment, the method comprises: determining a right atrium pressure difference between the right atrium pressure and a reference pressure measured at a reference location outside the right atrium and the intrapericardial space;

and indicating the occurrence probability based on differentiating between an ordinary pressure tamponade in case the right atrium pressure difference is above a predetermined right atrium pressure threshold, and a low pressure tamponade in case the right atrium pressure difference is below the right atrium pressure threshold.

According to an embodiment, the method comprises: comparing the trans-mural pressure difference with a predetermined trans-mural pressure threshold that is approximately 2 mm Hg = 267 Pa, and/or wherein the right atrium pressure threshold is approximately 7 mm Hg = 933 Pa (see ref.[1]).

A pressure measurement system based on a comparison with threshold values is relatively easy to implement. Practical experience has shown that the given threshold values mark characteristic inflection points of the probability distributions relating the respective pressure readings to the chance of actual occurrence of cardiac tamponade. Consequently, a measurement system based on comparison of trans-mural pressures and/or right atrium pressures to the given threshold values during use will yield an accurate indication of an increased risk of occurring tamponade, with a minimal amount of processing resources. An occurrence of a trans-mural pressure difference below 2 mm Hg will certainly indicate the occurrence of cardiac tamponade.

According to another embodiment, the method comprises: determining a plurality of intra pericardial pressure differences between each of a plurality of intra pericardial pressures measured at a set of distinct intra-pericardial portions, and the reference pressure; registering an occurrence of a pressure deviation for any one of the plurality of pressure differences from a set of intra pericardial threshold values; and correlating the intra-pericardial portion with the pressure deviation.

According to yet another embodiment, the method comprises: comparing an indication of cardiac output for the patient with a characteristic value of previous cardiac output measurements; and adapting the occurrence probability, based on a decrease of the cardiac output larger than a predefined cardiac output drop below the characteristic value.

According to a further embodiment, the method comprises: ultrasound imaging of a cross-section of the aorta through a right atrium wall; and determining the cardiac output from a blood flow measured in the aorta and the cross-section.

Preferably, the ultrasound transducer is positioned in the right atrium with its imaging aperture located at or near the right atrium wall and directed toward the

ascending aorta near a curved portion. By positioning the transducer with its ultrasound imaging beam (i.e. the ultrasonic main axis) near a curved ascending aorta portion, the ultrasound imaging beam can be directed substantially along the aortic blood flow located up/downstream beyond the curved portion, which enables more accurate Doppler flow-measurements along the ascending aorta. Thus, the accuracy of the continuous ultrasound based method of cardiac output measurement is improved.

According to further embodiment, the method comprises: determining the cardiac output from a thoracic electric bio impedance measurement between two impedance measurement locations on the patient.

According to another aspect of the method of the present disclosure and in accordance with effects described herein above, a method is provided, wherein the patient condition indication data comprise an early warning score for a patient based on a sum of score points attributed to measured values of at least two of the following parameters: respiratory rate, heart rate, systolic blood pressure, AVPU score, temperature, and urine production. Based on the early warning score and/or its development, a rate and intensity of monitoring the patient is provided.

According to a further aspect of the method of the present disclosure and in accordance with the effects described herein above, a method is provided, wherein the patient condition indication data comprise an early warning trend score for a patient based on a combination of trends over time of measured values of at least two of the following parameters: respiratory rate, heart rate, systolic blood pressure, AVPU score, temperature, and urine production. Based on the early warning trend score and/or its development, a rate and intensity of monitoring the patient is provided.

According to a third aspect of the present disclosure, a user terminal for use in the system as explained herein above for monitoring a condition of a plurality of patients is provided. The user terminal comprises a tag reader, and is configured for: reading a healthcare staff code from a healthcare staff tag, wherein a plurality of healthcare staff tags have been provided to members of a healthcare staff, each healthcare staff tag having a unique healthcare staff code assigned to it identifying a unique healthcare staff member; and reading a patient code from a patient tag provided to a particular patient, wherein a plurality of patient tags have been provided to the patients, each patient tag having a unique patient code assigned to it identifying a unique patient. An assignment of a specified healthcare staff code to a specified patient

code for each healthcare staff member assigned to monitor a patient identified by the specified patient code has been recorded. The user terminal is further configured for: determining whether an assignment of the read healthcare staff code to the read patient code is recorded; and, if said assignment is recorded, providing access through the user terminal to the patient condition data for the particular patient.

In a fourth aspect of the present disclosure, a computer program is provided. The computer program comprises computer instructions which, when implemented in a computer processing system of a user terminal, cause the user terminal to perform its functions. The patient condition data which are accessed with the user terminal may be stored in a memory of the user terminal, or may be stored in an external storage of a patient data processing system configured to be coupled to the user terminal. Processing of patient condition data to provide a patient condition indication may be performed in the user terminal, or may be performed in a patient data processing system configured to be coupled to the user terminal.

The above and other aspects of the present disclosure will be more readily appreciated as the same becomes better understood by reference to the following detailed description and considered in connection with the accompanying schematic drawings in which like reference symbols designate like parts. The drawings are only meant for illustrative purposes, and do not serve as restriction of the scope or the protection as laid down by the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 schematically depicts a system for monitoring a condition of a patient from a plurality of patients.

FIG. 2 schematically depicts a variant of the system of FIG. 1 illustrating an alternative data communication between devices/systems.

FIG. 3 schematically depicts an embodiment of a system for indicating an occurrence probability for cardiac tamponade in a patient.

FIG. 4 schematically depicts an embodiment of a system for indicating and localizing an occurrence probability for cardiac tamponade in a patient, the system comprising an ultrasound imaging device.

FIG. 5 depicts a flow chart for a method of indicating a probability of cardiac tamponade occurrence.

FIG. 6 schematically depicts a user interface of a user terminal for inputting patient condition data for a patient.

FIG. 7 schematically depicts a further user interface of a user terminal for displaying trends in patient condition data and patient condition indication data of a patient.

FIG. 8 schematically depicts a further user interface similar to the one as shown in FIG. 7, with part of the user interface extended to show related patient condition data in a graphical form.

FIG. 9 schematically depicts a further user interface for displaying patient condition data and patient condition indication data of a patient for various points in time.

FIG. 10 schematically depicts a further user interface for displaying tables of patient condition data and patient condition indication data for different patients.

FIG. 11 schematically depicts a further user interface for displaying trends in patient condition data or patient condition indication data of different patients for various points in time.

DETAILED DESCRIPTION

FIG. 1 schematically depicts a system for monitoring a condition of a plurality of patients, using patient data processing system including user terminals and user devices.

A patient 100 to be monitored has been provided with a patient tag 102 having a unique patient code assigned to it identifying the unique patient 100. Likewise, a healthcare staff member 104 monitoring the patient 100 has been provided with a healthcare staff tag 106 having a unique healthcare staff code assigned to it identifying the unique healthcare staff member 104.

A patient data processing system comprises at least one server 110, at least one administration workstation 112, and a plurality of user terminals 114, each comprising a user terminal tag reader 115. Only one user terminal 114 is shown in FIG. 1. The patient data processing system further may comprise at least one data collecting station 116 collecting sensor data from at least one sensor 118 configured to acquire data on the patient 100, such as respiratory rate, heart rate, systolic blood pressure, temperature, urine production, and/or cardiac parameters such as a right atrium pressure, an intra

pericardial pressure, a reference pressure, cardiac output, thoracic electro bio impedances, etc.. The different elements of the patient data processing system are mutually operatively coupled, e.g. through wired or wireless data communication links.

Before the patient data processing system can be used according to the present disclosure, the administration workstation 112 may be used to input data on healthcare staff members 104 (e.g. name, department, departments to manage, healthcare staff code assigned to healthcare staff tag, phone number), and patients 100 (e.g. name, date of birth, patient number, patient code assigned to patient tag). Healthcare staff codes and patient codes may be input using a workstation tag reader 113 reading the respective codes from the respective tags 106, 102. Furthermore, in the patient data processing system an assignment of a specified healthcare staff code to a specified patient code is recorded for each healthcare staff member assigned to monitor a patient identified by the specified patient code. Patient condition data are stored in the patient data processing system for each patient 100.

A healthcare staff tag 106 and/or a patient tag 102 may be of a type allowing it to be read only in the proximity of a corresponding tag reader 113, 115. Thus, the tag type may be of an NFC type, an RFID type, or a one-dimensional barcode or two-dimensional dotcode type. Accordingly, tag types are preferably chosen such that optical scanning or radio communication will allow the tag reader 113, 115 to read the tag 102, 106.

It is noted that data communication between the server 110, the at least one administration workstation 112, the user terminals 114 and the at least one data collecting station 116, and other devices to be described below, may be performed through various data communication networks, such as the Internet, as illustrated in FIG. 2 depicting the data communication network 200 in a patient data processing system. Also, a sensor 118 may be coupled in such patient data processing system, as shown in dashed lines, without use of a data collecting station 116 for the sensor 118 to be coupled to.

Referring to FIG. 1 again, in use of the patient data processing system, access to the patient condition data for the patient 100 in the patient data processing system is provided through the user terminal 114 in the following way.

A healthcare staff member 104 meets a patient 100, e.g. at the bedside of the patient. The healthcare staff member 104 carries the user terminal 114. To gain access

to the patient condition data of the patient 100, the healthcare staff member 104 reads the healthcare staff code from the healthcare staff tag 106, and reads the patient code from the patient tag 102. The patient data processing system then determines, e.g. in the user terminal 114 or the server 110, whether an assignment of the read healthcare staff code to the read patient code is recorded. Only if said assignment has been recorded, the healthcare staff member 104 is given access to the patient condition data for the patient 100 in the patient data processing system through the user terminal 114, possibly after a further authentication of the healthcare staff member 104. The user terminal 114 is configured to display, in a user interface, the patient condition data for the particular patient 100 to be input to, and/or retrieved from the patient data processing system. Examples of such user interfaces are discussed below and shown in Figures 6-11.

The patient data processing system may, for reasons of security, require the healthcare staff tag to be read before the patient tag is read. The patient data processing system may, also for reasons of security, require both the healthcare staff tag and the patient tag to be read with the same user terminal 114 within a predetermined time period of at most 3 seconds, or at most 5 seconds, to ensure that both tags and the corresponding persons are within a short distance from each other.

The patient data processing system may comprise a component for processing the patient condition data of a particular patient to provide patient condition indication data for the particular patient 100. The user terminal 114 is configured to display, in a user interface, the patient condition indication data. Examples of such user interfaces are discussed below and shown in Figures 6-11.

If the patient data processing system, during processing the patient condition data to provide patient condition indication data for the particular patient 100, determines that the patient condition indication data represent a critical patient condition, then the patient data processing system may send a message to a user device 120 of a healthcare staff member 104 identified by a healthcare staff code assigned to the patient code of the particular patient in the patient data processing system. As shown in FIG. 2, the user device 120 may be accessed through a data communication network 200. The message may be a short message as known in wireless communication networks, or any other message arranged to be delivered to the user

device 120. The user device 120 may be any digital device arranged to receive said message from said data communication network.

In some embodiments, the message comprises an access code for the user device of the healthcare staff member 104 to gain access to the patient condition data and/or the patient condition indication data of the particular patient 100 in the patient data processing system. Preferably, the access code allows the healthcare staff member, when the healthcare staff member 104 has access to the patient data processing system, to directly access the patient condition data and/or patient condition indication data that triggered the sending of the message in the first place. Accordingly, the healthcare staff member 104 can immediately decide upon adequate actions to be taken.

When a patient is monitored, the following general parameters, in particular relating to early warning monitoring of a patient, may be measured manually or automatically using appropriate sensors 118 possibly in combination with a data collection station 116, resulting in a collection of patient condition data: respiratory rate, heart rate, systolic blood pressure, AVPU score, temperature, urine production. Further parameters, in particular in relation to monitoring after cardiac surgery, may include the following, resulting in a further collection of patient condition data: right atrium pressure, intra-pericardial pressure, reference pressure, cardiac output, intra cardiac echo, thoracic electric bio impedance. Values of such variables, after input in the patient data processing system, may be processed to compare them with reference values and/or threshold values, while also trends in changes of values of the parameters, either separately or in combination, may be processed, to provide patient condition data and/or patient condition indication data.

Processing of the patient condition data by the patient data processing system, may result in patient condition indication data comprising an early warning score for a patient based on a sum of score points attributed to measured values of at two of the above parameters. As an example, the respiratory rate may be measured in breaths per minute by a breathing sensor well known in the art, wherein: if the respiratory rate is 9-14 , then the score point is 0; if the respiratory rate is lower than 9 or 15-20, then the score point is 1; if the respiratory rate is 21-29, then the score point is 2; and if the respiratory rate is higher than 29, then the score point is 3. The heart rate may be measured in beats per minute by a heart beat sensor well known in the art, wherein: if the heart rate is 51-100, then the score point is 0; if the heart rate is 41-50 or 101-110,

then the score point is 1; if the heart rate is lower than 41 or 111-129, then the score point is 2; and if the heart rate is higher than 129, then the score point is 3. The systolic blood pressure may be measured in mm Hg by a blood pressure sensor well known in the art, wherein: if the systolic blood pressure is 101-199, then the score point is 0; if the systolic blood pressure is 81-100, then the score point is 1; if the systolic blood pressure is 71-80 or higher than 199, then the score point is 2; and if the systolic blood pressure is lower than 71, then the score point is 3. The APVU score may be determined by a healthcare staff member based on responsiveness of the patient, wherein: if the patient is alert, then the score point is 0; if the patient is not alert, and reacts to voice, then the score point is 1; if the patient is not alert and does not react to voice, and reacts to pain, then the score point is 2; and if the patient is not alert and does not react to voice or pain, then the score point is 3. The temperature may be measured in °C by a temperature sensor well known in the art, wherein: if the temperature is 35-38.4, then the score point is 0; and if the temperature is lower than 35 or higher than 38.4, then the score point is 2. The urine production may be measured in ml per hour for two hours by a urine sensor well known in the art, or by a healthcare staff member inspecting a captured volume, wherein: if the urine production is 30-44, then the score point is 1; if the urine production is 10-29, then the score point is 2; and if the urine production is lower than 10, then the score point is 3.

The above processing of patient condition data by the patient data processing system leads to a sum of score points, as determined in accordance with the above rules. A sum above 0 may lead to an adapted rate and intensity of monitoring the patient by the healthcare staff.

Processing of the patient condition data by the patient data processing system may, in addition, result in a trend in the values of some of the above parameters from which patient condition indication data comprising an early warning trend score may be derived, as exemplified as follows. Such early warning trend score may indicate a need for specific monitoring despite the fact that the sum of score points of the same parameters may not indicate any special patient condition (sum = 0).

A trend in parameter values leading to an early warning trend score of “consider hypovolemic shock based on haemorrhage” may be a combination of high heart rate (but below 101 beats per minute), increase of breathing rate, decrease of urine production, and decrease of systolic blood pressure, after surgery.

A trend in parameter values leading to an early warning trend score of "consider septic shock" may be a combination of high heart rate (but below 101 beats per minute), increase of breathing rate, high temperature (but at most 38.4 °C), and decrease of urine production.

Further, processing of the patient condition data by the patient data processing system, may result in patient condition indication data indicating a probability of cardiac tamponade occurring in a patient. The collection of such relevant patient condition data is explained below by reference to FIG. 3, 4 and 5.

FIG. 3 shows a system 1 for indicating a probability of cardiac tamponade occurring in a patient 2. The pericardium 8 (also called the pericardial sac) is a sac-like membrane that contains the heart 3. The pericardium 8 consists of an outer fibrous layer and an inner serous layer. The fibrous pericardium constitutes a tough outer sac, and the inner serous layer is thin and located adjacent to the outer surface of the heart muscle (i.e. the epicardium 5, sometimes called the visceral pericardium). Excessive fluid or clot accumulation in the intra-pericardial space 6 (i.e. the space between the outer pericardial fibrous layer and the external surface of the heart) may cause substantial increases in intra-pericardial pressure, with hemodynamic consequences of decreased cardiac performance and hypotension (a condition known clinically as cardiac tamponade. The cardiac tamponade indication system 1 shown in FIG. 3 comprises a multitude of pressure sensors 10 that are configured for measuring a plurality of intra pericardial space pressures Pip at a set of measurement locations within the intra-pericardial space 6 around the heart 3 of a patient 2. The system 1 also has a further pressure sensor 9 for measuring a right atrium pressure Pra in a right atrium 4 of the patient 2, this right atrium pressure sensor 9 being provided on the distal end of a lead 28. Furthermore, the measurement system 1 has a reference pressure sensor 12 that is positioned at a reference location outside the right atrium 4 and outside the intra-pericardial space 6, the reference pressure sensor 12 being configured for measuring a reference pressure Pref.

The measurement system 1 comprises a data collecting station 14, that is operatively connected or coupled to the right atrium pressure sensor 9, to the plurality of intra pericardial pressure sensors 10, and to the reference pressure sensor 12, for receiving pressure data from the respective pressure sensors 9, 10, 12. Each intra pericardial pressure sensor 10 is surgically implantable and provided with a wireless

communication unit for wireless transmission of any pressure reading Pip to the data collecting station 14. Similarly, the data collecting station 14 has a wireless receiving unit 22 with an antenna 23 for receiving the wireless transmission of any pressure measurement Pip from any of the implantable pressure sensors 10 or the reference pressure sensor 12. Two-way communication means between the data collecting station 14 and the pressure sensors 9, 10, 12 may also be provided, so as to allow a user (e.g. medical practitioner) to request pressure readings from selected pressure sensors 9, 10, 12, as well as to activate/deactivate any pressure sensor 9, 10, 12 at will.

The data collecting station 14 provides for direct user input/output capabilities by means of a visual display 24 (which may be supplemented by other interface means 26 e.g. keyboard, voice command, a control panel, etc). Optionally, the data collecting station 14 may further be arranged to communicate with another device of a patient data processing system (compare with data collecting station 116 in FIG. 1). The data collecting station 14 may also receive data from various other components, as discussed below with reference to FIG. 4.

The data collecting station 14, or another processing device in the patient data processing system, is provided with a predetermined statistical distribution of pressure versus tamponade probabilities. Furthermore, the data collecting station 14, or another processing device in the patient data processing system, is configured for determining a trans-mural pressure difference ΔPtm between the right atrium pressure Pra and the intra pericardial pressure Pip, and configured for comparing the trans-mural pressure difference with the statistical distribution. The data collecting station 14, or another processing device in the patient data processing system, is then configured for indicating the occurrence probability, based on the trans-mural pressure difference comparison. Also, the data collecting station 14, or another processing device in the patient data processing system, is configured for determining a right atrium pressure difference ΔPra between the right atrium pressure Pra and the reference pressure Pref, and for refining the indication of occurrence probability, the refinement being based on differentiating between an ordinary pressure tamponade in case the right atrium pressure difference ΔPra is above a predetermined right atrium pressure threshold TPra, and a low pressure tamponade in case the right atrium pressure difference ΔPra is below the right atrium pressure threshold TPra.

Furthermore, data collecting station 14, or another processing device in the patient data processing system, is configured for determining a plurality of pressure differences ΔPip between each of the plurality of measured pressures Pip and the obtained reference pressure Pref. The data collecting station 14, or another processing device in the patient data processing system, is further configured for detecting an occurrence of a pressure deviation for any of the plurality of pressure differences ΔPip from a preset pericardial pressure threshold TPip. Furthermore, the data collecting station 14, or another processing device in the patient data processing system, is configured for correlating the pressure measurement location to the intra-pericardial space portion 6', so as to equate the location of pressure deviation with the localized intra-pericardial tamponade.

The method of localizing a cardiac tamponade induced by at least an intra-pericardial portion 6' of the intra-pericardial space 6 of a patient 2 comprises the positioning of a plurality of pressure sensors 10 at a set of measurement locations within the intra-pericardial space 6, e.g. by surgical implantation, and obtaining measurements of a plurality of intra-pericardial pressures Pip. As is further explained with reference to Fig. 5, embodiments of the method further comprise positioning at least one reference pressure sensor 12 at a reference location outside the pericardial space 6, and obtaining a reference pressure Pref at the reference location. Subsequently, a plurality of pressure differences ΔPip between each of the pressures Pip and the reference pressure Pref is determined. The plurality of pressure differences is then evaluated and any deviation occurring for each of the plurality of the individual pressure differences ΔPip from a predetermined pressure threshold Tpip is registered. A registered pressure deviation is exploited by correlating the measurement location in which the pressure deviation occurs, to the intra-pericardial space portion 6' that is assumed to be involved in or responsible for inducing the cardiac tamponade.

In the embodiment of the tamponade measurement system 1 shown in FIG. 4, the system 1 has cardiac performance detection means 16 for measuring indications of cardiac output Φco for the patient 2. Here, the data collecting station 14, or another processing device in the patient data processing system, is configured for: comparing the indication of cardiac output Φco with a stored characteristic value Φprev of previous cardiac output measurements, and adapting the occurrence probability, based

on a decrease of the cardiac output Φco larger than a predefined cardiac output drop Dco below the characteristic value Φprev.

The system 1 comprises a thoracic electric bio impedance measurement device 36 with a plurality of electrodes 44 fixable to predetermined measurement locations on the patient's thorax. The electrodes 44 are configured for collecting thoracic electric bio impedance readings Zteb between two impedance measurement locations, and monitoring the heart cycle based on these impedance measurements. The thoracic electric bio impedance measurement device 36 is connectable to the data collecting station 14 for transmitting the collected impedance measurements. It is a known technique that the electrical impedance or potential difference between two electrodes 44 may be intermittently or continuously measured (see for example ref.[2]). With the bio-impedance measurement technique, the cardiac performance of the heart 3 may be (approximately) measured.

The measurement system 1 of Fig. 4 comprises a lead 28 formed as an intra cardiac echo catheter 30 carrying both the right atrium pressure sensor 9 and a phased array ultrasonic imaging device or transducer 32 (e.g. circular ultrasonic transducer elements in a ring-shape around the catheter), and configured for measuring a blood flow velocity in the aorta 7 via Doppler imaging. The ultrasound transducer 32 is communicatively coupled to an ultrasound processing device 34, which in turn is coupled to the data collecting station 14, or another processing device in the patient data processing system, so as to determine the cardiac output Φco from the measured blood flow and an imaged cross-section of the aorta 7.

FIG. 4 also depicts a net, mesh support, or heart basket 40 that is deployable on the epicardium 5, and which includes the plurality of pressure sensors 10, arranged in a sensor array configuration and fixed to the deployable net 40. The net 40 serves as a deployable platform around and covering a portion of the epicarcium 5, for attaching and keeping the pericardial pressure sensors 10 in a fixed position with respect to the epicardium 5.

The indication and/or localization system 1 may take a variety of specific forms, including both especially designed and commercial-off-the-shelf components. Conventional and commercially available pressure sensors 9, 10, 12 and/or electrodes 44 may be employed, but also sensors that are particularly tailored and optimized to perform the task as described here. In general, known computer arrangements

(workstations, personal computers, etc.) may be programmed to perform any or all of the functions and calculations of the system and method as described herein.

FIG. 5 illustrates a detailed embodiment of a method of indicating an occurrence probability for cardiac tamponade in a patient 2. This method comprises the following actions:

- Measuring 50 an indication of cardiac output Φco for the patient 2. This action 50 may for example be achieved by ultrasound imaging of a cross-section of the aorta 7 through a right atrium 4 wall, by measuring a blood flow in the aorta 7, and by determining the cardiac output Φco from the blood flow and the cross-section. Alternatively or in addition, this action 50 may be achieved by measuring a thoracic electric bio impedance between two impedance measurement locations 37 on the patient 2, and determining the cardiac output Φco from the thoracic electric bio impedance measurement.
- Comparing 51 the indication of cardiac output Φco with a characteristic value Φprev of previous cardiac output measurements.
- Adapting 52 the occurrence probability for cardiac tamponade, based on a decrease of the cardiac output Φco larger than a predefined cardiac output drop below the characteristic value Φprev.
- Subsequently, measuring 53 a right atrium pressure Pra in a right atrium 4 of the patient 2.
- Simultaneously, measuring 54 a reference pressure Pref at a reference location outside the right atrium 4 and outside the intra-pericardial space 6.
- Determining 55 a right atrium pressure difference ΔPra between the right atrium pressure Pra and the reference pressure Pref. In this action 55, the right atrium pressure difference ΔPra may for example be compared to a right atrium pressure threshold TPra of approximately 7 mm Hg = 933 Pa.
- In order to differentiate between an ordinary tamponade and a low pressure tamponade, measuring 56 an intra pericardial pressure Pip in an intra-pericardial space portion 6' of the patient 2.
- Determining 57 a trans-mural pressure difference ΔPtm between the right atrium pressure Pra and the intra pericardial pressure Pip.
- Comparing 58 the trans-mural pressure difference ΔPtm with a predetermined statistical distribution of pressure versus tamponade probabilities. In this action 58, the

trans-mural pressure difference ΔPtm may for example be compared 58 with a predetermined trans-mural pressure threshold TPtm that is approximately 2 mm Hg = 267 Pa.

- Indicating 59, 60 the occurrence probability, based on the comparison 58 of the trans-mural pressure difference ΔPtm. In this action 59, 60, the occurrence probability may be related to differentiating between an ordinary pressure tamponade 59 in case the right atrium pressure difference ΔPra is above a predetermined right atrium pressure threshold TPra of approximately 7 mm Hg = 933 Pa, and a low pressure tamponade 60 in case the right atrium pressure difference ΔPra is below the right atrium pressure threshold TPra. A low likelihood of pressure tamponade occurrence may be indicated 61 if ΔPtm, after comparison 58 with the predetermined trans-mural pressure threshold TPtm, exceeds this trans-mural pressure threshold value of 2 mm Hg = 267 Pa.

Furthermore, in the action of measuring 56 an intra pericardial pressure Pip in an intra-pericardial space portion 6' of the patient 2, a plurality of intra pericardial pressures Pip at a set of distinct intra-pericardial portions 6' may be measured instead (not shown), followed by determining a plurality of intra pericardial pressure differences ΔPip between each of the intra pericardial pressures Pip and the reference pressure Pref.

Subsequently, an occurrence of a pressure deviation Dp for any one of the plurality of pressure differences ΔPip from a set of intra pericardial threshold values TPip is registered, and the pressure deviation Dp is correlated with the intra-pericardial portion 6' in which the pressure deviation occurs.

FIG. 6 schematically depicts an exemplary user interface 600 of a user terminal for inputting patient condition data, in particular for values of the parameters heart rate, temperature, respiratory rate, and another parameter.

In the example shown, the user terminal 114 (see FIG. 1) comprises a touch screen showing (part of) the user interface 600 , and enabling clear and simple user interaction and feedback while inputting values of said parameters.

As indicated at the top left-hand side at 602, a new check of a patient 100 is made. The check is made for a particular patient 100 carrying a patient tag 102 provided with a patient code. As explained above, a healthcare staff member 104 carrying a healthcare staff tag 106 provided with a healthcare staff code previously gained access to patient condition data in a patient data processing system through

reading the patient code and the healthcare staff code from the respective tags 102, 106. With the check, new patient condition data are measured and input into the patient data processing system by the healthcare staff member 104 operating the user terminal 114.

Date and time are displayed at 604, and these data are linked to the new patient condition data automatically by the patient data processing system.

The user interface 600 comprises one or more input fields for patient parameters. In FIG. 6, as an example four input fields 611, 612, 613 and 614 are shown.

Input field 611 has a symbol 6111 illustrating the parameter of which a measured value is to be recorded, in this case a heart symbol, combined with a text 6112 ("Heartrate (BPM)") expressing the parameter and the unit of measurement, in this case the heart rate measured in beats per minute, BPM. A slide bar 6113 and a slider 6114 are shown. The slider 6114 is slidable along the slide bar 6113 to the left or the right by dragging the slider 6114 with a fingertip or the like contacting the slider 6114 at the position shown on the touchscreen. A position of the slider 6114 along the slide bar 6113 indicates a particular value of the parameter, shown as a number ("140") at 6115. Below the slide bar 6113, an early warning score bar 6116 is shown, having ranges corresponding with ranges of the heart rate according to the slide bar 6113. Each range has an early warning score point "0", "1", "2" or "3" as indicated. The position of the slider 6114, corresponding with a value of the parameter, in this case the heart rate, can be projected on the early warning score bar 6116, and then immediately shows the early warning score point for the particular parameter, in this case "1". This early warning score point is shown at 6117.

When inputting the heart rate for the patient under consideration, the healthcare staff member places a fingertip on the slider 6114 and moves the fingertip to the left or right, thereby moving the slider 6114 accordingly along the slide bar 6113, until the number at 6115 shows the value of the heart rate that is measured at that time, e.g. shown on a heart rate monitor as known per se, or determined manually by sensing the blood pulses at the wrist in a predetermined time period.

The other input fields 612, 613 and 614 are operated in a similar way as the input field 611.

For this purpose, input field 612 has a symbol 6121 of a thermometer combined with text 6122 ("Temperature (ºC)") expressing the parameter and the unit of

measurement, in this case the temperature measured in °C. Input field 612 further comprises slide bar 6123, slider 6124, a temperature value ("36.5") shown at 6125, an early warning score bar 6126, and an early warning score point shown at 6127 ("0") , for the measured temperature.

Input field 613 has a symbol 6131 of lungs combined with text 6132 ("Respiratory Rate (BPM)") expressing the parameter and the unit of measurement, in this case the respiratory rate measured in breaths per minute. Input field 613 further comprises slide bar 6133, slider 6134, a respiratory rate value ("14") shown at 6135, an early warning score bar 6136, and an early warning score point shown at 6137 ("0"), for the measured respiratory rate.

Input field 614 has a further symbol 6141 combined with text 6142 (here, as an example, "Other Par. (xxx)") expressing the parameter and the unit of measurement, in this case the other parameter measured in xxx. Input field 614 further comprises slide bar 6143, slider 6144, an other parameter value ("188") shown at 6145, an early warning score bar 6146, and an early warning score point shown at 6147 ("0"), for the measured other parameter.

Under a heading "SCORE" shown at 617, the user interface 600 shows the sum of the early warning score points (the early warning score) shown at 6117, 6127, 6137 and 6147 at 615 ("1"), as well as an indication that this is the current early warning score ("current"). The user interface 600 further shows the last previous early warning score at 616 ("2"), as well as date and time ("today, 7:00pm") at which the last previous warning score was obtained.

The patient data processing system updates the user interface content when operating a slider 6114, 6124, 6134 or 6144, i.e. it updates the respective parameter values at 6115, 6125, 6135 and 6145, and the respective early warning score points at 6117, 6127, 6137 and 6147, as well as the early warning score at 615.

More generally formulated, the patient condition data (the parameter values) are processed to obtain patient condition indication data, in the above example the early warning score. A similar approach can be taken when measuring values of other parameters (such as the ones discussed above in the monitoring of cardiac tamponade), and processing these patient condition data to obtain patient condition indication data (such as an occurrence probability of cardiac tamponage).

As explained above with reference to FIG. 6, patient condition data relating to measured parameters relating to a patient are recorded in a patient data processing system. This storing of patient condition data may be local (e.g. in the user terminal 114), or remote (e.g. in the server 110). Since the patient condition data are stored at different times for the same patient 100, not only patient condition indication data for a particular point in time are obtained, but also trends in the patient condition data over time, and trends in the patient condition indication data over time can be determined and shown.

FIG. 7 illustrates trends in recorded patient condition data over time, and the corresponding patient condition indication over time. In a user interface 700, in four horizontally extending areas 711, 712, 713 and 714, respective graphs 7111, 7121, 7131 and 7141 illustrating respective trends in early warning score points for heart rate ("HR"), temperature ("Temp."), blood pressure ("BP") and urine production ("UP") are shown. A slider line 715 having a slider line handle 716 can be moved to the left or right across the graphs by dragging the slider line 715 with a fingertip or the like contacting the slider line handle 716 at the position shown on the touchscreen. In each position of the slider line 715, a respective early warning score point as recorded in each graph 7111, 7121, 7131 and 7141 for said position is shown next to the respective graph (graph 7111: "2", graph 7121: "0", graph 7131: "1", graph 7141: "3"), and the resulting early warning score (the sum of the respective early warning score points) is shown at 717 ("6"). Accordingly, a trend in the early warning score may be seen at 717 by moving the slider line 715 across the graphs 7111, 7121, 7131 and 7141. At 718, the latest early warning score is shown ("last EWS 2"). A virtual button 719 may be provided, carrying the text "Add EW check", which when operated by touching it, will change the user interface 700 to user interface 600 to allow the input of new patient condition data.

As further illustrated in FIG. 7, the user interface 700 may show the patient's name at 720 ("John Smith"), a picture 721 of the patient, and the ward where the patient is nursed at 722 ("Ward X").

FIG. 8 illustrates an expansion of area 711 of user interface 700 by pressing an expansion symbol 730 in FIG. 7. In reply to operating the expansion symbol 730, the patient condition data (in this case the heart rates) underlying the early warning score points are shown. Thus, the actual measured values of the parameter are shown for

detailed inspection by a healthcare staff member. The expansion of the area 711 may be reversed by again pressing the expansion symbol 730 in the situation depicted in FIG. 8.

FIG. 9 illustrates another user interface 900 related to user interface 700, in which merely the patient condition data as measured at the point in time indicated at the slider line handle 716 ("05-feb 20.00"), and again indicated at 901, and the corresponding early warning score points are shown for different parameters: in area 911, a heart rate of 140 and a corresponding early warning score point "2"; in area 912, a temperature of 36.5 and a corresponding early warning score point "0"; in area 913, a blood pressure of 200 and a corresponding early warning score point "1"; in area 914, a urine production of 2 and a corresponding early warning score point "3". Area 915 illustrates that further parameters may be shown. An early warning score being the sum of the respective early warning points is shown at 916 ("6").

In box 917, the slider line 715 and the slider line handle 716 are reproduced. By grabbing the slider line handle 716 (touching it with a fingertip or the like) and moving the slider line handle 716 to the left or right, date and time as shown at 901 may be selected earlier or later, respectively, and the corresponding patient condition data and patient condition indication date may be shown in the respective areas 911, 912, 913, 914, 915 for inspection by a healthcare staff member.

FIG. 10 illustrates a user interface 1000 showing patient condition indication data for different parameters for different patients in a table. Values of the different parameters may have been obtained in the patient data processing system manually or automatically, using sensors generating the parameter values or values which can be converted into the parameter values automatically by the patient data processing system. At 1001, a selected date and time are shown. In the column 1002 below it, a list of patients is shown. In the next columns 1003, 1004, 1005, 1006 and 1007, for each patient, early warning score points for different parameters (heart rate ("HR"), blood pressure ("BP"), temperature ("T"), urine production ("UP") and another parameter, respectively) are shown. In the rightmost column 1008, for each patient, the early warning score is shown. Different sorting and filtering of the data shown may be applied as indicated at 1009 and 1010, respectively.

FIG. 11 illustrates a user interface 1100 having an area 1111, 1112, 1113, 1114 for each patient. Each area shows a patient's name and ward ("John Smith", "Ward x";

"Nancy Jones", "Ward y"; "Patient No. 1", "Ward x"; "Patient No. 2", "Ward n"), a graph 1121, 1122, 1123, 1124, respectively, showing a trend of an early warning score or other patient condition indication data over time, and an early warning score or other patient condition indication data ("1", "2", "1", "0", respectively) at a point in time ("09-feb 09.00") selected by moving a slider line 1130 through moving a corresponding slider line handle 1131. Different sorting and filtering of the data shown may be applied as indicated at 1109 and 1110, respectively.

It is noted that other patient condition indication data than early warning scores can be shown in the various user interfaces. It is further noted that another presentation of the patient condition indication data than a number may be selected, such as a color, a symbol, a text, etc..

It is also noted that at least part, or all, of the patient condition data may be stored in the user terminal 114, or in another storage of the patient data processing system, such as the server 110, from where it can be retrieved to be displayed in a user interface of the user terminal 114. Patient condition data may be processed in the user terminal 114 for display in a user interface of the user terminal 14, or may be processed at another location in the patient data processing system, such as the server 110. Processing results, such as patient condition indication data, are shown in a user interface.

The user terminal 114 may comprise a so-called App, or application program, which may performing at least part of the patient condition data and patient condition indication data storage and processing, and display of these and other data in a user interface.

As explained above, in a system and method for monitoring a condition of a plurality of patients, patient tags having a patient code assigned to it are used to identify a patient. Healthcare staff tags having a healthcare staff code assigned to it are used to identify a healthcare staff member. A patient data processing system is configured for storing and processing patient condition data for each patient. A user terminal comprising a tag reader, and is configured for: reading a healthcare staff code from a healthcare staff tag; reading a patient code from a patient tag provided to a particular patient. The patient data processing system further is configured for: recording an assignment of a specified healthcare staff code to a specified patient code for each healthcare staff member assigned to monitor a patient identified by the specified patient

code; determining whether an assignment of the read healthcare staff code to the read patient code is recorded; and if said assignment is recorded, providing access through the user terminal to the patient condition data for the particular patient in the patient data processing system. The system and method can be used for indicating a general patient condition, and a possibility of a cardiac tamponade occurring in a patient.

The descriptions, terms and phrases used herein are intended to be illustrative, not limiting, and rather to provide an understandable description of the invention. It will be apparent to the person skilled in the art that alternative and equivalent embodiments of the invention can be conceived and reduced to practice. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the present invention in an appropriately detailed structure.

The terms "a"/"an", as used herein, are defined as one or more than one. The term plurality, as used herein, is defined as two or more than two. The term another, as used herein, is defined as at least a second or more. The terms including and/or having, as used herein, are defined as comprising (i.e., open language, not excluding other elements or steps). Any reference signs in the claims should not be construed as limiting the scope of the claims or the invention.

The mere fact that certain measures are recited in mutually different dependent claims does not indicate that a combination of these measures cannot be used to advantage.

The term coupled, as used herein, is defined as connected, although not necessarily directly, and not necessarily mechanically.

A single processor or other unit may fulfil the functions of several items recited in the claims.

The terms program, computer program, software application, and the like as used herein, are defined as a sequence of instructions designed for execution on a computer system. A program, computer program, or software application may include a subroutine, a function, a procedure, an object method, an object implementation, an executable application, an applet, a servlet, a source code, an object code, a shared library/dynamic load library and/or other sequence of instructions designed for execution on a computer system.

A computer program may be stored and/or distributed on a suitable medium, such as an optical storage medium or a solid-state medium supplied together with or as part of other hardware, but also be distributed in other forms, such as via the Internet or other wired or wireless telecommunication systems.

REFERENCES

[1] Sagristà-Sauleda et al, "Low Pressure Cardiac Tamponade: Clinical and Hemodynamic Profile", Circulation 2006, 114(9), pp.945-952

[2] Konings et al, "In-vivo validation of a new non-invasive continuous ventricular stroke volume monitoring system in an animal model", Critical Care 2011, 15:R165

LIST OF FIGURE ELEMENTS

1	tamponade measurement system
2	patient
3	heart
4	right atrium
5	epicardium
6	intra-pericardial space
6'	intra-pericardial portion
7	aorta
8	pericardium
9	right atrium pressure sensor
10	intra-pericardial pressure sensor
12	reference pressure sensor
14	processing device
16	cardiac performance detector
22	receiver unit
23	antenna
24	visual display unit
26	input/output
28	lead
30	intra cardiac echo catheter
32	ultrasound transducer
34	ultrasound processing device
36	thoracic electric bio impedance measurement device
37	impedance measurement location
38	sensor array
40	mesh support
44	electrode
46	reference electrode
50	measure indication of cardiac output Φco
51	compare indication of cardiac output Φco with characteristic value Φprev
52	adapt occurrence probability for cardiac tamponade
53	measure right atrium pressure Pra

54 measure reference pressure Pref

55 determine right atrium pressure difference ΔPra

56 measure intra-pericardial pressure Pip

57 determine trans-mural pressure difference ΔPtm

58 compare trans-mural pressure difference with statistical distribution of pressure versus tamponade probabilities

59 indicate ordinary pressure tamponade occurrence

60 indicate low pressure tamponade occurrence

61 indicate low likelihood of pressure tamponade

100 patient

102 patient tag

104 healthcare staff member

106 healthcare staff tag

110 server

112 administration workstation

113 workstation tag reader

114 user terminal

115 user terminal tag reader

116 data collecting station

118 sensor

120 user device

200 data communication network

600 user interface

611 input field

612 input field

613 input field

614 input field

615 current early warning score

616 last previous early warning score

617 early warning score

700 user interface

711 area

712 area

713 area
714 area
715 slider line
716 slider line handle
717 early warning score
718 latest early warning score
719 button
720 patient's name
721 picture
722 ward
730 expansion symbol
900 user interface
901 point in time
911 area
912 area
913 area
914 area
915 area
916 early warning score
917 box
1000 user interface
1001 date and time
1002 column
1003 column
1004 column
1005 column
1006 column
1007 column
1008 column
1009 sorting of data
1010 filtering of data
1100 user interface
1109 sorting of data

1110 filtering of data
1111 area
1112 area
1113 area
1114 area
1121 graph
1122 graph
1123 graph
1124 graph
1130 slider line
1131 slider line handle
6111 symbol
6112 text
6113 slide bar
6114 slider
6115 value number
6116 early warning score bar
6117 early warning score point
6121 symbol
6122 text
6123 slide bar
6124 slider
6125 value number
6126 early warning score bar
6127 early warning score point
6131 symbol
6132 text
6133 slide bar
6134 slider
6135 value number
6136 early warning score bar
6137 early warning score point
6141 symbol

6142 text

6143 slide bar

6144 slider

6145 value number

6146 early warning score bar

6147 early warning score point

7111 graph

7121 graph

7131 graph

7141 graph

Pra	right atrium pressure
Pip	intra pericardial space portion pressure
Pref	reference pressure
ΔPra	right atrium pressure difference
ΔPtm	trans-mural pressure difference
TPtm	trans-mural pressure threshold
TPra	right atrium pressure threshold
TPip	pericardial pressure threshold
Φco	cardiac output
Φprev	characteristic cardiac output
Dco	allowed cardiac output drop
Dp	pressure deviation
Zteb	thoracic electric bio impedance

CONCLUSIES

1. Systeem voor het bewaken van een conditie van een veelheid van patiënten (2, 100), waarbij het systeem omvat:

een veelheid van patiëntlabels (102) verschaft aan de patiënten (2, 100), waarbij elk patiëntlabel (102) een daaraan toegewezen unieke patiëntcode heeft die een unieke patiënt (2, 100) identificeert;

een veelheid van gezondheidszorgstaflabels (106) verschaft aan leden van een gezondheidszorgstaf, waarbij elk gezondheidszorgstaflabel (106) een daaraan toegewezen unieke gezondheidszorgstafcode heeft die een uniek gezondheidszorgstaflid (104) identificeert;

een patiëntdataverwerkend systeem geconfigureerd voor het opslaan en verwerken van patiëntconditiedata voor elke patiënt (2, 100); en

een gebruikersterminal (114) omvattende een labellezer (115),

waarbij de gebruikersterminal (114) is ingericht voor:

het lezen van een gezondheidszorgstafcode van een gezondheidszorgstaflabel (106);

het lezen van een patiëntcode van een patiëntlabel (102) verschaft aan een bepaalde patiënt (2, 100);

met het kenmerk, dat

het patiëntdataverwerkende systeem verder is geconfigureerd voor:

het registreren van een toewijzing van een gespecificeerde gezondheidszorgstafcode aan een gespecificeerde patiëntcode voor elk gezondheidszorgstaflid (104) dat is aangewezen om een patiënt (2, 100) die is geïdentificeerd door de gespecificeerde patiëntcode, te bewaken;

het bepalen of een toewijzing van de gelezen gezondheidszorgstafcode aan de gelezen patiëntcode is geregistreerd; en

indien genoemde toewijzing is geregistreerd, het verschaffen van toegang via de gebruikersterminal (114) tot de patiëntconditiedata voor de bepaalde patiënt (2, 100) in het patiëntdataverwerkende systeem.

2. Systeem volgens conclusie 1, waarbij ten minste een van het patiëntlabel (102) en het gezondheidszorgstaflabel (106) een NFC-type, een RFID-type, of een ééndimensionale of tweedimensionale barcode-type is, en de labellezer (115) is ingericht voor het lezen van het respectieve labeltype.

3. Systeem volgens conclusie 1 of 2, waarbij het patiëntdataverwerkende systeem en de gebruikersterminal (114) zijn geconfigureerd voor het met de hand invoeren van patiëntconditiedata voor de bepaalde patiënt (2, 100) in het patiëntdataverwerkende systeem.

4. Systeem volgens een of meer van de voorgaande conclusies, waarbij het patiëntdataverwerkende systeem werkzaam is verbonden met sensorinrichtingen (118) voor het meten van patiëntconditiedata, en is ingericht voor het verkrijgen en opslaan van de patiëntconditiedata.

5. Systeem volgens een of meer van de voorgaande conclusies, waarbij de gebruikersterminal (114) is ingericht voor het in een gebruikersinterface weergeven van uit het patiëntdataverwerkende systeem opgehaalde patiëntconditiedata voor de bepaalde patiënt (2, 100).

6. Systeem volgens een of meer van de voorgaande conclusies, waarbij het patiëntdataverwerkende systeem is ingericht voor het verwerken van de patiëntconditiedata voor het verschaffen van patiëntconditieindicatiedata voor de bepaalde patiënt (2, 100), waarbij de gebruikersterminal (114) is ingericht voor het in een gebruikersinterface weergeven van de patiëntconditieindicatiedata.

7. Systeem volgens een of meer van de voorgaande conclusies, waarbij het patiëntdataverwerkende systeem is geconfigureerd voor:

het verwerken van de patiëntconditiedata voor het verschaffen van patiëntconditieindicatiedata voor de bepaalde patiënt (2, 100);

het bepalen of de patiëntconditieindicatiedata een kritieke patiëntconditie weergeven, en indien dit het geval is, dan het zenden van een bericht naar een gebruikersinrichting (120) van een gezondheidszorgstaflid (104) geïdentificeerd door

een gezondheidszorgstafcode toegewezen aan de patiëntcode van de bepaalde patiënt (2, 100).

8. Systeem volgens conclusie 7, waarbij het bericht een toegangscode voor de gebruikersinrichting (120) van het gezondheidszorgstaflid (104) omvat om toegang te krijgen tot de patiëntconditiedata en/of de patiëntconditieindicatiedata van de bepaalde patiënt (2, 100) in het patiëntdataverwerkende systeem.

9. Systeem volgens een of meer van de conclusies 6-8, waarbij de patiëntconditieindicatiedata een optredingskans voor harttamponade in de bepaalde patiënt (2, 100) omvatten, waarbij het systeem verder omvat:

een rechteratriumdruksensor (9), geconfigureerd voor het meten van een rechteratriumdruk (Pra) in een rechteratrium (4) van de patiënt (2, 100);

een intrapericardiale druksensor (10), geconfigureerd voor het meten van een intrapericardiale druk (Pip) in een gedeelte van een intrapericardiale ruimte (6) van de patiënt; en

waarbij het patiëntdataverwerkende systeem werkzaam is verbonden met de druksensoren (9, 10), is voorzien van een vooraf bepaalde statistische verdeling van druk versus tamponadekansen, en is geconfigureerd voor:

het bepalen van een transmuraal drukverschil (ΔPtm) tussen de rechteratriumdruk (Pra) en de intrapericardiale druk (Pip);

het vergelijken van het transmurale drukverschil met de statistische verdeling;

het aangeven van de optredingskans voor harttamponade, gebaseerd op de vergelijking.

10. Systeem (1) volgens conclusie 9, omvattende een referentiedruksensor (12), geconfigureerd voor het meten van een referentiedruk (Pref) op een referentielocatie buiten het rechteratrium (4) en de intrapericardiale ruimte (6), waarbij het patiëntdataverwerkende systeem werkzaam is verbonden met de referentiedruksensor (12) en is geconfigureerd voor:

het bepalen van een rechteratriumdrukverschil (ΔPra) tussen de rechteratriumdruk (Pra) en de referentiedruk (Pref); en

het aangeven van de optredingskans, gebaseerd op het onderscheiden tussen een gewonedruktamponade indien het rechteratriumdrukverschil (ΔPra) boven een vooraf bepaalde rechteratriumdrukdrempel (TPra) is, en een lagedruktamponade indien het rechteratriumdrukverschil (ΔPra) onder de rechteratriumdrukdrempel (TPra) is.

11. Systeem (1) volgens conclusie 9, omvattende een veelheid van intrapericardiale druksensoren (10), geconfigureerd voor het meten van een veelheid van intrapericardiale drukken (Pip) in een aantal afzonderlijke intrapericardiale gedeelten (6'), waarbij het systeem verder een referentiedruksensor (12) omvat, geconfigureerd voor het meten van een referentiedruk (Pref) op een referentielocatie buiten het rechteratrium (4) en de intrapericardiale ruimte (6), waarbij het patiëntdataverwerkende systeem werkzaam is verbonden met de veelheid van intrapericardiale druksensoren (10) en met de referentiedruksensor (12), en is geconfigureerd voor:

het bepalen van een veelheid van intrapericardiale drukverschillen (ΔPip) tussen elk van de intrapericardiale drukken (Pip) en de referentiedruk (Pref);

het registreren van een optreden van een drukafwijking (Dp) voor een van de veelheid van drukverschillen (ΔPip) ten opzichte van een intrapericardiale drukdrempel (TPip); en

het correleren van de drukafwijking (Dp) met de locatie van het intrapericardiale gedeelte (6').

12. Systeem (1) volgens een of meer van de conclusies 9-11, omvattende een hartprestatiedetector (16) voor het meten van een indicatie van hartdebiet (Φco) voor de patiënt (2, 100), en waarbij het patiëntdataverwerkende systeem is geconfigureerd voor:

het vergelijken van de indicatie van het hartdebiet (Φco) met een opgeslagen karakteristieke waarde (Φprev) van eerdere hartdebietmetingen; en

het aanpassen van de optredingskans, gebaseerd op een afname van het hartdebiet (Φco) groter dan een vooraf bepaalde hartdebietafname (Dco) onder de karakteristieke waarde (Φprev).

13. Systeem (1) volgens een of meer van de conclusies 9-12, waarbij de rechteratriumdruksensor (9) gelegen is op een distaal einde van een sonde (28).

14. Systeem (1) volgens conclusie 13, waarbij de sonde (28) een intracardiale echokatheter (30) is, welke ultrageluidtransducent (32) omvat voor het afbeelden en meten van een bloedstroom in de aorta (7), en welke verbindbaar is met het patiëntdataverwerkende systeem, waarbij het patiëntdataverwerkende systeem is geconfigureerd voor:

het bepalen van het hartdebiet (Φco) uit de gemeten bloedstroom en een afgebeelde dwarsdoorsnede van de aorta (7).

15. Systeem (1) volgens conclusie 13 of 14, waarbij de hartprestatiedetector (16) een thoracale bio-elektrische impedantiemeetinrichting (36) omvat die verbindbaar is met het patiëntdataverwerkende systeem, waarbij het patiëntdataverwerkende systeem is geconfigureerd voor:

het bepalen van het hartdebiet (Φco) uit een meting van een thoracale bio-elektrische impedantie (Zteb) tussen twee impedantiemeetlokaties (37) op de patiënt (2, 100).

16. Systeem (1) volgens conclusie 11, waarbij de veelheid van intrapericardiale druksensoren (10) is aangebracht in een sensormatrix (38) en is bevestigd aan een ondersteuningsgaas (40) dat is geconfigureerd voor plaatsing op en rond een deel van een epicard (5) van de patiënt (2, 100).

17. Systeem (1) volgens conclusie 11, waarbij elke intrapericardiale druksensor (10) een draadloze zendeenheid (23) omvat voor het zenden van een draadloos signaal dat de intrapericardiale drukmeting (Pip) weergeeft, en waarbij het patiëntdataverwerkende systeem een ontvangereenheid (22) omvat voor het ontvangen van het draadloze signaal.

18. Systeem volgens een of meer van de conclusies 6-8, waarbij de patiëntconditieindicatiedata een vroege-waarschuwingsscore voor een patiënt (2, 100) omvatten gebaseerd op een som van scorepunten toegekend aan gemeten waarden van ten minste twee van de volgende parameters:

ademhalingsfrequentie, hartslag, systolische bloeddruk, AVPU-score, temperatuur en urineproductie,

waarbij de frequentie en intensiteit van het bewaken van de patiënt (2, 100) afhangen van de vroege-waarschuwingsscore en de ontwikkeling daarvan.

19. Systeem volgens een of meer van de conclusies 6-8, waarbij de patiëntconditieindicatiedata een vroege-waarschuwingstrendscore voor een patiënt (2, 100) omvatten gebaseerd op een combinatie van trends in de tijd van gemeten warden van ten minste twee van de volgende parameters:

ademhalingsfrequentie, hartslag, systolische bloeddruk, AVPU-score, temperatuur en urineproductie,

waarbij de frequentie en intensiteit van het bewaken van de patiënt (2, 100) afhangen van de vroege-waarschuwingstrendscore en de ontwikkeling daarvan.

20. Systeem volgens conclusie 18 of 19, waarbij het patiëntdataverwerkende system werkzaam is verbonden met sensorinrichtingen voor het meten van de waarden van de ten minste twee parameters, en is geconfigureerd voor het aangeven van de vroege-waarschuwingsscore en/of de vroege-waarschuwingstrendscore.

21. Werkwijze voor het bewaken van een conditie van een veelheid van patiënten (2, 100), waarbij de werkwijze de stappen omvat van:

het verschaffen aan de patiënten (2, 100) van een veelheid van patiëntlabels (102), waarbij elk patiëntlabel (102) een daaraan toegewezen unieke patiëntcode heeft die een unieke patiënt (2, 100) identificeert;

het verschaffen aan leden van een gezondheidszorgstaf van een veelheid van gezondheidszorgstaflabels (106), waarbij elk gezondheidszorgstaflabel (106) een daaraan toegewezen unieke gezondheidszorgstafcode heeft die een uniek gezondheidszorgstaflid (104) identificeert;

het verschaffen van een patiëntdataverwerkend system voor het opslaan en verwerken van patiëntconditiedata voor elke patiënt (2, 100);

het verschaffen van een gebruikersterminal (114) omvattende een labellezer (115);

het lezen, met de labellezer (115) van de gebruikersterminal (114), van een gezondheidszorgstafcode van een gezondheidszorgstaflabel (106);

het lezen, met de labellezer (115) van de gebruikersterminal (114), van een patiëntcode van een patiëntlabel (102) verschaft aan een bepaalde patiënt (2, 100),

gekenmerkt door

het in het patiëntdataverwerkende systeem registreren van een toewijzing van een gespecificeerde gezondheidszorgstafcode aan een gespecificeerde patiëntcode voor elk gezondheidszorgstaflid (104) dat is aangewezen voor het bewaken van een patiënt (2, 100) geïdentificeerd door de gespecificeerde patiëntcode;

het controleren, met het patiëntdataverwerkende systeem, of een toewijzing van de gelezen gezondheidszorgstafcode aan de gelezen patiëntcode is geregistreerd; en

indien genoemde toewijzing is geregistreerd, het verschaffen van toegang, via de gebruikersterminal (114), tot de patiëntconditiedata voor de bepaalde patiënt (2, 100) in het patiëntdataverwerkende systeem.

22. Werkwijze volgens conclusie 21, omvattende het met de hand invoeren van patiëntconditiedata voor de bepaalde patiënt (2, 100) in het patiëntdataverwerkende systeem.

23. Werkwijze volgens conclusie 21 of 22, verder omvattende:

het meten van patiëntconditiedata door sensorinrichtingen die werkzaam zijn verbonden met het patiëntdataverwerkende systeem; en

het verkrijgen en opslaan van de patiëntconditiedata door het patiëntdataverwerkende systeem.

24. Werkwijze volgens een of meer van de conclusies 21-23, verder omvattende:

het weergeven, in een gebruikersinterface van de gebruikersterminal (114), van patiëntconditiedata voor de bepaalde patiënt (2, 100) opgehaald uit het patiëntdataverwerkende systeem.

25. Werkwijze volgens een of meer van de conclusies 21-24, verder omvattende:

het verwerken van de patiëntconditiedata door het patiëntdataverwerkende systeem voor het verschaffen van patiëntconditieindicatiedata voor de bepaalde patiënt (2, 100); en

het weergeven, in een gebruikersinterface van de gebruikersterminal (114), van de patiëntconditieindicatiedata.

26. Werkwijze volgens een of meer van de conclusies 21-25, verder omvattende:

het verwerken van de patiëntconditiedata door het patiëntdataverwerkende system voor het verschaffen van patiëntconditieindicatiedata voor de bepaalde patiënt (2, 100); en

het bepalen, door het patiëntdataverwerkende system, of de patiëntconditieindicatiedata een kritieke patiëntconditie weergeven, en indien dit het geval is, dan het zenden van een bericht naar een gebruikersinrichting (120) van een gezondheidszorgstaflid (104) geïdentificeerd door een gezondheidszorgstafcode toegewezen aan de patiëntcode van de bepaalde patiënt (2, 100).

27. Werkwijze volgens conclusie 26, verder omvattende:

verkrijgen van toegang tot de patiëntconditiedata en/of de patiëntconditieindicatiedata van de bepaalde patiënt (2, 100) in het patiëntdataverwerkende system gebaseerd op een toegangscode voor de gebruikersinrichting (120) van het gezondheidszorgstaflid (104) opgenomen in het bericht voor het verkrijgen van toegang tot de patiëntconditiedata en/of de patiëntconditieindicatiedata van de bepaalde patiënt (2, 100) in het patiëntdataverwerkende systeem.

28. Werkwijze volgens een of meer van de conclusies 25-27, waarbij de patiëntconditieindicatiedata een optredingskans voor harttamponade in de bepaalde patiënt (2, 100) omvatten, waarbij de werkwijze verder omvat:

het bepalen van een transmuraal drukverschil (ΔPtm) tussen een rechteratriumdruk (Pra) gemeten in een rechteratrium (4) van de patiënt (2, 100), en een intrapericardiale druk (Pip) gemeten in een gedeelte (6') van een intrapericardiale ruimte van de patiënt (2, 100);

vergelijken (58) van het transmurale drukverschil (ΔPtm) met een vooraf bepaalde statische verdeling van druk versus tamponadekansen; en

het aangeven (59, 60) van de optredingskans, gebaseerd op de transmurale drukverschilvergelijking.

29. Werkwijze volgens conclusie 28, omvattende:

het bepalen van een rechteratriumdrukverschil (ΔPra) tussen de rechteratriumdruk (Pra) en een referentiedruk (Pref) gemeten op een referentielocatie buiten het rechteratrium (4) en de intrapericardiale ruimte (6); en

het aangeven (59, 60) van de optredingskans gebaseerd op het onderscheiden tussen een gewonedruktamponade indien het rechteratriumdrukverschil (ΔPra) boven een vooraf bepaalde rechteratriumdrukdrempel (TPra) is, en een lagedruktamponade indien het rechteratriumdrukverschil (ΔPra) onder de rechteratriumdrukdrempel (TPra) is.

30. Werkwijze volgens conclusie 28 of 29, omvattende:

het vergelijken (58) van het transmurale drukverschil (ΔPtm) met een vooraf bepaalde transmurale drukdrempel (TPtm) die ongeveer 2 mm Hg = 267 Pa bedraagt, en/of waarbij de rechteratriumdrukdrempel (TPra) ongeveer 7 mm Hg = 933 Pa bedraagt.

31. Werkwijze volgens conclusie 28, omvattende:

het bepalen van een veelheid van intrapericardiale drukverschillen (ΔPip) tussen elke van een veelheid van intrapericardiale drukken (Pip) gemeten op een aantal afzonderlijke intrapericardiale gedeelten (6'), en een referentiedruk (Pref) gemeten op een referentielocatie buiten het rechteratrium (4) en de intrapericardiale ruimte (6);

het registreren van een optreden van een drukafwijking (Dp) voor een van de veelheid van drukverschillen (ΔPip) ten opzichte van een aantal intrapericardiale drempelwaarden (TPip); en

het correleren van het intrapericardiale gedeelte (6') met de drukafwijking (Dp).

32. Werkwijze volgens een of meer van de conclusies 28-31, omvattende:

het vergelijken van een indicatie van het hartdebiet (Φco) voor de patiënt (2, 100) met een karakteristieke waarde (Φprev) van eerdere hartdebietmetingen; en

het aanpassen (52) van de optredingskans, gebaseerd op een afname van het hartdebiet (Φco) die groter is dan een vooraf bepaalde hartdebietafname (Dco) onder de karakteristieke waarde (Φprev).

33. Werkwijze volgens conclusie 32, omvattende:

het met ultrageluid afbeelden van een dwarsdoorsnede van de aorta (7) door een wand van het rechteratrium (4) ; en

het bepalen van het hartdebiet (Φco) uit een bloedstroom gemeten in de aorta (7) en de dwarsdoorsnede.

34. Werkwijze volgens conclusie 32 of 33, omvattende:

het bepalen van het hartdebiet (Φco) uit een meting van een thoracale bio-elektrische impedantie (Zteb) tussen twee impedantiemeetlokaties (37) op de patiënt (2, 100).

35. Werkwijze volgens een of meer van de conclusies 25-27, waarbij de patiëntconditieindicatiedata een vroege-waarschuwingsscore voor een patiënt (2, 100) omvatten, gebaseerd op een som van scorepunten toegekend aan gemeten waarden van ten minste twee van de volgende parameters:

ademhalingsfrequentie, hartslag, systolische bloeddruk, AVPU-score, temperatuur en urineproductie,

waarbij de frequentie en intensiteit van het bewaken van de patiënt (2, 100) afhangen van de vroege-waarschuwingsscore en de ontwikkeling daarvan.

36. Werkwijze volgens een of meer van de conclusies 26-27, waarbij de patiëntconditieindicatiedata een vroege-waarschuwingstrendscore voor een patiënt (2, 100) omvatten, gebaseerd op een combinatie van trends in de tijd van gemeten waarden van ten minste twee van de volgende parameters:

ademhalingsfrequentie, hartslag, systolische bloeddruk, AVPU-score, temperatuur en urineproductie,

waarbij de frequentie en intensiteit van het bewaken van de patiënt (2, 100) afhangen van de vroege-waarschuwingstrendscore en de ontwikkeling daarvan.

37. Werkwijze volgens conclusie 35 of 36, verder omvattende:

het meten van de waarden van de ten minste twee parameters door sensorinrichtingen die werkzaam zijn verbonden met het patiëntdataverwerkende systeem; en

het aangeven van de vroege-waarschuwingsscore en/of vroege-waarschuwingstrendscore.

38. Gebruikersterminal (114) voor gebruik in het systeem volgens conclusie 1 voor het bewaken van een conditie van een veelheid van patiënten (2, 100), waarbij de gebruikersterminal (114) een labellezer (115) omvat, en is geconfigureerd voor:

het lezen van een gezondheidszorgstafcode van een gezondheidszorgstaflabel (106), waarbij een veelheid van gezondheidszorgstaflabels (106) is verschaft aan leden van een gezondheidszorgstaf, waarbij elk gezondheidszorgstaflabel (106) een daaraan toegewezen unieke gezondheidszorgstafcode heeft die een uniek gezondheidszorgstaflid (104) identificeert; en

het lezen van een patiëntcode van een patiëntlabel (102) verschaft aan een bepaalde patiënt (2, 100), waarbij een veelheid van patiëntlabels (102) is verschaft aan de patiënten (2, 100), waarbij elk patiëntlabel (102) een daaraan toegewezen unieke patiëntcode heeft die een unieke patiënt (2, 100) identificeert,

met het kenmerk, dat

een toewijzing van een gespecificeerde gezondheidszorgstafcode aan een gespecificeerde patiëntcode voor elk gezondheidszorgstaflid (104) dat is aangewezen voor het bewaken van een patiënt (2, 100) geïdentificeerd door de gespecificeerde patiëntcode, is geregistreerd,

waarbij de gebruikersterminal (114) verder is geconfigureerd voor:

het bepalen of een toewijzing van de gelezen gezondheidszorgstafcode aan de gelezen patiëntcode is geregistreerd; en

indien genoemde toewijzing is geregistreerd, het verschaffen van toegang via de gebruikersterminal (114) tot de patiëntconditiedata voor de bepaalde patiënt (2, 100).

39. Computerprogramma omvattende computerinstructies welke, wanneer deze zijn geïmplementeerd in een computerverwerkingssysteem van een gebruikersterminal (114) volgens conclusie 38, de gebruikersterminal (114) de functies volgens conclusie 38 doen uitvoeren.

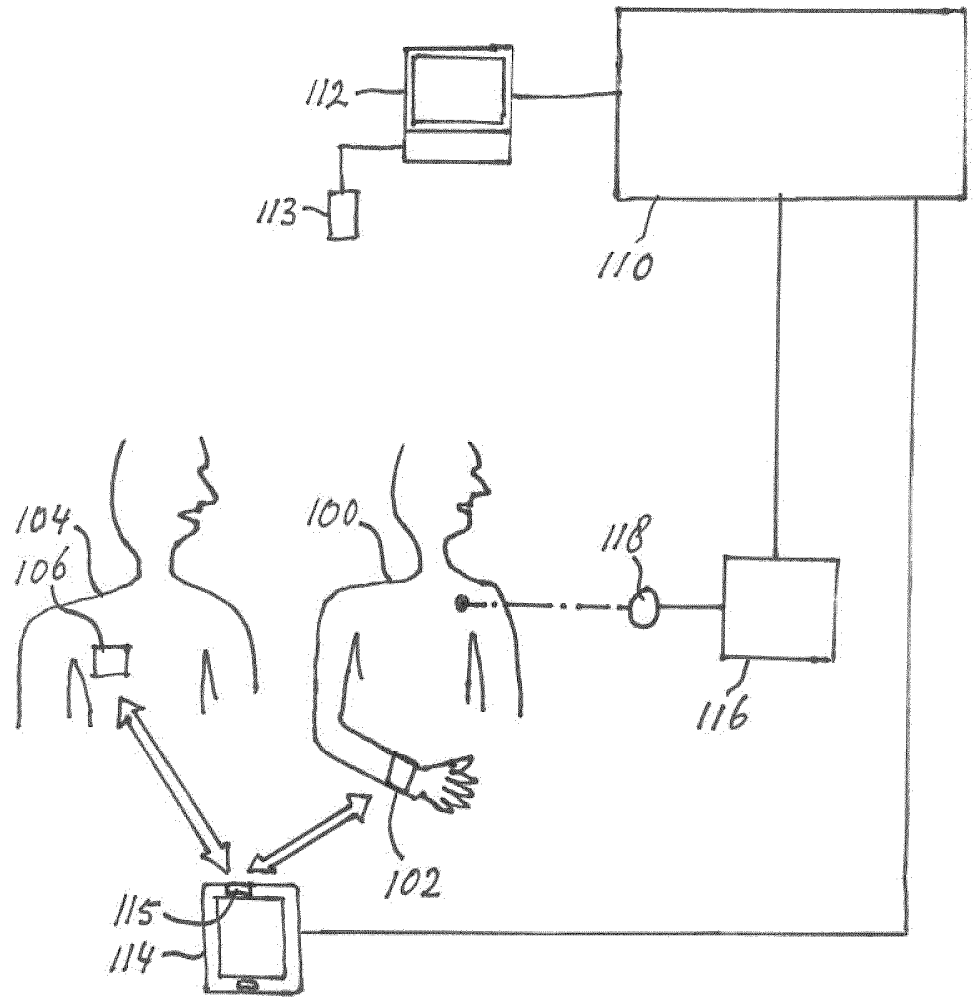
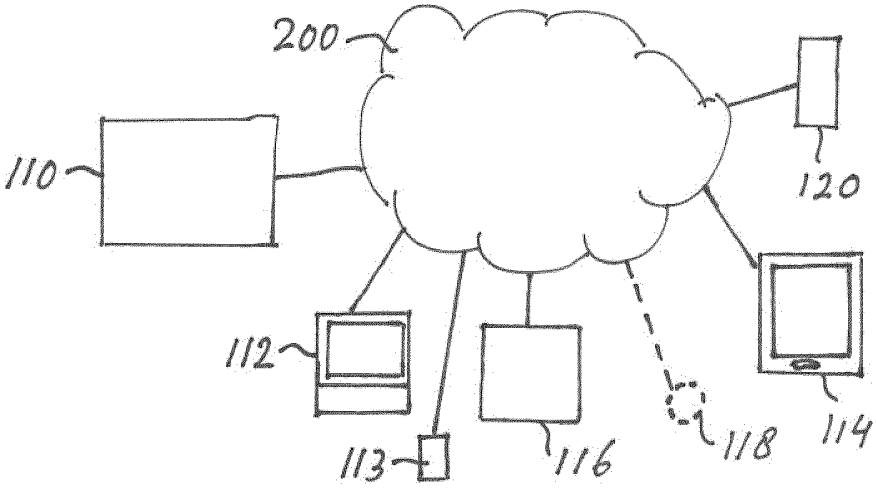

112
113
110
104
106
100
118
116
102
115
114

Fig. 1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120
112
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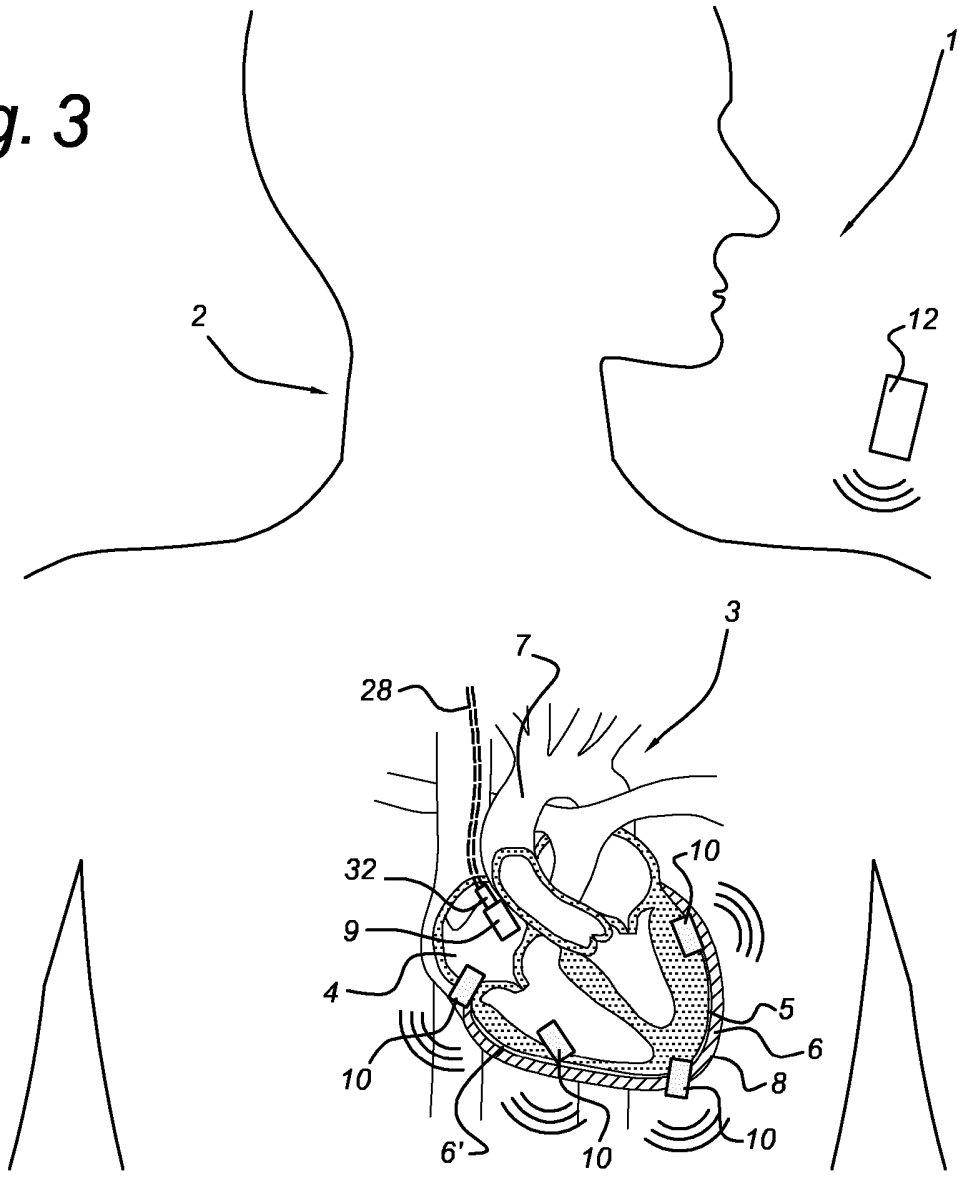
116
118
114

Fig. 2

Fig. 3



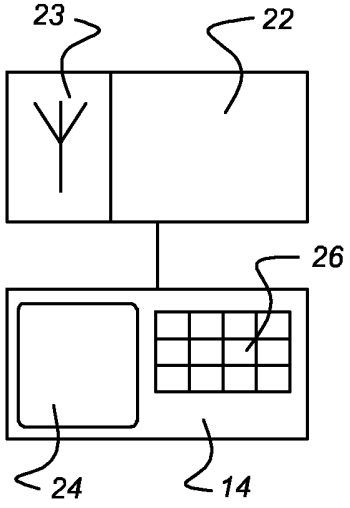
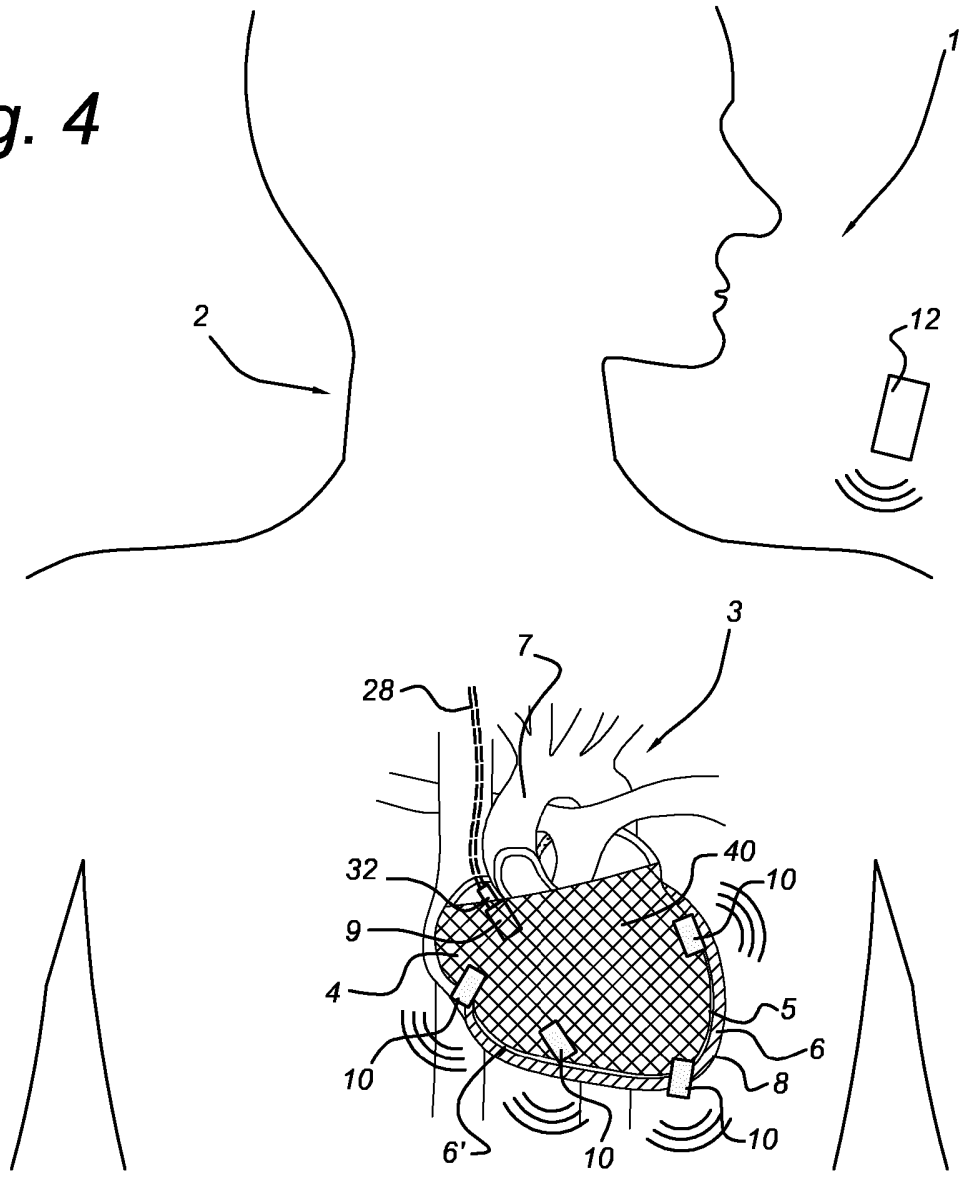


Fig. 4


1
2
12
3
7
28
32
9
4
10
40
10
5
6
8
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6'
10
10

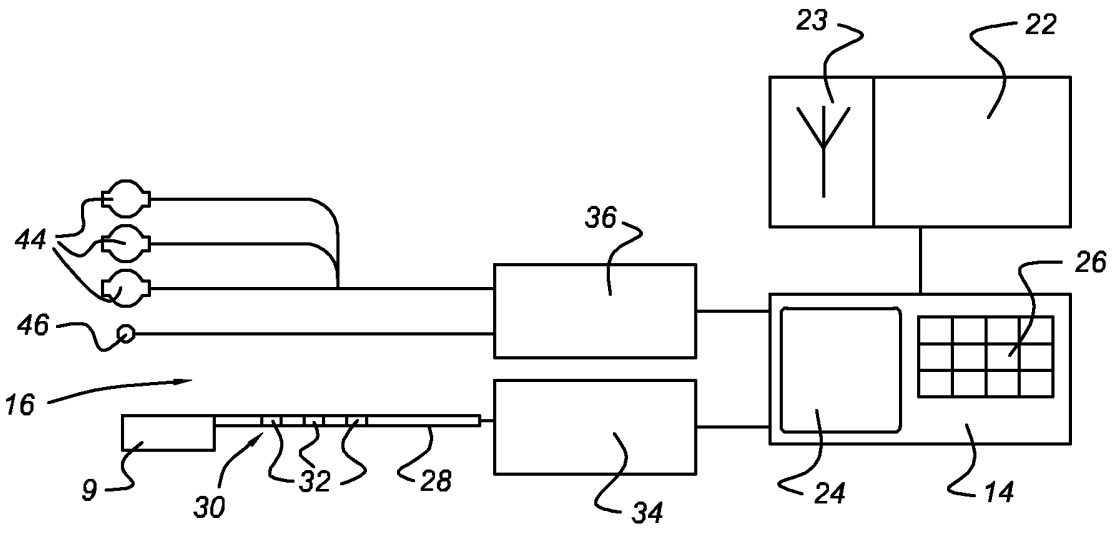
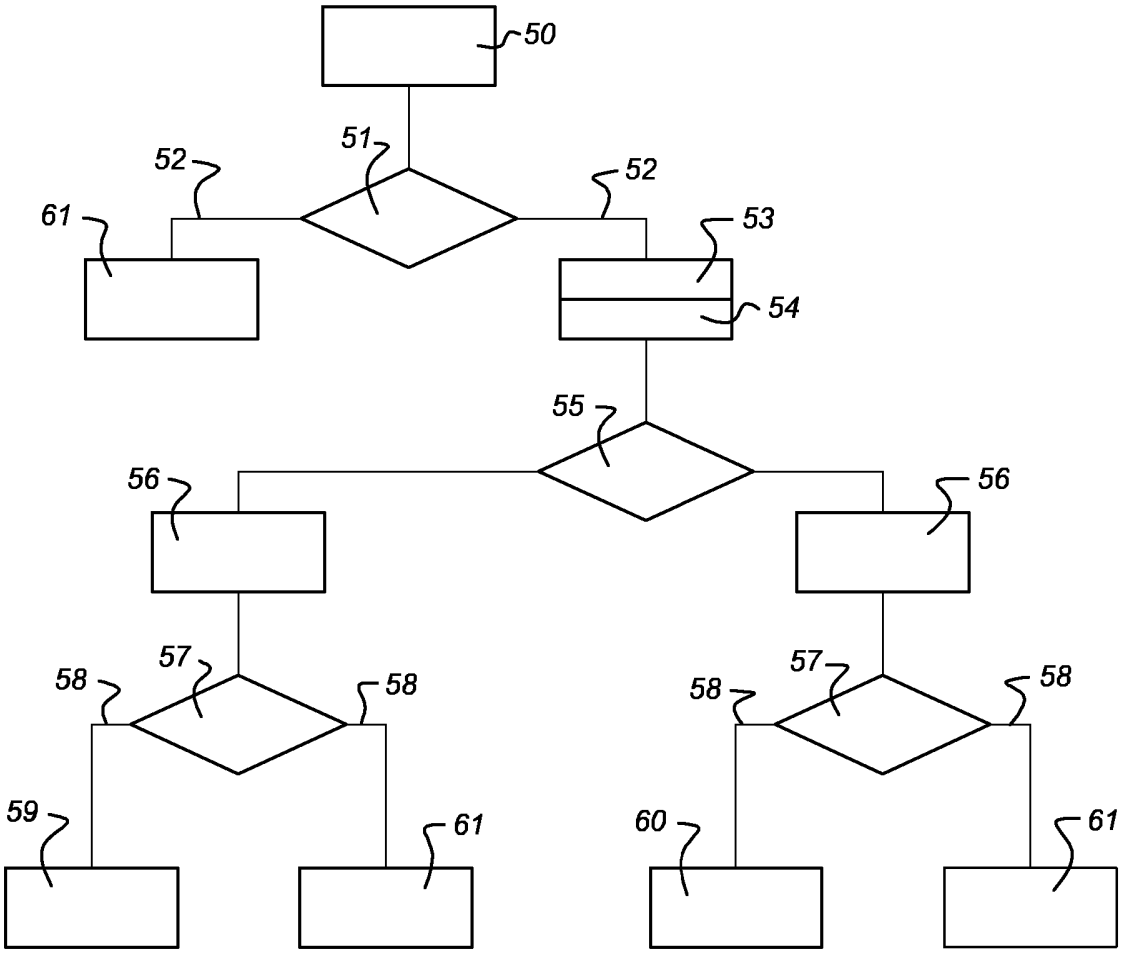

23
22
44
36
26
46
16
9
30
32
28
34
24
14

Fig. 5



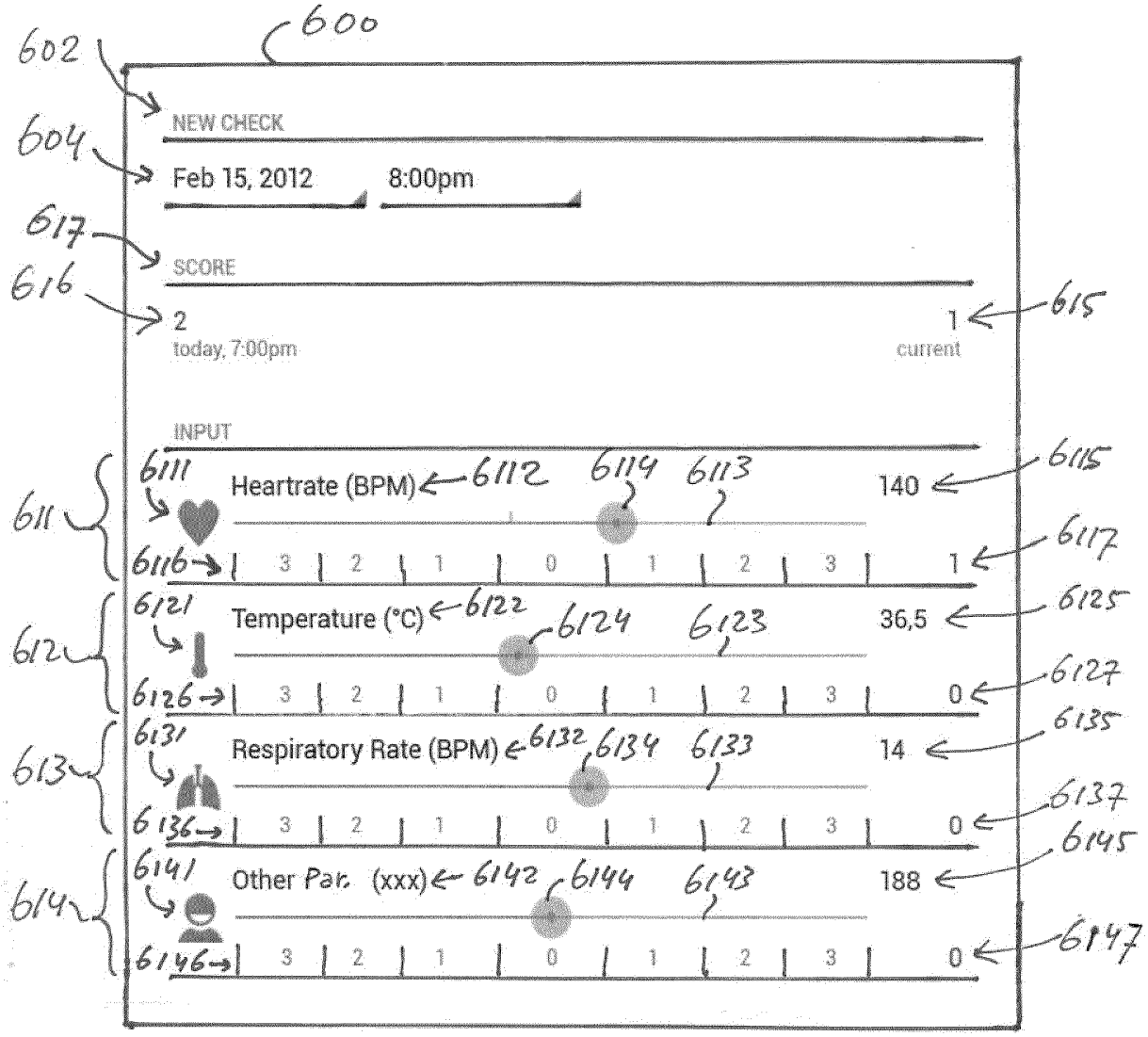
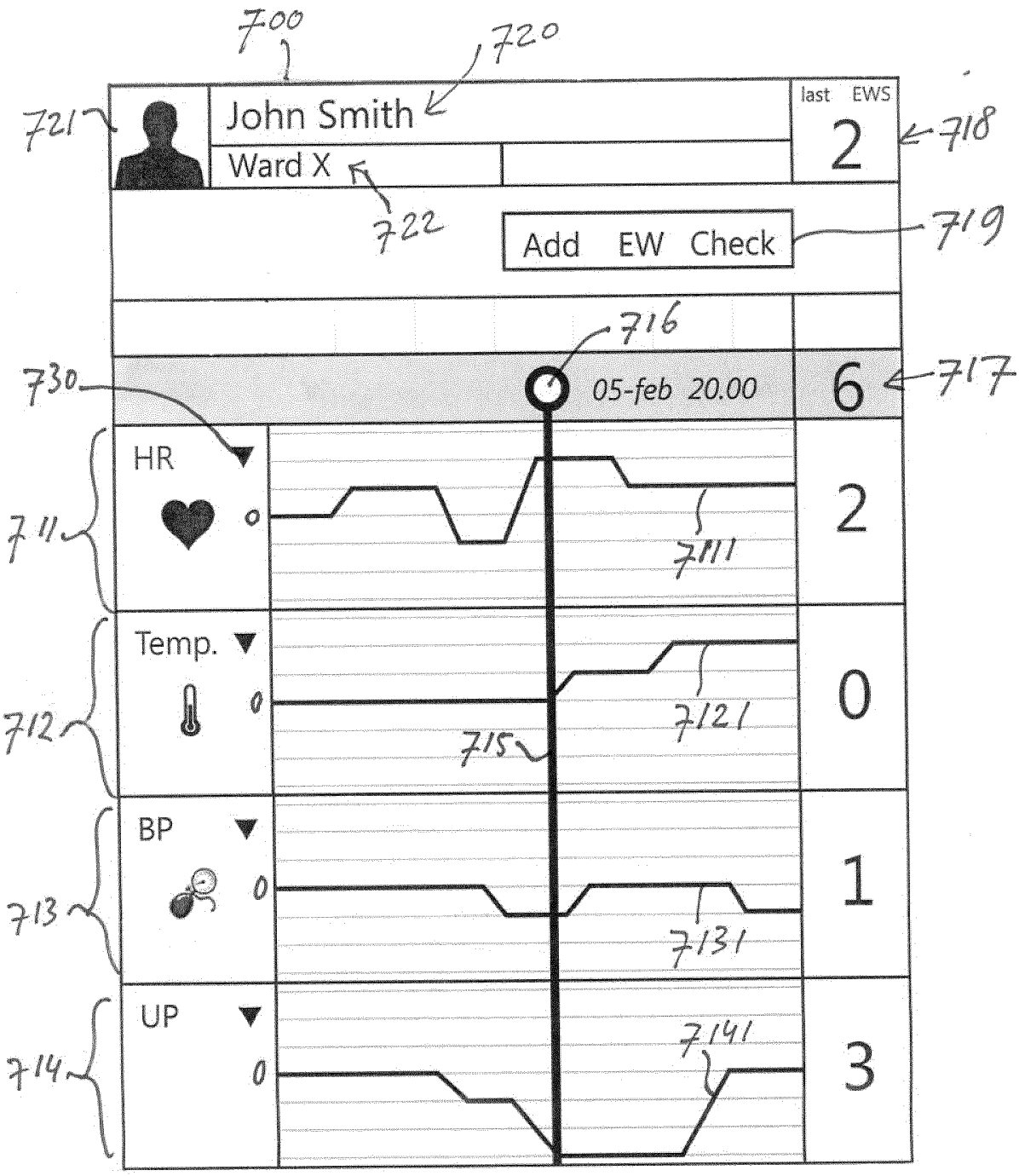

600
602
NEW CHECK
604
Feb 15, 2012
8:00pm
617
SCORE
616
2
today, 7:00pm
1
current
615
INPUT
611
6111
Heartrate (BPM)
6112
6114
6113
140
6115
6116
3 2 1 0 1 2 3
1
6117
612
6121
Temperature (°C)
6122
6124
6123
36,5
6125
6126
3 2 1 0 1 2 3
0
6127
613
6131
Respiratory Rate (BPM)
6132
6134
6133
14
6135
6136
3 2 1 0 1 2 3
0
6137
614
6141
Other Par. (xxx)
6142
6144
6143
188
6145
6146
3 2 1 0 1 2 3
0
6147

Fig. 6


700
720
721
John Smith
Ward X
722
last EWS
2
718
Add EW Check
719
716
730
05-feb 20.00
6
717
HR
0
711
7111
2
Temp.
0
712
7121
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BP
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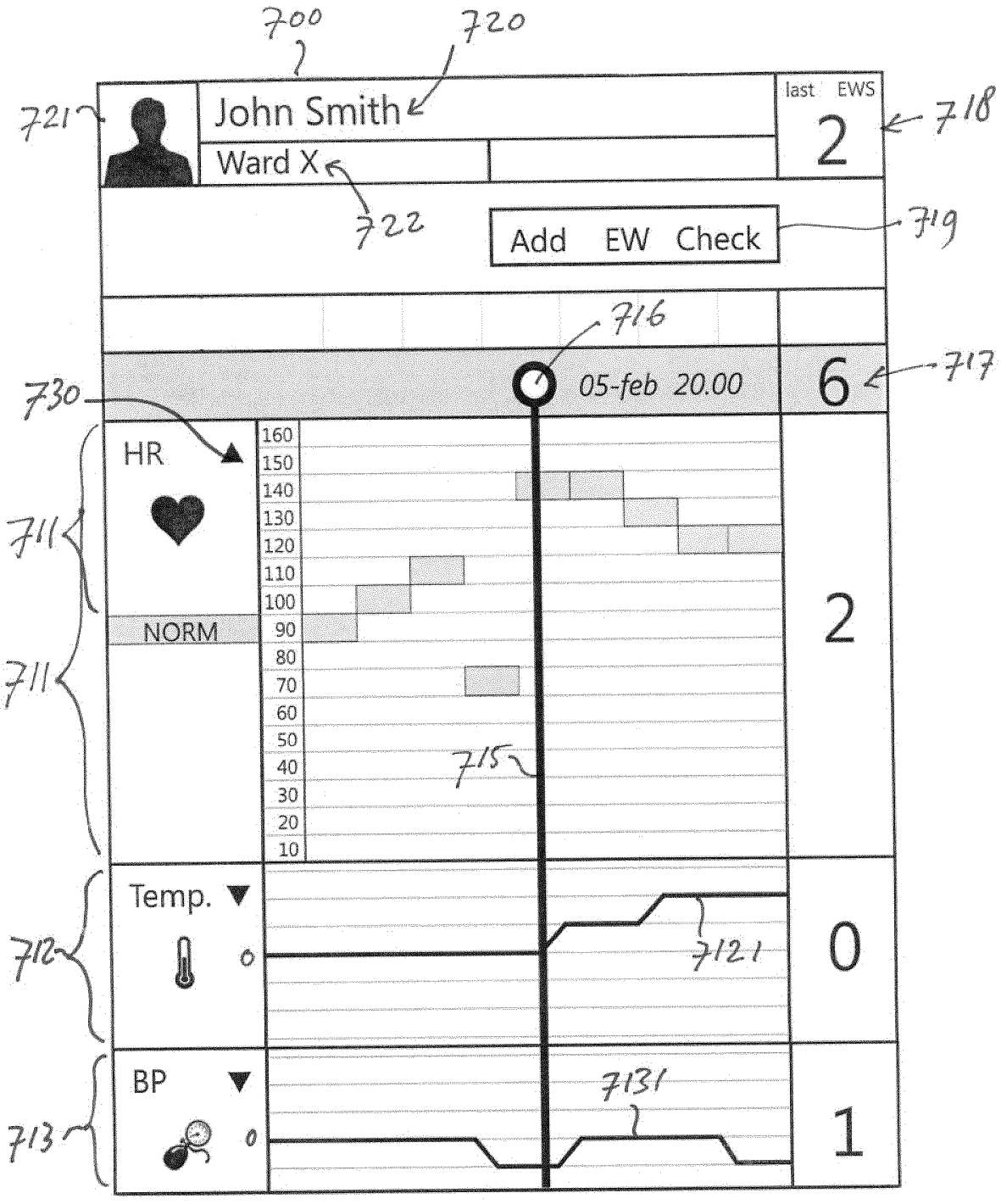
7141
3

Fig. 7


700
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John Smith
Ward X
722
last EWS
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718
Add EW Check
719
716
05-feb 20.00
6
717
730
HR
160
150
140
130
120
110
100
NORM
90
80
70
60
50
40
30
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711
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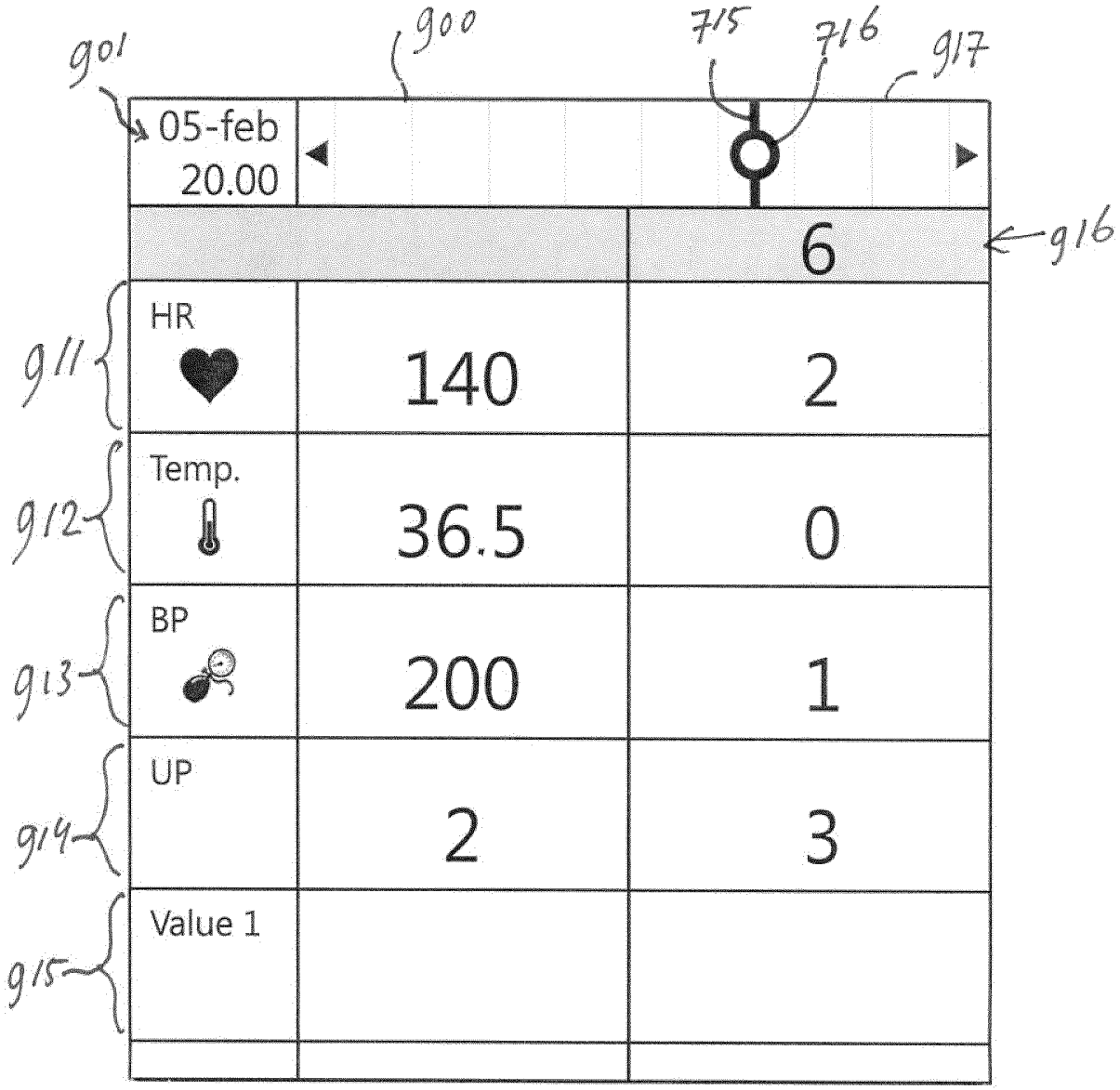
715
2
Temp.
0
712
7121
0
BP
7131
1
713

Fig.8


901
900
715
716
917
05-feb
20.00
6
916
HR
140
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911
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36.5
0
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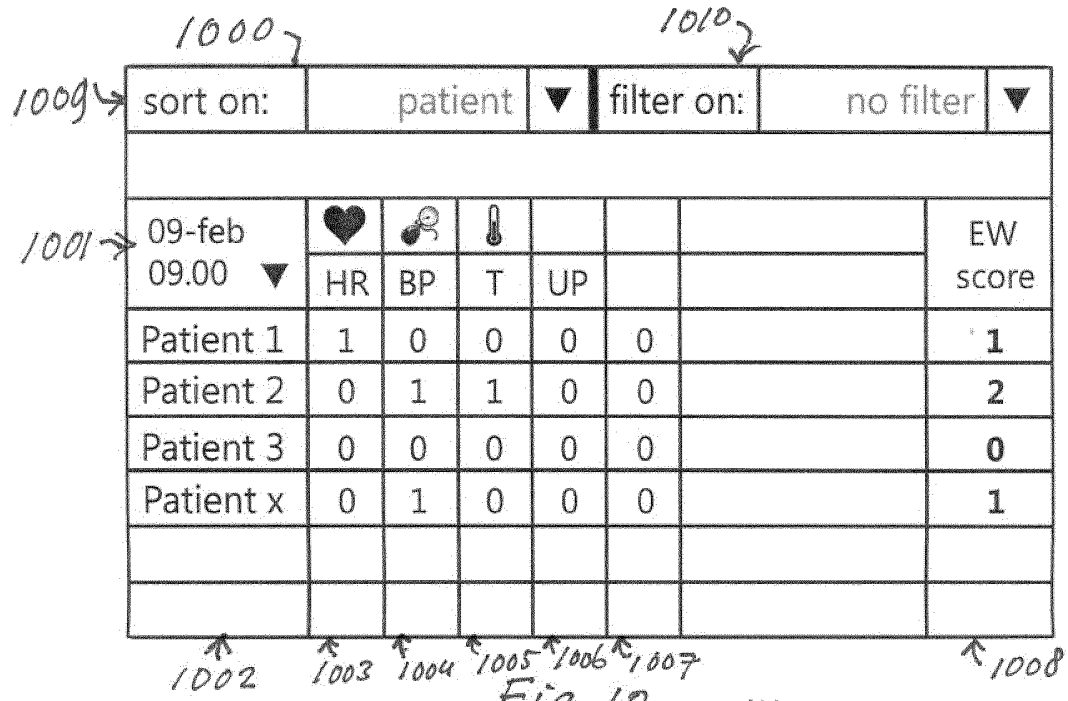
913
UP
2
3
914
Value 1
915

Fig. 9


1000
1010
1009
sort on:
patient
filter on:
no filter
1001
09-feb
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HR
BP
T
UP
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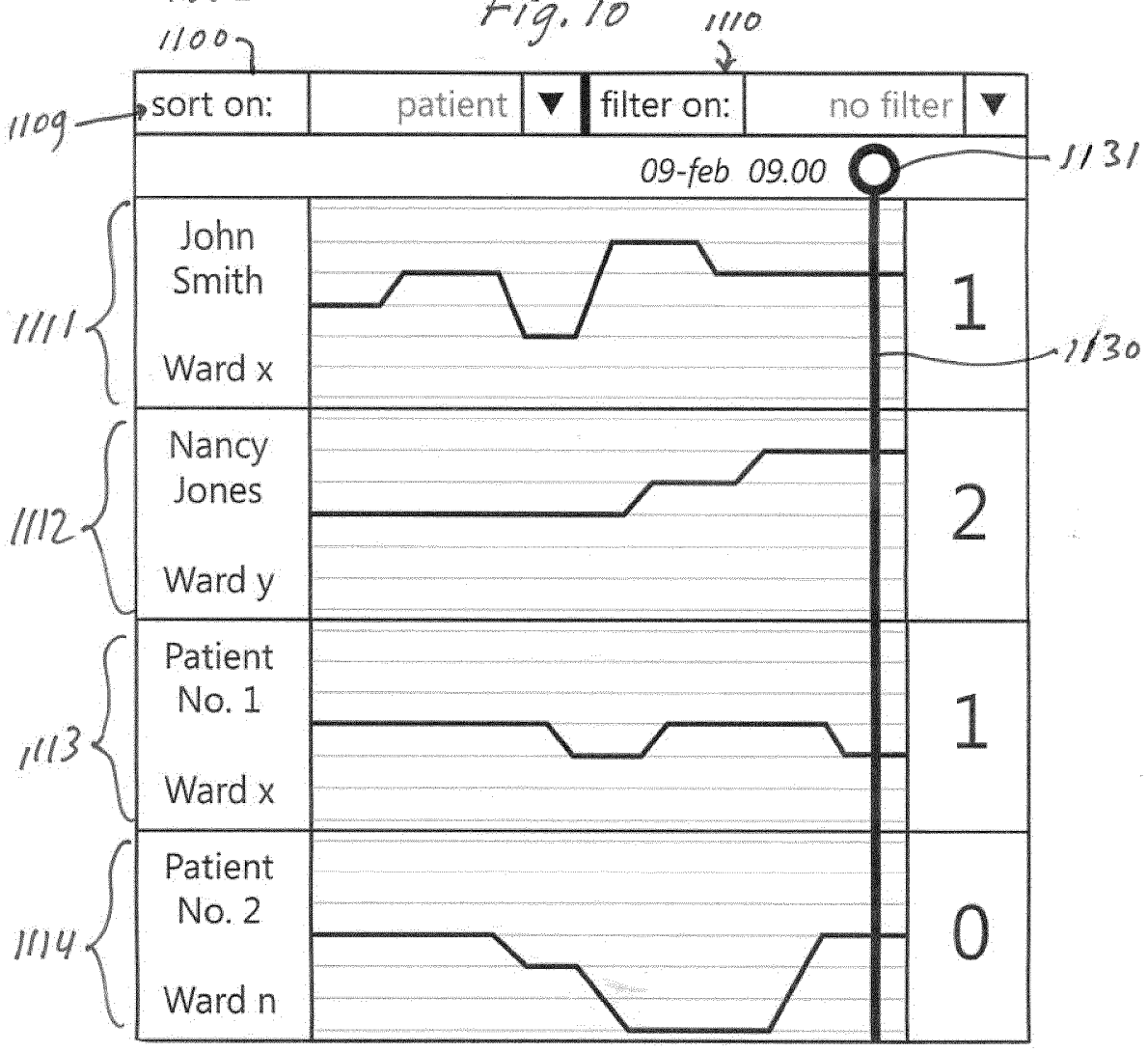
score
Patient 1 1 0 0 0 0 1
Patient 2 0 1 1 0 0 2
Patient 3 0 0 0 0 0 0
Patient x 0 1 0 0 0 1
1002
1003
1004
1005
1006
1007
1008

Fig. 10


1100
1110
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sort on:
patient
filter on:
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09-feb 09.00
1131
1130
1111
John
Smith
Ward x
1
1112
Nancy
Jones
Ward y
2
1113
Patient
No. 1
Ward x
1
1114
Patient
No. 2
Ward n
0

Fig. 11

SAMENWERKINGSVERDRAG (PCT)

RAPPORT BETREFFENDE NIEUWHEIDSONDERZOEK VAN INTERNATIONAAL TYPE

IDENTIFICATIE VAN DE NATIONALE AANVRAGE	KENMERK VAN DE AANVRAGER OF VAN DE GEMACHTIGDE
	P31704NL00/ME
Nederlands aanvraag nr. **2011295**	Indieningsdatum **12-08-2013**
	Ingeroepen voorrangsdatum
Aanvrager (Naam) **Global Factories Total Engineering and Manufacturing B.V.**	
Datum van het verzoek voor een onderzoek van internationaal type **05-10-2013**	Door de Instantie voor Internationaal Onderzoek aan het verzoek voor een onderzoek van internationaal type toegekend nr. **SN60811**

I. CLASSIFICATIE VAN HET ONDERWERP (bij toepassing van verschillende classificaties, alle classificatiesymbolen opgeven)

Volgens de internationale classificatie (IPC)

G06F19/00

II. ONDERZOCHTE GEBIEDEN VAN DE TECHNIEK

Onderzochte minimumdocumentatie

Classificatiesysteem	Classificatiesymbolen
IPC	**G06F**

Onderzochte andere documentatie dan de minimum documentatie, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen

III. ☐ **GEEN ONDERZOEK MOGELIJK VOOR BEPAALDE CONCLUSIES** (opmerkingen op aanvullingsblad)

IV. ☐ **GEBREK AAN EENHEID VAN UITVINDING** (opmerkingen op aanvullingsblad)

ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Nummer van het verzoek om een onderzoek naar de stand van de techniek
NL 2011295

A. CLASSIFICATIE VAN HET ONDERWERP
INV. G06F19/00
ADD.

Volgens de Internationale Classificatie van octrooien (IPC) of zowel volgens de nationale classificatie als volgens de IPC.

B. ONDERZOCHTE GEBIEDEN VAN DE TECHNIEK

Onderzochte miminum documentatie (classificatie gevolgd door classificatiesymbolen)
G06F

Onderzochte andere documentatie dan de mimimum documentatie, voor dergelijke documenten, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen

Tijdens het onderzoek geraadpleegde elektronische gegevensbestanden (naam van de gegevensbestanden en, waar uitvoerbaar, gebruikte trefwoorden)
EPO-Internal

C. VAN BELANG GEACHTE DOCUMENTEN

Categorie °	Geciteerde documenten, eventueel met aanduiding van speciaal van belang zijnde passages	Van belang voor conclusie nr.
X Y	US 2005/086072 A1 (FOX CHARLES S JR [US] ET AL) 21 april 2005 (2005-04-21) * het gehele document *	1-8, 21-27, 38,39 18-20, 35-37

X	DE 101 21 819 A1 (ROSNER WOLFGANG [DE]) 21 november 2002 (2002-11-21) * alinea [0069] - alinea [0084] * * alinea [0089] - alinea [0101] * * alinea [0118] - alinea [0126] *	1-8, 21-27, 38,39

Y A	US 2007/293740 A1 (BARDY GUST H [US]) 20 december 2007 (2007-12-20) * het gehele document *	18-20, 35-37 1,21,38, 39

	-/--	

[X] Verdere documenten worden vermeld in het vervolg van vak C.

[X] Leden van dezelfde octrooifamilie zijn vermeld in een bijlage

° Speciale categorieën van aangehaalde documenten

"A" niet tot de categorie X of Y behorende literatuur die de stand van de techniek beschrijft

"D" in de octrooiaanvrage vermeld

"E" eerdere octrooi(aanvrage), gepubliceerd op of na de indieningsdatum, waarin dezelfde uitvinding wordt beschreven

"L" om andere redenen vermelde literatuur

"O" niet-schriftelijke stand van de techniek

"P" tussen de voorrangsdatum en de indieningsdatum gepubliceerde literatuur

"T" na de indieningsdatum of de voorrangsdatum gepubliceerde literatuur die niet bezwarend is voor de octrooiaanvrage, maar wordt vermeld ter verheldering van de theorie of het principe dat ten grondslag ligt aan de uitvinding

"X" de conclusie wordt als niet nieuw of niet inventief beschouwd ten opzichte van deze literatuur

"Y" de conclusie wordt als niet inventief beschouwd ten opzichte van de combinatie van deze literatuur met andere geciteerde literatuur van dezelfde categorie, waarbij de combinatie voor de vakman voor de hand liggend wordt geacht

"&" lid van dezelfde octrooifamilie of overeenkomstige octrooipublicatie

Datum waarop het onderzoek naar de stand van de techniek van internationaal type werd voltooid	Verzenddatum van het rapport van het onderzoek naar de stand van de techniek van internationaal type
9 mei 2014	
Naam en adres van de instantie European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	**De bevoegde ambtenaar** Abbing, Ralf

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ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Nummer van het verzoek om een onderzoek naar de stand van de techniek
NL 2011295

C.(Vervolg). VAN BELANG GEACHTE DOCUMENTEN

Categorie °	Geciteerde documenten, eventueel met aanduiding van speciaal van belang zijnde passages	Van belang voor conclusie nr.
A	WO 2008/134755 A1 (GEM BIOSYSTEMS LLC [US]; GERTNER MICHAEL [US]) 6 november 2008 (2008-11-06) * samenvatting * * alinea [0008] - alinea [0097] * -----	9-20, 28-37
A	US 2010/071044 A1 (KHAN TAUSSIF [US]) 18 maart 2010 (2010-03-18) * het gehele document * -----	1-3,21, 22,38,39
A	SHABETAI R ET AL: "The pericardium and cardiac function", PROGRESS IN CARDIOVASCULAR DISEASES, SAUNDERS, PHILADELPHIA, PA, US, deel 22, nr. 2, 1 september 1979 (1979-09-01), bladzijden 107-134, XP026324533, ISSN: 0033-0620, DOI: 10.1016/0033-0620(79)90017-3 [gevonden op 1979-09-01] * het gehele document * -----	9-17, 28-34

1

ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Informatie over leden van dezelfde octrooifamilie

Nummer van het verzoek om een onderzoek naar de stand van de techniek
NL 2011295

In het rapport genoemd octrooigeschrift	Datum van publicatie	Overeenkomend(e) geschrift(en)	Datum van publicatie
US 2005086072 A1	21-04-2005	GEEN	
DE 10121819 A1	21-11-2002	GEEN	
US 2007293740 A1	20-12-2007	US 2004147981 A1	29-07-2004
		US 2007027723 A1	01-02-2007
		US 2007100667 A1	03-05-2007
		US 2007293740 A1	20-12-2007
		US 2014039327 A1	06-02-2014
		US 2014121545 A1	01-05-2014
WO 2008134755 A1	06-11-2008	US 2008275294 A1	06-11-2008
		US 2008275295 A1	06-11-2008
		WO 2008134755 A1	06-11-2008
US 2010071044 A1	18-03-2010	GEEN	

WRITTEN OPINION

File No.	Filing date *(day/month/year)*	Priority date *(day/month/year)*	Application No.
SN60811	12.08.2013		NL2011295

International Patent Classification (IPC)
INV. G06F19/00

Applicant
Global Factories Total Engineering and Manufacturing B.V.

This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the application
- ☒ Box No. VIII Certain observations on the application

	Examiner
	Abbing, Ralf

Application number

WRITTEN OPINION

NL2011295

Box No. I Basis of this opinion

1. This opinion has been established on the basis of the latest set of claims filed before the start of the search.

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ on paper

   ☐ in electronic form

   c. time of filing/furnishing:

   ☐ contained in the application as filed.

   ☐ filed together with the application in electronic form.

   ☐ furnished subsequently for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. V Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty	Yes:	Claims	9-20, 28-37
	No:	Claims	1-8, 21-27, 38, 39
Inventive step	Yes:	Claims	9-17, 28-34
	No:	Claims	1-8, 18-27, 35-39
Industrial applicability	Yes:	Claims	1-39
	No:	Claims	

2. Citations and explanations

see separate sheet

WRITTEN OPINION

Box No. VIII Certain observations on the application

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1	US 2005/086072 A1 (FOX CHARLES S JR [US] ET AL) 21 april 2005
D2	DE 101 21 819 A1 (ROSNER WOLFGANG [DE]) 21 november 2002
D3	US 2007/293740 A1 (BARDY GUST H [US]) 20 december 2007
D4	WO 2008/134755 A1 (GEM BIOSYSTEMS LLC [US]; GERTNER MICHAEL [US]) 6 november 2008
D5	SHABETAI R ET AL: "The pericardium and cardiac function", PROGRESS IN CARDIOVASCULAR DISEASES, SAUNDERS, PHILADELPHIA, PA, US, deel 22, nr. 2, 1 september 1979 (1979-09-01), bladzijden 107-134, XP026324533, ISSN: 0033-0620, DOI: 10.1016/0033-0620(79)90017-3

1 Independent Claims

1.1 Document D1 discloses a system for managing the condition of a plurality of patients (D1, [0009]), comprising the following features:

- a plurality of patient labels (D1, figure 1, reference 4: "*patient identification device*"), each patient label comprising a unique patient code to identify a patient (D1, [0009]: "*a patient machine-readable identifier*" and [0011]: "*... a database including patient data and a patient identifier for identifying a patient.*");
- a plurality of medical staff labels (D1, figure 1, reference 12: "*caregiver idetification device*"), each medical staff label comprising a unique medical staff code to identify a medical staff member (D1, [0027]: "*A caregiver identification device 12 may identify a caregiver 10.*");
- a patient management system to register the mapping of a medical staff code to a patient code for medical staff that is assigned to the patient and to manage and process the patient condition data of each patient (D1, [0030], [0036]);
- a user terminal comprising a label reader (D1, [0039]), which is adapted to:
  - read the medical staff code of the medical staff label (D1, [0039]);

- read the patient code of the patient label (D1, [0039]);

- whereby the patient amnagement system is adapted to:
  - check whether the medical staff code is registered to the patient code (D1, 0039]); and, if this is the case,
  - allow access, via the user terminal, to the patient condition data for the patient concerned in the patient managment system (D1, [0040])

The subject-matter of claim 1 is thus not new over the direct disclosure of document D1.

1.2 The subject-matter of claim 21 is technically corresponding in method terms to the subject-matter of claim 1, and the novelty objection brought forward against claim 1 is therefore, *mutatis mutandis*, also valid for claim 21.

The subject-matter of claims 21 is thus not new over the direct disclosure of D1 either.

1.3 The subject-matter of claim 38 is technically corresponding in terms of a user terminal to be used in a system according to the subject-matter of claim 1, and the novelty objection brought forward against claim 1 is therefore, *mutatis mutandis*, also valid for claim 38.

The subject-matter of claims 38 is thus not new over the direct disclosure of D1 either.

1.4 The subject-matter of claim 39 is technically corresponding to claim 1 in terms of a computer program comprising computer executable instructions implemented in a computer system. The novelty objection brought forward against claim 1 is therefore, *mutatis mutandis*, also valid for claim 39.

The subject-matter of claims 39 is thus not new over the direct disclosure of D1 either.

1.5 The subject-matter of independent claims 1, 21, 38 and 39 is also not new over the direct disclosure of document D2, see abstract and paragraphs [0069] - [0084], [0089] - [0101] and [0118] - [0126].

2 Dependent Claims

2.1 Document D1 also directly discloses the additional features of claims 2 - 8 and 22 - 28, i.e. the use of RFID-type labels (D1, [0036]), the manual input of data (D1, [0032]), the connection to further sensor equipment for measuring patient data (D1, [0027], [0042], [0052], [0054] and [0056]), a user interface to display (critical) patient data (D1, [0012], [0040], [0061], [0082], [0085] and figure 17

and to notify the medical staff of a critical (alarm) situation (D1, [0040], [0042]).

The subject-matter of claims 2 - 8 and 22 - 28 is thus also not new over the disclosure of document D1.

2.2 Document D1 does not disclose the additional features of claims 18 - 20 and 35 - 37, related to the generation of an "early warning trend score" based on certain medical parameters. However, such features are well known in the state of the art, see e.g. document D3, abstract, figures 7 - 11 and paragraphs [0012] - [0015], [0035] and [0044] - [0046].

It would be obvious to implement the corresponding features of the medical system disclosed in D3 in the system of D1 in order to extend the intended functionality of the medical system of D1 and to arrive at the subject-matter of claims 18 - 20 and 35 - 37.

Therefore, the subject-matter of claims 18 - 20 and 35 - 37 does not involve an inventive step.

2.3 The subject-matter of dependent claims 9 - 17 and 28 - 34 relates to features to determine the chance of a cardiac tamponade at one of the managed patients.

Even with due regard to the corresponding state of the art, expressed in documents D4 and D5, the addition of such features to the systems and methods disclosed in D1 or D2 would not be obvious to the person skilled in the art, as substantial technical and structural amendment would be necessary, which lie beyond the normal exploration and development skills of a person skilled in the art of patient management systems.

Hence, the subject-matter of claims 9 - 17 and 28 - 34 is new and comprises an inventive step.

3 **Re Item VIII**

Certain observations on the application

3.1 The subject-matter of claims 8 and 27 is technically unclear, as the claim defines the transmission of an access code for the user terminal, which , however, has to be present already before as otherwise the subject-matter of claims 7, 26, 1 and/or 21 would not have been technically possible. Claims 1 and 21 both already comprise the feature of accessing the user terminal.