(54) Title: SYSTEM AND METHOD FOR MONITORING THE HEART FUNCTION OF A PATIENT IN A HOME ENVIRONMENT

(57) Abstract: In order to provide a technique for reliably detecting atrial fibrillation in a home environment, a system (1) for monitoring the heart function of a patient (7) is suggested, the system (1) comprising an electrocardiographic device (2) adapted to measure the electrical activity of the patient's heart, an analyzing device (17) adapted to analyze said measuring results regarding the occurrence of an atrial fibrillation, and a notifying device (18) adapted to notify the patient of the analyzing results.
GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT,
RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA,
GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— with international search report
— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.
The present invention relates to a system and method for monitoring the heart function of a patient in a home environment. Furthermore the present invention relates to a computer program for monitoring the heart function of a patient in a home monitoring system comprising a computer.

There are different types of fibrillation. Ventricular fibrillation (VF) is the most commonly identified arrhythmia. This arrhythmia is a severe derangement of the heartbeat that usually ends in death within minutes unless corrective measures are promptly taken. A large number of systems for monitoring ventricular fibrillation are known from the prior art. Because permanent monitoring of the patient’s heart is needed, these systems are mostly realized in form of an implant.

Atrial fibrillation (AF) is an arrhythmia characterized by the uncoordinated contraction of the heart’s atrium. A major risk of AF is stroke caused by blood clots that form in the heart and are pumped into the brain, eventually blocking an artery. The disease is often undetected by the patient since up to 70% of all AF episodes come without symptoms. The diagnosis of AF is mainly based on electrocardiographic monitoring (ECG) showing typical changes like irregularity and missing P-waves. The therapy of AF can be coarsely divided into two strategies: re-establishing the physiological rhythm (rhythm control) or ensuring an adequate and regular ventricular rate without termination of AF (rate control). Depending on therapy and risk factors, the patients must take anti-arrhythmic drugs to maintain the sinus rhythm and anticoagulation drugs for stroke prevention on a continuous basis. The drugs for treatment of AF and prevention of stroke can have severe and even fatal side effects like arrhythmia and major hemorrhage. Only every three to six months a physician reassesses the patient’s condition and adjusts treatment and medication.
Due to the asymptomatic nature of most AF episodes and the long intervals between examinations, the current treatment of AF does not consider short-term changes of the patient's rhythm. Therefore, while in sinus rhythm, patients frequently unnecessarily take anti-arrhythmic and anti-coagulation drugs with the burden of possible severe side effects. On the other hand, relapses remain undetected over extended periods of time, leaving the patient without protection against stroke. In addition, the termination of AF becomes more difficult the longer the AF episode persists.

It is an object of the present invention to provide a technique for reliably detecting AF in a home environment.

This object is achieved according to the invention by a system for monitoring the heart function of a patient in a home environment, the system comprising an electrocardiographic device adapted to measure the electrical activity of the patient's heart, an analyzing device adapted to analyze said measuring results regarding the occurrence of an atrial fibrillation, and a notifying device adapted to notify the patient of the analyzing results.

The object of the present invention is also achieved by a method of monitoring the heart function of a patient in a home environment, the method comprising the steps of measuring the electrical activity of the patient's heart using an electrocardiographic method, analyzing the measuring results regarding the occurrence of an atrial fibrillation, and notifying the patient of the analyzing results.

The object of the present invention is also achieved by a computer program for monitoring the heart function of a patient in a home monitoring system comprising a computer, the computer program comprising computer instructions for analyzing measuring results regarding the occurrence of an atrial fibrillation, said measuring results being obtained prior to the analyzing step by measuring the electrical activity of the patient's heart using an electrocardiographic method, and computer instructions for notifying the patient about the analyzing results, when the computer program is executed in a computer. The technical effects necessary according to the invention can thus be realized on the basis of the instructions of the computer program in accordance with the invention. Such a computer program can be stored on a carrier
such as a CD-ROM or it can be available over the internet or another computer network. Prior to executing the computer program, it is loaded into the computer by reading the computer program from the carrier, for example by means of a CD-ROM player, or from the internet, and storing it in the memory of the computer. The computer includes inter alia a central processor unit (CPU), a bus system, memory means, e.g. RAM or ROM etc., storage means, e.g. floppy disk or hard disk units etc., and input/output units. Alternatively, the inventive method could be implemented in hardware, e.g. using one or more integrated circuits.

A core idea of the invention is to enable AF patients to monitor themselves daily at home. The patient does three to ten minutes of ECG recording every day with an ECG sensing garment. The system automatically analyses the ECG and notifies the patient whether or not AF is present. The main advantages of the invention are: early detection of asymptomatic AF episodes, reduced risk of stroke, reduced hospital stays due to fast reaction to AF onset, and decelerated progression of AF due to fast termination of AF episodes.

These and other aspects of the invention will be further elaborated on the basis of the following embodiments which are defined in the dependent claims.

According to a preferred embodiment of the invention, the notifying device is adapted to forward a treatment recommendation to the patient, in particular a treatment recommendation including a medication adjustment. In other words, the invention enables the patients to adjust their medication according to the feedback of the system. If a new onset of AF is detected the patient will receive a notification from the system, advising him to start or change medication in order to re-establish sinus rhythm and to prevent stroke. When the system acknowledges the termination of the AF episode the patient will receive a notification, advising him to stop or reduce the medication again. The main advantage of this embodiment is an improved quality of life due to reduced medication.

In contrast to VF monitoring, the interval between two measurements can be much longer, since the time to react usually is 24 to 48 hours. Therefore, according to another preferred embodiment of the invention, the electrocardiographic device is adapted to perform the measuring step at regular intervals, in particular once...
or twice a day. If the electrocardiographic device is adapted to perform the measurement automatically, a completely unsupervised cardiac monitoring system for AF patients is provided.

According to yet another preferred embodiment of the invention, a number of system components, in particular a number of components of the electrocardiographic device, are integrated into a patient-worn textile carrier or garment. The use of such a textile carrier or garment, in particular in form of standard clothing, e.g. underwear or the like, combines permanent monitoring on a daily basis and easy system handling.

These and other aspects of the invention will be described in detail hereinafter, by way of example, with reference to the following embodiments and the accompanying drawings; in which:

Fig. 1 shows a schematic block diagram of a system according to a first embodiment,

Fig. 2 shows a schematic block diagram of a system according to a second embodiment, and

Fig. 3 shows a schematic and simplified view of an ECG garment as worn by a patient.

In Fig. 1, an AF Management system 1 for home use is illustrated. The system 1 shows a centralized architecture of system components. The system 1 comprises an ECG garment 2 adapted to measure the electrical activity of a patient’s heart. ECG electrodes 3, cables 4, amplifier and digital electronics 5 are incorporated into a textile carrier 6, thus simplifying the daily ECG measurement, see Fig. 3. As a textile carrier 6 preferably a cardiac belt is used, which is adapted to be mounted around the chest of the patient 6. With the ECG electrodes 3, different tracings of the heart's electrical activity can be made and recorded. Even a single channel ECG device provides sufficient data for detecting AF.
The patient 7 controls the measurement procedure from a patient station 11. The patient station 11 is located in the vicinity of the patient 7, but separate from the ECG garment 2, and is adapted to communicate with the ECG garment 2 using a, preferably, short range wireless communication link 12, preferably employing the Bluetooth standard. For this purpose, ECG garment 2 and patient station 11 comprise corresponding transceiver units 13. The patient station 11 is adapted to read the ECG data from the ECG garment 2 after the ECG data has successfully passed a quality check performed by the ECG garment 2. The ECG data is then transmitted from the patient station 11 to a central server 14, preferably using a fixed or mobile telephone line or another communication link 15, e.g. GSM, satellite link, POTS or LAN systems etc. For this purpose, patient station 11 and central server 14 comprise corresponding transceiver units 16.

The central server 14 is adapted to handle the incoming calls from all patients, store the data in a patient database and run an algorithm that checks the ECG data for the presence of AF. The central server 14 comprises a processing unit 17 adapted to perform all tasks of calculating and computing the measured data as well as determining the presence of AF and assessing results. For this purpose, the processing unit 17 itself comprises functional modules, which may be implemented in form of hardware, software or in form of a combination of both. The complete process of data processing, detecting AF, assessing the analyzing results as well as generating a treatment recommendation is performed preferably by means of computer software comprising computer instructions adapted for carrying out the steps of the inventive method, when the software is executed in the processing unit 17 of the central server 14.

By means of the processing unit 17 the ECG measuring data is analysed. On the ECG three major waves of electric signals appear. Each one shows a different part of the heartbeat. The first wave is called the P wave. It records the electrical activity of the atria. The second and largest wave, the QRS wave, records the electrical activity of the ventricles. The third wave is the T wave. It records the heart's return to the resting state. From the shape and size of the waves as well as from the time between waves and the rate and regularity of beating, information about the heart rhythm can be
extracted. The analyzing algorithm as implemented in the processing unit 17 determines irregularities of the heart rhythm. For this purpose, the QRS complex is located and an analysis of the RR intervals is performed. Subsequently, the other segments (P-wave, T-wave) are located. Based on this segmentation, a statistical analysis of the ECG data is performed, leading to information about the regularity of the RR intervals.

Additionally, the presence of a P-wave can be used as an additional criterion for the final classification.

The central server 14 is further adapted to send the analyzing result back to the patient station 11. In order to inform the patient 7, the patient station 11 comprises a user interface 18 adapted to notify the patient 7 of the analyzing results including the treatment recommendation. For this purpose, the user interface 18 comprises a monitor to display a text message or graphical message to the patient. Alternatively, the analyzing results can be communicated to the patient via audio signals, e.g. using a speaker of the user interface 18, or via a printout, e.g. using a local printing device.

Physicians have access to the system via a physician station 21. The physician station 21 comprises a user interface 22 adapted to the specific needs of the physician. The user interface 22 of the physician station 21 comprises, inter alia, a data viewer. The physician station 21 is adapted to set up the system 1 once for every patient 7, and to control data quality and parameter settings for the AF detection algorithm. For that purpose, the physician station 21 is adapted to communicate with the ECG garment 2 over a short-range wireless link 12, preferably using the Bluetooth standard. For this purpose, physician station 21 comprises a corresponding transceiver unit 13. The physician can check the online data stream coming from the ECG garment 2 and being displayed at the physician station 21.

In order to set the parameters of the AF detection algorithms individually for each patient, the physician station 21 is adapted in a way that the physician can access a patient database 23 on the central server 14 via a wide area network (WAN) or another communication link 24. For this purpose, physician station 21 and central server 14 comprise corresponding transceiver units 25.

The physician station 21 is further adapted in a way that the physician
can use the same access to edit patient data, review recorded data and, if necessary, override the automatic ECG analysis result. The central server 14 is preferably adapted to inform the physician about all AF detection and unclear cases prompting for a manual check of that specific data.

In another embodiment (not shown), the patient station functionality, in particular the data transfer functionality and the user interface functionality, is included into the ECG garment 2 and the ECG garment 2 is adapted to communicate directly with the central server 14 and/or the physician station 21.

In Fig. 2, an AF Management system 1' for home use is illustrated. The system Y shows a decentralized architecture of system components. In the decentralized architecture most of the system intelligence is located in the ECG garment 2' and thus at the patient's home. No data is transmitted to a central server. In addition to the measurement means, the processing unit 17 implementing the AF detection algorithm and the patient database 23 are also included into the ECG garment 2'. In other words, the ECG garment 2' comprises the processing unit 17, which is adapted to perform all data processing tasks as described above. The user interface 18 for the patient is designed as an extra device implemented in the patient station 11. In another embodiment (not shown), the user interface functionality is also included into the ECG garment. In this case, besides the ECG garment no separate components are needed.

Again, the physician station 21 enables the physician to set up multiple systems 2', each for a specific patient 7, by checking the ECG quality and adjusting parameters of the detection algorithm. The physician station 21 is also used to review the data stored by the ECG garment 2'. In the decentralized architecture, the physician can access the patient database 23 implemented in the ECG garment via a wireless communication link 12, preferably using the Bluetooth standard, and the physician station 21 and the ECG garment 2' comprise a corresponding transceiver unit 13.

Irrespective of the kind of system architecture, in case of detection of an AF episode the system 1, 1' notifies the patient 7 of the analysing result, thus enabling the patient 7 to start stroke prevention and AF treatment. Preferably only data from positive AF detections and AF-like events are stored in the patient database 23 for later
review by a physician.

In all embodiments, the ECG garment 2, 2' is preferably adapted to perform ECG acquisition and processing automatically, once the patient 7 has put on the ECG garment 2, 2'.

It will be evident to those skilled in the art that the invention is not limited to the details of the foregoing illustrative embodiments, and that the present invention may be embodied in other specific forms without departing from the spirit or essential attributes thereof. The present embodiments are therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein. It will furthermore be evident that the word "comprising" does not exclude other elements or steps, that the words "a" or "an" do not exclude a plurality, and that a single element, such as a computer system or another unit, may fulfil the functions of several means recited in the claims. Any reference signs in the claims shall not be construed as limiting the claim concerned.
<table>
<thead>
<tr>
<th>REFERENCE NUMERALS</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>system</td>
</tr>
<tr>
<td>2</td>
<td>ECG garment</td>
</tr>
<tr>
<td>3</td>
<td>ECG electrode</td>
</tr>
<tr>
<td>4</td>
<td>cable</td>
</tr>
<tr>
<td>5</td>
<td>electronics</td>
</tr>
<tr>
<td>6</td>
<td>textile carrier</td>
</tr>
<tr>
<td>7</td>
<td>patient</td>
</tr>
<tr>
<td>8</td>
<td>(free)</td>
</tr>
<tr>
<td>9</td>
<td>(free)</td>
</tr>
<tr>
<td>10</td>
<td>patient station</td>
</tr>
<tr>
<td>11</td>
<td>(free)</td>
</tr>
<tr>
<td>12</td>
<td>communication link</td>
</tr>
<tr>
<td>13</td>
<td>transceiver unit</td>
</tr>
<tr>
<td>14</td>
<td>central server</td>
</tr>
<tr>
<td>15</td>
<td>communication link</td>
</tr>
<tr>
<td>16</td>
<td>transceiver unit</td>
</tr>
<tr>
<td>17</td>
<td>processing unit</td>
</tr>
<tr>
<td>18</td>
<td>user interface</td>
</tr>
<tr>
<td>19</td>
<td>(free)</td>
</tr>
<tr>
<td>20</td>
<td>(free)</td>
</tr>
<tr>
<td>21</td>
<td>physician station</td>
</tr>
<tr>
<td>22</td>
<td>user interface</td>
</tr>
<tr>
<td>23</td>
<td>patient database</td>
</tr>
<tr>
<td>24</td>
<td>communication link</td>
</tr>
<tr>
<td>25</td>
<td>transceiver unit</td>
</tr>
</tbody>
</table>
CLAIMS:

1. A system (1) for monitoring the heart function of a patient (7) in a home environment, the system (1) comprising
   - an electrocardiographic device (2) adapted to measure the electrical activity of the patient's heart,
   - an analyzing device (17) adapted to analyze said measuring results regarding the occurrence of an atrial fibrillation, and
   - a notifying device (18) adapted to notify the patient (7) of the analyzing results.

2. The system (1) as claimed in claim 1, characterized in that the notifying device (18) is adapted to forward a treatment recommendation to the patient (7), in particular a treatment recommendation including a medication adjustment.

3. The system (1) as claimed in claim 1, characterized in that the electrocardiographic device (2) is adapted to perform the measuring step automatically at regular intervals, in particular once or twice a day.

4. The system (1) as claimed in claim 1, characterized in that a number of system components, in particular a number of components of the electrocardiographic device (2), are integrated into a patient-worn textile carrier or garment (6).

5. A method of monitoring the heart function of a patient (7) in a home environment, the method comprising the steps of:
   - measuring the electrical activity of the patient's heart using an electrocardiographic method,
   - analyzing the measuring results regarding the occurrence of an atrial
fibrillation, and
- notifying the patient (7) of the analyzing results.

6. A computer program for monitoring the heart function of a patient (7) in a home monitoring system (1) comprising a computer (17), the computer program comprising
- computer instructions for analyzing measuring results regarding the occurrence of an atrial fibrillation, said measuring results being obtained prior to the analyzing step by measuring the electrical activity of the patient's heart using an electrocardiographic method, and
- computer instructions for notifying the patient (7) of the analyzing results,
when the computer program is executed in a computer (17).
**INTERNATIONAL SEARCH REPORT**

**International application No**
PCT/IB2006/053362

---

**A. CLASSIFICATION OF SUBJECT MATTER**

INV. A61B5/0245

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

---

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

A61B

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

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

EPO-Internal

---

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication where appropriate, of the relevant passages</th>
<th>Relevant to claim</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>US 5 348 008 A (BORNN ROBERT [US] ET AL) 20 September 1994 (1994-09-20) columns 7-10,41; figure 1</td>
<td>1-4,6</td>
</tr>
<tr>
<td>X</td>
<td>WO 02/30279 A (MAGILL ALAN REMY [GB]) 18 April 2002 (2002-04-18) the whole document</td>
<td>1</td>
</tr>
</tbody>
</table>

---

| X | See patent family annex |

Special categories of cited documents

- "X" document defining the general state of the art which is not considered to be of particular relevance.
- "E" earlier document but published on or after the international filing date.
- "L" document which may throw doubts on prior claims or which is cited to establish the publication date of another citation or other special reason (as specified).
- "O" document referring to an oral disclosure, use exhibition or other means.
- "P" document published prior to the international filing date but later than the priority date claimed.

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention.
- "X" document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone.
- "Y" document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "S" document member of the same patent family.

---

Date of the actual completion of the international search: 15 February 2007

Date of mailing of the international search report: 26/02/2007

Name and mailing address of the ISA/
European Patent Office, P B 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel (+31-70) 340-2040, Tx 31 651 epc nl
Fax (+31-70) 340-3016

Authorized officer:
Schoeffmann, Herbert

Form: PCT/ASW210 (second sheet) (April 2005)
## Box II  Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. **Claims Nos 5**
   - Because they relate to subject matter not required to be searched by this Authority, namely:
     - Rule 39.1(iv) PCT - Diagnostic method practised on the human or animal body

2. **Claims Nos**
   - Because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out specifically.

3. **Claims Nos**
   - Because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 64(a).

## Box III  Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

1. **As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims**

2. **As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee**

3. **As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos**

4. **No required additional search fees were timely paid by the applicant**
   - Consequently, this International Search Report is restricted to the invention first mentioned in the claims, it is covered by claims Nos.

### Remark on Protest

- [ ] The additional search fees were accompanied by the applicant's protest
- [ ] No protest accompanied the payment of additional search fees

---

Form PCT/ISA/210 (continuation of first sheet (2)) (January 2004)
<table>
<thead>
<tr>
<th>Patent document cited in search report</th>
<th>Publication date</th>
<th>Patent family member(s)</th>
<th>Publication date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>EP 0615424 A1</td>
<td>21-09-1994</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WO 9310706 A1</td>
<td>10-06-1993</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 5353793 A</td>
<td>11-10-1994</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1324692 A1</td>
<td>09-07-2003</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 2003212319 A1</td>
<td>13-11-2003</td>
</tr>
<tr>
<td>US 2004152993</td>
<td>05-08-2004</td>
<td>US 2005027331 A1</td>
<td>03-02-2005</td>
</tr>
</tbody>
</table>