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(54) **HEART STIMULATING DEVICE**

HERZSTIMULATIONSVORRICHTUNG

DISPOSITIF DE STIMULATION CARDIAQUE

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US-B1- 6 473 640

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Description

Field of the invention

[0001] The present invention relates to a heart stimulating device according to the preamble of the independent claim.

[0002] The present invention relates to a new way to measure and quantify the degree of congestive heart failure. The determined congestive heart failure indicator value - alone or together with other metrics - may advantageously be use in assessing the patient's status, titrating drugs and/or evaluating therapy.

Background of the invention

[0003] Approximately 23 million people worldwide are afflicted with congestive heart failure (CHF), and 2 million new cases of CHF are diagnosed each year worldwide. In contrast to other cardiovascular disorders that have actually declined during the past few decades, the incidence of heart failure is one that rises. It is, in fact, the most rapidly growing cardiovascular disorder in the United States.

[0004] Congestive heart failure is a chronic inability of the heart to maintain an adequate output of blood from one or both ventricles of the heart to meet the metabolic demands of the tissues. With a markedly weakened left ventricle or right ventricle or both, the volume of blood presented to the heart is in excess of the heart's capacity to move it along. Consequently, fluid builds up behind the heart. With a weakened left ventricle or right ventricle or both, there is a shift of large volumes of blood from the systemic circulation into the pulmonary (lung) circulation. If the inability to move the volume of blood forward is due to a left heart side problem without the right side falling as well, blood continues to be pumped into the lungs by the normal right heart side, while it is not pumped adequately out of the lungs by the left heart side. As the volume of blood in the lungs increases, the pulmonary vessels enlarge, pulmonary venous congestion develops, and, once the pulmonary capillary pressure rises above a critical point, fluid begins to filter out of the capillaries into the interstitial spaces and alveoli (air sacs in the lungs where exchange of oxygen and carbon dioxide occurs), resulting in pulmonary oedema. Subsequently this can lead to pleural effusion (effusion is the escape of fluid into a part) and abdominal effusion. If the abnormality lies in the right heart side or the pulmonary arteries, limiting the ability to move blood forward, then congestion occurs behind the right heart side (causing pleural effusion and/or build up of fluid in the abdomen).

[0005] Although advances in pharmacology have led to better treatment, 50% of the patients with the most advanced stage of heart failure die within a year. Typically, heart failure patient receive several chronic oral therapies, including diuretics, ACE inhibitors; beta-blockers and inotropic agents.

[0006] A majority of patients are treated with drug therapy, but for patients with advanced CHF, device-based therapy or transplantation are their only alternatives. A large number of patients with advanced CHF have received left ventricular assist devices, and a number of promising technologies, including biventricular pacing and defibrillators, ventricular remodelling, and ventricular assist devices represent exciting, growing markets

[0007] US-6,821,249 relates to a temperature monitoring of congestive heart failure patients as an indicator of worsening condition by using the analysis of the speed and pattern of temperature change in a way that is individualized toward patient's health condition. Body sites to measure body temperature can be characterized as "core" or "peripheral" sites, meaning deep inside the body or near the surface, but even sites classified in that manner do not necessarily behave in the same way. Temperature sensors may be any temperature sensor known that is practically applicable, and include thermocouples, resistance temperature detectors or thermistors, thermosensitive chromophores, thermosensitive liquid crystals, infrared detectors and ultrasound detectors.

[0008] In US-6,821,249 is also discussed the influence of the patient's activity that is suitably monitored by an accelerometer or a vibration sensor, that provides a signal that upon conversion to digital form is usable by a microprocessor for an adjustment to a temperature attribute or to the sensitivity of detection of that attribute. The same concepts for adjusting a temperature reading or sensitivity of a cut-off point apply as for medications, including use of a learning algorithm to personalize the effect of temperature change from different levels of activity.

[0009] At the onset of physical activity, the amount of blood reaching heart from the outer extremities is increased. As the temperature of the blood in the outer extremities is lower, there is a dip in the temperature of the blood in the heart. After the dip, the temperature rises with time to a level above the initial as a cause of the activity. The maximal increase in temperature as a result of activity is approximately 1.5 °C.

[0010] The temperature dip at the onset of activity is patient dependent, but especially pronounced in CHF patients. This is e.g. described in "Cardiac Pacing and ICDs", 3rd edition, Kenneth A. Ellenbogen & Mark A. Wood, page 110.

[0011] US-4,719,920 relates to an exercise-responsive rate-adaptive cardiac pacemaker adapted to distinguish between physiologically determined changes of the patient's blood temperature under conditions of exercise and non-exercise. The pacemaker is also capable of recognizing the blood temperature dip which is characteristic of the commencement of exercise.

[0012] The object of the present invention is to achieve a heart stimulating device having an improved capability of monitoring CHF and in particular temporal changes of the degree of CHF.

Summary of the invention

[0013] The above-mentioned object is achieved by the present invention according to the independent claim.

[0014] Preferred embodiments are set forth in the dependent claims.

[0015] Thus, the present invention is based upon the correlation of the activity level (e.g. measured by using an activity sensor of a heart stimulating device) and the initial decrease in temperature, "temperature dip", measured by a temperature sensor of a ventricular lead, and by using this correlation to determine (calculate) a CHF indicator value indicating the degree of CHF.

Short description of the appended drawings

[0016]

Figure 1 schematic block diagram illustrating a preferred embodiment of the present invention.
Figure 2 shows a diagram illustrating the correlation between the magnitude of the dip in temperature and level of activity.
Figure 3 shows a flow chart illustrating a preferred embodiment of the present invention.

Detailed description of preferred embodiments of the invention

[0017] Preferred embodiments of the present invention will now be described in detail with references to the figures. Figure 1 is a schematic block diagram illustrating a preferred embodiment of the present invention. In figure 1 is illustrated an implantable heart stimulating device for indicating congestive heart failure (CHF) comprising a processing means 2, an activity sensor means 6 for generating an activity signal in relation to patient activity, and a blood temperature sensing means 10 adapted to measure blood temperature inside the heart and for generating a temperature signal in dependence of the measured temperature. The activity signal and temperature signal are applied to the processing means that is provided with an - identifying means 4 adapted to identify a characteristic dip in the temperature signal related to a predetermined increase of the activity signal and also to measure the magnitude of the dip. The processing means then determines a CHF indicator value indicating the degree of CHF based upon the magnitude of the temperature signal dip, wherein the indicator value is determined in relation to previous indicator values. Preferably, the heart stimulating device comprises an electrode lead 8 adapted to apply stimulation pulses to the heart tissue and provided with the blood temperature sensing means.

[0018] Examples of suitable temperature sensing means may be found in the above-cited US-6,821,249 and in US-5,336,244 and US-5,564,434 that illustrate typical examples of a temperature sensor mounted on a ventricular lead which is applicable when realizing the present invention.

[0019] The activity sensing means is preferably housed within the casing of the stimulating device. Preferably, the activity sensing means comprises a known form of miniature piezoelectric crystal in the form of a weighted cantilever arm to detect movement of the patient. A suitable form of such an element is disclosed, for example, in US-4,140,132, but it will be understood that other known types of activity or motion sensors may alternatively be used. When the patient moves, the weighted cantilever arm undergoes vibration and the vibrations are converted to electrical signals by the piezoelectric crystal.

[0020] The patient' intrinsic P-wave rate, or the rate and/or volume of respiration as measured by impedance may also be used as a measure of activity.

[0021] Preferably, a linear relationship between the activity and temperature signals is determined, and that the linear relationship is used to determine the CHF indicator-value. Figure 2 shows a diagram illustrating the correlation (a linear relationship) between the magnitude of the dip in temperature and level of activity. A number of measure points (indicated with "x") of the magnitude of the temperature dip and corresponding activity level are marked in the diagram and a line having the slope k is determined by using a suitable mathematical method. For example the N last observations (N may be any number larger than 5) may be used to determine the slope of the curve which then is used as an CHF indicator value. The equation of the line is expressed as:

$$\text{Magnitude of temperature dip} = k * (\text{activity level}) + m,$$

where m is a constant.

[0022] In a preferred embodiment the slope k is used to determine the CHF indicator value such that a higher magnitude of the temperature signal dip in correlation with an increased activity signal, i.e. a larger k (a steeper line) results in an increased CHF indicator value indicating a higher degree of CHF.

[0023] In addition, the CHF indicator value may directly be determined in dependence of the quotient between the magnitude of the temperature signal dip and the activity signal

[0024] According to an alternative embodiment a non-linear model may be used in order to properly fit a curve to the measure points. In such a model e.g. a second order equation may be used.

[0025] The magnitude of the temperature signal dip is related to a normal temperature value bering the base level of the temperature during normal conditions. Typical values of the magnitude of the dip are in the range of 0,12 to 0,25 degree C for non-CHF patients. The base level may be determined in many different ways. In one embodiment the base level is determined as an average temperature value obtained during periods when the activity signal indicates that the activity level is below a threshold indicating low activity. According to another embodiment the base level is permanently set to a fixed value that need not be patient specific.

[0026] With references to figure 1 the processing means includes a storage means where the activity signal and temperature signal are stored and that the determination of a congestive heart failure indicator value indicating the degree of CHF is performed at a later time.

[0027] The heart stimulating device illustrated in figure 1 naturally includes further means, e.g. battery means, communicating means, omitted in the figure for reason of clarity.

[0028] According to a preferred embodiment the determination of the CHF indicator value is performed, e.g. at the time of follow-up, in an external programming means (not shown) outside the patient and in that case the activity and temperature values are transmitted from the implant to the programming means by per se known communication means. Preferably, the programming means is provided with a display means (not shown).

[0029] Figure 3 shows a flow chart illustrating a preferred embodiment of the present invention.

[0030] When the onset of activity is detected, the temperature of the ventricular blood is analyzed. The decrease in temperature compared to a normal value (the magnitude of the dip) is stored together with the corresponding activity level and these pairs of values are then stored and the CHF indicator value is determined.

[0031] As the temperature dip is patient dependent, each patient will act as their own control and the CHF indicator value may be used to track the regression or progression of the CHEF, but may not be used to compare the CHF status of two patients.

[0032] Primarily the heart stimulating device according to the present invention relates to a pacemaker but may also be included in a cardioverter or defibrillator.

[0033] The present invention is not limited to the above-described preferred embodiments. Various alternatives, modifications and equivalents may be used. Therefore, the above embodiments should not be taken as limiting the scope of the invention, which is defined by the appending claims.

Claims

1. Implantable heart stimulating device for indicating congestive heart failure CHF comprising a processing means (2), an activity sensor means (6) for generating an activity signal in relation to patient activity, and a blood temperature sensing means (10) adapted to measure blood temperature inside the heart and for generating a temperature signal in dependence of the measured temperature,
   characterized in that said activity signal and temperature signal are applied to the processing means that is provided with identifying means adapted to identify a characteristic dip in the temperature signal related to a predetermined increase of the activity signal and that said processing means then determines a congestive heart failure indicator value indicating the degree of CHF based upon the magnitude of the temperature signal dip, wherein the indicator value is determined in relation to previous indicator values.

2. Heart stimulating device according to claim 1, wherein the heart stimulator comprises an electrode lead adapted to apply stimulation pulses to the heart tissue and provided with said blood temperature sensing means.

3. Heart stimulating device according to claim 1, wherein a linear relationship between the activity and temperature signals is determined, and that said linear relationship is used to determine the CHF indicator value.

4. Heart stimulating device according to claim 1, wherein a greater magnitude of the temperature signal dip in correlation with an increased activity signal results in an increased CHF indicator value indicating a higher degree of CHF.

5. Heart stimulating device according to claim 1, wherein the CHF indicator value is determined in dependence of the quotient between the magnitude of the temperature signal dip and the activity signal.

6. Heart stimulating device according to claim 1, wherein the magnitude of the temperature signal dip is related to a normal temperature value being the base level of the temperature during normal conditions

7. Heart stimulating device according to claim 1, wherein the processing means includes a storage means (12) where the activity signal and temperature signal are stored and that the determination of the CHF indicator value indicating the degree of CHF is performed at a later time.

8. Heart stimulating device according to claim 7, wherein the determination of the CHF indicator value is performed by the processing means arranged in an external programming means outside the patient.

Patentansprüche

1. Implantierbare Herzstimulationsvorrichtung zum Anzeigen eines kongestiven Herzversagens CHF, enthaltend eine Verarbeitungsvorrichtung (2), eine Aktivitätssensorvorrichtung (6) zum Erzeugen eines Aktivitätssignals in Relation zur Patientenaktivität und eine Bluttemperaturabfühlvorrichtung (10), die ausgelegt ist, die Bluttemperatur innerhalb des Herzens zu messen und zum Erzeugen eines Temperatursignals abhängig von der gemessenen Temperatur, **dadurch gekennzeichnet, dass** das genannte Aktivitätssignal und das Temperatursignal der Verarbeitungsvorrichtung zugeführt werden, die mit einer Identifizierungsvorrichtung ausgestattet ist, welche ausgelegt ist, einen charakteristischen Abfall im Temperatursignal bezogen auf eine vorbestimmte Zunahme des Aktivitätssignals zu identifizieren, und dass die genannte Verarbeitungsvorrichtung dann einen Indikatorwert für ein kongestives Herzversagen bestimmt, der den Grad der CHF auf der Grundlage der Größe des Temperatursignalabfalls anzeigt, wobei der Indikatorwert in Relation zu früheren Indikatorwerten bestimmt wird.

2. Herzstimulationsvorrichtung nach Anspruch 1, bei der der Herzstimulator eine Elektrodenleitung enthält, die ausgelegt ist, dem Herzgewebe Stimulationsimpulse zuzuführen und die mit der genannte Bluttemperaturabfühlvorrichtung ausgestattet ist.

3. Herzstimulationsvorrichtung nach Anspruch 1, bei der eine linear Beziehung zwischen den Aktivitäts- und den Temperatursignalen bestimmt wird und bei der die genannte lineare Beziehung dazu benutzt wird, den CHF-Indikatorwert zu bestimmen.

4. Herzstimulationsvorrichtung nach Anspruch 1, bei der ein größerer Wert des Temperatursignalabfalls in Korrelation mit einem vergrößerten Aktivitätssignal zu einem vergrößerten CHF-Indikatorwert führt, der einen höheren Grad an CHF anzeigt.

5. Herzstimulationsvorrichtung nach Anspruch 1, bei der der CHF-Indikatorwert in Abhängigkeit vom Quotienten zwischen der Größe des Temperatursignalabfalls und des Aktivitätssignals bestimmt wird.

6. Herzstimulationsvorrichtung nach Anspruch 1, bei der die Größe des Temperatursignalabfalls auf einen Normaltemperaturwert bezogen wird, der den Basispegel der Temperatur während normaler Umstände darstellt.

7. Herzstimulationsvorrichtung nach Anspruch 1, bei der die Verarbeitungsvorrichtung eine Speichervorrichtung (12) enthält, in der das Aktivitätssignal und das Temperatursignal gespeichert werden, und bei der die Bestimmung des CHF-Indikatorwertes, der den Grad von CHF anzeigt, zu einem späteren Zeitpunkt ausgeführt wird.

8. Herzstimulationsvorrichtung nach Anspruch 7, bei der die Bestimmung des CHF-Indikatorwertes durch die in einer externen Programmiervorrichtung außerhalb des Patienten angeordnete Verarbeitungsvorrichtung erfolgt.

Revendications

1. Dispositif implantable de stimulation cardiaque pour indiquer une insuffisance cardiaque congestive CHF, comprenant un moyen (2) de traitement, un moyen (6) de détection de l'activité pour produire un signal d'activité en liaison avec une activité d'un patient et un moyen (10) de détection de la température du sang, conçu pour mesurer la

température du sang à l'intérieur du coeur et pour produire un signal de température en fonction de la température mesurée,
caractérisé en ce que le signal d'activité et le signal de température sont appliqués au moyen de traitement qui est muni d'un moyen d'identification, conçu pour identifier un abaissement caractéristique du signal de température relié à une augmentation déterminée à l'avance du signal d'activité et **en ce que** le moyen de traitement détermine ensuite une valeur d'indicateur d'une insuffisance cardiaque congestive indiquant le degré de CHF sur la base de l'amplitude de l'abaissement du signal de température, la valeur de l'indicateur étant déterminée en liaison avec des valeurs précédentes de l'indicateur.

2. Dispositif de stimulation cardiaque suivant la revendication 1, dans lequel le stimulateur cardiaque comprend une dérivation d'électrode conçue pour appliquer des impulsions de stimulation au tissu cardiaque et munie de moyens de détection de la température du sang.

3. Dispositif de stimulation cardiaque suivant la revendication 1, dans lequel une relation linéaire entre les signaux d'activité et de température est déterminée et cette relation linéaire est utilisée pour déterminer la valeur d'indicateur de CHF.

4. Dispositif de stimulation cardiaque suivant la revendication 1, dans lequel une amplitude plus grande de l'abaissement du signal de température en corrélation avec un signal d'activité accrue se traduit par une valeur d'indicateur de CHF accrue indiquant un degré plus grand de CHF.

5. Dispositif de stimulation cardiaque suivant la revendication 1, dans lequel la valeur d'indicateur de CHF est déterminée en fonction du quotient de l'amplitude de l'abaissement du signal de température par le signal d'activité.

6. Dispositif de stimulation cardiaque suivant la revendication 1, dans lequel l'amplitude de l'abaissement du signal de température, est reliée à une valeur normale de la température qui est le niveau de base de la température dans des conditions normales.

7. Dispositif de stimulation cardiaque suivant la revendication 1, dans lequel le moyen de traitement comprend un moyen (12) de mémorisation, dans lequel le signal d'activité et le signal de température sont mémorisés et en ce que la détermination de la valeur de l'indicateur de CHF indiquant le degré de CHF est effectuée à un instant ultérieur.

8. Dispositif de stimulation cardiaque suivant la revendication 7, dans lequel la détermination de la valeur d'indicateur de CHF est effectuée par le moyen de traitement disposé dans des moyens extérieurs de programmation à l'extérieur du patient.

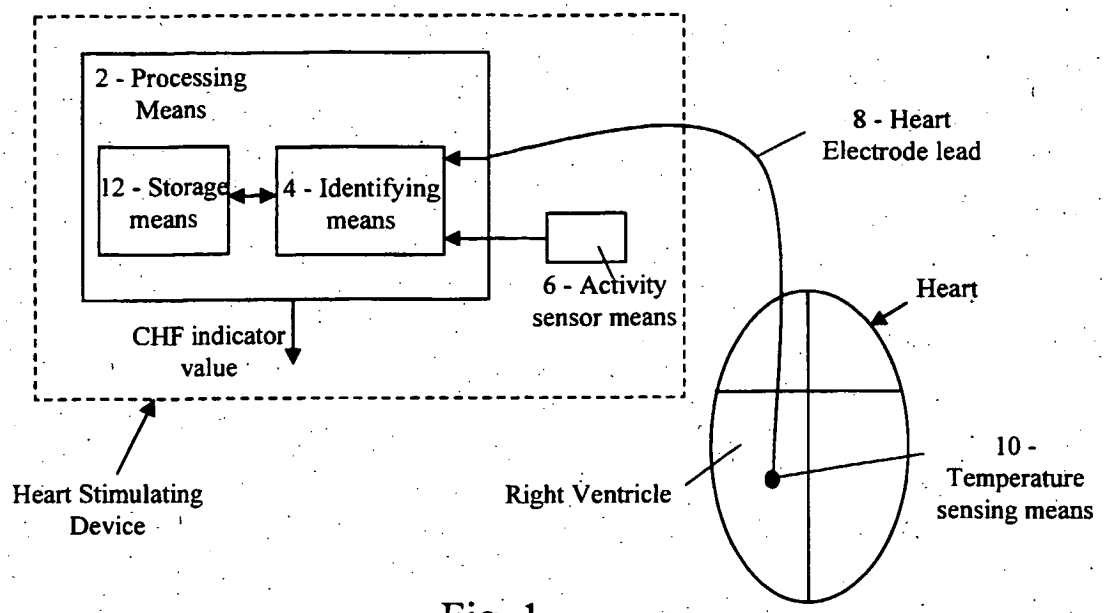
2 - Processing Means
12 - Storage means
4 - Identifying means
6 - Activity sensor means
8 - Heart Electrode lead
Heart
CHF indicator value
Heart Stimulating Device
Right Ventricle
10 - Temperature sensing means

Fig. 1

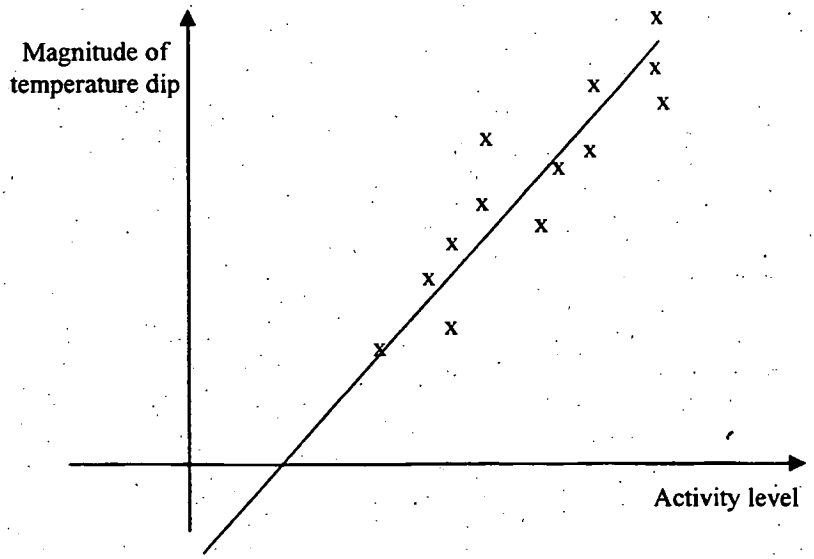
Magnitude of temperature dip
Activity level

Fig. 2

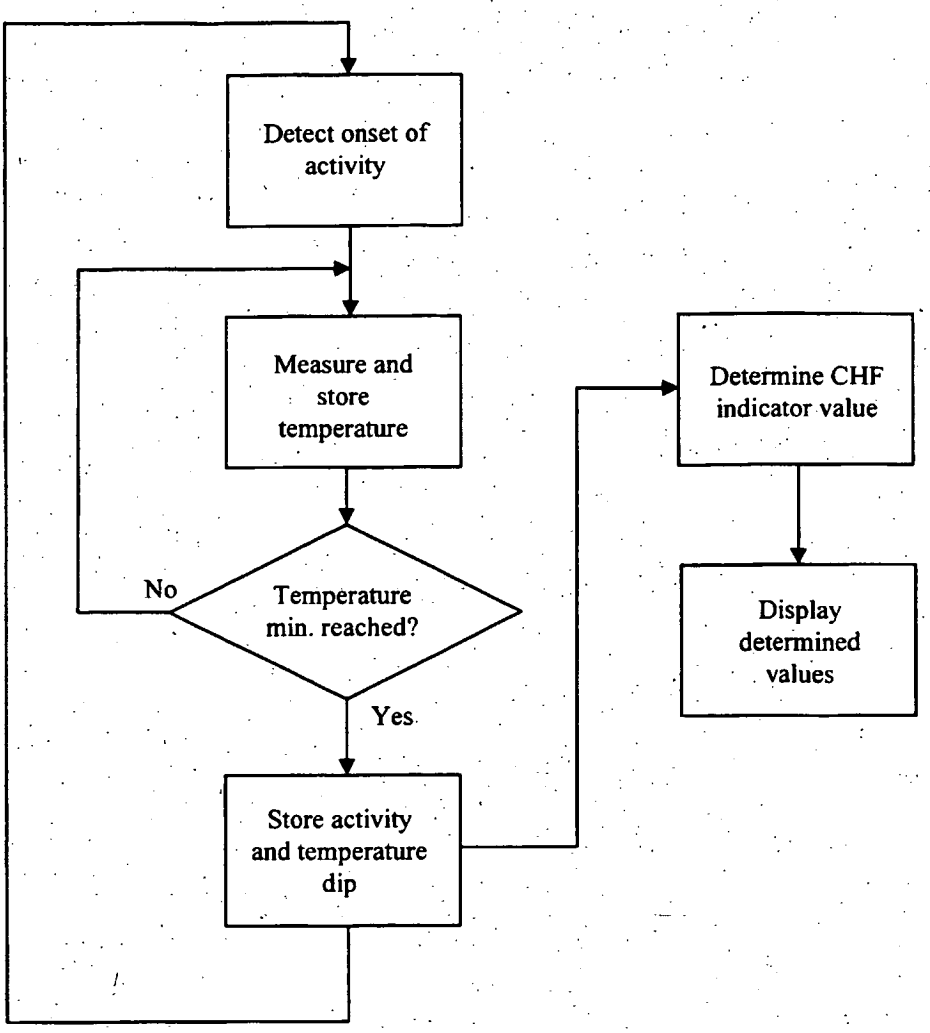
Detect onset of activity
Measure and store temperature
Temperature min. reached?
No
Yes
Store activity and temperature dip
Determine CHF indicator value
Display determined values

Fig. 3

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

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- US 5336244 A **[0018]**
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Non-patent literature cited in the description

- **KENNETH A. ELLENBOGEN ; MARK A. WOOD.** Cardiac Pacing and ICDs. 110 **[0010]**

专利名称(译)	心脏刺激装置		
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当前申请(专利权)人(译)	ST.犹达医疗用品AB		
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摘要(译)

用于指示充血性心力衰竭（CHF）的可植入心脏刺激装置，包括处理装置2，用于产生与患者活动相关的活动信号的活动传感器装置6，以及适于测量心脏内的血液温度的血液温度感测装置10。用于根据测量的温度产生温度信号。活动信号和温度信号被施加到处理装置，该处理装置设有识别装置，该识别装置适于识别与活动信号的预定增加有关的温度信号中的特征下降。然后，处理装置根据温度信号下降的大小确定指示CHF程度的充血性心力衰竭指示值，并且相对于先前的指示值确定指示值。