Abstract: The present invention relates to medical systems and methods for such systems, which systems include an implantable medical device of a patient, a programmer device, and an extracorporeal stress equipment adapted to exert a physiological stress on the patient, for automatically determining settings of a sensor for sensing a physiological parameter of the patient or for automatically determining a pacing setting of the device over a broad range of workloads of the equipment. The ingoing units and/or devices of the medical system, i.e. the implantable medical device of a patient, the programmer device, and the extracorporeal stress equipment, communicate bi-directionally with each other and form a closed loop.
A medical system and a method for determining settings of an implantable device

TECHNICAL FIELD
The present invention generally relates to cardiac pacing systems and, in particular, to methods and medical systems including implantable medical devices, for automatic characterization of sensors of such implantable medical devices and automatic evaluation of settings, e.g. pacing settings such as VV-delays, of such devices.

BACKGROUND OF THE INVENTION
Medical devices are implanted in human bodies for e.g. monitoring physiological conditions or treating diseases. One particular example of implantable medical devices is a cardiac rhythm management device including pacemakers and defibrillators implanted in a patient to treat irregular or other abnormal cardiac rhythms by delivering electrical pulses to the patient's heart. Pacemakers are often used to treat patients with bradyarrhythmias, that is, hearts that beat too slow or irregularly. Defibrillators are capable of delivering higher energy electrical stimuli to the heart and are often used to treat patients with tachyarrhythmias, that is, hearts that beat too quickly.

Such implantable medical devices comprises a number of sensors which are used to sense different physiological parameters of the patient, and in particular of the patient's heart, in order to deliver an accurate and reliable stimuli of the heart with respect to timing, amplitude etc. For example, sensors for determining an activity level of the patient, e.g. an accelerometer, sensors for determining a breathing rate of the patient are often included in such implantable medical devices. In order to obtain a reliable and correct operation of the implantable device, the characteristics and settings of the sensors must be determined in an accurate way.

Today, the normal procedure for determining the sensor characteristics and/or settings, e.g. of an activity sensor of an implanted medical device, is to start the collection of the sensor data via a programmer. The patient is then asked to lie down during a period of time and to
perform a walk during a second period of time. In this way, sensor data is registered at two different activity levels; namely at rest and at normal walking.

However, this mainly manual procedure for sensor characterization is associated with a number of drawbacks. For example, the sensor is characterized over a rather limited patient activity level range which may lead to an impaired function of the device due to a non-complete or limited sensor characterization. Furthermore, it may be difficult for the operator, e.g. the physician, conducting the patient test session to obtain reliable and reproducible results from the test, for example, due to the fact that the exerted workload during the walking is subjective for the patient and the actual workload is difficult to estimate.

A similar procedure is also conducted when setting up or adjusting pacing settings of an implanted medical device, e.g. setting up or adjusting a V-V timing of a pacemaker after an implantation. In this case, the physician and/or nurse measure the cardiac output and adjusts the V-V timing manually and this is repeated until satisfying results are obtained. This procedure is in some cases also combined with activity level measurements, i.e. the patient is asked to lie down during a period of time and to perform a walk during a second period of time. This manual procedure for setting up or adjusting the pacing settings of an implanted device, such as a pacemaker, may, apart from being time consuming, lead to unreliable results, for example, due to the fact that the cardiac output has to be interpreted and connected to a new V-V delay.

Thus, there is a need of an improved and automatized procedure for characterization of rate-responsive sensors of implantable medical devices, such as pacemakers, and for an improved and automatic procedure for evaluation and optimizing of pacing settings of implantable medical devices, such as pacemakers.

US 2004/0220636 discloses a system in which an IMD (Implantable Medical Device) programming device receives hemodynamic data from a hemodynamic measurement device (for example an external device) and programs one or more pacing parameters of the IMD as a function of the received pacing data. The IMD programming device is telemetrically linked to the IMD and may read, write, or store, for example, pacing
parameters of the IMD to the IMD and/or to the IMD programming device. The hemodynamic measurement device monitors the patient and generates updated hemodynamic data and the programmer may set or adjust the pacing parameters of the IMD as a function of the updated hemodynamic data. However, this system requires that a physician or nurse conducts the test and instructs the patient, for example, in case of determining sensor characteristics at different activity levels, to lie down and to walk during certain periods of time. Accordingly, the system according to US 2004/0220636 does not solve all the problems associated with the prior art procedures.

Hence, there remains a need within the art of an improved and automatized procedure for characterization of rate-responsive sensors of implantable medical devices, such as pacemakers, and for an improved and automatic procedure for evaluation and optimizing of pacing settings of implantable medical devices, such as pacemakers.

BRIEF DESCRIPTION OF THE INVENTION

Thus, an object of the present invention is to provide methods and medical systems including implantable medical devices such as pacemakers for automatic characterization of sensors of such devices and automatic evaluation of settings, e.g. pacing settings such as VV-delay settings or AV-delay settings, of such devices.

Another object of the present invention is to provide an improved and automatized procedure and medical system for characterization of rate-responsive sensors of implantable medical devices, such as pacemakers, and for an improved and automatic evaluation and optimizing of pacing settings of implantable medical devices, such as pacemakers that are capable of delivering reliable and accurate results.

A further object of the present invention is to provide an improved and automatized procedure and medical system for characterization of rate-responsive sensors of implantable medical devices, such as pacemakers, and for an improved and automatic evaluation and optimizing of pacing settings of implantable medical devices, such as pacemakers, for a broad range of activity levels.
Yet another object of the present invention is to provide an improved method and system for automatically evaluating and optimizing pacing settings of an implantable medical device, such as pacemakers, for a broad range of activity levels.

These and other objects of the present invention are achieved by means of medical systems and methods for such systems, a computer program product and a computer readable medium having the features defined in the independent claims. Preferable embodiments of the invention are characterized by the dependent claims.

In the context of this application, the term "hemodynamic parameter" refers to a parameter that can be measured, sensed or derived, for example, cardiac output, stroke volume, ejection fraction, blood pressure that reflects or relates to actual hemodynamic function.

For the purpose of clarification, the term "cardiogenic impedance" or "cardiac impedance" is defined as an impedance or resistance variation that origins from cardiac contractions, or in other words, an impedance of tissues measured between at least one electrode located within or at the heart and one or more electrodes located within, at or outside the heart.

According to an aspect of the present invention, there is provided a medical system for determining settings of an implantable medical device of the system, which device includes a controller or controlling circuit, a pulse generator adapted to produce cardiac stimulating pacing pulses and a communication unit. The system further comprises a programmer device including a control unit and a communication unit and at least one extracorporeal stress equipment adapted to, during use of/by the patient, exert a physiological stress on the patient, the equipment including a communication unit and a control device adapted to control the stress, wherein the extracorporeal stress equipment is adapted to, during operation, exert a physiological stress on a patient according to predetermined stress equipment workload settings. The programmer is adapted to downlink instructions to start a patient test session and to initiate an automatic setting determination procedure including starting an operation of the stress equipment, the implantable medical device comprises at least one sensor adapted to sense at least one sensor signal associated with a physiological parameter of the patient, wherein the controlling circuit is adapted to obtain at least one sensor value using the sensor signal for each workload level of the stress equipment.
workload settings during the determination procedure, and the controlling circuit of the implantable medical device is adapted to determine the settings and/or characteristics of the at least one sensor for each workload level using the obtained sensor values.

5

According to a second aspect of the present invention, there is provided a medical system for optimizing pacing settings of an implantable medical device of the system, which device includes a controller or controlling circuit, a pulse generator adapted to produce cardiac stimulating pacing pulses and a communication unit. The system further comprises a programmer device including a control unit and a communication unit and at least one extracorporeal stress equipment adapted to, during use of/by the patient, exert a physiological stress on the patient, the equipment including a communication unit and a control device adapted to control the stress, wherein: the extracorporeal stress equipment is adapted to, during operation, exert a physiological stress on a patient according to predetermined stress equipment workload settings; the programmer is adapted to downlink instructions to start a patient test session and to initiate an automatic setting determination procedure including starting an operation of the stress equipment; a circuit for obtaining a hemodynamical parameter of the heart of the patient during successive cardiac cycles for each workload level of the stress equipment workload settings, and an evaluation circuit adapted to evaluate the at least one hemodynamical parameter, and the workload data for each workload level of the stress equipment workload settings; and wherein the controlling circuit is adapted to iteratively control a delivery of the pacing pulses based on the evaluation and to determine optimal pacing settings for each workload level of the stress equipment workload settings.

25

According to a third aspect of the present invention, there is provided a method for determining settings of an implantable medical device in a medical system, the device including a pulse generator adapted to produce cardiac stimulating pacing pulses and a communication unit, wherein the system further comprises a programmer device including a control unit and a communication unit and at least one extracorporeal stress equipment adapted to, during use of/by the patient, exert a physiological stress on the patient according to an applied workload, the equipment including a communication unit and a control device adapted to control the applied workload. The method comprises the steps of: starting a patient test session; initiating an automatic setting determination procedure comprising the
steps of: starting an operation of the stress equipment, wherein the stress equipment, during operation, exerts a physiological stress on the patient according to predetermined stress equipment workload settings; sensing at least one sensor signal associated with a physiological parameter of the patient for each workload level of the stress equipment workload settings; obtaining at least one sensor value using the sensor signal; and determining the settings and/or characteristics of the at least one sensor for each workload level using the obtained sensor values.

According to a fourth aspect of the present invention, there is provided a method for optimizing pacing settings of an implantable medical device in a medical system, the device including a pulse generator adapted to produce cardiac stimulating pacing pulses and a communication unit, wherein the system further comprises a programmer device including a control unit and a communication unit and at least one extracorporeal stress equipment adapted to, during use of/by the patient, exert a physiological stress on the patient according to an applied workload, the equipment including a communication unit and a control device adapted to control the applied workload, the method comprising the steps of: starting a patient test session; initiating an automatic setting determination procedure comprising the steps of: starting an operation of the stress equipment, wherein the stress equipment, during the operation, exerts a physiological stress on the patient according to predetermined stress equipment workload settings; obtaining at least one hemodynamical parameter of the heart of the patient during successive cardiac cycles for each workload level of the stress equipment workload settings; obtaining workload data including a currently applied workload level; evaluating the at least one hemodynamical parameter, the sensor signal value and the workload data; iteratively controlling a delivery of the pacing pulses based on the evaluation; and determining optimal pacing settings for each workload level of the stress equipment workload settings.

According to a fifth aspect of the present invention, there is provided a computer program product, which when executed on a computer, performs steps in accordance with the second and third aspects of the present invention.
According to a further aspect of the present invention, there is provided a computer
readable medium comprising instructions for bringing a computer to perform steps of
methods according to the third and fourth aspects of the present invention.

Thus, the present invention is based on idea of interconnecting at least one implantable
medical device implanted in a patient, at least one programmer workstation, and at least one
extracorporeal stress equipment adapted to exert a physiological stress on the patient in a
medical system for automatically determining settings of a sensor for sensing a
physiological parameter of the patient or for automatically determining a pacing setting of
the device over a broad range of workloads of the equipment. The units and/or devices of
the medical system, i.e. the implantable medical device of a patient, the programmer
device, and the extracorporeal stress equipment, may communicate bi-directionally with
each other and form a closed loop during, for example, the patient test session and the
automatic setting determination procedure for automatically determining settings of a
sensor for sensing a physiological parameter of the patient or automatically determining a
pacing setting of the device over a broad range of workloads of the equipment and, hence,
for a broad range of exertion levels of the patient. In particular, the extracorporeal stress
equipment may be controlled by the implantable device or the programmer during the
patient test session, wherein a workload of the stress equipment is adjusted in accordance
with a predetermined workload setting such that the patient is exerted for different levels of
stress.

This invention provides several advantages in comparison with the prior art. For example, a
sensor can be characterized over a broad spectrum of patient stress levels. Thereby, the
sensor function can be improved. Furthermore, it is possible for the physician conducting
the patient test session to obtain reliable and reproducible results from the test, for example,
due to the fact that the applied workload during the different workload settings can be set
accurately by means of the stress equipment. Furthermore, the procedure for setting up or
adjusting pacing settings of an implanted medical device, e.g. setting up or adjusting a V-V
timing of a pacemaker after an implantation, can be done more efficiently since the
optimization is performed automatically at different activity levels of the patient. Thus, the
physician and/or nurse do not have to measure the cardiac output, adjust the V-V timing
manually and repeat this until satisfying results are obtained. In addition, the pacing settings
can be optimized over a broad range of patient stress level in an efficient and reliable manner with respect to hemodynamical function.

According to an embodiment of the present invention, the at least one sensor is an activity level sensor adapted to sense an activity level of the patient. There are a number of other physiological or hemodynamical parameters of the patient that may be used, for example, as an alternative or complement to the activity level including, without limitation, heart rate, breath rate, posture of the patient, blood temperature, etc. By using an activity sensor, a reliable and accurate measure of the exertion of the patient can be determined and, thus, the reliability and accuracy of, for example, the setting determination can be improved.

In a further embodiment, the implantable medical device further includes a memory circuit adapted to store the settings and/or characteristics of the at least one sensor value for each workload level. Accordingly, a complete sensor characterization may be stored, i.e. sensor signal value vs. stress equipment setting.

According to an embodiment of the present invention, the communication circuits, devices or units of the devices of the system, e.g. the programmer, the implantable medical device and the stress equipment, is RF telemetry circuits, devices, or units, which may be adapted for e.g. inductive telemetry or UHF telemetry.

In embodiments, a communication link between the programmer, the implantable medical device and the stress equipment is established, wherein two-way communications are enabled between the programmer, the implantable medical device and the stress equipment, respectively. Thus, the programmer may downlink data to the implantable medical device and data may be transferred uplink to the programmer from the implantable medical device. The two-way communication between the devices of the system can be realized by means of a number of different technologies including short-range communication links including BLUETOOTH, and IEEE 802.11b, or other types of short range wireless connections such as Infrared. Another alternative is using, for example, USB connections. Further, the devices of the system may communicate wirelessly with each other using RF-technology. The devices of the medical system may communicate with each other in a network forming a part of a wireless LAN ("Local Area Network"). For a given communication method, a
multitude of standard and/or proprietary communication protocols may be used. For example, and without limitation, wireless (e.g. radio frequency pulse coding, spread spectrum frequency hopping, time-hopping, etc.) and other communication protocols (e.g. SMTP, FTP, TCP/IP) may be used. Other proprietary methods and protocols may also be used. Furthermore, combination of two or more of the communication methods and protocols may also be used.

In one embodiment, the programmer is adapted to, upon receiving a patient test session initiation command, to establish the communication link. Further, the programmer is adapted to, upon after having established the communication link to the implantable medical device, send a command initiating the automatic determination procedure to the implantable medical device. However, master device and slave device in the medical system according to the present invention may vary during a session.

According to another embodiment, the controlling circuit of the implantable medical device is adapted to obtain a list of stress equipment workload settings comprising a predetermined number of different workload levels; and wherein the controlling circuit is adapted to send running instructions to the extracorporeal stress equipment instructing the extracorporeal stress equipment to operate according to the stress equipment workload settings of the list. The list may be stored in the memory circuit of the implantable medical device or in the programmer. Alternatively, the programmer may be connected to a communication network and the list can be obtained from a database connected to the network or a computer connected to the network, which may be, for example, a LAN ("Local Area Network") or a WAN ("Wide Area Network"). The programmer may be connected to the communication network via a network such as Internet.

In yet another embodiment of the present invention, the implantable medical device further comprises a signal processing unit adapted to process the at least one sensor signal from at least one sensor of the implantable device, which signal processing unit is adapted to start a signal processing procedure of the sensor signal a predetermined period of time after an adjustment of workload according to the workload settings. Further, the signal processing circuit may be adapted to perform an averaging process of the sensor signal during the
signal processing procedure. Alternatively or in addition, the signal processing circuit may be adapted to perform a filtering process of the obtained signals.

In yet another embodiment of the present invention, the circuit for obtaining a hemodynamical parameter comprises a circuit for measuring an impedance of tissues between right and left side of the heart for successive cardiac cycles; a circuit for measuring a heart rate of the patient; and wherein the circuit for obtaining a hemodynamical parameter is adapted to determine a relative cardiac output (CO) based on the measured impedance and the measured heart rate for successive cardiac cycles. Of course, as the skilled person within the art realizes, there are other hemodynamical parameters that can be measured, sensed or derived, for example, stroke volume, ejection fraction, heart sounds, blood pressure and used as metric of the hemodynamic function of the heart during the optimization procedure.

In a further embodiment of the present invention, the controlling circuit of the implantable medical device is adapted to: a) select an initial workload setting of the predetermined stress equipment workload settings; b) operate the stress equipment according to the selected workload setting; c) iteratively control the delivery of the pacing pulses based on the evaluation; d) determine optimal pacing settings for the initial workload level; e) store the optimal pacing setting and corresponding activity level for the initial workload level in the memory circuit of the implantable medical device; f) repeat steps b)-e) for each workload level of the stress equipment workload setting; and g) store a matrix of pacing settings and corresponding activity levels in the memory circuit.

According to embodiment, the pacing settings are VV-delay settings, but in alternative embodiments, the settings may be, for example, AV-delay settings.

The system according to the present invention may also comprise external diagnostic equipment, for example, an ultra sound machine connected to the patient. The ultra sound machine is adapted to communicate with the programmer and/or the implantable medical device and/or the stress equipment. For example, the programmer may control the ultra sound machine and the measurements results from the ultra sound machine can be used in
the automatic setting determination procedure to characterizing a sensor and/or the optimization of pacing settings such as VV-delay or AV-delay settings can be performed using the measurements from the ultrasound machine. As the skilled man realize, there are a number of alternative or complementing device that can be used, for example, a breath monitoring device may be connected to the patient to measure or sense, for example, a composition of the expiration air of the patient.

According to another embodiment of the present invention, the condition of the patient undergoing the patient test session at the stress equipment is monitored or supervised. In one embodiment, the cardiac output (CO) and the patient activity levels are monitored or observed. In case of worsening of the condition, e.g. if the cardiac output is found to exceed or fall below predetermined limits, the workload of the stress equipment may be reduced. Thereby, the safety of the patient can be enhanced during the test sessions.

As realized by the person skilled in the art, steps of the methods of the present invention, as well as preferred embodiment thereof, are suitable to realize as a computer program or a computer readable medium.

The features that characterize the invention, both as to organization and to method of operation, together with further objects and advantages thereof, will be better understood from the following description used in conjunction with the accompanying drawings. It is to be expressly understood that the drawings is for the purpose of illustration and description and is not intended as a definition of the limits of the invention. These and other objects attained, and advantages offered, by the present invention will become more fully apparent as the description that now follows is read in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS
In the following detailed description, reference will be made to the accompanying drawings, of which:

Fig. 1a schematically shows a medical system in accordance with an embodiment of the present invention;
Fig. 1b schematically shows a medical system in accordance with another embodiment of the present invention;

Fig. 2a schematically shows an embodiment of an implantable medical device of the system shown in Fig. 1;

Fig. 2b schematically shows a further embodiment of an implantable medical device of the system shown in Fig. 1;

Fig. 3 is a high-level flow chart of the methods for setting or characterizing a sensor of the implantable medical device or for optimizing a pacing setting of an implantable medical device according to the present invention;

Fig. 4 is a flow chart of a procedure for determining settings of a sensor or characterizing a sensor of the implantable medical device in accordance with the present invention;

Fig. 5 is a flow chart describing an algorithm for determining or optimizing a VV-delay of an implantable medical device in accordance with the present invention; and

Fig. 6 is a flow chart showing the optimization procedure according to the present invention shown in Fig. 5 in more detail.

DETAILED DESCRIPTION OF THE INVENTION

In the following, the present invention will be discussed in the context of a medical system comprising at least an implantable bi-ventricular pacemaker, an external or extracorporeal programmer workstation and an extracorporeal stress equipment. However, the present invention may also be implemented in system including other implantable devices such as a CRT (Cardiac Resynchronization Therapy) device, or an ICD (Implantable Cardioverter Defibrillator). Furthermore, the system may also comprise other devices, units or equipment such as, for example, an ultra sound machine.
With reference first to Figs. 1a and 1b, embodiments of the medical system of the present invention will be described. In one embodiment of the present invention shown in Fig. 1a, the medical system 1 comprises a programmer workstation 2, an implanted medical device 20 (which will be described in more detail with reference to Figs. 2a and 2b) implanted in a patient (not shown) and an extracorporeal stress equipment 6, for example, a treadmill. The programmer 2 includes a control unit 4 and a communication unit 5, i.e. an RF telemetry circuitry for providing bi-directional RF communications with, for example, the implanted medical device 20 and/or the stress equipment 6. The programmer 2 may downlink data, commands or instructions to the implanted medical device 20 and/or the stress equipment 6 and may receive data, commands or instructions uplink from the implanted medical device 20 and/or the stress equipment 6.

Further, the programmer 2 comprises a memory circuit 7 for storing, for example, predetermined stress equipment workload settings for different patients, a display unit or monitor, (not shown) for presenting information for a user by means of a graphical user interface (GUI), and input devices (not shown), for example, a keyboard and a mouse, which enable a user to, for example, input information and commands such as a command for starting or initiating a patient test session. The stress equipment 6 comprises a control unit 8 adapted to, for example, control a workload of the equipment for, during use of a patient, exerting a physiological stress on the patient or starting an operation of the equipment, and a communication unit 9, i.e. an RF telemetry circuitry for providing bi-directional RF communications with, for example, the implanted medical device 20 and/or the programmer 2. The operations of the stress equipment 6 may be controlled, via the control unit 8 of the stress equipment, by the programmer 2 or the implantable medical device 20, for example, the operations during a patient test session for characterizing or determining the settings of a sensor of an implanted medical device 20 or determining or optimizing pacing settings of the implanted medical device 20.

The programmer 2, the implantable medical device 20 and the stress equipment 6 or the medical system 1 may be interconnected in a telemetry communication system which allows two-way communication between the units or devices of the medical system 1. As the skilled person realizes, the two-way communication between the devices of the system can be implemented by means of a number of different technologies including short range
communication links including BLUETOOTH and IEEE 802.1 Ib, or other types of short-range wireless connections such as Infrared. Further, the devices of the system may communicate wirelessly with each other using RP-technology. Moreover, the devices of the medical system may communicate with each other in a network forming a part of a wireless LAN ("Local Area Network").

The programmer 2, the implantable medical device 20 and the stress equipment 6 of the medical system 1' may also communicate with each other via a communication network 12, such as, the internet or a wireless RF communication network 12, see Fig. 1b.

For a given communication method, a multitude of standard and/or proprietary communication protocols may be used. For example, and without limitation, wireless (e.g. radio frequency pulse coding, spread spectrum frequency hopping, time-hopping, etc.) and other communication protocols (e.g. SMTP, FTP, TCP/IP) may be used. Other proprietary methods and protocols may also be used. Further, combination of two or more of the communication methods and protocols may also be used.

The bi-directional communication between the implantable medical device 20 and the external stress equipment 6 may be a virtual bi-directional communication, i.e. the programmer 2 acts as an intermediary device between the implantable medical device 20 and the stress equipment 6.

In another embodiment of the present invention, the medical system also comprises external diagnostic equipment, for example, an ultra sound machine connected to the patient. Thereby, the automatic setting determination procedure to characterizing a sensor and/or the optimization of pacing settings such as VV-delay or AV-delay settings can be performed using the measurements from the ultra sound machine.

Turning now to Figs. 2a and 2b, the configuration including the primary components of embodiments of implantable medical devices of the system 1 described in Fig. 1 will be described.

In Fig. 2a, one embodiment of the implantable medical device according to the present invention is shown. The implantable medical device 20, such as a bi-ventricular pacemaker,
comprises a housing (not shown) being hermetically sealed and biologically inert.
Normally, the housing is conductive and may, thus, serve as an electrode. The pacemaker 20 is connectable to one or more pacemaker leads, where only two are shown in Fig. 1; namely a ventricular lead 26a implanted in the right ventricle of the heart (not shown) and one lead 26b implanted in a coronary vein of the left side of the heart (not shown). The leads 26a and 26b can be electrically coupled to the pacemaker 20 in a conventional manner. The leads 26a, 26b comprises one or more electrodes, such as a tip electrode or a ring electrode, arranged to, inter alia, measure the impedance or transmit pacing pulses for causing depolarization of cardiac tissue adjacent to the electrode (-s) generated by a pace pulse generator 25 under influence of a controller or controlling circuit 27 including a microprocessor. The controller 27 controls, inter alia, pace pulse parameters such as output voltage and pulse duration.

Furthermore, the implantable medical device 20 comprises at least one sensor 29 adapted to sense at least one sensor signal associated with a physiological parameter of the patient. In one embodiment, the sensor 29 is an activity level sensor adapted to sense an activity level of the patient, for example, an accelerometer. The sensor 29 is connected to a signal processing circuit 23 adapted to process sensed signals received from the sensor 29.

Moreover, a storage means 31 is connected to the controller 27, which storage means 31 may include a random access memory (RAM) and/or a non-volatile memory such as a read-only memory (ROM). Storage means 31 is connected to the controller 27 and the signal processing circuit 23. Detected signals from the patient’s heart are processed in an input circuit 33 and are forwarded to the controller 27 for use in logic timing determination in known manner. The implantable medical device 20 is powered by a battery (not shown), which supplies electrical power to all electrical active components of the implantable medical device 20. The implantable medical device 20 further comprises a communication unit 34, for example, an RF telemetry circuitry for providing RF communications. Thereby, for example, data contained in the storage means 31 can be transferred to a programmer (see Fig. 1) via the communication unit and a programmer interface (not shown) for use in analyzing system conditions, patient information, etc.
In one embodiment, the controller 27 is adapted to obtain at least one sensor value using the sensor signal for each workload level of the stress equipment workload settings during the determination procedure, which will be described in more detail below. Further, the controller 27 is adapted to determine the settings and/or characteristics of the at least one sensor for each workload level using the obtained sensor values.

With reference now to Fig. 2b, another embodiment of an implantable medical device in accordance with the present invention and that can be used in a medical system in accordance with the present invention will be described. Like or similar parts in Fig. 2a and 2b will be denoted with the same reference numeral and description of parts that have been described with reference to Fig 2a will be omitted. The implantable medical device 20', such as a bi-ventricular pacemaker, further comprises a circuit 35 for obtaining a hemodynamical parameter of the heart of the patient. In one embodiment, the circuit 35 comprises an impedance measuring circuit 36 for measuring an impedance of tissues between right and left side of the heart, which circuit 36 may be connected to the leads 26a and 26b. The impedance may be measured between electrodes placed inside or on the surface of the heart, integrated on a pacemaker lead, for example the leads 26a, 26b. Further, the circuit 35 for obtaining a hemodynamical parameter includes a heart rate sensor 37 for measuring a heart rate of the patient. The heart rate sensor can be incorporated in the device in accordance with conventional practice within the art. Of course, as the skilled person within the art realizes, there are other hemodynamical parameters that can be measured, sensed or derived, for example, stroke volume, ejection fraction, heart sounds, blood pressure. As used herein, a hemodynamical parameter encompasses any metric that reflects or relates to actual hemodynamic function.

Moreover, the circuit 35 for obtaining a hemodynamical parameter is adapted to determine a relative cardiac output (CO) based on the measured cardiac impedance and the measured heart rate. A portion of the cardiac impedance carries information of the amount of blood in the left ventricle and thus varies during the heart cycles. The impedance variation during a heart cycle corresponds to stroke volume, i.e. the volume of blood ejected per heart beat and equals end-diastolic volume minus end-systolic value. This portion of the measured impedance or impedance information is extracted in the impedance measuring circuit 36 or the circuit 35 for obtaining a hemodynamical parameter. Thereby, the circuit 35 for
obtaining a hemodynamical parameter may obtain a relative value of the cardiac output, i.e.
by knowing the heart rate and a relative value of the stroke volume of the left ventricle. The
cardiac output is the volume of blood, measured in litres, ejected by the heart per minute
and is determined by multiplying the heart rate and the stroke volume. Accordingly, the
value of the cardiac output obtained by the circuit 35 for obtaining a hemodynamical
parameter is a relative value.

Furthermore, the implantable medical device 20' comprises an evaluation circuit 38
adapted to evaluate the obtained hemodynamical parameter (in one embodiment the cardiac
output), the sensor signal (in one embodiment the activity level of the patient) and workload
data for each workload level of the stress equipment workload settings, which may be
stored in the memory circuit 31 of the implantable device 20' or in the programmer 2 (see
Fig. 1), in which case the stress equipment workload settings can be obtained by the
implantable device by means of a data transfer using the communication unit 34.

In one embodiment, the evaluation circuit 38 is adapted to evaluate the at least one
hemodynamical parameter, e.g. a relative value of the cardiac output as described above,
and the workload data for each workload level of the stress equipment workload settings.
Further, the controller 27 may be adapted to iteratively control a delivery of the pacing
pulses based on the evaluation and to determine optimal pacing settings for each workload
level of the stress equipment workload settings. In addition, the evaluation circuit 38 may
be adapted use at least one sensor signal from a sensor, wherein the at least one sensor is an
activity level sensor adapted to sense an activity level of the patient, for each workload
level of the stress equipment workload settings during the determination procedure in the
evaluation.

With reference now to Fig. 3, a high-level description of the steps of the methods for setting
or characterizing a sensor of the implantable medical device or for optimizing a pacing
setting of an implantable medical device according to the present invention will be given.
First, in step 40, a communication link between the devices of a medical system, e.g. the
devices of the system 1 in Fig. 1, is established. For example, this can be performed by an
operator of the programmer, e.g. a physician, using the input devices of the programmer 2.
Thereafter, at step 42, the operator of the programmer initiates the patient test session and
the automatic setting determination procedure, e.g. for characterizing the activity sensor of
the implantable medical device 20 or for determining a pacing setting of the implantable
medical device 20 such as a VV-delay. Subsequently, at step 44, the programmer 2 sends a
command or instruction to the implantable medical device to initiate the automatic setting
determination procedure. Then, at step 46, the automatic setting determination procedure is
initiated and executed as will be described in detail hereinafter. Finally, at step 48, the
operator of the programmer is presented for a message, e.g. on the display unit informing
the operator of the finalization of the automatic setting determination procedure.

Referring to Fig. 4, a procedure for determining settings of a sensor or characterizing a
sensor of the implantable medical device 20 will be described. First, at step 50, the
implantable medical device 20 receives an instruction to start the automatic setting
determination procedure from the programmer. That is, after the communication link
between the devices of a medical system, e.g. the devices of the system 1 in Fig. 1, has been
established the patient test session and the automatic setting determination procedure have
been initiated by the operator of the programmer 2. Then, at step 52, the controller 27 of the
device 20 obtains a stress equipment workload setting list, which can be stored in the
memory circuit 31 or in the memory circuit 7 of the programmer 2 and the device 20 sends
an instruction to the stress equipment 6 to start operate at an initial workload, for example,
at zero workload. Thus, the patient is exerted for an initial exertion or stress, for example,
on a treadmill. The stress equipment workload setting list may be a predetermined protocol
for the patient including a sequence of workload level settings, i.e. equipment speed,
equipment inclination in case of a treadmill and the duration of each workload level setting.
The controller 27 of the device 20 may control the stress equipment in accordance with the
predetermined workload setting or the protocol including the predetermined setting may be
transferred to the stress equipment. At step 54, the activity sensor response a predetermined
time after a new equipment setting is stored and associated with the present equipment
setting. Then, at step 56, it is checked whether all equipment settings of the list have been
used. If no, the procedure returns to step 58 and the next equipment setting is read from the
list and the stress equipment is instructed to adjust the workload in accordance to the new
settings. On the other hand, if all settings of the list have been used, the procedure proceeds
to step 60 where all sensor responses and corresponding stress equipment settings, i.e. the
sensor characterization (measured sensor signal vs. stress equipment setting) is stored in the
memory circuit 31 of the implantable medical device 20. Thereafter, a stop command is sent to the stress equipment 6 and to the programmer 2 informing them that the procedure is completed. The operator, e.g. a physician, may be informed of the results from the characterization procedure on the display unit via the graphical user interface of the programmer 2.

Turning now to Fig. 5, an algorithm for determining or optimizing a pacing setting such as a VV-delay of an implantable medical device will be described. First, at step 70, the implantable medical device 20 receives an instruction to start the automatic setting determination procedure from the programmer 2. That is, after the communication link between the units and/or devices of a medical system, e.g. the devices of the system 1 or 1' in Fig. 1a and 1b, respectively, has been established, the patient test session and the automatic setting determination procedure have been initiated by the operator of the programmer 2, the implantable medical device 20 receives the instruction to start the automatic setting determination procedure from the programmer 2. Then, at step 72, the controller 27 of the device 20 obtains a stress equipment workload setting list, which can be stored in the memory circuit 31 or in the memory circuit 7 of the programmer 2 and the device 20 sends an instruction to the stress equipment 6 to start operate at an initial workload, for example, at zero workload. Thus, the patient is exterted for a initial stress, for example, on a treadmill. The stress equipment workload setting list may be a predetermined protocol for the patient including a sequence of workload level settings, i.a. equipment speed, equipment inclination in case of a treadmill and the duration of each workload level setting. The controller 27 of the device 20 may control the stress equipment in accordance with the predetermined workload setting or the protocol including the predetermined setting may be transferred to the stress equipment.

Subsequently, at step 74, an optimization of the pacing settings of the device, for example, the VV-delay at the current workload is performed or executed. The optimization procedure will be described in more detail with reference to Fig. 6. Thereafter, at step 76, the optimal VV-delay and the corresponding sensor value, i.e. in this embodiment the activity level, are returned from the optimization subroutine and are stored. This is repeated for the sequence of workloads of the list and, hence, a matrix of optimal VV-delays and corresponding activity levels are created and stored, for example, in the memory circuit 31 of the
implantable medical device 20. Then, the automatic setting determination procedure is
terminated and the operator may be presented for the results on the display unit of the
programmer 2.

Referring now to Fig. 6, the optimization procedure according to the present invention will
be described in detail. The procedure is described with reference to an optimization of a
VV-delay but, however, as the skilled person realizes, the present optimization procedure
may also be performed to optimize other pacing settings of an implantable medical device,
such as, the AV-delay.

First, at step 80, an initialization is executed, the VV-delay is set to zero and the stress
equipment is instructed to operate according to the workload settings list, i.e. equipment
speed and inclination is set according to the list in case of a treadmill. The controller 27 of
the implantable medical device 20 may be adapted to obtain a VV-delay optimization
protocol including the initial or start VV-delay, the increments or step increase to use
during the optimization, maximum VV-delay, maximum negative VV-delay, and step
decrease to use during the optimization. This protocol may be stored in the memory circuit
31 of the implantable device or it may be obtained or transferred from the programmer
workstation 2 at initialization of the optimization procedure.

Then, at step 82, the heart is stimulated bi-ventricularly during a number of successive
cardiac cycles and a relative value of the cardiac output (CO) is obtained in accordance
with the description given above. At step 84, the activity level is obtained from the activity
sensor (or sensors) and stored. As the skilled person realizes, there are other conceivable
physiological parameters that can be used instead of, or as a complement to the activity
level to improve the optimization, for example, the posture of the patient or the breath rate
of the patient.

At step 86, the obtained CO-value is stored and linked to the present VV-delay and the
obtained activity level. Subsequently, at step 88, the VV-delay is increased with a
predetermined step in accordance with the VV-delay protocol. At step 90, the heart is
stimulated bi-ventricularly during a number of successive cardiac cycles and a relative
value of the cardiac output (CO) is obtained in accordance with the description given
above. Then, at step 92, the obtained CO-value is stored and linked to the present VV-delay and the obtained activity level. Thereafter, at step 94, it is checked whether the maximal VV-delay has been reached. If no, the algorithm returns to step 88 and, on the other hand, if yes, the algorithm proceeds to step 96 where the VV-delay is decreased with a predetermined step. Thereafter, at step 98, it is checked if the present VV-delay already has been processed. If yes, the algorithm returns to the previous step, step 98, and the VV-delay is decreased yet another step. If it is verified in step 96 that the present VV-delay not has been processed, the algorithm proceeds to step 100 where the heart is stimulated bi-ventricularly during a number of successive cardiac cycles and a relative value of the cardiac output (CO) is obtained in accordance with the description given above. Subsequently, at step 102, the obtained CO-value is stored and linked to the present VV-delay and the obtained patient activity level. After this, at step 104, it is checked whether the maximum negative VV-delay has been reached. If no, the algorithm returns to step 96 and the present VV-delay is decreased with a predetermined step. If it is verified that the maximum negative VV-delay has been reached, the algorithm instead proceeds to step 106 where the VV-delay which is correlated with the maximum CO value is identified and stored as the optimal VV-delay for the present activity level.

According to another embodiment of the present invention, the controller 27 of the implantable medical device is adapted to supervise the condition of the patient undergoing the patient test session at the stress equipment. This can be performed, for example, by monitoring or observing the cardiac output (CO) and the patient activity levels. In case of worsening of the condition, e.g. if the cardiac output is found to exceed or fall below predetermined limits, the controller may be adapted to, for example, reduce the speed or inclination of the stress equipment and thus reduce the workload of the patient. Thereby, the safety of the patient can be enhanced during the test sessions.

Although an exemplary embodiment of the present invention has been shown and described, it will be apparent to those having ordinary skill in the art that a number of changes, modifications, or alterations to the inventions as described herein may be made. Thus, it is to be understood that the above description of the invention and the accompanying drawings is to be regarded as a non-limiting example thereof and that the scope of protection is defined by the appended patent claims.
CLAIMS

1. A medical system for determining settings of an implantable medical device of said system, which device includes a controlling circuit, a pulse generator adapted to produce cardiac stimulating pacing pulses and a communication unit, said system further comprising a programmer device including a control unit and a communication unit and at least one extracorporeal stress equipment adapted to, during use of/by said patient, exert a physiological stress on said patient, said equipment including a communication unit and a control device adapted to control said stress, wherein said extracorporeal stress equipment is adapted to, during operation, exert a physiological stress on a patient according to predetermined stress equipment workload settings; said programmer is adapted to start a patient test session and to initiate an automatic setting determination procedure including starting an operation of said stress equipment; said implantable medical device comprises at least one sensor adapted to sense at least one sensor signal associated with a physiological parameter of said patient, wherein said controlling circuit is adapted to obtain at least one sensor value using said sensor signal for each workload level of said stress equipment workload settings during said determination procedure; and said controlling circuit of said implantable medical device is adapted to determine the settings and/or characteristics of said at least one sensor using said at least one sensor value for each workload level.

2. The system according to claim 1, wherein said at least one sensor is an activity level sensor adapted to sense an activity level of said patient.

3. The system according to claim 1 or 2, wherein said implantable medical device further includes a memory circuit adapted to store said settings and/or characteristics of said at least one sensor value for each workload level.
4. The system according to claims 1-3, wherein said programmer is adapted to, upon receiving an patient test session initiation command, establish a communication link: between said programmer, said implantable medical device and said stress equipment, wherein two-way communications are enabled between said programmer, said implantable medical device and said stress equipment, respectively.

5. The system according to claim 4, wherein said programmer is adapted to, upon after having established said communication link to said implantable medical device, send an initiation command initiating said automatic determination procedure to said implantable medical device.

6. The system according to claim 1-5, wherein said controlling circuit of said implantable medical device is adapted to obtain a list of stress equipment workload settings comprising at least a predetermined number of different workload levels; and wherein said controlling circuit is adapted to send running instructions to said extracorporeal stress equipment instructing said extracorporeal stress equipment to operate according to said stress equipment workload settings of said list.

7. The system according to claim 6, wherein said workload setting list is stored in said memory circuit of said implantable medical device as a predetermined protocol.

8. The system according to any one of preceding claims, wherein said implantable medical device further comprises a signal processing unit adapted to process the at least one sensor signal from at least one sensor of said implantable device, said signal processing unit being adapted to start a signal processing procedure of said sensor signal a predetermined period of time after an adjustment of workload according to said workload settings.

9. The system according to any one of preceding claims, wherein said implantable medical device further comprises a circuit for obtaining a hemodynamical parameter of the heart of said patient during successive cardiac cycles for each workload level of said stress equipment workload settings; an evaluation circuit
adapted to evaluate said at least one hemodynamical parameter, said sensor signal and said workload data for each workload level of said stress equipment workload settings; and wherein said controlling circuit is adapted to iteratively control a delivery of said pacing pulses based on said evaluation and to determine optimal pacing settings for each workload level of said stress equipment workload settings.

10. The system according to claim 9, wherein said circuit for obtaining a hemodynamical parameter comprises a circuit for measuring an impedance of tissues between right and left side of the heart for successive cardiac cycles; a circuit for measuring a heart rate of said patient; and wherein said circuit for obtaining a hemodynamical parameter is adapted to determine a relative cardiac output (CO) based on said measured impedance and said measured heart rate for successive cardiac cycles.

11. The system according to claim 9 or 10, wherein said controlling circuit of said implantable medical device is adapted to:
   a) select an initial workload setting of said predetermined stress equipment workload settings;
   b) operate said stress equipment according to said selected workload setting;
   c) iteratively control said delivery of said pacing pulses based on said evaluation;
   d) determine optimal pacing settings for said initial workload level;
   e) store said optimal pacing setting and corresponding activity level for said initial workload level in said memory circuit of said implantable medical device;
   f) repeat steps b)-e) for each workload level of said stress equipment workload setting; and
   g) store a matrix of pacing settings and corresponding activity levels in said memory circuit.

12. The system according to claim 9-11, wherein said pacing settings are VV-delay settings.
13. A medical system for determining settings of an implantable medical device of said system, which device includes a controlling circuit, a pulse generator adapted to produce cardiac stimulating pacing pulses and a communication unit, said system further comprising a programmer device including a control unit and a communication unit and at least one extracorporeal stress equipment adapted to, during use of/by said patient, exert a physiological stress on said patient, said equipment including a communication unit and a control device adapted to control said stress, wherein:

said extracorporeal stress equipment is adapted to, during operation, exert a physiological stress on a patient according to predetermined stress equipment workload settings;

said programmer is adapted to start a patient test session and to initiate an automatic setting determination procedure including starting an operation of said stress equipment;

a circuit for obtaining a hemodynamical parameter of the heart of said patient during successive cardiac cycles for each workload level of said stress equipment workload settings, and an evaluation circuit adapted to evaluate said at least one hemodynamical parameter, and said workload data for each workload level of said stress equipment workload settings; and wherein said controlling circuit is adapted to iteratively control a delivery of said pacing pulses based on said evaluation and to determine optimal pacing settings for each workload level of said stress equipment workload settings.

14. The system according to claim 13, wherein said implantable medical device further comprises at least one sensor adapted to sense at least one physiological parameter of said patient, wherein said controlling circuit is adapted to obtain at least one sensor value using at least one sensor signal from said sensor for each workload level of said stress equipment workload settings during said determination procedure; and wherein said evaluation circuit is adapted use said at least one sensor value in said evaluation.

15. The system according to claim 14, wherein said at least one sensor is an activity level sensor adapted to sense an activity level of said patient.
16. The system according to claim 13-15, wherein said implantable medical device further includes a memory circuit adapted to store said the settings and/or characteristics of said at least one sensor value for each workload level.

17. The system according to claims 13-16, wherein said programmer is adapted to, upon receiving an patient test session initiation command, establish a communication link between said programmer, said implantable medical device and said stress equipment, wherein two-way communications are enabled between said programmer, said implantable medical device and said stress equipment, respectively.

18. The system according to claim 17, wherein said programmer is adapted to, upon after having established said communication link to said implantable medical device, send a command initiating said automatic determination procedure to said implantable medical device.

19. The system according to claim 13-18, wherein said controlling circuit of said implantable medical device is adapted to obtain a list of stress equipment workload settings comprising a predetermined number of different workload levels; and wherein said controlling circuit is adapted to send running instructions to said extracorporeal stress equipment instructing said extracorporeal stress equipment to operate according to said stress equipment workload settings of said list.

20. The system according to claim 19, wherein said workload setting list is stored in said memory circuit of said implantable medical device as a predetermined protocol.

21. The system according to any one of preceding claims 13-20, wherein said implantable medical device further comprises a signal processing unit adapted to process the at least one sensor signal from at least one sensor of said implantable device, said signal processing unit being adapted to start a signal processing
procedure of said sensor signal a predetermined period of time after an adjustment of workload according to said workload settings.

22. The system according to any one of preceding claims 13-21, wherein said circuit for obtaining a hemodynamical parameter comprises a circuit for measuring an impedance of tissues between right and left side of the heart for successive cardiac cycles; a circuit for measuring a heart rate of said patient; and wherein said circuit for obtaining a hemodynamical parameter is adapted to determine a relative cardiac output (CO) based on said measured impedance and said measured heart rate for successive cardiac cycles.

23. The system according to any one of preceding claims 13-22, wherein said controlling circuit of said implantable medical device is adapted to:
   a) select an initial workload setting of said predetermined stress equipment workload settings;
   b) operate said stress equipment according to said selected workload setting;
   c) iteratively control said delivery of said pacing pulses based on said evaluation;
   d) determine optimal pacing settings for said initial workload level;
   e) store said optimal pacing setting and corresponding activity level for said initial workload level in said memory circuit of said implantable medical device;
   f) repeat steps b)-e) for each workload level of said stress equipment workload setting; and
   g) store a matrix of pacing settings and corresponding activity levels in said memory circuit.

24. The system according to any one of preceding claims 13-23, wherein said pacing settings are VV-delay settings.

25. The system according to any one of preceding claims, further comprising extracorporeal diagnostic equipment including a communication unit adapted to enable bi-directional communication with at least said programmer device and/or
said implantable medical device, said equipment being adapted to measure at least one physiological parameter of said patient, which at least one parameter is used in said automatic setting determination procedure.

26. The system according to claim 25, wherein said external diagnostic equipment is an ultrasound machine adapted to obtain an ultrasound of said patient.

27. A method for determining settings of an implantable medical device in a medical system, said device including a controlling circuit, a pulse generator adapted to produce cardiac stimulating pacing pulses and a communication unit, wherein said system further comprises a programmer device including a control unit and a communication unit and at least one extracorporeal stress equipment adapted to, during use of/by said patient, exert a physiological stress on said patient according to an applied workload, said equipment including a communication unit and a control device adapted to control said applied workload, the method comprising the steps of:

- starting a patient test session;
- initiating an automatic setting determination procedure comprising the steps of:
  - starting an operation of said stress equipment,
  wherein said stress equipment, during operation, exerts a physiological stress on said patient according to predetermined stress equipment workload settings;
  - sensing at least one sensor signal associated with a physiological parameter of said patient for each workload level of said stress equipment workload settings;
  - obtaining at least one sensor value using said sensor signal; and
  - determining the settings and/or characteristics of said at least one sensor using said at least one sensor value for each workload level.

28. The method according to claim 27, wherein the step of sensing at least one sensor signal from at least one sensor of said implantable device comprises the step of:

- sensing an activity level of said patient using an activity sensor.
29. The Method according to claim 27 or 28, wherein the step of determining the settings and/or characteristics of said at least one sensor further comprises the step of:

storing said at least one sensor signal for each workload level of said stress equipment workload settings and associating said sensor signal with an actual workload setting.

30. The method according to claim 27-29, wherein the step of starting a patient test session further comprises the step of:

establishing a communication link between said programmer, said implantable medical device and said stress equipment, wherein two-way communications are enabled between said programmer, said implantable medical device and said stress equipment, respectively.

31. The method according to claim 27-30, wherein the step of performing a determination procedure further comprises the steps of:

obtaining a list of stress equipment workload settings comprising a predetermined number of different workload levels; and running said stress equipment according to said stress equipment workload settings.

32. The method according to any one of preceding claims 27-31, wherein the step of sensing at least one sensor signal from at least one sensor of said implantable device comprises the step of:

starting a signal processing procedure of said sensor signal a predetermined period of time after an adjustment of workload according to said workload settings.

33. The method according to any one of preceding claims 27-32, wherein the determination procedure further comprises the steps of:
obtaining at least one hemodynamical parameter of the heart of said patient during successive cardiac cycles for each workload level of said stress equipment workload settings;

obtaining workload data for each workload level of said stress equipment workload settings;

evaluating said at least one hemodynamical parameter, said sensor signal and said workload data for each workload level of said stress equipment workload settings;

iteratively controlling a delivery of said pacing pulses based on said evaluation; and

determining optimal pacing settings for each workload level of said stress equipment workload settings.

34. The method according to claim 33, wherein the step of obtaining at least one hemodynamical parameter of the heart of said patient during successive cardiac cycles comprises the step of:

measuring an impedance of tissues between right and left side of the heart for successive cardiac cycles;

measuring a heart rate of said patient; and

determining a relative cardiac output (CO) based on said measured impedance and said measured heart rate for successive cardiac cycles.

35. The method according to claim 36 or 37, wherein the step of performing a determination procedure further comprises the steps of:

a) selecting an initial workload setting of said predetermined stress equipment workload settings;

b) operating said stress equipment according to said selected workload setting;

c) iteratively controlling said delivery of said pacing pulses based on said evaluation;

d) determining optimal pacing settings for said initial workload level;
e) storing said optimal pacing setting and corresponding activity level for said initial workload level;
f) repeating steps b)-e) for each workload level of said stress equipment workload setting; and

g) storing a matrix of pacing settings and corresponding activity levels.

36. The method according to any one of preceding claims 27-35, wherein said pacing settings are VV-delay settings.

37. The method according to any one of preceding claims 27-36, wherein the step of starting a patient test session further comprises the step of:

starting said patient test session by said programmer.

38. A method for determining settings of an implantable medical device in a medical system, said device including a controlling circuit, a pulse generator adapted to produce cardiac stimulating pacing pulses and a communication unit, wherein said system further comprises a programmer device including a control unit and a communication unit and at least one extracorporeal stress equipment adapted to, during use of/by said patient, exert a physiological stress on said patient according to an applied workload, said equipment including a communication unit and a control device adapted to control said applied workload, the method comprising the steps of:

starting a patient test session;

initiating an automatic setting determination procedure comprising the steps of:

starting an operation of said stress equipment, wherein said stress equipment, during said operation, exerts a physiological stress on said patient according to predetermined stress equipment workload settings;

obtaining at least one hemodynamical parameter of the heart of said patient during successive cardiac cycles for each workload level of said stress equipment workload settings;

obtaining workload data including a currently applied workload level;
evaluating said at least one hemodynamical parameter, and said workload data;
iteratively controlling a delivery of said pacing pulses based on said evaluation; and
determining optimal pacing settings for each workload level of said stress equipment workload settings.

39. The method according to claim 38, further comprising the steps of:
sensing at least one sensor signal associated with an physiological parameter of said patient during successive cardiac cycles for each workload level of said stress equipment workload settings;
obtaining at least one sensor value using said sensor signal; and wherein said sensor signal value is used in said step of evaluating.

40. The method according to claim 39, wherein the step of sensing at least one sensor signal from at least one sensor of said implantable device comprises the step of:
sensing an activity level of said patient using an activity sensor.

41. Method according to claim 39 or 40, wherein the step of starting a patient test session further comprises the step of:
establishing a communication link between said programmer, said implantable medical device and said stress equipment, wherein two-way communications are enabled between said programmer, said implantable medical device and said stress equipment, respectively.

42. The method according to claim 39-41, wherein the step of performing a determination procedure further comprises the steps of:
obtaining a list of stress equipment settings comprising a predetermined number of different workload levels; and running said stress equipment according to said stress equipment workload settings.
43. The method according to any one of preceding claims 39-42, wherein the step of
sensing at least one sensor signal from at least one sensor of said implantable
device comprises the step of:

starting a signal processing procedure of said

sensor signal a predetermined period of time after an adjustment of workload
according to said workload settings.

44. The method according to claim 39-43, wherein the step of obtaining at least one
hemodynamical parameter of the heart of said patient during successive cardiac
cycles comprises the step of:

measuring an impedance of tissues between right

and left side of the heart for successive cardiac
cycles;

measuring a heart rate of said patient; and
determining a relative cardiac output (CO)
based on said measured impedance and said measured heart rate for successive
cardiac cycles.

45. The method according to claim 39-44, wherein the step of performing a
determination procedure further comprises the steps of:

a) selecting an initial workload setting of
said predetermined stress equipment workload settings;

b) operating said stress equipment according to
said selected workload setting;

c) iteratively controlling said delivery of said pacing pulses based on said
evaluation;

d) determining optimal pacing settings for said initial workload level;

e) storing said optimal pacing setting and corresponding activity level for
said initial workload level;

f) repeating steps b)-e) for each workload level of said stress equipment
workload setting; and

g) storing a matrix of pacing settings and corresponding activity levels.
46. The method according to claim 39-45, wherein said pacing settings is a VV-delay setting.

47. The method according to claim 39-46, wherein the step of starting a patient test session further comprises the step of:
   starting said patient test session by said programmer.

48. The method according to any one of preceding claims 27-47, further comprising the step of obtaining at least one physiological parameter of said patient by means of an extracorporeal diagnostic equipment, which at least one parameter is used in said automatic setting determination procedure.

49. The system according to claim 48, wherein said at least one physiological parameter is ultrasound.

50. A computer program product, which when executed on a computer, performs steps in accordance with any one of claim 27-49.

51. A computer readable medium comprising instructions for bringing a computer to perform steps of a method according to any one of the preceding claims 27-49.
Establish a communication link between devices of the medical system

40

The operator initiates the patient test session and the automatic settings determining session

42

The programmer sends an instruction to the implantable medical device to start the determination procedure

44

Automatic setting determination procedure is executed

46

Procedure terminated, presenting results for the operator

48
The implantable medical device receives an instruction to start the automatic settings determining session.

The device obtains stress equipment workload settings and controls the stress equipment in accordance to the settings.

Activity sensor response and associated equipment setting is stored.

Check whether all settings of the list have been used?

Yes → Store the sensor characterization

No → Read next equipment setting from the list and instruct the equipment to operate according to the new setting.

Fig. 4
The implantable medical device receives an instruction to start the automatic settings determination session.

The device obtains stress equipment workload settings and controls the stress equipment in accordance with the settings.

Optimization procedure is executed.

Optimal pacing setting and corresponding activity level are stored for each workload.

Fig. 5
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER

IPC: see extra sheet
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)

IPC: A61N

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

SE, DK, FI, NO classes as above

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

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 No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>EP 0331309 A2 (WEBB, STUART CHARLES ET AL), 9 June 1989 (09.06.1989), whole document</td>
<td>1-51</td>
</tr>
<tr>
<td>A</td>
<td>WO 2004012808 A1 (MCDOWALL, PAUL, H.), 12 February 2004 (12.02.2004), page 9, line 5 - line 20, abstract</td>
<td>1-51</td>
</tr>
</tbody>
</table>

Further documents are listed in the continuation of Box C.

See patent family annex.

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

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

Date of the actual completion of the international search: 21 May 2007
Date of mailing of the international search report: 24-05-2007

Name and mailing address of the ISA/Authorized officer
Swedish Patent Office
Box 5055, S-102 42 STOCKHOLM
Facsimile No. +46 8 666 02 86
Anna Malmberg /itw
Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (April 2007)
### 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 No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>US 20050043895 A1 (S.O.SCHECHTER), 24 February 2005 (24.02.2005), [0029], [0055]-[0057], [0059], abstract</td>
<td>1-51</td>
</tr>
<tr>
<td>A</td>
<td>&quot;Treadmill assessment of an activity-modulated pacemaker: the importance of individual programming&quot;, McAlister H F; Soberman J; Klementowicz P; Andrews C; Furman S. ISSN 0147-8389, VOL:12, NR:3, PG:486 - 501 whole document</td>
<td>1-51</td>
</tr>
</tbody>
</table>
Box No. II  Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

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

1. | Claims Nos.: 27 - 49
   | because they relate to subject matter not required to be searched by this Authority, namely:
   | Claims 27-49 relate to a method of treatment of the human or animal body by surgery or by therapy, as well as diagnostic...

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

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

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

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

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 and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant’s protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.
methods /Rule 39.1(iv). Claims 50-51 relate to the claims 27-49 and do not involve anything more than what is mentioned in claims 27-49, therefore claims 50-51 also relate to subject matter not required to be searched by this Authority.

However, a search has been executed for the claims 27-51. The search has been based on the alleged effects of the device.
International patent classification (IPC)
A61N 1/372 (2006.01)
A61N 1/365 (2006.01)

Download your patent documents at www.prv.se
The cited patent documents can be downloaded at www.prv.se by following the links:
  • In English/Searches and advisory services/Cited documents (service in English) or
  • e-tjänster/anfördom dokument (service in Swedish).
Use the application number as username.
The password is SDBMLDVKFU.

Paper copies can be ordered at a cost of 50 SEK per copy from PRV InterPat (telephone number 08-782 28 85).

Cited literature, if any, will be enclosed in paper form.
<table>
<thead>
<tr>
<th>Code</th>
<th>Application No.</th>
<th>Date</th>
<th>Country</th>
<th>Application No.</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>EP</td>
<td>0331309</td>
<td>09/06/1989</td>
<td>SE</td>
<td>0331309</td>
<td>T3</td>
</tr>
<tr>
<td>CA</td>
<td>1322029</td>
<td>07/09/1993</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DE</td>
<td>68927447</td>
<td>03/04/1997</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DE</td>
<td>68929280</td>
<td>31/05/2001</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EP</td>
<td>0616819</td>
<td>28/09/1994</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SE</td>
<td>0616819</td>
<td>T3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GB</td>
<td>2216011</td>
<td>04/10/1989</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GB</td>
<td>8803613</td>
<td>00/00/0000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GB</td>
<td>8819268</td>
<td>00/00/0000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GB</td>
<td>8903597</td>
<td>00/00/0000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>US</td>
<td>5044365</td>
<td>03/09/1991</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>US</td>
<td>4886064</td>
<td>12/12/1989</td>
<td>DE</td>
<td>3885574</td>
<td>DJ</td>
</tr>
<tr>
<td>US</td>
<td>5372607</td>
<td>13/12/1994</td>
<td>AU</td>
<td>668049</td>
<td>B</td>
</tr>
<tr>
<td>JP</td>
<td>1195869</td>
<td>07/08/1989</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>JP</td>
<td>1195869</td>
<td>07/08/1989</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>JP</td>
<td>1195869</td>
<td>07/08/1989</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>JP</td>
<td>1195869</td>
<td>07/08/1989</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>JP</td>
<td>1195869</td>
<td>07/08/1989</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>JP</td>
<td>1195869</td>
<td>07/08/1989</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>JP</td>
<td>1195869</td>
<td>07/08/1989</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>JP</td>
<td>1195869</td>
<td>07/08/1989</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WO</td>
<td>2004012808</td>
<td>12/02/2004</td>
<td>CA</td>
<td>2494476</td>
<td>A</td>
</tr>
<tr>
<td>US</td>
<td>20050043895</td>
<td>24/02/2005</td>
<td>EP</td>
<td>1660176</td>
<td>A</td>
</tr>
<tr>
<td>EP</td>
<td>1660176</td>
<td>31/05/2006</td>
<td>US</td>
<td>7010347</td>
<td>B</td>
</tr>
<tr>
<td>US</td>
<td>7065400</td>
<td>20/06/2006</td>
<td>US</td>
<td>20050182447</td>
<td>A</td>
</tr>
<tr>
<td>US</td>
<td>20050182447</td>
<td>18/08/2005</td>
<td>US</td>
<td>20060235480</td>
<td>A</td>
</tr>
<tr>
<td>WO</td>
<td>2005018570</td>
<td>03/03/2005</td>
<td>WO</td>
<td>2005020025</td>
<td>A</td>
</tr>
<tr>
<td>US</td>
<td>2005020025</td>
<td>03/03/2005</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>US</td>
<td>20050043895</td>
<td>24/02/2005</td>
<td>EP</td>
<td>1620172</td>
<td>A</td>
</tr>
<tr>
<td>US</td>
<td>20040220636</td>
<td>04/11/2004</td>
<td>EP</td>
<td>1620172</td>
<td>A</td>
</tr>
<tr>
<td>US</td>
<td>6975904</td>
<td>13/12/2005</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>