

5

METHOD FOR PROGRAMMING AN IMPLANTABLE MEDICAL DEVICE

The present invention relates to a method for programming an implantable medical device for stimulating a human or animal heart according to the preamble of claim 1, to an
10 arrangement comprising an implantable medical device and a programming device according to the preamble of claim 12, and to a computer program product according to the preamble of claim 13.

Implantable medical devices for stimulating a human or animal heart, such as pacemakers,
15 have been known for a long time. They can perform different functions. Different stimulation programs can be carried out by an appropriate pacemaker to restore the treated heart to a normal state. Pacemakers are also known to stimulate the His bundle.

The His bundle is a bundle of specific heart muscle cells that is part of the cardiac conduction
20 system. The His bundle is located distally of the atrioventricular node towards the apex of the heart.

For His bundle pacing, a detecting (sensing) and stimulation electrode is not implanted into the ventricle of the human or animal heart to be treated, but rather at or near to the His bundle
25 of the heart. Such use of a His bundle electrode enables a particularly physiologic stimulation of the human or animal heart.

Programming conventional implantable cardiac devices for His bundle pacing (HBP) is technically complicated, time-consuming and is usually done manually by HBP experts.
30 Despite the advantages of HBP for the patients, this fact currently limits a wider adoption of HBP.

It is an object of the present invention to facilitate programming an implantable medical device for His bundle pacing.

This object is achieved with a method for programming an implantable medical device with
5 a programming device having the claim elements of claim 1. The implantable medical device serves for stimulating a human or animal heart and comprises a first processor, a first memory unit, a first stimulation unit and a first detection unit. The first stimulation unit is configured to stimulate a cardiac region of a human or animal heart. The first detection unit serves for detecting an electrical signal at the cardiac region of the same heart. The method
10 comprises the steps explained in the following.

First, a first input parameter is provided to the programming device. In this context, the first input parameter indicates whether the first stimulation unit is to be used to stimulate the His bundle of the heart.

15

If the first input parameter indicates that the first stimulation unit is to be used to stimulate the His bundle of the heart, a user of the programming device (e.g., a physician) is supported in configuring the implantable medical device for His bundle pacing. For this purpose, the programming device automatically offers at least one stimulation parameter and an assigned
20 stimulation parameter value specifically adapted for His bundle pacing. Thus, it will no longer be necessary for the user to input a specific stimulation parameter and an assigned stimulation parameter value on his or her own motion, but rather to be able to rely on a proposal of the programming device.

25 Subsequently, the user of the programming device is allowed to set the at least one stimulation parameter value and thus to program the implantable medical device for His bundle pacing. This approach makes it particularly easy for a user to adapt conventional implantable medical device for His bundle pacing so that also implantable medical devices the hardware of which has not been adapted for His bundle pacing can be reliably used for
30 His bundle pacing. By this automatic assistance in choosing appropriate stimulation parameters and assigned stimulation parameter values, it is no longer necessary that His bundle pacing experts take care of programming an implantable medical device for His

bundle pacing. Rather, the presently claimed method enables a much broader group of users to reliably program an implantable medical device for His bundle pacing.

Within the frame of this application the term stimulation parameter is understood in the sense of a parameter, which is set to influence the actual stimulation of the heart. Consequently the stimulation parameter within the frame of the application could be the mode of pacing including values like VVI(R), AAI(R), DDD(R), DDI(R), DVI(R), a specific parameter of applied stimulation pulses like pulse width, pulse rate or pulse amplitude, a sensing parameter like sensing threshold or gain, a timing parameter like atrio-ventricular delay, ventricular-to-ventricular delay, atrio-hisian delay, hisian-ventricular delay or first paced chamber, and/or a stimulation parameter value like on/off enabling or disabling subprograms. A stimulation parameter could be set in dependency of the heart rate.

In an embodiment, the first input parameter is manually set by a user of the programming device, e.g., by pushing a (virtual) button on the programming device, the button confirming the intention to use the stimulation unit for His bundle pacing. In another embodiment, it is automatically detected whether a His bundle electrode is connected to the stimulation unit. A His bundle electrode is an electrode that is connected to the stimulation unit and is implanted at or near to the His bundle of the heart to be stimulated. Such a His bundle electrode enables stimulation of the His bundle. If such connection of a His bundle electrode is confirmed, this is taken as first input parameter. Then, the user does not need to manually confirm the presence of a His bundle electrode. Such an automatic detection of the His bundle electrode enhances the overall reliability of the method.

In an embodiment, not only a single stimulation parameter and its value, but rather a set of stimulation parameters and assigned stimulation parameter values specifically adapted for His bundle pacing is automatically proposed by the programming device. Then, the user will be easily guided through a complete stimulation program containing a plurality of stimulation parameters and assigned values that are particularly appropriate for His bundle pacing. Such a set of stimulation parameters and assigned values can also be denoted as therapy setting. By proposing a pre-specified therapy setting to the user, programming the implantable medical device for His bundle pacing is made particularly easy.

In an embodiment, at least one second input parameter is provided prior to the step of supporting a user of the programming device to configure the implantable medical device. In such a case, the at least one stimulation parameter and the assigned stimulation parameter value are not only proposed in dependence on the first input parameter, but also in additional
5 dependency on the at least one second input parameter. Thus, it is possible by the at least one second input parameter that the programming device proposes the at least one stimulation parameter and the assigned value or a complete set of stimulation parameters and their assigned values that are specifically adapted to the concrete (medical) need of the
10 patient to be treated by the implantable medical device.

As stated above with respect to the first input parameter the second input parameter could be manually set by the user of the programming device or it is automatically detected whether a His bundle electrode is connected to the stimulation unit. In addition it might also
15 be possible to receive the second input parameter from an external database.

In an embodiment, the at least one second input parameter is an indication on the port of the implantable medical device to which a His bundle electrode is connected. The implantable medical device may have a right atrial (RA) and/or a right ventricular (RV) and/or a left
20 ventricular (LV) and/or a His bundle (HIS) port for connecting according electrode or leads. Conventional implantable medical devices that are not specifically adapted for His bundle pacing typically do not comprise a His bundle port nor any non-specific port labelled as His bundle port. In an embodiment, the His bundle electrode is connected to the RV port of the implantable medical device. In this or another embodiment, a right atrial electrode (if present
25 at all) is connected to the RA port. In this or another embodiment, a right ventricular electrode (if present at all) is connected to the LV port (since the His bundle electrode is already connected to the RV port). Furthermore, if a left ventricular electrode is used instead of a right ventricular electrode, the left ventricular electrode is connected to the LV port. Furthermore the second input parameter could be the kind (manufacturer, model and/or
30 length of the electrode) of connected His bundle electrode as well.

Alternatively or additionally to the embodiments explained in the preceding paragraph, the at least one second input parameter is an indication on the patient's cardiac disease to be treated with the implantable medical device.

5 Alternatively or additionally, the at least one second input parameter is an indication on the type of the implantable medical device. To give some examples, the implantable medical device can be an implantable pulse generator (IPG), an implantable cardioverter-defibrillator (ICD), or a device for cardiac resynchronization therapy (CRT).

10 Alternatively or additionally, the at least one second input parameter is an indication on a model of the implantable medical device. To give some examples for different models, the implantable medical device can be a single chamber device (appropriate for stimulating a single cardiac chamber), a dual chamber device (appropriate for stimulating two cardiac chambers), or a triple chamber device (appropriate for stimulating three cardiac chambers).

15 Alternatively or additionally, the at least one second input parameter is an indication on the number of ports of the implantable medical device. An appropriate number of ports is a number from 1 to 4 (i.e., 1, 2, 3, or 4). A single chamber device has typically one port, whereas a dual chamber device has typically two ports and a triple chamber device comprises typically three ports.

20

Alternatively or additionally, the at least one second input parameter is an indication on a cardiac chamber into which a lead or an electrode connected to a port of the implantable medical device is placed or implanted, respectively. To give an example, this indication may indicate that the LV lead is placed in the coronary sinus (CS) of the heart or that the LV lead
25 is placed in the right ventricle (RV) of the heart.

The more second input parameters are used in addition to the first input parameter, the more specific is the proposal of the at least one stimulation parameter and its value to the user of the programming device. Thus, it is possible to fine-tune the proposals of stimulation
30 parameters and assigned values on the basis of the first and second input parameters.

In an embodiment, the at least one second input parameter comprises information on the kind of the patient's cardiac disease to be treated with the implantable medical device, wherein this information is retrieved by the programming device from a database, such as a clinical information system. Such an automatic transmission of information on the health status of the patient to be treated with the implantable medical device (or, to be more specific, information on the cardiac disease of the patient to be treated with the implantable medical device), input errors can be minimized so that the risk of proposing an improper stimulation parameter by the programming device is significantly reduced. A particularly high reliability of the presently described and claimed method can be achieved if an automatic detection of the presence of a His bundle electrode and an automatic retrieval of the kind of the patient's cardiac disease to be treated with the implantable medical device takes place. This combined embodiment reduces human interaction with the programming device so that possible error sources are eliminated.

In an embodiment, the patient's cardiac disease to be treated with the implantable medical device is chosen from the group consisting of bradycardia with permanent atrial fibrillation or flutter, paroxysmal or permanent high-degree atrio-ventricular block, heart failure, heart failure with normal sinus rhythm, heart failure with permanent atrial fibrillation or flutter, sick-sinus syndrome, brady-tachy syndrome, sick-sinus syndrome with chronotropic competence, dual node disease and permanent atrio-ventricular block, dual node disease and paroxysmal atrio-ventricular block, vasovagal syncope, symptomatic first-degree atrio-ventricular block, infrequent paroxysmal cardiac pauses. Infrequent paroxysmal cardiac pauses denote less than 10 % paroxysmal cardiac pauses with respect to all expected cardiac contractions in a given time period, in particular less than 8 %, in particular less than 5 %, in particular less than 3 %, in particular less than 1 % (but always necessarily more than 0 %).

If the model of the implantable medical device has been specified to be a single chamber device, the possible patient's cardiac diseases to be chosen are limited, in an embodiment, to bradycardia with permanent atrial fibrillation or flutter, and infrequent paroxysmal cardiac pauses.

If the model of the implantable medical device has been specified to be a dual chamber device, the possible patient's cardiac diseases to be chosen are limited, in an embodiment, to sick-sinus syndrome, brady-tachy syndrome, sick-sinus syndrome with chronotropic competence, bradycardia with permanent atrial fibrillation or flutter, paroxysmal or
5 permanent high-degree atrio-ventricular block, dual node disease and permanent atrio-ventricular block, dual node disease and paroxysmal atrio-ventricular block, vasovagal syncope, and symptomatic first-degree atrio-ventricular block.

If the model of the implantable medical device has been specified to be a triple chamber
10 device, the possible patient's cardiac diseases to be chosen are limited, in an embodiment, to heart failure, heart failure with normal sinus rhythm, and heart failure with permanent atrial fibrillation or flutter.

In an embodiment, the second input parameter is automatically determined. This
15 embodiment is particularly appropriate if the second input parameter is chosen from the group consisting of an indication on a port of the implantable medical device to which a His bundle electrode is connected, an indication on the type of the implantable medical device, an indication on a model of the implantable medical device, an indication on the number of ports of the implantable medical device, and an indication on the cardiac chamber into which
20 a lead connected to a port of the implantable medical device is placed. All of these parameters can be particularly easy auto-detected by the programming device by reading out information provided by the implantable medical device in an electronic (in particular digital) way.

25 In an embodiment, the programming device enables a change of the stimulation parameter value assigned to the at least one proposed stimulation parameter. Then, the user of the programming device can adjust the proposed stimulation parameter value according to his or her knowledge, if desired. This enables an even finer tuning of the subsequent His bundle pacing and makes the method even more attractive for experts in the field of His bundle
30 pacing.

In an embodiment, the programming device enables to save a set of stimulation parameter and assigned stimulation parameter values, wherein the set comprises at least one stimulation parameter value changed with respect to an original setting. Thus, if a user of the programming device has changed the proposed stimulation parameter value, it is possible to
5 save the complete set of stimulation parameters and assigned values comprising the changed stimulation parameter value so that the programming device can restore this set of stimulation parameters and assigned values at a later stage to facilitate programming of another implantable medical device by using the same (amended) stimulation parameter set.

10 In an embodiment, the programming device performs an automatic check to identify a potential conflict between the changed stimulation parameter value and other stimulation parameter values of the same stimulation parameter set. Such an automatic check reduces the risk of an improperly balanced therapy setting and serves for increasing the overall quality of a subsequently applied His bundle pacing making use of the His bundle
15 stimulation parameters.

In an embodiment, an alert is created in case of an identified conflict so as to inform the user on a potential improper setting of a stimulation parameter and to urge the user to amend the stimulation parameter value once again.

20

In an embodiment, a program consult page creator (PCPC) is provided depicting a software module comprising one or more algorithms to support the programming of His bundle pacing via a display of the programming device. The PCPC enables one or more interactions between the user and the software module.

25 In an embodiment, the PCPC provides a table or list of pre-specified program consult pages to the user, wherein the user can finally select one of these pages.

In an aspect, the present invention relates to an arrangement comprising an implantable medical device and a programming device.

30

The implantable medical device serves for stimulating a human or animal heart and comprises a first processor, a first memory unit, a first stimulation unit and a first detection

unit. The first stimulation unit is configured to stimulate a cardiac region of a human or animal heart. The first detection unit serves for detecting an electrical signal at the cardiac region of the same heart.

- 5 The second memory unit comprises a computer-readable program that causes the second processor to perform the steps explained in the following when executed on the second processor.

First, a first input parameter is provided to the programming device. In this context, the first
10 input parameter indicates whether the first stimulation unit is to be used to stimulate the His bundle of the heart.

If the first input parameter indicates that the first stimulation unit is to be used to stimulate the His bundle of the heart, a user of the programming device (e.g., a physician) is supported
15 in configuring the implantable medical device for His bundle pacing. For this purpose, the programming device automatically offers at least one stimulation parameter and an assigned stimulation parameter value specifically adapted for His bundle pacing.

Subsequently, the user of the programming device is allowed to set the at least one
20 stimulation parameter value and thus to program the implantable medical device for His bundle pacing.

In an embodiment, the programming device comprises a display for displaying a graphical user interface. Such a display facilitates interaction with the user of the programming device
25 and makes it particularly easy to offer the proposed stimulation parameter and assigned values to the user.

In an embodiment, the implantable medical device comprises a first data communication unit and the programming device comprises a second data communication unit. Then, a data
30 transmission between the implantable medical device and the programming device can be performed with the help of the first data communication unit and the second data communication unit.

In an embodiment, the first and second data communication units serve for transferring data to the programming device in a wireless manner. All standard data transmission protocols or specifications are appropriate for such a wireless data communication. Examples of standard
5 data transmission protocols or specifications are the Medical Device Radiocommunications Service (MICS), the Bluetooth Low Energy (BLE) protocol and the Zigbee specification.

In an aspect, the present invention relates to a computer program product comprising computer-readable code that causes the processor to perform the steps explained in the
10 following when executed on the processor.

First, a first input parameter is provided to the programming device. In this context, the first input parameter indicates whether a first stimulation unit of an implantable medical device is to be used to stimulate the His bundle of the heart.

15 If the first input parameter indicates that the first stimulation unit is to be used to stimulate the His bundle of the heart, a user of a programming device (e.g., a physician) is supported in configuring the implantable medical device for His bundle pacing. For this purpose, the programming device automatically proposes at least one stimulation parameter and an
20 assigned stimulation parameter value specifically adapted for His bundle pacing.

Subsequently, the user of the programming device is allowed to set the at least one stimulation parameter value and thus to program the implantable medical device for His bundle pacing.

25 All embodiments of the described method can be combined in any desired way and can be transferred either individually or in any arbitrary combination to the arrangement, and to the computer program product. Furthermore, all embodiments described with respect to the arrangement can be combined in any desired way and can be transferred either individually
30 or in any arbitrary combination to the described method or to the described computer program product. Finally, all embodiments described with respect to the computer program

product can be combined in any desired way and can be transferred either individually or in any arbitrary combination to the described arrangement or to the described method.

Further details of aspects of the present invention will be described in the following making
5 reference to exemplary embodiments and an accompanying Figure.

Figure 1 shows an arrangement of a pacemaker and a programming device.

Figure 1 shows an arrangement of a pacemaker 1 and programming device 2. The pacemaker
10 1 comprises a port 3 into which a His bundle electrode 4 is inserted. The His bundle electrode 4 comprises an electrode 5 at its distal end which is implanted at the His bundle 6 of a human heart 7.

The programming device 2 comprises a display 8 for enabling an interaction with a user of
15 the programming device 2. The programming device 2 and the pacemaker 1 are operatively coupled to each other by a wireless radio communication 9. Due to this wireless radio communication 9, it is possible to program the pacemaker 1 with the help of the programming device 2. For carrying out such programming, the programming device 2 first requests an input whether a His bundle electrode is connected to the pacemaker 1. In the
20 present embodiment, the His bundle electrode 4 is connected to the pacemaker 1 so that an according question is to be answered by "yes". This can be done manually by confirming a corresponding prompt. Alternatively, the respective information can be automatically obtained by the programming device 2 from the implantable pacemaker 1.

25 Depending on further input parameters such as the type of the pacemaker 1, the health status of the patient the heart 7 of which is to be stimulated by the pacemaker 1 and the port 3 into which the His bundle electrode 4 is plugged in, the programming device 2 proposes an appropriate therapy setting for stimulating the His bundle 6 of the human heart 7. Individual parameters of this therapy setting can be adjusted by a user, if desired. Afterwards, the choice
30 of the optionally adjusted therapy setting is confirmed and transferred to the pacemaker 1 so that the pacemaker 1 will start operation or continue operation by using the transmitted therapy setting.

In the following some exemplary pre-configured programs (so-called program consult programs) are listed below that can be proposed to the user of the programming device 2 upon indicating that the His bundle electrode 4 is connected to the port 3 of the pacemaker

1.

Depending on the patient condition and the type of implant a configuration for the placement of the electrodes is proposed to the user. The following table list some examples of pre-configured programs to support adequate programming of His bundle pacing for different device types: SR (single chamber device), DR (dual chamber device), and HF (triple chamber device); Atrial Fibrillation (AF); Atrio-ventricular (AV); Left-Ventricular (LV); Right-Ventricular (RV); Coronary-Sinus (CS).

Device Type	Program	Configuration: port >> chamber/placement
SR	Bradycardia with permanent AF and His placement	RVport >> HIS placement
DR	Permanent high-degree AV block with His placement	RAport >> RA placement plugged RVport >> HIS placement
HF	Heart failure, normal sinus, RV His placement, LV in RV	RAport >> RA placement plugged RVport >> HIS placement LVport >> RV placement (backup)
HF	Heart failure, normal sinus, RV His placement, LV in CS	RAport >> RA placement plugged RVport >> HIS placement LVport >> CS placement (backup)

The pre-configured programs could propose different pulse widths for the stimulation pulses (for example a pulse width of 1 millisecond if the His bundle is stimulated), a different detection or sensing threshold, and/or an amplification gain, a rate-dependent atrio-hisian (AH) delay (for example an AH1 delay after Pace of 70 milliseconds at a rate of 60 beats

per minute) and/or a hisian-ventricular (HV) delay (for example a HV delay after Pace of 30 milliseconds), for example if the His bundle is stimulated for patients with normal sinus rhythm, equipped with a conventional triple chamber device and the His bundle pacing lead connected to the RV port of the device, and where the LV lead is placed in the coronary
5 sinus.