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**IMPLANTABLE MEDICAL DEVICE ALLOWING AN ADJUSTMENT OF A
MAXIMUM SENSITIVITY OF A CHANNEL OF ITS DETECTION UNIT**

The present invention relates to an implantable medical device for stimulating a human or
10 animal heart according to the preamble of claim 1, to an arrangement comprising such
implantable medical device according to the preamble of claim 10, and to a method for
programming such an implantable medical device according to the preamble of claim 14.

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. It is also known to use conventional pacemakers for stimulating the His bundle,
i.e., for His bundle pacing (HBP).

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

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

In many cases, conventional pacemakers are used for His bundle pacing. In such a case, the
30 port to which the His bundle electrode is connected needs to be provided with specific
stimulation/sensing parameters in order to achieve an appropriate sensing of electric signals
at the His bundle and to allow a sufficient but still physiologic stimulation of the His bundle

in case His bundle pacing is applied. Thus, there are special requirements for the His channel of a detection unit of an implantable medical device. However, conventional pacemakers only allow conventional programming parameters of the available channels.

- 5 If a dual chamber or triple chamber pacemaker is used for His bundle pacing in an atrial-controlled stimulation mode, only a single highly sensitive input channel is available – namely the atrial channel. To achieve proper dual chamber timing, it is not possible to connect another electrode such as the His electrode to this channel. However, not only His-bundle specific signals are detectable at the His bundle, but also atrial and ventricular signals
10 due to far-field effects. Special requirements for the input channel of a His bundle electrode result from this complex signal and interference surroundings.

It is an object of the present invention to provide an implantable medical device that is intended to be used for His bundle pacing and that allows a reliable detection of His bundle
15 signals.

This object is achieved with an implantable medical device for stimulating a human or animal heart having the features of claim 1. Such a device comprises a first processor, a first memory unit, a stimulation unit, and a detection unit. The stimulation unit is designed and
20 arranged to stimulate a first cardiac region of a human or animal heart. The detection unit is designed and arranged to detect an electric signal at the first cardiac region of the same heart. On the one hand, the detection unit comprises an electrode lead having an electrode pole. On the other hand, the detection unit comprises a first channel for measuring electric signals provided by the electrode lead. Thus, if the electrode pole detects an electric signal, it
25 transmits this electric signal via the electrode lead to the first channel of the detection unit. Expressed in other words, the first channel serves for processing input signals provided by the electrode lead.

According to an aspect of the present invention, a maximum sensitivity of the first channel
30 of the detection unit is adjustable in dependence on a stimulation site of the electrode pole. In this context, the maximum sensitivity of the first channel lies within a range of from 0.1 mV to 0.4 mV, in particular from 0.15 mV to 0.35 mV, in particular of from 0.2 mV to 0.3

mV, if the electrode pole is intended to detect electric signals at a first stimulation site. In this context, the first stimulation site is the His bundle of the heart. Thus, if the first electrode is a His bundle electrode, the maximum sensitivity of the first channel lies within the precedingly mentioned range.

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Such a high sensitivity is typically not available for the first channel of the detection unit if the implantable medical device is operated in an atrial-controlled stimulation mode. Rather, in such a case only a ventricular channel of the detection unit is available, wherein such a ventricular channel typically has a maximum sensitivity which is not better than 0.5 mV.

10 With such a maximum sensitivity, however, it is not possible to reliably detect electric signals at the His bundle and to distinguish the detected signals from each other and correctly assign them to their physiologic source.

By making the maximum sensitivity adjustable in dependence on the kind of electrode being
15 connected to the detection unit and providing input signals to the first channel, this problem is solved in a very easy and elegant way. By applying a higher maximum sensitivity lying in a range of from 0.1 mV to 0.4 mV, His bundle signals and other electric signals detectable at the His bundle (such as atrial signals and ventricular signals) can be safely detected and reliably distinguished from each other.

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Due to the increased maximum sensitivity of the first channel serving as His bundle electrode channel, two highly sensitive channels are available in the implantable medical device in an embodiment, namely, an atrial channel and the first channel.

25 In an embodiment, the implantable medical device is an implantable pulse generator (IPG), an implantable cardioverter-defibrillator (ICD), or a device for cardiac resynchronization therapy (CRT).

In an embodiment, a sensitivity range of the first channel of the detection unit lies in a range
30 of from the maximum sensitivity of the first channel to a minimum sensitivity of the first channel. In this context, the minimum sensitivity of the first channel lies in a range of from 5.0 mV to 10.0 mV, in particular from 5.5 mV to 9.5 mV, in particular from 6.0 mV to 9.0

mV, in particular from 6.5 mV to 8.5 mV, in particular from 6.5 mV to 8.0 mV, in particular from 7.0 mV to 7.5 mV. Thus, it is possible to cover a sensitivity range of from 0.1 mV (maximum sensitivity) to 10.0 mV (minimum sensitivity) for the first channel. A particularly appropriate range is a sensitivity range of from 0.1 mV to 7.5 mV. Other ranges that can be
5 built up from the precedingly mentioned maximum sensitivity values and minimum sensitivity values are likewise appropriate.

In an embodiment, the sensitivity of the first channel of the detection unit is adjustable in steps of from 0.05 mV to 0.75 mV, in particular of from 0.1 mV to 0.7 mV, in particular of
10 from 0.15 mV to 0.65 mV, in particular of from 0.20 mV to 0.60 mV, in particular of from 0.25 mV to 0.55 mV, in particular of from 0.30 mV to 0.50 mV, in particular of from 0.35 mV to 0.45 mV, in particular of from 0.30 mV to 0.40 mV.

In an embodiment, the sensitivity of the first channel of the detection unit can be adjusted in
15 different steps depending on the sensitivity range considered. To be more precise, the sensitivity of the first channel is, in this embodiment, adjustable in first steps in a sensitivity range of from the maximum sensitivity of the first channel to a first intermediate sensitivity and in second steps in a sensitivity range of from the first intermediate sensitivity to a minimum sensitivity of the first channel. In this context, the first intermediate sensitivity lies
20 within a range of from 0.5 mV to 3.0 mV, in particular from 1.0 mV to 2.5 mV, in particular from 1.5 mV to 2.0 mV. The minimum sensitivity of the first channel lies within a range of from 5.0 mV to 10.0 mV, in particular from 5.5 mV to 9.5 mV, in particular from 6.0 mV to 9.0 mV, in particular from 6.5 mV to 8.5 mV, in particular from 6.5 mV to 8.0 mV, in particular from 7.0 mV to 7.5 mV. The first steps are smaller than the second steps and lie
25 within a range of from 0.05 mV to 0.4 mV, in particular from 0.1 mV to 0.35 mV, in particular of from 0.15 mV to 0.30 mV, in particular from 0.20 mV to 0.25 mV.

In this embodiment, it is possible to adjust the sensitivity in higher sensitivity ranges (corresponding to lower voltage values) in smaller or finer steps than in lower sensitivity
30 ranges (corresponding to higher voltage values). This facilitates fine-tuning the sensitivity of the first channel of the detection unit.

In an embodiment, the second steps lie in a range of from 0.4 mV to 0.75 mV, in particular of from 0.45 mV to 0.7 mV, in particular of from 0.50 mV to 0.65 mV, in particular of from 0.55 mV to 0.60 mV.

5 In an embodiment, the maximum sensitivity of the first channel lies within a range of from 0.5 mV to 4.0 mV, in particular from 1.0 mV to 3.5 mV, in particular from 1.5 mV to 3.0 mV, in particular from 2.0 mV to 2.5 mV, if the electrode pole is intended to detect electric signals at a second stimulation site. In this context, the second stimulation site is chosen from a right ventricle and a left ventricle of the heart. Ventricular electric signals can be typically
10 detected with a much lower sensitivity than atrial signals or His bundle signals. Therefore, it is possible to reduce the sensitivity of the first channel if only ventricular signals are to be detected. This results in less noise and interference signals being detected with the electrode when implanted in or at the right or left ventricle.

15 In an embodiment, the detection unit comprise a second electrode lead and a second channel for measuring an electric signal at an atrium of the heart. In this context, the electric signal is provided to the second channel by the second electrode lead. For this purpose, an electrode pole of the second electrode lead is implanted in an atrium of the heart. In this embodiment, a sensitivity range of the second channel of the detection unit lies within a range of from a
20 maximum sensitivity of the second channel to a minimum sensitivity of the second channel. For this purpose, the maximum sensitivity of the second channel lies within a range of from 0.1 mV to 1.0 mV, in particular from 0.2 mV to 0.9 mV, in particular from 0.3 mV to 0.8 mV, in particular from 0.4 mV to 0.7 mV, in particular from 0.5 mV to 0.6 mV. At the same time, the minimum sensitivity of the second channel lies within a range of from 1.5 mV to
25 5.0 mV, in particular from 2.0 mV to 4.5 mV, in particular from 2.5 mV to 4.0 mV, in particular from 3.0 mV to 3.5 mV.

Such a second channel serving as atrial channel is also a highly sensitive input channel of the detection unit. If a His bundle electrode is connected to an electrode port of the detection
30 unit, the implantable medical device comprises, in this embodiment, two highly sensitive input channels, namely a His bundle channel (first channel) and an atrial channel (second

channel). Then, the implantable medical device is particularly appropriate to be used in His bundle pacing under atrial control.

In an embodiment, the detection unit comprises a third electrode lead and a third channel for
5 measuring an electric signal at a right ventricle or a left ventricle of the heart with the third
electrode lead. For this purpose, an electrode pole of the third electrode lead is implanted in
or at the right ventricle or the left ventricle, in particular in an apical region of the right
ventricle or in the coronary system of the left ventricle. In this context, a sensitivity range of
the third channel of the detection unit lies within a range of from a maximum sensitivity of
10 the third channel to a minimum sensitivity of the third channel. For this purpose, the
maximum sensitivity of the third channel lies within a range of from 0.5 mV to 4.0 mV, in
particular from 1.0 mV to 3.5 mV, in particular from 1.5 mV to 3.0 mV, in particular from
2.0 mV to 2.5 mV. At the same time, the minimum sensitivity of the third channel lies within
a range of from 5.0 mV to 10.0 mV, in particular from 5.5 mV to 9.5 mV, in particular from
15 6.0 mV to 9.0 mV, in particular from 6.5 mV to 8.5 mV, in particular from 6.5 mV to 8.0
mV, in particular from 7.0 mV to 7.5 mV.

Such a third channel has a lower sensitivity than the first channel (if the first channel is
intended to receive His bundle input signals) and the second channel. However, such lower
20 sensitivity is fully sufficient to safely detect ventricular signals.

In an embodiment, the first memory unit comprises a first computer-readable program that
causes the first processor to perform the steps explained in the following when executed on
the first processor.

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First, a dataset indicating whether the electrode pole is intended to detect electric signals at
the first stimulation site (i.e. whether the electrode is to be used as His bundle electrode) or
at the second stimulation site (i.e., whether the electrode is to be used as ventricular
electrode) is retrieved or received. Retrieving such a dataset can be done by restoring it from
30 the second memory unit. Receiving such a dataset can be done by using a (wireless)
communication unit. The dataset may be received from a programming device.

Afterwards, the maximum sensitivity of the first channel is adjusted to a value lying within a range of from 0.1 mV to 0.4 mV, in particular from 0.15 mV to 0.35 mV, in particular of from 0.2 mV to 0.3 mV, if the electrode pole is intended to detect electric signals at the first stimulation site. In contrast, if the electrode pole is intended to detect electric signals at the
5 second stimulation site, the maximum sensitivity of the first channel is adjusted to a value lying in a range of from 0.5 mV to 4.0 mV, in particular from 1.0 mV to 3.5 mV, in particular from 1.5 mV to 3.0 mV, in particular from 2.0 mV to 2.5 mV. Thus, this embodiment allows an automatic adjustment of the maximum sensitivity of the first channel in dependence on the intended stimulation site of the electrode operatively coupled to the first channel of the
10 detection unit of the implantable medical device.

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

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In an embodiment, the programming device comprises a second processor and a second memory unit. In this context, the second memory unit comprises a second computer-readable program that causes the second processor to perform the step explained in the following when executed on the second processor.

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An adjustment of the maximum sensitivity of the first channel of the detection unit of the implantable medical device to a value lying within a range of from 0.1 mV to 0.4 mV, in particular from 0.15 mV to 0.35 mV, in particular of from 0.2 mV to 0.3 mV, is made possible if an electrode pole of an electrode of the detection unit is intended to detect electric
25 signals at a first stimulation site, the first stimulation site being the His bundle of the heart. Thus, if the electrode is intended to be used as His bundle electrode, the second computer-readable program serves for an automatic adjustment of the maximum sensitivity of the first channel of the detection unit to the precedingly mentioned values.

30 In an embodiment, the programming device comprises a second processor and a second memory unit, wherein the second memory unit comprises a second computer-readable

program that causes the second processor to perform the steps explained in the following when executed on the second processor.

First, a selection of one of at least two electrode lead configurations of the implantable medical device is made possible. In this context, the at least two electrode lead configurations comprise a first electrode lead configuration and a second electrode lead configuration. In the first electrode lead configuration, a detection unit of the implantable medical device comprises a His bundle electrode lead. Furthermore, a first channel of the detection unit serves for measuring electric signals provided by the His bundle electrode lead, i.e., the first channel serves for measuring electric signals detected at the His bundle. In the second lead configuration, the implantable medical device does not comprise a His bundle electrode lead. Rather, the first channel of the detection unit serves, in the second electrode lead configuration, for measuring electric signals provided by an electrode lead that is not a His bundle electrode lead. To give an example, the electrode lead can be used to detect ventricular signals, i.e. signals from a right ventricle or a left ventricle, e.g. from an apical region of the right ventricle.

If the first electrode lead configuration is selected, the maximum sensitivity of the first channel is set to a value lying within a range of from 0.1 mV to 0.4 mV, in particular from 0.15 mV to 0.35 mV, in particular of from 0.2 mV to 0.3 mV.

If the second electrode lead configurations are selected, the maximum sensitivity of the first channel is set to a value lying within a range of from 0.5 mV to 4.0 mV, in particular from 1.0 mV to 3.5 mV, in particular from 1.5 mV to 3.0 mV, in particular from 2.0 mV to 2.5 mV.

In an embodiment, the programming device comprises a second processor and a second memory unit, wherein the second memory unit comprises a second computer-readable program that causes the second processor to perform the steps explained in the following when executed on the second processor.

First, a selection of one of at least two electrode lead configurations of the implantable medical device is made possible. In this context, the at least two electrode lead configurations comprise a first electrode lead configuration and a second electrode lead configuration. In the first electrode lead configuration, a detection unit of the implantable medical device
5 comprises a His bundle electrode lead. Furthermore, a first channel of the detection unit serves for measuring electric signals provided by the His bundle electrode lead, i.e., the first channel serves for measuring electric signals detected at the His bundle. In the second lead configuration, the implantable medical device does not comprise a His bundle electrode lead. Rather, the first channel of the detection unit serves, in the second electrode lead
10 configuration, for measuring electric signals provided by an electrode lead that is not a His bundle electrode lead. To give an example, the electrode lead can be used to detect ventricular signals, i.e. signals from a right ventricle or a left ventricle, e.g. from an apical region of the right ventricle.

15 Afterwards, a dataset is transmitted from the programming device to the implantable medical device, wherein the dataset indicates whether the first electrode lead configuration or the second electrode lead configuration has been selected. In an embodiment, the implantable medical device can then use this dataset to automatically adjust the maximum sensitivity of the first channel of the detection unit, depending on whether the first channel serves as His
20 bundle electrode input channel or as ventricular electrode input channel.

In an aspect, the present invention relates to a method for programming an implantable medical device according to the preceding explanations with a programming device. In this context, the implantable medical device additionally comprises a first data communication
25 unit, and the programming device comprises a second data communication unit. The method comprises the steps explained in the following.

First, one of at least two electrode lead configurations of the implantable medical device is selected. In this context, the at least two electrode lead configurations comprise a first
30 electrode lead configuration and a second electrode lead configuration. In the first electrode lead configuration, a detection unit of the implantable medical device comprises a His bundle electrode lead. Furthermore, a first channel of the detection unit serves for measuring electric

signals provided by the His bundle electrode lead, i.e., the first channel serves for measuring electric signals detected at the His bundle. In the second lead configuration, the implantable medical device does not comprise a His bundle electrode lead. Rather, the first channel of the detection unit serves, in the second electrode lead configuration, for measuring electric signals provided by an electrode lead that is not a His bundle electrode lead. To give an example, the electrode lead can be used to detect ventricular signals, i.e. signals from a right ventricle or a left ventricle, e.g. from an apical region of the right ventricle.

After having made this selection, a dataset is generated with the programming device. This dataset comprises instructions for setting a maximum sensitivity of the first channel to a specific value. This value lies within a range of from 0.1 mV to 0.4 mV, in particular from 0.15 mV to 0.35 mV, in particular of from 0.2 mV to 0.3 mV, if the first electrode lead configuration has been selected. This value lies within in a range of from 0.5 mV to 4.0 mV, in particular from 1.0 mV to 3.5 mV, in particular from 1.5 mV to 3.0 mV, in particular from 2.0 mV to 2.5 mV, if the second electrode lead configuration has been selected.

Afterwards, this dataset is transmitted with the second data communication unit from the programming device to the implantable medical device. At the implantable medical device, the dataset is received with the first data communication unit.

Finally, the maximum sensitivity of the first channel of the detection unit is set by using the received dataset.

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

All embodiments of the implantable medical device can be combined in any desired way and can be transferred either individually or in any arbitrary combination to the described

arrangement, and to the described method. Furthermore, all embodiments described with respect to the arrangement can be combined in any desired way and can be transferred either individually or in any arbitrary combination to the described implantable medical device and to the described method. Likewise, all embodiments of the described method can be
5 combined in any desired way and can be transferred either individually or in any arbitrary combination to the implantable medical device and to the arrangement.

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

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

Figure 1 shows an arrangement of a pacemaker 1 serving as implantable medical device and a programming device 2. The pacemaker 1 comprises a port 3 serving as electrode lead port into which a His bundle electrode lead 4 is inserted. The His bundle electrode lead 4
15 comprises an electrode pole 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 the programming device 2. The programming device 2 and the pacemaker 1 are operatively
20 coupled to each other by a wireless radio communication 9. This wireless radio communication 9 is established by a first data communication unit in the programming device 2 and a second data communication unit in the pacemaker 1. Due to this wireless radio communication 9, it is possible to program the pacemaker 1 with the help of the
25 programming device 2.

For carrying out such programming, the programming device 2 first requests a selection between two electrode lead configurations. The first electrode lead configuration is an electrode lead configuration in which a His bundle electrode lead is present. The second
30 electrode lead configuration is a standard electrode lead configuration with an atrial electrode lead and a right ventricular electrode lead. In the present embodiment, the His bundle electrode 4 is connected to the electrode port 3 of the pacemaker 1 so that the first

electrode lead configuration is selected. This automatically results in setting a maximum sensitivity of an input channel of a detection unit of the pacemaker 1 to a value of 0.1 mV. Then, signals to be detected with the His bundle electrode lead 4 at the His bundle 6 can reliably be detected.