

Claims

1. An implantable system for stimulating a human heart or an animal heart, comprising a processor, a memory unit, a stimulation unit for stimulating a His bundle or another cardiac region of a human heart or an animal heart, a sensing unit for sensing an electrical signal of this heart, and a diagnostic unit for checking functional parameters of the implantable system,
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- characterized in that**
- the memory unit includes a computer-readable program, which prompts the processor to carry out the following steps when the program is being executed on the processor:
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- a) detecting, by means of the diagnostic unit, whether at least one malfunction state of the implantable system is present;

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 - b) checking (220) whether an electrode provided for stimulating a His bundle of a human heart or an animal heart is connected to the stimulation unit; and

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 - c) switching an operating state of the implantable system into a safety mode when a malfunction state was detected, the safety mode being selected at least from a first safety mode (230) and a second safety mode (240), wherein

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 - i) the first safety mode (230) is selected when the checking (220) carried out in step b) has shown that no electrode provided for stimulating a His bundle of a human heart or an animal heart is connected to the stimulation unit, the first safety mode (230) resulting in a first safety operation of the implantable system, in which the implantable system does not meet any specific requirements for His bundle pacing; and

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 - ii) the second safety mode (240) is selected when the checking (220) carried out in step b) has shown that an electrode provided for stimulating a His bundle of a human heart or an animal heart is connected to the

stimulation unit, the second safety mode (240) resulting in a second safety operation of the implantable system in which the implantable system is able to meet specific requirements for His bundle pacing.

- 5 2. The implantable system according to claim 1, **characterized in that** the pieces of information that are required for switching the system into the safety mode are stored in a non-volatile memory, a redundant memory or a recoverable memory of the implantable system.
- 10 3. The implantable system according to claim 1 or 2, **characterized in that** the checking (220) as to whether an electrode provided for stimulating a His bundle of a human heart or an animal heart is connected to the stimulation unit is carried out based on information stored in the memory unit.
- 15 4. The implantable system according to any one of the preceding claims, **characterized in that** the diagnostic unit is configured to detect the malfunction state based on at least one of the following events: a memory error, a software runtime error, a software status error, a detected cyberattack, a parameter error, an activation of a reset state of the implantable system, a battery drainage, and outside electromagnetic
20 interference of the implantable system.
- 25 5. An implantable system according to any one of the preceding claims, **characterized in that** the second safety operation is characterized by at least one of the following configurations: a His bundle pacing setting of an electrode terminal of the stimulation unit to which an electrode provided for stimulating a His bundle of a human heart or an animal heart is connected; a stimulation energy of a stimulation to be delivered by an electrode provided for stimulating a His bundle of a human heart or an animal heart; a sensing sensitivity of the sensing unit for sensing His bundle-specific signals; a stimulation operating mode of the implantable system; a
30 stimulation frequency of a stimulation to be delivered by an electrode provided for stimulating a His bundle of a human heart or an animal heart; and a His bundle

pacing setting of a second electrode terminal of the stimulation unit to which a second electrode for stimulating a human heart or an animal heart is connected.

6. An implantable system according to any one of the preceding claims, **characterized**
5 **in that** the program prompts the processor to additionally carry out the following step:
- a) switching an operating state of the implantable system into a protective mode
10 when the protective mode was activated by an external signal, the protective mode being selected at least from a first and a second protective mode, wherein
- i) the first protective mode is selected when the checking (220) carried out
15 in step b) has shown that no electrode provided for stimulating a His bundle of a human heart or an animal heart is connected to the stimulation unit, the first protective mode resulting in a first protective operation of the implantable system in which the implantable system does not meet any specific requirements for His bundle pacing; and
- ii) the second protective mode is selected when the checking carried out in
20 step b) has shown that an electrode provided for stimulating a His bundle of a human heart or an animal heart is connected to the stimulation unit, the second protective mode resulting in a second protective operation of the implantable system in which the implantable system is able to meet specific requirements for His bundle pacing.
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7. An implantable system according to any one of the preceding claims, **characterized**
30 **in that** the second safety operation is characterized by at least one of the following configurations: a His bundle pacing setting of an electrode terminal of the stimulation unit to which an electrode provided for stimulating a His bundle of a human heart or an animal heart is connected; a stimulation energy of a stimulation to be delivered by an electrode provided for stimulating a His bundle of a human heart or an animal heart; a sensing sensitivity of the sensing unit for sensing His bundle-

specific signals; a stimulation operating mode of the implantable system; a stimulation frequency of a stimulation to be delivered by an electrode provided for stimulating a His bundle of a human heart or an animal heart; and a His bundle pacing setting of an additional electrode terminal of the stimulation unit to which an electrode provided for stimulating a His bundle of a human heart or an animal heart is connected.

8. The implantable system according to any one of the preceding claims, **characterized in that** the program prompts the processor to establish or individually adapt the configuration of the second safety operation as a function of settable programming parameters.

9. The implantable system according to any one of claims 1 to 7, **characterized in that** the program prompts the processor to automatically determine the configuration of the second safety operation as a function of pieces of information stored in the implantable system.

10. The implantable system according to any one of the preceding claims, **characterized in that** the implantable system comprises a data remote transmission unit, the program prompting the processor to transmit an activation of the safety mode to a remote monitoring system by means of the data remote transmission unit.

11. A method for controlling the operation of an implantable system for stimulating a human heart or an animal heart according to any one of the preceding claims, **characterized by** the following steps:

a) detecting, by means of a diagnostic unit for checking functional parameters of the implantable system, whether at least one malfunction state of the implantable system is present;

b) checking (220) whether an electrode provided for stimulating a His bundle of a human heart or an animal heart is connected to a stimulation unit for

stimulating a His bundle or a similar cardiac region of a human heart or an animal heart; and

5 c) switching an operating state of the implantable system into a safety mode when a malfunction state was detected, the safety mode being selected at least from a first safety mode (230) and a second safety mode (240), wherein

10 i) the first safety mode (230) is selected when the checking (220) carried out in step b) has shown that no electrode provided for stimulating a His bundle of a human heart or an animal heart is connected to the stimulation unit, the first safety mode (230) resulting in a first safety operation of the implantable system in which the implantable system does not meet any specific requirements for His bundle pacing; and

15 ii) the second safety mode (240) is selected when the checking (220) carried out in step b) has shown that an electrode provided for stimulating a His bundle of a human heart or an animal heart is connected to the stimulation unit, the second safety mode (240) resulting in a second safety operation of the implantable system in which the implantable
20 system is able to meet specific requirements for His bundle pacing.

12. A computer program product including computer-readable code, which prompts a processor to carry out the following steps when the code is being executed on the processor:

25 a) detecting, by means of a diagnostic unit for checking functional parameters of an implantable system for stimulating a human heart or an animal heart, whether at least one malfunction state of the implantable system is present;

30 b) checking (220) whether an electrode provided for stimulating a His bundle of a human heart or an animal heart is connected to a stimulation unit for

stimulating a His bundle or a similar cardiac region of a human heart or an animal heart; and

5 c) switching an operating state of the implantable system into a safety mode when a malfunction state was detected, the safety mode being selected at least from a first safety mode (230) and a second safety mode (240), wherein

10 i) the first safety mode (230) is selected when the checking (220) carried out in step b) has shown that no electrode provided for stimulating a His bundle of a human heart or an animal heart is connected to the stimulation unit, the first safety mode (230) resulting in a first safety operation of the implantable system in which the implantable system does not meet any specific requirements for His bundle pacing; and

15 ii) the second safety mode (240) is selected when the checking (220) carried out in step b) has shown that an electrode provided for stimulating a His bundle of a human heart or an animal heart is connected to the stimulation unit, the second safety mode (240) resulting in a second safety operation of the implantable system in which the implantable
20 system is able to meet specific requirements for His bundle pacing.

13. A method for treating a human patient or an animal patient requiring such treatment by means of an implantable system for stimulating a human heart or an animal heart, the implantable system comprising a stimulation unit for stimulating a His bundle or
25 another cardiac region of a human heart or an animal heart, a sensing unit for sensing an electrical signal of this heart, and a diagnostic unit for checking functional parameters of the implantable system, the method comprising the following steps:

30 a) detecting, by means of the diagnostic unit, whether at least one malfunction state of the implantable system is present;

- b) checking (220) whether an electrode provided for stimulating a His bundle of a human heart or an animal heart is connected to the stimulation unit; and
- c) switching an operating state of the implantable system into a safety mode when a malfunction state was detected, the safety mode being selected at least from a first safety mode (230) and a second safety mode (240), wherein
 - i) the first safety mode (230) is selected when the checking (220) carried out in step b) has shown that no electrode provided for stimulating a His bundle of a human heart or an animal heart is connected to the stimulation unit, the first safety mode (230) resulting in a first safety operation of the implantable system in which the implantable system does not meet any specific requirements for His bundle pacing; and
 - ii) the second safety mode (240) is selected when the checking (220) carried out in step b) has shown that an electrode provided for stimulating a His bundle of a human heart or an animal heart is connected to the stimulation unit, the second safety mode (240) resulting in a second safety operation of the implantable system in which the implantable system is able to meet specific requirements for His bundle pacing,
- d) carrying out a stimulation of the human or animal heart in the safety operation of the implantable system specified by the selected safety mode.