Active medical device capable of identifying coughing

The present invention relates to an active medical device according to the preamble of claim 1, to an arrangement comprising such an active medical device according to the preamble of claim 9, and to a computer program product according to the preamble of claim 12.

Coughing is early indicator for infection, e.g., for a viral infection such as influenza or COVID-19.

US 2004/0133079 A1 describes the general possibility to use transthoracic impedance variation patterns or acceleration data for identifying an occurrence of a disease like asthma or COPD.

US 2020/0038660 A1 discloses detecting of coughing or other body reactions as side effect of an action potential evoked by a cardiac implant. Furthermore, this patent application discloses the possibility to postpone or adjust the application of action potentials in reaction to detected coughing.

However, it turned out that simply relying on bare data provided by acceleration sensors or transthoracic impedance sensors does not always allow detection of coughing with a sufficient sensitivity and/or specificity.

One or more examples may provide a possibility to automatically detect coughing of a patient with a higher reliability than according to prior art techniques.

According to one aspect there may be provided an active medical device having the claim elements of claim 1.

An “active medical device” is typically defined to be any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity.

The presently claimed active medical device comprises a processor, a memory unit, and at least one of an accelerometer (i.e., a device for detecting an acceleration) and a detection unit configured to detect a body impedance.

According to aspect, the memory unit comprises a computer-readable program that causes the processor to perform the steps explained in the following when executed on the processor.

In a first step, a body impedance of a patient is measured with the detection unit during a first period of time. As a result, time-dependent impedance data is obtained. This time-dependent impedance data is used to calculate a power spectral density of the impedance data. The power spectral density (PSD) describes how the power of a signal or a time series is distributed over frequency. The power spectral density is sometimes also referred to as power spectrum.

Alternatively or additionally to the precedingly explained step, an acceleration of the body of the patient is measured with the accelerometer during the first period of time. As a result, time-dependent acceleration data is obtained. This acceleration data is then used for calculating a power spectral density of the acceleration data. Thus, either a single power spectral density or two different power spectral densities are calculated.

Subsequently, a coughing (or a coughing event) of the patient is identified on the basis of the calculated power spectral density. To be more precise, a coughing of the patient is identified if at least 1%, in particular at least 2%, in particular at least 3%, in particular at least 4%, in particular at least 5%, in particular at least 6%, in particular at least 7%, in particular at least 8%, in particular at least 9%, in particular at least 10%, in particular at least 15%, in particular at least 20%, in particular at least 25%, in particular at least 30%, in

particular at least 40%, in particular at least 50% of all values of the power spectral density have a frequency of at least 1 Hz, in particular of at least 1.5 Hz, in particular at least 2 Hz, in particular at least 2.5 Hz, in particular at least 3 Hz.

According to a particular embodiment, coughing of the patient is identified if the relative power in a frequency band above 1Hz is at least 60% of the total power in the PSD.

In case of natural respiration, typically more than 80% of the total power in the power spectral density of acceleration data or impedance data of a patient lies within frequencies less than 1 Hz. Therewith, the power spectral density constitutes a powerful tool in distinguishing natural respiration from coughing events. In contrast, by simply evaluating the bare acceleration or the bare impedance data, it is often difficult to distinguish a coughing event from the natural respiration since the acceleration changes or impedance changes are rather moderate. Furthermore, it is necessary to define a distinct threshold for acceleration change and a distinct threshold for impedance change to make a distinction between natural respiration and coughing. In contrast, by using the power spectral density, the same threshold values can be used for the obtained impedance data and the obtained acceleration data since the frequency domain of this data is evaluated. This facilitates data evaluation, reduces the risk of erroneously incorrect assigned or interpreted data and makes an automatic coughing detection much more reliable than this was possible by applying prior art techniques. The power spectral density can thus be seen as a universal tool making it possible to evaluate different kinds of data (namely, acceleration data and impedance data) in the same way for an automatic coughing detection.

In an embodiment, the power spectral density at a frequency k for a discrete-time acceleration or impedance signal x(n) is calculated according to the following equation:

$$P(k) = \frac{|X(k)|^2}{f_s N}$$

where X(k) is the discrete fourier transform (DFT) of the signal x(n), f_s is the sampling frequency of the signal x(n), and N is the number of samples in x(n). Given a frequency

range of interest 0Hz to f_b Hz (where $f_b < f_s/2$), the relative power in a subset of that band [f_l Hz to f_h Hz] is then given by:

$$\frac{\sum_{k=f_l}^{f_h} P(k)}{\sum_{k=0}^{f_b} P(k)}$$

In an embodiment, the relative power in the subset frequency band above 1 Hz lies in a range between f_l = 1 Hz and f_h = 8 Hz, in particular between 1.5 Hz and 12.5 Hz, in particular between 2 Hz and 10 Hz, in particular between 2.5 Hz and 9 Hz, in particular between 3 Hz and 8 Hz (including the upper and lower limit in each case). Thus coughing is identified if:

$$\frac{\sum_{k=1Hz}^{8Hz} P(k)}{\sum_{k=0Hz}^{8Hz} P(k)} > 0.6$$

In an embodiment, the first period of time is a time period lying in a range of from 10 seconds to 1 day, in particular from 15 seconds to 23 hours, in particular from 20 seconds to 22 hours, in particular from 30 seconds to 21 hours, in particular from 45 seconds to 20 hours, in particular from 1 minute to 19 hours, in particular from 2 minutes to 18 hours, in particular from 3 minutes to 17 hours, in particular from 4 minutes to 16 hours, in particular from 5 minutes to 15 hours, in particular from 6 minutes to 14 hours, in particular from 10 minutes to 13 hours, in particular from 15 minutes to 12 hours, in particular from 30 minutes to 11 hours, in particular from 45 minutes to 10 hours, in particular from 1 hour to 9 hours, in particular from 2 hours to 8 hours, in particular from 3 hours to 7 hours, in particular from 4 hours to 6 hours.

In an embodiment, the active medical device is a wearable device. Thus, in this embodiment, the active medical device can be worn by patient on the body. This makes an application of the active medical device particularly simple. An appropriate wearable device is a wearable device in form of a wristband or in form of a chest band. In an embodiment, the active medical device is realized in form of a smartwatch.

In an embodiment, the active medical device is an active implantable medical device. An "active implantable medical device" is typically defined to be any active medical device

which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.

Further details on active implantable medical implants can be found, e.g., in the consolidated text of the Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices with subsequent amendments in the version published on 11 October 2007. The consolidated text of this Council Directive is freely accessible under the following link: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01990L0385-20071011

In an embodiment, the active implantable medical device is an implantable pulse generator (IPG), an implantable cardioverter-defibrillator (ICD), a device for cardiac resynchronization therapy (CRT), or an implantable cardiac monitor. An appropriate cardiac monitor is a loop recorder.

The detection unit configured to detect the body impedance typically comprises at least two electrodes between which an impedance is measured. In some instances, a housing of the active medical device can be used as one of these electrodes. In an embodiment, the detection unit is configured to detect a transthoracic body impedance. The transthoracic impedance is particularly responsive to sudden movements of the thorax of the patient, such as in case of a coughing event.

In an embodiment, the computer-readable program causes the processor to additionally detect a position of the patient relative to a ground and/or an activity status of the patient. For this purpose, the accelerometer is used. In an embodiment, the accelerometer is a 3-axis accelerometer. Such a 3-axis accelerometer makes it particularly easy to measure patient activity and/or patient position.

In an embodiment, the computer-readable program causes the processor to indicate a validity (i.e., a reliability) of the identification of coughing on the basis of the detected position and/or the detected activity status of the patient. An appropriate activity status is “active” (as in case

of walking, running or moving otherwise), “non-active” (as in case of resting or sitting calmly) or “in between” (as in case of an activity status lying between “active” and “non-active”). To give an example, if the position of the patient was identified to be supine and the activity status of the patient was identified to be “non-active”, then signals in the power spectral density having a frequency of more than 1 Hz are particularly specific for a coughing event since no other physiologic movements of the thorax of the patient with such a frequency are to be expected in such a position and such an activity status. Thus, in such a case, the validity value assigned to the identified coughing event is high to indicate a high reliability of the identification of the coughing.

In an embodiment, the computer-readable program causes the processor to identify an amount (e.g., a number) of identified coughing events of the patient. This amount of identified coughing events can be stored in the active medical device and can be reported immediately or with a temporal postponement to an external server such as a cloud computing device. The amount of identified coughing events is, in an embodiment, referred to a specific timeframe, such as the first time period. To give an example, the amount of identified coughing events per day can be stored within the active medical device or can be transferred to an external computing device so that medical staff such as a physician can further review and evaluate the data afterwards.

In an embodiment, the computer-readable program causes the processor to create an alert if the amount of identified coughing events of the patient, in particular of identified coughing events per time period, exceeds a predetermined threshold. Such an alert can be used to indicate that an infection of the patient is likely. This can be used as an indication that the patient is suffering from a disease such as a viral disease like influenza or COVID-19. A physician can then decide on necessary clinical or pandemic measures, in particular after having further examined the patient and after having made a diagnosis of a specific disease or a prognosis on the likelihood that the patient suffers from a specific disease. Alternatively, the alert on a suspected coughing-related infection (e.g., a potential influenza infection or a potential COVID-19 infection) can be automatically processed and communicated to the patient.

In an embodiment, the threshold lies in a range of from 1 cough per minute to 5 coughs per 10 seconds, in particular from 2 coughs per minute to 4 coughs per 10 seconds, in particular from 3 coughs per minute to 3 coughs per 10 seconds, in particular from 4 coughs per minute to 2 coughs per 10 seconds, in particular from 5 coughs per minute to 1 cough per 10 seconds.

An aspect relates to an arrangement comprising an active medical device, in particular an active medical device according to the preceding explanations, and an evaluation unit separate from the active medical device. In this context, the active medical device comprises a first processor, a first memory unit, at least one of an accelerometer and a detection unit configured to detect body impedance, and a data communication unit.

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.

First, a body impedance of a patient is measured with the detecting unit during the first period of time. In doing so, time-dependent impedance data is obtained.

Alternatively or additionally to the step of measuring a body impedance, an acceleration of the body of the patient is measured during the first period of time to obtain time-dependent acceleration data.

The impedance data and/or the acceleration data is then transmitted via the data communication unit to the evaluation unit located outside a body of the patient.

The evaluation unit 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 steps explained the following when executed on the second processor.

First, the transmitted impedance data and/or the transmitted acceleration data (depending on which kind of data has been transmitted to the evaluation unit) is stored in the second memory unit.

Afterwards, a power spectral density of the impedance data and/or a power spectral density of the acceleration data (depending on which kind of data has been transmitted to the evaluation unit and stored in the second memory unit) is calculated.

Afterwards, a coughing of the patient is automatically identified on the basis of the calculated power spectral density. In this context, an event is considered to be coughing if at least 60% of the power in the power spectral density is contained in the frequency band of 1 to 8 Hz.

All embodiments explained above with respect to the memory unit and/or the processor can be transferred to the first memory unit or the first processor, respectively, and/or the second memory unit or the second processor, respectively, of the described arrangement.

In an embodiment, the data communication unit serves for transferring data to the evaluation unit 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.

An aspect relates to a computer program product comprising computer-readable code that causes a processor to perform the steps explained in the following when executed on the processor.

In a first step, a body impedance of a patient is measured with a detection unit of an active medical device during a first period of time. As a result, time-dependent impedance data is obtained. This time-dependent impedance data is used to calculate a power spectral density of the impedance data.

Alternatively or additionally to the precedingly explained step, an acceleration of the body of the patient is measured with an accelerometer of the active medical device during the first period of time. As a result, time-dependent acceleration data is obtained. This acceleration data is then used for calculating a power spectral density of the acceleration data. Thus, either a single power spectral density or two different power spectral densities are calculated.

Subsequently, a coughing (or a coughing event) of the patient is identified on the basis of the calculated power spectral density. To be more precise, a coughing of the patient is identified if at least 60% of the power in the power spectral density is contained in the frequency band of 1 to 8 Hz.

An aspect relates to a method for automatically detecting coughing of a patient. Thereby, the method comprises the steps explained in the following.

In a first step, a body impedance of a patient is measured with a detection unit of an active medical device during a first period of time. As a result, time-dependent impedance data is obtained. This time-dependent impedance data is used to calculate a power spectral density of the impedance data.

Alternatively or additionally to the precedingly explained step, an acceleration of the body of the patient is measured with an accelerometer of the active medical device during the first period of time. As a result, time-dependent acceleration data is obtained. This acceleration data is then used for calculating a power spectral density of the acceleration data. Thus, either a single power spectral density or two different power spectral densities are calculated.

Subsequently, a coughing (or a coughing event) of the patient is identified on the basis of the calculated power spectral density. To be more precise, a coughing of the patient is identified if at least 60% of the power in the power spectral density is contained in the frequency band of 1 to 8 Hz.

In an embodiment, the method comprises the step of indicating to the patient or to medical staff an increased risk of an infection, in particular of a viral infection such as an influenza

or COVID-19 infection if an amount of identified coughing events, in particular an amount of identified coughing events per time period, of the patient exceeds a predetermined threshold.

All embodiments of the described active medical device can be combined in any desired way and can be transferred either individually or in any arbitrary combination to the described arrangement, the described computer program product and the described method. Furthermore, all embodiments of the described arrangement can be combined in any desired way and can be transferred either individually or in any arbitrary combination to the active medical device, to the computer program product and to the described method. Likewise, all embodiments of the computer program product can be combined in any desired way and can be transferred either individually or in any arbitrary combination to the active medical device, to the arrangement and to the described method. Lastly, 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 active medical device, to the arrangement and to the computer program product.

Further details of aspects of the present invention will be explained in the following with respect to exemplary embodiments and accompanying Figures. In the Figures:

Fig. 1 shows an active medical device in accordance with the present invention implanted in a patient and worn by a patient and in communication with an external evaluation unit;

Fig. 2 shows a schematic view of an active medical device in accordance with the present invention;

Fig. 3 shows a schematic view of an evaluation unit in accordance with the present invention;

Fig. 4A shows time-dependent acceleration data of a patient having natural respiration;

Fig. 4B shows time-dependent impedance signals of a patient having natural respiration;

Fig. 5A shows time-dependent acceleration data of a coughing patient;

Fig. 5B shows time-dependent impedance signals of a coughing patient;

Fig. 6A shows the power spectral density of the acceleration signal of Figure 4A;

Fig. 6B shows the power spectral density of the impedance signal of Figure 4B;

Fig. 7A shows the power spectral density of the acceleration signal of Figure 5A; and

Fig. 7B shows the power spectral density of the impedance signal of Figure 5B.

Fig. 1 illustrates the active medical device 10A which is wearable by a patient 30, and the active medical device 10B implanted in a human patient 30 (although it could also be implanted in an animal) and attached to the heart 20. The heart 20 includes a right ventricle 21 and a right atrium 22 (and corresponding left ventricle and atrium – now shown). The active medical device 10A, 10B communicates with an evaluation unit 40 positioned outside the patient's body.

Fig. 2 illustrates the active medical device 10B attached to the heart 20 that serves for monitoring a human or animal heart 20. The active medical device 10B is connected to the heart 20 at tissue contacts, and comprises a processor 120, a memory unit 122, a detection unit 126, a data communication unit 128, and an accelerometer 132. The detection unit 126 serves for detecting an electrical signal of the heart 20 and measuring a body impedance. The accelerometer 132 serves for measuring an acceleration of the body of the patient 30.

According to an example, the memory unit 122 comprises a computer-readable program 130 that causes the processor 120 to perform the steps a) to c) of claim 1 or 9 executed on the

processor 120, wherein the computer-readable program 130 causes the processor 120 to identify coughing of the patient on the basis of the calculated power spectral density if at least 60% of the power in the power spectral density is contained in the frequency band of 1 to 8 Hz.

As shown in Fig. 3, the evaluation unit 40 comprises a second processor 420 and a second memory unit 422. In this context, the second memory unit 422 comprises a second computer-readable program 430 that causes the second processor 420 to perform the steps d) to f) of claim 9 executed on the second processor 420.

Figure 4A shows an acceleration measured by an active medical device over time during a patient's natural respiration. A low amplitude, low-frequency periodic waveform can be observed. A similar signal yet on a different scale and somewhat less pronounced can be observed in case of a transthoracic impedance measured by an active medical device over time (cf. Figure 4B).

In contrast, coughing of the patient leads to more or less regularly distributed spikes both in the acceleration signal (Figure 5A) and in the impedance signal (Figure 5B). Both the acceleration signal of Figure 5A and the impedance signal of Figure 5B relates to five coughs of the patient. It can be easily seen from Figures 5A and 5B that not all of these coughs are equally pronounced. Thus, while individual spikes might be correctly assigned to coughs, this is not true with respect to other spikes, e.g., the signal at approximately 13 seconds in Figure 5A. Thus, the "disturbances" observed in the acceleration signal and the impedance signal are difficult to evaluate and to be correctly assigned to coughing events.

When looking at the power spectral densities (or shortly power spectra) of Figures 6A to 7B, the situation changes. Here, the power spectrum of the acceleration signal of the patient's natural respiration depicted in Figure 6A and the power spectrum of the impedance signal of the patient's natural respiration depicted in Figure 6B basically only contain signals having a frequency below 1 Hz. This threshold is valid both for the acceleration signal and the impedance signal, even though the bare signals are measured on a totally different scale. In

this particular example, the relative power in the frequency band from 1Hz to 8Hz in Figure 6A is only 9%.

In contrast, the power spectrum of the acceleration data of the coughing patient (Figure 7A) and the power spectrum of the impedance signal of the coughing patient (Figure 7B) show a huge amount of signals having a frequency of more than 1 Hz, namely of between 1 Hz and 8 Hz. This high-frequency content in the power spectra of the acceleration data and the impedance data is used for identifying coughing of the patient and represents a much more reliable measure of such coughing than relying on the bare acceleration and impedance data depicted in Figures 5A to 5B. In this particular example, the relative power in the frequency band from 1Hz to 8Hz in Figure 7A is 80%, well above the 60% threshold proposed to identify coughing.

Claims

1. An active medical device, comprising a processor, a memory unit, and at least one of an accelerometer and a detection unit configured to detect a body impedance,
wherein the memory unit comprises a computer-readable program that causes the processor to perform the following steps when executed on the processor:
   a) measuring a body impedance of a patient with the detection unit during a first period of time to obtain time-dependent impedance data and calculating a power spectral density of the impedance data;
   b) alternatively or additionally to step a), measuring an acceleration of a body of the patient with the accelerometer during the first period of time to obtain time-dependent acceleration data and calculating a power spectral density of the acceleration data;
   c) identifying coughing of the patient on the basis of the calculated power spectral density, if at least 1% of all values of the power spectral density have a frequency of at least 1 Hz;

   wherein the computer-readable program is configured to cause the processor to identify coughing of the patient on the basis of the calculated power spectral density if at least 60% of the power in the power spectral density is contained in the frequency band of 1 to 8 Hz.

2. The active medical device according to claim 1, wherein the active medical device is a wearable device or an active implantable medical device.

3. The active medical device according to claim 1 or 2, wherein the active medical device is an implantable pulse generator, an implantable cardioverter-defibrillator, a cardiac resynchronization therapy device, or an implantable cardiac monitor.

4. The active medical device according to any of the preceding claims, wherein the detection unit is configured to detect a transthoracic body impedance.

5. The active medical device according to any of the preceding claims, wherein the computer-readable program is configured to cause the processor to additionally detect at least one of a position of the patient relative to a ground and an activity status of the patient with the accelerometer.

6. The active medical device according to claim 5, wherein the computer-readable program is configured to cause the processor to indicate a validity of the identification of coughing on the basis of at least one of the detected position and the detected activity status of the patient.

7. The active medical device according to any of the preceding claims, wherein the computer-readable program is configured to cause the processor to identify an amount of identified coughing events of the patient.

8. The active medical device according to claim 7, wherein the computer-readable program is configured to cause the processor to create an alert if the amount of identified coughing events of the patient exceeds a predetermined threshold.

9. An arrangement, comprising an active medical device and an evaluation unit separate from the active medical device, wherein the active medical device comprises a first processor, a first memory unit, at least one of an accelerometer and a detection unit configured to detect a body impedance, and a data communication unit,
wherein the first memory unit comprises a first computer-readable program configured to cause the first processor to perform the following steps when executed on the first processor:
   a) measuring a body impedance of a patient with the detection unit during a first period of time to obtain time-dependent impedance data;
   b) alternatively or additionally to step a), measuring an acceleration of a body of the patient during the first period of time to obtain time-dependent acceleration data;

c) transmitting impedance data obtained in step a) and/or acceleration data obtained in step b) via the data communication unit to the evaluation unit located outside a body of the patient;

wherein the first computer-readable program causes the first processor to identify coughing of the patient on the basis of the calculated power spectral density if at least 60% of the power in the power spectral density is contained in the frequency band of 1 to 8 Hz;

and wherein the evaluation unit 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 following steps when executed on the second processor:

d) storing the transmitted impedance data and/or the transmitted acceleration data in the second memory unit;

e) calculating a power spectral density of the impedance data and/or calculating a power spectral density of the acceleration data;

f) identifying coughing of the patient on the basis of the calculated power spectral density if at least 1% of all values of the power spectral density have a frequency of at least 1 Hz.

10. The arrangement according to claim 9, wherein the data communication unit is configured to transfer data to the evaluation unit via a wireless data communication.

11. The arrangement according to claim 10, wherein the wireless data communication is configured to use a standard data transmission protocol or specification, a Medical Device Radiocommunications Service(MICS), a Bluetooth Low Energy (BLE) protocol or a Zigbee specification.

12. A computer program product comprising computer-readable code configured to cause a processor to perform the following steps when executed on the processor:

a) determining a body impedance of a patient with a detection unit of an active medical device during a first period of time to obtain time-dependent impedance data and calculating a power spectral density of the impedance data;

b) alternatively or additionally to step a), determining an acceleration of a body of the patient with an accelerometer of the active medical device during the first period of time to obtain time-dependent acceleration data and calculating a power spectral density of the acceleration data;

c) identifying coughing of the patient on the basis of the calculated power spectral density if at least 1% of all values of the power spectral density have a frequency of at least 1 Hz;

wherein the computer-readable code causes a processor to identify coughing of the patient on the basis of the determined power spectral density if at least 60% of the power in the power spectral density is contained in the frequency band of 1 to 8 Hz.