# PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

**PCT**

To:
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## INVITATION TO PAY ADDITIONAL FEES AND, WHERE APPLICABLE, PROTEST FEE

(PCT Article 17(3)(a) and Rule 40.1 and 40.2(e))

| | |
|---|---|
| | Date of mailing *(day/month/year)*: 4 March 2020 (04-03-2020) |
| Applicant's or agent's file reference | **PAYMENT DUE** within **ONE MONTH** from the above date of mailing |
| International application No.: PCT/US2019/064653 | International filing date *(day/month/year)*: 5 December 2019 (05-12-2019) |
| Applicant: MEDTRONIC, INC. | |

1. This International Searching Authority

(i) considers that there are 7 *(number of)* inventions claimed in the international application covered by the claims indicated on an extra sheet:

(ii) therefore considers that **the international application does not comply with the requirements of unity of invention** (Rules 13.1, 13.2 and 13.3) for the reasons indicated on an extra sheet:

(iii) [X] has carried out a partial international search (see Annex) [ ] will establish the international search report on those parts of the international application which relate to the invention first mentioned in claims Nos.:

see extra sheet

(iv) will establish the international search report on the other parts of the international application only if, and to the extent to which, additional fees are paid.

2. Consequently, the applicant is hereby **invited to pay,** within the time limit indicated above, the amount indicated below:

| EUR 1.775,00 | x | 6 | = | EUR 10.650,00 |
|---|---|---|---|---|
| Fee per additional invention | | number of additional inventions | | currency/total amount of additional fees |

3. The applicant is informed that, according to Rule 40.2(c), **the payment of any additional fee may be made under protest,** i.e., a reasoned statement to the effect that the international application complies with the requirement of unity of invention or that the amount of the required additional fee is excessive, where applicable, subject to the payment of a protest fee.

Where the applicant pays additional fees under protest, the applicant is hereby invited, within the time limit indicated above, to pay a protest fee (Rule 40.2(e)) in the amount of EUR 875,00 *(currency/amount)*

Where the applicant has not, within the time limit indicated above, paid the required protest fee, the protest will be considered not to have been made and the International Searching Authority will so declare.

4. [ ] Claim(s) Nos. _____ have been found to be unsearchable under Article 17(2)(b) because of defects under Article 17(2)(a) and therefore have not been included with any invention.

| Name and mailing address of the International Searching Authority | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL-2280 HV Rijswijk<br>Tel. (+31-70) 340-2040<br>Fax: (+31-70) 340-3016 | BößWETTER, Ruth<br>Tel: +49 (0)89 2399-4162 |

Form PCT/ISA/206 (April 2005)

Registered Mail

INVITATION TO PAY ADDITIONAL FEES

International application No.
PCT/US2019/064653

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-3, 16, 20

A pacemaker configured to determine a median or a distribution of the determined features and to set the atrial event sensing parameter based on the median or a percentile of the distribution.

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2. claim: 4

A pacemaker configured to set a non-atrial tracking pacing mode prior to identifying the plurality of ventricular electrical events and to sense the atrial systolic event from the motion signal during an subsequent atrial tracking pacing mode using the atrial event sensing parameter set in the non-atrial tracking pacing mode.

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3. claim: 5

A pacemaker configured to determine the feature of the motion signal by determining a maximum amplitude of each one of a plurality of vector signals of an multi-axismotion sensor.

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4. claims: 6-9

A pacemaker configured to determine the feature of the motion signal by determining a latest crossing time of a first threshold amplitude by the motion signal during each of the sensing windows.

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5. claims: 10-15

A pacemaker configured to set a passive ventricular filling window following each of the plurality of ventricular electrical events.

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6. claim: 17

A pacemaker configured to start the determination of the feature of the motion signal during each of the sensing windows after a time delay after receiving a communication signal from another medical device.

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7. claims: 18, 19

A pacemaker configured to abort determination of the feature of the motion signal in response to detecting an abort condition.

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The prior art, which is represented by the disclosure of document US2018/0154154 (D1), discloses all the features of independent claim 1:

A pacemaker (D1, fig. 1,3; par. [0028]) comprising:
a pulse generator configured to generate pacing pulses (D1, fig. 3 (202); par. [0050], l. 1-3);
a sensing circuit comprising an R-wave detector for sensing R-waves from a cardiac electrical signal (D1, fig. 3 (204, 224); par. [0054], [0055]);
a motion sensor configured to produce a motion signal comprising an atrial event signal corresponding to an atrial systolic event (D1, fig. 3 (212); par. [0033], [0051]); and
a control circuit coupled to the motion sensor and the pulse generator and configured to (D1, fig. 3 (206); par. [0057]; par. [0063]):
identify a plurality of ventricular electrical events, wherein each of the plurality of ventricular electrical events is one of an R-wave sensed by the sensing circuit or a ventricular pacing pulse generated by the pulse generator (D1, fig. 5 (302); par. [0071], l. 11-16; par. [0072]; par. [0076], l. 5-8);
following each of the plurality of ventricular electrical events, set a sensing window (D1, par. [0055], l. 5-17; par. [0075]; par. [0077]);
determine a feature of the motion signal during each of the sensing windows (D1, par. [0075]; par. [0078], l. 5-9);
set an atrial event sensing parameter based on the determined features (D1, par. [0077], [0082]);
sense the atrial systolic event based on the atrial event sensing parameter (D1, fig. 5 (312, YES); par. [0079]); and
produce an atrial sensed event signal in response to sensing the atrial systolic event (D1, fig. 5 (YES, 314); par. [0080]).

Note, that document D1 also discloses the subject-matter of dependent claims 16 and 20 (see D1, in the references given above and par. [0080]; par. [0096], l. 1-5).

It follows that the following technical features of claims 2 or 3, 4, 5, 6, 10 or 14, 17 and 18 make a contribution over the prior art and can be considered as special technical features:

1. Claim 2 or 3:
Determination of a median or a distribution of the determined features and setting of the atrial event sensing parameter based on the median or a percentile of the distribution.

2. Claim 4:
Setting of a non-atrial tracking pacing mode prior to identifying the plurality of ventricular electrical events and sense the atrial systolic event from the motion signal during an subsequent atrial tracking pacing mode using the atrial event sensing parameter set in the non-atrial tracking pacing mode.

3. Claims 5:

Determination of the feature of the motion signal by determining a maximum amplitude of each one of a plurality of vector signals f an multi-axismotion sensor.

4. Claim 6:
Determination of the feature of the motion signal by determining a latest crossing time of a first threshold amplitude by the motion signal during each of the sensing windows.

5. Claim 10 or 14
Setting of a passive ventricular filling window following each of the plurality of ventricular electrical events.

6. Claim 17:
Starting the determining of the feature of the motion signal during each of the sensing windows after a time delay after receiving a communication signal from another medical device.

7. Claim 18:
Abort determining the feature of the motion signal in response to detecting an abort condition.

Obviously, claims 2 or 3, 4, 5, 6, 10 or 14, 17 and 18 do not share a common inventive concept and solve different problems:

1. How to reliably determine signal features.

2. How to determine initial atrial event sensing parameters.

3. How to select an optimal motion signal.

4. How to detect fusion of A4 events in the A3 window.

5. How to establish early and late A4 event sensing thresholds.

6. How to allow for external triggering of the feature determination.

7. How to react to unreliabilty of the feature detection due to patient activity or a worsened heart condition.

In conclusion, the groups of claims are not linked by common or corresponding special technical features and define seven different inventions not linked by a single general inventive concept. The application, hence does not meet the requirements of unity of invention as defined in Rules 13.1 and 13.2 PCT.

**Annex to Form PCT/ISA/206**
**COMMUNICATION RELATING TO THE RESULTS OF THE PARTIAL INTERNATIONAL SEARCH**

International Application No
PCT/US2019/064653

1. The present communication is an Annex to the invitation to pay additional fees (Form PCT/ISA/206). It shows the results of the international search established on the parts of the international application which relate to the invention first mentioned in claims Nos.:
see 'Invitation to pay additional fees'
2. This communication is not the international search report which will be established according to Article 18 and Rule 43.

3. If the applicant does not pay any additional search fees, the information appearing in this communication will be considered as the result of the international search and will be included as such in the international search report.

4. If the applicant pays additional fees, the international search report will contain both the information appearing in this communication and the results of the international search on other parts of the international application for which such fees will have been paid.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | US 2018/154154 A1 (SHELDON TODD J [US] ET AL) 7 June 2018 (2018-06-07) | 1,16,20 |
| Y | figures 1, 3, 5<br>paragraph [0028] - paragraph [0033]<br>paragraph [0050] - paragraph [0097] | 2,3 |
| Y | WO 2018/165289 A1 (CARDIAC PACEMAKERS INC [US]) 13 September 2018 (2018-09-13)<br>paragraph [0061] | 2,3 |
| A | US 2018/161580 A1 (DEMMER WADE M [US] ET AL) 14 June 2018 (2018-06-14)<br>the whole document | 1-3,16, 20 |

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family



Form PCT/ISA/206 (Annex, first sheet) (July 1992; reprint January 2004)

# Patent Family Annex

Information on patent family members

International Application No
PCT/US2019/064653

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| US 2018154154 A1 | 07-06-2018 | CN 110022933 A | 16-07-2019 |
| | | EP 3548141 A1 | 09-10-2019 |
| | | US 2018154154 A1 | 07-06-2018 |
| | | WO 2018102639 A1 | 07-06-2018 |
| WO 2018165289 A1 | 13-09-2018 | CN 110573068 A | 13-12-2019 |
| | | EP 3592220 A1 | 15-01-2020 |
| | | US 2018256059 A1 | 13-09-2018 |
| | | WO 2018165289 A1 | 13-09-2018 |
| US 2018161580 A1 | 14-06-2018 | CN 110072592 A | 30-07-2019 |
| | | EP 3554629 A1 | 23-10-2019 |
| | | US 2018161580 A1 | 14-06-2018 |
| | | US 2019308021 A1 | 10-10-2019 |
| | | WO 2018111993 A1 | 21-06-2018 |

Application no:
Demande nº:
Anmelde-Nr: PCT/US2019/064653

DISCLAIMER

The attached provisional opinion on the patentability of the first invention searched serves only as information.
A reply addressing the points raised in the opinion is **not** required and will **not** be taken into account when issuing the final search report and opinion on patentability.

AVERTISSEMENT

L'avis provisoire ci-joint sur la brevetabilité de la première invention recherchée ne sert qu'à titre d'information.
Une réponse abordant les points soulevés dans l'avis n'est **pas** nécessaire et ne sera **pas** prise en compte lors de l'établissement du rapport final de la recherche et de l'avis sur la brevetabilité.

DISCLAIMER

Die beigefügte vorläufige Stellungnahme zur Patentierbarkeit der ersten geprüften Erfindung dient lediglich zur Information.
Eine Antwort auf die erhobenen Punkte in der Stellungnahme ist **nicht** erforderlich und bleibt bei der Erstellung des endgültigen Recherchenberichts und der Stellungnahme zur Patentierbarkeit **unberücksichtigt**.

## Re Item IV

### Lack of unity of invention

This Authority considers that the application does not meet the requirements of unity of invention and that there are seven inventions covered by the claims indicated as follows:

1. Claims 2, 3; 1, 16 and 20

A pacemaker configured to determine a median or a distribution of the determined features and to set the atrial event sensing parameter based on the median or a percentile of the distribution.

2. Claim 4:

A pacemaker configured to set a non-atrial tracking pacing mode prior to identifying the plurality of ventricular electrical events and to sense the atrial systolic event from the motion signal during an subsequent atrial tracking pacing mode using the atrial event sensing parameter set in the non-atrial tracking pacing mode.

3. Claim 5:

A pacemaker configured to determine the feature of the motion signal by determining a maximum amplitude of each one of a plurality of vector signals of an multi-axismotion sensor.

4. Claims 6-9:

A pacemaker configured to determine the feature of the motion signal by determining a latest crossing time of a first threshold amplitude by the motion signal during each of the sensing windows.

5. Claims 10-15:

A pacemaker configured to set a passive ventricular filling window following each of the plurality of ventricular electrical events.

6. Claim 17:

A pacemaker configured to start the determination of the feature of the motion signal during each of the sensing windows after a time delay after receiving a communication signal from another medical device.

7. Claims 18 and 19:

A pacemaker configured to abort determination of the feature of the motion signal in response to detecting an abort condition.

The reasons for which the inventions are not so linked as to form a single general inventive concept, as required by Rule 13.1 PCT, are as follows:

The prior art, which is represented by the disclosure of document US2018/0154154 (D1), discloses all the features of independent claim 1:

A pacemaker (D1, fig. 1,3; par. [0028]) comprising:

a pulse generator configured to generate pacing pulses (D1, fig. 3 (202); par. [0050], l. 1-3);

a sensing circuit comprising an R-wave detector for sensing R-waves from a cardiac electrical signal (D1, fig. 3 (204, 224); par. [0054], [0055]);

a motion sensor configured to produce a motion signal comprising an atrial event signal corresponding to an atrial systolic event (D1, fig. 3 (212); par. [0033], [0051]); and

a control circuit coupled to the motion sensor and the pulse generator and configured to (D1, fig. 3 (206); par. [0057]; par. [0063]):

identify a plurality of ventricular electrical events, wherein each of the plurality of ventricular electrical events is one of an R-wave sensed by the sensing circuit or a ventricular pacing pulse generated by the pulse generator (D1, fig. 5 (302); par. [0071], l. 11-16; par. [0072]; par. [0076], l. 5-8);

following each of the plurality of ventricular electrical events, set a sensing window (D1, par. [0055], l. 5-17; par. [0075]; par. [0077]);

determine a feature of the motion signal during each of the sensing windows (D1, par. [0075]; par. [0078], l. 5-9);

set an atrial event sensing parameter based on the determined features (D1, par. [0077], [0082]);

sense the atrial systolic event based on the atrial event sensing parameter (D1, fig. 5 (312, YES); par. [0079]); and

produce an atrial sensed event signal in response to sensing the atrial systolic event (D1, fig. 5 (YES, 314); par. [0080]).

Note, that document D1 also discloses the subject-matter of dependent claims 16 and 20 (see D1, in the references given above and par. [0080]; par. [0096], l. 1-5).

It follows that the following technical features of claims 2 or 3, 4, 5, 6, 10 or 14, 17 and 18 make a contribution over the prior art and can be considered as special technical features:

1. Claim 2 or 3:

Determination of a median or a distribution of the determined features and setting of the atrial event sensing parameter based on the median or a percentile of the distribution.

2. Claim 4:

Setting of a non-atrial tracking pacing mode prior to identifying the plurality of ventricular electrical events and sense the atrial systolic event from the motion signal during an subsequent atrial tracking pacing mode using the atrial event sensing parameter set in the non-atrial tracking pacing mode.

3. Claims 5:

Determination of the feature of the motion signal by determining a maximum amplitude of each one of a plurality of vector signals f an multi-axismotion sensor.

4. Claim 6:

Determination of the feature of the motion signal by determining a latest crossing time of a first threshold amplitude by the motion signal during each of the sensing windows.

5. Claim 10 or 14

Setting of a passive ventricular filling window following each of the plurality of ventricular electrical events.

6. Claim 17:

Starting the determining of the feature of the motion signal during each of the sensing windows after a time delay after receiving a communication signal from another medical device.

7. Claim 18:

Abort determining the feature of the motion signal in response to detecting an abort condition.

Obviously, claims 2 or 3, 4, 5, 6, 10 or 14, 17 and 18 do not share a common inventive concept and solve different problems:

1. How to reliably determine signal features.

2. How to determine initial atrial event sensing parameters.

3. How to select an optimal motion signal.

4. How to detect fusion of A4 events in the A3 window.

5. How to establish early and late A4 event sensing thresholds.

6. How to allow for external triggering of the feature determination.

7. How to react to unreliabilty of the feature detection due to patient activity or a worsened heart condition.

In conclusion, the groups of claims are not linked by common or corresponding special technical features and define seven different inventions not linked by a single general inventive concept. The application, hence does not meet the requirements of unity of invention as defined in Rules 13.1 and 13.2 PCT.

According to Article 17(3) PCT, the search report has been established on the first invention mentioned in the claims.

## Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following documents:

| | |
|---|---|
| D1 | US 2018/154154 A1 (SHELDON TODD J [US] ET AL) 7 June 2018 (2018-06-07) |
| D2 | WO 2018/165289 A1 (CARDIAC PACEMAKERS INC [US]) 13 September 2018 (2018-09-13) |

1 First invention: Claims 1, 2, 3, 16 and 20

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1, 16 and 20 is not new in the sense of Article 33(2) PCT and the subject-matter of claim 2 does not involve an inventive step in the sense of Article 33(3) PCT.

1.1 Claims 1, 16 and 20

The subject-matter of claims 1, 16 and 20 is disclosed in document D1(see references given above).

1.2 Claims 2 and 3

D1 lacks to disclose that the pacemaker isconfigured to determine a median or a distribution of the determined features and to set the atrial event sensing parameter based on the median or a percentile of the distribution.

D1 already discusses the reliablity of determined atrial motion signal features in the context of an intraventricular pacemaker and the problem of the A4 fusing with the A3 event (D1, par. [0102], [0141], [0142]). For the skilled peson, it would consequently be obvious to search for alternative statistically sound decision criteria when evaluating a signal for cardiac depolarization events. Many standard solutions for reliably extracting cardiac depolarisation features from measurements over a plurality of cardiac cycles are well known in the prior art, as e.g. in document D2 (D2, par. [0061]) proposing inter alia the median and a percentle of a distribution of determined signal features. Consequently, the subject-matter of claims 2 and 3 lacks an inventive step in the sense of Article 33(3) PCT.

## Re Item VII

### Certain defects in the international application

1 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.

2 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

3 The independent claim is not in the two-part form in accordance with Rule 6.3(b) PCT.

4 The incorporation of documents by reference (see for example description, par. [0046], [0052], ) is not allowable in some of the Designated States.