

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**
(PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2004/012094

International filing date (day/month/year)
19.04.2004

Priority date (day/month/year)
25.04.2003

International Patent Classification (IPC) or both national classification and IPC
A61N1/37, A61B5/0452, A61B5/0472

Applicant
MEDTRONIC, INC.

1. This opinion contains indications relating to the following items:
 - Box No. I Basis of the opinion
 - Box No. II Priority
 - Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - Box No. IV Lack of unity of invention
 - Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - Box No. VI Certain documents cited
 - Box No. VII Certain defects in the international application
 - Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:

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Box No. 1 Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - a sequence listing
 - table(s) related to the sequence listing
 - b. format of material:
 - in written format
 - in computer readable form
 - c. time of filing/furnishing:
 - contained in the international application as filed.
 - filed together with the international application in computer readable form.
 - furnished subsequently to this Authority for the purposes of search.
3. In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. II Priority

1. The following document has not been furnished:

copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- the entire international application,
- claims Nos. 1-25

because:

- the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
- the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- no international search report has been established for the whole application or for said claims Nos. 1-25
- the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form has not been furnished
 - does not comply with the standard
 - the computer readable form has not been furnished
 - does not comply with the standard
- the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- See separate sheet for further details

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	26-54
Inventive step (IS)	Yes: Claims	
	No: Claims	26-54
Industrial applicability (IA)	Yes: Claims	26-54
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

No search report has been established for claims 1-25 since these claims relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Indeed, claim 1 involves the step of delivering a pacing pulse to a chamber of a heart, which is considered to pertain to a method of treatment of the human body by **therapy**. Further, this step involves the preliminary **surgical** step of implanting a pacemaker into the human body. Consequently, no opinion will be formulated with respect to the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Re Item V

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

1. Reference is made to the following documents:

- D1: US-A-6 029 087 (WOHLGEMUTH WERNER PETER) 22 February 2000
- D2: US 2001/049542 A1 (BRADLEY KERRY ET AL) 6 December 2001
- D3: US-A-5 431 693 (SCHROEPEL EDWARD A) 11 July 1995
- D4: US-B-6 477 4221 (SPLETT VINCENT E) 5 November 2002
- D5: US 2002/138111 A1 (SCHALDACH MAX ET AL) 26 September 2002

2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 26-31 and 52-54 is not new in the sense of Article 33(2) PCT.

2.1 Claims 26 and 54

Document **D1** (see in particular col. 6, l. 8- col. 8, l. 62) discloses an implantable medical device comprising:

- a sensor (DSP block 36) to sense a signal from within a chamber of a heart following delivery of a pacing pulse; and
- a processor (30, 65, 66, 68) to determine whether the pacing pulse captured the

chamber of the heart based one or more morphological characteristics of the sensed signal.

In **D1**, the device is microprocessor-based and thus **D1** also discloses a computer-readable medium as defined in claim 54, since these features correspond to those expressed in claim 26.

Further, **D2** (see in particular p. 3, [0028] + p. 8, [0091]-[0103] + figs. 2, 6) also shows an implantable medical device comprising:

- a sensor (A/D converter 90) to sense a signal from within a chamber of a heart following delivery of a pacing pulse; and
- a processor (morphology detector 64) to determine whether the pacing pulse captured the chamber of the heart based one or more morphological characteristics of the sensed signal.

Moreover, **D3** (col. 2, l. 44 - col. 3, l. 11 and figs. 1, 8, 9), **D4** (col. 11, l. 17 - col. 12, l. 40 and figs. 4-5) and **D5** (p. 4, [0051]-[0056] and figs. 1-3) all disclose an implantable medical device with a microprocessor-based capture verification using a morphological analysis of the sensed signal as defined in claims 1 and 54 of the present application.

2.1 Claims 27-29

The device of **D1** is further configured to measure the morphology characteristic and comprises a lead having a proximal end and a distal end, the lead having an electrode on the distal end, a pulse generator to generate a pacing pulse for delivery to a chamber of the heart via the electrode (see col. 4, l. 1-52 and fig. 1).

2.2 Claim 30-31.

The processor of **D2** is configured to process the sensed signal to identify the morphology characteristic, to compare the identified morphology characteristic to one or more morphology criteria, and to determine that the pacing pulse captured the chamber when the morphology characteristics satisfy the morphology criteria (see **D2**, p. 8, [0091]-[0103]). If the morphology characteristics do not satisfy the morphology criteria, the processor determines that the pacing pulse did not capture the chamber.

2.3 Claims 52-53

The device of **D1** (see fig. 2A) comprises a filter (65) to filter the sensed signal, an amplifier (62) to amplify the sensed signal and an A/D-converter (64) to convert the signal to a digital signal.

3. Dependent claims 32-51 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, since these features are either known from the available documents D1-D5 (Article 33 (2) PCT) or they become obvious over the combination thereof (Article 33 (3) PCT). Further, most of the features concern straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to perform a morphological analysis of a sensed heart signal (Article 33 (3) PCT).