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(54) Title: METHODS AND SYSTEMS FOR CONTROLLING BLOOD PRESSURE

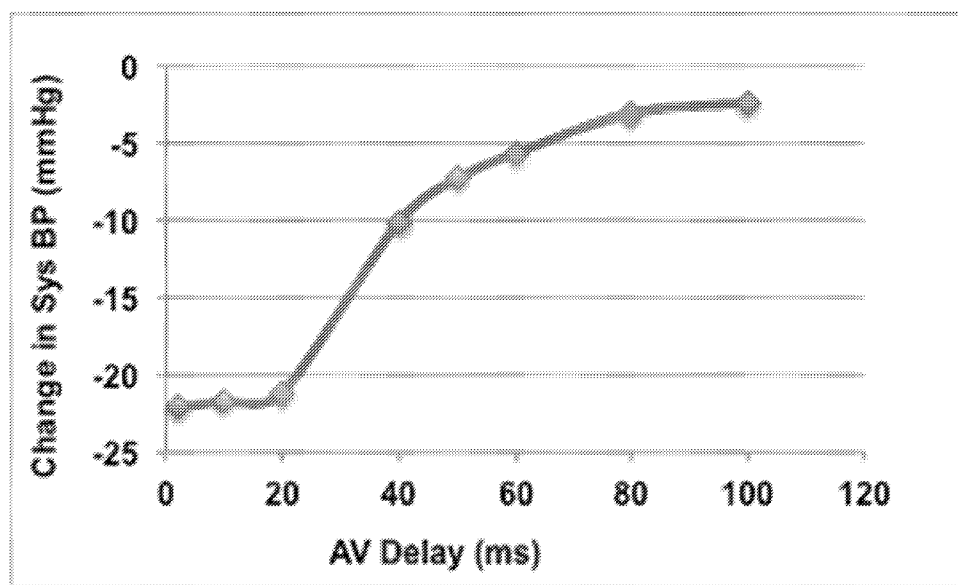


FIG. 24

(57) **Abstract:** Systems and methods for controlling blood pressure via electrical stimulation of the heart are disclosed. Embodiments may include at least two different stimulation patterns, each configured to reduce blood pressure to a different degree, and may alternate between stimulation patterns based on the need of a patient, for example, alternating between day and night or between periods of strenuous and light activity. Some embodiments may take advantage of a slow baroreflex response that occurs after treatment is stopped, suspending treatment for extended periods, and then resuming treatment before blood pressure levels reach pretreatment values. Embodiments may control blood pressure by controlling atrial pressure and atrial stretch.



KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US17/28715

A. CLASSIFICATION OF SUBJECT MATTER

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CPC - A61N1/05, 1/32, 1/36, 1/36117, 1/362, 1/365, 1/36514, 1/36564, 1/368, 1/3682

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- A	US 2015/0258342 A1 (MIKA, Y et al.) 17 September 2015; paragraphs [0007], [0069]-[0075], [0134], [0143], [0157], [0225]-[0229], [0280], [0292]-[0294], [0304], [0338], [0343], [0351]-[0358], [0361], [0392], [0398]; claims 1, 8, 9, 16, 41	1-9, 11-20, 22-34, 36 ----- 10, 21, 35, 39-45
A	US 2009/0118783 A1 (PATANGAY, A et al.) 7 May 2009; paragraph [0035]	10, 21
A	CHALIKI, HP et al.; "Pulmonary venous pressure: relationship to pulmonary artery, pulmonary wedge, and left atrial pressure in normal, lightly sedated dogs"; Catheterization and Cardiovascular Interventions; volume 56, issue 3; 17 June 2002; page 432, abstract	10, 21
A	US 2015/0360035 A1 (BACKBEAT MEDICAL, INC.) 17 December 2015; paragraph [0334]	35, 39-45
A	CA 2933278 A1 (BACKBEAT MEDICAL, INC.) 25 June 2015; paragraph [0011]	35, 39-45
A	US 2015/0335895 A1 (BACKBEAT MEDICAL, INC.); paragraphs [0010], [0182]-[0184], [0192]	1-36, 39-45
A	US 2005/0143785 A1 (LIBBUS, I) 30 June 2005; figure 7; paragraphs [0055], [0121]	1-36, 39-45

☐ Further documents are listed in the continuation of Box C.☐ See patent family 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 application or patent 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

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US17/28715

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Group I: Claims 1-36 and 39-45 are directed toward a system for reducing blood pressure in a patient, the system comprising a first stimulation pattern and a second stimulation, wherein the first reduction amount is greater than the second reduction amount, and wherein the second reduction amount is greater than zero.

Group II: Claims 37 and 38 are directed toward a method for delivering a blood pressure reducing electrical stimulation to a heart of a patient, the method comprising comparing the first blood pressure change to the desired blood pressure change and adjusting the second delay to a third delay.

---Continued Within the Next Extra Sheet---

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-36, 39-45

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US17/28715

-Continued from Box III - Observations where unity of invention is lacking-

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

Group I has at least one controller configured to execute the delivery of one or more stimulation patterns of stimulation pulses to the at least one cardiac chamber over a time interval, wherein a first stimulation pattern of the one or more stimulation patterns reduces the blood pressure of the patient by a first reduction amount, wherein a second stimulation pattern of the one or more stimulation patterns reduces the blood pressure of the patient by a second reduction amount, wherein the first reduction amount is greater than the second reduction amount, and wherein the second reduction amount is greater than zero and discontinuing application of the first therapy and delivering a resting stimulation pattern, measuring, during delivery of the resting stimulation pattern, a second blood pressure of the patient that Group II does not have.

Group II has at least a pacing a first chamber of the heart and, after a first delay, pacing a second chamber of the heart to obtain a desired blood pressure change, sensing a first intrinsic excitation of the first chamber and, after a second delay, pacing the second chamber, determining a first blood pressure change resulting from the second delay, comparing the first blood pressure change to the desired blood pressure change, adjusting the second delay to a third delay intended to adjust the first blood pressure change closer to the desired blood pressure change; sensing a second intrinsic excitation of the first chamber and, after the third delay, pacing the second chamber; determining a second blood pressure change resulting from the third delay; determining that the second blood pressure change is substantially equal to the desired blood pressure change; and delivering stimulation patterns to the heart that comprise pulses having the third delay between sensing intrinsic excitation of the first chamber and delivering a stimulation pulse to the second chamber that Group I does not have.

The common technical features of Groups I and II are at least a system for reducing blood pressure in a patient, the system comprising: a stimulation circuit configured to deliver a stimulation pulse to at least one cardiac chamber of a heart of the patient and delivery of one or more stimulation patterns of stimulation pulses to the at least one cardiac chamber over a time interval, at least one controller, comparing the first blood pressure to the second blood pressure to determine a blood pressure change, and comparing the first blood pressure change to the desired blood pressure change, and adjusting stimulation..

These common features are disclosed by US 2015/0335895 A1 to BACKBEAT MEDICAL, INC. (hereinafter 'Backbeat'). Backbeat discloses a system for reducing blood pressure in a patient (systems and methods for reducing blood pressure, abstract), the system comprising a stimulation circuit configured to deliver a stimulation pulse to at least one cardiac chamber of a heart of the patient (stimulation circuit stimulating atrial or ventricle chambers of the heart, abstract) and delivery of one or more stimulation patterns of stimulation pulses to the at least one cardiac chamber over a time interval (providing varied stimulation patterns over time, abstract), at least one controller (controller for executing stimulation pattern, paragraph [0010]), comparing the first blood pressure to the second blood pressure to determine a blood pressure change (comparing pre-treatment blood pressure with blood pressure after stimulation pattern has been applied, paragraph [0183]), and comparing the first blood pressure change to the desired blood pressure change (comparing pre-treatment blood pressure to a target blood pressure, paragraph [0184]), and adjusting stimulation (periodically adjusting the stimulation, paragraphs [0182] and [0192]).

Since the common technical features are previously disclosed by the Backbeat reference, these common features are not special and so Groups I and II lack unity.