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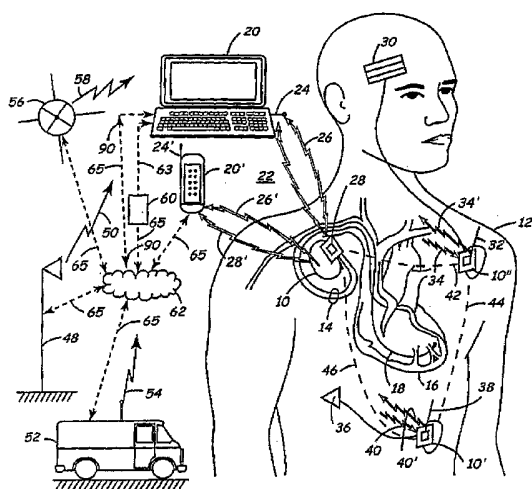
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- (74) Agents: CHAPIK, Daniel, G. et al.; MS LC340, 710 Medtronic Parkway, Minneapolis, MN 55432 (US).
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Declarations under Rule 4.17:

— as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS,

[Continued on next page]

(54) Title: A COMMUNICATIONS SYSTEM FOR AN IMPLANTABLE MEDICAL DEVICE AND A DELIVERY DEVICE



(57) Abstract: A closed loop system for monitoring drug dose, intake and effectiveness includes a drug delivery device in data communications with at least one implantable medical device. The system is preferably implemented in a web-enabled environment in which a remote data center communicates with the implantable devices (IMDs) in a patient via a programmer or the pill dispenser. A physician, clinician, or other user may access the remote data center to review and monitor the IMDs or the drug delivery regime remotely. The system further provides a dynamic drug management system, compatible with a web-enabled interactive data communication environment that accurately monitors dose and specific drug effectiveness in a patient to enhance patient care.

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- JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)*
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for all designations

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/024740

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 7 A61B5/00 A61N1/08 G06F19/00

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)
 IPC 7 A61B A61N G06F

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
 EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 471 645 B1 (WARKENTIN DWIGHT H ET AL) 29 October 2002 (2002-10-29) the whole document	1-11
X	US 2002/111542 A1 (WARKENTIN DWIGHT H ET AL) 15 August 2002 (2002-08-15) the whole document	1-11
X	EP 1 022 035 A (SUN MICROSYSTEMS, INC) 26 July 2000 (2000-07-26) the whole document	1-11
X	US 6 553 262 B1 (LANG BERNHARD ET AL) 22 April 2003 (2003-04-22) the whole document	1-11
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Further documents are listed in the continuation of box C. Patent family members are listed in annex.

* Special categories of cited documents :

<p>*A* document defining the general state of the art which is not considered to be of particular relevance</p> <p>*E* earlier document but published on or after the international filing date</p> <p>*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)</p> <p>*O* document referring to an oral disclosure, use, exhibition or other means</p> <p>*P* document published prior to the international filing date but later than the priority date claimed</p>	<p>*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</p> <p>*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</p> <p>*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.</p> <p>*Z* document member of the same patent family</p>
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Date of the actual completion of the international search	Date of mailing of the international search report
14 February 2005	02/03/2005

Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer <p style="text-align: center;">Ceccarelli, D</p>
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INTERNATIONAL SEARCH REPORT

In **International Application No**
PCT/US2004/024740

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01/48676 A (MEDTRONIC, INC) 5 July 2001 (2001-07-05) the whole document	1-11
A	US 6 386 882 B1 (LINBERG KURT R) 14 May 2002 (2002-05-14) the whole document	1-11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2004/024740

Box 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.: 12-40
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy. The steps of "adjusting a therapy" and "communicating instructions to the drug delivery device" are explicitly claimed in the independent claims.
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 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:

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 an additional fee, this Authority did not invite payment of any additional fee.
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.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

 International Application No
 PCT/US2004/024740

Patent document cited in search report	Publication date	Patent family member(s)	Publication date	
US 6471645	B1	29-10-2002	EP 1246663 A2 WO 0149364 A2 US 2002111542 A1 US 2004077995 A1	09-10-2002 12-07-2001 15-08-2002 22-04-2004
US 2002111542	A1	15-08-2002	US 6471645 B1 US 2004077995 A1 EP 1246663 A2 WO 0149364 A2	29-10-2002 22-04-2004 09-10-2002 12-07-2001
EP 1022035	A	26-07-2000	EP 1022035 A1 US 6358202 B1	26-07-2000 19-03-2002
US 6553262	B1	22-04-2003	DE 19844296 A1 EP 0987047 A2	23-03-2000 22-03-2000
WO 0148676	A	05-07-2001	DE 60012368 D1 EP 1244994 A1 WO 0148676 A1 US 2001037220 A1 US 2001039375 A1 US 2001031997 A1	26-08-2004 02-10-2002 05-07-2001 01-11-2001 08-11-2001 18-10-2001
US 6386882	B1	14-05-2002	DE 10055171 A1 FR 2800892 A1 JP 2001216421 A	13-06-2001 11-05-2001 10-08-2001