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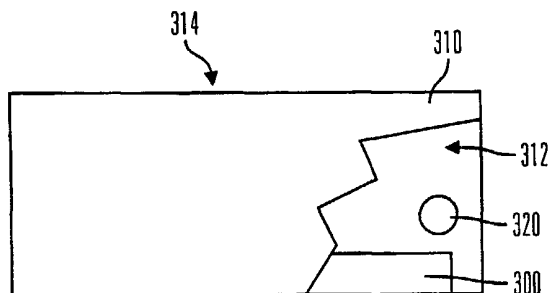
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(54) Title: GLUCOSE SENSOR PACKAGE SYSTEM



(57) Abstract: A glucose sensor package system that includes a glucose sensor (300) and a protective package (310) that indicates exposure to temperature changes to indicate proper temperature control. Also covered are methods of transporting and sterilizing the package. In addition, glucose sensors directed to various sizing and positioning of the electrodes on the glucose sensor are covered.

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/03856

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/00

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 B65D C12Q A61L

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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	<p>US 5 390 671 A (P. C. LORD ET AL) 21 February 1995 (1995-02-21) cited in the application</p> <p>abstract</p> <p style="text-align: center;">--- -/-</p>	<p>1,2,5,7, 11, 16-18, 21,23, 27, 32-34, 37,39, 43,51, 52,55,61</p>

☒ 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

Date of the actual completion of the international search

9 October 2000

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 00/03856

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 98 38112 A (VISUAL INDICATOR TAG SYSTEMS - VITSAB AB ET AL) 3 September 1998 (1998-09-03) page 1, line 13 -page 5, line 7 ---	1,2,5,7, 11, 16-18, 21,23, 27, 32-34, 37,39, 43,51, 52,55, 61,73
A	US 5 299 571 A (J. J. MASTROTOTARO) 5 April 1994 (1994-04-05) cited in the application column 3, line 55 -column 4, line 51 abstract ---	1-68, 74-95
A	US 5 476 792 A (R. I. EZRIELEV ET AL) 19 December 1995 (1995-12-19) column 2, line 60 -column 3, line 25 ---	1-68, 74-95
X	US 4 655 880 A (CHUNG-CHIUN LIU) 7 April 1987 (1987-04-07) column 4, line 41 -column 6, line 11 ---	69-72
Y	column 13, line 19 -column 14, line 24; figure 7 ---	73
X	WO 98 42252 A (CYGNUS INC.) 1 October 1998 (1998-10-01) page 3, line 24 -page 4, line 2 ---	69,72
A	page 14, line 29 -page 18, line 11 ---	70,71
X	US 5 384 028 A (NARUSHI ITO) 24 January 1995 (1995-01-24) column 1, line 57 -column 2, line 2 ---	69
A	column 3, line 24 - line 40 ---	70-73
A	US 5 344 017 A (P. M. WITTRUCK) 6 September 1994 (1994-09-06) column 1, line 62 -column 2, line 21 ---	74-95
A	DE 43 31 934 C (ELBAU ELEKTRONIK BAUELEMENTE GMBH) 4 May 1995 (1995-05-04) page 2, line 42 - line 60 ---	74-95
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 00/03856

Box I Observations where certain claims were found unsearchable (Continuation of item 1 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 II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

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

see additional 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 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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. Claims: 1-16, 17-32, 33-50, 51-68

Glucose sensor package systems for storing and transporting glucose sensors, comprising a protective package for a glucose sensor and a temperature exposure indicator to determine if the protective package has been exposed to temperatures relative to a predetermined temperature;

and related methods for transporting glucose sensors, comprising a step of using a temperature exposure indicator to determine if the protective package has been exposed to temperatures relative to a predetermined temperature.

2. Claims: 69-73

A glucose sensor, comprising a substrate, a working electrode including at least one enzyme, a counter electrode, and a reference electrode.

3. Claims: 74-84, 85-95

A glucose sensor package system for sterilizing a glucose sensor using electron beam sterilization, comprising a protective package for a glucose sensor and a radiation exposure indicator to determine if the protective package has been exposed to a predetermined exposure level of electron beam sterilization;

and a related method for sterilizing a glucose sensor using electron beam sterilization, comprising a step of using a radiation exposure indicator to determine if the protective package has been exposed to a predetermined exposure value.

INTERNATIONAL SEARCH REPORT

information on patent family members

Intern 1al Application No

PCT/US 00/03856

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