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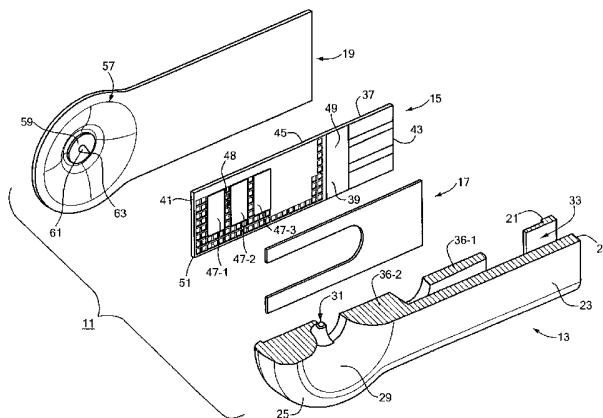
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- (88) Date of publication of the international search report:
9 March 2006

[Continued on next page]

(54) Title: ANALYTE TEST DEVICE



(57) Abstract: An analyte test device (11) is constructed as an integrated, single-use, disposable cartridge which can be releasably installed into a compatible analyte test monitor. In use, the device can be used in conjunction with the monitor to lance the skin of a patient to create a blood sample, express the blood sample from the wound site using vacuum forces and calculate the concentration of a particular analyte in the expressed blood sample. In one embodiment, the device includes a base (13) which includes a top surface and a bottom surface. The base is also shaped to define an aperture (31) which extends transversely through its top and bottom surfaces. An electrochemical test sensor (15) is affixed to the base in such a manner so that a vacuum path is at least partially defined between the base and the test sensor, the vacuum path being in fluid communication with the aperture. A cover (19) is affixed to the top surface (21) of the base over the aperture, the cover comprising a flexible dome-shaped member (57) and a lancet (61) coupled to the member, the lancet being orientated such that its longitudinal axis extends at an approximate right angle relative to the longitudinal axis of the test sensor. The bottom surface of the base is shaped to include a skin receiving surface which at least partially defines the aperture in the base, the skin receiving surface having a steep inward contour to distend the skin of the patient when pressed thereagainst.



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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/US2005/014855

A. CLASSIFICATION OF SUBJECT MATTER A61B5/15		
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) A61B		
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, WPI Data, PAJ		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/087775 A (EYELAB GROUP, LLC; COHAN, BRUCE, E; CHA, GEUN, SIG; MEYERHOFF, MARK, E;) 23 October 2003 (2003-10-23) figure 6	1-20
X	----- WO 03/025559 A (ARKRAY, INC; SAKATA, TETSUYA; MATSUMOTO, DAISUKE; KUSAKA, YASUhide) 27 March 2003 (2003-03-27) the whole document	1-20
P,X	- & EP 1 426 758 A (ARKRAY, INC) 9 June 2004 (2004-06-09) figure 3	1-20
X	----- EP 1 389 443 A (BAYER HEALTHCARE, LLC) 18 February 2004 (2004-02-18) figure 3	1-20
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<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C.		
<input checked="" type="checkbox"/> 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	"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	
"E" earlier document but published on or after the international filing date	"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	
"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)	"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.	
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family	
"P" document published prior to the international filing date but later than the priority date claimed		
Date of the actual completion of the international search 5 August 2005	Date of mailing of the international search report 19.01.2006	
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 Clevorn, J	

INTERNATIONAL SEARCH REPORT

International Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/049129 A1 (QI YAN) 11 March 2004 (2004-03-11) paragraph [0036]; figures 3A,5A -----	1-20
X	US 2002/099308 A1 (BOJAN PETER M ET AL) 25 July 2002 (2002-07-25) figure 3 -----	1-20

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2005/014855

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.:
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 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:

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.:

see annex

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: 1-20

the base and the test sensor together at least partially defining a vacuum path in fluid communication with said aperture

2. claims: 21-35

the flexible member comprising a lancet adapted to selectively penetrate through the aperture in the substrate

INTERNATIONAL SEARCH REPORT
Information on patent family members

International Application No
PCT/US2005/014855

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
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