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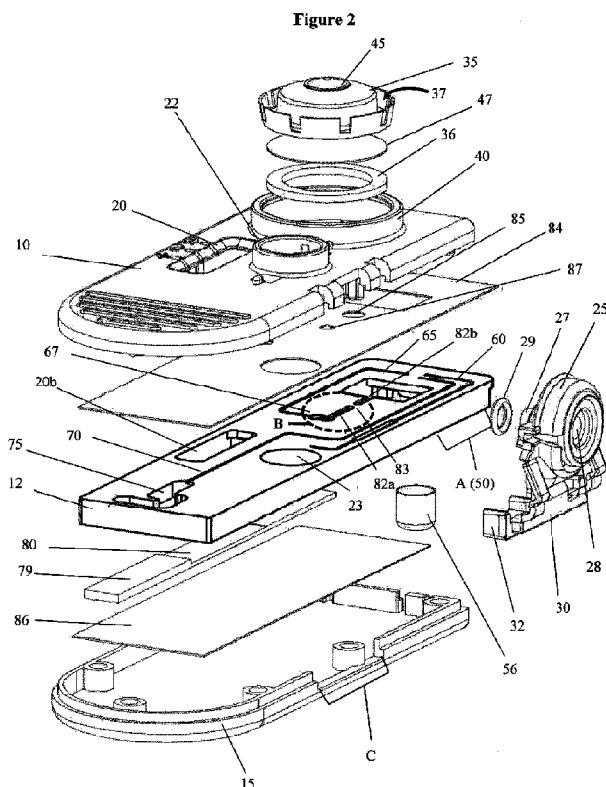
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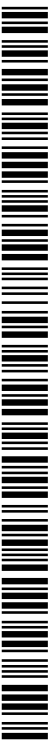
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[Continued on next page]

(54) Title: DEVICE AND APPARATUS



(57) Abstract: There is provided a device (1) for carrying out an assay to detect a target nucleic acid in a sample, the device (1) comprising a body in which is formed: • a) a sample entry well location comprising a sample entry well (22) or means for engaging with a sample entry well (22), the sample entry well (22) having a first volume; • b) an amplification well location comprising an amplification well (56) or means for engaging with an amplification well (56), the well (56) having a second volume less than or the same as the first volume and in which a nucleic acid amplification reaction of the target nucleic acid may be effected; • c) a first channel (60) linking the sample entry well (22) with the amplification well (56); • d) a diluent well location comprising a diluent well (35) or means for engaging with a diluent well (35), the well (35) being sealed, having a third volume greater than the second volume and being openable to an unsealed configuration; • e) a second channel (65) linking the diluent well (35), when in an unsealed configuration, with the amplification well (56); • f) a third channel (70) extending from the amplification well (56); and • g) a lateral flow channel (80) arranged to receive sample from the third channel (70) and detect the target nucleic acid therein.





UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(88) Date of publication of the international search report:

7 August 2014

Published:

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INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2013/053192

A. CLASSIFICATION OF SUBJECT MATTER
INV. B01L7/00 B01L3/00
ADD.
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)
B01L
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 practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2011/051735 A2 (SEC DEP FOR ENVIRONMENT FOOD & RURAL AFFAIRS [GB]; WAKELEY PHILIP [GB]) 5 May 2011 (2011-05-05) cited in the application the whole document	1-28, 33-40
X	US 2010/035349 A1 (BAU HAIM H [US] ET AL) 11 February 2010 (2010-02-11) paragraphs [0040] - [0045], [0046], [0064]; figures 13-15b ----- -/--	1,11, 19-26, 38-40

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

Date of the actual completion of the international search 14 March 2014	Date of mailing of the international search report 17/06/2014
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Pessenda García, P

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2013/053192

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.: 41
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:
see FURTHER INFORMATION sheet PCT/ISA/210

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:

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 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.:
1-28, 34-40(completely); 33(partially)

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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. claims: 1-28, 34-40(completely); 33(partially)

A device and a method for carrying out an assay to detect a target nucleic acid in a sample, the device comprising a body in which is formed:

- a) a sample entry well having a first volume;
- b) an amplification well, the well having a second volume less than or the same as the first volume and in which a nucleic acid amplification reaction of the target nucleic acid may be effected;
- c) a first channel linking the sample entry well with the amplification well;
- d) a diluent well, the well being sealed, having a third volume greater than the second volume and being openable to an unsealed configuration;
- e) a second channel linking the diluent well, when in an unsealed configuration, with the amplification well;
- f) a third channel extending from the amplification well;
- and
- g) a lateral flow device arranged to receive sample from the third channel and detect the target nucleic acid therein.

2. claims: 29-32(completely); 33(partially)

An apparatus for carrying out a chemical or biochemical reaction, the apparatus comprising:

- a) means for receiving a device, the device comprising an amplification well and a diluent well; and
- b) heating means arranged to controllably heat the amplification well so as to allow a chemical or biochemical reaction to be carried out therein.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 41

It is not possible to establish an opinion on claim 41 because a meaningful search could not be performed. According to Rule 6.2(a) PCT, the claims shall not rely on references to the description or drawings, therefore claim 41 does not meet the requirements of this Rule and it was not searched.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2013/053192

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>WO 2008/076395 A2 (UNIV PENNSYLVANIA [US]; CHEN ZONGYUAN [US]; BAU HAIM H [US]; MAUK MICH) 26 June 2008 (2008-06-26)</p> <p>paragraphs [0064], [0074], [0075], [0087], [0092], [0102], [0111], [0112], [0144] - [0147], [0150] - [0154]; figures 1a-17</p> <p style="text-align: center;">-----</p>	<p>1,3,11, 12,17, 19-26, 36-40</p>
X	<p>WO 2004/065010 A2 (MICRONICS INC [US]; BATTRELL C FREDERICK [US]; WEIGL BERNHARD H [US];) 5 August 2004 (2004-08-05) cited in the application claims 1,14; figures 1a-7b</p> <p style="text-align: center;">-----</p>	<p>1,38</p>

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/GB2013/053192

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2011051735 A2	05-05-2011	AU 2010311138 A1 CA 2778329 A1 CN 102655938 A EP 2496351 A2 JP 2013509173 A US 2012270225 A1 WO 2011051735 A2	03-05-2012 05-05-2011 05-09-2012 12-09-2012 14-03-2013 25-10-2012 05-05-2011

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