SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
INVENTARIO

Industria y Comercio

SUPERINTENDENCIA

Organizacion CSA Ltda

NOV 27

Delegatura de propiedad Industrial

División de Nuevas Creaciones

PCT

SOLICITUD

PATENTE DE INVENCIÓN

21. **EXPEDIENTE No.** 07-123569

54. **TÍTULO** *DISPOSITIVO DE ENSAYO (Nuevo Título folio 98)*

DISPOSITIVO DE ENSAYO QUE TIENE UNA PLATAFORMA ROTATORIA CON UNA CAMARA DE PRUEBA Y DETECTOR VOLADIZO.

51. **CLASIFICACIÓN INTERNACIONAL**

71. **SOLICITANTE** *RMIT UNIVERSITY*

DOMICILIO *MELBOURNE, VICTORIA, AUSTRALIA*

74. **APODERADO** *DILIA MARIA RODRIGUEZ D'ALEMAN*

22. **BOGOTÁ, D. C.,** *NOVIEMBRE 22, 2007*

(FORMA P-10)

PETITO

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

No. 07-123569- -00000-0000

Fecha: 2007-11-22 15:34:17 Dep. 2020 NUECREACIONE
Tra. 11 PATENTEIYII Eve: 379 FASENACIONALII
Act. 411 PRESENTACION Folios: 94

Industria y Comercio
SUPERINTENDENCIA

FORMULARIO ÚNICO DE SOLICITUD DE PATENTE
PCT
ENTRADA EN FASE NACIONAL 20 dic 2007

1) SOLICITUD DE:

☒ Patente de invención ☐ Patente de Modelo de Utilidad

☐ Capitulo I. ☒ Capitulo II.

2) SOLICITANTE (71)	**Nombre: RMIT UNIVERSITY** **Dirección: 124 La Trobe Street, Melbourne, Victoria 3000 Australia** **Nacionalidad o domicilio: Melbourne, Victoria, Australia** **Lugar de constitución: Australia**	**IDENTIFICACIÓN** **C.C.** ☐ **NIT:** ☐ **C.E.** ☐ **OTRO** ☐ **Cual** _____ **NÚMERO** _____
	Teléfono: Fax: **E. Mail:**	
3) REPRESENTANTE O APODERADO	Nombre: DILIA MARÍA RODRÍGUEZ D´ALEMAN Dirección: Carrera 11 N°. 86-53 Piso 6 Bogotá D.C. Teléfono: 6181088 Fax: 6350824 E. Mail: info@clarkemodet.com.co	**IDENTIFICACIÓN** **C.C.** ☒ **NIT:** ☐ **C.E.** ☐ **OTRO** ☐ **NÚMERO:** 41.654.882 **TP:** 20824 CSJ
4) INVENTOR (ES) (72)	**Nombre: 1. CHAFFEY, Jason; 2. STAPLETON , Murray.** **Dirección: 1. 7/104 Sixth Avenue, St Peters, South Australia 5069 Australia; 2. Mediversity Pty Ltd, Ground Floor, 40-46 The Esplanade, Brighton, Victoria 3186, Australia** **Nacionalidad o Domicilio: Todos los anteriores, Australia**	

5) PCT (86)

Solicitud Internacional No. PCT/AU2006/000656 Fecha: Mayo 17, 2006

Publicación Internacional No. WO2006/122360 A1 Fecha: Nov. 23, 2006

6)Título (54) DISPOSITIVO DE ENSAYO (Nuevo título folio 18).

7) Clasificación Internacional: G01N 33/48 G01N 33/50 B01N 33/53

8) PRIORIDAD	**33) País de Origen**	**(32) Fecha**	**(31) Número de Solicitud**
SI ☒ **NO** ☐	**AUSTRALIA**	**Mayo 20, 2005**	**2005902630**

9) Comprobante de pago N°.

Instrucciones para el diligenciamiento del presente formulario. Ver reverso de esta pagina

10) ANEXOS

- [x] Comprobante de pago de la tasa de presentación de la solicitud
- [ ] Comprobante de pago por reivindicación de prioridad
- [ ] Documento que acredita la existencia y representación legal cuando el solicitante sea persona Jurídica
- [ ] Poderes, si fuera el caso
- [ ] Documento de cesión del inventor al solicitante o a su causante
- [ ] Declaraciones
- [x] Copia de la solicitud Internacional. (Resumen, descripción, reivindicación, Dibujos).
- [x] Traducción de la solicitud internacional al castellano. (Resumen, descripción, reivindicación, Dibujos)
- [x] Copia del examen preliminar efectuado por la IPEA
- [ ] De ser el caso, copia del contrato de acceso
- [ ] De ser el caso, documento que acredite la licencia o autorización de uso de conocimientos tradicionales de las comunidades indígenas
- [ ] De ser el caso, certificado de depósito del material biológico
- [ ] Arte final 12 x 12 y 6 x 6 cm
- [ ] De ser el caso, información sobre otras solicitudes de patente o títulos obtenidos en el extranjero por el mismo titular o su causante, relacionados parcial o totalmente con la invención de esta solicitud.
- [x] Otros:
  1. Reporte internacional de búsqueda
  2. Modificación dirección inventor
  3. IB306, IB304
  4. Request

11) FIGURA CARACTERÍSTICA:

12) Solicitud concesión de la patente,

NOMBRE: DILIA RODRÍGUEZ D´ALEMAN

FIRMA: _____

C.C. 41.654.882 de Bogota **TP** 20824 CSJ

Instrucciones para el diligenciamiento del presente formulario. Ver reverso de esta pagina

RECIBO DE CAJA APLICADO AL EXPEDIENTE No._____

3

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

No. 07-123569- -00000-0000

Fecha: 2007-11-22 15:34:17 Dep. 2020 NUECREACIONE
Tra. 11 PATENTEIYII Eve: 379 FASENACIONALII
Act. 411 PRESENTACION Folios: 94

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 800176089-2

RECIBO OFICIAL DE CAJA : 07 - 81,206
FECHA : OCTUBRE 2 DE 2007

***** C O N S I G N A C I O N *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PGO	Vr. PAGO
CLARKE MODET Y CO. COLOMB	CONSIGNACION	BANCO POPULAR	050-00110-6	66408802	02/10/2007	18,575,000.00

***** C O N C E P T O *****

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-01 SOLICITUDES	8 PROC. DE DEPOSITO DE NOMBRES Y EN	438,000.00
		TOTAL : $	438,000.00

SON: CUATROCIENTOS TREINTA Y OCHO MIL PESOS

RESPONSABLE : _____

3

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 800176089-2

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
No. 07-123569- -00000-0000
Fecha: 2007-11-22 15:34:17 Dep. 2020 NUECREACIONE
Tra. 11 PATENTE!Y!! Eve: 379 FASENACIONALII
Act. 411 PRESENTACION Folios: 94

RECIBO OFICIAL DE CAJA : 07 - 93,100
FECHA : NOVIEMBRE 15 DE 2007

***** C O N S I G N A C I O N *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PGO	Vr. PAGO
CLARKE MODET Y CO. COLOMB	CONSIGNACION	BANCO POPULAR	050-00110-6	71030246	15/11/2007	28,740,000.00

***** C O N C E P T O *****

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-09 OTROS SERVICIOS DE PROPIEDAD I	54 INFORMACION DETALLADA DE UN TRAMI	22,000.00
		TOTAL : $	22,000.00

SON: VEINTIDOS MIL PESOS

RESPONSABLE : _____

RECIBO DE CAJA APLICADO AL EXPEDIENTE No._____

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 800176089-2

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

No. 07-123569- -00000-0000

Fecha: 2007-11-22 15:34:17 Dep. 2020 NUECREACIONE
Tra. 11 PATENTE!YII Eve: 379 FASENACIONALII
Act. 411 PRESENTACION Folios: 94

RECIBO OFICIAL DE CAJA : 07 - 93,101
FECHA : NOVIEMBRE 15 DE 2007

***** C O N S I G N A C I O N *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PGO	Vr. PAGO
CLARKE MODET Y CO. COLOMB	CONSIGNACION	BANCO POPULAR	050-00110-6	71030246	15/11/2007	28,740,000.00

***** C O N C E P T O *****

CANT.	RENTISTICO	CONCEPTO		TOTAL CONCEPTO
1	50005-01-09 OTROS SERVICIOS DE PROPIEDAD I	54	INFORMACION DETALLADA DE UN TRAMI	22,000.00
			TOTAL : $	22,000.00

SON: VEINTIDOS MIL PESOS

RESPONSABLE : _____

RECIBO DE CAJA APLICADO AL EXPEDIENTE No._____

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

PCT

(43) International Publication Date
23 November 2006 (23.11.2006)

(10) International Publication Number
WO 2006/122360 A1

(51) International Patent Classification:
G01N 33/48 (2006.01) *G01N 33/53* (2006.01)
G01N 33/50 (2006.01)

(21) International Application Number:
PCT/AU2006/000656

(22) International Filing Date: 17 May 2006 (17.05.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
2005902630 20 May 2005 (20.05.2005) AU

(71) Applicant *(for all designated States except US)*: **RMIT UNIVERSITY** [AU/AU]; 124 La Trobe Street, Melbourne, Victoria 3000 (AU).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **CHAFFEY, Jason** [AU/AU]; 7/104 Sixth Avenue, St Peters, South Australia 5069 (AU). **STAPLETON, Murray** [AU/AU]; Mediversity Pty Ltd, Ground Floor, 40-46 The Esplanade, Brighton, Victoria 3186 (AU).

(74) Agents: **HENSHAW, Damon** et al.; Davies Collison Cave, 1 Nicholson Street, Melbourne, Victoria 3000 (AU).

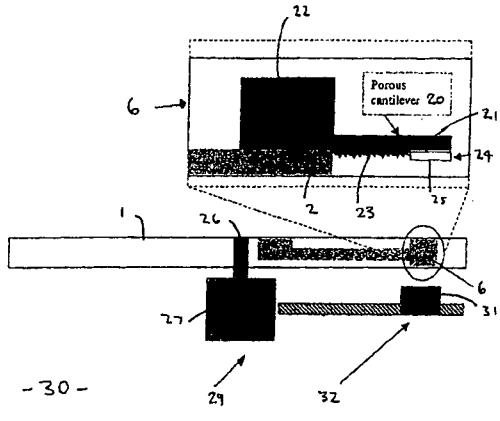
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

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.

(54) Title: ASSAY DEVICE



(57) Abstract: An assay device (1) having a rotatable platform (2) with a test chamber (6) and a sensor (20) which undergoes displacement when subject to a particular substance such as a chemical, biological species or other organism. The sensor is a cantilever beam (21) with a porous section (23) to enhance sensitivity.

WO 2006/122360 A1

ASSAY DEVICE

Field of the Invention

The present invention relates to an assay device and a cantilevered detector.

Background of the Invention

It is known to use compact discs (CDs) for chemical testing. The CDs are provided with micro-fluidic structure which defines various fluid input ports in communication with associated channels and fluid mixing chambers. In order to conduct a test, fluid is deposited into the input ports and the CD is spun so that the fluid is forced by centrifugal pumping through the relevant channels to the mixing chambers. Significantly modified CD optics and addressing technology can be used to capture images of specific mixing chambers to determine the test results of any chemical reaction within the chambers.

It is also known that microcantilever beams have been considered as a means for detecting the results of chemical reactions, but the limited sensitivity of the beams studied has not resulted in any widespread application of the technology.

Summary of the Invention

In accordance with the invention, there is provided an assay device having a rotatable platform with a test chamber and a sensor which undergoes displacement when subject to a particular substance such as a chemical, biological species or other organism.

Preferably, the sensor is a cantilever beam.

Preferably, the device includes microfluidic paths in communication with associated channels and the test chamber or an associated plurality of test chambers.

Preferably, the or each test chamber includes one or more cantilever beams.

Preferably, the sensor includes a porous section. The porous section can give the sensor a sensitivity which enables the presence of the particular substance i.e., a selected chemical, species or organism, to be detected.

Preferably, the sensor is functionalised with receptors, antibodies, antigens or enzymes which will selectively attract and bond with the particular substance to be detected.

Preferably, the porous section is coated with a gold layer which attaches the receptors to the beam, functionalising the beam for bonding with preselected species or organism within the fluid in the test chamber.

Preferably, the sensor includes a surface to be monitored, which is subject to displacement upon movement of the sensor, the position of the monitored surface being monitored by an apparatus into which the assay device is loaded.

Preferably, the surface is a reflective surface.

Preferably, the apparatus is a CD drive connected to a computer allowing the position of the reflective surface to be determined and displayed by the computer.

Preferably, the assay device includes a micro-fluidic system for conveying a test fluid from an inlet port to the test chamber containing the cantilever beam and on to a waste chamber.

Preferably, the waste chamber is separated from the test chamber by a micro-mechanical valve which is actuated above a threshold angular velocity of the device.

Preferably, the device can accept the whole fluid to be tested and includes a filter for filtering material from the whole fluid after insertion into the inlet port to provide fluid in a form suitable for testing. More preferably, the filter is formed of a porous silicon.

Preferably, the system includes provision for secondary chamber connected to the test chamber to allow the cycling of fluid between the secondary and test chamber.

Preferably, the device is in the form of a compact disc (CD).

In another aspect, there is provided a test apparatus for receiving an assay device, as described above, including a drive unit for rotating the device and a read unit for monitoring the sensor.

Preferably, the apparatus is adapted to display information derived from the read unit.

More preferably, the apparatus is in the form of CD drive and the read unit forms part of an existing optical read/write head of the CD drive.

More preferably, the apparatus is connected directly to a computer, on which is installed a computer program which controls the operation of the CD drive to initiate the filtering process, the transfer of fluid between chambers and the optical reading system to measure the displacement of the sensor.

Preferably, the assay process is initiated by using the computer to input data defining the test to be performed and presenting the results with this same identification.

In another aspect, there is provided a chemical assay method including introducing fluid to a sensing chamber on a rotatable platform, wherein the sensing chamber includes a sensor arranged for displacement upon detection of a particular substance, such as a selected molecule, within the chamber, and monitoring the sensor to detect the displacement.

In yet another aspect, there is provided a cantilever sensor, as described above.

Brief Description of the Drawings

The invention is now described, by way of non-limiting example only, with reference to the accompanying drawings in which:

Figure 1 is a diagrammatic representation of a plan view of an assay device;
Figure 2 is a diagrammatic cross-sectional view of a test apparatus;
Figure 3a is a diagrammatic side view of a microcantilever;
Figure 3b is a diagrammatic side view of the microcantilever, illustrating deflection;
Figure 4 is a graph illustrating a relationship between resonant frequency and porosity of a cantilever;
Figure 5 is a diagrammatic perspective view of a cantilever sensor and a read/write head of a CD drive;
Figure 6 is a graph illustrating a relationship between intensity and time, for the purpose of detecting displacement of the sensor;
Figure 7 is a flow chart of a test procedure; and
Figure 8 is a graph illustrating comparative deflection of a porous and non-porous cantilever.

Detailed Description

An assay device 1 is illustrated in Figure 1 as including a rotatable platform 2, in the form of a compact disc (CD), with a microfluidic system 3 including an inlet port 4, a secondary chamber 5, a test chamber 6 and a waste chamber 7 interconnected by respective channels 8,9,10. A filter 11 is provided in one of the channels 8, adjacent the inlet port 4 for filtering material such as cellular material from the test fluid introduced into the inlet port 4. The filter 11 is preferably formed of porous silicon 12. A micro-mechanical valve 13 is also provided in the channel 10 separating the test chamber 6 and waste chamber 7. The valve 13 moves from a closed position, indicated by dashed lines 14, to an open position, indicated by arrow 15, when the angular velocity of the device 1 is above a predetermined threshold.

In operation, fluid is introduced into the inlet port 4 and the device 1 is rotated at a required speed to effect centrifugal pumping so that the fluid is forced through the channel 8 into the secondary chamber 5 and subsequently the test chamber 6 where a sensor is provided for the purpose of detecting the presence of a particular substance, such as a selected chemical, biological species or other organisms within the fluid. The device 1 is then rotated at higher angular velocity to open the valve 13 and allow the fluid to exit the test chamber 6.

Referring now to Figure 2, the test chamber 6 of the device 1 is shown in enlarged section as including a cantilever sensor 20, which projects from the platform 2 of the device 1. More specifically, the porous cantilever sensor 20 is formed of a beam 21 which projects from a silicon block 22 and includes a porous section 23 and a surface 24 formed of, for example, a section of gold 25 or other suitable metallic or reflective substance.

The device 1 is shown fitted on a spindle 26 of a drive unit 27 of a test apparatus 30, which is preferably in the form of a computer, with a CD drive 29 and the drive unit 27 forms part of the drive 29, together with a read unit 31, which monitors any displacement of the reference surface 24 and thereby the cantilever sensor 20. The read unit 31 preferably forms part of an existing read/write head 32 of the CD drive 31, without modification.

The structure of the cantilever sensor 20 is now described in more detail with reference to Figure 3. Figure 3a shows an enlarged part 33 of the sensor 20 as including a porous layer 35 and a silicon layer 34 both coated with gold which is provided with antibody receptors 36 for capturing molecules 37 such as antigen ligands. The binding of the molecules 37 to the receptors 36 will lead to a deflection of the beam 21, as illustrated in Figure 3b, which can then be detected.

By forming the cantilever beam of porous material, the deflection is enhanced. More particularly, the characteristics of the cantilever sensor 20 rely on surface processes such as adsorption , desorption, surface reconstruction and reorganisation to induce a surface stress

in the active surface layer of the cantilever beam 39. Modifying the surface stress on surface 39 of the beam 21 will induce a differential stress across the cantilever sensor 20, causing it to bend.

The curvature of the beam 21 is proportional to the differential stress gradient across the beam. Increasing surface stress on surface 39 compared to the surface 40 or layer 34 increases the differential stress gradient. Porous silicon at surface 39 can be used as the layer 35 to increase surface area and hence sensitivity. To the best of our knowledge, no research or development has been focussed on increasing the sensitivity of the cantilever based sensing technique by modifying the beam geometry or material structure. The beam 21 increases the maximum surface stress that can be induced by the chemical analyte by introducing the porous layer 35 and modifying the beam geometry.

Analysis and tests have shown that by modifying the beam, geometry and material structures as described, the increased beam deflection for increased porosity can be varied as shown in Figure 8.

Accordingly, in Figure 5, the sensor 20 allows for increased deflection of the cantilever beam 21, as compared to a conventional beam of the same thickness and length, by fabricating a porous section on surface 23 of the beam 21. This has three affects on the mechanical response of the beam 21:

1. It reduces the effective thickness of the beam where it is porous, reducing the second moment of inertia of the beam, making the beam less rigid;
2. The spring constant of the beam is also reduced where it is porous; and
3. The surface area of the beam is also increased due to the increased porosity of the cantilever beam of the cantilever beam.

These three physical affects have a combined effect to increase the deflection of the beam and sensitivity to surface-combination events over current cantilever based biosensors. Increasing the differential stress induced between the layers 35,34 of the beam, Figure 3b

leads to an increase in the deflection. Further to this, the surface area to be functionalised, i.e. provided with receptors for bonding with selected molecules, is increased, allowing for a greater density of functionalised groups to be attached to the surface, thereby increasing the sensitivity and induced surface stress for the same concentration of chemical or biological species.

This enables a more concentrated binding of the species and also enables less variation in deflection for the same chemical or species concentrate.

Another affect of modifying the geometry of the beam is that the resonant frequency of the beam is changed since the resonant frequency is a direct measure of the amount of porosity.

The resonant frequency change according to the beam geometry has the following relationship: $fo = \frac{1}{2\pi\sqrt{\frac{k}{m}}}$

where fo = resonance frequency

k = spring constant

m = mass of the beam

A change of porosity changes the resonant frequency of the cantilever beam 21 and is an additional sensing capability of the sensor, which could be applied to detection of corrosion or chemical reaction caused by fluid, for example, measurement of corrosion on a marine vessel or detection of acid rain or similar events for environmental monitoring.

The change in resonance frequency with porosity is illustrated in Figure 4 which indicates that there is a minimum resonant frequency for a range of porosity levels. In the apparatus

30, however, it is only the deflection of the beam 21 that needs to be monitored. Conventional systems for detecting such deflection use a laser and a position sensitive detector to detect the deflection. The detection system is an external set-up and requires the laser to be optical aligned to the cantilever beam. The detection system used in the apparatus 30, on the other hand, uses the inherent optical detection system of the CD drive 29. The read/write head (RWH) 32 of the drive 29 is used to interrogate the cantilever sensor 20 and monitor the position of the reference surface 24. In addition the laser of the RWH may be used to control the temperature of the test and secondary chambers 5,6.

More particularly, to sense the deflection of the sensor 20, the RWH is moved over the position of the porous cantilever beam 21, as illustrated in Figure 5. The CD device 1 can be rotating while sensing the deflection. The laser of the RWH is focused onto the cantilever beam 21 and the reflected intensity from the reference surface 24 of the beam 21 is measured prior to loading a test fluid into the test chamber 4, for calibration purposes. The test fluid is then caused to enter the test chamber 6 and subsequently exhausted to the waste chamber 7. The change in reflected intensity from the cantilever beam 21 after the test fluid has been removed from the test chamber 6 is measured. The change in reflected intensity is a measure of the sensor deflection. Secondary to this, the deflection can also be measured as a change in focus. When the laser is initially focused onto the beam 21 prior to loading the test fluid into the test chamber 6, the focus position can be measured. After the test fluid has been removed from the test chamber the beam 21 will have deflected and the reflective surface 24 will have moved out of focus. A graphical representation illustrating the affect of a change in focus on the measured intensity of reflected laser light is illustrated in Figure 6. The change in focus is an indirect measure of the deflection and can be measured as a change in current or voltage output from the RWH.

Application of Assay Device to Testing of Blood.

A detailed example of use of the assay device 1 and apparatus 20 is described with reference to Figure 7. Specifically, a diagnostic test procedure 40 is shown as including a step 41 of drawing blood from a client and inserting the blood into the inlet port 4 of the

device 1 at step 42. The CD device 1 is then inserted into a computer at step 43 and disc information is read from the CD. Relevant software is then employed at step 44 to initiate testing which commences at step 45 with the reflected intensity from the cantilever sensor 20 being measured for calibration purposes. The CD is then spun at step 46 to force the blood into the first channel 8 and through the filter 11, where cellular material is removed. The resulting serum is then passed through the secondary chamber 5 (if required) and into the test chamber 6. If required, the serum is then heated at step 47 by a laser of the RWH resulting in the serum being cycled back and forth between the test chamber 6 and secondary chamber 5 to improve interaction with the receptors. The CD is then spun at a higher angular velocity at step 48, to move the valve 13 into the open position so that the serum may exit the test chamber 6 and pass into the waste chamber 7 at step 49. The RWH may then be used to measure the reflected intensity of the displaced cantilever beam 21 at step 50 and the output of the RWH is then returned at step 51 for analysis at step 52, where the measured intensity is read and compared with calibrated data to determine the presence of a relevant chemical or molecule. The test results are then logged, a user notified of the results at step 53, and the CD ejected at step 54, as required. The CD may then be disposed of or stored for the purpose of a permanent record of the test result.

Other Applications

The technology enables near patient health pathology to be performed, avoiding the need for use of expensive laboratory equipment and the associated delay in provision of results. Examples of the range of applications include:

- Human Health Pathology

  Detection of - Prostate Specific Antigen
  - Cardiac Enzymes
  - Infectious diseases (Hepatitis, HIV)
  - Snake bite venom

- Environment Pathology

  Detection of - Leionella bacteria

- Hepatitis in water ways
- E-coli levels

- Animal Health Pathology

  Detection of - Johne's disease

- Fluid Quality Measurement

  Detection of - Wine fermentation

- Industrial Measurement

  Detection of electrical insulation deterioration.

The invention has been described by way of non-limiting example only and many modifications and variations may be made thereto without departing from the spirit and scope of the invention described.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. An assay device having a rotatable platform with a test chamber and a sensor which undergoes displacement when subject to a particular substance such as a chemical, biological species or other organism.

2. An assay device as claimed in claim 1, wherein the sensor is a cantilever beam.

3. An assay device as claimed in claim 1 or 2, wherein the device includes microfluidic paths in communication with associated channels and the test chamber or an associated plurality of test chambers.

4. An assay device as claimed in claim 3, wherein the or each test chamber includes one or more cantilever beams.

5. An assay device as claimed in claim 1 or 2, wherein the sensor includes a porous section.

6. An assay device as claimed in claim 5, wherein the sensor is functionalised with receptors, antibodies, antigens or enzymes which will selectively attract and bond with the particular substance to be detected.

7. An assay device as claimed in claim 6, wherein the porous section is coated with a gold layer which attaches the receptors to the beam, functionalising the beam for bonding with preselected species or organism within the fluid in the test chamber.

8. An assay device as claimed in claim 1, wherein the sensor includes a surface to be monitored, which is subject to displacement upon movement of the sensor, the position of the monitored surface being monitored by an apparatus into which the assay device is loaded.

9. An assay device as claimed in claim 8, wherein the surface is a reflective surface.

10. An assay device as claimed in claim 8, wherein the apparatus is a CD drive connected to a computer allowing the position of the reflective surface to be determined and displayed by the computer.

11. An assay device as claimed in claim 1, wherein the assay device includes a micro-fluidic system for conveying a test fluid from an inlet port to the test chamber containing the cantilever beam and on to a waste chamber.

12. An assay device as claimed in claim 11, wherein the waste chamber is separated from the test chamber by a micro-mechanical valve which is actuated above a threshold angular velocity of the device.

13. An assay device as claimed in claim 11 or 12, wherein the device can accept the whole fluid to be tested and includes a filter for filtering material from the whole fluid after insertion into the inlet port to provide fluid in a form suitable for testing.

14. An assay device as claimed in claim 13, wherein the filter is formed of a porous silicon.

15. An assay device as claimed in claim 14, wherein the system includes provision for secondary chamber connected to the test chamber to allow the cycling of fluid between the secondary and test chamber.

16. An assay device as claimed in any previous claim, wherein the device is in the form of a compact disc (CD).

17. A test apparatus for receiving an assay device, as described above, including a drive unit for rotating the device and a read unit for monitoring the sensor.

18. A test apparatus as claimed in claim 17, wherein the apparatus is adapted to display information derived from the read unit.

19. A test apparatus as claimed in claim 17 or 18, wherein the apparatus is in the form of CD drive and the read unit forms part of an existing optical read/write head of the CD drive.

20. A test apparatus as claimed in any one of claims 17 to 19, wherein the apparatus is connected directly to a computer, on which is installed a computer program which controls the operation of the CD drive to initiate the filtering process, the transfer of fluid between chambers and the optical reading system to measure the displacement of the sensor.

21. A chemical assay method including introducing fluid to a sensing chamber on a rotatable platform, wherein the sensing chamber includes a sensor arranged for displacement upon detection of a particular substance, such as a selected molecule, within the chamber, and monitoring the sensor to detect the displacement.

22. A cantilever sensor as claimed in any one of the preceding claims.

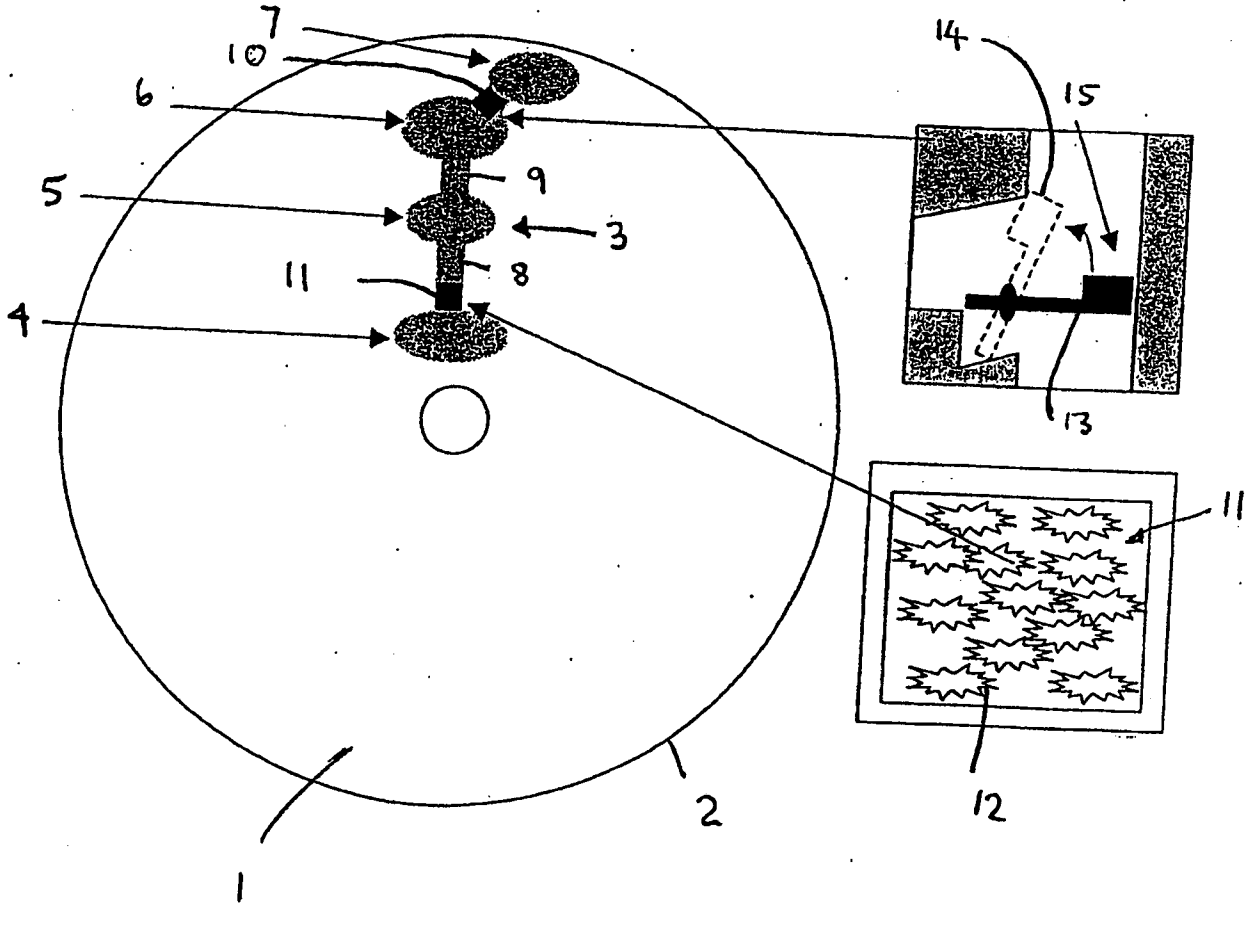


FIG 1

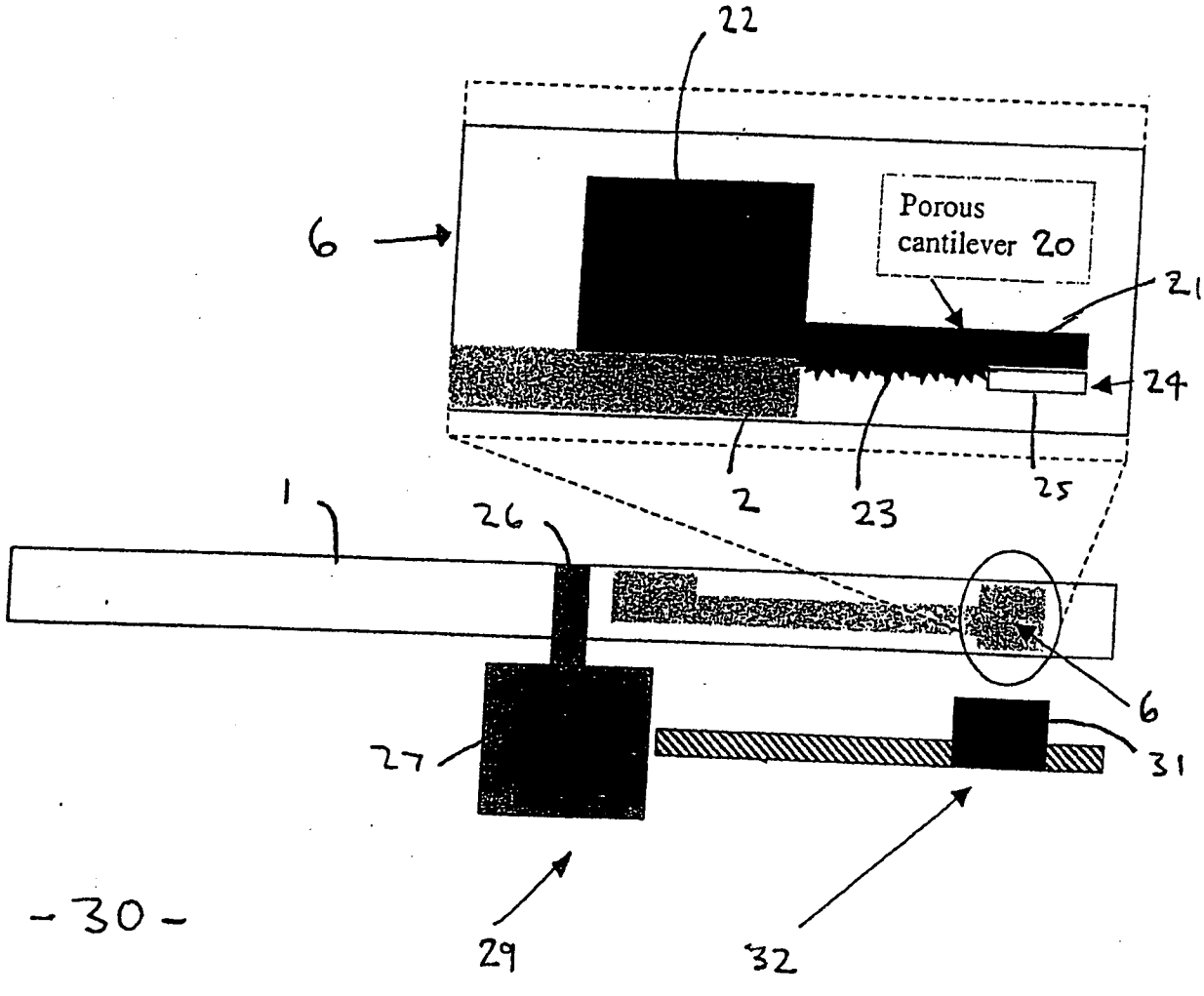


FIG 2

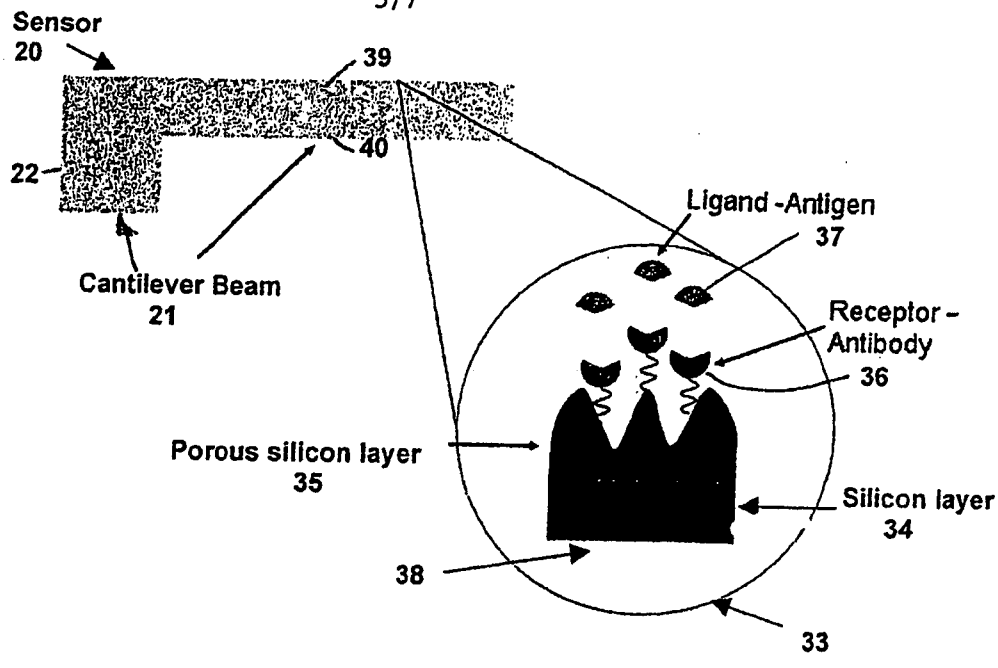

Sensor
20
39
40
22
Cantilever Beam
21
Ligand -Antigen
37
Receptor -
Antibody
36
Porous silicon layer
35
Silicon layer
34
38
33

FIG 3a

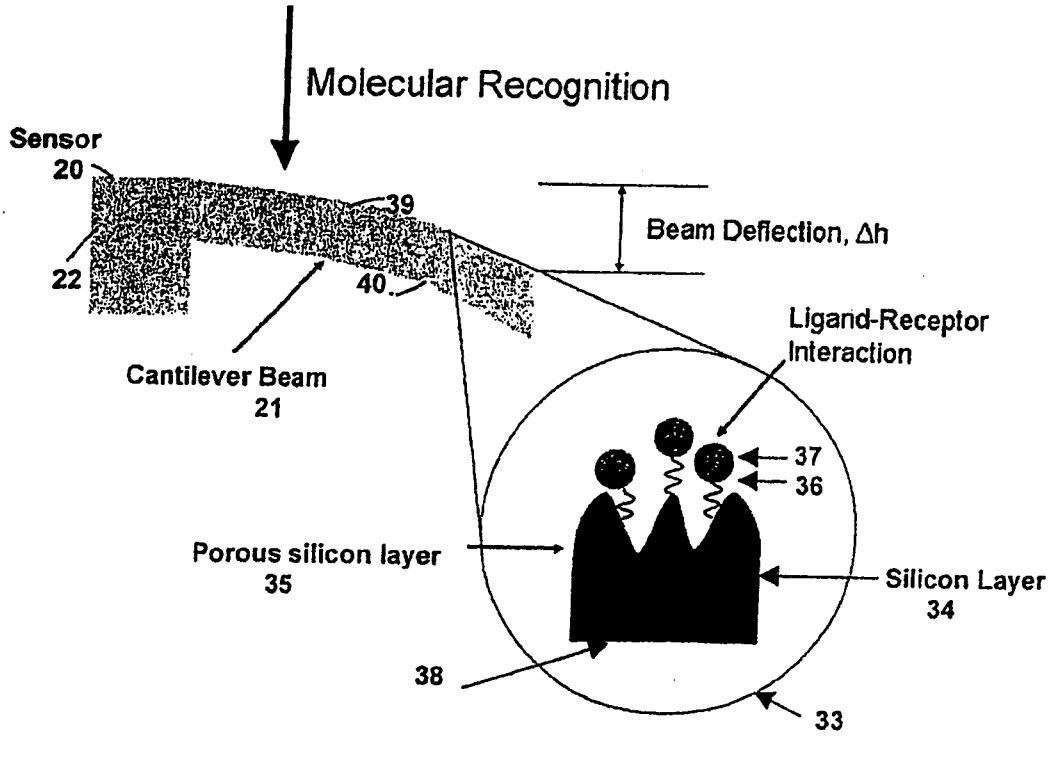

Molecular Recognition
Sensor
20
39
Beam Deflection, Δh
22
40
Ligand-Receptor
Interaction
Cantilever Beam
21
37
36
Porous silicon layer
35
Silicon Layer
34
38
33

FIG 3b

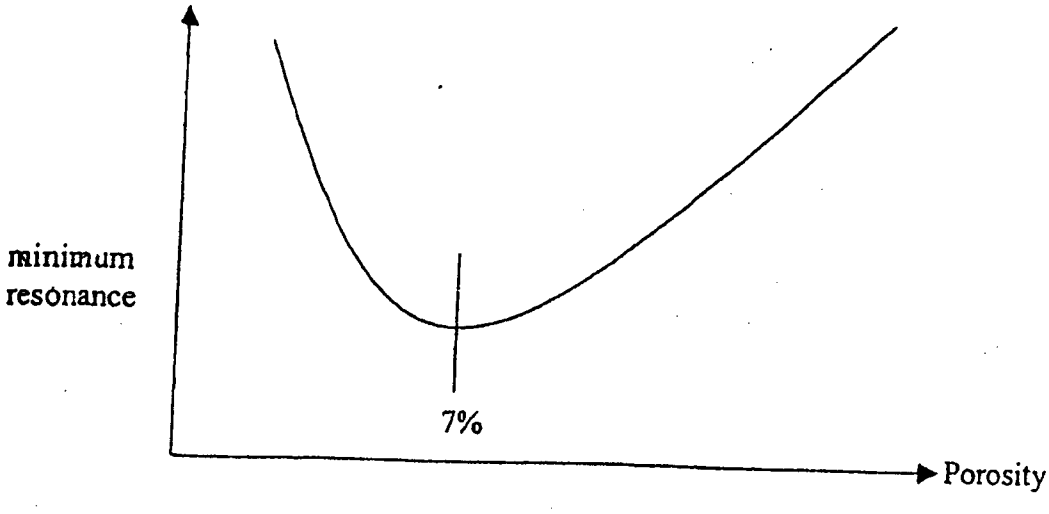


FIG 4

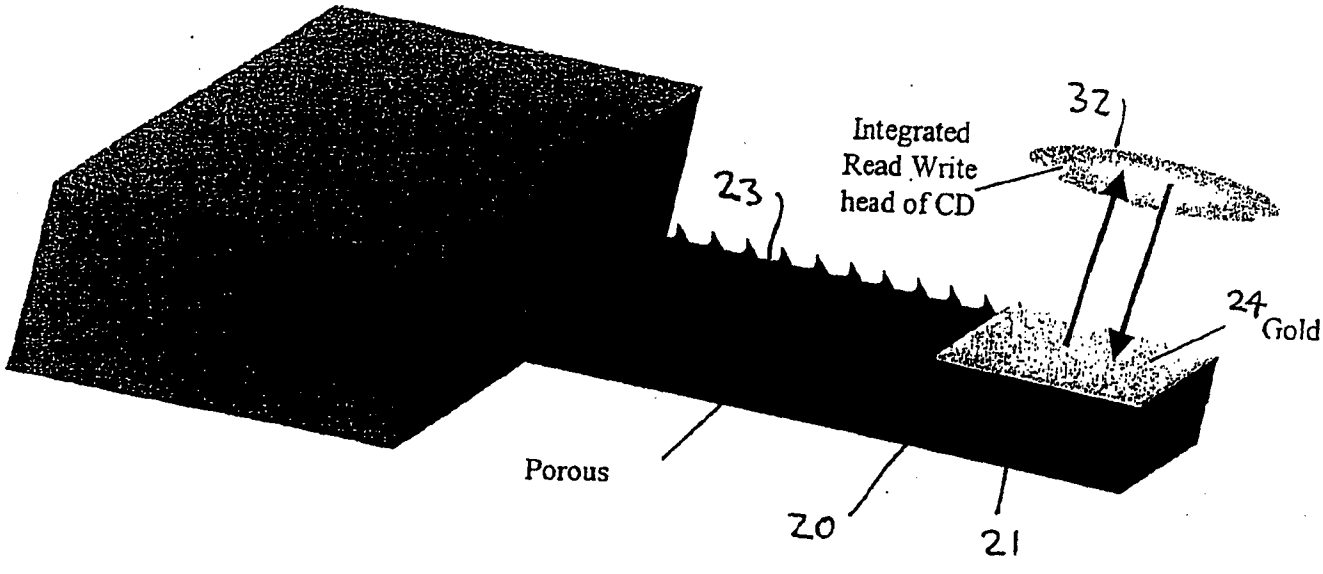

32
Integrated
Read Write
head of CD
23
24
Gold
Porous
20
21

FIG 5

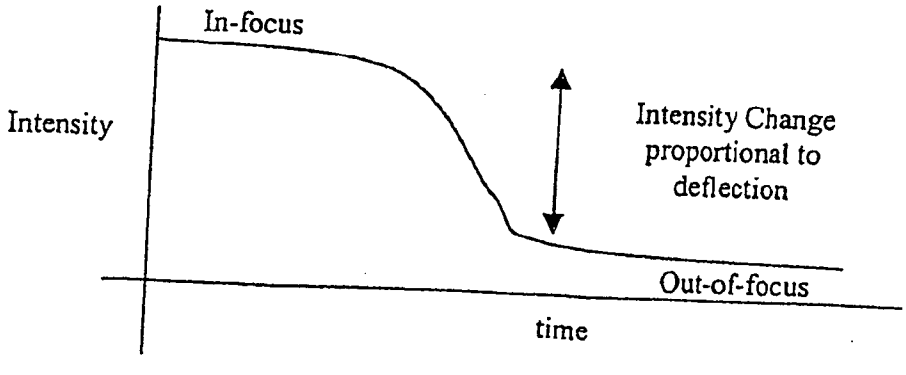

In-focus
Intensity
Intensity Change
proportional to
deflection
Out-of-focus
time

FIG 6

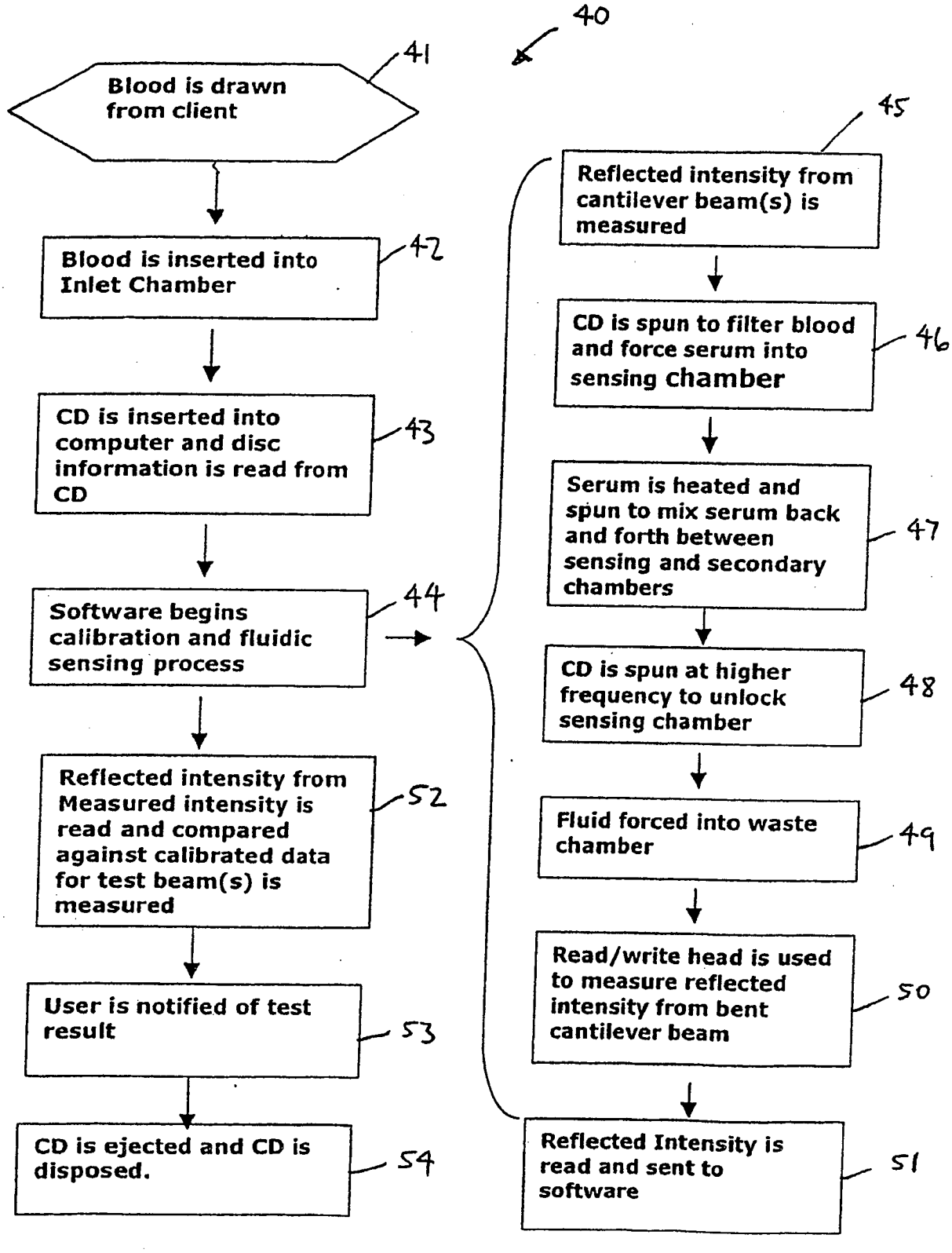

40
41
Blood is drawn from client
42
Blood is inserted into Inlet Chamber
43
CD is inserted into computer and disc information is read from CD
44
Software begins calibration and fluidic sensing process
52
Reflected intensity from Measured intensity is read and compared against calibrated data for test beam(s) is measured
53
User is notified of test result
54
CD is ejected and CD is disposed.
45
Reflected intensity from cantilever beam(s) is measured
46
CD is spun to filter blood and force serum into sensing chamber
47
Serum is heated and spun to mix serum back and forth between sensing and secondary chambers
48
CD is spun at higher frequency to unlock sensing chamber
49
Fluid forced into waste chamber
50
Read/write head is used to measure reflected intensity from bent cantilever beam
51
Reflected Intensity is read and sent to software

FIG 7

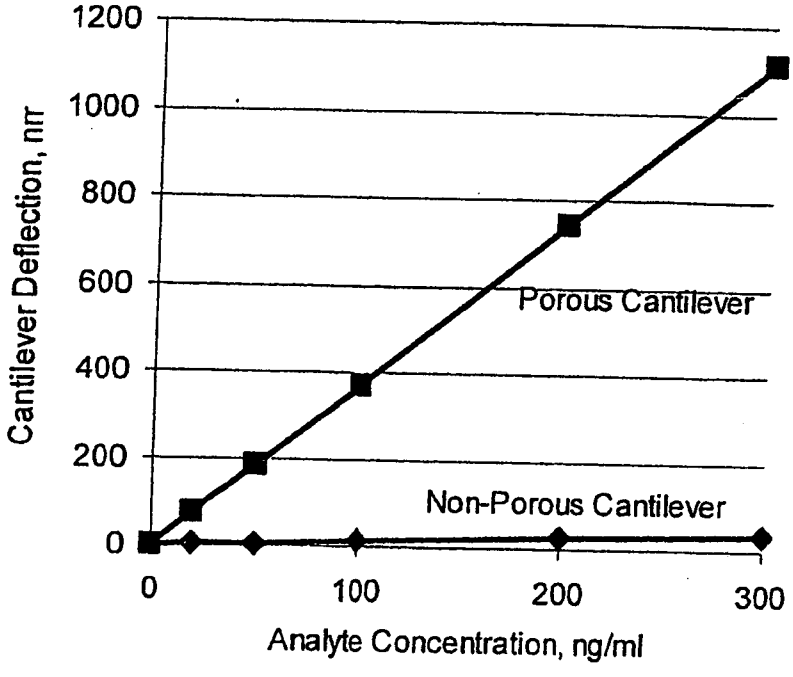

Cantilever Deflection Vs Analyte Concentration
(Cantilever Dimensions: 150µm x 10µm x 0.5µm)
Cantilever Deflection, nm
1200
1000
800
600
400
200
0
Porous Cantilever
Non-Porous Cantilever
0
100
200
300
Analyte Concentration, ng/ml

FIG 8

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 12768920	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. **PCT/AU2006/000656**	International filing date *(day/month/year)* 17 May 2006	(Earliest) Priority Date *(day/month/year)* 20 May 2005
Applicant RMIT UNIVERSITY et al		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 5 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language,** the international search was carried out on the basis of:

[X] The international application in the language in which it was filed.

[ ] A translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. [ ] With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. [ ] **Certain claims were found unsearchable** (See Box No. II).

3. [ ] **Unity of invention is lacking** (See Box No. III).

4. With regard to the **title,**

[X] the text is approved as submitted by the applicant.

[ ] the text has been established by this Authority to read as follows:

With regard to the **abstract,**

[ ] the text is approved as submitted by the applicant.

[X] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings,**

a. the figure of the **drawings** to be published with the abstract is Figure No. **2**

[X] as suggested by the applicant.

[ ] as selected by this Authority, because the applicant failed to suggest a figure.

[ ] as selected by this Authority, because this figure better characterizes the invention.

b. [ ] none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2006/000656

Box No. IV Text of the Abstract (Continuation of item 5 of the first sheet)

An assay device (1) having a rotatable platform (2) with a test chamber (6) and a sensor (20) which undergoes displacement when subject to a particular substance such as a chemical, biological species or other organism. The sensor is a cantilever beam (21) with a porous section (23) to enhance sensitivity.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2006/000656

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

G01N 33/48 (2006.01) *G01N 33/50* (2006.01) *G01N 33/53* (2006.01)

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)

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)
DWPI and keywords: assay, test, rotate, turn, spin, compact, disk, disc, micro-fluidic, cantilever, beam, displace, deflect, curve, porous, hole, and other similar terms.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6854317 B2 (PORTER ET AL) 15 February 2005 See Abstract and Figure 1	22
X Y	US 2004/0029108 A1 (BOTTOMLEY ET AL) 12 February 2004 See Abstract and figures See page 3 paragraph 26	22 1-4, 6, 8-13, 15-21
X	US 2003/0010097 A1 (PORTER ET AL) 16 January 2003 See abstract and figures	22

[X] Further documents are listed in the continuation of Box C [X] 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	Date of mailing of the international search report
15 June 2006	26 JUN 2006
Name and mailing address of the ISA/AU	Authorized officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	**Lynn Bloomfield** Telephone No : (02) 6283

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2006/000656

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	US 2005/0003459 A1 (KRUTZIK) 6 January 2005	
X	See figure 1 and page 2 paragraph 22 and 23	17
Y	See page 1 paragraph 8 to page 2 paragraph 23	1-4, 6, 8-13, 15-21
	US 2003/0224457 A1 (HURT ET AL) 4 December 2003	
X	See figure 1 and page 6 paragraph 47	17
Y	See page 2 paragraph 14 to page 7 paragraph 57	1-4, 6, 8-13, 15-21
	Certain claims do not involve and inventive step when document US 2004/0029108 A1 is combined with US 2005/0003459 A1 or US 2003/0224457 A1.	

28

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/AU2006/000656

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
US	6854317	AU	2003238869	AU	2003239961	CN	1668247
		CN	1714291	EP	1514096	EP	1531731
		US	6823717	US	2004194534	US	2004211243
		US	2006053871	WO	03101304	WO	03102218
US	2004029108	CA	2459462	EP	1425548	US	2003068655
		WO	03023363				
US	2003010097	US	6523392				
US	2005003459	US	2003096434				
US	2003224457	AU	39289/02	AU	2002362005	AU	2003256488
		CA	2467740	CA	2513012	EP	1410042
		EP	1410045	EP	1451589	EP	1583973
		US	7026131	US	2002098528	US	2002196435
		US	2005002827	WO	0242780	WO	02059622
		WO	03043403	WO	2004065964		

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX

DISPOSITIVO DE ENSAYO

CAMPO DE LA INVENCIÓN

La presente invención se refiere a un dispositivo de ensayo y a un detector voladizo.

ANTECEDENTES DE LA INVENCIÓN

Se conoce el uso de discos compactos (CD) para pruebas químicas. Los CD se proveen con una estructura de microfluido que define varios puertos de entrada de fluido en comunicación con canales asociados y cámaras de mezclado del fluido. Con el fin de conducir una prueba, el fluido se deposita en los puertos de entrada y el CD se hace girar de tal forma que el fluido es empujado por el bombeo centrífugo a través de los canales relevantes hacia las cámaras de mezclado. Puede utilizarse tecnología óptica y de direccionamiento de CD significantemente modificada para capturar las imágenes de las cámaras de mezclado específico para determinar los resultados de prueba de cualquier reacción química dentro de las cámaras.

También se conoce que las varillas microvoladizas han sido consideradas como medios para detectar los resultados de las reacciones químicas, pero la limitada sensibilidad de las varillas estudiadas no ha dado como resultado una aplicación extensa de esa tecnología.

SUMARIO DE LA INVENCION

De acuerdo con la invención, se provee un dispositivo de ensayo que tiene una plataforma rotatoria con una cámara de prueba y un sensor que sufre un desplazamiento cuando se somete a la presencia de una sustancia particular tal como un espécimen químico, biológico u otro organismo.

Preferentemente el sensor es una varilla voladiza.

Preferentemente el dispositivo incluye trayectorias de microfluido en comunicación con los canales asociados y la cámara de prueba o una pluralidad asociada de cámaras de prueba.

Preferentemente la o cada cámara de prueba incluye una o más varillas voladizas.

Preferentemente el sensor incluye una sección porosa. La sección porosa pude dar al sensor una sensibilidad que permite detectar la presencia de una sustancia particular, esto es un producto químico, un espécimen o un organismo seleccionados.

Preferentemente el sensor está equipado funcionalmente con receptores, anticuerpos, antígenos o enzimas que selectivamente atraen y se enlazan con la sustancia particular que va a ser detectada.

Preferentemente la sección porosa se recubre

con una capa de oro que enlaza los receptores a la varilla, funcionalizando la varilla para que se ligue con especimenes u organismos preseleccionados dentro del fluido en la cámara de prueba.

Preferentemente el sensor incluye una superficie que va a ser monitoreada, que está sujeta al desplazamiento después del movimiento del sensor, la posición de la superficie monitoreada se monitorea por medio de un aparato en el cual se coloca el dispositivo de ensayo.

Preferentemente, la superficie es una superficie reflectora.

Preferentemente el aparato es una unidad de CD conectada a una computadora que permite que la posición de la superficie reflectora sea determinada y mostrada por medio de la computadora.

Preferentemente el dispositivo de ensayo incluye un sistema de microfluido para transportar un fluido de prueba desde un puerto de entrada a la cámara de prueba que contiene la varilla voladiza y de allí a una cámara para desechos.

Preferentemente la cámara para desechos se separa de la cámara de prueba por medio de una válvula micro-mecánica que es accionada por encima de una velocidad angular de umbral del dispositivo.

Preferentemente el dispositivo puede aceptar el fluido entero que se va analizar e incluye un filtro para filtrar el material del fluido entero después de la inserción el puerto de entrada para proporcionar fluido en una forma adecuada para las pruebas. Más preferentemente, el filtro se forma de un silicio poroso.

Preferentemente el sistema incluye la provisión de una segunda cámara conectada a la cámara de prueba para permitir el ciclo del fluido entre la cámara secundaria y la cámara de prueba.

Preferentemente, el dispositivo tiene la forma de un disco compacto (CD).

En otro aspecto se provee un aparato de prueba para recibir un dispositivo de ensayo, como se describe antes, que incluye una unidad de impulsión para hacer rotar el dispositivo y una unidad de lectura para monitorear el sensor.

Preferentemente el aparato está adaptado para mostrar la información derivada de la unidad de lectura.

Más preferentemente, el aparato tiene la forma de una unidad de CD y la unidad de lectura forma parte de un cabezal de lectura/escritura óptica de la unidad de CD.

Más preferentemente, el aparato se conecta directamente a una computadora, en la cual se instala un programa de computadora que controla la operación de la unidad de CD para iniciar el proceso de filtrado, la transferencia de fluido entre las cámaras y el sistema de lectura óptico para medir el desplazamiento del sensor.

Preferentemente el proceso de ensayo se inicia al usar la computadora para introducir datos que definan la prueba que se va a realizar y presentar los resultados con a misma identificación.

En otro aspecto se provee un método de ensayo químico que incluye el introducir el fluido a una cámara sensora en una plataforma rotatoria, en donde la cámara sensora incluye un sensor colocado para desplazarse al detectar una sustancia particular, tal como una molécula seleccionada, dentro de la cámara y monitorear el sensor para detectar el desplazamiento.

En todavía otro aspecto se provee un sensor voladizo tal como se describe antes.

BREVE DESCRIPCION DE LAS FIGURAS

La figura 1 es una representación diagramática de una vista de planta de un dispositivo de ensayo;

La figura 2 es una vista transversal diagramática de un aparato de prueba;

La figura 3a es una vista lateral diagramática de un micro-soporte voladizo;

La figura 3b es una vista lateral diagramática de un micro-soporte voladizo que ilustra la deflexión;

La figura 4 es una gráfica que lustra una relación entre la frecuencia resonante y la porosidad de un soporte voladizo;

La figura 5 es una vista diagramática en perspectiva del sensor voladizo y un cabezal de lectura/escritura de una unidad de CD;

La figura 6 es una gráfica que ilustra una relación entre la intensidad y el tiempo con el propósito de detectar el desplazamiento del sensor.

La figura 7 es una diagrama de flujo de un procedimiento de prueba; y

La figura 8 es una gráfica que ilustra la deflexión comparativa entre un soporte voladizo poroso y uno no poroso.

DESCRIPCIÓN DETALLADA DE LA INVENCIÓN

Se ilustra en la figura 1 un dispositivo de ensayo 1 que incluye una plataforma rotatoria 2 en la forma de un disco compacto (CD), con un sistema de

microfluido 3que incluye un puerto de entrada 4, una cámara secundaria 5, una cámara de prueba 6 y una cámara para desechos 7 interconectados por medio de canales respectivos 8,9, 10. Se provee un filtro en uno de los canales 8, adyacentes al puerto de entrada para filtrar material tal como material celular del fluido de prueba introducido en el puerto de entrada 4. El filtro 11 preferentemente se forma de silicio poroso 12. Una válvula micro-mecánica 12 también se provee en el canal 10 que separa la cámara de prueba y la cámara para desechos. La válvula 13 se mueve de una posición cerrada indicada con líneas punteadas 14 a una posición abierta indicada por una flecha 15, cuando la velocidad angular del dispositivo 1 se encuentra por encima de un umbral predeterminado.

Durante la operación el fluido se introduce en el puerto de entrada 4 y el dispositivo 1 se hace rotar a la velocidad requerida para efectuar el bombeo centrífugo de tal forma que el fluido es forzado a través del canal 8 hacia la cámara secundaria 5 y subsecuentemente la cámara de prueba 6 en donde el sensor se provee con el propósito de detectar la presencia de una sustancia particular, tal como un espécimen químico, biológico u otro organismo dentro del fluido. El dispositivo 1

entonces se hace rotar a una velocidad angular mayor para abrir la válvula 13 y permitir que el fluido salga de la cámara de prueba 6.

Refriéndonos ahora a la figura 2, la cámara de prueba 6 del dispositivo 1 se muestra en una sección agrandada incluyendo un sensor voladizo 20, que se proyecta desde la plataforma 2 del dispositivo 1. Más específicamente, el sensor voladizo poroso 20 se forma de una varilla 21 que se proyecta desde un bloque de silicio 22 y que incluye una sección porosa 23 y una superficie 24 formada de por ejemplo una sección de oro 25 u otra sustancia metálica o reflectora adecuada.

El dispositivo 1 se muestra colocado en un perno 26 de una unidad de impulsión 27 del aparato de prueba 30, que preferentemente tiene la forma de una computadora con una unidad de CD 29 y la unidad de impulsión 27 forma parte de la unidad 29 junto con una unidad de lectura 31, que monitorea cualquier desplazamiento de la superficie de referencia 24 y con esto del sensor voladizo 20. La unidad de lectura 31 preferentemente forma parte de un cabezal existente de lectura/escritura 32 de la unidad de CD 31, sin modificación.

La estructura del sensor voladizo 20 ahora

se describe a más detalle con referencia a la figura 3. La figura 3a muestra una parte agrandada 33 del sensor 20 que incluye una capa porosa 35 y una capa de silicio 34 ambos recubiertos con oro que se provee con receptores de anticuerpos 36 para capturar las moléculas 37 tales como ligandos de antígenos. El ligado de las moléculas 37 a los receptores conducirá a una deflexión de la varilla 21, tal como se ilustra en la figura 3b que entonces puede detectarse.

Al formar la varilla voladiza de material poroso se mejora la deflexión. Más particularmente las características del sensor voladizo 20 se basan en los procesos superficiales tales como adsorción, desorción, reconstrucción superficial y reorganización para inducir una tensión superficial en la capa superficie de la varilla voladiza 39. La modificación de la tensión superficial sobre la superficie 39 de la varilla 21 inducirá una tensión diferencia a través del sensor voladizo 20, provocando que se flexione.

La curvatura de la varilla 21 es proporcional al gradiente de tensión diferencial a través de la varilla. El aumento de la tensión superficial sobre la superficie 39 en comparación con la superficie 40 o capa 34 aumenta el gradiente de

tensión superficial. El silicio poroso en la superficie 39 puede usarse como capa 35 para aumentar el área superficial y por lo tanto la sensibilidad. A lo mejor de nuestro conocimiento no se han enfocado la investigación o el desarrollo en el aumento de la sensibilidad del soporte voladizo en base a la técnica sensora de modificar la geometría de la varilla o la estructura del material. La varilla 21 aumenta la tensión superficial máxima que puede inducirse por medio del analito químico al introducir la capa porosa 35 y modificar la geometría de la varilla.

Los análisis y las pruebas han mostrado que al modificar la varilla, la geometría y las estructuras del material como se describe, puede variarse la mayor deflexión de la varilla para una mayor porosidad, tal como se muestra en la figura 8.

De acuerdo con esto en la figura 5, el sensor 20 permite la deflexión de la varilla voladiza 21, en comparación con una varilla convencional del mismo grosor y longitud, al fabricar una sección porosa en la superficie 23 de la varilla 21. Esto tiene tres efectos sobre la respuesta mecánica de la varilla:

1. Reduce el grosor efectivo de la varilla en donde

es porosa, reduciendo el segundo momento de inercia de la varilla haciendo que la varilla sea menor rígida;

2. La constante elástica de la varilla también se reduce en donde es porosa;
3. El área superficial de la varilla también se reduce debido a la mayor porosidad de la varilla voladiza.

Esos tres efectos tienen un efecto combinado al aumentar la deflexión de la varilla y los eventos de combinación de sensibilidad con superficie en comparación con los biosensores a base de soportes voladizos actuales. Al aumentar la tensión diferencial inducida entre las capas 35,34 de la varilla, la figura 3b conduce a un aumento en la deflexión. Además de esto, se aumenta el área superficial para volverla funcional, esto es proveerla con receptores para ligarse con moléculas seleccionadas, permitiendo que una mayor densidad de grupos funcionalizados se enlacen en la superficie aumentando la sensibilidad y la tensión superficial inducida para la misma concentración de especimenes químicos o biológicos.

Esto permite un enlace más concentrado de las especies también permite menos variaciones en la

deflexión para el mismo concentrado químico o de especimenes.

Otro efecto de la modificación de la geometría de la varilla es que la frecuencia resonante de la varilla se modifica ya que la frecuencia resonante es una medida directa de la cantidad de porosidad.

El cambio de frecuencia resonante de acuerdo con la geometría de la varilla tiene la siguiente relación: $$fo = \frac{1}{2\pi\sqrt{\frac{k}{m}}}$$

en la cual: fo = frecuencia resonante

k = constante elástica

m = masa de la varilla

Un cambio de porosidad cambia la frecuencia resonante de la varilla voladiza 21 y es una capacidad sensora adicional del sensor, que podría aplicarse a la detección de la corrosión o reacción química provocada por el fluido, por ejemplo la medición de la corrosión en un buque marino o la detección de la lluvia ácida o eventos similares para el monitoreo ambiental.

El cambio de la frecuencia de resonancia con la porosidad se ilustra en la figura 4 que indica que hay una frecuencia resonante mínima para un rango de

niveles de porosidad. En el aparato 30 sin embargo, es solo la deflexión de la varilla la que necesita ser monitoreada. Los sistemas convencionales para detectar tal deflexión usan un láser y un detector sensible a la posición para detectar la deflexión. El sistema de deflexión es un accesorio externo y requiere que el láser sea alienado óptimamente a la varilla voladiza. El sistema de detección usado en el aparato 30 por otro lado usa el sistema de deflexión óptica inherente de la unidad de CD 29. El cabezal de lectura/escritura (RWH) 32 de la impulsión 29 se usa para interrogar al sensor del soporte voladizo 20 y monitorear la posición de la superficie de referencia 24. Además el láser del RWH puede usarse para controlar la temperatura de la prueba y las cámaras secundarias 5,6.

Más particularmente para captar la deflexión del sensor 20, el RWH se mueve sobre la posición de la varilla voladiza porosa 21, tal como se ilustra en la figura 5. La unidad de CD 1 puede rotar mientras que capta la deflexión. El láser del RWH se enfoca en la varilla voladiza 21 y la intensidad reflejada de la superficie de referencia 24 de la varilla 21 se mide antes de cargar un fluido de prueba en la cámara de prueba 4, para los propósitos de calibración. El

fluid de prueba entones se hace entrar a la cámara de prueba 6 y subsecuentemente se expulsa a la cámara para desechos 7. Se mide el cambio en la intensidad reflejada de la varilla voladiza 21 después de que el fluido de prueba ha sido retirado de la cámara de prueba 6. El cambio en la intensidad reflejada es una medida de la deflexión del sensor. En segundo lugar la deflexión también puede medirse como un cambio en el enfoque. Cuando el láser se enfoca inicialmente en la varilla 21 antes de cargar el fluido de prueba antes de cargar el fluido de prueba en la cámara de prueba 6, la posición de enfoque puede medirse. Después de que el fluido de prueba ha sido removido de la cámara la varilla 21 se habrá presentado una deflexión y la superficie reflectora 24 se habrá movido fuera de foco. Una representación gráfica que ilustra el efecto de un cambio en el enfoque de la intensidad medida de la luz láser reflejada, se ilustra en la figura 6. El cambio de enfoque es una medida indirecta de la deflexión y puede medirse como un cambio en la salida de corriente o voltaje del RWH.

Aplicación del Dispositivo de Ensayo a Pruebas Sanguíneas

Un ejemplo detallado del uso del dispositivo

de ensayo 1 y el aparato 20 se describen con referencia a la figura 7. Específicamente se muestra un procedimiento de prueba de diagnóstico 40 que incluye una etapa 41 de extraer sangre de un paciente e insertar la sangre en el puerto de entrada 4 del dispositivo 1 en la etapa 42. El dispositivo CD 1 entonces se inserta en una computadora en ala etapa 43 y la información del disco es leída del CD. Se emplea entonces en la etapa 44 un software relevante para iniciar las pruebas que comienzan en la etapa 45 con la intensidad reflejada del sensor voladizo 20 que se mide con propósitos de calibración. El CD entonces se hace girar en la etapa 46 para enviar la sangre al primer canal 8 y a través del filtro 11, en donde se retira el material celular. El suero resultante entonces se hace pasar a través de la cámara secundaria 5 (si se requiere) y hacia la cámara de prueba 6. Si se requiere, el suero entonces se calienta en la etapa 47 por medio de un láser del RWH dando como resultado que el suero realice ciclos entre la cámara de prueba 6 y la cámara secundaria 5 para mejorar la interacción con los receptores. El CD entonces se hace girar a una velocidad angular mayor en la etapa 48 para mover la válvula 13 a la posición abierta de tal forma que el suero pueda salir de la

cámara de prueba 6 y pasar hacia la cámara para desechos 7 en la etapa 49. El RWH entonces puede usarse para medir la intensidad reflejada de la varilla voladiza desplazada 21 en la etapa 50 y la salida del RWH entonces regresa a la etapa 51 para el análisis en la etapa 52, en donde la intensidad medida se lee y se compara con los datos calibrados para determinar la presencia del químico o la molécula relevantes. Los resultados de prueba entonces se almacenan, un usuario notifica los resultados en la etapa 53, y el CD se expulsa en la etapa 54 si se requiere. El CD entonces puede desechar se o almacenarse con el propósito de conservar un registro permanente del resultado de prueba.

Otras aplicaciones

La tecnología permite realizar exámenes patológicos cerca del paciente, evitando la necesidad de uso de equipo de laboratorio caro y el retraso asociado en la entrega de los resultados. Ejemplos del rango de aplicaciones incluyen:

- Patología humana

  Detección de - Antígeno específico a la próstata
  - Enzimas cardiacas
  - Enfermedades infecciosas

(Hepatitis, VIH)

- Veneno de mordida de víbora

- Patología ambiental

  Detección de - bacterias Leionella

  - hepatitis en vías acuáticas

  - niveles de E. coli

- Patología animal

  Detección de la enfermedad de Johne

- Medidas de la calidad de fluidos

  Detección de la fermentación del vino

- Mediciones industriales

  Detección del deterioro del aislamiento eléctrico.

La invención ha sido descrita únicamente por medio de un ejemplo no limitante y pueden realizarse varias modificaciones y variaciones in salirse del espíritu y alcance de la invención descrita.

NOVEDAD DE LA INVENCION

Habiéndose descrito la invención como antecede, se reclama como propiedad lo contenido en las siguientes:

REIVINDICACIONES

1. Un dispositivo de ensayo caracterizado porque tiene una plataforma rotatoria con una cámara de prueba y un sensor que sufre un desplazamiento cuando se somete a la presencia de una sustancia particular tal como un espécimen químico, biológico u otro organismo.

2. Un dispositivo de ensayo de acuerdo con la reivindicación 1, caracterizado porque el sensor es una varilla voladiza.

3. Un dispositivo de ensayo de acuerdo con la reivindicación 1 ó 2, caracterizado porque el dispositivo incluye trayectorias de microfluido en comunicación con los canales asociados y la cámara de prueba o una pluralidad asociada de cámaras de prueba.

4. Un dispositivo de ensayo de acuerdo con la reivindicación 3, caracterizado porque la o cada cámara de prueba incluye una o más varillas voladizas.

5. Un dispositivo de ensayo de acuerdo con

la reivindicación 1 ó 2, caracterizado porque el sensor incluye una sección porosa. La sección porosa pude dar al sensor una sensibilidad que permite detectar la presencia de una sustancia particular, esto es un producto químico, un espécimen o un organismo seleccionados.

6. Un dispositivo de ensayo de acuerdo con la reivindicación 5, caracterizado porque el sensor está equipado funcionalmente con receptores, anticuerpos, antígenos o enzimas que selectivamente atraen y se enlazan con la sustancia particular que va a ser detectada.

7. Un dispositivo de ensayo de acuerdo con la reivindicación 6, caracterizado porque la sección porosa se recubre con una capa de oro que enlaza los receptores a la varilla, funcionalizando la varilla para que se ligue con especimenes u organismos preseleccionados dentro del fluido en la cámara de prueba.

8. Un dispositivo de ensayo de acuerdo con la reivindicación 1, caracterizado porque el sensor incluye una superficie que va a ser monitoreada, que está sujeta al desplazamiento después del movimiento del sensor, la posición de la superficie monitoreada se monitorea por medio de un aparato en el cual se

coloca el dispositivo de ensayo.

9. Un dispositivo de ensayo de acuerdo con la reivindicación 8, caracterizado porque, la superficie es una superficie reflectora.

10. Un dispositivo de ensayo de acuerdo con la reivindicación 8, caracterizado porque el aparato es una unidad de CD conectada a una computadora que permite que la posición de la superficie reflectora sea determinada y mostrada por medio de la computadora.

11. Un dispositivo de ensayo de acuerdo con la reivindicación 1, caracterizado porque el dispositivo de ensayo incluye un sistema de microfluido para transportar un fluido de prueba desde un puerto de entrada a la cámara de prueba que contiene la varilla voladiza y de allí a una cámara para desechos.

12. Un dispositivo de ensayo de acuerdo con la reivindicación 11, caracterizado porque la cámara para desechos se separa de la cámara de prueba por medio de una válvula micro-mecánica que es accionada por encima de una velocidad angular de umbral del dispositivo.

13. Un dispositivo de ensayo de acuerdo con la reivindicación 11 ó 12, caracterizado porque el

dispositivo puede aceptar el fluido entero que se va analizar e incluye un filtro para filtrar el material del fluido entero después de la inserción el puerto de entrada para proporcionar fluido en una forma adecuada para las pruebas.

14. Un dispositivo de ensayo de acuerdo con la reivindicación 13, caracterizado porque, el filtro se forma de un silicio poroso.

15. Un dispositivo de ensayo de acuerdo con la reivindicación 14, caracterizado porque el sistema incluye la provisión de una segunda cámara conectada a la cámara de prueba para permitir el ciclo del fluido entre la cámara secundaria y la cámara de prueba.

16. Un dispositivo de ensayo de acuerdo con cualquiera de las reivindicaciones anteriores, caracterizado porque, el dispositivo tiene la forma de un disco compacto (CD).

17. Un aparato de prueba para recibir un dispositivo de ensayo, como se describe antes, que incluye una unidad de impulsión para hacer rotar el dispositivo y una unidad de lectura para monitorear el sensor.

18. Un aparato de prueba de acuerdo con la reivindicación 17, caracterizado porque el aparato

está adaptado para mostrar la información derivada de la unidad de lectura.

19. Un aparato de prueba de acuerdo con la reivindicación 17 ó 18, caracterizado porque, el aparato tiene la forma de una unidad de CD y la unidad de lectura forma parte de un cabezal de lectura/escritura óptica de la unidad de CD.

20. Un aparato de prueba de acuerdo con una de las reivindicaciones 17 a 19, caracterizado porque, el aparato se conecta directamente a una computadora, en la cual se instala un programa de computadora que controla la operación de la unidad de CD para iniciar el proceso de filtrado, la transferencia de fluido entre las cámaras y el sistema de lectura óptico para medir el desplazamiento del sensor.

21. Un método de ensayo químico que incluye el introducir el fluido a una cámara sensora en una plataforma rotatoria, en donde la cámara sensora incluye un sensor colocado para desplazarse al detectar una sustancia particular, tal como una molécula seleccionada, dentro de la cámara y monitorear el sensor para detectar el desplazamiento.

22. Un sensor voladizo de acuerdo con cualquiera de las reivindicaciones anteriores.

RESUMEN DE LA INVENCION

Un dispositivo de ensayo (1) que tiene una plataforma rotatoria (2) con una cámara de prueba (6) y un sensor (20) que sufre un desplazamiento cuando se somete a la presencia de una sustancia particular tal como un espécimen químico, biológico u otro organismo. El sensor es una varilla voladiza (21) con una sección porosa (23) para mejorar la sensibilidad.

1/1

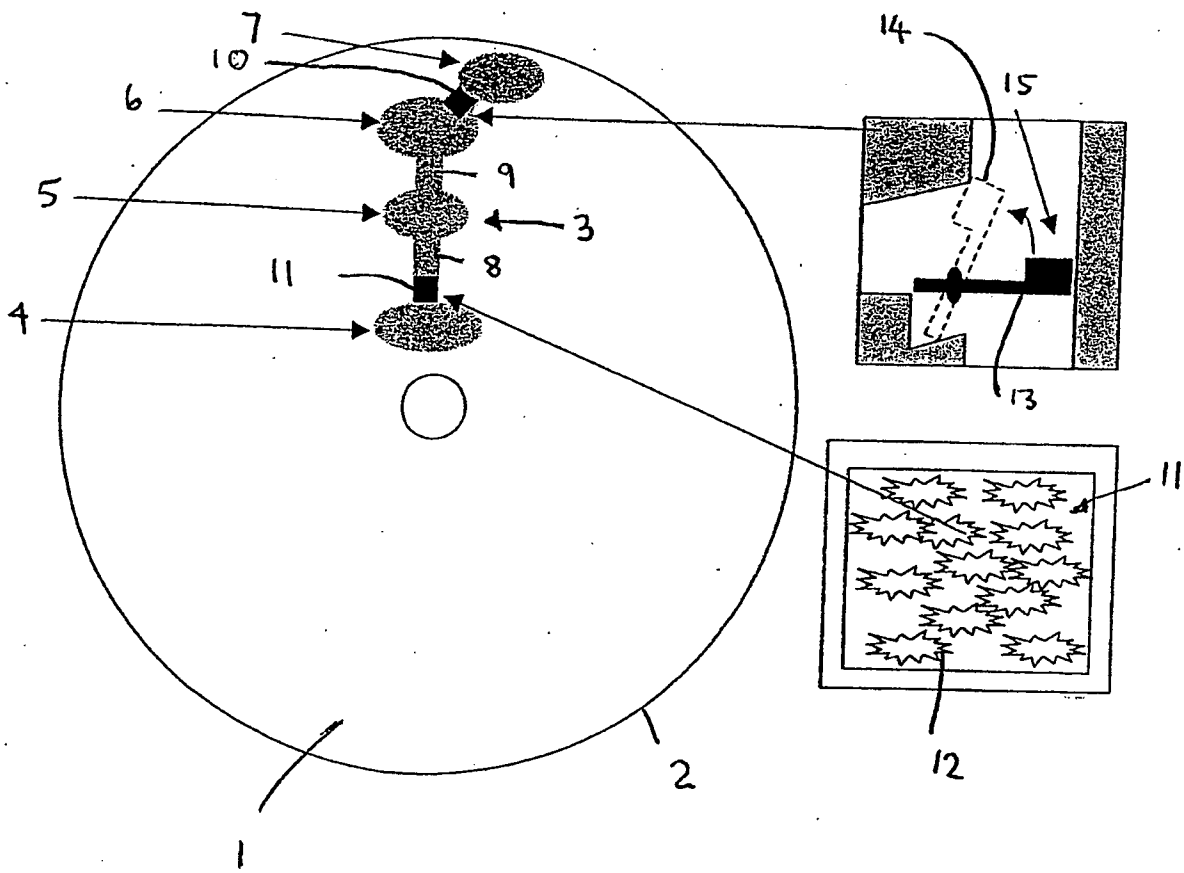


FIG 1

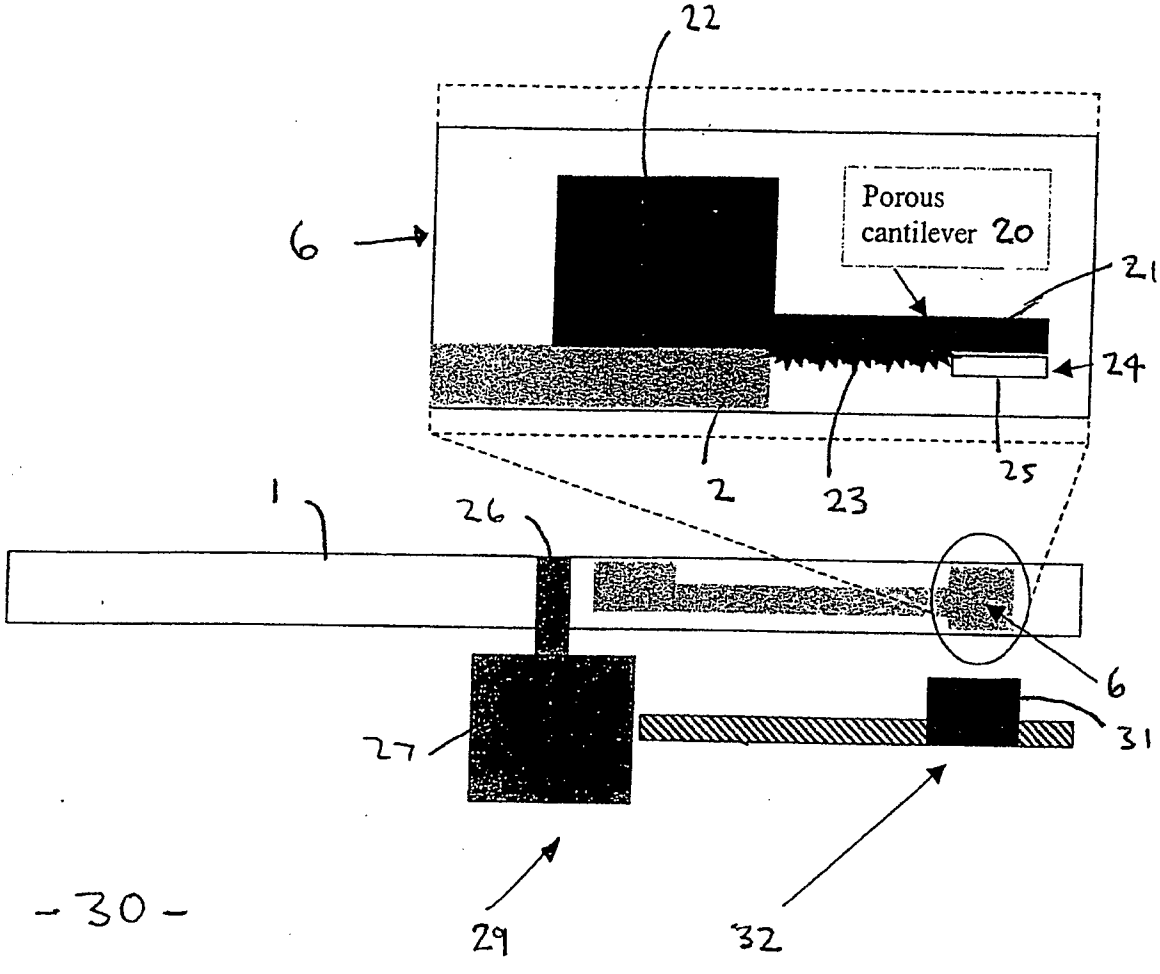


FIG 2

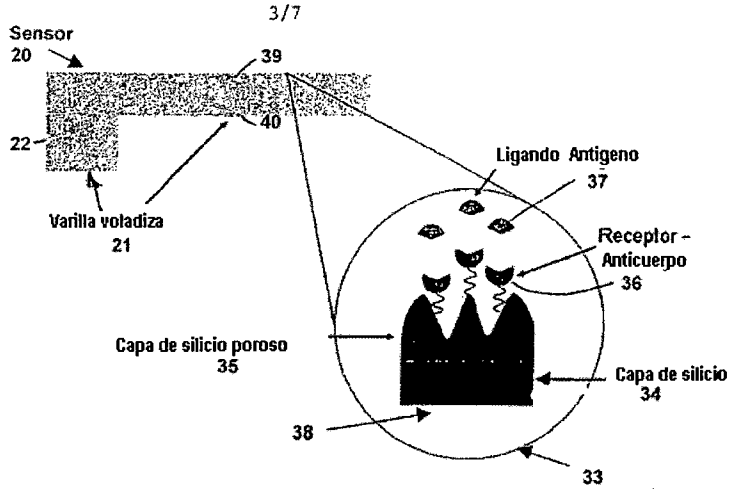

Sensor
20
39
40
22
Varilla voladiza
21
Ligando Antigeno
37
Receptor -
Anticuerpo
36
Capa de silicio poroso
35
Capa de silicio
34
38
33

FIG 3a

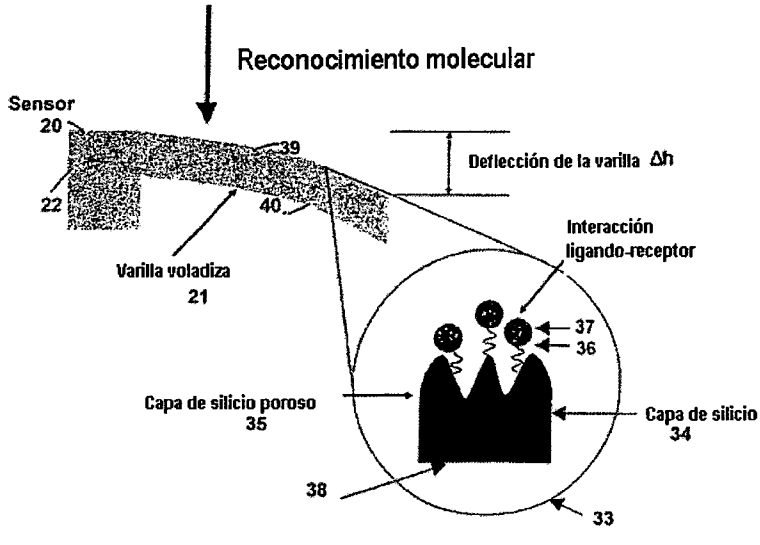

Reconocimiento molecular
Sensor
20
39
Deflección de la varilla Δh
22
40
Interacción
ligando-receptor
Varilla voladiza
21
37
36
Capa de silicio poroso
35
Capa de silicio
34
38
33

FIG 3b

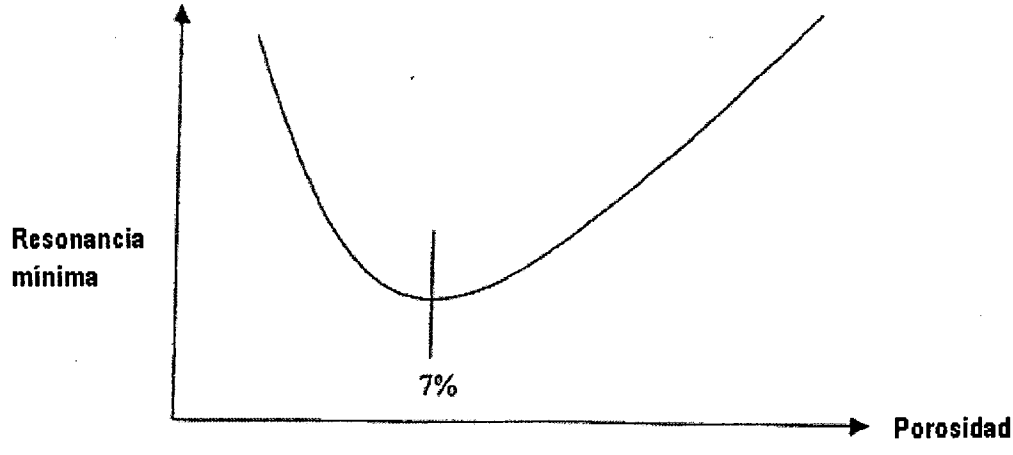


Fig. 4

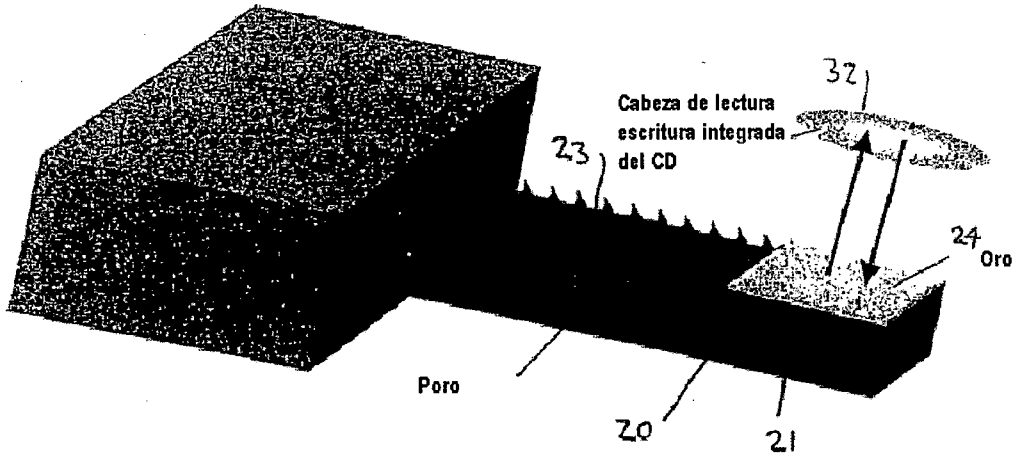


Figura 5

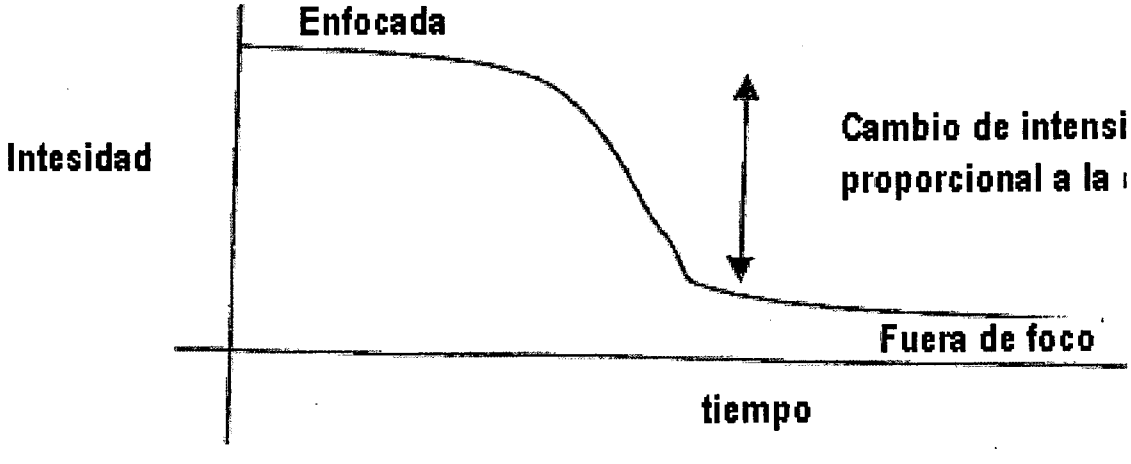


FIG. 6

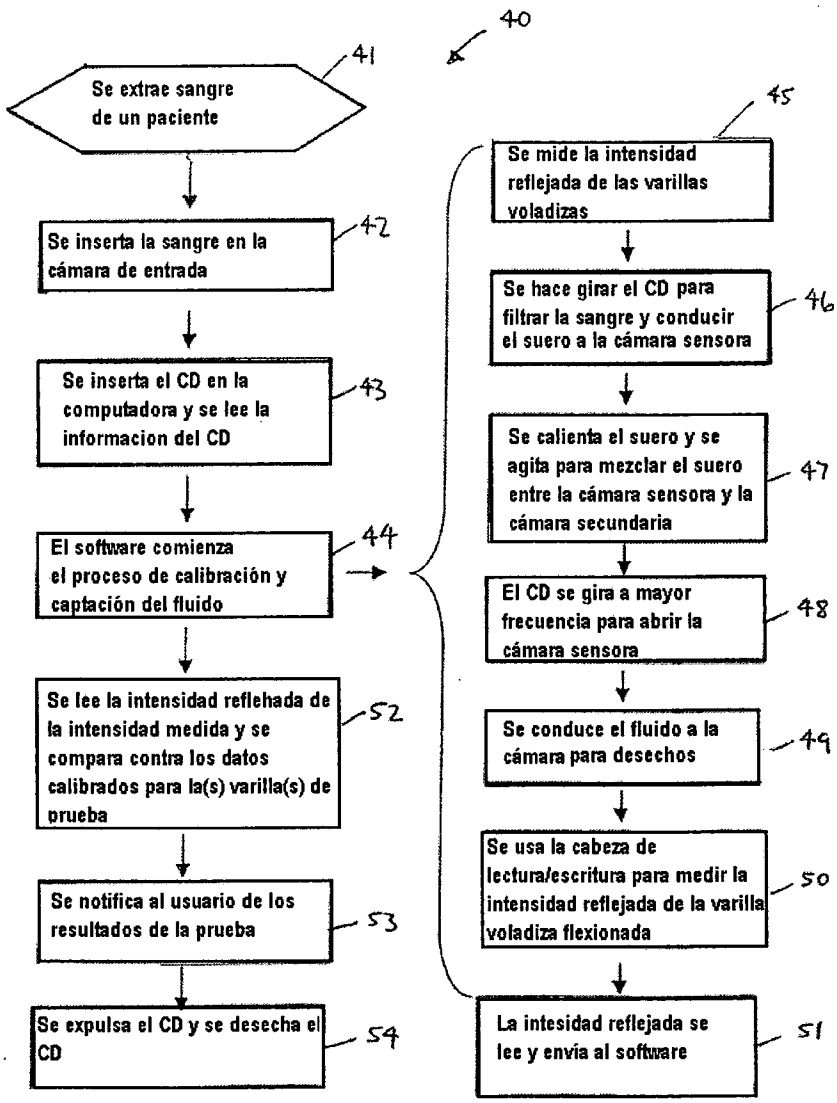

40
41
Se extrae sangre de un paciente
42
Se inserta la sangre en la cámara de entrada
43
Se inserta el CD en la computadora y se lee la informacion del CD
44
El software comienza el proceso de calibración y captación del fluido
52
Se lee la intensidad reflehada de la intensidad medida y se compara contra los datos calibrados para la(s) varilla(s) de prueba
53
Se notifica al usuario de los resultados de la prueba
54
Se expulsa el CD y se desecha el CD
45
Se mide la intensidad reflejada de las varillas voladizas
46
Se hace girar el CD para filtrar la sangre y conducir el suero a la cámara sensora
47
Se calienta el suero y se agita para mezclar el suero entre la cámara sensora y la cámara secundaria
48
El CD se gira a mayor frecuencia para abrir la cámara sensora
49
Se conduce el fluido a la cámara para desechos
50
Se usa la cabeza de lectura/escritura para medir la intensidad reflejada de la varilla voladiza flexionada
51
La intesidad reflejada se lee y envía al software

Fig. 7

Deflexión del soporte voladizo vs Concentración del analito
(dimensiones del soporte voladizo: 150µm x 10 µm x 0.5 µm)

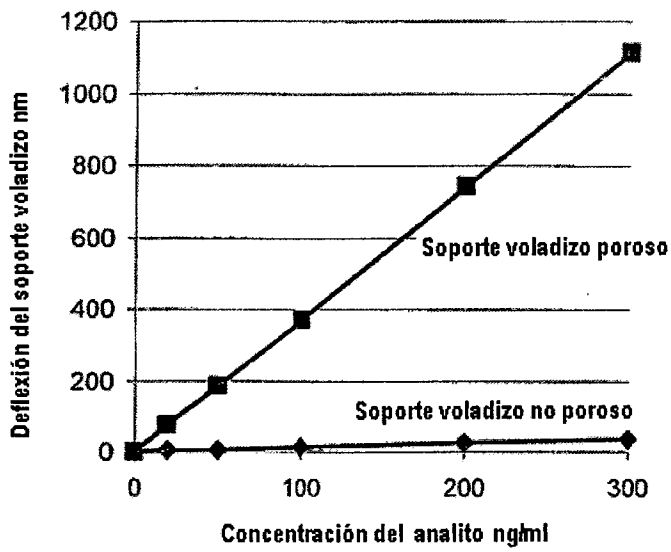


FIG 8

62

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:

Davies Collison Cave
Level 15
1 Nicholson Street
MELBOURNE VIC 3000

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

	Date of mailing *(day/month/year)* 26 JUN 2006
Applicant's or agent's file reference 12768920	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. **PCT/AU2006/000656**	International filing date *(day/month/year)* 17 May 2006
Applicant RMIT UNIVERSITY et al	

1. [X] The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.
Filing of amendments and statement under Article 19:
The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):
When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.
Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 82 70
For more detailed instructions, see the notes on the accompanying sheet.

2. [ ] The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. [ ] **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
   [ ] the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
   [ ] no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/AU	Authorized officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	**Lynn Bloomfield** Telephone No. (02) 6283 2851

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: Agent :

Davies Collison Cave
Level 15
1 Nicholson Street
MELBOURNE VIC 3000

PCT

NOTIFICATION OF RECEIPT
OF DEMAND BY COMPETENT INTERNATIONAL
PRELIMINARY EXAMINING AUTHORITY

(PCT Rule 59.3(e) and 61.1(b), first sentence
and Administrative Instructions, Section 601(a))

FV

Date of mailing *(day/month/year)*	1 SEP 2006 (1/9/2006)
Applicant's or agent's file reference	12768920/DH
	IMPORTANT NOTIFICATION

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/AU2006/000656	17 MAY 2006 (17/5/2006)	20 MAY 2005 (20/5/2005)

Applicant

RMIT University (et al.)

1. The applicant is hereby **notified** that this International Preliminary Examining Authority considers the following date as the date of receipt of the demand for international preliminary examination of the international application:

29 AUG 2006 (29/8/2006)

2. That date of receipt is:

☒ the actual date of receipt of the demand by this Authority (Rule 61.1(b)).

☐ the actual date of receipt of the demand on behalf of this Authority (Rule 59.3(e)).

☐ the date on which this Authority has, in response to the Invitation to correct defects in the demand (Form PCT/IPEA/404), received the required corrections.

3. ☐ **Attention:** That date of receipt is **after** the expiration of 19 months from the priority date. Consequently, in respect of some Offices, the demand does not have the effect of postponing the entry into the national phase until 30 months from the priority date (or later in some Offices) (Article 39(1)) and the acts for entry into the national phase must therefore be performed within 20 months from the priority date (or later in some Offices). **However**, in respect of some other Offices, the time limit of 30 months (or later) may nevertheless apply. See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

☐ *(If applicable)* This notification confirms the information given by telephone, facsimile transmission or in person on:

4. Only where paragraph 3 applies, a copy of this notification has been sent to the International Bureau.

Name and mailing address of the IPEA/AU	Authorized officer
AUSTRALIAN PATENT OFFICE **PO BOX 200, WODEN ACT 2606, AUSTRALIA** E-mail: pct@ipaustralia.gov.au Facsimile No. 02 6285 3929	PCT Authorized Officer Telephone No (02) 6283 2999

Form PCT/IPEA/402 (April 2002)

61

64

PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

16 APR 2007

To:

Davies Collison Cave
Level 15
1 Nicholson Street
MELBOURNE VIC 3000

DJF

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	13 APR 2007
Applicant's or agent's file reference 12768920	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/AU2006/000656	17 May 2006	20 May 2005

Applicant

RMIT UNIVERSITY et al

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translations to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the *PCT Applicant's Guide.*

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed invention is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the IPEA/AU	Authorized officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Owen Haggar AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No. (02) 6283 2109

62

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 12768920	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/AU2006/000656	International filing date *(day/month/year)* 17 May 2006	Priority date *(day/month/year)* 20 May 2005

International Patent Classification (IPC) or national classification and IPC

Int. Cl.

G01N 33/48 (2006.01) ***G01N 33/50*** (2006.01) ***G01N 33/53*** (2006.01)

Applicant

RMIT UNIVERSITY et al

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. [X] *(sent to the applicant and to the International Bureau)* a total of 7 sheets, as follows:
      - [X] sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      - [ ] sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. [ ] *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:

[X]	Box No. I	Basis of the report
[ ]	Box No. II	Priority
[ ]	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
[ ]	Box No. IV	Lack of unity of invention
[X]	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
[ ]	Box No. VI	Certain documents cited
[ ]	Box No. VII	Certain defects in the international application
[ ]	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
29 August 2006	10 April 2007
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer **Owen Haggar** AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No. (02) 6283 2109

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2006/000656

Box No. I Basis of the report

1. With regard to the **language,** this report is based on:

[X] The international application in the language in which it was filed

[ ] A translation of the international application into , which is the language of a translation furnished for the purposes of:

[ ] international search (under Rules 12.3(a) and 23.1 (b))

[ ] publication of the international application (under Rule 12.4(a))

[ ] international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

[ ] the international application as originally filed/furnished

[X] the description:

pages **4-6, 8-10** as originally filed/furnished
pages* **1-3, 7** received by this Authority on **29 August 2006** with the letter of 29 August 2006
pages* received by this Authority on with the letter of

[X] the claims:

pages as originally filed/furnished
pages* as amended (together with any statement) under Article 19
pages* **11-13** received by this Authority on **29 August 2006** with the letter of 29 August 2006
pages* received by this Authority on with the letter of

[X] the drawings:

pages **1-7** as originally filed/furnished
pages* received by this Authority on with the letter of
pages* received by this Authority on with the letter of

[ ] a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. [ ] The amendments have resulted in the cancellation of:

[ ] the description, pages
[ ] the claims, Nos.
[ ] the drawings, sheets/figs
[ ] the sequence listing *(specify)*:
[ ] any table(s) related to the sequence listing *(specify)*:

4. [ ] This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

[ ] the description, pages
[ ] the claims, Nos.
[ ] the drawings, sheets/figs
[ ] the sequence listing *(specify)*:
[ ] any table(s) related to the sequence listing *(specify)*:

5. [ ] This report has been established taking into account **the rectification of an obvious mistake** authorized by or notified to the Authority under Rule 91 (Rule 70.2(e)).

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2006/000656

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	**1-21**	**YES**
	Claims		**NO**
Inventive step (IS)	Claims	**1-21**	**YES**
	Claims		**NO**
Industrial applicability (IA)	Claims	**1-21**	**YES**
	Claims		**NO**

2. Citations and explanations (Rule 70.7)

Novelty (N) and Inventive Step (IS)

The claims defining the invention are considered to be novel and inventive over the prior art documents cited in the International Search Report.

None of the prior art document disclose an assay device having a rotatable platform with a test chamber and a sensor with a **porous section**, the sensor undergoing displacement when subject to a particular substance such as a chemical, biological species or other organism.

Furthermore, given the prior art documents, a person skilled in the art would not directly and by routine steps alone come to the conclusion to include a porous section as part of the sensor. It is clear from the description that the porous section gives the sensor an enhanced sensitivity which enables the presence of a particular substance to be more accurately detected. As none of the prior art documents teach or suggest this, it is considered that the porous section is inventive over the cited art.

Claims 1-21 are therefore novel and involve an inventive step.

ASSAY DEVICE

Field of the Invention

The present invention relates generally to an assay device, cantilevered detector and/or chemical assay method.

Background of the Invention

It is known to use compact discs (CDs) for chemical testing. The CDs are provided with micro-fluidic structure which defines various fluid input ports in communication with associated channels and fluid mixing chambers. In order to conduct a test, fluid is deposited into the input ports and the CD is spun so that the fluid is forced by centrifugal pumping through the relevant channels to the mixing chambers. Significantly modified CD optics and addressing technology can be used to capture images of specific mixing chambers to determine the test results of any chemical reaction within the chambers.

It is also known that microcantilever beams have been considered as a means for detecting the results of chemical reactions, but the limited sensitivity of the beams studied has not resulted in any widespread application of the technology.

Summary of the Invention

In accordance with the invention, there is provided an assay device having a rotatable platform with a test chamber and a sensor with a porous section, the sensor undergoing displacement when subject to a particular substance such as a chemical, biological species or other organism.

Preferably, the sensor is a cantilever beam.

Preferably, the device includes microfluidic paths in communication with associated

channels and the test chamber or an associated plurality of test chambers.

Preferably, the or each test chamber includes one or more cantilever beams.

The porous section can give the sensor a sensitivity which enables the presence of the particular substance i.e., a selected chemical, species or organism, to be detected.

Preferably, the sensor is functionalised with receptors, antibodies, antigens or enzymes which will selectively attract and bond with the particular substance to be detected.

Preferably, the porous section is coated with a gold layer which attaches the receptors to the beam, functionalising the beam for bonding with preselected species or organism within the fluid in the test chamber.

Preferably, the sensor includes a surface to be monitored, which is subject to displacement upon movement of the sensor, the position of the monitored surface being monitored by an apparatus into which the assay device is loaded.

Preferably, the surface is a reflective surface.

Preferably, the apparatus is a CD drive connected to a computer allowing the position of the reflective surface to be determined and displayed by the computer.

Preferably, the assay device includes a micro-fluidic system for conveying a test fluid from an inlet port to the test chamber containing the cantilever beam and on to a waste chamber.

Preferably, the waste chamber is separated from the test chamber by a micro-mechanical valve which is actuated above a threshold angular velocity of the device.

Preferably, the device can accept the whole fluid to be tested and includes a filter for filtering material from the whole fluid after insertion into the inlet port to provide fluid in a

form suitable for testing. More preferably, the filter is formed of a porous silicon.

Preferably, the system includes provision for secondary chamber connected to the test chamber to allow the cycling of fluid between the secondary and test chamber.

Preferably, the device is in the form of a compact disc (CD).

In another aspect, there is provided a test apparatus for receiving an assay device, as described above, including a drive unit for rotating the device and a read unit for monitoring the sensor.

Preferably, the apparatus is adapted to display information derived from the read unit.

More preferably, the apparatus is in the form of CD drive and the read unit forms part of an existing optical read/write head of the CD drive.

More preferably, the apparatus is connected directly to a computer, on which is installed a computer program which controls the operation of the CD drive to initiate the filtering process, the transfer of fluid between chambers and the optical reading system to measure the displacement of the sensor.

Preferably, the assay process is initiated by using the computer to input data defining the test to be performed and presenting the results with this same identification.

In another aspect, there is provided a chemical assay method including introducing fluid to a sensing chamber on a rotatable platform, wherein the sensing chamber includes a sensor with a porous section, the sensor being arranged for displacement upon detection of a particular substance, such as a selected molecule, within the chamber, and monitoring the sensor to detect the displacement.

In yet another aspect, there is provided a cantilever sensor, as described above.

leads to an increase in the deflection. Further to this, the surface area to be functionalised, i.e. provided with receptors for bonding with selected molecules, is increased, allowing for a greater density of functionalised groups to be attached to the surface, thereby increasing the sensitivity and induced surface stress for the same concentration of chemical or biological species.

This enables a more concentrated binding of the species and also enables less variation in deflection for the same chemical or species concentrate.

Another affect of modifying the geometry of the beam is that the resonant frequency of the beam is changed since the resonant frequency is a direct measure of the amount of porosity.

The resonant frequency change according to the beam geometry has the following relationship: $fo = \frac{1}{\pi}\sqrt{\frac{k}{m}}$

where fo = resonance frequency

k = spring constant

m = mass of the beam

A change of porosity changes the resonant frequency of the cantilever beam 21 and is an additional sensing capability of the sensor, which could be applied to detection of corrosion or chemical reaction caused by fluid, for example, measurement of corrosion on a marine vessel or detection of acid rain or similar events for environmental monitoring.

The change in resonance frequency with porosity is illustrated in Figure 4 which indicates that there is a minimum resonant frequency for a range of porosity levels. In the apparatus

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. An assay device having a rotatable platform with a test chamber and a sensor with a porous section, the sensor undergoing displacement when subject to a particular substance such as a chemical, biological species or other organism.

2. An assay device as claimed in claim 1, wherein the sensor is a cantilever beam.

3. An assay device as claimed in claim 1 or 2, wherein the device includes microfluidic paths in communication with associated channels and the test chamber or an associated plurality of test chambers.

4. An assay device as claimed in claim 3, wherein the or each test chamber includes one or more cantilever beams.

5. An assay device as claimed in claim 1, wherein the sensor is functionalised with receptors, antibodies, antigens or enzymes which will selectively attract and bond with the particular substance to be detected.

6. An assay device as claimed in claim 5, wherein the porous section is coated with a gold layer which attaches the receptors to the beam, functionalising the beam for bonding with preselected species or organism within the fluid in the test chamber.

7. An assay device as claimed in claim 1, wherein the sensor includes a surface to be monitored, which is subject to displacement upon movement of the sensor, the position of the monitored surface being monitored by an apparatus into which the assay device is loaded.

8. An assay device as claimed in claim 7, wherein the surface is a reflective surface.

9. An assay device as claimed in claim 7, wherein the apparatus is a CD drive

connected to a computer allowing the position of the reflective surface to be determined and displayed by the computer.

10. An assay device as claimed in claim 1, wherein the assay device includes a micro-fluidic system for conveying a test fluid from an inlet port to the test chamber containing the cantilever beam and on to a waste chamber.

11. An assay device as claimed in claim 10, wherein the waste chamber is separated from the test chamber by a micro-mechanical valve which is actuated above a threshold angular velocity of the device.

12. An assay device as claimed in claim 10 or 11, wherein the device can accept the whole fluid to be tested and includes a filter for filtering material from the whole fluid after insertion into the inlet port to provide fluid in a form suitable for testing.

13. An assay device as claimed in claim 12, wherein the filter is formed of a porous silicon.

14. An assay device as claimed in claim 13, wherein the system includes provision for secondary chamber connected to the test chamber to allow the cycling of fluid between the secondary and test chamber.

15. An assay device as claimed in any previous claim, wherein the device is in the form of a compact disc (CD).

16. A test apparatus for receiving an assay device, as defined in any one of claims 1 to 15, including a drive unit for rotating the device and a read unit for monitoring the sensor.

17. A test apparatus as claimed in claim 16, wherein the apparatus is adapted to display information derived from the read unit.

18. A test apparatus as claimed in claim 16 or 17, wherein the apparatus is in the form of CD drive and the read unit forms part of an existing optical read/write head of the CD drive.

19. A test apparatus as claimed in any one of claims 16 to 17, wherein the apparatus is connected directly to a computer, on which is installed a computer program which controls the operation of the CD drive to initiate the filtering process, the transfer of fluid between chambers and the optical reading system to measure the displacement of the sensor.

20. A chemical assay method including introducing fluid to a sensing chamber on a rotatable platform, wherein the sensing chamber includes a sensor with a porous section, the sensor being arranged for displacement upon detection of a particular substance, such as a selected molecule, within the chamber, and monitoring the sensor to detect the displacement.

21. A cantilever sensor with a porous section as claimed in any one of the preceding claims.

DATED this 29th day of August, 2006

RMIT University

by DAVIES COLLISON CAVE

Patent Attorneys for the applicant

DISPOSITIVO DE ENSAYO

CAMPO DE LA INVENCIÓN

La presente invención se refiere a un dispositivo de ensayo, un detector voladizo y/o método de ensayo químico.

ANTECEDENTES DE LA INVENCIÓN

Se conoce el uso de discos compactos (CD) para pruebas químicas. Los CD se proveen con una estructura de microfluido que define varios puertos de entrada de fluido en comunicación con canales asociados y cámaras de mezclado del fluido. Con el fin de conducir una prueba, el fluido se deposita en los puertos de entrada y el CD se hace girar de tal forma que el fluido es empujado por el bombeo centrífugo a través de los canales relevantes hacia las cámaras de mezclado. Puede utilizarse tecnología óptica y de direccionamiento de CD significantemente modificada para capturar las imágenes de las cámaras de mezclado específico para determinar los resultados de prueba de cualquier reacción química dentro de las cámaras.

También se conoce que las varillas microvoladizas han sido consideradas como medios para detectar los resultados de las reacciones químicas, pero la limitada sensibilidad de las varillas estudiadas no ha dado como resultado una aplicación extensa de esa tecnología.

SUMARIO DE LA INVENCION

De acuerdo con la invención, se provee un dispositivo de ensayo que tiene una plataforma rotatoria con una cámara de prueba y un sensor con una sección porosa, el sensor que sufre un desplazamiento cuando se somete a la presencia de una sustancia particular tal como un espécimen químico, biológico u otro organismo.

Preferentemente el sensor es una varilla voladiza.

Preferentemente el dispositivo incluye trayectorias de microfluido en comunicación con los canales asociados y la cámara de prueba o una pluralidad asociada de cámaras de prueba.

Preferentemente la o cada cámara de prueba incluye una o más varillas voladizas.

La sección porosa pude dar al sensor una sensibilidad que permite detectar la presencia de una sustancia particular, esto es un producto químico, un espécimen o un organismo seleccionados.

Preferentemente el sensor está equipado funcionalmente con receptores, anticuerpos, antígenos o enzimas que selectivamente atraen y se enlazan con la sustancia particular que va a ser detectada.

Preferentemente la sección porosa se recubre

con una capa de oro que enlaza los receptores a la varilla, funcionalizando la varilla para que se ligue con especimenes u organismos preseleccionados dentro del fluido en la cámara de prueba.

Preferentemente el sensor incluye una superficie que va a ser monitoreada, que está sujeta al desplazamiento después del movimiento del sensor, la posición de la superficie monitoreada se monitorea por medio de un aparato en el cual se coloca el dispositivo de ensayo.

Preferentemente, la superficie es una superficie reflectora.

Preferentemente el aparato es una unidad de CD conectada a una computadora que permite que la posición de la superficie reflectora sea determinada y mostrada por medio de la computadora.

Preferentemente el dispositivo de ensayo incluye un sistema de microfluido para transportar un fluido de prueba desde un puerto de entrada a la cámara de prueba que contiene la varilla voladiza y de allí a una cámara para desechos.

Preferentemente la cámara para desechos se separa de la cámara de prueba por medio de una válvula micro-mecánica que es accionada por encima de una velocidad angular de umbral del dispositivo.

Preferentemente el dispositivo puede aceptar el fluido entero que se va analizar e incluye un filtro para filtrar el material del fluido entero después de la inserción el puerto de entrada para proporcionar fluido en una forma adecuada para las pruebas. Más preferentemente, el filtro se forma de un silicio poroso.

Preferentemente el sistema incluye la provisión de una segunda cámara conectada a la cámara de prueba para permitir el ciclo del fluido entre la cámara secundaria y la cámara de prueba.

Preferentemente, el dispositivo tiene la forma de un disco compacto (CD).

En otro aspecto se provee un aparato de prueba para recibir un dispositivo de ensayo, como se describe antes, que incluye una unidad de impulsión para hacer rotar el dispositivo y una unidad de lectura para monitorear el sensor.

Preferentemente el aparato está adaptado para mostrar la información derivada de la unidad de lectura.

Más preferentemente, el aparato tiene la forma de una unidad de CD y la unidad de lectura forma parte de un cabezal de lectura/escritura óptica de la unidad de CD.

Más preferentemente, el aparato se conecta directamente a una computadora, en la cual se instala un programa de computadora que controla la operación de la unidad de CD para iniciar el proceso de filtrado, la transferencia de fluido entre las cámaras y el sistema de lectura óptico para medir el desplazamiento del sensor.

Preferentemente el proceso de ensayo se inicia al usar la computadora para introducir datos que definan la prueba que se va a realizar y presentar los resultados con a misma identificación.

En otro aspecto se provee un método de ensayo químico que incluye el introducir el fluido a una cámara sensora en una plataforma rotatoria, en donde la cámara sensora incluye un sensor colocado para desplazarse al detectar una sustancia particular, tal como una molécula seleccionada, dentro de la cámara y monitorear el sensor para detectar el desplazamiento.

En todavía otro aspecto se provee un sensor voladizo tal como se describe antes.

conduce a un aumento en la deflexión. Además de esto, se aumenta el área superficial para volverla funcional, esto es proveerla con receptores para ligarse con moléculas seleccionadas, permitiendo que una mayor densidad de grupos funcionalizados se enlacen en la superficie aumentando la sensibilidad y la tensión superficial inducida para la misma concentración de especimenes químicos o biológicos.

Esto permite un enlace más concentrado de las especies también permite menos variaciones en la deflexión para el mismo concentrado químico o de especimenes.

Otro efecto de la modificación de la geometría de la varilla es que la frecuencia resonante de la varilla se modifica ya que la frecuencia resonante es una medida directa de la cantidad de porosidad.

El cambio de frecuencia resonante de acuerdo con la geometría de la varilla tiene la siguiente relación: $$fo = \frac{1}{\pi\sqrt{\frac{k}{m}}}$$

en la cual: fo = frecuencia resonante

k = constante elástica

m = masa de la varilla

Un cambio de porosidad cambia la frecuencia

resonante de la varilla voladiza 21 y es una capacidad sensora adicional del sensor, que podría aplicarse a la detección de la corrosión o reacción química provocada por el fluido, por ejemplo la medición de la corrosión en un buque marino o la detección de la lluvia ácida o eventos similares para el monitoreo ambiental.

El cambio de la frecuencia de resonancia con la porosidad se ilustra en la figura 4 que indica que hay una frecuencia resonante mínima para un rango de niveles de porosidad. En el aparato 30 sin embargo,

LAS REIVINDICACIONES QUE DEFINEN LA INVENCION SON COMO SIGUEN:

1. Un dispositivo de ensayo caracterizado porque tiene una plataforma rotatoria con una cámara de prueba y un sensor con una sección porosa, el sensor que sufre un desplazamiento cuando se somete a la presencia de una sustancia particular tal como un espécimen químico, biológico u otro organismo.

2. Un dispositivo de ensayo de acuerdo con la reivindicación 1, caracterizado porque el sensor es una varilla voladiza.

3. Un dispositivo de ensayo de acuerdo con la reivindicación 1 ó 2, caracterizado porque el dispositivo incluye trayectorias de microfluido en comunicación con los canales asociados y la cámara de prueba o una pluralidad asociada de cámaras de prueba.

4. Un dispositivo de ensayo de acuerdo con la reivindicación 3, caracterizado porque la o cada cámara de prueba incluye una o más varillas voladizas.

5. Un dispositivo de ensayo de acuerdo con la reivindicación 1, caracterizado porque el sensor está equipado funcionalmente con receptores, anticuerpos, antígenos o enzimas que selectivamente

atraen y se enlazan con la sustancia particular que va a ser detectada.

6. Un dispositivo de ensayo de acuerdo con la reivindicación 5, caracterizado porque la sección porosa se recubre con una capa de oro que enlaza los receptores a la varilla, funcionalizando la varilla para que se ligue con especimenes u organismos preseleccionados dentro del fluido en la cámara de prueba.

7. Un dispositivo de ensayo de acuerdo con la reivindicación 1, caracterizado porque el sensor incluye una superficie que va a ser monitoreada, que está sujeta al desplazamiento después del movimiento del sensor, la posición de la superficie monitoreada se monitorea por medio de un aparato en el cual se coloca el dispositivo de ensayo.

8. Un dispositivo de ensayo de acuerdo con la reivindicación 7, caracterizado porque, la superficie es una superficie reflectora.

9. Un dispositivo de ensayo de acuerdo con la reivindicación 7, caracterizado porque el aparato es una unidad de CD conectada a una computadora que permite que la posición de la superficie reflectora sea determinada y mostrada por medio de la computadora.

10. Un dispositivo de ensayo de acuerdo con la reivindicación 1, caracterizado porque el dispositivo de ensayo incluye un sistema de microfluido para transportar un fluido de prueba desde un puerto de entrada a la cámara de prueba que contiene la varilla voladiza y de allí a una cámara para desechos.

11. Un dispositivo de ensayo de acuerdo con la reivindicación 10, caracterizado porque la cámara para desechos se separa de la cámara de prueba por medio de una válvula micro-mecánica que es accionada por encima de una velocidad angular de umbral del dispositivo.

12. Un dispositivo de ensayo de acuerdo con la reivindicación 10 u 11, caracterizado porque el dispositivo puede aceptar el fluido entero que se va analizar e incluye un filtro para filtrar el material del fluido entero después de la inserción el puerto de entrada para proporcionar fluido en una forma adecuada para las pruebas.

13. Un dispositivo de ensayo de acuerdo con la reivindicación 12, caracterizado porque, el filtro se forma de un silicio poroso.

14. Un dispositivo de ensayo de acuerdo con la reivindicación 13, caracterizado porque el sistema

incluye la provisión de una segunda cámara conectada a la cámara de prueba para permitir el ciclo del fluido entre la cámara secundaria y la cámara de prueba.

15. Un dispositivo de ensayo de acuerdo con cualquiera de las reivindicaciones anteriores, caracterizado porque, el dispositivo tiene la forma de un disco compacto (CD).

16. Un aparato de prueba para recibir un dispositivo de ensayo de acuerdo con cualquiera de las reivindicaciones 1 a 15, que incluye una unidad de impulsión para hacer rotar el dispositivo y una unidad de lectura para monitorear el sensor.

17. Un aparato de prueba de acuerdo con la reivindicación 16, caracterizado porque el aparato está adaptado para mostrar la información derivada de la unidad de lectura.

18. Un aparato de prueba de acuerdo con la reivindicación 16 ó 17, caracterizado porque, el aparato tiene la forma de una unidad de CD y la unidad de lectura forma parte de un cabezal de lectura/escritura óptica de la unidad de CD.

19. Un aparato de prueba de acuerdo con una de las reivindicaciones 16 a 17, caracterizado porque, el aparato se conecta directamente a una

computadora, en la cual se instala un programa de computadora que controla la operación de la unidad de CD para iniciar el proceso de filtrado, la transferencia de fluido entre las cámaras y el sistema de lectura óptico para medir el desplazamiento del sensor.

20. Un método de ensayo químico que incluye el introducir el fluido a una cámara sensora en una plataforma rotatoria, en donde la cámara sensora incluye un sensor colocado para desplazarse al detectar una sustancia particular, tal como una molécula seleccionada, dentro de la cámara y monitorear el sensor para detectar el desplazamiento.

21. Un sensor voladizo con una sección porosa de acuerdo con cualquiera de las reivindicaciones anteriores.

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING
SUBMISSION OR TRANSMITTAL
OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

To:

HENSHAW, Damon
Davies Collison Cave
1 Nicholson Street
Melbourne, Victoria 3000
AUSTRALIE

Date of mailing *(day/month/year)* 15 June 2006 (15.06.2006)	
Applicant's or agent's file reference 12768290	**IMPORTANT NOTIFICATION**
International application No. PCT/AU2006/000656	International filing date *(day/month/year)* 17 May 2006 (17.05.2006)
International publication date *(day/month/year)* **Not yet published**	Priority date *(day/month/year)* 20 May 2005 (20.05.2005)
Applicant RMIT UNIVERSITY et al	

1. By means of this Form, which replaces any previously issued notification concerning submission or transmittal of priority documents, the applicant is hereby notified of the date of receipt by the International Bureau of the priority document(s) relating to all earlier application(s) whose priority is claimed. Unless otherwise indicated by the letters "NR", in the right-hand column or by an asterisk appearing next to a date of receipt, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).

2. *(If applicable)* The **letters "NR"** appearing in the right-hand column denote **a priority document which, on the date of mailing of this Form, had not yet been received by the International Bureau** under Rule 17.1(a) or (b). Where, under Rule 17.1(a), the priority document must be submitted by the applicant to the receiving Office or the International Bureau, but the applicant fails to submit the priority document within the applicable time limit under that Rule, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

3. *(If applicable)***An asterisk (*)** appearing next to a date of receipt, in the right-hand column, denotes **a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b)** (the priority document was received after the time limit prescribed in Rule 17.1(a) or the request to prepare and transmit the priority document was submitted to the receiving Office after the applicable time limit under Rule 17.1(b)). Even though the priority document was not furnished in compliance with Rule 17.1(a) or (b), the International Bureau will nevertheless transmit a copy of the document to the designated Offices, for their consideration. In case such a copy is not accepted by the designated Office as the priority document, Rule 17.1(c) provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

Priority date	Priority application No.	Country or regional Office or PCT receiving Office	Date of receipt of priority document
20 May 2005 (20.05.2005)	2005902630	AU	30 May 2006 (30.05.2006)

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. +41 22 338 82 70

Authorized officer
Dorothée Mülhausen
Facsimile No. +41 22 338 87 40
Telephone No. +41 22 338 96 72

PATENT COOPERATION TREATY

PCT/AU2006/000656

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92*bis*.1 and Administrative Instructions, Section 422)

To:

HENSHAW, Damon
Davies Collison Cave
1 Nicholson Street
Melbourne, Victoria 3000
AUSTRALIE

Date of mailing *(day/month/year)*
05 July 2006 (05.07.2006)

Applicant's or agent's file reference
12768290

IMPORTANT NOTIFICATION

International application No.
PCT/AU2006/000656

International filing date *(day/month/year)*
17 May 2006 (17.05.2006)

1. The following indications appeared on record concerning:

☒ the applicant ☒ the inventor ☐ the agent ☐ the common representative

Name and Address
CHAFFEY, Jason
7/104 Sixth Avenue
St Peters, South Australia 5096
Australia

State of Nationality: AU
State of Residence: AU
Telephone No.:
Facsimile No.:
Teleprinter No.:

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐ the person ☐ the name ☒ the address ☐ the nationality ☐ the residence

Name and Address
CHAFFEY, Jason
7/104 Sixth Avenue
St Peters, South Australia 5069
Australia

State of Nationality: AU
State of Residence: AU
Telephone No.:
Facsimile No.:
Teleprinter No.:

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

☒ the receiving Office
☒ the International Searching Authority
☐ the International Preliminary Examining Authority
☐ the designated Offices concerned
☐ the elected Offices concerned
☐ other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. +41 22 338 82 70

Authorized officer
Boccard Paulette
Facsimile No. +41 22 338 87 40
Telephone No. +41 22 338 81 47

PATENT COOPERATION TREATY

WO 2006/122360
PCT/AU2006/000656

From the INTERNATIONAL BUREAU

PCT

SECOND AND SUPPLEMENTARY NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION (TO DESIGNATED OFFICES WHICH APPLY THE 30 MONTH TIME LIMIT UNDER ARTICLE 22(1))

(PCT Rule 47.1(c))

To:

HENSHAW, Damon
Davies Collison Cave
1 Nicholson Street
Melbourne, Victoria 3000
AUSTRALIE

057

Date of mailing *(day/month/year)*	
20 September 2007 (20.09.2007)	
Applicant's or agent's file reference 12768290 ~~12768290~~	**IMPORTANT NOTICE**
International application No. PCT/AU2006/000656	International filing date *(day/month/year)* 17 May 2006 (17.05.2006)
Priority date *(day/month/year)* 20 May 2005 (20.05.2005)	
Applicant RMIT UNIVERSITY et al	

1. **ATTENTION**: For any designated Office(s), for which the time limit under Article 22(1), as in force from 1 April 2002 (30 months from the priority date), **does not apply**, please see Form PCT/IB/308(First Notice) issued previously.

2. Notice is hereby given that the following designated Office(s), for which the time limit under Article 22(1), as in force from 1 April 2002, **does apply**, has/have requested that the communication of the international application, as provided for in Article 20, be effected under Rule 93*bis*.1. The International Bureau has effected that communication on the date indicated below:
23 November 2006 (23.11.2006)

AU, AZ, BY, CN, CO, DZ, EP, HU, KG, KP, KR, MD, MK, MZ, NA, NG, PG, RU, SY, TM, US

In accordance with Rule 47.1(c-*bis*)(i), those Offices will accept the present notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

3. The following designated Offices, for which the time limit under Article 22(1), as in force from 1 April 2002, **does apply**, have not requested, as at the time of mailing of the present notice, that the communication of the international application be effected under Rule 93*bis*.1 :

AE, AG, AL, AM, AP, AT, BA, BB, BG, BR, BW, BZ, CA, CR, CU, CZ, DE, DK, DM, EA, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, ID, IL, IN, IS, JP, KE, KM, KN, KZ, LC, LK, LR, LS, LT, LV, LY, MA, MG, MN, MW, MX, NI, NO, NZ, OA, OM, PH, PL, PT, RO, SC, SD, SG, SK, SL, SM, TJ, TN, TR, TT, UA, UZ, VC, VN, YU, ZA, ZM, ZW

In accordance with Rule 47.1(c-*bis*)(ii), those Offices accept the present notice as conclusive evidence that the Contracting State for which that Office acts as a designated Office does not require the furnishing, under Article 22, by the applicant of a copy of the international application.

4. **TIME LIMITS for entry into the national phase**

For the designated or elected Office(s) listed above, the applicable time limit for entering the national phase will, **subject to what is said in the following paragraph,** be **30 MONTHS** from the priority date.

In practice, **time limits other than the 30-month time limit** will continue to apply, for various periods of time, in respect of certain of the designated or elected Office(s) listed above. For **regular updates on the applicable time limits** (30 or 31 months, or other time limit), Office by Office, refer to the *PCT Gazette*, the *PCT Newsletter* and the *PCT Applicant's Guide*, Volume II, National Chapters, all available from WIPO's Internet site, at http://www.wipo.int/pct/en/index.html.

It is the applicant's **sole responsibility** to monitor all these time limits.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. +41 22 338 82 70

Authorized officer
Dorothée Mülhausen

e-mail: pt01.pct@wipo.int

87

12768290

PCT REQUEST

Original (for **SUBMISSION**)

0	**For receiving Office use only**	
0-1	International Application No.	
0-2	International Filing Date	
0-3	Name of receiving Office and "PCT International Application"	

0-4	**Form PCT/RO/101 PCT Request**	
0-4-1	Prepared Using	PCT-SAFE [EASY mode] Version 3.50 (Build 0002.162)
0-5	**Petition** The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty	
0-6	**Receiving Office (specified by the applicant)**	Australian Patent Office (RO/AU)
0-7	**Applicant's or agent's file reference**	12768290
I	**Title of Invention**	ASSAY DEVICE
II	**Applicant**	
II-1	This person is	applicant only
II-2	Applicant for	all designated States except US
II-4	Name	RMIT UNIVERSITY
II-5	Address	124 La Trobe Street Melbourne, Victoria 3000 Australia
II-6	State of nationality	AU
II-7	State of residence	AU
II-8	Telephone No.	--
II-9	Facsimile No.	--
II-10	e-mail	--
III-1	**Applicant and/or inventor**	
III-1-1	This person is	applicant and inventor
III-1-2	Applicant for	US only
III-1-4	Name (LAST, First)	CHAFFEY, Jason
III-1-5	Address	7/104 Sixth Avenue St Peters, South Australia 5069 Australia
III-1-6	State of nationality	AU
III-1-7	State of residence	AU

12768/00

PCT REQUEST

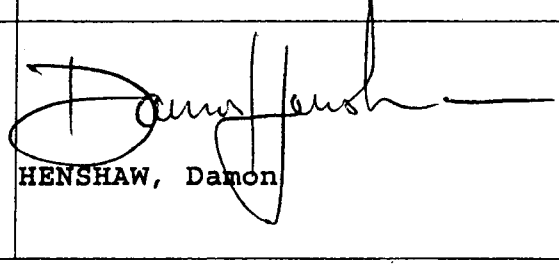
Original (for **SUBMISSION**)

III-2	**Applicant and/or inventor**	
III-2-1	This person is	applicant and inventor
III-2-2	Applicant for	US only
III-2-4	Name (LAST, First)	STAPLETON, Murray
III-2-5	Address	Mediversity Pty Ltd Ground Floor 40-46 The Esplanade Brighton, Victoria 3186 Australia
III-2-6	State of nationality	AU
III-2-7	State of residence	AU
IV-1	**Agent or common representative; or address for correspondence**	
	The person identified below is hereby/ has been appointed to act on behalf of the applicant(s) before the competent International Authorities as:	agent
IV-1-1	Name (LAST, First)	HENSHAW, Damon
IV-1-2	Address	Davies Collison Cave 1 Nicholson Street Melbourne, Victoria 3000 Australia
IV-1-3	Telephone No.	+613 9254 2777
IV-1-4	Facsimile No.	+613 9254 2770
IV-1-5	e-mail	mail@davies.com.au
IV-2	**Additional agent(s)**	additional agent(s) with same address as first named agent
IV-2-1	Name(s)	HIND,Raymond; ALLEN,Leon
V	**DESIGNATIONS**	
V-1	**The filing of this request constitutes under Rule 4.9(a), the designation of all Contracting States bound by the PCT on the international filing date, for the grant of every kind of protection available and, where applicable, for the grant of both regional and national patents.**	
VI-1	**Priority claim of earlier national application**	
VI-1-1	Filing date	20 May 2005 (20.05.2005)
VI-1-2	Number	2005902630
VI-1-3	Country	AU

12768290

PCT REQUEST

Original (for **SUBMISSION**)

VI-2	**Priority document request** The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s):	VI-1	
VII-1	**International Searching Authority Chosen**	Australian Patent Office (ISA/AU)	
VIII	**Declarations**	Number of declarations	
VIII-1	Declaration as to the identity of the inventor	-	
VIII-2	Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent	-	
VIII-3	Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application	-	
VIII-4	Declaration of inventorship (only for the purposes of the designation of the United States of America)	-	
VIII-5	Declaration as to non-prejudicial disclosures or exceptions to lack of novelty	-	
IX	**Check list**	number of sheets	electronic file(s) attached
IX-1	Request (including declaration sheets)	4	✓
IX-2	Description	10	-
IX-3	Claims	3	-
IX-4	Abstract	1	✓
IX-5	Drawings	7	-
IX-7	TOTAL	25	
	Accompanying Items	paper document(s) attached	electronic file(s) attached
IX-8	Fee calculation sheet	✓	-
IX-17	PCT-SAFE physical media	-	✓
IX-19	**Figure of the drawings which should accompany the abstract**	2	
IX-20	**Language of filing of the international application**	English	
X-1	**Signature of applicant, agent or common representative**		
X-1-1	Name (LAST, First)	HENSHAW, Damon	
X-1-2	Name of signatory		
X-1-3	Capacity		

12768290

PCT REQUEST

Original (for **SUBMISSION**)

FOR RECEIVING OFFICE USE ONLY

10-1	**Date of actual receipt of the purported international application**	
10-2	**Drawings:**	
10-2-1	Received	
10-2-2	Not received	
10-3	**Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application**	
10-4	**Date of timely receipt of the required corrections under PCT Article 11(2)**	
10-5	**International Searching Authority**	ISA/AU
10-6	**Transmittal of search copy delayed until search fee is paid**	

FOR INTERNATIONAL BUREAU USE ONLY

11-1	**Date of receipt of the record copy by the International Bureau**	

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

No. 07-123569- -00000-0000

Fecha: 2007-11-22 15:34:17 Dep. 2020 NUECREACIONE
Tra. 11 PATENTEIYII Eve: 379 FASENACIONALII
Act. 411 PRESENTACION Folios: 94

Industria y Comercio
SUPERINTENDENCIA

REQUISITOS MINIMOS PARA ADMISION A TRAMITE PCT

PATENTE DE INVENCION [✓] MODELO DE UTILIDAD [ ]

- Indicación de que se solicita la concesión de una patente [✓]
- Datos de identificación del solicitante o de la persona que presenta la solicitud [✓]
- Descripción de la invención [✓]
- Dibujos de ser estos pertinentes [ ]
- Comprobante de pago de las tasas establecidas [✓]

COMPLETA [ ] INCOMPLETA [ ]

DISEÑO INDUSTRIAL [ ]

- Indicación de que se solicita el registro de Diseño Industrial [ ]
- Datos de identificación del solicitante o de la persona que presenta la solicitud [ ]
- Representación gráfica y fotográfica del Diseño Industrial o muestra del material que incorpora el diseño [ ]
- Comprobante de pago de las tasas establecidas [ ]

COMPLETA [ ] INCOMPLETA [ ]

ESQUEMA DE TRAZADO [ ]

- Indicación de que se solicita el registro de un Esquema de Trazado [ ]
- Datos de identificación del solicitante o de la persona que presenta la solicitud [ ]
- Representación gráfica del esquema trazado [ ]
- Comprobante de pago de las tasas establecidas [ ]

COMPLETA [ ] INCOMPLETA [ ]

Claudia M Neva Cortes
Firma Responsable

Fecha_____

Carrera 13 No. 27-00 Piso 5, 7 y 10
Conmutador: 3 82 08 40
Fax: 350 52 20
E-mail: info@sic.gov.co
www.sic.gov.co
Bogotá, D.C., Colombia