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[Continued on next page]

(54) Title: TEST DEVICE

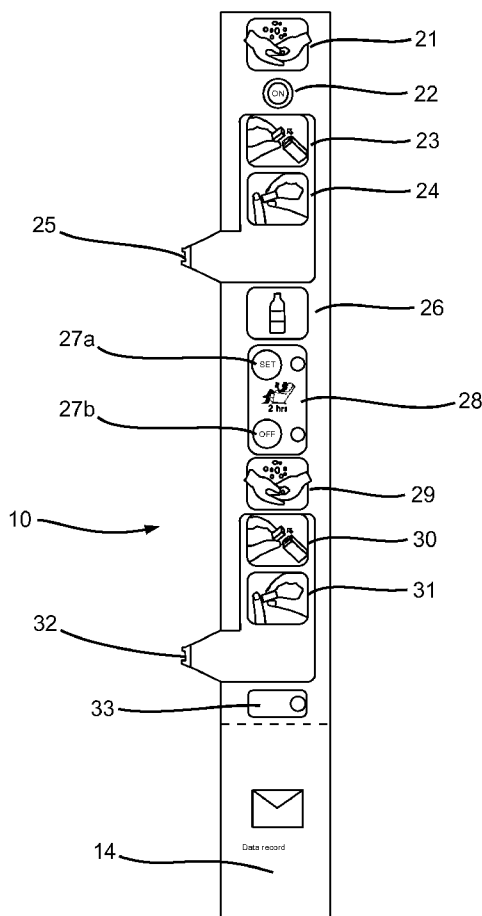


Fig 2

(57) Abstract: A biological test device with at least one zone containing a biosensor and/or reagent media to accept a sample of a biological material, where the zone is covered until use by a removable humidity resistant cover. The cover may be slidably removable or have a peel-off configuration and may incorporate a desiccant material. The cover may also act as an actuator associated with electronic timing and/or signalling components carried by the device.





KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

Published:

— *with international search report (Art. 21(3))*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

TEST DEVICE

This invention relates to devices for testing materials, preferably biological materials, and it relates especially, though not exclusively, to
5 glucose tolerance testing devices, such as (by way of example only) those described in WO-A-2009/024794. Such devices test blood samples and enable patients to make at home, or in other convenient locations, tests which would otherwise require their attendance at a clinic or other medical institution, thereby to develop clinical data which can be
10 displayed by the device and/or forwarded elsewhere for expert clinical analysis.

Devices of the kind described above have particular value to patients lacking ready access to clinical facilities, but the collection of critical
15 evaluation data by patients themselves in domestic or other non-clinical surroundings can compromise the quality of the data.

In such circumstances it is necessary to reduce, so far as is reasonably possible, extraneous factors that might significantly influence the quality
20 of the data resulting from the test.

One such extraneous factor, which is particularly prevalent in territories where these devices can be of greatest use, is humidity and it is an object of this invention to provide test devices of the kind described in which
25 adverse effects of humidity are reduced or eliminated.

According to the invention there is provided a test device comprising at least one zone containing biosensor means and/or reagent media and designated to accept a sample of a material, wherein said zone is covered until use by a removable humidity resistant cover.

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According to a further aspect of the invention there is provided a biological test device comprising at least one zone containing biosensor means and/or reagent media and designated to accept a sample of a biological material, wherein said zone is covered until use by a removable
10 humidity resistant cover.

Preferably, said device comprises first and second zones each containing respective biosensor means and/or reagent media and designated to accept material samples in a predetermined timing sequence, wherein at least the
15 zone designated to accept the later sample is covered until use by a removable humidity resistant cover.

Preferably, respective removable and humidity resistant covers are associated with both of said zones.

20

In a preferred embodiment of the invention, the or each humidity resistant cover comprises a shaped cover made of a plastics material and adapted to be slidably attached to and removed from the device.

25 The shaped covers are preferably made by injection moulding.

Preferably, the or each cover incorporates a dessicant material.

In an alternative configuration, the or each cover comprises a peel-off strip of material which is self-adhesively secured to the device so as to temporarily cover its respective zone.

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In any event, it is preferred that the or each cover is adherent not only over its respective zone, but also over an adjoining portion of the device so as to cover, until removed, certain procedural instructions relating to the conduct of the test.

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It is further preferred that a cover is configured to interact with actuator means associated with electronic components of said device to place the device into an operational, or fully operational, state and/or to cancel an alarm signalling an action point in the test procedure. In a particularly preferred arrangement, the removal of said cover turns the device on or alters the operational state of the device, for example from a low power-consumption “stand-by” mode to a fully operational mode in which the device consumes more power. It is further preferred that the time of removal of the cover is recorded by electronic means within the device.

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In further preferred embodiments of the invention, the device includes electronic means for recording time and for sensing and recording temperature and/or humidity, whereby results that may be compromised due to over-exposure of the device to excessive heat and/or humidity can be identified and assessed accordingly.

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Typically, the biological material may be blood, saliva or urine, but the actual materials sensed are not critical to the use of the invention.

In order that the invention may be clearly understood and readily carried
5 into effect, one embodiment of the invention will now be described, by way of example only, with reference to the accompanying drawings of which:

Figure 1 shows a test device in accordance with one example of the
10 invention packaged for storage until use, and with anti-humidity covers provided over sensor zones thereof;

Figure 2 shows in more detail the test device of Figure 1 with its anti-humidity covers removed as for use; and
15

Figure 3 shows schematically, and by way of example only, a typical operating sequence for devices of the general kind described with reference to Figures 1 and 2.

20 Referring now to Figure 1, a test device 10 in accordance with one example of the invention is packaged for storage within an hermetically sealed pouch 12. If desired, a dessicant medium may be included in the pouch, either as a separate inclusion or incorporated into the envelope 12.

25 The simple, strip-like form of the device 10 is exemplary only; the requirement for the device being that it presents the various essential stages of the test in a logical sequence that can be readily followed by

patients without external guidance. To this end, there is provided on the device a series of graphic images which show the actions to be carried out at each stage of the sequence. Written instructions are also provided, but it is intended that the graphics provide easily understood immediate and topical reference data for patient reassurance and guidance.

The fundamental procedure of the test involves the patient taking a blood sample, for example by way of a finger-prick as is common with routine, day-to-day diabetic testing, both before and after ingesting a glycaemic load, typically a glucose drink, thereby to test the patient's tolerance to glucose.

The two blood samples are applied to different sensors in a reasonably strict timing sequence; the sensors developing respective electrical signals that are sent to a data logging area 14 of the device 10, where the signals can be stored as they are, and/or with further processing carried out on them, depending upon the amount of electronic processing incorporated into the device 10. When the process is complete, the device 10 as a whole, or alternatively just the removable data log 14, can be sent or collected for analysis of the test results recorded therein. Alternatively, or in addition, the results may be displayed on the device 10 in a manner suitable for ready interpretation by or for the person undergoing the test.

As can be seen in Figure 1, and as will be more fully described hereinafter, the strip-like device 10 as packaged is, in this example, fitted with two removable covers 16 and 18, each covering a respective one of the two sensors. In this example, the covers 16 and 18 are injection

moulded in plastics material and are configured to be a sliding fit on the strip-like device 10. In some embodiments of the invention, the covers are dimensioned and shaped to fit tightly over the device, but they need not be so configured, as it has been found on testing that even a loosely fitted cover can provide the device 10 with significant protection against exposure to high humidity.

Referring now to Figure 2, the strip-like device 10 is made of any convenient self-supporting material, but it is preferably of plastics material since it is relatively easy to produce reliably and repeatedly in volume; however, non-plastic, water-impermeable or water resistant sheet material can be used if preferred. The device 10 may bear easily legible images, as the graphics displayed thereon perform, as has been mentioned, an important function in guiding the patient through the procedure. Alternatively, the device may be provided with an insert or attachment of material which carries the graphics.

In any event, in the present example, a first graphic 21 indicates to the patient that the hands should be washed and dried before starting the procedure. The patient then actuates a switch device 22 to place the device 10 in a fully operational state. Prior to the actuation of the switch device 22, the device 10 may be completely switched off, or its circuitry may be switched to a stand-by mode in which it consumes little power.

The first cover 16 is then removed, revealing graphics 23, 24 designed to guide the patient through the first finger-prick to produce a first blood sample to be dropped on to a receptor 25 which is configured in known

manner to convey the blood to a first sensor (not shown); the receptor and its associated sensor constituting a first test zone. The cover 16 of course, importantly, covers the receptor 25 until it needs to be exposed to receive the blood sample, thereby protecting the associated sensor against the possible effects of humidity after the device 10 has been removed from the pouch 12. It is preferred, though not necessary, for the cover 16 to cover the graphics 23 and 24 as well as the receptor 25 and its associated sensor, as this expedient reduces the amount of instructional data to which the patient is initially exposed and thus assists the patient to take on board the necessary operations.

Preferably, the cover 16 is configured so that its removal either actuates the switch 22, or otherwise automatically places the device 10 in a fully operational state; thereby providing a fail-safe mode of operation, in case the patient should fail to actuate the switch 22.

In such an embodiment, the switch device 22 may be a spring-loaded, mechanically operated switch that is normally held open by the presence of the cover 16, but is closed upon withdrawal of the cover 16. Alternatively, for example, it may comprise a light-sensitive device and the cover 16, or at least the part thereof that covers the switch device 22 when fitted to the strip-like device 10, may be made of or coloured with an opaque substance such that the switch device 22 is only exposed to light when the cover 16 is withdrawn therefrom. In general, it will be appreciated that the switch device 22 may be of any convenient kind and its interaction with the cover 16 can be achieved in any convenient way.

In further alternative arrangements, the cover 16 need not actuate the switch 22, but may be configured to replicate its effect automatically, by suitable interconnection means communicating directly with the electronics carried by the device 10.

5

Proceeding further with the present example, the patient is then instructed, by way of graphic 26, to inject a prescribed glycaemic load, typically a glucose drink which is provided in a suitable vessel, and then presses a button 27a to start a fixed time period of (in this example) 15
10 minutes. Other periods can clearly be used if desired or if necessary given differing test conditions and criteria; and in some embodiments the preferred time period is 120 minutes. Graphic 28 instructs the patient to relax until the device 10 produces an audio and/or visual warning that the relevant time period has elapsed and it is necessary to complete the test
15 procedure.

At this point, the patient is, in this example though not necessarily, instructed to press a second button 27b which cancels the timer and switches off the warning that indicates the end of the relaxation period.

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The second cover 18 is then removed, exposing graphics 29, 30 and 31 which replicate the graphics 21, 23 and 24 respectively, and which if followed result in the patient applying a second blood sample to a receptor 32, associated with a second sensor, which has remained covered
25 by the cover 18 throughout the procedure to date. The cover 18 can be configured so that its removal either actuates the switch 27b, or otherwise automatically cancels the alarm should the patient not already have done

so. In some embodiments of the invention, the button 27b is omitted, and its function replicated automatically in response to removal of the cover 18.

- 5 The receptor 32 and its associated sensor constitute a second test zone.

Once the second sample has been applied to the receptor 32, and the necessary electronic operations have been carried out, the results of the test are transferred to electronic storage and/or processing means in the data logging area 14; the successful transfer and thus completion of the test procedure being indicated by the illumination of a lamp device 33, such as an LED. Successful completion of the procedure may also, or instead, be confirmed audibly.

- 15 The data logging area 14 is then preferably detached from the remainder of the device 10 and forwarded to an analysis station such as a clinic or other medical centre. In more sophisticated arrangements, the device 10 may be provided with means to calculate the results of the test and to display them, for example on an on-board LCD (not shown), in a readily interpretable manner. Alternatively, or in addition, the data logging section 14 may be fitted with a suitable connector, such as a USB connector, allowing the clinical data resulting from the procedure to be up-loaded via a computer or another suitable electronic device for local display and/or for direct transmission to an analysis centre.

25

In the above described arrangement, the switch 22 is intended to be actuated by the patient to place the electronic circuitry in the device 10

into its fully operational state but, if this is not done, the removal of cover 16 automatically achieves the same result as a back-up. In some preferred embodiments of the invention, however, the switch 22 is omitted and the removal of cover 16 is effective to automatically place the device 10 into its fully operational state and in preparation for the addition of the first sample to the receptor 25.

Preferably, in any event, the electronics within the device 10 include means to record either the time of removal of the covers 16 and 18 or a time-related index permitting the time of removal to be calculated. This provides a facility whereby a test relating to a sample applied to the receptor 25 too long after the removal of the cover 16, or to the receptor 32 too long after the removal of the cover 18, can be rejected if it appears that the results may have been compromised.

The stability of the sensors associated with the receptors 25 and 32 is influenced not only by humidity, but also by other factors such as temperature. It is thus preferred that the device 10 incorporates at least a temperature sensor, and optionally a humidity sensor too. This facility enables the temperature and possibly also humidity to be recorded, for correlation with the times of application of the samples to the receptors 25 and 32; which times are logged automatically, and can be cross-referenced to the times of removal of the covers 16 and 18. On subsequent review of the data recorded by device 10, or of test results derived from such data, the test may be invalidated if it is found that the sensors in the device have been exposed to certain levels of temperature and/or humidity for certain periods of time. All such assessments,

however, are preferably made individually, and it is not intended that invalidations should be made on the basis of predetermined exclusion criteria.

- 5 The covers 16 and 18 may each contain or house a dessicant material, in addition to any dessicant that may be included in the original packaging.

As previously mentioned, it is highly desirable for the arrangement to be such that removal of the covers 16 and 18 from the device 10 actuates a component that logs either the precise times of their removal or a time-related index permitting the time of removal to be calculated.

In some embodiments of the invention the rigid, slide on/slide off, covers 16, 18 may be replaced by peel-off covers which may comprise a plurality of layers, at least one of which may be a dessicant layer.

In some embodiments of the invention, the cover 16 associated with the first test zone comprising blood receptor 25 and its associated sensor may be omitted on the expectation that the pouch 12 is not opened until immediately prior to the commencement of the test procedure, and therefore protection from moisture may not be required for the receptor 25 whereas such protection may remain a requirement for the receptor 32.

The blocks representing the various steps in the sequence of operations represented schematically, and by way of example only, in Figure 3 bear legends which are self-explanatory in the light of the preceding description. However, in addition and where appropriate, the blocks also

carry for the reader's convenience reference numbers consistent with those used in Figures 1 and 2.

The device 10 typically contains an on-board microcontroller (not shown) which is conditioned to receive inputs from the sensors associated with receptors 25 and 32; from the switches such as 22, 27a and 27b and/or means detecting the removal of covers 16 and 18; from environmental sensors such as temperature and/or humidity sensors; and from an RFID transceiver. The microcontroller provides outputs operating, among other things, warning or guidance LEDs and sounders used at appropriate times to prompt or warn a user; and also provides outputs when appropriate to the transceiver.

Claims:

1. According to the invention there is provided a biological test device comprising at least one zone containing biosensor means and/or reagent media and designated to accept a sample of a biological material, wherein said zone is covered until use by a removable humidity resistant cover.
2. A device according to claim 1 wherein the test device is a biological test device designated to accept a sample of biological material.
3. A device according to either of claims 1 or 2, comprising first and second zones each containing respective biosensor means and/or reagent media and designated to accept material samples in a predetermined timing sequence, wherein at least the zone designated to accept the later sample is covered until use by a removable humidity resistant cover.
4. A device according to any preceding claim, wherein respective removable and humidity resistant covers are associated with both of said zones.
5. A device according to any preceding claim, wherein the, or each, humidity resistant cover comprises a shaped cover made of a plastics material and adapted to be slidably attached to and removed from the device.

6. A device according to claim 5, wherein the, or each, cover is injection moulded.

7. A device according to any of claims 1 to 4, wherein the, or each,
5 cover comprises a peel-off strip of material which is self-adhesively secured to the device so as to temporarily cover its respective zone.

8. A device according to any preceding claim, wherein the, or each, cover incorporates a desiccant material.

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9. A device according to any preceding claim, wherein the, or each, cover covers not only its respective zone, but also an adjoining portion of the device so as to cover, until removed, certain procedural instructions relating to the conduct of the test.

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10. A device according to any preceding claim, wherein a cover is configured to interact with, or to replicate the functionality of, an actuator means intended for manual operation by a user of the device and associated with electronic timing and/or signalling components carried by
20 said device.

11. A device according to any of claims 1 to 9, wherein removal of a cover is effective to place the device into an operational mode or configuration.

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12. A device according to any of claims 1 to 9, wherein removal of a cover is effective to cancel an alarm indication signalling the need for a procedural step, involving a test zone covered by the cover, to be taken.
- 5 13. A device according to any preceding claim further comprising timing means for recording the time of removal of the or each cover or a time-related index permitting the time of removal to be calculated.
14. A device according to any preceding claim further comprising
10 means for sensing and recording temperature.
15. A device according to any preceding claim further including means for sensing and recording humidity.
- 15 16. A device according to any preceding claim further comprising electronic means for developing electrical signals indicative of a condition of the patient for transfer to a data logging zone for storing and/or further processing said electrical signals.
- 20 17. A device according to claim 16, wherein said data logging zone is detachable from the remainder of said device and can be forwarded for analysis of the signals transferred thereto.
18. A device according to any preceding claim further comprising
25 electronic means for processing data relating to said sample or samples and for displaying a result of the test.

19. A biological test device substantially as herein described with reference to and/or as shown in the accompanying drawings.

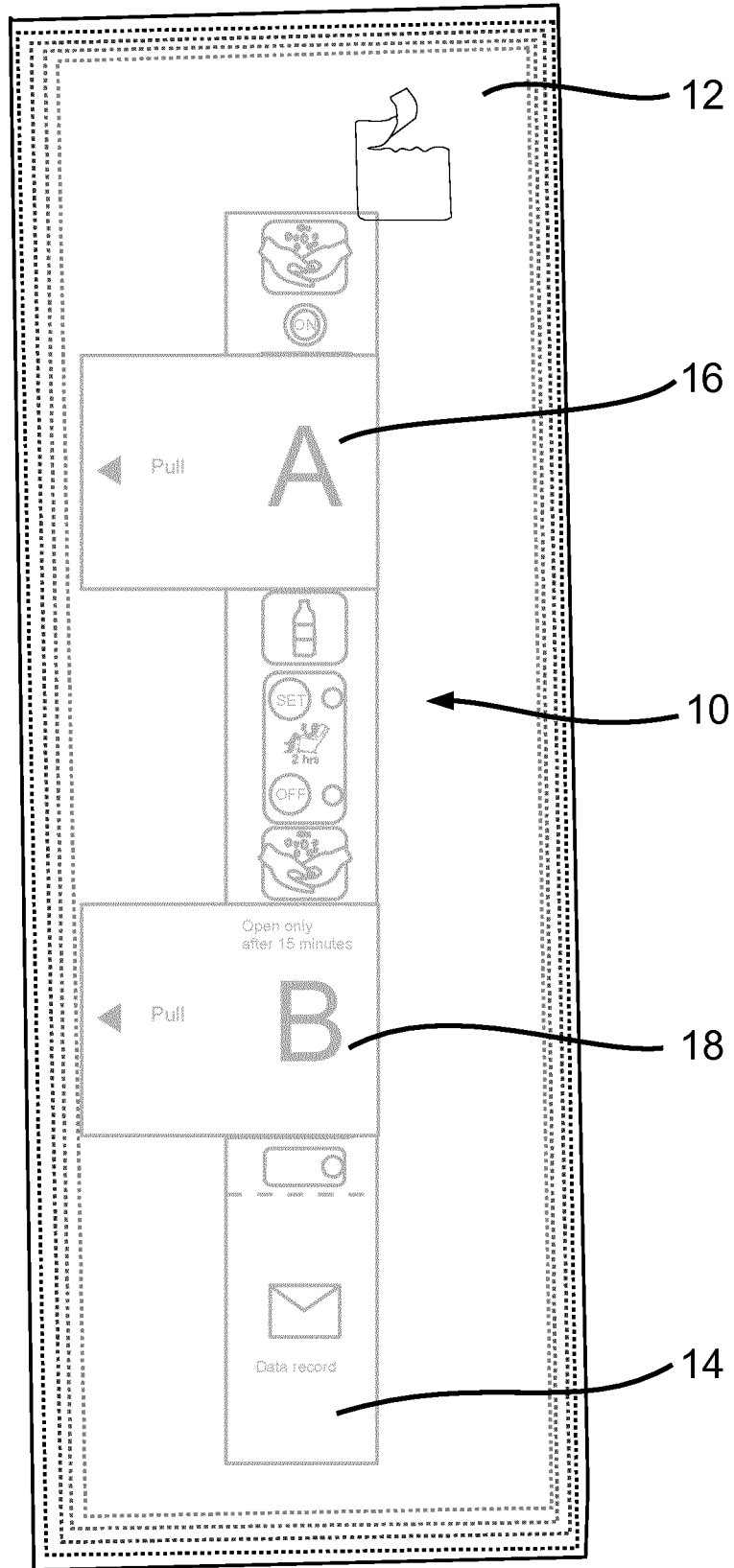


Fig 1

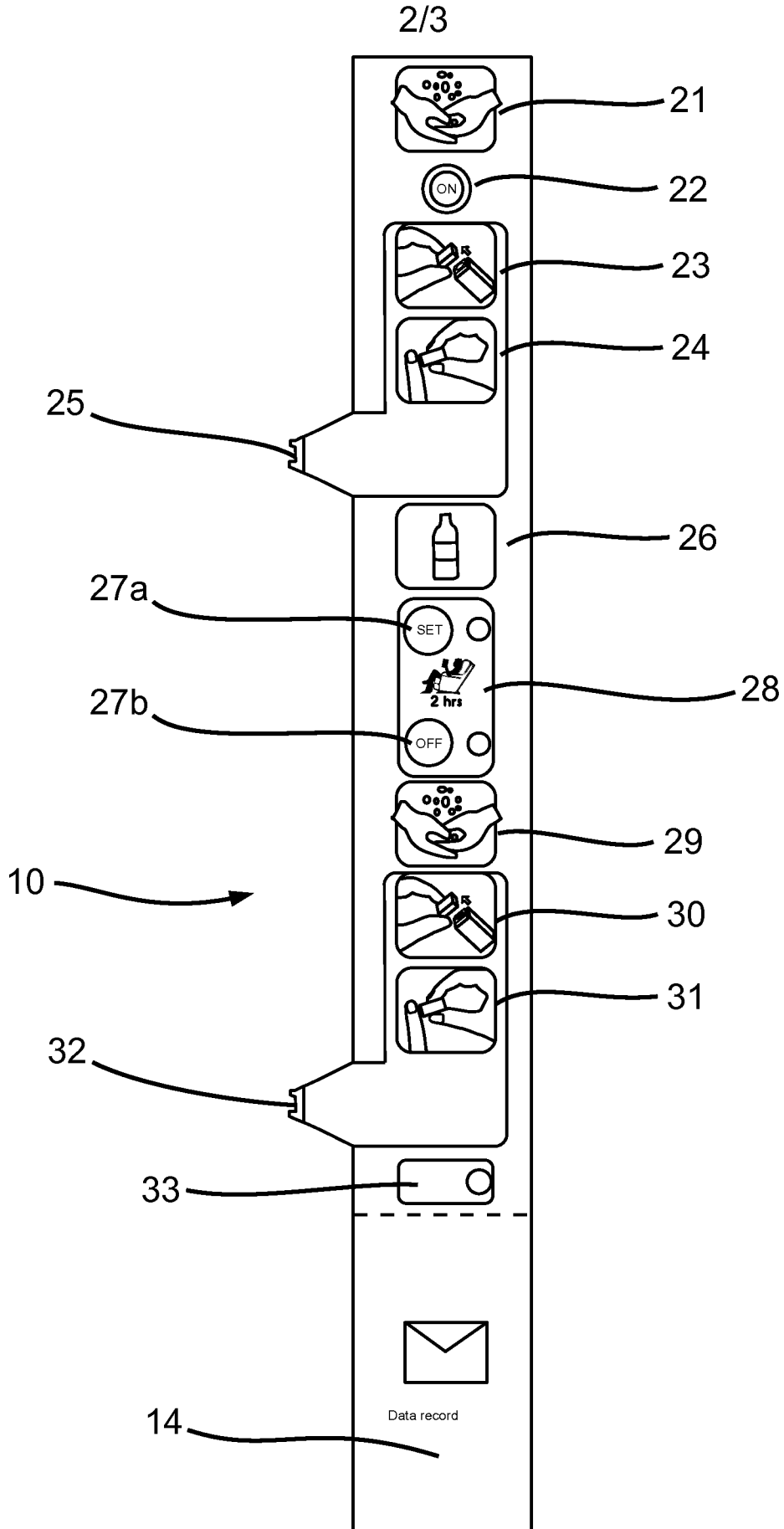


Fig 2

3/3

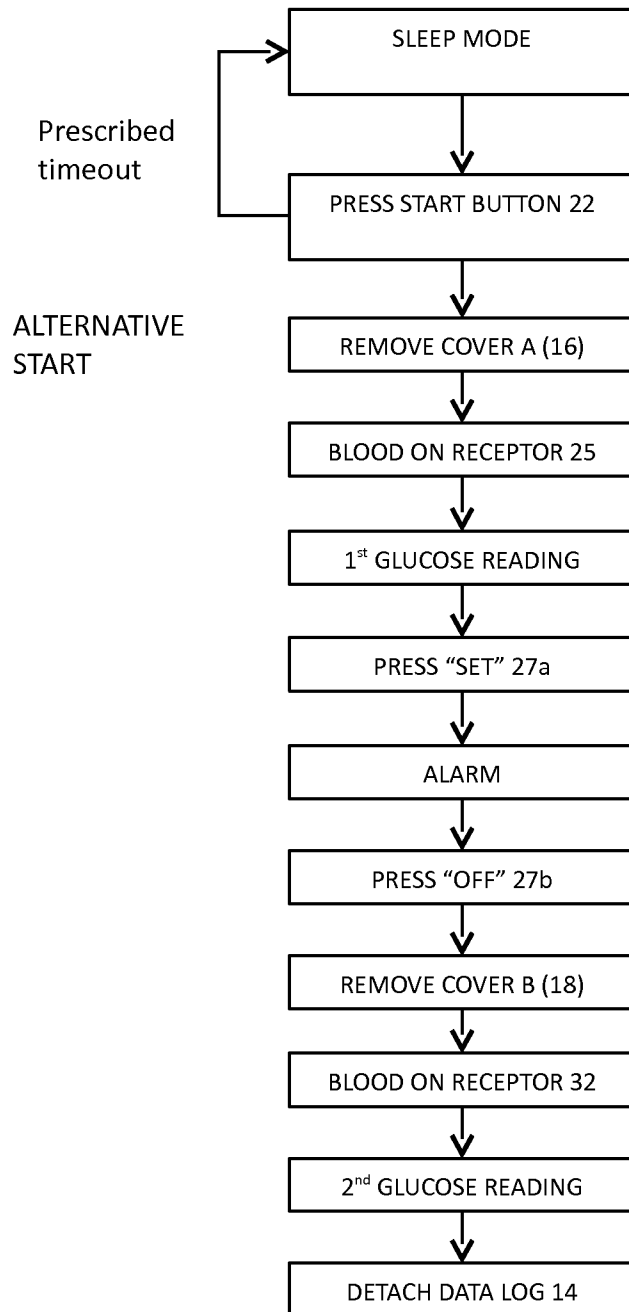


Fig 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2013/053771

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 19
because they relate to subject matter not required to be searched by this Authority, namely:
No technical features defined (Article 6 PCT).

2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2013/053771

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/15 A61B5/155 A61B5/157 A61B5/145
ADD.
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
Minimum documentation searched (classification system followed by classification symbols)
A61B
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2009/024794 A1 (SMARTSENSOR TELEMED LTD [GB]; JACKSON JAMES [GB]) 26 February 2009 (2009-02-26) cited in the application the whole document	1-18
A	US 2011/230743 A1 (INCIARDI SALVATORE RICHARD [US] ET AL) 22 September 2011 (2011-09-22) abstract; figure 4	1
A	EP 1 174 716 A2 (ROCHE DIAGNOSTICS GMBH [DE]; HOFFMANN LA ROCHE [CH]) 23 January 2002 (2002-01-23) abstract paragraph [0037]	1
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Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier application or patent but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search 19 June 2013	Date of mailing of the international search report 28/06/2013
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Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Nielsen, Michael
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INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2013/053771

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2005/096513 A1 (OZGUZ VOLKAN H [US] ET AL) 5 May 2005 (2005-05-05) abstract paragraph [0049] -----	1
A	US 2010/311090 A1 (BAE BYEONG-WOO [KR] ET AL) 9 December 2010 (2010-12-09) abstract -----	1
A	WO 02/07064 A2 (LABNETICS INC [US]) 24 January 2002 (2002-01-24) abstract -----	1
A	WO 2007/112034 A2 (BECTON DICKINSON CO [US]; BERGSTROM CHRIS [US]; BUTTERBRODT JAY [US];) 4 October 2007 (2007-10-04) abstract -----	1
A	EP 0 199 484 A2 (AUDIO BIONICS INC [US]) 29 October 1986 (1986-10-29) abstract; figure 2 -----	1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2013/053771

Patent document cited in search report	Publication date	Patent family member(s)	Publication date	
WO 2009024794	A1	26-02-2009	CN 101835418 A	15-09-2010
			EP 2180824 A1	05-05-2010
			JP 2010537185 A	02-12-2010
			US 2010240079 A1	23-09-2010
			WO 2009024794 A1	26-02-2009
US 2011230743	A1	22-09-2011	EP 2550520 A1	30-01-2013
			KR 20130039717 A	22-04-2013
			US 2011230743 A1	22-09-2011
			WO 2011119644 A1	29-09-2011
EP 1174716	A2	23-01-2002	AT 278955 T	15-10-2004
			CA 2353214 A1	20-01-2002
			DE 60106152 D1	11-11-2004
			DE 60106152 T2	13-10-2005
			EP 1174716 A2	23-01-2002
			ES 2230217 T3	01-05-2005
			JP 3779894 B2	31-05-2006
			JP 3869817 B2	17-01-2007
			JP 2002098661 A	05-04-2002
			JP 2003337114 A	28-11-2003
			US 6488828 B1	03-12-2002
			US 2003047451 A1	13-03-2003
US 2005096513	A1	05-05-2005	NONE	
US 2010311090	A1	09-12-2010	CN 102458249 A	16-05-2012
			EP 2438858 A2	11-04-2012
			JP 2012529038 A	15-11-2012
			KR 20100130900 A	14-12-2010
			US 2010311090 A1	09-12-2010
			WO 2010140769 A2	09-12-2010
WO 0207064	A2	24-01-2002	AU 7348601 A	30-01-2002
			US 2002059030 A1	16-05-2002
			WO 0207064 A2	24-01-2002
WO 2007112034	A2	04-10-2007	CA 2646279 A1	04-10-2007
			EP 1998840 A2	10-12-2008
			EP 2529783 A1	05-12-2012
			EP 2529784 A1	05-12-2012
			JP 2009532768 A	10-09-2009
			JP 2012210441 A	01-11-2012
			US 2010069730 A1	18-03-2010
			US 2013030841 A1	31-01-2013
			WO 2007112034 A2	04-10-2007
EP 0199484	A2	29-10-1986	AT 86843 T	15-04-1993
			AU 5699086 A	05-11-1986
			DE 3687994 D1	22-04-1993
			DK 589486 A	08-12-1986
			EP 0199484 A2	29-10-1986
			US 4637403 A	20-01-1987
			WO 8605966 A1	23-10-1986