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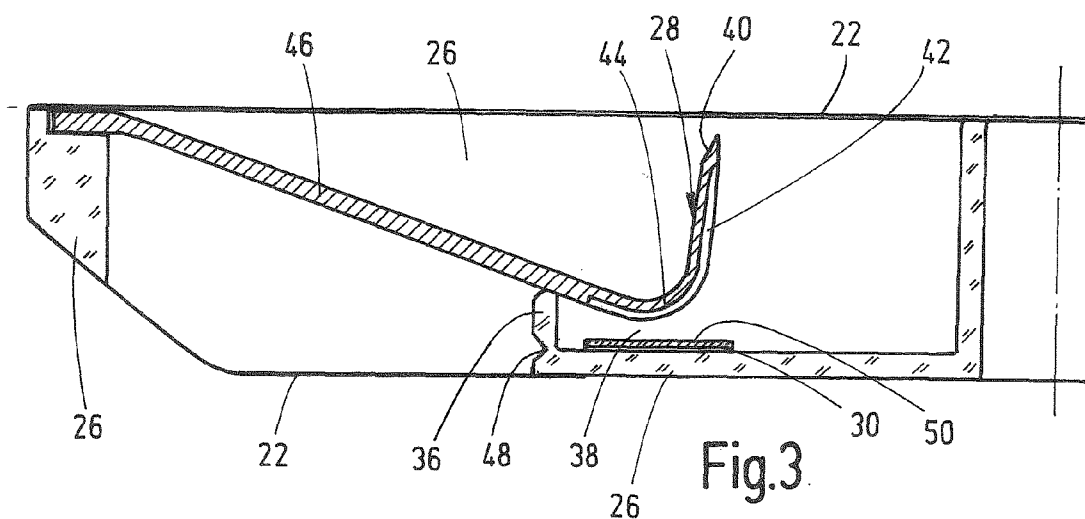
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(54) Title: DISPOSABLE DEVICE FOR ANALYZING BODY FLUID



(57) Abstract: The invention concerns a disposable device for analyzing body fluid especially for blood sugar tests comprising a container which can be inserted into a measuring apparatus, a sampling member provided in the container to pierce skin of a body part and sample body fluid, and a test member for receiving body fluid obtained by the skin-piercing. According to the invention it is proposed that the test member is fixed in a retaining chamber of the container, and the sampling member is configured in the same retaining chamber such that it is separated at a distance from the test member in an initial state and is in contact with the test member to transfer body fluid in a transfer state after the skin-piercing.

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## Disposable device for analyzing body fluid

### Description

5 The invention concerns a disposable device for analyzing body fluid especially for blood sugar tests comprising a container which can be inserted into a measuring apparatus, a sampling member provided in the container to pierce skin of a body part and sample body fluid, and a test member for receiving body fluid obtained by the skin-piercing. The invention  
10 further concerns an according analyzing process.

Such methods and withdrawal devices for small amounts of body fluids are used above all by diabetics for the self-monitoring of blood sugar which should be carried out several times daily. Recent concepts envisage a  
15 microneedle including a test element as a disposable in a hand-held device to generate a skin puncture, to remove a small amount of blood therefrom utilizing capillary forces and to analyse this blood sample. Generally, in such devices the lancing member and the test element are monolithically integrated and must be handled as combined units, where the lancing  
20 and blood transfer require separate actuation.

On this basis the object of the invention is to improve the devices known in the prior art and to provide a simple and low cost concept for an integrated sampling and measuring device and process.

25

The combination of features stated in the independent patent claims are proposed to achieve this object. Advantageous embodiments and further developments are derived from the dependent claims.

30 The invention is based on the idea of keeping the sampling member off the test element in a common space until use, where only the sampling member

is actuated. Accordingly with regard to a device it is proposed that the test member is fixed in a retaining chamber of the container, and the sampling member is configured in the same retaining chamber such that it is separated at a distance from the test member in an initial state and is in contact with the test member to transfer body fluid in a transfer state after the skin-piercing. In this manner it is possible to avoid a contamination of the sampling member especially with loose chemistry particles of the test element before the skin contact. Further, the fixed connection of the test member in the container facilitates manufacture of the disposable and allows a simplified sample transfer, while ensuring a safe disposal of the used and potentially bio-hazardous material. Accordingly, the sampling member is actuated to carry out a piercing movement outwards and backwards into the container, and the test member is arranged stationary inside the container.

In order to further improve the inventive concept, a preferred embodiment stipulates that the sampling member is separated from the test member by means of a spacer which can be put out of function during the skin-piercing. In order to provide a free space between the sampling member and the test member in the initial state, the spacer extends over a distance in direction of a piercing movement of the sampling member.

Advantageously, the spacer is removable by an actuator configured to actuate piercing movement of the sampling member. In this respect it is beneficial if the spacer is formed, preferably with a predetermined breaking point, at a wall of the container defining the retaining chamber, and is cut off the wall to achieve the transfer phase. Alternatively, it is possible that the spacer is connected to the sampling member, and a stopper of the container is removable such the spacer is inoperable in the transfer state.

Another improvement is achieved in that the sampling member is urged against the test member by means of a resilient element, thus ensuring an

automatic sample transfer. In this configuration, the sampling member is deflected against a restoring force of the resilient element during the skin-piercing. This can be realized by a sampling member that has a flexible bending link forming the resilient element. In addition it is advantageous  
5 when the sampling member is formed as a hooked needle, and a spring-arm of the hooked needle is pre-tensioned against the test member.

For the application it is also advantageous the sampling member has a tip to pierce the skin and a capillary structure to uptake body fluid, wherein the  
10 capillary structure is in fluidic connection with the test element during the transfer phase. A preferred embodiment provides that the sampling member comprises a pointed piercing arm, and a laterally open channel is extending along the piercing arm preferably having a bent section that can be contacted with the test member.

15 In order to precisely define the actuation, the sampling member may comprise an engagement slot to receive an actuator rod for driving a piercing movement.

20 For the application it is also advantageous when the test member is formed as a reagent pad having a reactive layer which is sensitive to an analyte in the body fluid, and the flat-material pad is attached to a wall of the container defining the retaining chamber. In this configuration it is possible that the test member is configured to be mounted in the container as a unit separate  
25 from the sampling member.

Another improvement is achieved in that the container is sealed against the environment by a sealing foil, and at least a piercing part of the sampling member is penetrated through the sealing foil to allow the skin-piercing. The  
30 container can include a wall structure which defines the retaining chamber and comprises a desiccant material to keep the test chemistry dry.

A further advantage in usability is achieved when the container is formed as a magazine to contain a plurality of sampling members and test members preferably arranged in pairs in respective retaining chambers. To achieve a compact design, it is advantageous when the container comprises a disk-like configuration and contains a plurality of sampling members formed as a lancet wheel, and when the sampling members are actuated through a side face of the disk.

10 It is advantageous for a mass production when the lancet wheel is formed in one piece preferably by etching or cutting a metallic sheet material. It is further beneficial when the container includes a hub to engage a rotary drive for successive rotary positioning of the sampling members with respect to a sampling port of the apparatus constructed to receive the body part.

15

The invention also concerns a process for analyzing body fluid especially for blood sugar tests in which a container is inserted into a measuring apparatus, a sampling member provided in the container is actuated to pierce skin of a body part and sample body fluid, and body fluid obtained by the skin-piercing is transferred to a test member, wherein the test member is stationary maintained in a retaining chamber of the container, and the sampling member is held separated at a distance from the test member in an initial state and is brought in contact with the test member to transfer body fluid in a transfer state after the skin-piercing.

25

The invention is further elucidated in the following on the basis of the embodiment example shown schematically in the drawing figures.

Fig. 1 shows a hand held measuring apparatus for blood glucose tests with an inserted disk-like cartridge;

30

Fig. 2 shows the cartridge in a sectional diagrammatic view;

Fig. 3 shows a chamber of the cartridge including a sampling member and a test member in a radial section;

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Fig. 4 to 6 show different states of the blood sampling and transfer in a view according to Fig. 3.

The apparatus 10 shown in Fig. 1 allows self-withdrawal of a blood sample  
10 by a user for analytical purposes and in particular for blood sugar monitoring. It comprises a housing 12 with a lid 14 to allow the change of a disposable test container or cartridge 16. In the closed state, a body part and in particular a fingertip can be pressed against a port 18 of the lid 14 in order to take a blood sample by skin-piercing. The apparatus 10 further  
15 comprises drive and processing units for an automatic measurement operation (not shown). The measurement result can be indicated on a display 20.

As shown in Fig. 2, the cartridge 16 comprises a disk-like configuration  
20 where the side faces are sealed against the environment by foils 22. The inner space between the foils is divided in sectors by a wall structure 24. Thereby, a magazine with a plurality of retaining chambers 26 is defined to accommodate in each chamber a sampling member 28 and a test member 30 in pair-wise configuration. The wall structure 24 can be formed as a  
25 single frame by injection molding with a desiccant material co-molded to keep the chambers 26 free from moisture. It is further conceivable to photo-etch or cut and then pre-form the plurality of sampling members 28 as a one piece lancet wheel 32 that can be inserted into the frame 26. In order to successively position the sampling members 28 with respect to the port 18,  
30 the frame 26 includes a hub 34 for engaging a rotary drive of the apparatus 10.

Fig. 3 shows an initial configuration of a retaining chamber 26 with the sampling member 28 being hold at a distance with respect to the test member 30 by means of a spacer 36. Due to the free space 38 kept by the spacer 36, the sampling member 28 is hold off the chemistry film of the test member 30 until the test is performed.

The sampling member 28 is formed as a hooked needle, which is accessible for actuation and allows piercing by break-through of the foils 22. For collecting a small amount of blood from a body part, the sampling member 28 comprises a pointed tip 40 and a capillary channel 42. The channel 42 is laterally open along his length and extents into a curved section 44 facing the test member 30. The sampling member 28 is linked to the periphery of the frame 26 via a flexible spring-arm 46. The spring-arm 46 is under pretension, such that the section 44 including the proximal part of the channel 42 is urged against the removable spacer 36 and the test member 30, respectively.

In order to allow a blood transfer from the channel 42 onto the test member 30, the spacer 36 can be removed during the skin-piercing procedure. This is facilitated by means of a breaking point 48 at the basis of the spacer 36. Alternatively, it is possible that the spacer is connected to the sampling member and abuts a removable counterpart, e.g. the sealing foil 22.

The test member 30 is formed as a reagent pad having a reactive layer 50. The reagent pad can be mounted as a unitary ring which is fixed to the bottom of the frame 26. The reactive layer 50 comprises a dried enzyme chemistry which is sensitive blood glucose, such that a colour change occurs which can be optically detected through the transparent frame 26. The detection of blood glucose in particular by means of contact-free optical

methods is known in the prior art and is therefore not elucidated in more detail here.

5 Figs. 4 to 6 illustrate the sampling and transfer procedure, where the sampling member 28 is actuated to carry out a piercing movement outwards and backwards (arrows 52, 54) into the respective retaining chamber 26 of the cartridge 16, while the test member is kept stationary.

10 In the forward movement 52, the sampling member 28 is deflected against the restoring force of the spring-arm 46 by means of an actuator rod 56. The rod 56 is driven in direction of arrow 58 by a drive unit of the apparatus, thereby penetrating the bottom foil 22 and sliding along the spring-arm 46. It is also conceivable that the rod 56 is provided with an engaging piece for a form-locking engagement with the sampling member (not shown). While the  
15 actuator rod 56 is accessing the spring-arm 46, the needle tip 40 is breaking through the upper foil 22 and pierces the skin of the fingertip applied on the port 18. During the skin-piercing, blood and/or interstitial liquid is received in the channel 42 preferably by capillary action.

20 During the following resilient retraction 54 of the sampling member, the actuator rod 56 engages the spacer 36 with a hook piece 60 (Fig. 5). Subsequently, the rod 56 is pulled back in direction of arrow 62, whereby the spacer 36 is torn off the frame 26 (Fig. 6). This allows contact of the curved section 44 of the sampling member 28 with the test element 30, thereby  
25 initiating a transfer phase in which the sampled liquid is automatically transferred to the test element for an immediate analysis.

**What is claimed is**

1. A disposable device for analyzing body fluid especially for blood sugar tests comprising a container which can be inserted into a measuring apparatus, a sampling member provided in the container to pierce skin of a body part and sample body fluid, and a test member for receiving body fluid obtained by the skin-piercing, wherein the test member is fixed in a retaining chamber of the container, and the sampling member is configured in the same retaining chamber such that it is separated at a distance from the test member in an initial state and is in contact with the test member to transfer body fluid in a transfer state after the skin-piercing.
2. The device according to claim 1, wherein the sampling member is actuated to carry out a piercing movement outwards and backwards into the container, and the test member is arranged stationary inside the container.
3. The device according to claim 1 or 2, wherein the sampling member is separated from the test member by means of a spacer which can be put out of function during the skin-piercing.
4. The device according to claim 3, wherein the spacer extends over a distance in direction of a piercing movement of the sampling member in order to provide a free space between the sampling member and the test member.
5. The device according to claim 3 or 4, wherein the spacer is removable by an actuator configured to actuate piercing movement of the sampling member.

6. The device according to any one of claims 3 to 5, wherein the spacer is formed, preferably with a predetermined breaking point, at a wall of the container defining the retaining chamber, and that the spacer is cut off the wall to achieve the transfer phase.
- 5
7. The device according to any one of claims 3 to 6, wherein the spacer is connected to the sampling member, and a stopper of the container is removable such the spacer is inoperable in the transfer state.
- 10
8. The device according to any one of claims 1 to 7, wherein the sampling member is urged against the test member by means of a resilient element.
9. The device according to any one of claims 1 to 8, wherein the sampling member is deflected against a restoring force of the resilient element during the skin-piercing.
- 15
10. The device according to claim 9, wherein the sampling member has a flexible bending link forming the resilient element.
- 20
11. The device according to any one of claims 1 to 10, wherein the sampling member is formed as a hooked needle, and a spring-arm of the hooked needle is pre-tensioned against the test member.
- 25
12. The device according to any one of claims 1 to 11, in which the sampling member has a tip to pierce the skin and a capillary structure to uptake body fluid, wherein the capillary structure is in fluidic connection with the test element during the transfer phase.
- 30
13. The device according to any one of claims 1 to 12, wherein the sampling member comprises a pointed piercing arm, and a laterally

open channel is extending along the piercing arm preferably having a bent section that can be contacted with the test member.

- 5 14. The device according to any one of claims 1 to 13, wherein the sampling member has an engagement slot to receive an actuator rod for driving a piercing movement.
- 10 15. The device according to any one of claims 1 to 14, wherein the test member is formed as a reagent pad having a reactive layer which is sensitive to an analyte in the body fluid, and that the flat-material pad is attached to a wall of the container defining the retaining chamber.
- 15 16. The device according to any one of claims 1 to 15, wherein the test member is configured to be mounted in the container as a unit separate from the sampling member.
- 20 17. The device according to any one of claims 1 to 16, wherein the container is sealed against the environment by a sealing foil, and at least a piercing part of the sampling member is penetrated through the sealing foil to allow the skin-piercing.
- 25 18. The device according to any one of claims 1 to 17, wherein the container includes a wall structure which defines the retaining chamber and comprises a desiccant material.
- 30 19. The device according to any one of claims 1 to 18, wherein the container is formed as a magazine to contain a plurality of sampling members and test members preferably arranged in pairs in respective retaining chambers.

20. The device according to any one of claims 1 to 19, wherein the container comprises a disk-like configuration and contains a plurality of sampling members formed as a lancet wheel, and the sampling members are actuated through a side face of the disk.

5

21. The device according to any one of claims 1 to 20, wherein the lancet wheel is formed in one piece preferably by etching or cutting a metallic sheet material.

10 22. The device according to any one of claims 1 to 21, wherein the container includes a hub to engage a rotary drive for successive rotary positioning of the sampling members with respect to a sampling port of the apparatus constructed to receive the body part.

15 23. A process for analyzing body fluid especially for blood sugar tests in which a container is inserted into a measuring apparatus, a sampling member provided in the container is actuated to pierce skin of a body part and sample body fluid, and body fluid obtained by the skin-piercing is transferred to a test member, wherein the test member is maintained  
20 stationary in a retaining chamber of the container, and the sampling member is disposed at a distance from the test member in an initial state and is brought in contact with the test member to transfer body fluid in a transfer state after the skin-piercing

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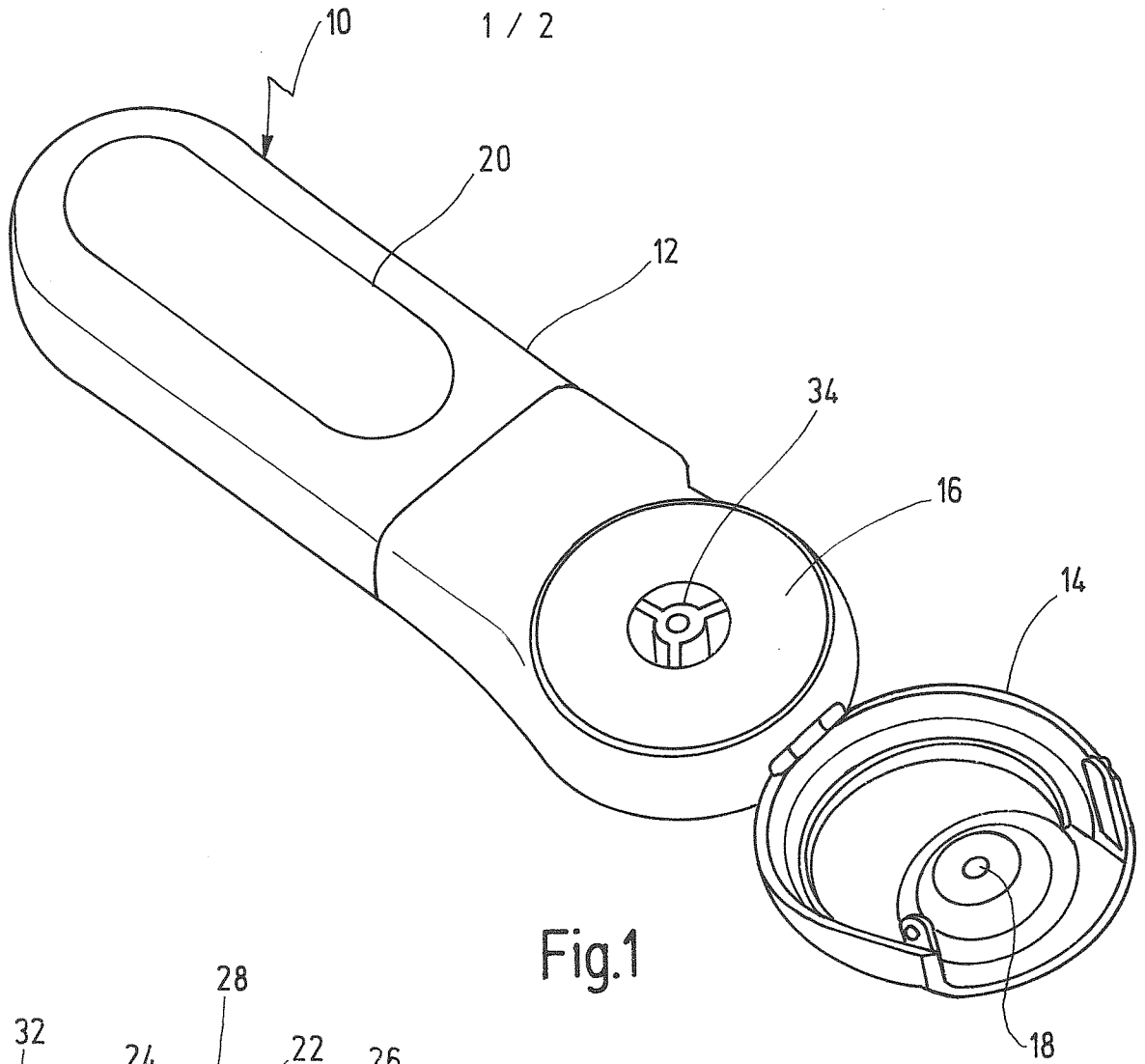


Fig.1

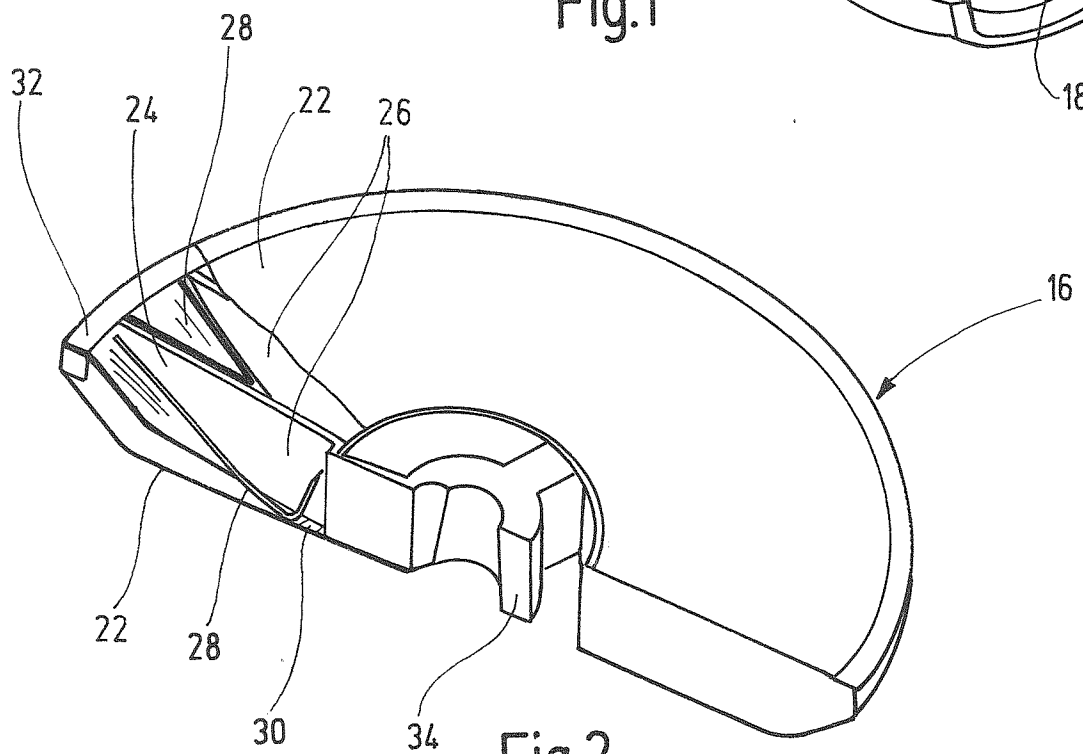
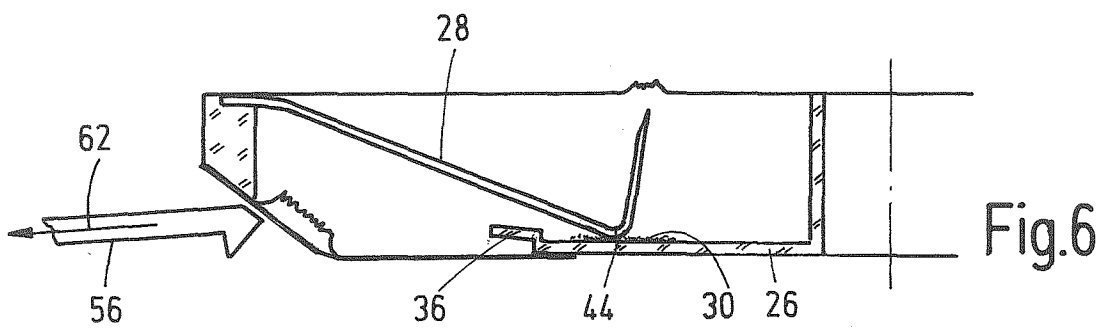
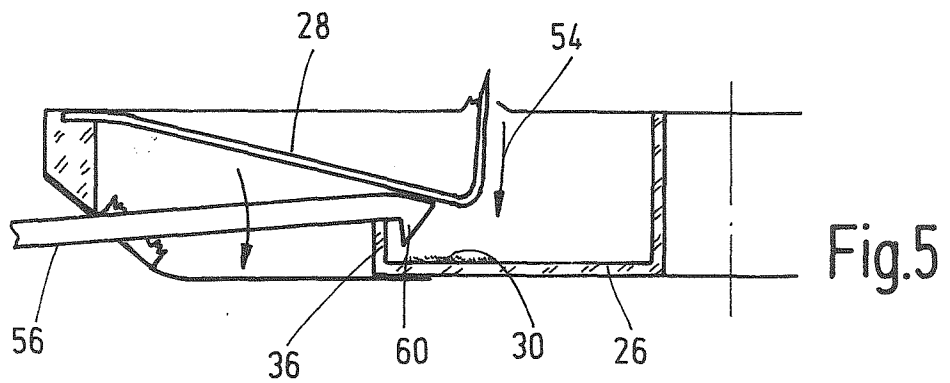
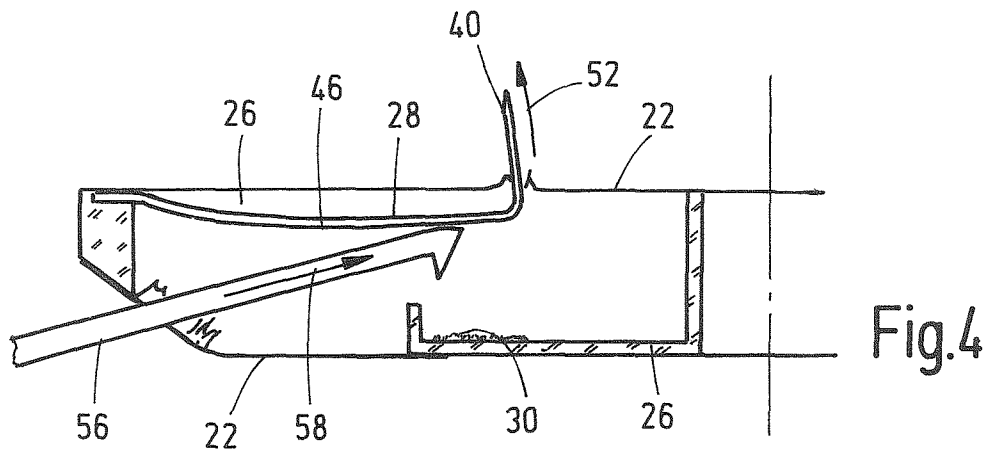
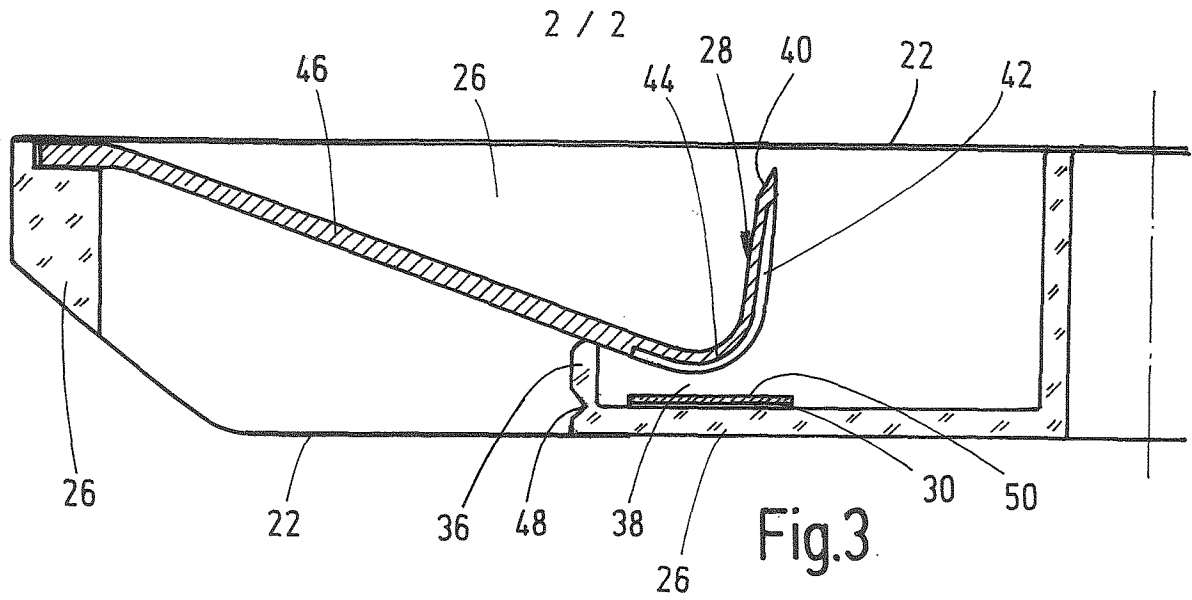


Fig.2



## INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2008/062130

## A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B5/151

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1 759 633 A (HOFFMANN LA ROCHE [CH]; ROCHE DIAGNOSTICS GMBH [DE]) 7 March 2007 (2007-03-07) paragraph [0026] - paragraph [0035]; figures	1,2, 12-15, 17,19,22
X	US 2007/016103 A1 (CALASSO IRIO [CH] ET AL) 18 January 2007 (2007-01-18)  paragraph [0086] - paragraph [0092]; figures 7-12	1,3-5,8, 12, 14-17, 19,20
X	DE 103 45 663 A1 (SENSLAB GES ZUR ENTWICKLUNG UN [DE]) 20 January 2005 (2005-01-20) paragraph [0058] - paragraph [0087]; figures	1,2, 8-10,15, 19
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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 document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

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

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

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

\*Z\* document member of the same patent family

Date of the actual completion of the international search

8 January 2009

Date of mailing of the international search report

03/02/2009

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2  
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Authorized officer

Strubel, Christine

## INTERNATIONAL SEARCH REPORT

International application No  
PCT/EP2008/062130

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/EP2008/062130

## 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.: 23  
because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery. Skin-piercing and body fluid sampling are inherent steps, conferring surgical nature to claim 23.
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

Information on patent family members

International application No

PCT/EP2008/062130

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