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**Declarations under Rule 4.17**:

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(54) **Title**: LANCING DEVICE WITH CAM-ACTUATED DRIVE AND SEPARATE GUIDANCE

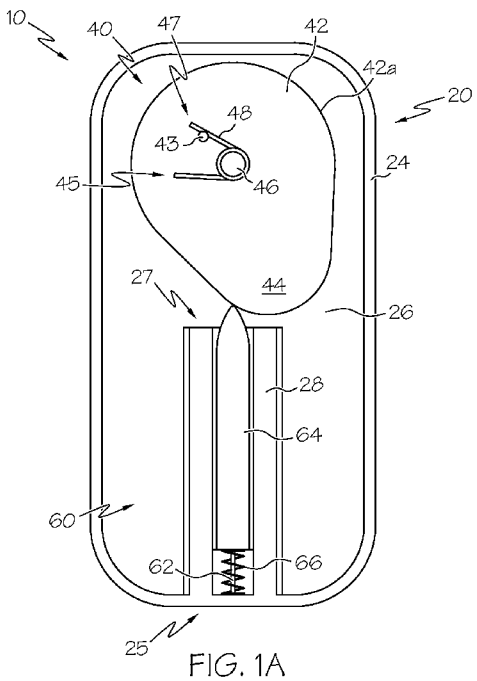


FIG. 1A

(57) **Abstract**: A lancet assembly (10) comprises a housing (20) and a needle carriage (64) movably housed within the housing, the needle carriage adapted to support a needle (62) thereon, the needle carriage having a first end (63) and a second end (65) generally opposite thereto. A needle is mounted to the needle carriage and a guide element (28) is positioned within the housing for guiding the needle carriage for reciprocating translation. A pivotal drive cam (42) is provided for driving the needle carriage in translation and has a cam lobe (44) for engaging the second end of the needle carriage, wherein the needle carriage is guided by the guide element and driven in translation by the pivotal drive cam such that the guidance and drive are kept separate.

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# LANCING DEVICE WITH CAM-ACTUATED DRIVE AND SEPARATE GUIDANCE

## Cross-Reference to Related Application

**[0001]** This application claims the benefit of U.S. Provisional Patent Application Serial No. 61/556,897, filed November 8, 2011, the entirety of which is hereby incorporated herein by reference for all purposes.

## Technical Field

**[0002]** The present invention relates generally to the field of medical devices, and more particularly to an improved lancing device for blood testing and typing applications.

## Background

**[0003]** In typical known lancets, a needle (lance) is affixed to some sort of movable needle carrier, such as a sled or carriage. A drive spring urges the needle carrier outwardly toward an extended position in which the needle extends beyond the housing to penetrate the skin or tissue of the user. Another spring is positioned for urging the needle carrier inwardly toward a retracted position in which the needle withdrawn and does not extend beyond the housing. In such a device it is common to try to balance these springs more or less to try to avoid "bouncing" of the needle and a double strike of the user by the lancing device. This balancing effort can be difficult. Typically, these springs, which tend to urge the needles toward extended and retracted positions, are acting on the same part of the lancing device (normally the carrier). Having the drive springs act on parts that are also involved in guidance tends to distort the guidance efforts, as well as the drive efforts. Thus, by having one mechanism involved in both functions, both functions are diminished somewhat.

## Summary

**[0004]** In example embodiments, the present invention provides a lancet assembly having a housing and a needle carriage movably housed within the housing. The needle carriage is adapted to support a needle thereon, and has a first end and a second end generally opposite thereto. A needle is mounted to the needle carriage and a guide element is positioned within the housing for guiding the needle carriage for reciprocating translation. A pivotal drive cam is provided for driving the needle carriage in translation and has a cam lobe for engaging the second end of the needle carriage. The needle carriage is guided by the guide element and is driven in translation by the pivotal drive cam such that the guidance and drive functions are kept substantially separate from one another.

**[0005]** Preferably, the pivotal drive cam is movable between (1) a cocked, retracted position, (2) a fired, retracted position, and (3) an extended position between the cocked retracted position and the fired, retracted position.

**[0006]** Optionally, the lancet assembly further comprises a guidance biasing spring for biasing the needle carriage toward a retracted position and a separate drive spring for storing potential energy for pivoting the pivotal drive cam. Advantageously, these springs need not act against one another and need not be carefully balanced one against the other. Optionally, the second end of the needle carriage can include a cam follower portion for engaging the cam lobe and being driven thereby.

**[0007]** The needle carriage can be provided with an elongate guided surface extending generally axially between the first and second ends of the needle carriage and the guide element can include a guide surface for engaging and guiding the guided surface of the needle carriage. In one preferred form, the guide element within the housing and the guided surface of the needle carriage define a sliding dovetail connection.

**[0008]** These and other aspects, features and advantages of the invention will be understood with reference to the drawing figures and detailed description herein, and will be realized by means of the various elements and combinations particularly pointed out in the appended claims. It is to be understood that both the foregoing general description and the following brief description of the drawings and detailed description of the invention are exemplary and explanatory of preferred embodiments of the invention, and are not restrictive of the invention, as claimed.

**Brief Description of the Drawings**

**[0009]** **FIGURE 1A** is a side view of a lancing device with cam-actuated drive and separate guidance according to a first example embodiment of the present invention.

**[0010]** **FIGURE 1B** is another side view of the lancing device with cam-actuated drive and separate guidance of **Figure 1A**.

**[0011]** **FIGURE 1C** is a perspective view of the lancing device with cam-actuated drive and separate guidance of **Figure 1A**.

**[0012]** **FIGURE 1D** is a side view of the lancing device guide surface and needle carriage according to a preferred embodiment of the present invention.

**[0013]** **FIGURE 2A** is a side view of a lancing device with cam-actuated drive and separate guidance according to another example embodiment.

**[0014]** **FIGURE 2B** is another side view of the lancing device with cam-actuated drive and separate guidance of **Figure 2A**.

**[0015]** **FIGURE 3A** is a side view of a lancing device with cam-actuated drive and separate guidance according to another example embodiment.

**[0016]** **FIGURE 3B** is another side view of the lancing device with cam-actuated drive and separate guidance of **Figure 3A**.

**Detailed Description of Example Embodiments**

**[0017]** The present invention may be understood more readily by reference to the following detailed description of the invention taken in connection with the accompanying drawing figures, which form a part of this disclosure. It is to be understood that this invention is not limited to the specific devices, methods, conditions or parameters described and/or shown herein, and that the terminology used herein is for the purpose of describing particular embodiments by way of example only and is not intended to be limiting of the claimed invention. Any and all patents and other publications identified in this specification are incorporated by reference as though fully set forth herein.

**[0018]** Also, as used in the specification including the appended claims, the singular forms "a," "an," and "the" include the plural, and reference to a particular numerical value includes at least that particular value, unless the context clearly dictates otherwise. Ranges may be expressed herein as from "about" or "approximately" one particular value and/or to "about" or "approximately" another particular value. When such a range is expressed, another embodiment includes from the one particular value and/or to the other particular value. Similarly, when values are expressed as approximations, by use of the antecedent "about," it will be understood that the particular value forms another embodiment.

**[0019]** With reference now to the drawing figures, wherein like reference numbers represent corresponding parts throughout the several views, **Figures 1A-3B** depict various embodiments of lancing devices according to example embodiments of the present invention. In general, the lancing devices herein include a lancet assembly having a housing and a needle carriage movably housed within the housing, the needle carriage

adapted to support a needle thereon, the needle carriage having a first end and a second end generally opposite thereto. A needle is mounted to the needle carriage and a guide element is positioned within the housing for guiding the needle carriage for reciprocating translation. A pivotal drive cam is provided for driving the needle carriage in translation and has a cam lobe for engaging the second end of the needle carriage, wherein the needle carriage is guided by the guide element and driven in translation by the pivotal drive cam such that the guidance and drive are kept separate.

**[0020]** **Figures 1A-3C** depict a lancing device **10** with cam-actuated drive and separate guidance according to a first example embodiment of the present invention. In general, the lancing device **10** includes a housing **20** containing a cam assembly **40** and needle assembly **60**. In example embodiments, the housing **20** includes a peripheral wall **24** that stretches substantially along the perimeter edge and together with a floor defines a recessed interior portion **26.** The housing also includes a guide element **28** and a needle passage **23** integrally formed therein. Optionally, the wall **24** has a substantially constant thickness and the recessed interior portion preferably maintains a thickness substantially similar or greater than the wall thickness.

**[0021]** The guide element **28** includes a first exterior end **25** adjacent to wall **24** and a second interior end **27** located within the recessed interior portion **26**. In preferred example embodiments, a needle carriage **64**, having a first end **63** and a second end **65** generally opposite thereto, is movably housed within the housing **20** and is adapted to support a needle **62**. As best seen in **Figure 1D,** the needle carriage **64** can be provided with an elongate guided surface **67** extending generally axially between the first and second ends of the carriage and the guide element **28** can include a guide surface **21** for engaging and guiding the guided surface 67 of the needle carriage **64**. In one preferred embodiment, the guide element **28** within the housing **20** and the guided surface **67** of the needle carriage **44** comprise a sliding dovetail connection). Optionally the guide element 28

is a one-piece construction, but the guide element can be provided as a multi-piece construction. Also, multiple smaller guide elements can be employed, as desired.

**[0022]** A pivotal drive cam **42**, having an outer surface or profile **42a**, is provided for driving the needle carriage in translation and includes a cam lobe **44** for engaging the second end of the needle carriage. The pivotal drive cam is pivotally mounted to a pivot on a mounting pin **46** within the interior portion **26**. The needle carriage **64** is guided by the guide element **28** and driven in translation by the drive cam **42** such that the guidance and drive are kept separate from one another.

**[0023]** In example embodiments, the lancet device **10** can optionally include a guidance biasing spring **66** for biasing the needle carriage toward a retracted position and a separate drive spring **48** for storing potential energy for driving the pivotal drive cam **42**. In preferred example embodiments, the guidance biasing spring **66,** located within the guide element **28,** is fixed between the first end **63** of the needle carriage **64** and guide element first end **25** (best seen in **Figures 1A-C**). The biasing spring is axially aligned with the needle carriage **64** and the needle **62**. In other example embodiments, the biasing spring **66** is located at the second end **27** of the needle carriage **64**. A proximal end **66a** of spring **46**, axially aligned with the needle carriage, mounts below a flat cam follower portion **50** that extends beyond the outer edge of the needle carriage and a distal end **66b** of the spring is fixed at the second end **27** of guide element **28** (best seen in **Figures 2A-B**).

**[0024]** In other example embodiments, the biasing spring can comprise a leaf spring **52** fixed between the first and second ends of the guide element **28** (best seen in **Figures 3A-B**). The leaf spring sits perpendicular to the translational movement of the needle carriage **64** and is secured by side stops **29,** front housing pins **29a,** and rear housing pins **29b**. Additionally, the bottom surface of the needle carriage **64 preferably** includes a protrusion (not shown). The protrusion extends from the bottom surface of the needle

carriage **64** towards recessed interior portion **26** and initiates contact with the biasing spring **52** when acted upon by the drive cam **22**.

**[0025]** Referring again to **Figure 1** *et seq.*, the drive spring **48** has a first arm/end **45** fixed to the interior portion **26** and a second arm/end **47** fixed to the drive cam pin **43.** The drive spring **48** permits potential energy to be stored for pivoting the pivotal drive cam **42** and driving the needle carriage **64** in translation. In example embodiments, the pivotal drive cam is movable between a cocked, retracted position (best seen in **Figures 1A, 2A, 3A**), a fired, retracted position (best seen in **Figures 1B, 2B,3B**), and an extended position between the cocked retracted position and the fired, retracted position (best seen in **Figure 1C**). The drive spring **48** is preferably a compression spring. In additional embodiments, the pivotal drive cam **42** can be altered to receive a compression spring. **Figures 3A-B** depict a cam assembly **40** comprising a compression spring. The compression drive spring **30,** having a first end **45** fixed to the interior spring mount **22** and a second end **47** fixed to a pivotal drive cam arm **49**, additionally permits storing potential energy for pivoting the pivotal drive cam **42** and driving a needle carriage **64** in translation. Alternately, other types of springs could be used.

**[0026]** In example embodiments, the cam lobe **44** can be designed to achieve a variety of motions for a variety of purposes. For example, the cam lobe can be designed to have a shape that minimized the time duration of the needle exposure or that minimizes the stroke to just barely jut the needle from the end of the housing. The lobe can also be designed to control the acceleration of the needle as it enters the skin (the lobe can be designed to cause the needle to be accelerating, decelerating, or maintaining a more or less constant velocity as the needle enters the skin). For example, if the shortest skin or tissue penetration is desired, the lobe could be further pointed so that there is a very small duration of time when the lobe is engaged with the needle carriage. Alternatively, if a longer skin or tissue penetration is desired, the lobe could be further rounded and

extended so that there is a longer duration of time when the lobe is engaged with the needle carriage. By careful design of the cam lobe, the motion and acceleration of the needle into and out of the skin can be carefully controlled. Additionally, to further adjust the speed and acceleration of the needle, the mass of the cam and the carriage can be altered relative to one another to provide a desired force-to-mass ratio (and consequent acceleration as the cam lobe accelerates through its motion). Those skilled in the art will also appreciate that the drive cam spring strength also plays a role.

**[0027]** In operation, the cocking and releasing of the pivotal drive cam **42** can be performed in a variety of different ways. In preferred example embodiments, the cam **42** can have a recessed knob or button (not shown) that extends through the housing **20**. The knob permits cocking the cam to a cocked, retracted position, and also includes a function to permit firing.

**[0028]** The components discussed and described herein can be formed from a variety of materials as desired by a user. In example embodiments, the lancet device and components can be formed from plastics (e.g,. polystyrene), other polymers, glass, metals, metal alloys, resins, rubbers, rubber derivatives, elastomerics (i.e. santoprene), silicones or other known materials. In preferred embodiments, the drive cam or the needle carriage may be formed from a low friction material. Materials of such low friction properties can include nylon or PTFE. Additionally, the springs can be formed from plastics, other polymers, metals, metal alloys, resins, rubbers, rubber derivatives, or other known materials.

**[0029]** While the invention has been described with reference to preferred and example embodiments, it will be understood by those skilled in the art that a variety of modifications, additions and deletions are within the scope of the invention, as defined by the following claims.

**What is Claimed is:**

1. A lancet assembly comprising;

a housing;

a needle carriage movably mounted within the housing, the needle carriage adapted to support a needle thereon, the needle carriage having a first end and a second end generally opposite thereto;

a needle mounted to the needle carriage;

a guide element positioned within the housing for guiding the needle carriage for reciprocating translation; and

a pivotal drive cam for driving the needle carriage in translation and having a cam lobe for engaging the second end of the needle carriage;

wherein the needle carriage is guided by the guide element and driven in translation by the pivotal drive cam such that guidance of the needle carriage and drive of the needle carriage are kept substantially separate from one another.

2. A lancet assembly as claimed in Claim 1 wherein the pivotal drive cam is movable between a cocked, retracted position, a fired, retracted position, and an extended position between the cocked retracted position and the fired, retracted position.

3. A lancet assembly as claimed in Claim 1 further comprising a guidance biasing spring for biasing the needle carriage toward a retracted position and a drive spring for storing potential energy for pivoting the pivotal drive cam.

4. A lancet assembly as claimed in Claim 1 further comprising a biasing spring for biasing the needle carriage toward a retracted position and a drive spring for storing potential energy for pivoting the pivotal drive cam, and wherein these springs are separate springs from one another.

5. A lancet assembly as claimed in Claim 3 wherein the biasing spring is operative for biasing the needle carriage in translation and the drive spring is operative for pivoting the pivotal drive cam.

6. A lancet assembly as claimed in Claim 1 wherein the second end of the needle carriage comprises a cam follower portion for engaging the cam lobe and being driven thereby.

7. A lancet assembly as claimed in Claim 1 wherein the needle carriage has an elongate guided surface extending generally axially between the first and second ends of the needle carriage and wherein the guide element includes a guide surface for engaging and guiding the guided surface of the needle carriage.

8. A lancet assembly as claimed in Claim 7 wherein the guide element within the housing and the guided surface of the needle carriage define a sliding dovetail connection.

9. A lancet assembly comprising;

a housing;

a needle carriage movably mounted within the housing, the needle carriage adapted to support a needle thereon, the needle carriage having a first end and a second end generally opposite thereto;

a needle mounted to the needle carriage;

a guide element positioned within the housing for guiding the needle carriage for reciprocating translation; and

a drive mechanism for driving the needle carriage in translation;

wherein the needle carriage is guided by the guide element and driven in translation by the drive mechanism and wherein the guidance of the needle carriage and drive of the needle carriage are kept substantially separate from one another.

10. A lancet assembly as claimed in Claim 9 wherein the drive mechanism comprises a pivotal drive cam movable between a cocked, retracted position, a fired, retracted position, and an extended position between the cocked retracted position and the fired, retracted position.

11. A lancet assembly as claimed in Claim 9 further comprising a guidance biasing spring for biasing the needle carriage toward a retracted position and a drive spring for storing potential energy for pivoting the drive mechanism.

12. A lancet assembly as claimed in Claim 9 further comprising a biasing spring for biasing the needle carriage toward a retracted position and a drive spring for storing potential energy for pivoting the drive mechanism, and wherein these springs are separate springs from one another.

13. A lancet assembly as claimed in Claim 9 wherein the drive mechanism comprises a drive cam having a cam lobe and wherein a second end of the needle carriage comprises a cam follower portion for engaging the cam lobe and being driven thereby.

14. A lancet assembly as claimed in Claim 9 wherein the needle carriage has an elongate guided surface extending generally axially between the first and second ends of the needle carriage and wherein the guide element includes a guide surface for engaging and guiding the guided surface of the needle carriage.

15. A lancet assembly as claimed in Claim 14 wherein the guide element within the housing and the guided surface of the needle carriage define a sliding dovetail connection.

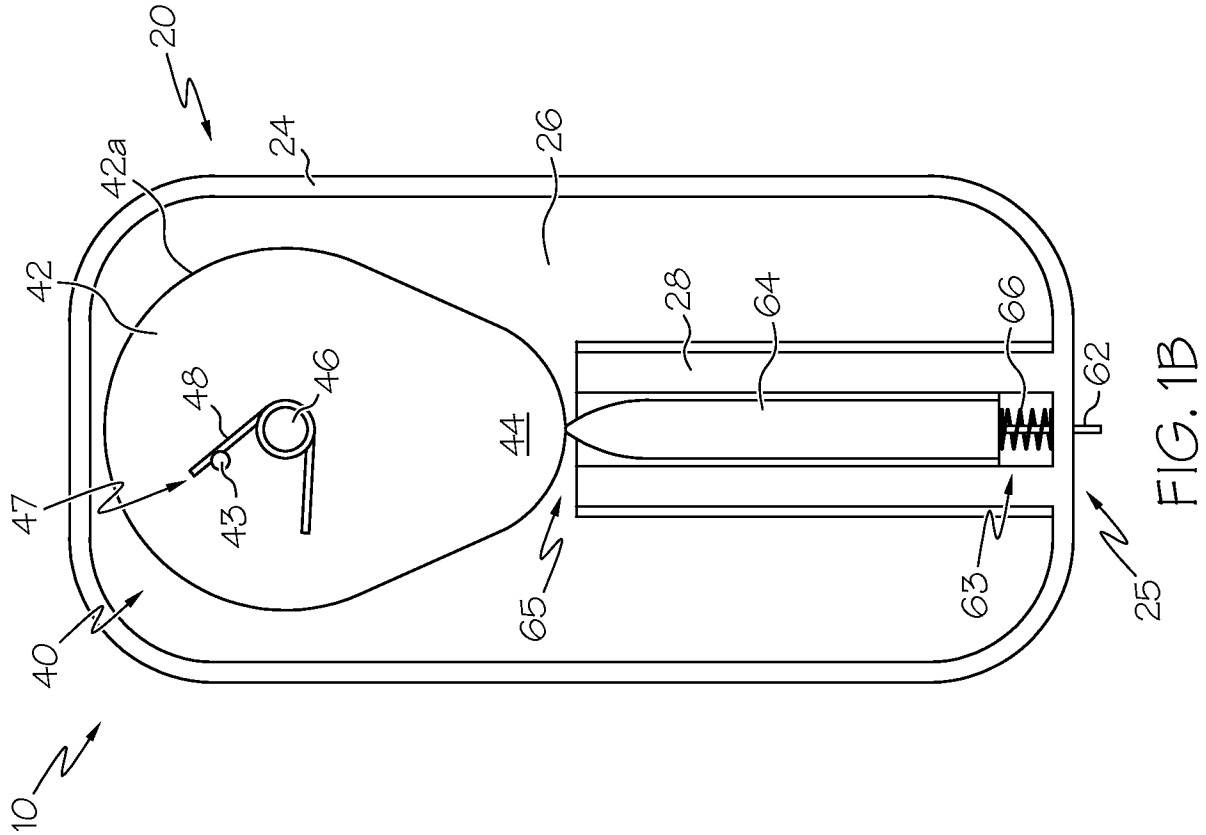
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FIG. 1B

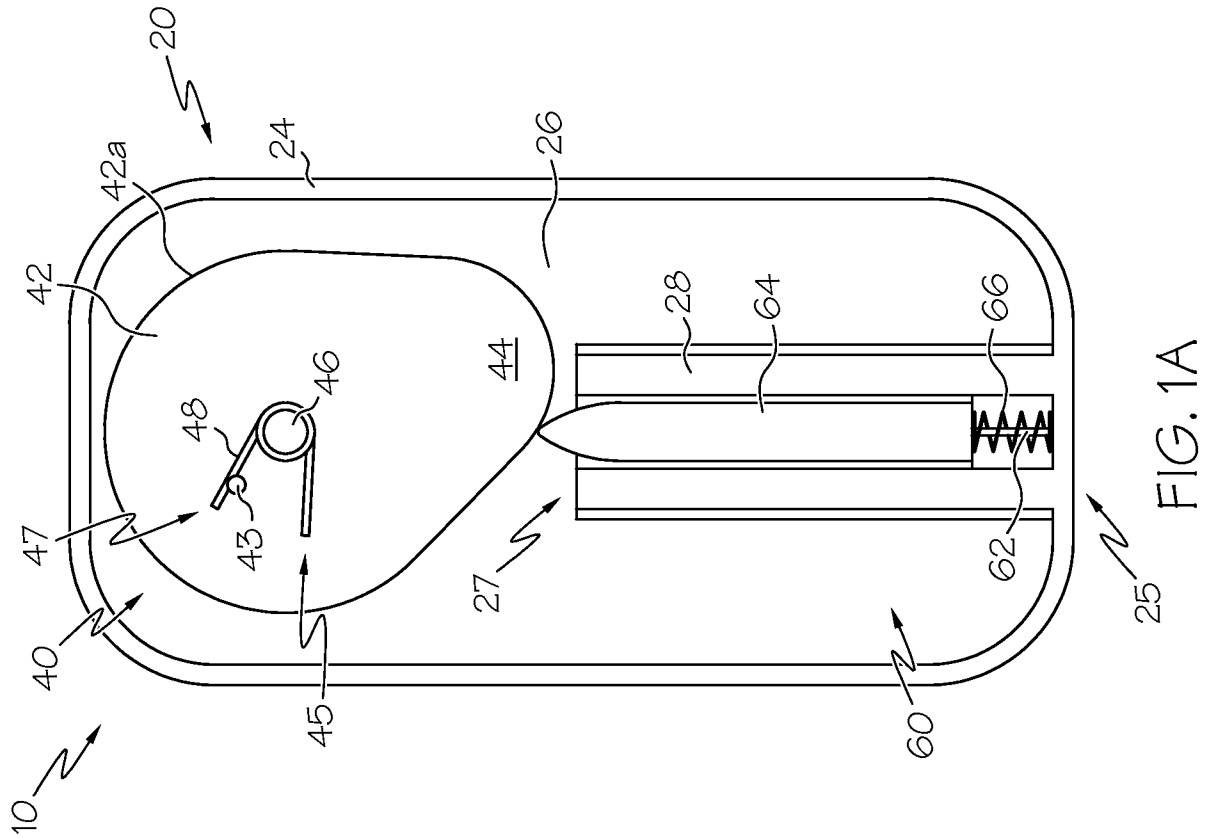
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FIG. 1A

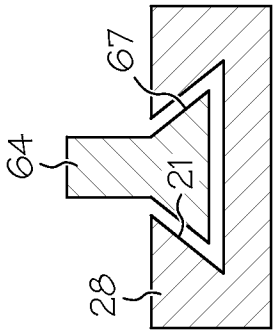


FIG. 1D

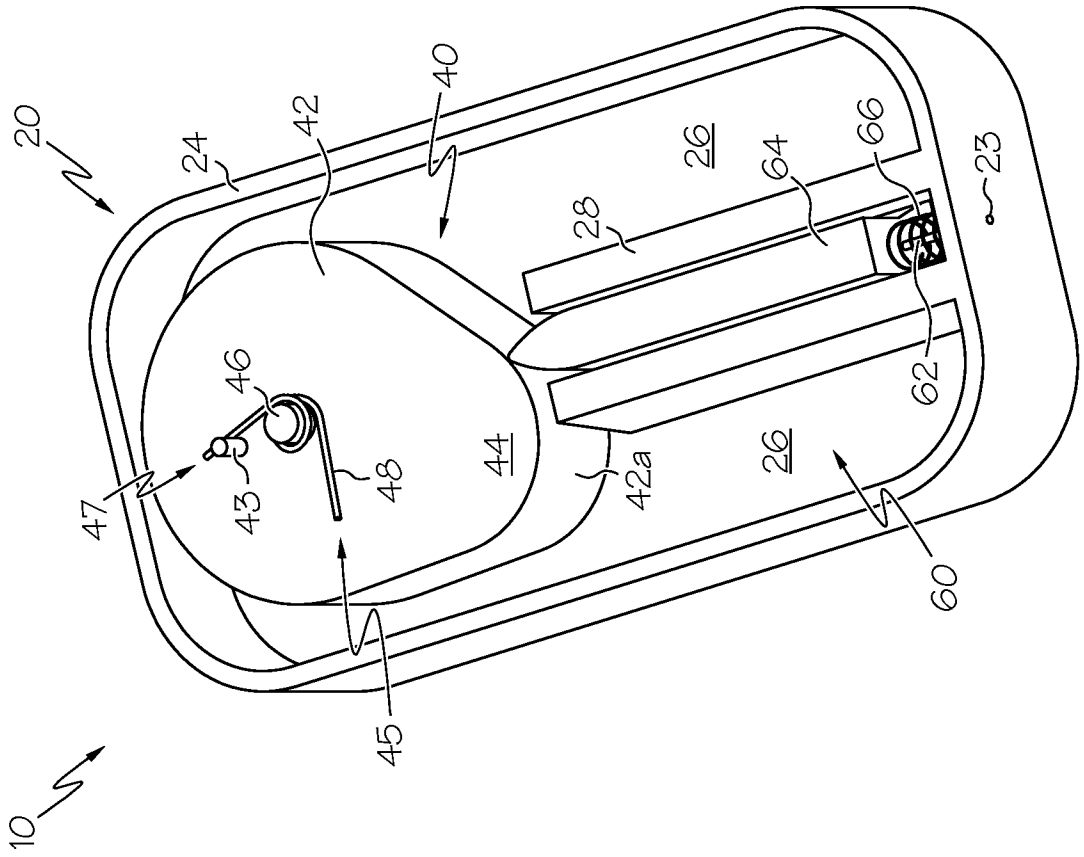


FIG. 1C

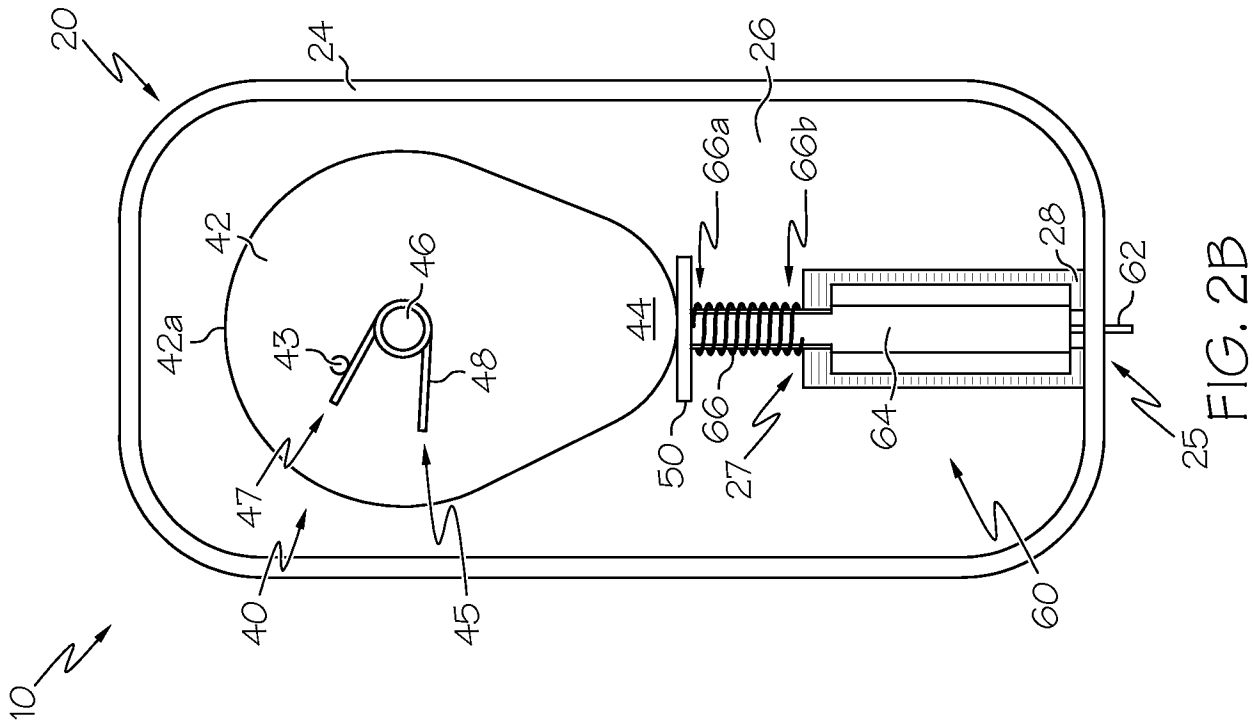
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FIG. 2B

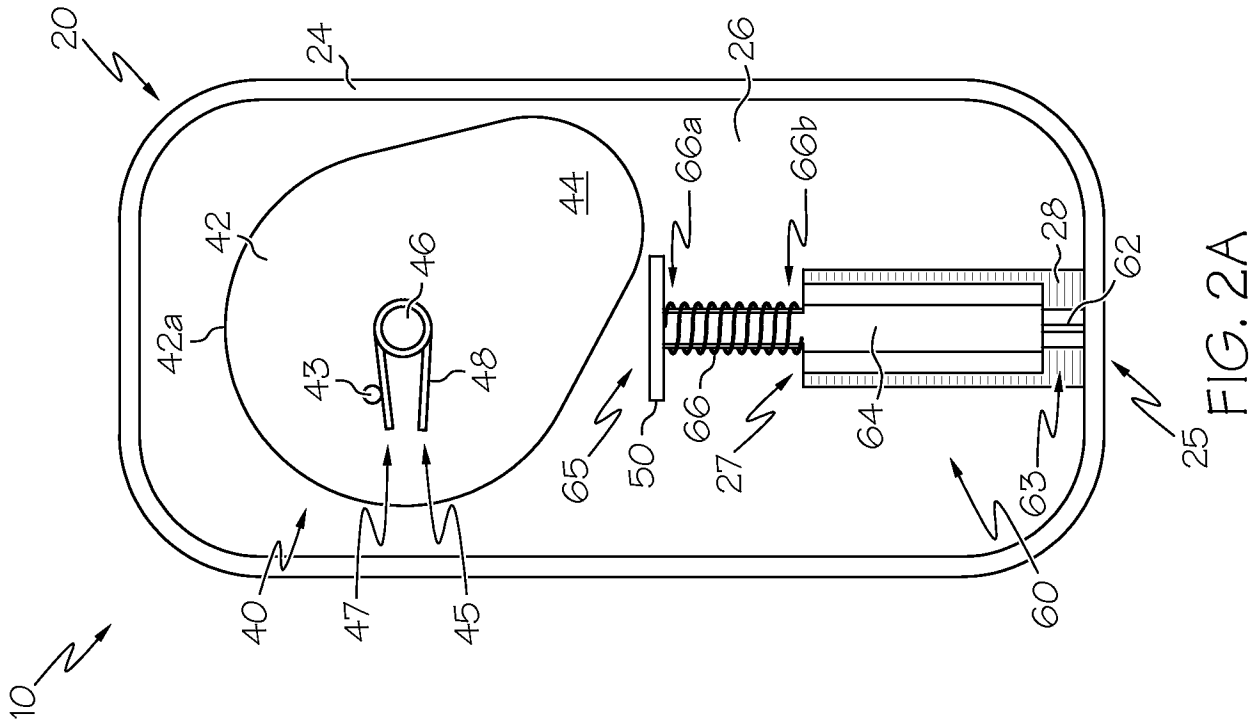
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FIG. 2A

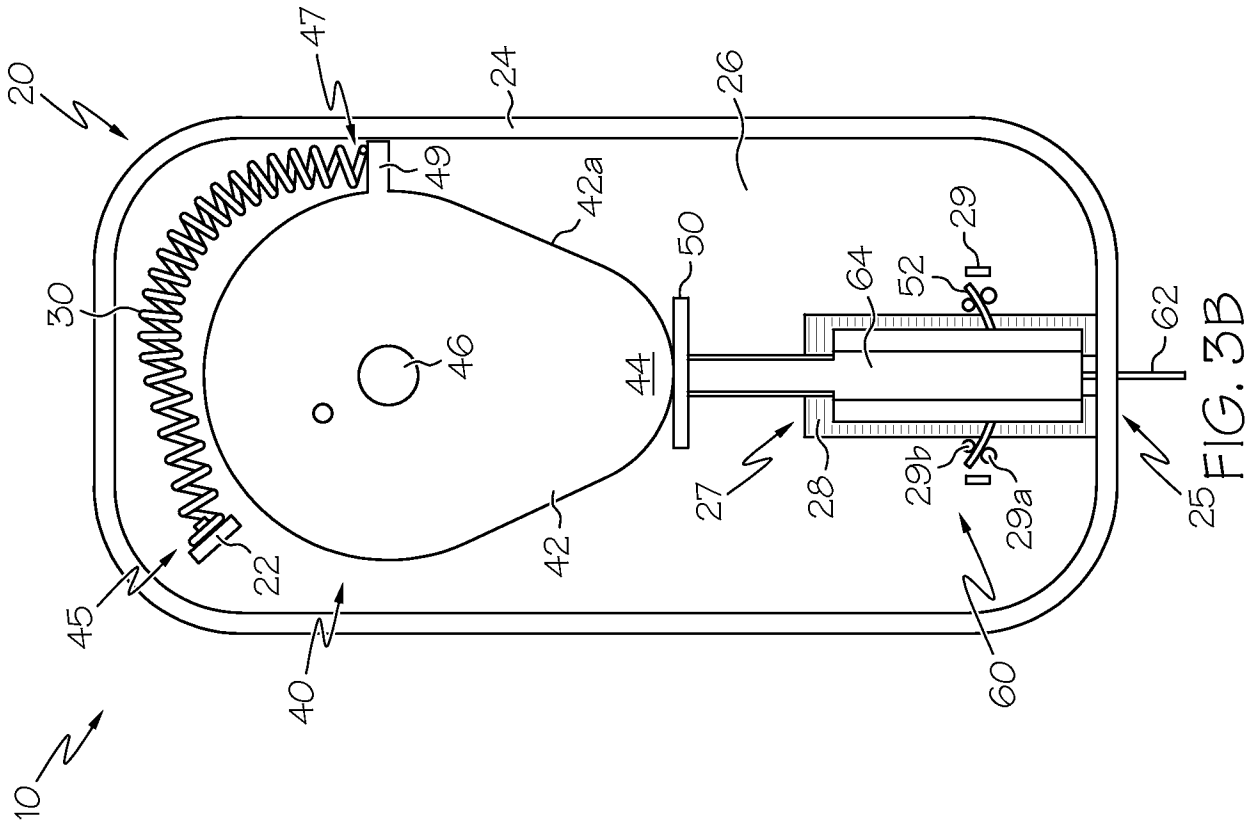
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FIG. 3B

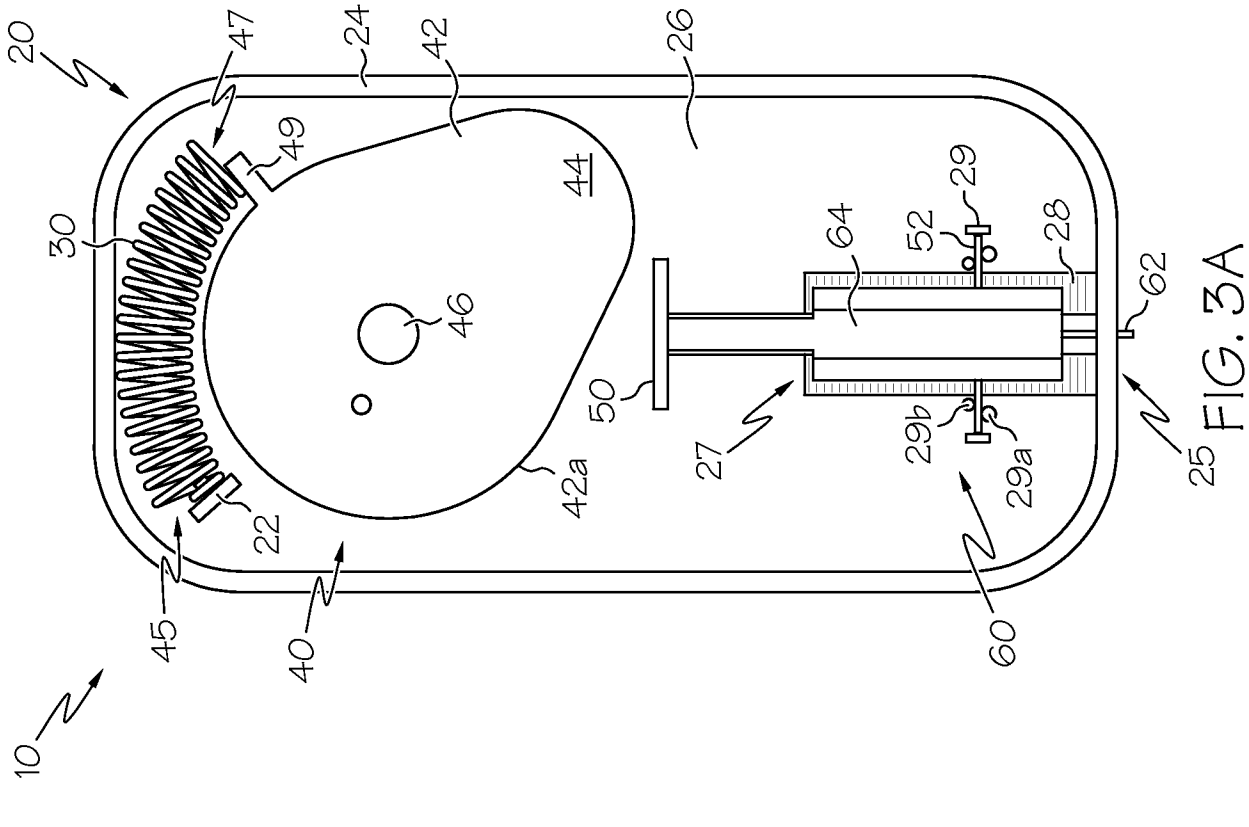
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FIG. 3A

# INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/063015

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/15 A61B5/151
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 | EP 1 090 584 A2 (ROCHE DIAGNOSTICS GMBH [DE]) 11 April 2001 (2001-04-11) | 1,2,6,7, 9,10,13, 14 |
| Y | figures | 8,15 |
| | --- | |
| Y | EP 2 218 392 A1 (ROCHE DIAGNOSTICS GMBH [DE]; HOFFMANN LA ROCHE [CH]) 18 August 2010 (2010-08-18) | 8,15 |
| A | paragraphs [0009], [0019] figure 4 | 1,9 |
| | --- | |
| X | WO 2006/058654 A2 (ROCHE DIAGNOSTICS GMBH [DE]; HOFFMANN LA ROCHE [CH]; WINHEIM SVEN [DE]) 8 June 2006 (2006-06-08) figures 6-7B | 1,6-9, 13-15 |
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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 18 December 2012 | 07/01/2013 |

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| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040,<br>Fax: (+31-70) 340-3016 | Schultz, Ottmar |

# INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/063015

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | WO 2008/107382 A1 (GERRESHEIMER WILDEN GMBH [DE]; WESSEL ROBERT [DE]) 12 September 2008 (2008-09-12) figures 1a-2c | 1,2, 6-10, 13-15 |
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