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(54) CAPSULE WITH BLOOD DETECTING SENSOR

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WO-A1-00/13003 WO-A2-2013/088444
US-A1- 2006 231 749 US-A1- 2014 296 666

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Description

[0001] The present invention relates to a capsule equipped with a sensor device being adapted to detect blood especially gastrointestinal bleedings.

Background of the invention

[0002] Acute upper gastrointestinal bleedings from ulcers or esophago-gastric varices are life threatening medical conditions which require immediate endoscopic therapy. Despite successful endoscopic hemostasis, there is a significant risk of rebleeding often requiring close surveillance of these patients in the intensive care unit. Any time delay to recognize bleeding may lead to a high blood loss and increases the risk of death.

Prior art

[0003] For example from the prior art document EP 2 057 934 A1 of the present inventor, the content of which is also made to the subject matter of the present invention, a telemetric real-time bleeding sensor is known which can help to indicate blood in the stomach. This known sensor is swallowed to detect active bleeding or is anchored endoscopically on/at the gastrointestinal wall close to the potential bleeding source/area. By telemetric communication with an extracorporeal receiver, information about the bleeding status is displayed.

[0004] In order to be able to safely detect the presence of blood the sensor being used in the above described capsule is adapted to measure characteristic optical properties of blood. More concrete, blood has the characteristic optical property of high absorption of violet light, while red light is comparatively well transmitted. This optical property of blood is used for the sensor.

[0005] At the minimum at about 415nm (violet), transmission is up to three orders of magnitude lower than transmission at a wavelength of about 720nm (red) depending on the optical density of the blood sample. According to these optical characteristics of blood, a quotient of the measured intensity of red light divided by the measured intensity of violet light is used as a single indicator value to predict the presence of blood. Thus the quotient increases with decreasing violet intensity indicating a higher concentration of blood.

[0006] The optical sensor according to the above-mentioned prior art document is a ratiometric intensity-based sensor. It is designed to be miniaturized for integration into a swallowable or implantable capsule. The aim is to compare the transmission of light at about 415nm to the transmission of light at about 700, preferably 720nm. For this purpose, the implant cast or housing provides at least one recess, through which light from two LED's of the respective wavelengths is transmitted sequentially. The recess is dimensioned to allow fluids to flow into the optical pathway of the sensor crossing the recess substantially orthogonal thereto into the width direction of the

recess. The remaining intensity of the light after its travel through the recess (in the width direction thereof) is measured by a photo transistor being arranged opposite to the LED's on the other side of the recess. This allows the swallowed/implanted capsule to calculate the ratio between the received violet and the red light. Since LED's are known to have relevant tolerances, due to manufacturing and temperature dependency, each individual sensor is/can be calibrated in post-processing to compensate for these effects.

[0007] Despite of the above technical properties of the well-known sensor device being used in capsules of this kind and the provision of the calibrating mode before taking the sensor device into use it turned out that the measuring results sometimes deviate from each other although the outer boundary conditions (presence of a pre-determined amount of blood in a test sample) has not been changed. Accordingly, such kind of deviations generally make the reliability of the sensor device and the capsule having such a sensor device inappropriate for its use in the intensive care unit.

[0008] WO 2013/088444 A2 describes an in-vivo diagnostic system for the detection of bleeding inside the GI tract of a patient comprising a device which has a housing having a gap which remains in contact with bodily fluids and through which the fluids pass when the device is within the GI tract, and a sensing head which has at least three LEDs on a first side of the gap and a light detector photodiode on the second side of the gap.

[0009] For the above reason, it is an objective object of the present invention to improve the accuracy of measurement for capsules equipped with a sensor device being adapted to detect blood to allow reproducibility of a plurality of measuring results for same (non-changed) boundary conditions.

[0010] The applicant has carried out a plurality of tests and investigations and realised that a part of the light (violet and/or red) emitted by the LED's on one side of the recess is not transmitted through the fluid within the recess to the light receiving sensor on the other side of the recess (direct light path between LED's and sensor) but is fed through the capsule casing bypassing the recess and the fluid collected within the recess. The amount/percentage of light being fed by/through the capsule casing does not depend on the absorption properties of the fluid within the recess but depends on the light feeding property (translucence) of the material of the capsule casing which is substantially constant and to the surface quality of the capsule casing facing the recess. Accordingly, in case the casing surface is covered by, for example, a plaque material generated by the fluid within the recess, the amount/percentage of light entering the capsule material might be reduced wherein in case the casing surface is not covered by, for example, a plaque material, the amount/percentage of light entering the capsule material might be increased.

[0011] In order to avoid such kind of noise the present invention is a medical capsule as defined by claim 1. The

capsule is equipped with a sensor device which is adapted to detect blood especially gastrointestinal bleeding, wherein the capsule/the casing of the capsule is provided with a shielding plate/layer/membrane being arranged at least at/near the bottom of the recess and extending along the width of the recess preferably to protrude/exceed the recess on its both sides into its width direction.

[0012] According to a second advantageous aspect of the present invention the size/dimension of the shielding plate/layer/membrane may be adjusted such that it fits between the light emitting (LED's) and the light receiving element (light sensor) in the width direction of the recess.

[0013] According to another advantageous aspect of the present invention the shielding plate/layer/membrane may be embedded and/or moulded within the casing material (preferably made of resin). Preferably, the shielding plate/layer/membrane represents the bottom of the recess, which means it is exposed to the free surroundings at the bottom of the recess to provide an interruption/block/wall for stopping/prohibiting the transmission of light from the light emitting member to the light receiving member through the material of the capsule casing. It shall be noted here, that "freely exposed" does not necessarily mean that the plate material having the shielding characteristic (for example copper or the like) is freely exposed. This would be only one option. Another option would be to cover the plate material having the shielding characteristic with a (very thin) layer or film made of biocompatible material, wherein the thickness of such a film is selected/adjusted such that its light-transmission-capabilities are negligible.

[0014] According to another advantageous aspect of the present invention the shielding plate/layer/membrane may be a member separate/different to a circuit board accommodated within the capsule wherein the light emitting and light receiving members may be mounted on that circuit board.

[0015] According to another advantageous aspect of the present invention the shielding plate/layer/membrane may be arranged in a parallel distance to a direct light path between the light emitting and light receiving members

[0016] According to another advantageous aspect of the present invention the shielding plate/layer/membrane may be mounted on the circuit board preferably on its outer surface being directed to the recess.

[0017] Further advantageous developments of the inventive capsule are subject matter of the sub claims.

[0018] In the following the present invention will be described on the basis of a preferred embodiment by reference of the enclosed figure.

[0019] The enclosed figure shows a front/rear part of a medical capsule for detecting the presence of blood by using a blood sensor/detecting device of well-known design and function.

[0020] According to the enclosed figure, the inventive capsule 1 equipped with a sensor device 2 being adapted to detect blood especially gastrointestinal bleedings

comprises a capsule casing 4 having a substantially cylindrical outer shape with rounded end portions and being made preferably of a resin material generally having light transmitting/light permeable properties. Within the capsule 1 at least one circuit board 6 is accommodated in a fluid-tight manner (moulded-in) at which a plurality of electronic facilities, representing the standard features of well-known medical capsules of this kind, are mounted like a data memory and/or data transmission member (memory chip, Blue Tooth, IR-transceiver), a calculator (CPU), light emitting and receiving members etc., being not shown in the figure. Furthermore, the capsule 1 contains an energy source, for example, a battery (not shown).

[0021] The casing 4 of the capsule 1 is provided with a gap or recess 8 being orientated substantially rectangular to the longitudinal axis A of the cylindrical capsule 1 such that its recess width extends in the longitudinal direction of the capsule. On one side 8a of the recess 8, when seen in the width direction thereof, a light emitting element/member 10 (for example, one or two LED's) is provided and oriented such that it admits light in violet and visual red range (at about 415nm and at about 720nm) through the recess 8 along the longitudinal direction of the capsule which light is detected by a light receiving element/member 12 (for example a light-sensitive sensor) which is located on the other side 8b of the recess 8, when seen in the width direction thereof opposite to the light emitting element/member 10. Accordingly, between the light emitting member 10 and light receiving member 12 a direct light transmission path P is generated having a predetermined / fixed path length and passing the recess 8 in its width direction.

[0022] At a bottom 8c of the recess 8, a shielding plate/layer/membrane 14 is provided within the capsule 1 having the property to block (substantially fully reflect or substantially fully absorb) at least the violet and red light being emitted by the light emitting element. More concrete, the shielding plate/layer/membrane is located within the capsule 1 in an area between the light emitting 10 and light receiving member 12 (just) below the recess 8. Preferably, the shielding plate/layer/membrane 14 represents/provides in a middle portion of it (at least partly) the bottom 8c of the recess 8 wherein in that portion the membrane 14 is freely exposed to the inner space (surroundings) of the recess 8. Finally, the shielding plate/layer/membrane 14 is orientated substantially parallel to the direct light transmission path P between the light emitting 10 and receiving members 12.

[0023] To achieve a parallel distance D between the shielding plate/layer/membrane 14 and the direct light transmission path/track P the light emitting 10 and light receiving members 12 are located on sockets 10a, 12a having a pre-selected height and being mounted on the circuit board 6. The parallel distance D is also pre-selected such that the direct light transmission path P (which corresponds to the measuring track) is located at about the middle height of the recess 8. Furthermore, it shall

be noted that, in the present preferred embodiment of the invention, the recess 8 does not have a rectangular shape in its cross section but substantially trapezoid such that the recess width continuously narrows in the direction to the recess bottom 8c.

[0024] As can be also seen from the enclosed figure, the shielding plate/layer/membrane 14 is a member being separate from the circuit board 6 but which may be mounted on the circuit board 8, for example by gluing. Preferably, it is embedded within the resin material of the capsule casing 4 wherein that portion of the shielding plate/layer/membrane 14 representing/providing the bottom 8c of the recess 8 is kept non-covered by the resin.

[0025] The function of the shielding plate/layer/membrane 14 can be described as follows:

The shielding plate/layer/membrane 14 extends beyond the recess 8 at its both sides in the width direction thereof. Furthermore, at least at one (middle) portion of the shielding plate/layer/membrane 14, it is freely exposed to the internal space/gap within the recess 8. Accordingly, in case the light emitting member (LED's) 10 starts emitting (violet and/or red) light into the recess 8, at least a part/amount of the emitted light will most probably also enter the capsule material having some light transmission characteristic. However, because of the provision of the shielding plate/layer/membrane 14 as described above, the already entered light will be blocked at least at that (middle) portion of the membrane 14 being freely exposed to the internal space of the recess 8 from further traveling within the casing material parallel to the direct light transmission path P. In addition, because the shielding plate/layer/membrane 14 is provided between the light emitting and receiving elements 10, 12, wherein it exceeds both sides 8a, 8b of the recess 8 in its width direction the already entered light is prohibited from bypassing/surrounding the shielding plate/layer/membrane 14 at its side being averted from the recess 8 (back-side with respect to the recess 8)

[0026] The shielding plate/layer/membrane 14 can be made, for example, of a metal or aluminium sheet extending parallel (or vertical) to the direct light transmission path/track P as defined above to provide an entering and/or travelling block/wall for light waves especially violet and red light.

[0027] To summarise the subject matter of the present invention a medical capsule is disclosed herewith being equipped with a sensor device 2 comprising light emitting and light receiving elements 10, 12. The sensor device 2 is adapted to detect blood especially gastrointestinal bleeding on the basis of light absorption properties of the blood, wherein the capsule 1 is provided with a casing 4 forming a recess or gap 8 at its outer surface. The recess 8 has a pre-selected width which represents a fixed measuring track between the light emitting and light receiving elements 10, 12 being arranged at opposing sides 8a, 8b of the recess or gap 8 when seen in its width direction. The medical capsule 1 is provided with a shielding plate/layer/membrane 14 being arranged at least at

or near the bottom 8c of the recess or gap 8 and extending along the width direction of the recess or gap 8 preferably to exceed the recess 8 at its both sides 8a, 8b into its width direction to prohibit emitted light from bypassing the recess 8 via the casing material of the capsule 1.

Claims

- 10 1. A medical capsule (1) being equipped with a sensor device (2) comprising light emitting and light receiving elements (10, 12), the sensor device (2) is adapted to detect blood especially gastrointestinal bleeding on the basis of light absorption properties of the blood, wherein the capsule (1) is provided with a casing (4) forming a recess or gap (8) at its outer surface having a recess width which represents a fixed measuring track between the light emitting and light receiving elements (10, 12) being arranged at opposing sides (8a, 8b) of the recess or gap (8) when seen in its width direction, wherein the recess or gap (8) comprises a recess bottom (8c), wherein the medical capsule (1) is provided with a shielding plate/layer/membrane (14) being arranged at least at or near the bottom (8c) of the recess or gap (8) and extending along the width direction of the recess or gap (8) to exceed the recess or gap (8) at its both sides (8a, 8b) into its width direction, wherein the shielding plate/layer/membrane (14) is embedded and/or moulded in the casing (4); **characterised in that** the shielding plate/layer/membrane (14) comprises at least one middle portion being freely exposed to the inner space of the recess (8) at the recess bottom (8c) to provide an interruption/block/wall for stopping/prohibiting the transmission of light from the light emitting member (10) to the light receiving member (12) through the material of the capsule casing (4).
- 25 2. A medical capsule (1) according to claim 1, wherein the size or dimension of the shielding plate/layer/membrane (14) is adjusted such that it fits between the light emitting and the light receiving elements (10, 12) along the width direction of the recess or gap (8).
- 30 3. A medical capsule (1) according to claim 1 or 2, wherein the casing (4) is made of resin.
- 35 4. A medical capsule according to any one of claims 1 to 3, wherein the shielding plate/layer/membrane (14) is a plate material or the plate material covered by a film of biocompatible material.
- 40 5. A medical capsule according to any one of claims 1 to 4, wherein the shielding plate/layer/membrane (14) is a member being separate from a circuit board

(6) accommodated within the capsule (1) or capsule casing (4) wherein the light emitting and light receiving members (10, 12) are mounted on that circuit board (6) preferably via sockets (10a, 12a), respectively.

6. A medical capsule according to any one of claims 1 to 5, wherein the shielding plate/layer/membrane (14) is arranged in a parallel distance (D) to a direct light path (P) between the light emitting and light receiving members (10, 12).
7. A medical capsule according to claim 5, wherein the shielding plate/layer/membrane (14) is mounted on the circuit board (6) preferably on that outer side of the circuit board (6) facing the recess (8).
8. A medical capsule according to any one of claims 1 to 6, wherein the shielding plate/layer/membrane (14) is made from metal or metal alloy, preferably copper.
9. A medical capsule according to any one of claims 1 to 8, wherein the recess or gap (8) has the bottom wall (8c) and the two opposing side walls (8a, 8b) which are orientated non-parallel to each other.
10. A medical capsule according to claim 9, wherein the recess or gap (8) has a trapezoid shape in a cross-sectional view.

Patentansprüche

1. Medizinische Kapsel (1), die mit einer Sensorvorrichtung (2) ausgestattet ist, die lichtemittierende und lichtempfangende Elemente (10, 12) umfasst, wobei die Sensorvorrichtung (2) so ausgebildet ist, dass sie Blut, insbesondere gastrointestinale Blutungen, auf der Grundlage der Lichtabsorptionseigenschaften des Blutes erfasst, wobei die Kapsel (1) mit einem Gehäuse (4) versehen ist, das an seiner Außenfläche eine Vertiefung oder Spalt (8) ausbildet und eine Vertiefungsbreite aufweist, die eine feste Messspur zwischen den lichtemittierenden und den lichtempfangenden Elementen (10, 12) darstellt, die in Breitenrichtung gesehen an gegenüberliegenden Seiten (8a, 8b) der Vertiefung oder des Spalts (8) angeordnet sind, wobei die Vertiefung oder der Spalt (8) einen Vertiefungsboden (8c) umfasst, wobei die medizinische Kapsel (1) mit einer Abschirmplatte/-schicht/-membran (14) versehen ist, die zumindest am oder in der Nähe des Bodens (8c) der Vertiefung oder des Spalts (8) angeordnet ist und sich entlang der Breitenrichtung der Vertiefung oder des Spalts (8) erstreckt, um über die Vertiefung oder den Spalt (8) an ihren/seinen beiden Seiten (8a, 8b) in ihrer/seiner Breitenrichtung herauszuragen, wobei die

Abschirmplatte/-schicht/-membran (14) in das Gehäuse (4) eingebettet und/oder eingegossen ist; **dadurch gekennzeichnet, dass**

- 5 die Abschirmplatte/-schicht/-membran (14) zumindest einen mittleren Abschnitt umfasst, der zum Innenraum der Vertiefung (8) am Vertiefungsboden (8c) freiliegt, um eine Unterbrechung/Block/Wand zum Stoppen/Verhindern der Lichtübertragung vom lichtemittierenden Element (10) zum lichtempfangenden Element (12) durch das Material des Kapselgehäuses (4) bereitzustellen.
- 10 2. Medizinische Kapsel (1) nach Anspruch 1, wobei die Größe oder Dimension der Abschirmplatte/-schicht/-membran (14) so eingestellt ist, dass sie zwischen die lichtemittierenden und den lichtempfangenden Elementen (10, 12) entlang der Breitenrichtung der Vertiefung oder des Spalts (8) passt.
- 15 3. Medizinische Kapsel (1) nach Anspruch 1 oder 2, wobei das Gehäuse (4) aus Harz hergestellt ist.
- 20 4. Medizinische Kapsel nach einem der Ansprüche 1 bis 3, wobei die Abschirmplatte/-schicht/-membran (14) ein Plattenmaterial oder das Plattenmaterial bedeckt mit einem Film aus biokompatiblen Material ist.
- 25 5. Medizinische Kapsel nach einem der Ansprüche 1 bis 4, wobei die Abschirmplatte/-schicht/-membran (14) ein Element ist, das von einer Leiterplatte (6) getrennt ist, die in der Kapsel (1) oder dem Kapselgehäuse (4) untergebracht ist, wobei die lichtemittierenden und lichtempfangenden Elemente (10, 12) auf dieser Leiterplatte (6) vorzugsweise über jeweilige Sockel (10a, 12a) montiert sind.
- 30 6. Medizinische Kapsel nach einem der Ansprüche 1 bis 5, wobei die Abschirmplatte/-schicht/-membran (14) in einem parallelen Abstand (D) zu einem direkten Lichtweg (P) zwischen dem lichtemittierenden und dem lichtempfangenden Element (10, 12) angeordnet ist.
- 35 7. Medizinische Kapsel nach Anspruch 5, wobei die Abschirmplatte/-schicht/-membran (14) auf der Leiterplatte (6), vorzugsweise auf der der Vertiefung (8) zugewandten Außenseite der Leiterplatte (6), montiert ist.
- 40 8. Medizinische Kapsel nach einem der Ansprüche 1 bis 6, wobei die Abschirmplatte/-schicht/-membran (14) aus Metall oder einer Metalllegierung, vorzugsweise Kupfer, hergestellt ist.
- 45 9. Medizinische Kapsel nach einem der Ansprüche 1 bis 8, wobei die Vertiefung oder der Spalt (8) die Bodenwand (8c) und die beiden gegenüberliegen-
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den Seitenwände (8a, 8b) aufweist, die nicht parallel zueinander ausgerichtet sind.

10. Medizinische Kapsel nach Anspruch 9, wobei die Vertiefung oder der Spalt (8) in einer Querschnittsansicht eine trapezförmige Form aufweist.

Revendications

1. Capsule médicale (1) qui est équipée d'un dispositif capteur (2) comprenant des éléments d'émission de lumière et de réception de lumière (10, 12), le dispositif capteur (2) est adapté pour détecter du sang en particulier une hémorragie gastrointestinale sur la base de propriétés d'absorption de la lumière du sang, dans lequel la capsule (1) est dotée d'un logement (4) formant un renforcement ou un vide (8) au niveau de sa surface externe ayant une largeur de renforcement qui représente une piste de mesure fixe entre les éléments d'émission de lumière et de réception de lumière (10, 12) qui est agencée au niveau de côtés opposés (8a, 8b) du renforcement ou du vide (8) lorsqu'on l'observe dans sa direction de la largeur, dans lequel le renforcement ou le vide (8) comprend un fond de renforcement (8c), dans lequel la capsule (1) médicale est dotée d'une plaque/couche/membrane de protection (14) qui est agencée au moins au niveau ou près du fond (8c) du renforcement ou du vide (8) et s'étendant le long de la direction de la largeur du renforcement ou du vide (8) pour dépasser le renforcement ou le vide (8) au niveau de ses deux côtés (8a, 8b) dans sa direction de la largeur, dans lequel la plaque/couche/membrane de protection (14) est incorporée et/ou moulée dans le logement (4) ; **caractérisée en ce que** la plaque/couche/membrane de protection (14) comprend au moins une partie centrale qui est exposée librement à l'espace interne du renforcement (8) au niveau du fond de renforcement (8c) pour fournir une interruption/bloc/paroi pour arrêter/empêcher la transmission de lumière à partir de l'élément émetteur de lumière (10) vers l'élément récepteur de lumière (12) à travers le matériau du logement de capsule (4).

2. Capsule médicale (1) selon la revendication 1, dans laquelle la taille ou la dimension de la plaque/couche/membrane de protection (14) est ajustée de telle sorte qu'elle s'adapte entre les éléments d'émission de lumière et de réception de lumière (10, 12) le long de la direction de la largeur du renforcement ou du vide (8).

3. Capsule médicale (1) selon la revendication 1 ou 2, dans laquelle le logement (4) est réalisé en résine.

4. Capsule médicale selon l'une quelconque des revendications 1 à 3, dans laquelle la plaque/couche/membrane de protection (14) est un matériau en plaque ou le matériau en plaque recouvert par une pellicule de matériau biocompatible.

5. Capsule médicale selon l'une quelconque des revendications 1 à 4, dans laquelle la plaque/couche/membrane de protection (14) est un élément qui est séparé d'une carte de circuit imprimé (6) logée au sein de la capsule (1) ou du logement de capsule (4), dans laquelle les éléments d'émission de lumière et de réception de lumière (10, 12) sont montés sur cette carte de circuit imprimé (6) de préférence via des connecteurs (10a, 12a), respectivement.

6. Capsule médicale selon l'une quelconque des revendications 1 à 5, dans laquelle la plaque/couche/membrane de protection (14) est agencée à une distance parallèle (D) par rapport à une trajectoire de lumière directe (P) entre les éléments d'émission de lumière et de réception de lumière (10, 12).

7. Capsule médicale selon la revendication 5, dans laquelle la plaque/couche/membrane de protection (14) est montée sur la carte de circuit imprimé (6) de préférence sur ce côté externe de la carte de circuit imprimé (6) qui fait face au renforcement (8).

8. Capsule médicale selon l'une quelconque des revendications 1 à 6, dans laquelle la plaque/couche/membrane de protection (14) est réalisée à partir de métal ou d'alliage de métal, de préférence de cuivre.

9. Capsule médicale selon l'une quelconque des revendications 1 à 8, dans laquelle le renforcement ou le vide (8) a la paroi de fond (8c) et les deux parois de côtés opposés (8a, 8b) qui sont orientées de manière non parallèle entre elles.

10. Capsule médicale selon la revendication 9, dans laquelle le renforcement ou le vide (8) a une forme trapézoïdale dans une vue en coupe transversale.

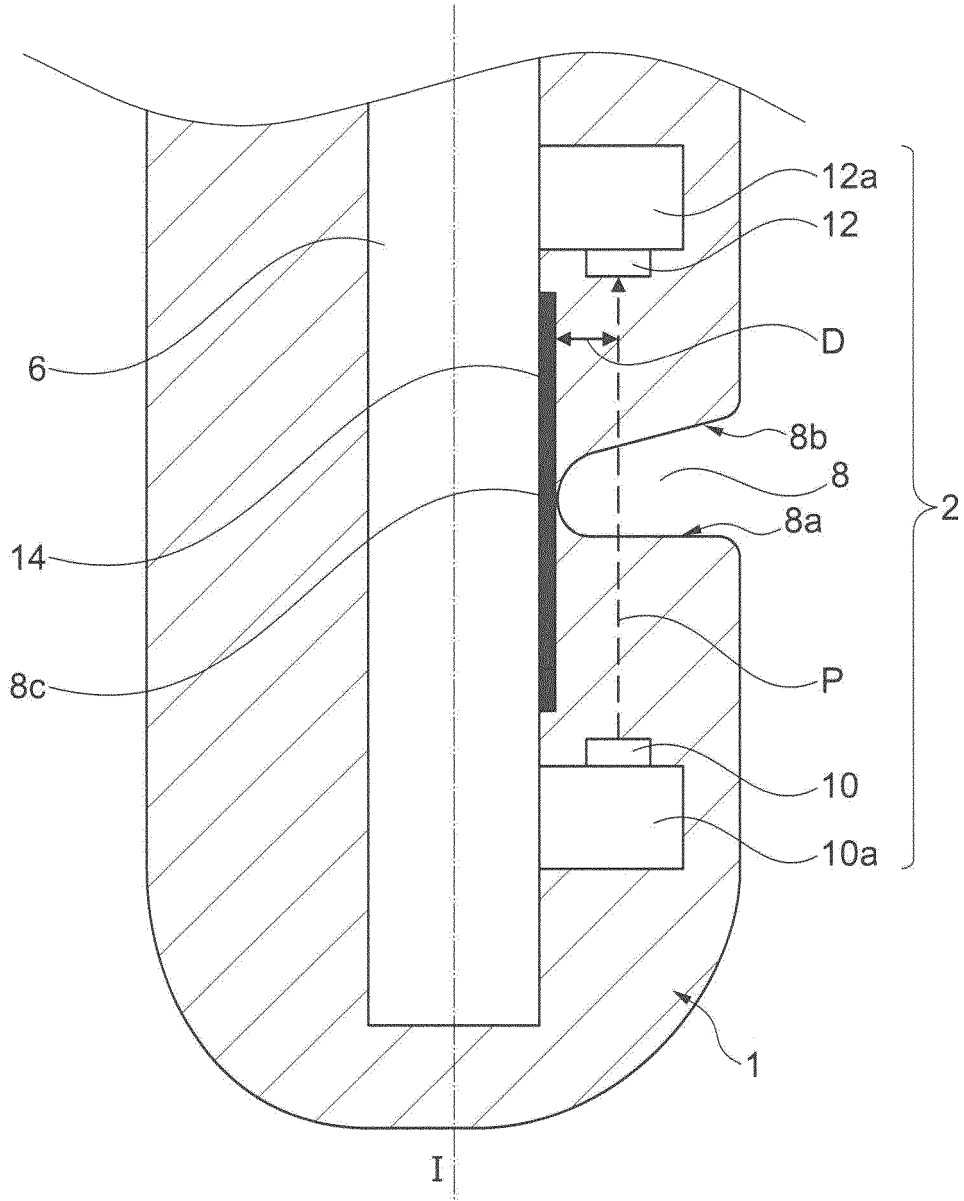


Fig. 1

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

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- WO 2013088444 A2 [0008]

专利名称(译)	带有血液检测传感器的胶囊		
公开(公告)号	EP3269298B1	公开(公告)日	2019-11-13
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当前申请(专利权)人(译)	OVESCO内镜AG		
[标]发明人	SCHURR MARC O SCHOSTEK SEBASTIAN		
发明人	SCHURR, MARC O. SCHOSTEK, SEBASTIAN		
IPC分类号	A61B5/00 A61B5/07 A61B1/04		
CPC分类号	A61B1/041 A61B5/0075 A61B5/02042 A61B5/073 A61B2562/0238 A61B2562/162 A61B2562/166		
其他公开文献	EP3269298A1		
外部链接	Espacenet		

摘要(译)

医用胶囊技术领域本发明涉及一种配备有包括发光元件和受光元件的传感器装置的医用胶囊。传感器装置适于基于血液的光吸收特性来检测血液，特别是胃肠道出血，其中，胶囊具有在其外表面形成凹部或间隙的壳体。凹部具有预先选择的宽度，当在其宽度方向上观察时，该宽度代表布置在凹部或间隙的相对侧处的发光元件和光接收元件之间的固定测量轨道。所述医疗胶囊具有至少在所述凹口或间隙的底部处或附近布置的屏蔽板/层/膜，并且沿所述凹口或间隙的宽度方向延伸，优选地在其两侧超过所述凹口的宽度方向，以防止发射的光通过胶囊的外壳材料绕过凹槽。

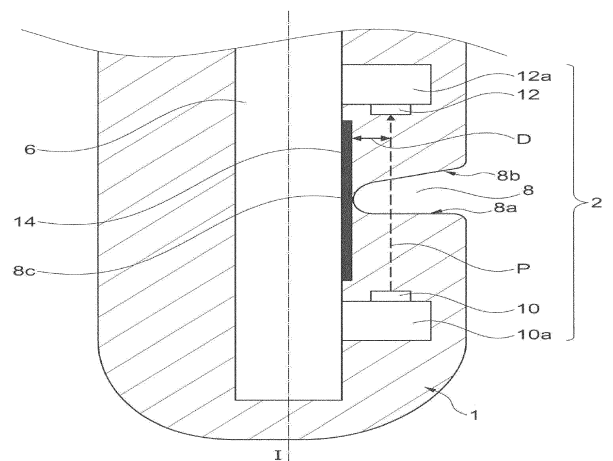


Fig. 1