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(54) **SYSTEM FOR DETERMINING THE BLOOD FLOW OF THE GASTROINTESTINAL TRACT**  
SYSTEM ZUR BESTIMMUNG DES BLUTFLUSSES IM MAGEN-DARM-TRAKT  
SYSTEME POUR DETERMINER L'ECOULEMENT SANGUIN DU TRACTUS GASTRO-INTESTINAL

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**US-A- 6 071 237      US-A1- 2004 127 800**  
**US-B1- 6 315 733**

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## Description

**[0001]** The present invention relates to a system allowing for measuring changes in volume of the blood present in the gastrointestinal tract, in which the measured changes in volume are a measure for the blood flow of the gastrointestinal tract and its course in time. In the medical world, measurements of volume changes in organs and/or body parts as a result of their blood flows are known under the term plethysmography.

**[0002]** Methods for determining the blood flow of the gastrointestinal tract are known per se, namely: indocyanine green clearing, stomach tonometry, videoscopy of the tongue blood flow and determination of the oxygen saturation of the large intestine. The most significant disadvantage of these methods is that they are either indirect methods in which the final result is only obtained after some time in the laboratory, or experimental methods, which have not yet been validated. Additionally, the reliability of these methods is not very high, certainly where it concerns determinations in or at body parts and/or organs of which the direct relation to the gastrointestinal tract is not convincing.

**[0003]** For example, US-A-2004 127 800 discloses a probe having a laser-Doppler blood flow sensor for placement in the gastrointestinal tract. The output of the sensor can be detected by a device which electronically converts the sensor output to provide the blood flow on a display.

**[0004]** US-B-6 315 733 discloses an inflatable tamponade balloon inserted into the esophagus and a sensor to monitor the portal blood pressure.

**[0005]** However, in severe situations, it is of great importance to be able to know immediately how the blood flow of the gastrointestinal tract is. Here, one can think of e.g. patients being in shock, by whatever cause. In case of a shock, there is a redistribution of the blood flow to the vital organs such as brains, heart and muscles, causing a reduced blood flow in other organs, including the gastro-intestinal tract. If such a situation lasts too long, this can cause a significant deterioration in the function of the gastrointestinal tract, which may lead to a further deterioration in the general physical condition of the patient. The described process can go very quickly and may result in death of the patient. The process can be influenced by medicaments, in which, however, it is of great importance that the effect (s) of said medicaments can be determined immediately.

**[0006]** Apart from said shock condition, in many other situations too it could be very important to be able to monitor the blood flow of the gastrointestinal tract in real time. Here, one can think of operating room and Intensive Care, where the blood flow of the gastrointestinal tract can be immediately compared to the heart performance (cardiac output) and the treating physician can act directly and adequately on the basis of those data.

**[0007]** In order to allow for realization of such immediate determination of the blood flow of the gastrointestinal tract, the invention provides for a system, comprising an

intestinal probe being provided with a supporting body at or near its distal end, with at least one pressure sensor mounted on said supporting body. The supporting body is an inflatable flexible body.

**[0008]** In most cases, the intestinal probe having the measuring member is positioned into the intestine through the oral cavity with a gastroduodenojejunoscope, which is in the standard equipment of a gastroenterologist. The supporting body with the pressure sensor mounted thereon will abut the intestinal wall, which will happen by inflating the inflatable flexible body. The inflatable flexible body has the advantage that it can be brought under exactly the desired pressure so that the pressure sensor will abut the intestinal wall without squeezing or otherwise affecting the blood flow of the intestinal wall at that location.

**[0009]** Said intestinal probe can be a probe which is intended substantially for inserting the measuring member. However, this probe can be designed for simultaneously serving as a nutritional probe. The opposite is also possible, namely, that the measuring member is mounted on a nutritional probe, such as a jejunum probe, as a result of which insertion of the nutritional probe simultaneously provides the possibility of monitoring the blood flow of the gastrointestinal tract. The latter is especially important in case of severely ill patients that must be artificially fed enterally and thus need not be additionally loaded unnecessarily.

**[0010]** Further, said measuring member can also be mounted on nutritional probes that are not inserted through the oral cavity, but are positioned in the small intestine directly through the abdominal wall.

**[0011]** Especially with a probe which is also used as a nutritional probe, it is important that when used with an inflatable flexible body, it will not be squeezed on tensioning of said inflatable flexible body. To that end, according to the invention it is provided for, that the inflatable flexible body engages the outer side of the intestinal probe and encloses it across part of its length. Further, it is provided for, that only the outer circumference of said inflatable body is at least partly flexible, to wit in such a way that no deformation is possible at the location where the inflatable body engages the probe.

**[0012]** It is important that the inflatable body, with the desired pressure, will only abut the intestinal wall where the pressure probe is mounted on the inflatable flexible body. To that end, it is provided for, that the inflatable flexible body, seen in longitudinal direction of the intestinal probe, has an approximately elliptical cross-section. Preferably, it is also provided for, that the inflatable flexible body has an approximately circular cross-section transverse to the longitudinal direction of the intestinal probe. With such a design, the inflatable flexible body is normally in peripheral contact with the inner side of the intestine. The inflatable flexible body mounts at least one pressure sensor. Thus, the blood flow is hindered in the least possible way by the measuring member abutting the intestinal wall, and the pressure sensor can provide

a reliable measurement of pressure differences in the blood flow of the gastrointestinal tract. It is possible to employ several pressure sensors, in which the individual signals can be used to check the reliability of the measurements, among other things.

**[0013]** The pressure applied in the flexible body must therefore not be higher than the average pressure in the discharging blood vessels or the pressure in the abdominal cavity. Usually, this means that the pressure in the inflatable flexible body will not be higher than about 5 cm H<sub>2</sub>O (3,68 mmHg).

**[0014]** According to another embodiment, it is provided for, that the inflatable flexible body has an approximately elliptical cross-section transverse to the longitudinal direction of the intestinal probe. In this embodiment, the inflatable flexible body normally has two opposite points of contact or tangent planes with the intestinal wall. At least one of these locations mounts a pressure sensor. Thus, the blood flow is hindered in the least possible way by the measuring member abutting the intestinal wall and the pressure sensor can provide a reliable measurement of pressure differences in the blood flow. It is possible to employ two opposite pressure sensors, in which the individual signals can be used for checking the reliability of the measurements.

**[0015]** According to a further development, the inflatable flexible body also serves for establishing and/of measuring the intestinal peristalsis. By measuring pressure variations in the inflatable flexible body, one can establish immediately whether or not the peristalsis of the intestine is functioning and, if this is the case, what its force and frequency are. Besides the blood flow of the gastrointestinal tract, this is a further important parameter for intestine functioning.

**[0016]** Further, the system of the invention comprises a device intended for cooperation with the intestinal probe, the device being provided with means for registration of the pressure measured in real time by the pressure sensor and means for reproducing it graphically or otherwise, as well as means for calculating the blood flow of the gastrointestinal tract from the pressure registered in real time have been provided. This can occur by taking the surface below the curve of the course of the pressure in real time as a measure for the blood flow of the gastrointestinal tract.

**[0017]** Preferably, further means are provided for comparing the calculated blood flow of the gastrointestinal tract to a predetermined value and/or to a value that can be determined elsewhere in the body through measuring blood pressure. This latter value can be a value calculated directly from a blood pressure measured directly in the heart or one of the major blood vessels.

**[0018]** The device according to the invention is further provided with means for bringing the inflatable flexible body at a predetermined pressure. The required instrument, such as an air pump, for example, can be part of the device; however it is also possible to provide means by which an external instrument can be operated. The

device according to the invention further comprises means for real time registration of the pressure in the inflatable flexible body and means for reproducing it graphically or otherwise.

**[0019]** The intestine peristaltis can be carefully monitored through the pressure variations in the inflatable flexible body. Here, signalling means can further be provided for signalling exceeding of threshold values in frequency and pressure.

**[0020]** The intestine peristaltis also provides for a change in the pressure measured with the pressure sensor. However, the frequency of the peristaltis and the frequency of the pressure signal measured with the pressure sensor are so different from one another, that the changes in the measurements of the pressure sensor caused by the peristaltis can be simply filtered out by software. The means for doing this are also part of the device.

**[0021]** The invention is further explained by way of the example given in the drawing, in which:

fig. 1 illustrates schematically a probe with the measuring member and the device to which the measuring member is connected;

fig. 2 illustrates a cross-section on an enlarged scale, of the measuring member and the probe;

fig. 3 illustrates a cross-section on an enlarged scale, of the probe; and

fig. 4 illustrates two curves of a blood pressure measured directly and a pressure measured using a plethysmograph.

**[0022]** Fig. 1 shows schematically an illustration of an intestinal probe 1 to which an inflatable flexible body 2 is mounted at or near its distal end. An air line 3, intended for inflating the inflatable flexible body, extends from said inflatable flexible body past the intestinal probe to a device 4. The air line 3 is coupled to an air pump not further indicated in the drawing, which can be an air pump incorporated in the device 4 or an external air pump being driven from the device 4. At the same time, the air line 3 and the inflatable flexible body 2 are used together for registration of any occurrence of pressure changes in the inflatable flexible body 2 as a consequence of the intestine peristaltis or the lack of it.

**[0023]** A pressure sensor 5 is mounted on the inflatable body 2 and is connected to the device 4 through a connection 6. Preferably, the pressure sensor 5 is an electronic sensor that produces an electric signal corresponding to the pressure or the pressure changes. The flexible inflatable body 2 is elliptical in longitudinal direction and has a circular cross-section in the direction transverse to it (see also fig. 2), so that the pressure sensor 5 will abut the intestinal wall with certainty when the measuring member is inserted in the intestine. Further, the inflatable flexible body 2 is formed in such a way, that it is not deformable at the location of engagement with the intestinal probe 1 or the fixed connection with it, so that the

intestinal probe 1 can not be squeezed. Therefore, the intestinal probe 1 can at the same time continue being used as nutritional probe.

**[0024]** Fig. 3 shows the cross-section of the intestinal probe 1 having the air line 3 of said inflatable flexible body 2 and the connection 6 of said pressure sensor 5 mounted on it. Air line 3 and connection 6 can be fixedly connected to the intestinal probe 1 by e.g. glueing or otherwise adhering it, or by mounting intestinal probe 1, air line 3 and connection 6 within a tight-fitting and sealing outer enclosure.

**[0025]** Fig. 4 shows an example of a graphical image that can be obtained on device 4, of e.g. a blood pressure 7 measured through a tube in an artery and a pressure 8 measured with a plethysmograph, which could be e.g. a pressure sensor 5 located against the intestinal wall. The surface below the measured pressure curve represents a measure for the blood flow, which is indicated by shading 9 for the curve 8. Shading 9 extends across the entire illustrated curve 8 in the drawing, but this measure for the blood flow can be taken in any desired time interval. Depending on the measuring method and the location where the measurement is carried out, it may be necessary to apply a correction factor for being able to calculate the actual blood flow from the measured progress of pressure. Such a correction factor can be applied to the measurement data by software.

#### Claims

1. A system for determining the blood flow of the gastrointestinal tract, comprising an intestinal probe (1) having an inflatable flexible body (2) disposed at its distal end, at least one pressure sensor (5) disposed on the inflatable flexible body and configured to generate a pressure signal, and a device (4) intended for cooperation with the intestinal probe (1), the device comprising a means (4) for registering the pressure in real time measured with the pressure sensor (5) and a means for graphically or otherwise reproducing it, wherein the device comprises a means (4) for calculating the blood flow of the gastrointestinal tract from the pressure signal.
2. The system according to claim 1, **characterized in that** only the outer circumference of said inflatable body (2) is at least partly flexible, said pressure sensor (5) being mounted on said outer circumference.
3. The system according to claim 1 or 2, **characterized in that** said device (4) processes the pressure signal to generate a signal corresponding to intestinal peristalsis.
4. The system according to claim 3, **characterized in that** the device comprises a means (4) for bringing the inflatable flexible body (2) at a predetermined

pressure.

5. The system according to claim 1, **characterized in that** the device comprises a means (4) for comparing the calculated blood flow of the gastrointestinal tract with a predetermined value and/or with a value determined elsewhere in the body by measurement of blood pressure.
6. The system according to any of claims 1 to 5, wherein the device filters the pressure signal to derive a signal corresponding to intestinal peristalsis within the gastrointestinal tract at the location of the electronic sensor.
7. The system according to any of claims 1 to 6, wherein said inflatable flexible body has an elliptical cross-sectional configuration.
8. The system according to any of claims 1 to 7, wherein the intestinal probe is configured for positioning within the gastrointestinal tract through an oval cavity.
9. The system according to any of claims 1 to 8, wherein the intestinal probe is configured to serve as a nutritional probe.

#### Patentansprüche

1. System zur Bestimmung des Blutstroms des Gastrointestinaltraktes, umfassend eine Darmsonde (1) mit einem aufblasbaren flexiblen Körper (2), der an ihrem distalen Ende angeordnet ist, wenigstens einem Drucksensor (5), der auf dem aufblasbaren flexiblen Körper angeordnet ist und konfiguriert ist, um ein Drucksignal zu erzeugen, und einer Vorrichtung (4), die zum Zusammenwirken mit der Darmsonde (1) bestimmt ist, wobei die Vorrichtung ein Mittel (4) zum Registrieren des mit dem Drucksensor (5) gemessenen Drucks in Echtzeit und ein Mittel zu dessen grafischer oder anderweitiger Wiedergabe umfasst, wobei die Vorrichtung ein Mittel (4) für die Berechnung des Blutstroms des Gastrointestinaltraktes von dem Drucksignal umfasst.
2. System gemäß Anspruch 1, **dadurch gekennzeichnet, dass** nur der äußere Umfang des genannten aufblasbaren Körpers (2) wenigstens teilweise flexibel ist, wobei der genannte Drucksensor (5) auf dem genannten äußeren Umfang montiert ist.
3. System gemäß Anspruch 1 oder 2, **dadurch gekennzeichnet, dass** die genannte Vorrichtung (4) das Drucksignal verarbeitet, um ein Signal zu erzeugen, das der Darmperistaltik entspricht.
4. System gemäß Anspruch 3, **dadurch gekennzeichnet,**

**net, dass** die Vorrichtung ein Mittel (4) umfasst, um den aufblasbaren flexiblen Körper (2) mit einem bestimmten Druck zu beaufschlagen.

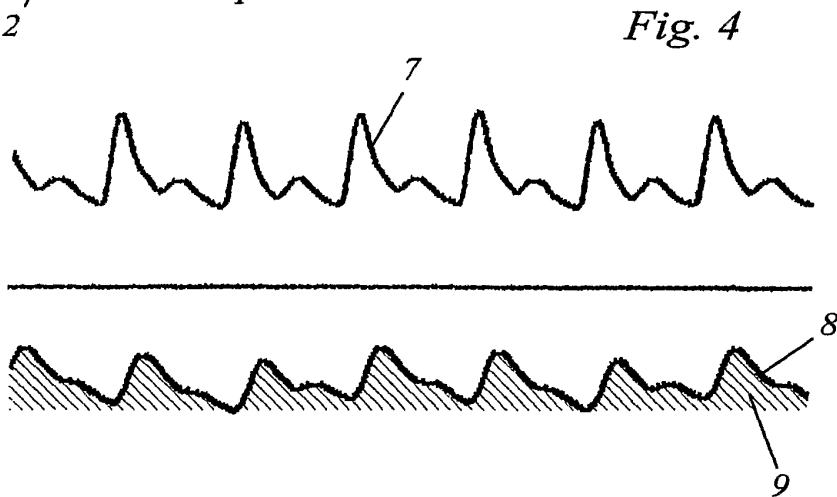
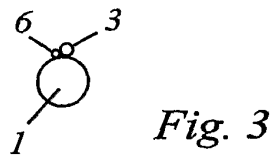
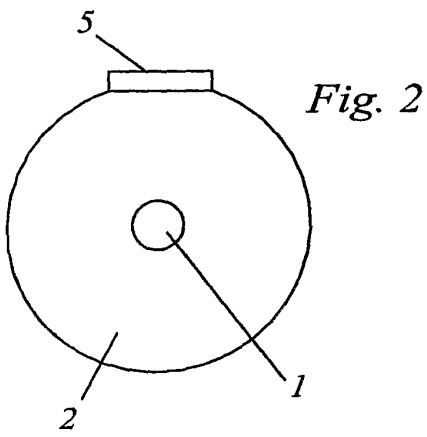
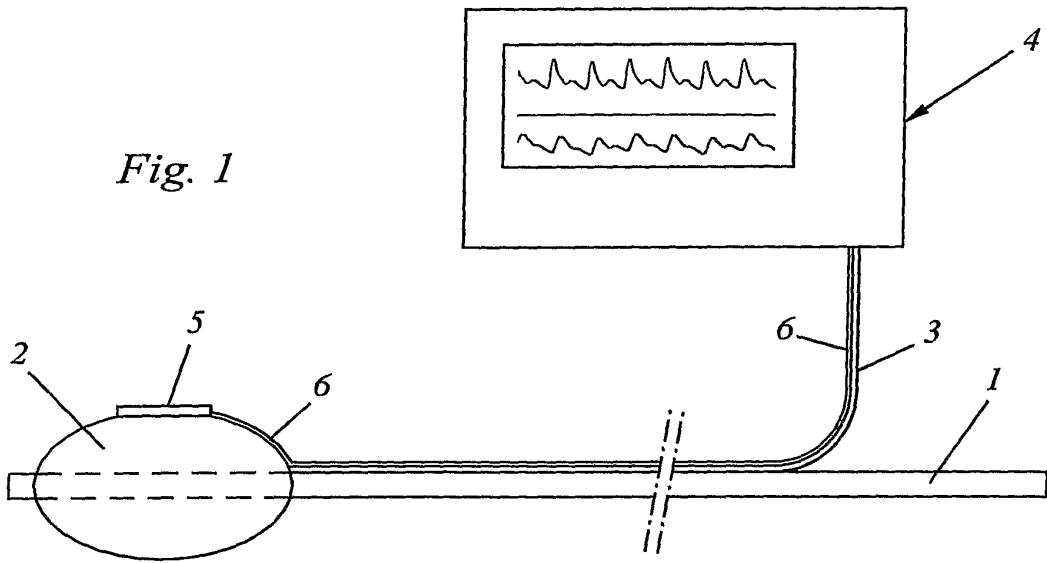
5. System gemäß Anspruch 1, **dadurch gekennzeichnet, dass** die Vorrichtung ein Mittel (4) zum Vergleichen des berechneten Blutstroms des Gastrointestinaltrakts mit einem vorbestimmten Wert und / oder mit einem auf andere Weise bestimmten Wert in dem Körper durch Messung des Blutdrucks umfasst.
6. System gemäß Anspruch 1 bis 5, wobei die Vorrichtung das Drucksignal filtert, um ein Signal abzuleiten, das der Darmperistaltik innerhalb des Gastrointestinaltraktes an der Stelle des elektronischen Sensors entspricht.
7. System gemäß Anspruch 1 bis 6, wobei der genannte aufblasbare flexible Körper eine elliptische Querschnittskonfiguration hat.
8. System gemäß Anspruch 1 bis 7, wobei die Darmsonde zur Positionierung innerhalb des Gastrointestinaltrakts durch eine ovale Aushöhlung konfiguriert ist.
9. System gemäß Anspruch 1 bis 8, wobei die Darmsonde konfiguriert ist, um als Ernährungs- sonde zu dienen.

#### Revendications

1. Système destiné à déterminer le flux sanguin du tractus gastro-intestinal, comprenant une sonde intestinale (1) possédant un corps flexible gonflable (2) disposé à son extrémité distale, au moins un capteur de pression (5) disposé sur le corps flexible gonflable et configuré pour générer un signal de pression, et un dispositif (4) destiné à coopérer avec la sonde intestinale (1), le dispositif comprenant un moyen (4) destiné à enregistrer la pression en temps réel mesurée à l'aide du capteur de pression (5), et un moyen destiné à la reproduire graphiquement ou d'une autre manière, dans lequel le dispositif comprend un moyen (4) destiné à calculer le flux sanguin du tractus gastro-intestinal à partir du signal de pression.
2. Système selon la revendication 1, **caractérisé en ce que** seule la circonférence extérieure dudit corps gonflable (2) est au moins partiellement flexible, ledit capteur de pression (5) étant monté sur ladite circonférence extérieure.
3. Système selon la revendication 1 ou 2, **caractérisé en ce que** ledit dispositif (4) traite le signal de pression afin de générer un signal correspondant à un

péristaltisme intestinal.

4. Système selon la revendication 3, **caractérisé en ce que** le dispositif comprend un moyen (4) destiné à amener le corps flexible gonflable (2) à une pression prédéterminée.
5. Système selon la revendication 1, **caractérisé en ce que** le dispositif comprend un moyen (4) destiné à comparer le flux sanguin calculé du tractus gastro-intestinal à une valeur prédéterminée et/ou à une valeur déterminée ailleurs dans le corps par mesure de la pression artérielle.
6. Système selon l'une quelconque des revendications 1 à 5, dans lequel le dispositif filtre le signal de pression afin de dériver un signal correspondant un péristaltisme intestinal dans le tractus gastro-intestinal à l'endroit du capteur électronique.
7. Système selon l'une quelconque des revendications 1 à 6, dans lequel ledit corps flexible gonflable présente une configuration à coupe transversale elliptique.
8. Système selon l'une quelconque des revendications 1 à 7, dans lequel la sonde intestinale est configurée pour se positionner dans le tractus gastro-intestinal par une cavité ovale.
9. Système selon l'une quelconque des revendications 1 à 8, dans lequel la sonde intestinale est configurée pour servir de sonde d'alimentation.



**REFERENCES CITED IN THE DESCRIPTION**

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**Patent documents cited in the description**

- US 2004127800 A [0003]
- US 6315733 B [0004]

专利名称(译)	用于确定胃肠道血流的系统		
公开(公告)号	<a href="#">EP1865837B1</a>	公开(公告)日	2015-10-21
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发明人	BEUTE, JAN		
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外部链接	<a href="#">Espacenet</a>		

摘要(译)

本发明涉及一种测量构件和一种用于确定胃肠道血流的装置，所述测量构件包括肠探针，其远端设有柔性可充气体，并且至少一个压力传感器安装在其上。支持身体。在将可充气柔性体带到预定压力之后，压力传感器将邻接肠壁，并且测量的压力发展（其代表胃肠道血流的量度）在设备的帮助下被转换成图形图像。和/或转化为胃肠道血流的实际值。此外，测量构件测量可膨胀柔性体内的压力的发展，其代表肠蠕动的量度。

