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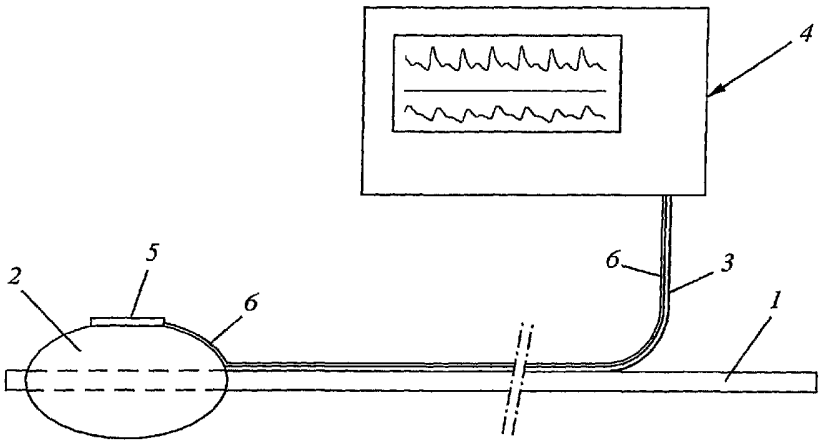
(54) **Title:** MEASURING MEMBER AND DEVICE FOR DETERMINING THE BLOOD FLOW OF THE GASTROINTESTINAL TRACT, AS WELL AS FOR REGISTRATING THE INTESTINAL PERISTALSIS



(57) **Abstract:** The invention relates to a measuring member and a device to be used for determining the blood flow of the gastrointestinal tract, said measuring member comprising an intestinal probe, having its distal end provided with a flexible inflatable body and at least one pressure sensor mounted on this supporting body. After bringing the inflatable flexible body at the predetermined pressure, the pressure sensor will abut the intestinal wall and the measured pressure development, which represents a measure for the blood flow of the gastrointestinal tract, is transformed into a graphical image with the help of the device and/or is transformed into actual values for the blood flow of the gastrointestinal tract. Further, the measuring member measures the development of the pressure within the inflatable flexible body, which represents a measure for the intestinal peristalsis.

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Measuring member and device for determining the blood flow of the gastrointestinal tract, as well as for registrating the intestinal peristalsis

The present invention relates to a measuring member 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.

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.

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 gastrointestinal 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.

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.

In order to allow for realization of such immediate determination of the blood flow of the gastrointestinal tract, the invention provides for a measuring member, 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. According to a further development, it is preferably provided for, that the supporting body is an inflatable flexible body.

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 in case of an inflatable flexible body will happen by inflating it. 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.

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 jejenum 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.

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 abdomenal wall.

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.

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.

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 abdomenal cavity. Usually, this means that the pressure in the inflatable flexible body will not be higher than about 5 cm H_2O.

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.

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.

Further, the invention provides for a device intended for cooperation with the measuring member, the device being provided with means for registration of the pressure measu-

red in real time by the pressure sensor and means for reproducing it graphically or otherwise. According to a further development, means for calculating the blood flow of the gastrointestinal tract from the presssure 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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

C L A I M S

1. Measuring member to be used for determining the blood flow of the gastrointestinal tract, said measuring member comprising an intestinal probe, at or near its distal end being provided with a supporting body and at least one pressure sensor being mounted on the supporting body.

2. Measuring member according to claim 1, characterized in that the supporting body is an inflatable flexible body.

3. Measuring member according to claim 2, characterized in that the inflatable flexible body engages the outer side of the intestinal probe and encloses it across a part of its length.

4. Measuring member according to claim 3, characterized in that only the outer circumference of the inflatable body is at least partly flexible.

5. Measuring member according to claim 1, characterized in that the inflatable flexible body, seen in longitudinal direction of the intestinal probe, has an approximately elliptical cross-section.

6. Measuring member according to claim 5, characterized in that the inflatable flexible body, has an approximately circular or elliptical cross-section when seen transverse to the longitudinal direction of the intestinal probe.

7. Measuring member according to claims 2-5, characterized in that the pressure sensor(s) is/are mounted on a position or on positions located at the greatest distance from the intestinal probe in case of an inflated flexible body.

8. Measuring member according to claims 2-7, characterized in that connection(s) for the pressure sensor(s) and an air line for the inflatable flexible body are provided along the outer side of the intestinal probe and are fixedly connected to it.

9. Measuring member according to claims 1-8, characterized in that at least one pressure sensor is an electronic pressure sensor.

10. Device intended for cooperation with a measuring member according to claims 1-9, characterized in that it comprises means for registrating the pressure in time measured with the pressure sensor and means for graphically or otherwise reproducing it.

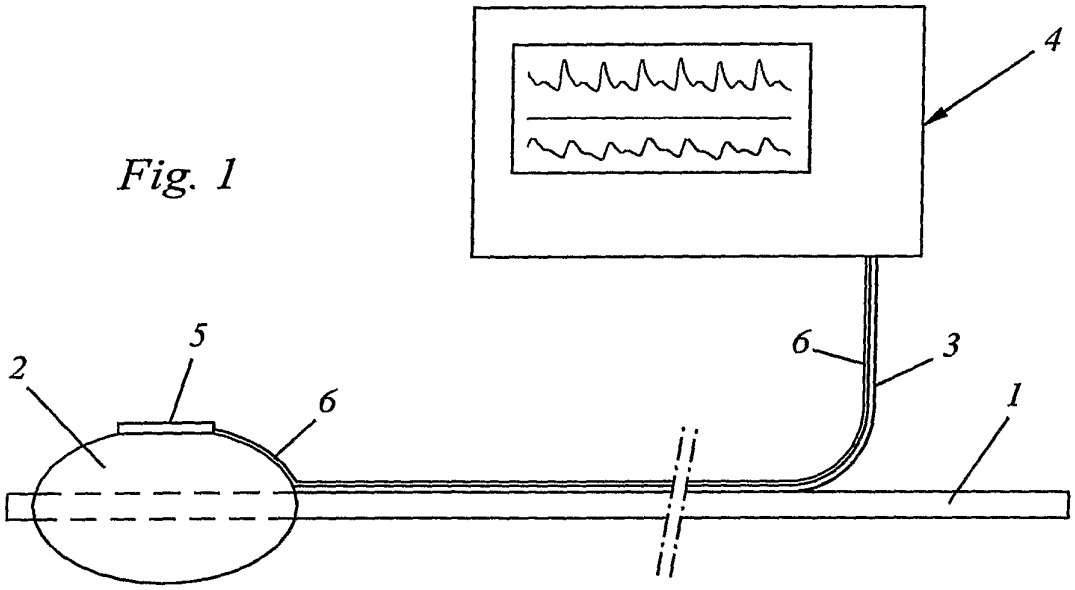
11. Device according to claim 10, characterized in that it comprises means for registrating the pressure in the inflatable flexible body in time and means for graphically or otherwise reproducing it.

12. Device according to claim 11, characterized in that it is provided with means for bringing the inflatable flexible body at a predetermined pressure.

13. Device according to claims 10-12, characterized in that means for calculating the blood flow of the gastrointestinal tract from the pressure registrated in time are provided.

14. Device according to claim 13, characterized in that further means are provided for comparing the calculated blood flow of the gastrointestinal tract to a predetermined value and/or to a value determined elsewhere in the body by measurement of blood pressure.

Fig. 1



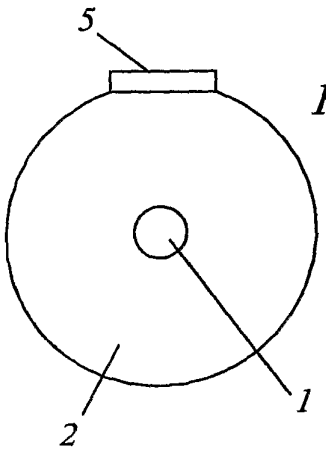


Fig. 2

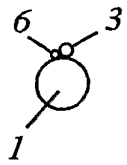
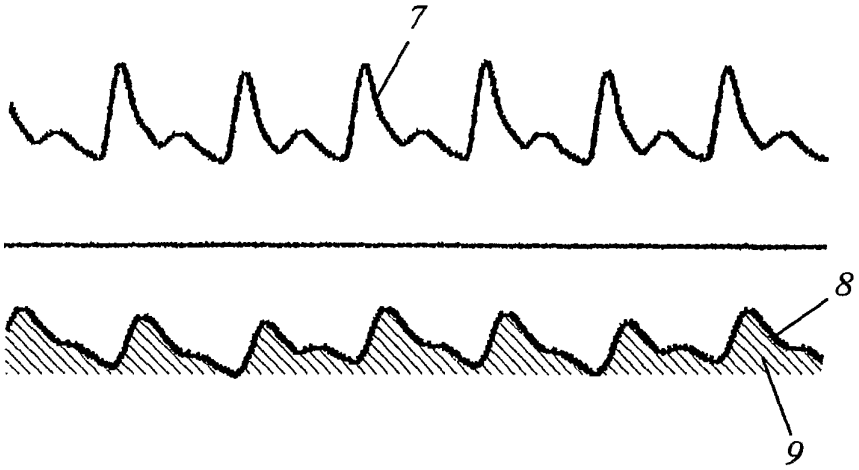


Fig. 3

Fig. 4



INTERNATIONAL SEARCH REPORT

International application No
PCT/NL2006/000065

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/0285 A61M25/10

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 A61M

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, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 315 733 B1 (ZIMMON DAVID S) 13 November 2001 (2001-11-13) column 2, line 56 - column 3, line 14 column 5, lines 26,27; figure 6	1-14
X	US 6 071 237 A (WEIL ET AL) 6 June 2000 (2000-06-06) column 2, line 66 - column 3, line 41 column 4, line 55 - column 6, line 14	1
X	US 2004/127800 A1 (KIMBALL VICTOR E ET AL) 1 July 2004 (2004-07-01) paragraphs [0007], [0069]	1

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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INTERNATIONAL SEARCH REPORT

Information on patent family members

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