(51) International Patent Classification:
A61B 1/05 (2006.01) A61B 5/07 (2006.01)

(21) International Application Number:
PCT/IB20 11/05 1323

(22) International Filing Date:
29 March 2011 (29.03.2011)

(25) Filing Language:
Italian

(26) Publication Language:
English

(30) Priority Data:
FI2010A000055 29 March 2010 (29.03.2010)

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Published:
— with international search report (Art. 21(3))

(54) Title: ENDOSCOPI CAL CAPSULE, SYSTEM AND METHOD

(57) Abstract: The present invention relates to the field of endoscopic devices and more precisely it refers to an endoscopic capsule, in particular but not exclusively a video-capsule with diagnostic and/or therapeutic aims, adapted to move in the gastrointestinal lumen subject to an external control system, and namely to move forward and back in the colon or other natural or iatrogenic, real or virtual body cavities. Moreover the invention regards an endoscopic system including the capsule and a method of use of the system.

Fig. 1
— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))
ENDOSCOPIC CAPSULE, SYSTEM AND METHOD

Description

Technical field of the invention

The present invention relates to the field of endoscopic devices and more precisely it refers to an endoscopic capsule, in particular but not exclusively a video-capsule with diagnostic and/or therapeutic aims, adapted to move in the gastrointestinal lumen subject to an external control system, and namely to move forward and back in the colon or other natural or iatrogenic, real or virtual body cavities. Moreover the invention regards an endoscopic system including the capsule and a method of use of the system.

Background of the invention

Optical flexible colonoscopy is considered the gold standard diagnostic method to evaluate colon pathologies. However, traditional colonoscopy, consisting in introducing a tube-type endoscope through anal verge, is an invasive exam that can be painful, and perceived with embarrass and discomfort, so that a lot of patients are reluctant to be examined.

Thus, alternative diagnostic procedures have been developed. In these procedures use is made of a capsule provided with a micro camera (video-capsule), adapted to be swallowed by the patient, to image the walls of the intestinal lumen as passing through it, and to transmit the acquired images to an external recorder via a wireless system.

In a first and less advanced solution, the progression of the video-capsule in the gastrointestinal lumen is passive, that is the capsule is moved by physiologic peristalsis. In these cases the exam is normally conducted outside the hospital. In fact, the captured images are recorded by a storage device worn by the patient, who in the meantime can attend to normal daily activities. Data acquisition requires a certain number of hours, and the capsule is expelled with faeces after a physiological time, if no complications arise. Then, the physician or staff in the medical laboratory make us of suitable appliances for downloading and evaluating the images from the portable unit, once the same has been handed back, along with the capsule.
This method not only has several logistic and time-span drawbacks, but also results unsatisfactory due to the passive motion feature. This kind of progression can bring about a sufficiently accurate evaluation for bowel where lumen diameter is small (small intestine). On the contrary, in the colon, where lumen diameter is bigger, the capsule can freely rotate in all directions so that images collection become random. Consequently, the accuracy and completeness of the resulting diagnostic picture fall down, right where relevant and more serious pathologic lesions are much more frequent. Furthermore, because of the larger diameter of the lumen, the capsule is not able to focus the micro-camera over the whole wall surface; the capsule can even fall from one colon segment to another without accurately examining the section in between. Furthermore, a not completely accurate preliminary cleaning of the colon lumen can remarkably affect the imaging (this being a major drawback, considering that the cleaning is often hasty not to cause too much pain and discomfort to the patient). Moreover, sometimes the battery of the capsule does not work long enough for the capsule to reach the colon.

In more advanced solutions, it was then envisaged to provide the medical operator with the possibility of actively controlling the movement of the capsule, stopping and placing it in the points of higher clinical interest to get a more accurate mucosal inspection. In this way, several advantages are achieved: better diagnostic reliability, wider clinical use, shorter examination time and consequent smaller size of the battery supplying energy to the camera and to the data transmission system, and lower risks for the patient.

Two main approaches have been followed for orientation and movement control of the endoscopic video capsule: external drive system (movement induced by external devices) and internal ones (drive devices onboard the capsule).

Disregarding, as far as the present description is concerned, internal drive systems, the capsules with external drive usually employ magnetic fields as a propulsion means. Numerous examples of these kind of wireless video-capsules have been proposed, driven by external magnetic forces that react with forces generated by permanent magnets onboard the capsule. Generally speaking, an external apparatus comprising multiple magnets is operated directly or indirectly by medical staff in order
to drive and guide the capsule and capture images, whereby the same capsule, provided with magnets having suitable arrangements is displaced depending on the interaction with the external magnetic field.

This type of endoscopic capsules offer the advantage of having inside the capsule only a little bulk determined by the permanent magnet or inductive coils. On the other hand, the external apparatus is very sizeable and expensive, and for this reason the exam can be carried out only in specialized centres provided with the necessary facilities. Moreover, the motion can be hindered in blocked sections, or where the tissue is collapsed.

Background art also comprises, as disclosed in International patent publication n. WO2008062997, a capsule with a double body including an external shell and an inner body freely rotating within the shell unit. The inner body supports camera means and, in an embodiment, a counterweight at the opposite side with respect to the camera so that as the capsule rests over a plan under the effect of gravity, the camera tends to face upwards. The counterweight can be a magnet, so that the capsule can be driven inside the human body under the action of an external magnetic field. However, the orientation of the camera means cannot be controlled, and the external magnetic field generators consist of a very bulky, fixed apparatus that is made to surround the patient.

**Summary of the invention**

The main object of the present invention is to provide an endoscopic capsule with a new configuration which allows for carrying out the medical examination by means of an external system which is simply structured, inexpensive, of reduced bulk and usable in normal outpatient settings.

Another object of the present invention is to provide a capsule of the above mentioned kind, of which the control is made more accurate, enabling a more precise orientation of the image capturing means and obtaining a better view field in comparison to traditional capsule endoscopes.

Still another object of the present invention is to provide a capsule of the above mentioned type, adapted to be moved expeditely and without affecting the image capturing even in case of obstructions or portion along which the tissue is collapsed.
A further object of the present invention is to provide a capsule of the above mentioned type which is adapted to be constructed in a very small size.

These and other objects are achieved with the magnetic drive and control endoscopic capsule according to the invention, the essential characteristics of which are defined by the first of the attached claims. Other aspects of the invention provide for an endoscopic system and a relative method of use, the essential characteristics of which are respectively mentioned in attached claims 16 and 20.

**Brief description of the drawings**

The characteristics and advantages of the magnetic drive and control endoscopic capsule according to the invention will become apparent from the following description of embodiments thereof, made as an example and not limitative, with reference to the annexed drawings in which:

- figure 1 is a schematic view in a diametric section of a capsule according to the invention;
- figures from 2a to 2e schematically represent how a capsule according to the invention works in different phases of an endoscopic examination procedure, in some of them there being also shown, for the sake of comparison, the behaviour of a traditional capsule in the same conditions;
- figures 3a, 3b and 3c represent other phases of examination using the system comprising an external handpiece and the capsule according to the invention;
- figure 4 shows a transversal section of an example of the external handpiece
- figure 5 represents a schematic view of the capsule in an alternative embodiment.

**Detailed description of the invention**

With reference to the above mentioned figures, and in particular for the time being to figure 1, a capsule according to the invention comprises an outer capsule body 1, preferentially with spherical or spheroid shape, made of a dataflow transparent material, at least as far as a part or the body surface is concerned, and preferably in its entirety. Dataflow typically, but not exclusively, include imaging data. Accordingly, in the depicted example, the mentioned transparency is to be intended as a transparency to light radiation.
Inside body 1 there is rotatably arranged an inner body 2, which, thanks to a
distribution of supports 3 in contact with the inner surface 1a of the outer body 1 is
adapted to be freely oriented at 360° in every direction with respect to the same outer
body, around the centre thereof. Accordingly, the two bodies are in practice mutually
movable in the fashion of the elements of a spherical joint. The supports 3 can have for
example and preferably the arrangement of the balls of a rolling-element bearing,
suitably constrained by a cage, not represented in the figure. The cage can however
consist of the same structure of the inner body. In any case, the two bodies constitute,
as made clearer hereafter, a rolling or friction bearing system.

The inner body 2 houses and supports all the capsule main components, and in
particular data capturing means, typically image capturing means such as a
microcamera 4 oriented in such a way as to face the outside, through the external body
1, with its lens. The inner body 2 also houses means responsive to an external
magnetic field, schematically represented in the example by a permanent magnet 5
placed at a substantially antipodal part with respect to the microcamera 4. Moreover,
even if not represented in the figure, there are arranged a battery power source, and
data transmitting-receiving means for transferring the captured images and receiving
operation control inputs to/from the outside.

According to the invention the weight distribution on the inner body 2 is such that
the centre of mass, represented in the figure by the point B, is in an off-centred position
with respect to the centre O of the inner body 1, and in particular displaced towards the
magnet 5. Thus, in the absence of external forces, that is as a result of the gravity field
only, magnet 5 tends to drop down and accordingly the microcamera 4 is made to
move and face upside. Microcamera 4 is preferably oriented or orientable so that an
axis Y of its own vision field, having an angular aperture normally equal to about 150°,
meets with axis X defined by the centre of mass B and by the common centre O of the
two bodies 1, 2, forming an acute angle α of preferably at least 30°, even more
preferably of about 45°, said acute angle being open on the opposite hemisphere with
respect to the hemisphere with the centre of mass.

In order to assist the above mentioned arrangement of the centre of mass, the
magnet 5 can have a flattened shape with crescent section extending over the
periphery of the inner body 2. According to a further option, it is preferred that the capsule is provided with lock means for preventing the mutual rotation of the bodies, for example comprising a radially moving small piston 6 supported by a guide 7 so that it projects out of the inner body 2, through an opening 2a shut by an elastic membrane 8 which isolates the inside of the same body 2. The piston 6 is adapted to project to such an extent to contact, with the interposition of membrane 8, the inner surface of the outer body 1, so that the two bodies, thanks to static friction, become integral and rotate together. Clearly, the outer body 1 can also be provided with a seating adapted to receive the piston at its maximally displaced projection, so as to make the engagement even safer and steadier. The piston is driven by an actuator controlled form the outside, not shown, or, through centrifugal effect, as described in greater detail further on.

In use, referring now to figures from 2a to 2e, a capsule according to the invention is made to move in a colon lumen C, schematized by an intestinal wall Ca, near the anterior abdominal wall Aa, and an intestinal wall Cp again schematically represented near the posterior abdominal wall Ap. Anterior abdominal wall Aa is the patient abdomen on which the physician entrusted with the conduct of the examination applies to this purpose a handpiece M with means adapted to generate a magnetic field to which the magnet in the capsule is responsive. Still according to the above mentioned schematic representation, there is also illustrated a pathologic lesion P inside the lumen. Lumen typical shape is characterized by the characteristic cavities and protrusions called pouches or haustra. Inside the haustra the dark coloured regions represents faecal residues normally present in the colon even after an adequate preliminary cleaning procedure.

In the absence of an external magnetic field (figure 2a), while patient is laying supine, and still according to the figure schematization, capsule lays resting on the posterior intestinal wall Cp and, thanks to the off-centred weight distribution in the inner body 2, microcamera is turned upside allowing a wide view involving in particular, but not only, the anterior intestinal wall Ca. When capsule movement is driven by gravity or intestinal peristalsis, this occurs with the outer body 1 rolling, while the inner body 2 remains stable in its orientation, thanks to the off-centred centre of mass and the
rotating support, with the microcamera proficiently faced towards the lumen. Figure 2d actually illustrates capsule a capsule progression step thanks to gravity force, assisted by making the patient take on an appropriately lifted position to let the lumen become inclined in the desired direction, while in figure 2e the capsule is illustrated after reaching a position near the pathologic lesion P, with the patient again in a supine horizontal position.

Figure 2b and 2c show instead the capsule functional behaviour in presence of an external magnetic field generated by the handpiece M. The capsule is drawn until it contacts the anterior intestinal wall Ca, the magnet 5 being attracted towards the handpiece causing inner body 2 to rotate and consequently the microcamera 4 face also in this case opposite and away the wall with which the capsule is in contact; therefore, the camera provides a wide view involving the lumen and now in particular, but not exclusively, the posterior intestinal wall Cp.

By displacing the handpiece over patient abdomen (figure 2c) the capsule is thus made to progress, still with outer body 1 rolling, while the orientation of the inner body 2 and the microcamera view field are kept stable towards the posterior intestinal wall Cp, the lumen and, in the distance, the anterior intestinal wall Ca with possible pathologic lesions P on it. A rotational movement of the handpiece M (figure 2b) can instead cause the inner body, and the microcamera along with it, to rotate around its own axis. If the inner and the outer capsule bodies are mutually locked thanks to the specific system, also outer body rotates accordingly. The rotation occurs over a plane substantially parallel with the abdominal wall, i.e. so as to make the camera turn sideways in the lumen, besides to forwards and backward in the advancement direction. These kind of movements can be achieved also and more preferably with the assistance of a rotation/pulse of the magnetic field, generated by one or more magnets/electromagnets suitably controlled as will be further illustrated hereafter.

It is to be also noted in the figures from 2a to 2d that with a traditionally shaped capsule T, not spherical and moving only thanks to peristalsis and gravity, not only the position can not be controlled, but also, in similar conditions, a much worse view field can be obtained, limited to a single area of a single wall. Moreover, the progression of a traditional capsule can be hindered or prevented by the irregular lumen shape, and
the capsule is easily dirtied, with consequent problems of obtaining clear images, by faeces residues in which it may become immersed to a variable extent. The control of the capsule according to the invention is in practice of a manual type, and therefore extremely easy and direct.

As far as capsule cleaning is concerned, according with the invention, it can be advantageously achieved through the induction of inner body rotation, preceded by the actuation of the locking/anchoring means of the inner body to the outer body. Cleaning is obtained by detaching the residues from the outer surface of the capsule thanks to the centrifugal force generated by a rotation of the magnetic force field, carried out via electronic systems, or manually (see again the example in figure 2b). A pulsated magnetic field can also have the effect of inducing capsule vibration, strongly enough to determine a cleaning by shaking.

The locking means, as mentioned, can be activated either through an electro-mechanic switch wirelessly controlled from the outside, or through the same centrifugal force. This force indeed can push out the piston 6, normally in a retracted position with the provision of elastic return means, until it contacts with the outer body inner surface, as centrifugal force overwhelms the elastic return forces. As the piston is urged against the outer body, the friction grows and locks together the two bodies resulting in the integral rotation of the whole capsule. The locking system can make use also of different constructions, for example it can comprise a lubricant fluid between the inner and outer body, having the property of enhancing its viscosity until preventing mutual rotation of the same bodies, as a result of the interaction with the external magnetic field.

More than one locking piston can be arranged. For example, two pistons can be made to engage with corresponding seats (similar to the above mentioned membrane opening or having a different nature, even of prominent structure), possibly distributed over the whole inner surface of the outer body. The two pistons can for instance be arranged so as to define between each other an angle of about 60°, allowing for various imaging shot angles to be obtained, and reducing the obstruction to the visual field of the videocamera 4. In order to assist the insertion of the pistons in the corresponding seatings, the latter can be made of, or comprise parts of, a
ferromagnetic material. The exact position for piston insertion can be for example determined through a search rotation (leaving pistons pushed out until they become settled into position once in correspondence with the seatings), or targeting a reference mark in the view field of the camera 4.

The handpiece M can then comprise one or more magnets/electromagnets adapted to generate a force vector field to which the magnet of the capsule is responsive. More generally, as mentioned, a plurality of electromagnets can be employed to create a complex system of magnetic forces, still with the aim of adjusting/controlling the movement of the capsule in the most appropriate manner.

Specifically, a handpiece for inducting a rotational movement can comprise three windings arranged, when the handpiece is seen in the transversal section as in figure 4, with axis mutually angled at 120° degrees. If the three windings are fed with three currents that form a balanced three-phase system, there is obtained a sinusoidal power progress, and consequently a magnetic field that rotates at constant speed.

The working principle of the linear motors may also be used to induce a linear capsule progression. In other words, the movement of the capsule can be obtained and controlled by making electric current flow through solenoids arranged in a linear sequence.

Turning back again to the method of using the system comprising the capsule and the handpiece, it is clear that the electromagnetic field will be generated only when the medical operator activates the appropriate commands. The generated magnetic field will have a maximum power strong enough to lift up the capsule from an height or maximal distance (that is, a distance between the skin-contact surface of the handpiece and the surface of the capsule when the latter rests on a horizontal plan) of about 50 cm.

Safety devices will be provided in the system for reducing the risk of adverse events due to accidental or uncontrolled magnetic field generation, as can be put in practice in an obvious manner. These devices may include, for example: a supplementary pedal switch that has necessarily to be turned on simultaneously with a trigger switch of the handpiece to generate the magnetic field; a magnetic field maximal power threshold (maximal power will be indicated in terms of the above mentioned
maximal distance in centimetres); a contact detection switch detecting contact between
the handpiece surface and the patient skin surface, adapted to prevent the generation
of the magnetic field if the handpiece does not contact the patient's body; a handpiece
ergonomic trigger the operation of which induces a magnetic field directly proportional
with the intensity of the manual pressure on the same trigger, until the preset maximal
power is reached, whereas an automatic setting will establish a pulsed magnetic field
proportional with the maximal distance; an emergency switch off; controls of the
distance between the handpiece and the patient's body, of the speed and acceleration
of the capsule, and of the attractive force applied, with power reduction or stop in case
predetermined safety threshold values are exceeded.

With reference to figure 3a, a minimal handpiece-capsule distance MS can also
be checked by using a transceiver device (not shown in the figure) housed inside the
handpiece. As such minimal distance MS is reached, this will be signalled by the
emission of acoustic and/or visual warnings.

In order to locate the position of the capsule in the patient's body, a number (e.g.
three) of signal receivers can be stuck to the patient's abdomen, via adhesive or
vacuum means. A magnetostrictive member in the capsule, when capturing the
electromagnetic pulse generated by the handpiece, will in turn generate a pulse
captured by the said abdominal receivers. Through digital data computing of obvious
nature, the capsule position and its distance from the handpiece will be obtained, and
consequently the capsule speed and acceleration. These data will be exploited to
automatically adjust the intensity of the magnetic field. As an alternative, a piezoelectric
member can be provided inside the capsule, emitting acoustic waves to be captured by
the handpiece to assess the position of the capsule.

The capsule can be thus driven by the handpiece according to four main
modalities:

1. Isotonic and isometric attraction and dragging (rolling, see the already
mentioned figure 2c). The handpiece is put at the minimal capsule-handpiece distance
that can be reached in the absence of a magnetic field (passive minimal distance). As
the operator activates the handpiece, the distance between the same handpiece and
the capsule is calculated, and proportionally the handpiece generates an appropriately
intense attractive magnetic field, that is, strong enough to lift up the capsule and let it 
adhore to the mucosal surface nearest to the handpiece. Once the capsule stops, the 
magnetic field will be adjusted so as not to exceed the double of the capsule weight, in 
order to avoid excessive pressure on mucosal surface. As a balance is reached and 
the capsule is still (active minimal distance), the operator can rotate the handpiece to 
change the orientation of the videocamera. When the lumen of the colon is framed, the 
operator can displace the handpiece in the desired direction. In this way, the magnet of 
the inner body is driven along a certain advance direction, and accordingly the outer 
body rolls. As the capsule moves, its distance from the handpiece will be kept 
substantially constant (isometric dragging) or fluctuate in a range of few centimetres, so 
that the handpiece generates a substantially constant magnetic field (isotonic 
attraction).

2. Isotonic attraction (non isometric) and approaching (figure 3b). In this 
modality the handpiece is not put at the minimal passive distance, but in 
correspondence to a point of the patient's skin at a chosen distance, along the axis of 
the colon lumen and in the direction in which the capsule is to be displaced. The 
operator will tilt the handpiece towards the position of the capsule and then turn the 
capsule on. Once calculated the distance form the capsule, the handpiece will generate 
a magnetic pulse proportional with such distance, to drive the same capsule. In order to 
avoid a too quick approach and the application of an excessive force on the capsule, 
as the two elements become closer, the magnetic field will be of pulsed type and of 
proportionally reduced intensity. The pulse will be characterized by a short band and 
wide amplitude (Dirac Delta function pulse). In this way, the capsule will be subject to 
an electromagnetic drive with short controlled displacement steps. As the distance 
between the capsule and the handpiece decreases, and also depending on the 
distance to be subsequently run by the capsule, the Delta pulse intensity will be 
decreased proportionally.

3. Isotonic and isometric attraction and rotation (figure 3c). In this modality 
the operator puts the handpiece at the above mentioned minimal passive distance. 
Subsequently, a magnetic field can be generated as above described at point 1) to 
stabilize the capsule at the nearest mucosal surface.(minimal active distance). As
balance is obtained and capsule is still, the operator can induce a magnetic field rotational movement (as above described). The rotation can be limited to a fraction of a complete turn, as needed (45°, 90°, 180°, etc) or a continuous rotational movement can be induced. In the first case, the rotation of the field is useful to change the camera direction without turning the handpiece. The continuous rotation can instead be employed to carry out the cleaning of the outer surface of the capsule, after locking the two capsule bodies to each other. To further assist the detachment of the dirty residues from the capsule, the rotation can be suddenly stopped, and a rotational motion in the opposite verse be induced.

4. Linear shift (launch). In this modality the handpiece is put at the minimal passive distance and turned on to obtain the minimal active distance. Then the camera is turned towards the colon lumen in the direction chosen for the capsule progression. A magnetic linear accelerator can at this point be activated to launch away the capsule.

All above described manoeuvres can be control through an external control and management unit which can be obviously implemented in its hardware and software components by any skilled person of the electronic and informatics field.

In any case, according to the invention, the external magnetic means can be manually gripped and applied directly on the patient abdomen, with a relative radiation emitting head in proximity, or in contact, with the patient's body, and then at few centimetres from the internal magnet onboard the capsule. This reduced the weight and bulk with respect to the drive systems of known apparatus, also in consideration of the lower magnetic force required to drive the capsule.

The external device (handpiece) is compact and adapted to be transported and made suitable to the room of great part of common outpatient settings (like an ultrasound scanner. Magnetic field intensity can be appropriately adjusted according to specific needs. The handpiece can be provided with cooling means, when necessary, and with devices, known as such, aimed at checking the distance between handpiece and capsule, or the absolute spatial position of the capsule.

According to the invention, therefore, magnetic responsive components inside inner body 1, which can be capsule-shaped or have a differently shaped structure, are adapted to determine a rotation of the same inner body relatively to outer body,
consequently changing the orientation of the visual field of the image capturing means, in response to an appropriate modulation of the external magnetic field.

Preferably, the arrangement of the centre of mass, the responsive magnetic means and the image capturing means (e.g. the microcamera) is such that, in the absence and in presence of an external magnetic field, the microcamera becomes oriented, respectively, in opposite directions; a first orientation is determined by the gravity-driven rotation of the inner body, resulting from the off-centred arrangement of the centre of mass; while a second orientation is driven by the external magnetic field that attracts the magnetic means of the capsule. This behaviour can be obtained through different mass distributions, components and shapes than those in the depicted example.

By changing the orientation of the external magnetic field, it is possible to carry out the rotation of the inner body, and thus of the view field. If the external magnetic handpiece is shifted tangentially with respect to the lumen axis, the operator can have the capsule rolling along the colon lumen. The rolling can also be assisted by gravity, making the patient change his/her position (by tilting the bed or simply changing the posture as needed). These manoeuvres can also be useful to remove dirty liquids from a colon segment to another one currently not subject to examination.

The rolling motion allows to decrease the dynamic friction, assisting the progression even in presence of irregular mucosal surface; moreover, a reduced external magnetic force need be employed, and consequently the external magnetic system is less bulky, less expensive and easier to be managed. Considering that the dirty colon residues lay over posterior intestinal wall (or floor, considering a patient in the supine position), if capsule rolls over the anterior intestinal wall (or roof), this can avoid the contact with dirty liquids that could impair the camera view field.

The structure with a double body permits to change microcamera orientation independently from the surrounding space and from the position in the lumen. The microcamera inside the inner body is somewhat distanced from the surface on which the capsule rolls, and this, in comparison with a traditional capsule, results in a wider view field.

Spherical or pseudo-spherical (spheroid) shape can be preferred; however, the
advantages of the invention can be appreciated also with different shapes of the outer body and/or the inner body. As already mentioned, the microcamera can be replaced by other data acquisition devices, such as infrared detectors, ultrasound generators etc..

The capsule can be recuperated and then used multiple times with consequent examination cost decrease. On the other hand, it can be easily sterilized thanks to its smooth surface and the absence of millimetric canals like those of traditional endoscopes.

Summarizing, a number of important advantages have been illustrated, making the endoscopic capsule according to the invention extremely effective compared with both known endoscopic devices, and standard optical flexible colonoscopy.

According to a different embodiment, represented in figure 5 (corresponding reference numerals indicate the same or corresponding components as of the previous embodiment), the outer body 11, instead of being free to rotate, can be prearranged to be linked, or directly linked, by two cables 19 connected at mutually opposite poles of the same body. Then, the outer body can rotate only around the axis connecting these two poles where the cables are connected. Data and energy needed for the operation of the capsule can be transported through these cables. The two cables 19, of semi rigid structure, mutually join in a single cable at a few centimetre distance from the capsule, and said single cable is inserted in a double duct catheter 20. A first duct 20a (guide duct) holds the single cable up to its branching off, while duct 20b, parallel with the other, can be used as operative canal. In fact, through the second duct air and water can be sucked or sprayed, and possibly endoscopic accessories such as needles and biopic forceps 21 can be introduced. The cleaning of the capsule can be obtained in this case not thanks to centrifugal force, but spraying water as needed. The guide canal has two main functions: promoting the movement of the capsule and reducing the friction of the single cable, that otherwise would be in contact with the mucosal surface.

In this embodiment the capsule progression in the colon lumen is carried out with two main modes that can be combined with each other: magnetic dragging as already described for the previous embodiment; and mechanical thrust by the catheter 20
and/or the single cable. In this way, the progression in the colon lumen can be obtained also by exploiting a mechanical thrust, while energy and data transmission can be continuously supplied without significant limits, and there is also the possibility of pulling the capsule to the anus, to make the same capsule more easily recovered.

However, in comparison with a commonly shaped capsule connected at one point of the surface, and with a single wire, the previously described arrangement allows to preserve the advantages of the double body capsule, as already described, and namely: changing the orientation of the external surface possibly dirtied by faecal residues; changing the camera orientation as desired without interfering with the outer environment; assisting the progression through the colon lumen by means of an attractive magnetic field potentially generated even by a single external magnet or electromagnet; decreasing the friction between the capsule and the mucosal surface thanks to the spherical shape and the rolling movement.

A further different embodiment, here not shown, can be provided with not only a single responsive element, but two magnetic elements arranged at opposite sides of the inner body, so as to assist the gravity driven orientation with a supplementary thrust deriving in turn by a modulation of the external magnetic field.

As far as the productive technology needed for reducing the capsule to practise is concerned, it is possible to employ expedients of relatively elementary nature, and in any case, when considered as such, available on the market. The battery can be of rechargeable type, possibly through wireless recharging systems. The movement between the two bodies with no significant friction can be achieved, as mentioned, through rolling bearing systems or the like, even with controlled lubricated friction with a lubricant liquid, film or lining (in a material such as Teflon®). The microcamera can also be driven relatively to the inner body by a micromotor controlled from the outside. Micromotor drive devices can even be envisaged to assist the mutual rotation of the bodies. The microcamera will be clearly associated with lighting means, in turn having intrinsically known characteristics.

The present invention has been described so far with reference to preferred embodiments. However, other different embodiments may be provided for, all falling within the scope of protection of the attached claims.
CLAIMS

1. An endoscopic capsule, comprising a capsule outer body (1), capturing means (4) for capturing information in a capture field on at least predefined segments of the gastrointestinal tract of a patient, energy supply means, signal receiving/transmitting means for transferring the captured information and for receiving operational controls, and means (5) responsive to an external magnetic field, said capsule outer body (1) being at least partially transparent to the passage of said information, wherein at least said responsive means (5) and said capturing means (4) are mounted on an inner body (2) rotatable with respect to said capsule outer body (1), said inner body (2) having a centre of mass (B) off-centered with respect to said outer capsule body (1) in a direction substantially opposite that of said capture field of said capturing means (4), said responsive means (5) being adapted to drive a rotation of said inner body (2) with respect to said outer body (1), and consequently a change in orientation of said capture field of said capturing means (4), in response to a determined variation of said external magnetic field.

2. The endoscopic capsule according to claim 1, wherein said responsive means (5) are adapted to make said capture field of said capturing means (4) become oriented in diametrically opposed directions, respectively in the presence and absence of said external magnetic field.

3. The endoscopic capsule according to claim 2, wherein said inner and outer body are mutually rotatable around a center (O), said responsive means (5) being arranged on said inner body (2) in a substantially diametrically opposed position with respect to said capturing means (4), said centre of mass (B) being arranged eccentrically with respect to the centre (O) of said outer body (1), namely displaced towards said responsive means (5).

4. The endoscopic capsule according to claim 3, wherein said information are visual information, said capturing means including a microcamera (4).

5. The endoscopic capsule according to any of previous claims, wherein said capturing means (4) are oriented so that the axis (Y) of its capture field intersects the axis (X) defined by said centre of mass (B) and by the common centre of the two
bodies with an angle (a) of at least 3π/4, preterminately about 45°, said angle being opened on the side opposite that of said centre of mass (B).

6. The endoscopic capsule according to any of the previous claims, wherein said responsive means (5) include a flattened shaped magnet (5) with a crescent section, extending over the periphery of the inner body (2).

7. The endoscopic capsule according to any of the previous claims, wherein said inner body (2) is connected with said outer body (1) through rolling support means (3).

8. The endoscopic capsule according to any of the claims 1 to 6, wherein said body is engaged within said outer body (1) via sliding friction means.

9. The endoscopic capsule according to any of previous claims, further comprising locking means (6) adapted to lock the mutual rotation between said inner body (2) and said outer body (1).

10. The endoscopic capsule according to claim 9, wherein said locking means (6) are associated with drive means controlled from the outside.

11. The endoscopic capsule according to claim 9 or 10, wherein said locking means include at least one piston (6) radially movable on said inner body with the support of a guide (7), said piston (6) being adapted to project from said inner body (2) to engage with said outer body (1).

12. The endoscopic capsule according to any of the previous claims, wherein said inner body (2) and said outer body (1) are spheroidal or substantially spheroidal, and are adapted to mutually rotate in a spherical fashion.

13. The endoscopic capsule according to any of previous claims, comprising lighting means associated or adapted to be associated to said capturing means (4).

14. The endoscopic capsule according to any of previous claims, comprising drive means controllable from the outside, adapted to change at least the orientation of said capturing means (4) with respect to said inner body (2).

15. The endoscopic capsule according to any of the previous claims, wherein said outer body (11) is adapted to be linked, or directly linked, with two cables (19) having a structure at least partially rigid or substantially rigid, to be connected with the body in two opposite poles, whereby the outer body (11) is adapted to rotate only around an axis that joins the junction points of the two cables to the capsule.
16. The endoscopic capsule according to any of the previous claims, wherein said responsive means (5) comprise two magnets arranged at diametrically opposed sides of said inner body (2).

17. An endoscopy examination system comprising an endoscopic capsule according to any of the previous claims, and a handpiece (M) comprising means for generating a magnetic field adapted to interact with said responsive means (5) of said capsule, said handpiece (M) comprising a magnetic field emitting head adapted to be moved in contact with or in proximity to the body surface of a patient.

18. The system according to claim 17, wherein said handpiece (M) is adapted to generate a rotating or pulsating magnetic field.

19. The system according to claim 18, wherein said handpiece comprises three windings arranged, when the handpiece is seen in transversal section, with axis mutually angled at 120° degrees and fed with three currents that form a balanced three-phase system.

20. The system according to claim 19, wherein said handpiece comprises a plurality of solenoids arranged in a linear sequence.

21. A method of using the system according to any of the claims from 17 to 20, wherein said handpiece is brought close to the body of said patient and, concurrently or not concurrently with a displacement of the handpiece, the emission of said electromagnetic field is activated to drive the controlled rotation of said inner body with respect to the outer body of said capsule and to control the displacement of the capsule inside the patient.
**INTERNATIONAL SEARCH REPORT**

**International application No**
PCT/IB2011/051323

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**A. CLASSIFICATION OF SUBJECT MATTER**

INV. A61B1/05 A61B5/07

ADD.

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

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**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

A61B

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

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

EPO-Internal

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**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

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Further documents are listed in the continuation of Box C.  
See patent family annex.

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* Special categories of cited documents:
  * "A" document defining the general state of the art which is not considered to be of particular relevance
  * "E" earlier document but published on or after the international filing date
  * "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
  * "O" document referring to an oral disclosure, use, exhibition or other means
  * "P" document published prior to the international filing date but later than the priority date claimed
  * "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
  * "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
  * "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
  * "A" document member of the same patent family

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Date of the actual completion of the international search: 14 July 2011

Date of mailing of the international search report: 21/07/2011

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Name and mailing address of the ISA:
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NL-2280 HV Rijswijk
Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016

Authorized officer: Alvazzi Delfrate, S
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## INTERNATIONAL SEARCH REPORT

Information on patent family members

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Form PCT/ISA/210 (patent family annex) (April 2005)
## Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [ ] Claims Nos.:
   - because they relate to subject matter not required to be searched by this Authority, namely:

2. [ ] Claims Nos.:
   - 21
   - because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
     
     see FURTHER INFORMATION sheet PCT/ISA/210

3. [ ] Claims Nos.:
   - because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 64(a).

## Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers:
   
   - the invention first mentioned in the claims; it is covered by claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

[ ] The additional search fees were accompanied by the applicant’s protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant’s protest but the applicable protest was received after the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.
Claim 21 relates to subject-matter mentioned in Rule 39.1(iv) PCT, in particular to a method of surgical treatment of the human body (the method of using an endoscopy examination system comprising an endoscopic capsule is carried out within the body, and therefore it is clearly a surgical method). Under terms of Art. 17(2) (a) (i) an International Searching Authority is not required to carry out a search of such claim.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examination Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the applicant proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.2), should the problems which led to the Article 17(2) declaration be overcome.