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(54) Title: A method and apparatus for controlling insufflation of a vessel during a surgical or investigative procedure

(72) Inventor: JOHN O'DEA

(73) Patent Granted to: CROSPON LIMITED, An Irish Company, Galway Business Park, Dangan, Galway, Ireland

"A method and apparatus for controlling insufflation of a vessel during a surgical or investigative procedure"

The present invention relates to apparatus for controlling insufflation of a vessel, lumen or cavity during a surgical or investigative procedure in a human or animal body. The invention also relates to a method for controlling insufflation of a vessel, lumen or cavity during a surgical or investigative procedure on a human or animal body. Further, the invention relates to a system and a method for insufflating a vessel, lumen or cavity in a human or animal body.

Throughout this specification the use of the term "vessel" is intended to include vessels, lumens, cavities and other such vessels in a human or animal body.

During an investigative and surgical procedure in a vessel in a human or animal body which is carried out by an imaging device and/or surgical instruments which are passed into the vessel through an endoscope or a laparoscope or other such insertion element for accommodating instruments into the vessel, the vessel, is insufflated with a fluid inflating medium for maintaining the vessel inflated to facilitate the investigative or surgical procedure. The fluid inflating medium, in general, is a gas such as carbon dioxide or air, but may be other suitable gases. However, the fluid inflating medium may also be liquid, such as a saline solution, water or other suitable liquid. Indeed, more recently in investigative and surgical procedures in the colon, it is common to insufflate the colon with a liquid. In cases where the fluid inflating medium is a gas, the gas for insufflating a vessel may be derived from a compressed gas source or a pumped gas source. Where the inflating medium is carbon dioxide, the carbon dioxide, in general, is provided from a source of compressed carbon dioxide, which is delivered to the vessel through a pressure regulating valve and a flow control valve. In the case of air being the inflating medium, the air may be provided from a compressed air source, and delivered to the vessel through a pressure regulating valve and a flow control valve. Alternatively, the air inflating medium may be provided by an air pump or an air blower. In general, a liquid inflating medium is provided from a pumped source of the liquid

medium. The inflating medium is delivered through the bore of the endoscope or laparoscope.

However, it is essential that the vessel in which the procedure is being carried out should not be over or hyper-inflated, but at the same time should be maintained inflated at a suitable pressure to avoid collapsing of the vessel during the procedure. Additionally, due to leaking of the inflating medium from the vessel, either through or along the outer surface of the endoscope or laparoscope, pressure may also fall in the vessel, thus leading to the collapse of the vessel. Such leaking of inflating medium from a vessel may also occur through a vessel wall, as a result of an incision made during surgery in the vessel. This requires monitoring the pressure of the inflating medium with which the vessel is being inflated. In general, a pressure sensor is located externally of the vessel and externally of the human or animal body, and typically, is located in a conduit through which the inflating medium is being delivered to the vessel, and in general, the pressure sensor is located in the conduit adjacent the source from which the inflating medium is provided. However, since the inflating medium source is normally located some distance from the vessel, a pressure drop results between the vessel and the pressure sensor. Thus, in order to determine the pressure of the inflating medium in the vessel being inflated, it is necessary to compensate for the pressure drop between the vessel and the pressure sensor. This requires computing the pressure drop which is equal to the product of the flow of the inflating medium and the resistance to flow of the inflating medium. The computed pressure drop must then be added to the pressure read by the pressure sensor. Since the flow rate of the inflating medium may fluctuate, and in particular, since the resistance to flow of the inflating medium in the conduit may, and in general, will always vary as a result of bends, kinks and the like in the conduit, it is difficult, if not impossible, to obtain a true value of the pressure in the vessel which is being insufflated during insufflating thereof. This is undesirable.

The present invention is directed towards providing apparatus for controlling insufflation of a vessel in a human or animal body which addresses this problem. The invention is also directed towards providing a method for controlling insufflation

of a vessel in a human or animal body which addresses the problem. The invention is also directed towards a system for insufflating a vessel in human or animal body, and further the invention is directed towards providing a method for insufflating a vessel in a human or animal body.

According to the invention there is provided apparatus for controlling insufflation of a vessel in a human or animal body with a fluid inflating medium, the apparatus comprising a first pressure sensing means configured for monitoring the pressure of the inflating medium in the vessel, and a control means for controlling delivery of the inflating medium to the vessel in response to the pressure thereof monitored by the first pressure sensing means.

In one aspect of the invention the first pressure sensing means is configured for monitoring the pressure of the inflating medium directly in the vessel. Preferably, the first pressure sensing means is located for monitoring the pressure of the inflating medium directly in the vessel.

In another aspect of the invention the control means is responsive to the pressure of the inflating medium in the vessel monitored by the first pressure sensing means for controlling delivery of the inflating medium to the vessel for maintaining the pressure of the inflating medium in the vessel substantially at a first predefined pressure.

Preferably, the first pressure sensing means is configured for monitoring the pressure of the inflating medium in the vessel adjacent a leading end of a primary insertion element for insertion into the vessel to accommodate instruments therethrough into the vessel, and preferably, the first pressure sensing means is configured for monitoring the pressure at the leading end of the primary insertion element.

In one aspect of the invention the first pressure sensing means is configured for locating in the vessel, and preferably, the first pressure sensing means is mounted on the primary insertion element. Advantageously, the first pressure sensing means

is mounted on the primary insertion element adjacent the leading end thereof, and preferably, is mounted on the primary insertion element at the leading end thereof.

In another aspect of the invention the first pressure sensing means is adapted for mounting on the primary insertion element, and advantageously, for releasably mounting on the primary insertion element. In a further aspect of the invention the first pressure sensing means is adapted for retrofitting on the primary insertion element. Preferably, the first pressure sensing means is configured for mounting on the primary insertion element externally thereof. Alternatively, the first pressure sensing means is configured for mounting in a bore extending through the primary insertion element, and in another aspect of the invention the first pressure sensing means is configured for inserting into the vessel through a bore in the primary insertion element.

Advantageously, a first coupling means, and preferably, a releaseable first coupling means is provided for releaseably coupling the first pressure sensing means to the primary insertion element.

In one aspect of the invention an elongated inflating conduit is provided for delivering the inflating medium into the vessel. Preferably, the inflating conduit terminates in a first end through which the inflating medium is delivered into the vessel.

In one embodiment of the invention the inflating conduit is configured for mounting on the primary insertion element, and preferably, the inflating conduit is configured for mounting on the primary insertion element with the first end thereof adjacent the leading end of the primary insertion element.

In another aspect of the invention the inflating conduit is configured for mounting on the primary insertion element externally thereof. Advantageously, the inflating conduit is configured for releaseable mounting on the primary insertion element.

In another aspect of the invention the inflating conduit is configured for retrofitting to

the primary insertion element. Preferably, a conduit coupling means is provided for coupling the inflating conduit to the primary insertion element. Advantageously, the conduit coupling means comprises a releaseable conduit coupling means for releaseably coupling the inflating conduit to the primary insertion element.

In another aspect of the invention the first pressure sensing means is located on the inflating conduit, and preferably, the first pressure sensing means is located adjacent the first end of the inflating conduit, and advantageously, the first pressure sensing means is located at the first end of the inflating conduit.

Preferably, the first pressure sensing means is located in a bore of the inflating conduit through which the inflating medium is delivered to the vessel.

Alternatively, the first pressure sensing means is located externally of the first vessel, and in another aspect of the invention the first pressure sensing means is located externally of the human or animal body.

In one aspect of the invention a first tubular element extending between a first end and a second end is configured so that the first end thereof extends into the vessel and the second end extends externally of the human or animal body, the first tubular element having a bore extending between the first and second ends, and a static fluid located in the bore thereof, the pressure of the static fluid being indicative of the pressure of the inflating medium in the vessel, and preferably, the first pressure sensing means is coupled to the first tubular element for monitoring the pressure of the static fluid therein, and preferably, the first pressure sensing means communicates with the bore of the first tubular element for monitoring pressure of the static fluid therein.

Preferably, the first tubular element is located relative to the primary insertion element so that the first end of the first tubular element extends into the vessel, and preferably, terminates adjacent the leading end of the primary insertion element, and preferably, terminates at the leading end of the primary insertion element.

In one aspect of the invention the first tubular element is configured for mounting on the primary insertion element, and advantageously, the first tubular element is configured for releaseably mounting on the primary insertion element, and preferably, is configured for retrofitting to the primary insertion element.

In one embodiment of the invention the first tubular element is configured for mounting on the primary insertion element externally thereof, and in an alternative aspect of the invention the first tubular element is configured for extending through a bore of the primary insertion element.

In another aspect of the invention a second coupling means is provided for coupling the first tubular element to the primary insertion element, and preferably, the second coupling means comprises a releasable second coupling means for releaseably engaging the first primary insertion element.

In one aspect of the invention the first end of the first tubular element terminates in a flexible membrane configured to flex relative to the first tubular element in response to pressure fluctuation of the inflating medium in the vessel for in turn proportionately varying the pressure of the static fluid in the first tubular element. Advantageously, the first pressure sensing means is located adjacent the second end of the first tubular element.

In another aspect of the invention the first pressure sensing means communicates with the control means, and advantageously, and in one aspect of the invention the first pressure sensing means is hard wired to the control means. Alternatively, the first pressure sensing means communicates with the control means wirelessly, and preferably, through a first wireless communicating means.

Preferably, the first pressure sensing means comprises a first pressure sensor, which advantageously, comprises a miniature pressure sensor, and preferably, the first pressure sensing means comprises a piezoelectric pressure sensor.

In another aspect of the invention a second pressure sensing means is provided for monitoring the pressure of the inflating medium in a vessel adjacent the vessel being insufflated, and communicating with the vessel being insufflated, the control means being responsive to the pressure of the inflating medium monitored by the second pressure sensing means for one of producing an alarm signal in response to the monitored pressure reaching a second predefined pressure, and controlling delivery of the inflating medium to the vessel being insufflated for preventing the pressure in the adjacent vessel exceeding the second predefined pressure.

Preferably, the second pressure sensing means is associated with a carrier element configured to extend from the primary insertion element, and preferably, the carrier element terminates in a first end, and the carrier element is moveable relative to the primary insertion element for urging the first end of the carrier element into the adjacent vessel, and preferably, for urging the carrier element into the adjacent vessel through the vessel being insufflated.

Advantageously, the carrier element is urgeable through the primary insertion element, and preferably, is urgeable through a bore of the primary insertion element.

In one aspect of the invention the second pressure sensing means is mounted on the carrier element, and preferably, is mounted on the carrier element adjacent the first end of the carrier element, and advantageously, is mounted on the carrier element at the first end of the carrier element.

In another aspect of the invention the second pressure sensing means is located externally of the human or animal body, and preferably, a second tubular element extends between a first end and a second end, and is configured so that the first end extends into the adjacent vessel and the second end extends externally of the human or animal body, the second tubular element having a bore extending between the first and second ends, and a static fluid located in the bore, the pressure of the static fluid in the bore being indicative of the pressure of the inflating medium in the

adjacent vessel.

Advantageously, the second pressure sensing means communicates with the bore of the second tubular element for monitoring the pressure of the static fluid therein.

In another aspect of the invention the second tubular element terminates at its first end in a flexible membrane configured to flex relative to the second tubular element for altering the pressure of the static fluid in the bore of the second tubular element in response to pressure fluctuations of the inflating medium in the adjacent vessel.

Preferably, the second pressure sensing means communicates with the bore in the second tubular element adjacent the second end thereof for monitoring the pressure of the static fluid therein.

In one aspect of the invention the second tubular element is carried on the carrier element, and preferably, the first end of the second tubular element is located adjacent the first end of the carrier element, and preferably, at the first end of the carrier element.

In one aspect of the invention the second pressure sensing means communicates with the control means, and in another aspect of the invention the second pressure sensing means is hard wired to the control means. Alternatively, the second pressure sensing means communicates with the control means wirelessly, and preferably, through a second wireless communicating means.

In one aspect of the invention the second pressure sensing means comprises a second pressure sensor, which advantageously, comprises a miniature pressure sensor, and preferably, the second pressure sensing means comprises a second piezoelectric pressure sensor.

In a further aspect of the invention a third pressure sensing means is provided for monitoring pressure in a vessel external of the vessel being insufflated, and within

which the vessel being insufflated is located, the control means being responsive to the third pressure sensing means for one of producing an alarm signal in response to the pressure in the external vessel reaching a third predefined pressure, and controlling one of delivery of the inflating medium to the vessel being insufflated, and a vacuum pump communicating with the external vessel for preventing the pressure in the external vessel exceeding the third predefined pressure.

In one aspect of the invention the third pressure sensing means communicates with the external vessel, and advantageously, the third pressure sensing means is adapted for location in the external vessel.

In another aspect of the invention the third pressure sensing means is located externally the human or animal body, and communicates with the external vessel through a vacuum conduit configured to communicate the vacuum pump with the external vessel.

In an alternative embodiment of the invention the third pressure sensing means is configured for locating externally of the human or animal body, and preferably, a third tubular element extending between a first end and a second end is configured so that the first end extends into the external vessel and the second end extends externally of the human or animal body, the third tubular element having a bore extending between the first and second ends thereof, and a static fluid in the bore, the pressure of which is indicative of the pressure in the external vessel, and preferably, the third pressure sensing means is configured to communicate with the bore of the third tubular element for monitoring the pressure of the static fluid therein.

In another aspect of the invention a secondary insertion element is provided for inserting one of the third pressure sensing means and the first end of the third tubular element into the external vessel.

Advantageously, the secondary insertion element comprises a needle having a bore extending therethrough for accommodating the one of the third pressure sensing

means and the third tubular element therein. Advantageously, the first end of the third tubular element terminates in the bore of the needle, and in another aspect of the invention the third pressure sensing means is located in the bore of the needle. In a further aspect of the invention a second end of the needle is coupled to the vacuum conduit, and preferably, is coupled to the vacuum conduit through a needle hub. Advantageously, the third pressure sensing means communicates with the external vessel through a connecting element Teed off adjacent the needle hub.

In one aspect of the invention the primary insertion element comprises an endoscope, and in an alternative aspect of the invention the primary insertion element comprises a laparoscope.

In another aspect of the invention the inflating medium is derived from an inflating medium source. In one aspect of the invention the inflating medium comprises a gaseous inflating medium, and the inflating medium sources comprises a compressed source of the gaseous inflating medium. Preferably, the inflating medium is delivered from the compressed source of the inflating medium through an inflating medium control means. Advantageously, the inflating medium control means comprises a flow control valve, and preferably, the flow control valve is operated under the control of the control means for controlling delivery of the inflated medium to the vessel. Advantageously, the inflating medium control means further comprises a pressure regulating vale for regulating the pressure of the inflating medium from the source of the compressed inflating medium.

Alternatively, the inflating medium source comprises a pump or a blower for pumping the inflating medium or for blowing the inflating medium. Preferably, the blower or pump is operated under the control of the control means. In another aspect of the invention the inflating medium comprises air, and the source of the inflating medium comprises a compressed air source. Alternatively, the source of the inflating medium comprises an air blower or a pump for delivering the air to the vessel.

In a further aspect of the invention the gaseous inflating medium comprises carbon

dioxide.

In a still further aspect of the invention the inflating medium comprises a liquid inflating medium, and preferably, the source of the liquid inflating medium comprises a pump for pumping the liquid inflating medium to the vessel, and advantageously, the pump for pumping the liquid inflating medium is operated under the control of the control means.

The invention also provides a system for insufflating a vessel in a human or animal body, the system comprising the apparatus according to the invention for controlling insufflation of the vessel. Preferably, the system comprises a source of the fluid inflating medium, and the source of the fluid inflating medium is operated under the control of the control means. Preferably, the system also comprises a vacuum pump configured for coupling to the external vessel of the human or animal subject.

In a further aspect of the invention the system comprises the primary insertion element, and preferably, the first pressure sensing means is coupled to the primary insertion element, and preferably, is externally coupled to the primary insertion element, and advantageously, is releaseably coupled to the primary insertion element.

The invention also provides a method for controlling insufflation of a vessel in a human or animal body by a fluid inflating medium, the method comprising monitoring the pressure of the inflating medium directly in the vessel, and controlling delivery of the inflating medium to the vessel in response to the monitored pressure of the inflating medium in the vessel.

Preferably, delivery of the inflating medium to the vessel is controlled in response to the monitored pressure of the inflating medium in the vessel for maintaining the pressure of the inflating medium in the vessel substantially at a first predefined pressure.

In one aspect of the invention a first pressure sensing means is provided for monitoring the pressure of the inflating medium in the vessel, and a control means is provided for controlling delivery of the inflating medium to the vessel in response to the pressure monitored by the first pressure sensing means.

In one aspect of the invention pressure is monitored in a vessel which is adjacent the vessel being insufflated and which communicates with the vessel being insufflated, and one of an alarm signal is produced in response to the monitored pressure in the adjacent vessel reaching a second predefined pressure, and delivery of the inflating medium to the vessel being insufflated is controlled for preventing the pressure in the adjacent vessel exceeding the second predefined pressure, in response to the monitored pressure in the adjacent vessel.

In another aspect of the invention a second pressure sensing means is provided for monitoring the pressure in the adjacent vessel, and delivery of the inflating medium to the vessel being insufflated is controlled by the control means in response to the pressure monitored by the second pressure sensing means for preventing the pressure in the adjacent vessel exceeding the second predefined pressure.

In a further aspect of the invention the control means is responsive to the pressure monitored by the second pressure sensing means for producing the alert signal in response to the monitored pressure in the adjacent vessel reaching the second predefined pressure.

In another aspect of the invention pressure is monitored in a vessel which is external of the vessel being insufflated, and in which the vessel being insufflated is located, and one of an alert signal is produced in response to the monitored pressure in the external vessel reaching a third predefined pressure, and one of delivery of the inflating medium to the vessel being insufflated is controlled, and the external vessel is evacuated for preventing the pressure in the external vessel exceeding the third predefined pressure in response to the monitored pressure in the external vessel.

In a further aspect of the invention a third pressure sensing means is provided for monitoring the pressure in the external vessel, and the control means is responsive to the pressure monitored by the third pressure sensing means for controlling one of delivery of the inflating medium to the vessel being insufflated and a vacuum pump connected to the external vessel for preventing the pressure in the external vessel exceeding the third predefined pressure.

In another embodiment of the invention the control means is responsive to the third pressure sensing means for producing the alarm.

The invention will be more clearly understood from the following description of some embodiments thereof, which are given by way of example only, with reference to the accompanying drawings, in which:

Fig. 1 is a schematic representation, not to scale, of a system according to the invention for insufflating a vessel during a surgical or investigative procedure in a human or animal body,

Fig. 2 is a schematic representation, not to scale, of a system according to another embodiment of the invention for insufflating a vessel during a surgical or investigative procedure in a human or animal body,

Fig. 3 is a cross-sectional side elevational view of a detail of the system of Fig. 2,

Fig. 4 is a schematic representation, not to scale, of a system according to a further embodiment of the invention for insufflating a vessel during a surgical or investigative procedure in a human or animal body,

Fig. 5 is an enlarged side view of a detail of the system of Fig. 4, and

Fig. 6 is an enlarged end view of the detail of Fig. 5 of the system of Fig. 4.

Referring to the drawings and initially to Fig. 1, there is illustrated a system according to the invention indicated generally by the reference numeral 6 for insufflating a vessel in a human or animal body, which in this embodiment of the invention is a rectum 2 of a human body, during a surgical or investigative procedure in the rectum 2. The rectum 2 is located in the abdominal cavity 3 between the colon 4 and the anus 5 of the human or animal body, only a portion of a human body 6 is illustrated. The system of Fig. 1 comprises apparatus also according to the invention, indicated generally by the reference numeral 1, for controlling insufflation of the vessel 2. The apparatus in this embodiment of the invention comprises an elongated primary insertion element, which may be an endoscope, a laparoscope or other such similar element, and which in this case is an endoscope 8. The endoscope 8 defines an elongated bore 9 extending therethrough for accommodating, for example, an imaging device, for example, carrying out an investigative procedure in the rectum 2 and if the primary insertion element is a laparoscope, the bore would be suitable for accommodating surgical instruments, for carrying out surgery on the rectum 2. Such endoscopes and laparoscopes with one or more bores extending therethrough will be known to those skilled in the art, and it is not intended to discuss the primary insertion element 8 in further detail.

An insufflator 10 comprising a housing 11, illustrated in broken lines, houses a fluid inflating medium source, from which fluid inflating medium, in this case air is delivered to the rectum 2 for insufflating thereof; in this embodiment of the invention the fluid inflating medium source comprises a source of compressed gas stored in a compressed gas vessel 12, in this case compressed air in a compressed air vessel 12. Air from the compressed air vessel 12 is delivered to the rectum 2 through an inflating conduit 14. A pressure regulating valve 13 controls the pressure at which air is delivered from the compressed air vessel 12 to the inflating conduit 14. Pressure regulated air is delivered from the pressure regulating valve 13 to the inflating conduit 14 through an electrically operated solenoid or motor operated flow control valve 16, which controls delivery of the air from the compressed air vessel 12 to the inflating conduit 14, and in turn to the rectum 2. The inflating conduit 14 is

passed into the rectum 2 through the bore 9 in the endoscope 8 for delivering air thereto. Typically, air is delivered to the rectum 2 at a rate of 1 litre per minute to 20 litres per minute.

A first pressure sensing means, namely, a first pressure sensor 15 is recessed into a leading end 17 of the endoscope 8 for directly monitoring the pressure of the air in the rectum 2 adjacent the leading end 17 of the endoscope 8. In this embodiment of the invention the first pressure sensor 15 is a miniature pressure sensor, and preferably, comprises a piezoelectric pressure sensor.

A control means, which in this embodiment of the invention comprises a signal processor, namely, a microcontroller 18, which is located in the housing 11 of the insufflator 10, is electrically coupled to the first pressure sensor 15 by electrically conductive wires 19, so that the microcontroller 18 can read signals from the first pressure sensor 15 which are indicative of the monitored air pressure in the rectum 2 adjacent the leading end 17 of the endoscope 8. The wires 19 from the first pressure sensor 15 extend through the bore 9 of the endoscope 8. The microcontroller 18 is programmed to read the signals from the first pressure sensor 15 and to control the flow control valve 16 for controlling the supply of air from the compressed air vessel 12 to the rectum 2 for in turn maintaining the air pressure in the rectum 2 at a first predefined pressure. In this embodiment of the invention the first predefined pressure is selectable and is enterable into the microcontroller 18 through an interface 20 located in the housing 11 of the insufflator 10. The interface 20 may be any suitable interface, for example, a keypad interface, a touch screen or the like. The value of the first predefined pressure will be dependent upon the vessel being insufflated, and in particular, will be dependent on the resilience of the vessel being insufflated, and the strength or weakness of the vessel. However, typically, the first predefined pressure will lie in the range of 5mm mercury to 20mm mercury, and in the case of a rectum, the first predefined pressure will normally be of the order of 15mm mercury.

A second pressure sensing means, namely, a second pressure sensor 23 is located

on a first end 24 of a carrier element 25 which is urgeable through the bore 9 of the endoscope 8 until the first end 24 of the carrier element 25, and in turn the second pressure sensor 23 is located in a vessel adjacent the rectum, namely, the colon 4 which communicates with the rectum 2 for monitoring the pressure in the colon 4. The second pressure sensor 23 is a miniature pressure sensor, and preferably, comprises a piezoelectric pressure sensor. The carrier element 25 is adapted to be moveable through the bore 9 of the endoscope 8 for facilitating locating of the second pressure sensor 23 at a desired location in the colon 4. Electrically conductive wires 28 extending from the second pressure sensor 23 along the carrier element 25 extend through the bore 9 of the endoscope 8, and in turn are connected to the microcontroller 18, so that the microcontroller 18 can read signals from the second pressure sensor 23 which are indicative of the air pressure in the colon 4. The microcontroller 18 is programmed to read the signals from the second pressure sensor 23 and to control the operation of the flow control valve 16 for controlling delivery of the air into the rectum 2, so that the air pressure in the colon 4 does not exceed a second predefined pressure. The second predefined pressure is selectable and is enterable into the microcontroller through the interface 20. The value of the second predefined pressure will be dependent upon the nature of the adjacent vessel, and in particular, the strength or weakness of the adjacent vessel. However, in general, the second predefined pressure will be higher than the first predefined pressure, and could be up to thirty percent higher than the first predefined pressure. In the case of a colon where the rectum in being insufflated, the second predefined pressure typically will be set at a value of the order of 5mm mercury above the first predefined pressure.

A third pressure sensing means, namely, a third pressure sensor 30 is located in a secondary insertion element, namely, a needle 32 having an elongated bore 33 extending therethrough for monitoring the pressure in a vessel external of the rectum 2, namely, for monitoring the pressure in the abdominal cavity 3 in the event of a leak from the rectum 2 into the abdominal cavity 3. The third pressure sensor 30 in this embodiment of the invention is a miniature pressure sensor, and preferably, comprises a piezoelectric pressure sensor. The needle 32 in this embodiment of the

invention comprises a Veress needle, which terminates in a first end 34 which is sharpened to a point 37 for penetrating the tissue in the body of a subject for inserting the first end 34 of the needle 32 into the abdominal cavity 3, typically, through the navel 40 of the human body.

The third pressure sensor 30 is located in the bore 33 of the needle 32 adjacent the first end 34 thereof so that when the first end 34 of the needle 32 is inserted in the abdominal cavity 3, the pressure detected by the third pressure sensor is the true pressure in the abdominal cavity 3. Electrically conductive wire 35 from the third pressure sensor 30 connect the third pressure sensor 30 to the microcontroller 18. The microcontroller 18 is programmed to read the signals from the third pressure sensor 30 which are indicative of the pressure in the abdominal cavity 3, and to control the operation of either or both of the flow control valve 16 and a vacuum pump 36 in the insufflator 10 for preventing the air pressure in the abdominal cavity 3 exceeding a third predefined pressure in the event of a leak of air into the abdominal cavity 3 from either the rectum 2 or the colon 4. Such a leak from the rectum 2 to the abdominal cavity 3 would typically arise in the event of surgery being carried out in the rectum 2, as will be described below. The third predefined pressure is selectable and is enterable into the microcontroller 18 through the interface 20. The value of the third predefined pressure will be dependent on the nature of the vessel being insufflated, and the external vessel in which the vessel being insufflated is located. In general the value of the third predefined pressure will be sufficiently less than the first predefined pressure in order to maintain an adequate pressure difference between the pressure in the vessel being insufflated, and the external vessel in which the vessel being insufflated is located, in order to avoid the vessel being insufflated, collapsing or being inadequately insufflated. Typically, the third predefined pressure will be not more than half the value of the first predefined pressure, and in the case where a rectum is being inflated the value of the third predefined pressure will be 7mm mercury or less. The vacuum pump 36 is connected to the needle 32 by a vacuum conduit 38, so that the vacuum pump 36 communicates with the abdominal cavity 3 through the bore 33 of the needle 32 for evacuating air from the abdominal cavity 3. The vacuum conduit 38 is connected to

a hub 42 of the needle 32.

A power supply 39 located in the housing 11, which may be powered either by mains electricity or by a battery or a plurality of batteries in series, which may be rechargeable batteries or non-chargeable batteries provides power to the microcontroller 18, the flow control valve 16, the vacuum pump 36 and the first, second and third pressure sensors 15, 23 and 30, respectively.

In use, when the system 6 is required for insufflating the rectum 2 in order to allow an investigative procedure to be carried out in the rectum 2, only the first and second pressure sensors 23 are required. Thus, with the first pressure sensor 15 and the second pressure sensor 23 electrically connected to the microcontroller 18, and with the inflating conduit 14 connected to the compressed air vessel 12 through the pressure regulating valve 13 and the flow control valve 16, the system 6 and the apparatus 1 are ready for use. The values of the first and second predefined pressures are entered into the microcontroller 18 through the interface 20. The endoscope 8 is inserted by its leading end 17 through the anus 5 into the rectum 2 with the leading end 17 of the endoscope 8 located in the rectum 2. The inflating conduit 14 is inserted into the rectum 2 through the bore 9 of the endoscope 8, and the flow control valve 16 is initially operated for initially insufflating the rectum 2 in order to allow the carrier element 25 to be urged through the rectum 2 into the colon 4. The carrier element 25 is urged through the bore 9 of the endoscope 8 through the rectum 2, and in turn into the colon 4 with the second pressure sensor 23 on the first end 24 of the carrier element 25 located at a desired location in the colon 4 for directly monitoring air pressure in the colon 4.

The flow control valve 16 is again operated under the control of the microcontroller 18 for maintaining the rectum 2 inflated at the first predefined pressure. The microcontroller 18 reads the signals from the first pressure sensor 15 and operates the flow control valve 16 in order to maintain the air pressure in the rectum 2 at the first predefined pressure. The microcontroller 18 also reads the signals from the second pressure sensor 23 during insufflating of the rectum 2, and the

microcontroller 18 compares the pressure read from the second pressure sensor 23 with the second predefined pressure. On the microcontroller 18 determining that the air pressure in the colon 4 has reached the second predefined pressure, the microcontroller 18 operates the flow control valve 16 in order to prevent the air pressure in the colon 4 exceeding the second predefined pressure, and in turn to avoid hyper-inflating of the colon 4. When the air pressure in the colon 4 has fallen below the second predefined pressure, the microcontroller 18 again operates the flow control valve 16 for maintaining the rectum 2 insufflated at the first predefined pressure. The microcontroller 18 may also be programmed to activate an alarm which may be a visual or aural alarm or both on the pressure in the colon 4 being determined as having reached the second predefined pressure.

On the rectum 2 being insufflated to the first predefined pressure, an imaging device and/or investigative instruments required for carrying out the investigative procedure are inserted through the bore 9 of the endoscope 8 into the rectum 2 in a manner which will be well known to those skilled in the art, and the investigative procedure is carried out on the rectum 2. On completion of the investigative procedure, the imaging device and the investigative instruments are withdrawn from the rectum 2 through the bore 9 of the endoscope 8. The carrier element 25 with the second pressure element 23 are withdrawn from the colon 4 through the rectum 2 and in turn through the bore 9 of the endoscope 8 and the endoscope 8 is then withdrawn from the rectum 2 through the anus 5. As the withdrawal of the endoscope 8 through the anus 5 is just about completed, the flow control valve 16 is operated into the off state for isolating the inflating conduit 14 from the compressed air vessel 12.

In the event that the system 6 and the apparatus 1 is to be used in connection with a surgical procedure to be carried out on the rectum 2, and in particular, where a full thickness resection of cancers of the rectum are to be removed, which could result in leakage of air from the rectum during insufflating thereof into the abdominal cavity 3, the third pressure sensor 30 is required to monitor the pressure in the abdominal cavity 3. The value of the third predefined pressure is entered into the microcontroller 18 through the interface 20. The primary insertion element, which in

this case would be a laparoscope 8 is inserted through the anus 5 and located in the rectum 2 as already described, and the inflating conduit 14 is urged into the rectum 2 through the bore 9 in the laparoscope 8. After initial insufflation of the rectum 2, the carrier element 25 is urged through the bore 9 in the laparoscope 8 to locate the second pressure sensor 23 in a desired location in the colon 4 also as already described. The needle 32 is inserted through the navel 40 or any other suitable location in the abdominal wall, so that the first end 34 of the needle 32 is located in the abdominal cavity 3 with the third pressure sensor 30 monitoring the pressure in the abdominal cavity 3. The vacuum conduit 38 from the vacuum pump 36 is connected to the needle 32.

The flow control valve is operated under the control of the microcontroller 18 for insufflating the rectum 2 as already described with reference to the use of the apparatus 1 and the system 6 for carrying out the investigative procedure in the rectum 2. The microprocessor 18 monitors the signals from the first pressure sensor 15 and the second pressure sensor 23, for maintaining the air pressure in the rectum 2 substantially at the first predefined pressure, and for preventing the pressure in the colon 4 exceeding the second predefined pressure as already described. The microcontroller 18 also reads signals from the third pressure sensor 30 which are indicative of the pressure in the abdominal cavity 3 resulting from leakage of air from the rectum 2. On the microprocessor 18 determining that the signals read from the third pressure sensor 30 are indicative of the pressure in the abdominal cavity 3 reaching the third predefined pressure, the microprocessor 18 operates the vacuum pump 36 for exhausting air from the abdominal cavity 3 until the air pressure in the abdominal cavity 3 falls below the third predefined pressure. Alternatively, the microcontroller 18, instead of operating only the vacuum pump 36 on the pressure in the abdominal cavity 3 reaching the third predefined pressure, the microcontroller 18 may control the operation of both the vacuum pump 36 and the flow control valve 16 to reduce the pressure in the rectum 2 for in turn reducing the pressure in the abdominal cavity 3 below the third predefined pressure. In which case the microcontroller 18 would operate the vacuum pump 36 first, and if the vacuum pump 36 failed to reduce the pressure in the abdominal cavity 3 below the third predefined

pressure, the microcontroller 18 would operate the flow control valve 16 to reduce the pressure in the rectum 2 until the pressure in the abdominal cavity 3 had fallen below the third predefined pressure. The microcontroller 18 would then continue to operate the flow control valve 16 for maintaining the pressure in the rectum 2 at the first predefined pressure. Additionally, the microcontroller 18 may be programmed to operate an audible or visual alarm in response to the pressure in the abdominal cavity reaching the third predefined pressure.

On the rectum 2 being insufflated to the first predefined pressure, an imaging device and/or surgical implements required for carrying out the resectioning procedure or other surgical procedure are inserted through the bore 9 of the laparoscope 8 into the rectum 2 in a manner which will be well known to those skilled in the art, and the resectioning procedure or other surgical procedure is carried out in the rectum 2. On completion of the surgical procedure, the imaging device and the surgical implements are withdrawn from the rectum 2 through the bore 9 of the laparoscope 8. The carrier element 25 with the second pressure element 23 is withdrawn from the colon 4 through the rectum 2 and in turn through the bore 9 of the laparoscope 8. The laparoscope 8 is then withdrawn from the rectum 2 through the anus 5. As the withdrawal of the laparoscope 8 through the anus 5 is just about completed, the flow control valve 16 is operated into the off state to isolate the inflating conduit 14 from the compressed air vessel 16.

The needle 32 is then withdrawn from the abdominal cavity.

The advantages of the apparatus according to the invention are many. By virtue of the fact that the first pressure sensor is physically located in the rectum, the pressure detected by the first pressure sensor is the true air pressure in the insufflated rectum. Therefore, the need to compensate for pressure drops in an inflating conduit between a pressure sensor and the vessel within which the procedure is being carried out due to the fact that the air is flowing in the inflating conduit is no longer required in order to obtain the actual air pressure in the rectum or other vessel in which a procedure is being carried out. A particularly important advantage

of the invention is that irrespective of leakage of air from the rectum or other vessel being insufflated, the pressure in the rectum or such other vessel being insufflated is maintained substantially constant at the first predefined pressure. This is a particularly important advantage of the invention, since leakages from the rectum or other vessel being insufflated may in many cases be considerable. For example, in the case of the rectum, in general, leakage from the rectum through the anus around the outside of the endoscope or laparoscope is quite common, and leakage from the rectum can also occur through the bore or bores of the endoscope or laparoscope. Furthermore, in the case of resection surgery of the rectum, significant leakage can occur from the rectum into the abdominal cavity. Thus, irrespective of the leakages from the rectum or other such vessel being insufflated, the pressure of the vessel being insufflated is maintained substantially constant at the first predefined pressure throughout the procedure.

By virtue of the fact that the air pressure in the abdominal cavity is also controlled, and prevented from exceeding the third predefined pressure, there is no danger of the pressure in the abdominal cavity reaching a pressure which could be substantially similar to the pressure within the rectum, thus resulting in the rectum collapsing on itself. Additionally, by continuously monitoring the pressure in the abdominal cavity and preventing the pressure in the abdominal cavity exceeding the third predefined pressure, there is little or no risk to patient ventilation, which could otherwise result from hyper-inflation of the abdominal cavity, as a result of leakage into the abdominal cavity from the rectum or other vessel being insufflated. Additionally, by monitoring the pressure in the colon, which communicates directly with the rectum, there is no danger of hyper-inflation of the colon.

Referring now to Figs. 2 and 3, there is illustrated a system 51 according to another embodiment of the invention for insufflating a vessel in a human or animal body, which in this embodiment of the invention is also the rectum 2 during a surgical or investigative procedure in the rectum 2. The system 51 comprises apparatus which is also according to another embodiment of the invention and indicated generally by the reference numeral 50 for controlling insufflation of the rectum 2 during the

surgical or investigative procedure 2. Both the system 51 and the apparatus 50 are substantially similar to the system 6 and the apparatus 1 described with reference to Fig. 1 hereof, and similar components are identified by the same reference numerals, as are similar organs and vessels of the human body likewise identified by the same reference numerals as those in Fig. 1. The system 51 comprises a primary insertion element, which in this embodiment of the invention may be an endoscope 8 for carrying out an investigative procedure on the rectum 2, or a laparoscope 8 for carrying out surgery in the rectum 2.

The only difference between the apparatus 50 and the apparatus 1 is that instead of the first, second and third primary sensors 15, 23 and 30 being configured to be located in the rectum 2, the colon 4 and the abdominal cavity 3, respectively, the first, second and third pressure sensors 15, 23 and 30 are located remotely in the housing 11 of the insufflator 10. In this embodiment of the invention the first, second and third pressure sensors 15, 23 and 30 are coupled to first, second and third elongated tubular elements 53, 54 and 55, respectively, which extend from the first, second and third pressure sensors 15, 23 and 30 into the rectum 2, the colon 4 and the abdominal cavity 3, respectively. Each of the three tubular elements 53, 54 and 55 extend between respective first ends 57 and second ends 58. A bore 56 extends through each tubular element 53, 54 and 55 from the first end 57 to the second end 58.

The first end 57 of each of the three tubular elements 53, 54 and 55 terminates in a bulb 60 which is closed by a flexible membrane 61 which is impermeable to air and to any other fluids which may be located in the rectum 2, the colon 4 and the abdominal cavity 3. The corresponding one of the first pressure sensor 15, the second pressure sensor 23 and the third pressure sensor 30 is coupled to the second end 58 of the corresponding one of the first, second and third tubular elements 53, 54 and 55, and communicates with the corresponding bore 56 therein. Thus, the bores 56 extending through the three tubular elements 53, 54 and 55 are sealably closed at both ends, and contain a static fluid, which in this embodiment of the invention is air. The flexible membrane 61 of each first, second and third tubular

element 53, 54 and 55 is sufficiently flexible, so that fluctuations in the pressure in the corresponding one of the rectum 2, the colon 4 and the abdominal cavity 3 induces a corresponding change in pressure in the static fluid in the bore 56 of the corresponding tubular element 53, 54 and 55. Thus, the pressure detected by the first, second and third pressure sensors 15, 23 and 30 is indicative of, and in this embodiment of the invention identical to the current pressure in the corresponding one of the rectum 2, colon 4 and abdominal cavity 3, respectively. Accordingly, although the first, second and third pressure sensors 15, 23 and 30 are remotely located of the respective rectum 2, colon 4 and abdominal cavity 3, the pressure detected by the first, second and third pressure sensors 15, 23, and 30 is identical to the respective pressures in the rectum 2, the colon 4 and the abdominal cavity 3.

In this embodiment of the invention the first tubular element 53 is located in the bore 9 of the endoscope 8 or laparoscope 8 and is secured to the endoscope 8 or laparoscope 8, so that the bulb 60 of the first tubular element 53 is located substantially adjacent the leading end 17 of the endoscope 8 or laparoscope 8, so that the pressure detected by the first pressure sensor 15 is the exact pressure in the rectum 2 adjacent the leading end 17 of the endoscope 8 or laparoscope 8.

The second tubular element 54 is located on the carrier element 25 and extends the length of the carrier element 25 and terminates in the bulb 60 adjacent the first end 24 of the carrier element 25. The third tubular element 55 extends into the needle 32 and terminates in the bulb 60 adjacent the first end 34 of the needle 32. The third tubular element 55 extends from the bulb 60 through the needle 32 and into the conduit 38, and exits the conduit 38 at 62 within the housing 11 of the insufflator 10.

Otherwise, use and operation of the system 51 and the apparatus 50 is similar to use and operation of the system 6 and the apparatus 1, and the advantages achieved by the system 6 and the apparatus 1 are also achieved by the system 51 and the apparatus 50.

Referring now to Figs. 4 to 6, there is illustrated a system according to the invention,

indicated generally by the reference numeral 70, for insufflating a vessel, in this case a rectum 2. The system 70 comprises apparatus also according to the invention, indicated generally by the reference numeral 71, for controlling insufflation of the rectum 2 during insufflation thereof. The apparatus 71 comprises the inflating conduit 14, which in this embodiment of the invention is configured for releaseably securing externally to the endoscope 8 or the laparoscope 8, as the case may be, and is also configured for extending into the rectum 2 through the anus 5 along with and externally of the endoscope 8 or the laparoscope 8. A releasable conduit coupling means, which in this embodiment of the invention comprises releasable first clips 73, which are secured to the inflating conduit 14. Each first clip 73 comprises a pair of resilient arcuate legs 74 for extending around and gripping the endoscope 8 or the laparoscope 8. Typically, the first clips 73 are of a resilient stainless steel material. The inflating conduit 14 terminates in a first end 75, and the inflating conduit 14 and the first clips 73 are configured so that when the inflating conduit 14 is clipped externally onto the endoscope 8 or the laparoscope 8, the first end 75 of the inflating conduit 14 is located adjacent the leading end 17 of the endoscope 8 or the laparoscope 8. A bore 76 extends through the inflating conduit 14 for accommodating the inflating medium therethrough to the rectum 2.

The first pressure sensor 15 is located in the bore 76 of the inflating conduit 14 adjacent the first end 75 for detecting and monitoring the pressure in the rectum 2 during insufflation thereof. The wires 19 from the first pressure sensor 15 extend through the bore 76 of the inflating conduit 14 and exit the inflating conduit 14 through a port 78 adjacent the flow control valve 16. The wires 19 are sealably secured in the port 78 in order to avoid leakage of the inflating medium therethrough.

Turning now to the needle 32 and the third pressure sensor 30, in this embodiment of the invention a Teed port 79 extends from the hub 42 of the needle 32. The third pressure sensor 30, which in this embodiment of the invention may be any suitable pressure sensor is mounted on the port 79 and communicates with the bore 33 through the needle 32 for monitoring the pressure in the abdominal cavity 3. The wires 35 from the third pressure sensor 30 are clipped to the vacuum conduit 38 by

second clips 80. The second clips 80 secure the wires 35 to the vacuum conduit 38 from the needle 38 to the housing 11 of the insufflator 10.

Additionally, in this embodiment of the invention the compressed gas vessel 12, instead of comprising compressed air, comprises compressed carbon dioxide, and the carbon dioxide from the compressed gas vessel 12 is delivered through the pressure regulating valve 13 where the pressure of the carbon dioxide is regulated and in turn through the flow control valve 16 which is controlled by the microcontroller 18, and in turn through the inflating conduit 14 into the rectum 2.

In use, the inflating conduit 14 is releasably secured to the endoscope 8 or the laparoscope 8, as the case may be by the first clips 73 so that the first end 75 of the inflating conduit 14 substantially coincides with the leading end 17 of the endoscope 8 or the laparoscope 8. With the inflating conduit 14 secured to the endoscope 8 or the laparoscope 8 by the first clip 73, the endoscope 8 or the laparoscope 3 is inserted through the anus 5 into the rectum 2 with the leading end 17 of the endoscope 8 or the laparoscope 8 located in the rectum 2, and with the first end 75 of the inflating conduit 14 located in the rectum 2 adjacent the leading end 17 of the endoscope or the laparoscope 8. The carrier element 25 with the second pressure sensor 23 mounted thereon is inserted through the bore 9 in the endoscope 8 or the laparoscope 8 as already described with reference to the system 6 and apparatus 1 of Fig. 1. The needle 32 is then inserted into the abdominal cavity 3 through the navel 40 or through any other suitable part of the abdominal wall.

Otherwise, the system 70 and the apparatus 71 for insufflating and controlling the insufflating of the rectum 2 is similar to the system 6 and the apparatus 1 described with reference to Fig. 1, and the operation of the system 70 and the apparatus 71 is likewise similar to that already described with reference to the system 6 and apparatus 1 of Fig. 1. Furthermore, the advantages achieved by the system 70 and the apparatus 71 are similar to those achieved by the system 6 and the apparatus 1.

It is envisaged that the conduit coupling means of the apparatus 71 of Figs. 4 to 6,

instead of being provided by the first clips, may be provided by a cap, which typically would be of a silicone material, and would fit over the end of the endoscope or the laparoscope, such silicone caps are commonly used in connection with imaging devices to prevent contact between the lens of the imaging device and tissue. The inflating conduit would be releasably retained along the outer surface of the endoscope or the laparoscope between the cap and the endoscope or the laparoscope.

It is also envisaged that the first pressure sensor of the apparatus 71 of Figs. 4 to 6 may be located in a separate conduit to that of the inflating conduit, and the pressure sensor conduit would be releasably secured to the outer surface of the endoscope or the laparoscope by suitable conduit coupling means, such as a clip or clips, although most likely the inflating conduit and the pressure sensor conduit would be secured together to the endoscope or the laparoscope by a silicone cap. It will also be appreciated that the pressure sensor conduit may be provided by an elongated tubular element similar to the first tubular element 53 of the apparatus 50 of Figs. 2 and 3, and in which case the first pressure sensor would be located remotely of the first end of the endoscope or the laparoscope, and typically, would be located in the housing of the insufflator.

In the system 6 of Fig. 1 the apparatus comprises the first pressure sensor 15, and since the first pressure sensor 15 is recessed into the endoscope 8 or laparoscope 8, the apparatus 1 also comprises the endoscope 8 and the laparoscope 8 as the case may be. Additionally, the apparatus of Fig. 1 comprises the second pressure sensor 23 and the carrier element 24. The apparatus 1 also comprises the third pressure sensor 30. The apparatus 1 comprises the microcontroller 18 and the interface 20, as well as the wires 19, 28 and 35 which couple the first, second and third pressure sensors 15, 23 and 30 to the microcontroller 18. The inflating conduit 14 of the apparatus of Fig. 1 may or may not form part of the apparatus 1, however, if the inflating conduit 14 does not form part of the apparatus 1, the inflating conduit 14 would form part of the system 6 of Fig. 1. The apparatus of Fig. 1 may or may not comprise the flow control valve 16. However, in general, it is envisaged that the

apparatus 1 would comprise the flow control valve 16. Similarly, the apparatus 1 of Fig. 1 may or may not comprise the vacuum pump 36, although in general, it is envisaged that the apparatus 1 would comprise the vacuum pump 36. The needle 32 and the vacuum conduit 38 of the apparatus 1 of Fig. 1 may or may not constitute the apparatus, although in general, the needle and the vacuum conduit would form part of the apparatus 1 of Fig. 1. The system 6 of Fig. 1 includes the compressed air vessel 12 and the regulator 13, although the regulator 13 may comprise part of the apparatus 1 of Fig. 1. In cases where the apparatus 1 of Fig. 1 does not include the flow control valve 16 and the vacuum pump 36, these two components would form part of the system 6.

Turning now to the apparatus 50 and the system 51 of Figs. 2 and 3, in this embodiment of the invention neither the endoscope nor the laparoscope form a part of the apparatus 50 of the invention of Figs. 2 and 3. The first, second and third tubular elements 53, 54 and 55 do form part of the apparatus 50 of Figs. 2 and 3. Thereafter the components which constitute the apparatus 50 and the system 51 of Figs. 2 and 3 are similar to those described with reference to the apparatus 1 and the system 6 of Fig. 1.

Referring now to the system 70 and the apparatus 71 of Figs. 4 to 6, in this case the inflating conduit 14 together with the first pressure sensor 15 and the first clips 73 form part of the apparatus 71 of Figs. 4 to 6. In this case neither the endoscope 8 nor the laparoscope 8 form a part of the apparatus 71. Thereafter the remaining components form respective parts of the apparatus 71 and the system 70 in a similar manner as already described with reference to the apparatus 1 and the system 6 of Fig.1.

While in the apparatus 1 the first pressure sensor has been described as being located directly on the leading end of the primary insertion element, be it an endoscope, a laparoscope or other such insertion element, the first pressure sensor may be located at any suitable location adjacent the leading end thereof which would result in the first pressure sensor directly monitoring the pressure within the rectum

or other vessel in which the surgical or investigative procedure is being carried out.

While the apparatus has been described for maintaining the rectum in which an investigative or surgical procedure is being carried out insufflated to allow the procedure to be carried out, it will be readily apparent to those skilled in the art that the apparatus may be used for insufflating any vessel, lumen or cavity in a human or animal body during carrying out of an investigative or surgical procedure in such a vessel, lumen or cavity. For example, it is envisaged that the apparatus and the system may be used for insufflating a colon, an intestine, a stomach, an oesophagus or any other vessel, lumen or cavity in the digestive system of a human or animal subject. The apparatus and the system may also be used for insufflating a vessel, lumen or cavity in the arterial, venal or cardiovascular system of a human or animal subject.

Additionally, the system and the apparatus may be used for insufflating and controlling the insufflation of a lung in which an investigative or surgical procedure is being carried out, and in which case, leakage into the thoracic cavity could arise. In which case the third pressure sensor would be located in the thoracic cavity or would be provided for monitoring the pressure in the thoracic cavity in the event of leakage from the lung being insufflated. Additionally, it is envisaged that the system and apparatus may be provided for insufflating and controlling the insufflation of the thoracic cavity during the carrying out of an investigative or surgical procedure in the thoracic cavity, and in which case, the third pressure sensing means would be located in the abdominal cavity or one or both lungs, or would be provided communicating with the abdominal cavity or one or both lungs for monitoring an increase in pressure in the abdominal cavity or the lung or lungs resulting from leakage from the thoracic cavity into the abdominal cavity or the lung or lungs.

While the apparatus has been described as comprising a third pressure sensor, in certain cases, it is envisaged that the third pressure sensor may be omitted. It is also envisaged that in certain cases, the second pressure sensor may also be omitted. Indeed, in its basic form the apparatus for controlling insufflation of a vessel

will comprise the first pressure sensing means and the control means communicating with each other, whereby the controller would be configured to control delivery of the inflating medium into the vessel being insufflated.

While the microcontroller has been described as being responsive to the third pressure sensor for controlling the vacuum pump in order to prevent the air pressure in the abdominal cavity exceeding the third predefined pressure, it is envisaged that the microcontroller may be responsive to the pressure monitored by the third pressure sensor for controlling operation of the flow control valve in order to prevent the pressure within the abdominal cavity exceeding the third predefined pressure. Indeed, in certain cases, it is envisaged that the microcontroller may be responsive to the pressure monitored by the third pressure sensor for operating both the vacuum pump and the flow control valve simultaneously or sequentially for preventing the pressure in the abdominal cavity exceeding the third predefined pressure.

It will be appreciated that while the control means has been described as comprising a microcontroller, any other suitable control means may be provided, which may be any type of signal processor, for example, a microprocessor.

It will also be appreciated that while the first, second and third pressure sensors have been described as being piezoelectric pressure sensors, any other suitable first, second and third pressure sensing means may be provided.

It is also envisaged that while the first, second and third pressure sensors have been described as being hardwired to the microcontroller 18, the signals from the first, second and third pressure sensors indicative of the respective air pressures could be wirelessly communicated to the microcontroller 18, for example, by radio transmitters which could operate under any of the near and medium field communication protocols, for example, a Near Field Communication protocol, Bluetooth or other suitable wireless communications protocol, and signals from the transmitters would be received by a radio receiver communicating with the microcontroller.

It is also envisaged that while it is preferable, the first pressure sensing means instead of being located on the primary insertion element adjacent the leading end thereof, the first pressure sensing means could be mounted on a carrier element which would be inserted into the vessel in which the procedure is being carried out through the primary insertion element, and typically, through the bore 9 of the primary insertion element. The location of the carrier element of the first pressure sensing means in the vessel in which the procedure is being carried out could be adjusted so that the first pressure sensing means is located at the exact location at which the pressure of the inflating air is to be monitored, which typically, would be at a location adjacent the leading end of the primary insertion element.

It will also be appreciated that while the gaseous inflating medium for insufflating the vessel has been described as air or carbon dioxide, any other suitable gaseous inflating medium may be provided. Indeed, in cases where the gaseous inflating medium is air, the air could be delivered to the vessel being insufflated by an air blower or an air pump.

It is also envisaged that in the insufflation of certain vessels in the human or animal body in which an investigative or surgical procedure is being carried out, the inflating medium may be a liquid inflating medium, for example, a saline solution, water or other suitable liquid. In particular, it is envisaged that in the case of insufflating the colon during an investigative or surgical procedure being carried out, the insufflation of the colon may be carried out by delivering a liquid inflating medium to the colon. Needless to say, a liquid inflated medium may also be used in the insufflation of other vessels in a human or animal body.

While the tubular elements of the apparatus 50 have been described as terminating in first ends in bulbs closed by membranes, other suitable arrangement of membranes adjacent the first ends of the tubular elements may be provided for detecting the pressure in the corresponding vessel. Indeed, in certain cases the first end of some of the tubular elements may be open to communicate directly with the

corresponding vessel. In which case, the fluid in the bore of the tubular element would be the same as the fluid in the vessel, and since the fluid in the bore of the tubular element would be static (not flowing), the pressure detected by the corresponding pressure sensor would be the true pressure of the air in the corresponding vessel.

It is also envisaged that the first tubular element may be configured to be secured externally onto the endoscope or laparoscope or other such primary insertion element, and in which case, suitable clips, which would typically be configured for releaseably securing the first tubular element externally onto the endoscope or laparoscope would be provided.

It will also be appreciated that where the tubular elements are provided closed at both ends, the fluid in the bore may be any suitable fluid, air or other gas, or liquid.

It is also envisaged that the microcontroller may be configured to store two third predefined pressures, namely, an upper third predefined pressure and a lower third predefined pressure. In which case, it is envisaged that the microcontroller would be configured to control the vacuum pump 36 so that when the pressure in the abdominal cavity, or other such external vessel reached the upper third predefined pressure, the vacuum pump 36 would be operated to evacuate the abdominal cavity, until the pressure monitored by the third pressure sensing means fell to the lower third predefined pressure, at which case, the microcontroller would deactivate the vacuum pump 36 until the pressure monitored by the third pressure sensing means in the abdominal cavity or other such external vessel reached the upper third predefined pressure. Typically, the upper third predefined pressure would be of value of approximately half the first predefined pressure, and the lower third predefined pressure would be of value of approximately one quarter of the first predefined pressure, although needless to say, the upper and lower third predefined pressures may be of any suitable or desirable values.

It will also be appreciated that the first, second and third predefined pressures may

be pre-programmed into the microcontroller.

The invention is not limited to the embodiments hereinbefore described, which may be varied in construction and detail.

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Claims

1. Apparatus for controlling insufflation of a vessel in a human or animal body with a fluid inflating medium, the apparatus comprising a first pressure sensing means configured for monitoring the pressure of the inflating medium in the vessel, a second pressure sensing means for monitoring the pressure of the inflating medium in a vessel adjacent the vessel being insufflated, and communicating with the vessel being insufflated, and a control means for controlling delivery of the inflating medium to the vessel being insufflated, the control means being responsive to the pressure of the inflating medium monitored by the first pressure sensing means for controlling delivery of the inflating medium to the vessel being insufflated, and the control means being responsive to the pressure of the inflating medium monitored by the second pressure sensing means for one of producing an alarm signal in response to the monitored pressure reaching a predefined pressure for the adjacent vessel, and controlling delivery of the inflating medium to the vessel being insufflated for preventing the pressure in the adjacent vessel exceeding the predefined pressure for the adjacent vessel.

2. Apparatus as claimed in Claim 1 in which the second pressure sensing means is mounted on a carrier element, the carrier element being configured to extend into the adjacent vessel.

3. Apparatus as claimed in Claim 1 in which the second pressure sensing means is located externally of the human or animal body, and a tubular element extending between a first end and a second end is configured so that the first end extends into the adjacent vessel and the second end extends externally of the human or animal body, the tubular element having a bore extending therethrough between the first and second ends, and a static fluid located in the bore, the pressure of the static fluid in the bore being indicative of the pressure of the inflating medium in the adjacent vessel, and the second pressure sensing means communicates with the bore of the tubular element adjacent the second end thereof for monitoring the pressure of the static fluid therein.

4. Apparatus as claimed in any preceding claim in which the first pressure sensing means is configured for monitoring the pressure of the inflating medium directly in the vessel.

5. Apparatus as claimed in any preceding claim in which the control means is responsive to the pressure of the inflating medium in the vessel being insufflated monitored by the first pressure sensing means for controlling delivery of the inflating medium to the vessel for maintaining the pressure of the inflating medium in the vessel substantially at a predefined pressure for the vessel being insufflated.

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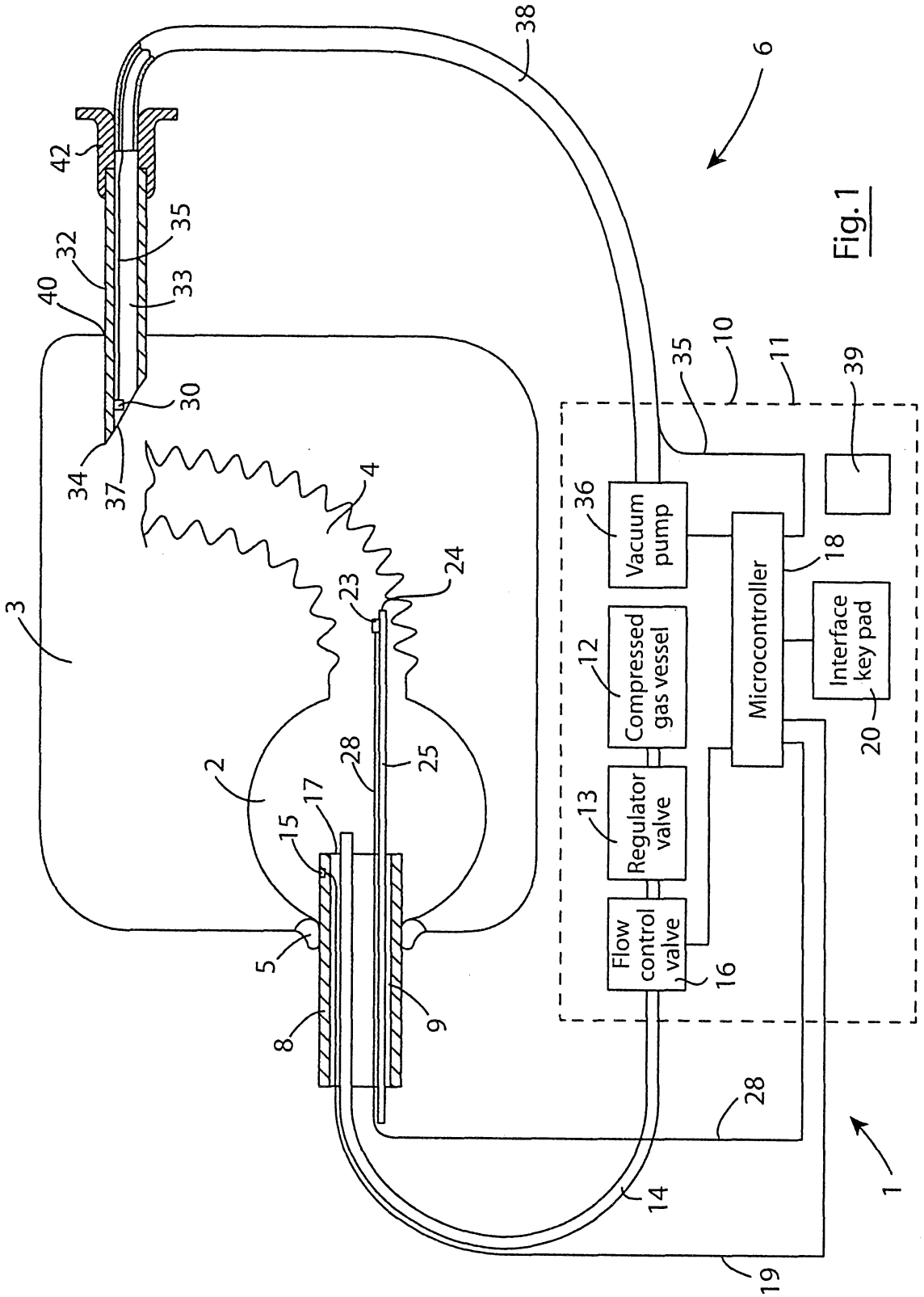
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Vacuum pump
Compressed gas vessel
Regulator valve
Flow control valve
Microcontroller
Interface key pad
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Fig. 1

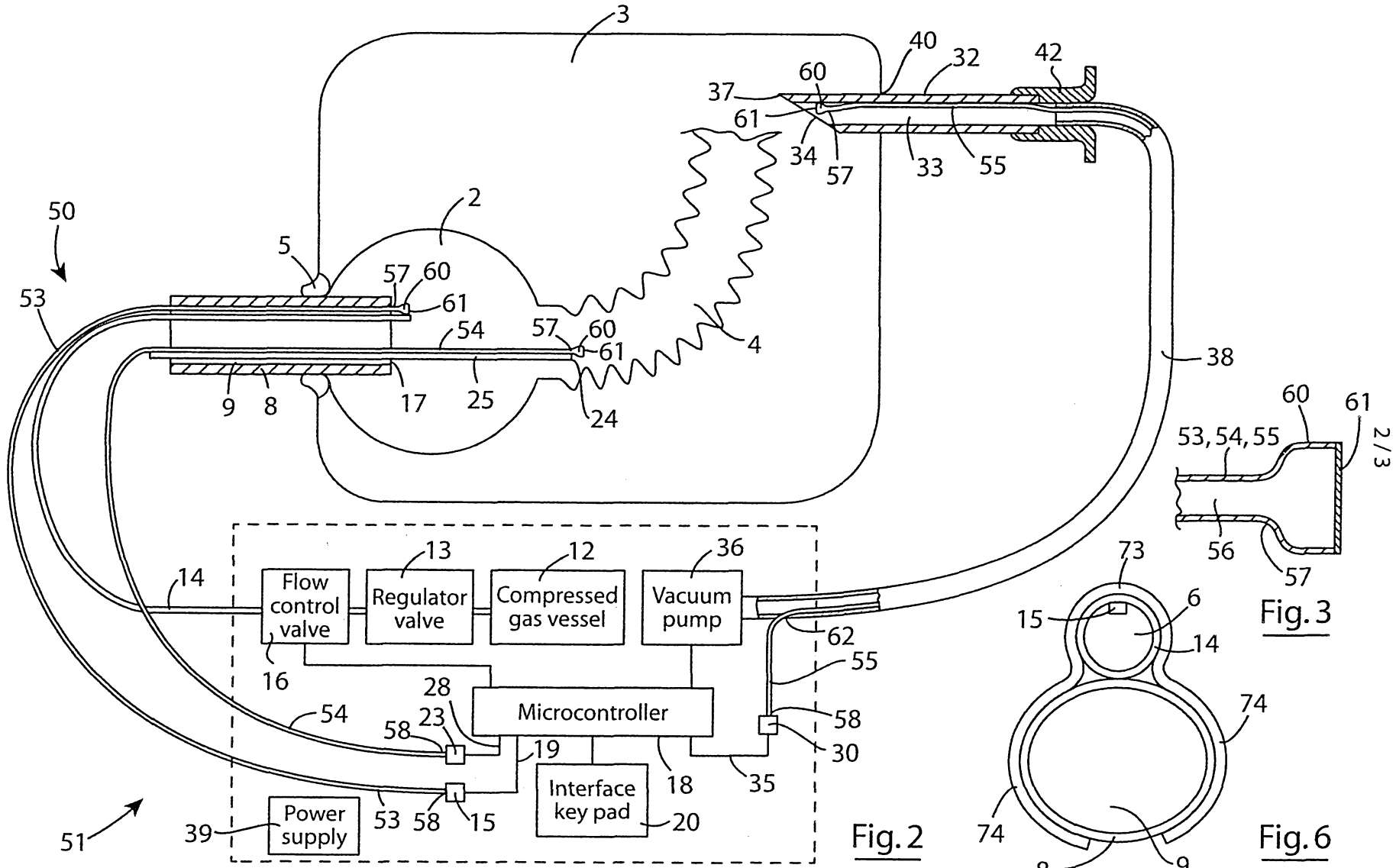
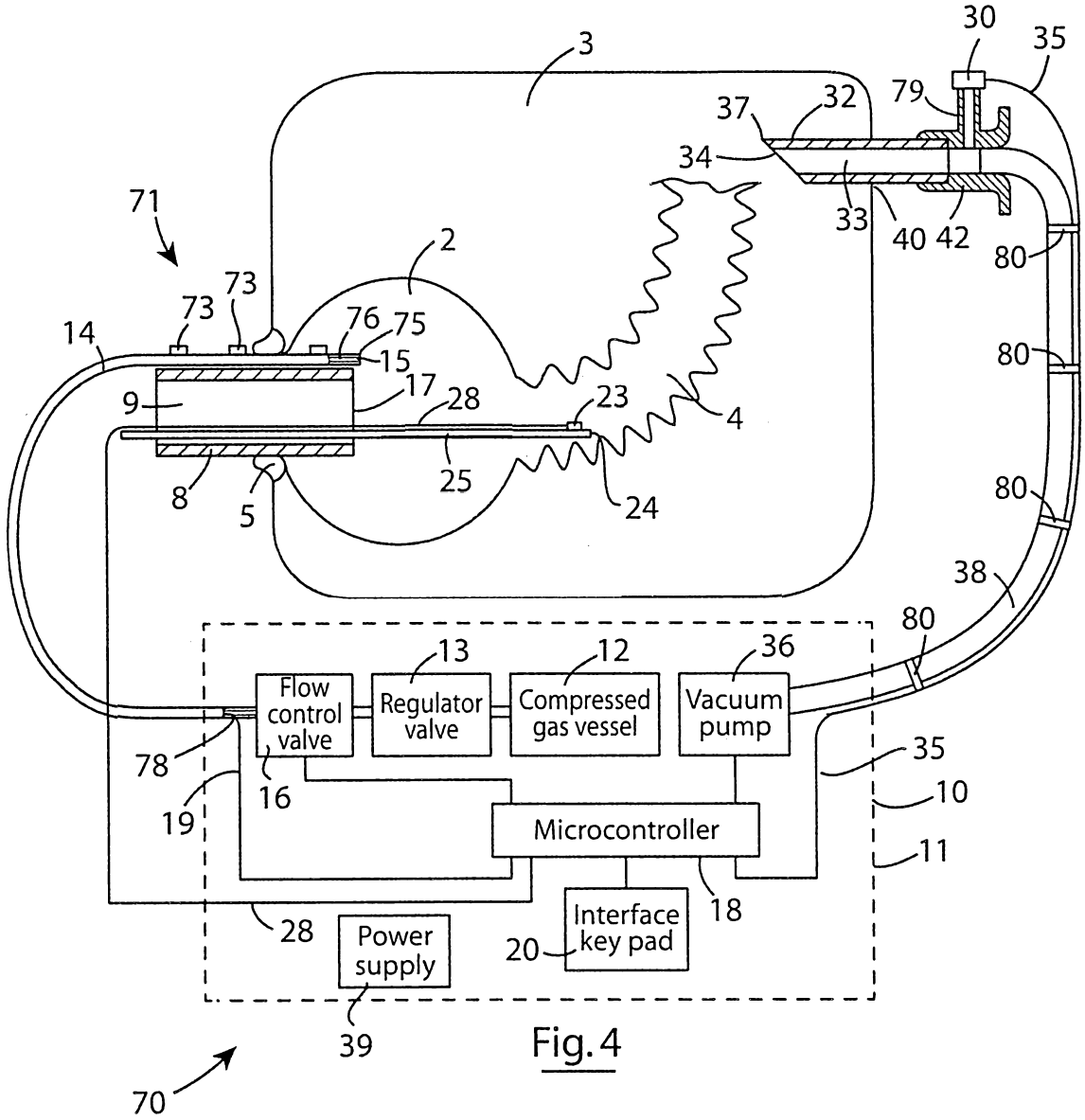


Fig. 2

Fig. 3

Fig. 6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80
80
38
80
13
12
36
Flow control valve
Regulator valve
Compressed gas vessel
Vacuum pump
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Microcontroller
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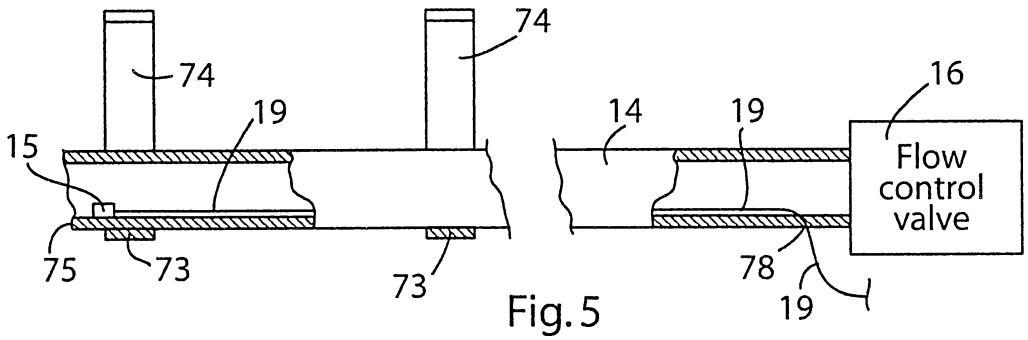
18
28
Power supply
Interface key pad
20
39
70

Fig. 4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74
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73
14
19
16
Flow control valve
78
19

Fig. 5