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— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for all designations*
— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for the following designation US*
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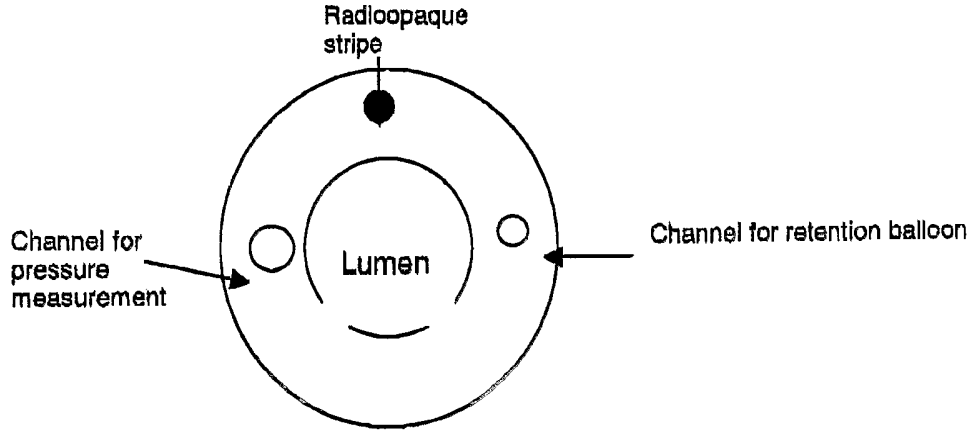
(54) Title: INTRA-ABDOMINAL PRESSURE MONITORING UNINARY CATHETER



(57) Abstract: A urinary catheter apparatus for measuring the internal pressure of a human or other mammal comprising an elongated urinary catheter having at least two lumen extending longitudinally there-through, at least one channel where the wall is composed of a material being substantially impermeable to liquid, where the interior of the catheter allows the transmission of change of pressure through lumen via a pressure transmitting medium, and pressure sensor means for measuring the pressure of pressure transmitting medium.

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INTRA-ABDOMINAL PRESSURE MONITORING URINARY CATHETER

The following statement is a full description of the invention and includes the best method of performing it.

This invention relates medical diagnostic equipment and methods and is particularly concerned measuring intra-abdominal pressure using direct or remote sensing of pressure within the organ in particular intra-abdomial pressure and related pressure within adjacent organs

The following statement is a full description of the invention and includes the best method of performing it.

Until the advent of recent publication in relating to renal failure and complication of pressure after surgery few considered intra-abdominal pressure measurement to be important. It is now recognised as an important part of post-operative care.

Currently intra-abdominal pressure is measured using a urinary catheter requiring insertion of an extra T-piece or a needle directly into the urinary catheter to allow the pressure to be measured using a transducer or a manometer.

A wide variety of innovative techniques have been used to measure IAP in nearly every part of the abdominal cavity, including the rectum, stomach, urinary bladder, uterus, liver, inferior vena cava, and free within the intra-peritoneal cavity

Rectal pressure measurement was experimentally popular in the early part of this century, using a Miller Abbott tube .It would appear generally it is a simple but slightly unreliable technique.

McCarthy in 1982 in a study of 12 patients undergoing urodynamic evaluation and laparoscopic tubal ligation found that there was a good correlation between intra-abdominal and rectal pressures. He expressed concern that reliability of this technique required the catheter to remain 10cm above the anal verge otherwise the values were greater than the abdominal values. Presumably this was due to the spontaneous activity of the rectal sphincters . Shafik used rectal pressure in many of his experiments in humans on rectal detrusor muscle activity . He used a urinary catheter with an outer diameter of 1.2mm and found that there was good visual correlation between intravesical and rectal pressures.

Intra-gastric measurement was used in the early part of this century with a Hamilton manometer, which afforded the simplest and most reliable technique at the time.

Simple techniques using nasogastric tubes to measure IAP have been used by Cullen, Fietsam and Collee. Concern has been expressed about simple perfusion techniques using a nasogastric tube, and Lacey in an animal study found that the use of gastric pressure measurement through an irrigational portal of the nasogastric tube is not reproducible. Collee, from London, used an unperfused nasogastric tube to obtain 141 paired measurements in 26 general surgery patients in ICU. He found using appropriate statistical modelling, that gastric pressure may be 2.5cm of water above or below intra-vesical pressure.

This is discussed in more detail in Chapter 5. The intra gastric route has two specific advantages. It can be used when there has been trauma to the bladder or where the patient does not have a urinary catheter in place. Gastric pressures are also very useful when there is a tense pelvic haematoma following pelvic trauma, as vesical pressures in this situation may not reflect general IAPs.

Direct cannulation of the peritoneal cavity had been used experimentally, but it is not as accurate as the intravesical technique and is invasive .

Motew used a Verres needle to measure IAP in an experiment on 12 women undergoing tubal ligation. The use of a Verres needle to measure IAP may not be accurate during flow states. It is also dependent on the degree of muscle relaxation required for the laparoscopy. Obeid and colleagues, from Detroit, reported in 1995 a comparison of IAP measurement using four techniques in 26 patients. These included an intra-gastric route via a simple NG, a laparoscopic insufflator, rectal pressure via a modified oesophageal stethoscope and a standard intra-vesical method with a urinary catheter. Obeid found that with a standard 6mmHg rise in IAP, as measured by the insufflator, this was best correlated with the intravesical measurements, with a rise of 5.7mmHg (±9.8). The gastric and rectal pressures were less reliable with the following changes recorded, −0.7± 9.8mmHg and 3.3± 8.8mmHg respectively. He found the rectal and gastric pressures were more position dependent and less reliable than the intravesical approach. The specific limitation of the laparoscopic technique in Obeid's study is the lack of validation of the Stryker endoscopy high flow insufflator, which was used as the gold standard to compare with the other methods. In clinical practice pressures measured with such laparoscopic insufflators may fluctuate widely during surgery. This can be related to

the depth of anaesthesia and port mechanics including blockage with blood or other products.

Because of the fluid dynamics in the abdominal cavity, IAP can also be measured through a central venous line if its tip is in the inferior vena cava. This has been utilised by a number of researchers . Lacey in a study of rabbits, comparing different sites of IAP measurement found an excellent correlation between IVC pressures and vesical IAP readings .. It should be remembered that these experiments were performed in rabbits, under general anaesthesia.

In addition Lacey found that there was poor correlation between superior vena cava, rectus abdominus and rectal pressure

The gold standard for IAP measurement has been the intravesical technique . Unfortunately Kron did not test the reliability of his technique and validation of the intravesical technique was undertaken and published by Iberti and colleagues at Mount Sinai medical centre in 1989. In a study of post-operative patients with closed intra-abdominal drains they compared urinary catheter measurements with those recorded from the abdominal drains. They used the pubis as the zero point which may give rise to slightly reduced as it lies above the mid point of the abdominal cavity.

Iberti's investigations revealed a good correlation between intra-abdominal and intra-vesical pressure. In addition he found that there was little effect of positive end expiratory pressure (PEEP) on IAP. I have modified the technique slightly and the technique used in this project is according to the protocol below;

Other techniques, including installation of saline into the bladder and holding the catheter in the air have also been described. They are cumbersome, do not provide on-line monitoring or are time consuming.

Previously the direct on-line monitoring of urinary catheters has not been reported as a measure of intra-abdominal pressure. Urinary catheters usually contain two lumens, one for the balloon and one for the urine flow.

For patients with haematuria, triple lumen catheters have been used for years. They allow irrigation through the third lumen. They have not been used or reported to measure intra-abdominal pressure.

The present problems with intra-abdominal pressure measurement are overcome by the present invention, which provides direct access to the triple lumen urinary catheters third lumen, allowing direct transducing of intra-abdominal pressure directly, without interruption of urine flow.

In one embodiment of the invention, the urinary catheter contains a Luer lock, allowing direct connection to a transducing manometer or remote sensor (figure 1).

The line is irrigated with a liquid and connected to a pressure transducer for on-line pressure measurement. A cross section of the tube is shown in figure 2.

In yet another aspect or embodiment the device uses, a T-piece attached either to the pressure transducing channel to allow remote pressure reading. Optionally when a temperature sending means is required this may be added to the catheter.
In an embodiment of the present invention a pressure transmitting channel which is filled with a medium either air or liquid can be attached to a Luer lock with a three way tap allowing irrigation or perfusion of that channel. The change in pressure at the end of the catheter is thereby transmitted and communicated to the to the pressure transducing medium.
In an embodiment of the invention the pressure transmission can be connected to a manometer or liquid column at he patient bedside.

The pressure measuring urinary catheter may be left in the patient for unspecified times and measurement recoded continuously or at intervals. The catheter may be made of a material meeting international standards for medical use, silicone, pvc latex or other material.

The urinary catheter is inserted through the urethra, under standard sterile conditions, with use of the retention balloon insufflated with saline.

The claims defining the invention are as follows:

1. A urinary catheter apparatus for measuring the internal pressure of a human or other mammal using:

   an elongated urinary catheter having at least two lumen extending longitudinally there-through, a least one channel where the wall is composed of a material being substantially impermeable to liquid and where the interior of the catheter allows the transmission of change of pressure through said lumen via a pressure transmitting medium and

   pressure sensor means for measuring the pressure of said pressure transmitting medium.

2. The pressure-measuring device of claim 1 may be of a luer-lock direct female-male connection type or a three-way tap, or a T-piece insertion.
3. An apparatus according to claim 2 wherein said pressure transmitting material is air
4. An apparatus according to claim 3 wherein said pressure transmitting material is a saline solution
5. An apparatus according to claim 4 wherein said pressure sensor means further comprises a pressure transducer
6. An apparatus according to claim 5 wherein said pressure sensor means further comprises a manometer located external to said human or mammal
7. An apparatus according to claim 6 wherein said pressure sensor means further comprises a manometer
8. An apparatus according to claim 7 which is made of silicone

9. In the case of the intra-abdominal pressure measuring urinary catheter, the connections may be made of different materials, silicone, PVC or other material consistent with standard medical equipment.

10. An intra-abdominal pressure-measuring catheter as herein described with reference to the accompanying drawing.

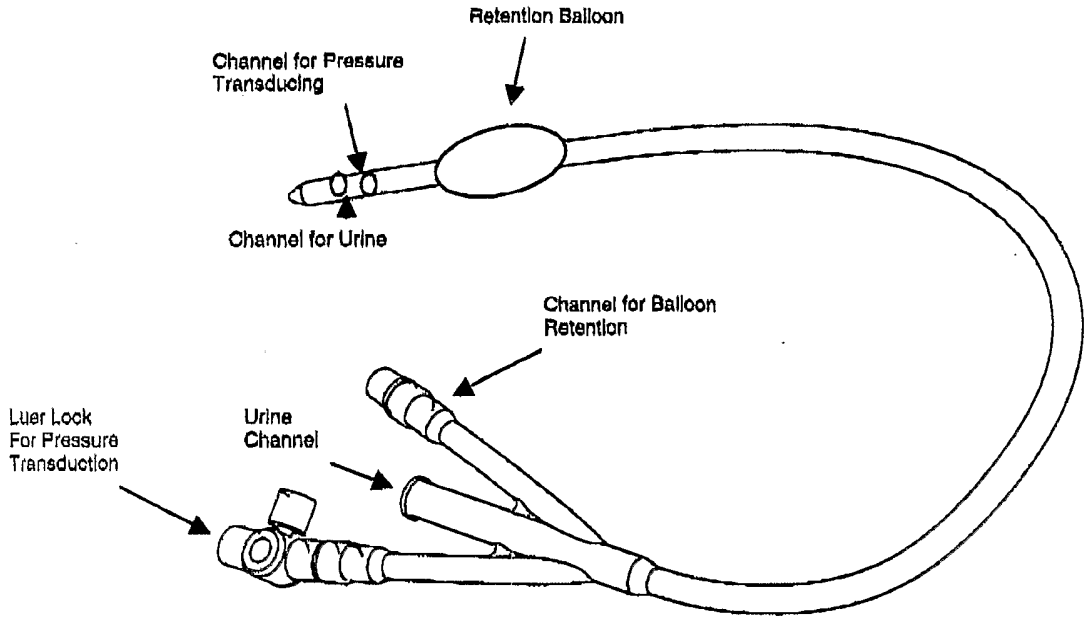
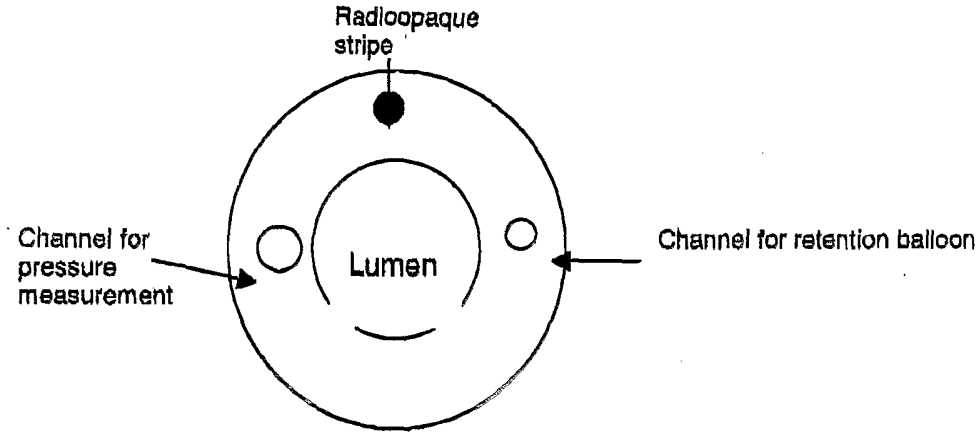


Figure 1 Components of the Intra-abdominal Pressure Measuring Urinary Catheter

Figure 2 Cross Section of Intra-abdominal Pressure Measuring Urinary Catheter



INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2004/000282

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]: A61M 25/12, A61M 25/00

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DWPI: IPC A61M 25/00, A61B, A61D; Keywords: IAP, pressure, bladder, urinary, organ, rectum, stomach, abdomen, gastric, measure, monitor, sensor, detector, transducer, manometer, channel, lumen, liquid, fluid, air, gas, saline, luer, balloon

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5385563 A (GROSS) 31 January 1995 See entire document	1-10
X	GB 2123300 A (UROTEK INC.) 1 February 1984 See entire document	1-10
X	US 4217911 A (LAYTON) 19 August 1980 See entire document	1-10

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

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"O" Document referring to an oral disclosure, use, exhibition or other means

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"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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
7 April 2004	28 APR 2004
Name and mailing address of the ISA/AU	Authorized officer
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INTERNATIONAL SEARCH REPORT

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	JP 11155821 A (KAWASUMI LAB INC) 15 June 1999 See abstract; figures 1, 5-8	1-10
X	DE 19530440 A1 (ECHTLE) 20 February 1997 See in particular abstract; figures 1, 2	1-10
X	US 2002065472 A1 (BROCKWAY et al) 30 May 2002 See in particular abstract; paragraph 0013-0034; figures 1-5, 8	1-10
X	EP 0258690 B1 (HEINZ) 9 March 1988 See in particular abstract; figures 1, 4a-4c	1-10

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/AU2004/000282

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
US	5385563						
GB	2123300	CA	1176929	DE	3324747	FR	2530149
		JP	59022561				
US	4217911	CA	1131045	US	4301811		
JP	11155821						
DE	19530440						
US	20020065472						
EP	0258690	DE	3629732				

END OF ANNEX