Abstract:

A device and method for reducing unnecessary ionizing radiation to patients undergoing a voiding cystourethrogram (VCUG) is provided. The device can include a sensor which detects patient voiding and then actuates an alarm that alerts the radiologist to begin taking x-ray images of the patient. The device can be configured so that the sensor directly actuates a fluoroscopy machine to begin taking x-ray images of the patient once the sensor detects the patient has begun voiding.
VOIDING CYSTOURETHROGRAM RADIATION REDUCING DEVICE

BACKGROUND

Field

[0001] This application is directed to devices and methods for reducing patient exposure to radiation during a voiding cystourethrogram.

Background

[0002] Voiding cystourethrogram (VCUG) is a fluoroscopic examination that is commonly performed in pediatric patients. VCUG uses ionizing radiation to examine how well the patient's kidneys, ureters, bladder, and urethra are working. Urine normally travels from the kidneys via the ureters to the bladder and exits the human body through the urethra. Vesicoureteral reflux (VUR) is an abnormal backward flow of urine from the bladder into the ureters and/or kidneys. Newborns with VUR may be lethargic with failure to thrive, while infants and young children typically present with pyrexia (fever), dysuria (painful urination), frequent urination, and gastrointestinal tract symptoms.

[0003] In healthy individuals, the ureters enter the urinary bladder obliquely and run submucosally for some distance. In addition, the ureters' muscular attachments help secure and support the ureter during storage and voiding of urine. In people with VUR, this sealing mechanism fails with resultant retrograde flow of urine towards the kidney. Bladder pressure increases during urination, making it more likely that VUR will occur during urination. Accordingly, VCUG requires fluoroscopic imaging of the patient during urination so that the patient's propensity for VUR is evaluated under the conditions where VUR is most likely to occur.

[0004] VCUG examination consists of initially inserting a Foley catheter through the urethra and into the urinary bladder. The bladder is then filled with a contrast solution. Multiple fluoroscopic x-ray images of the bladder, ureters, and kidneys are then taken during the examination. In addition, x-ray images are taken of the urethra while the patient is voiding in order to see the entire anatomy of the urethra and flow dynamic. These images allow the radiologist to diagnose any anatomical or functional abnormalities in the flow of urine through the urinary system.
SUMMARY

[0005] A device is disclosed in accordance with certain embodiments. The device comprises: a sensor configured to detect a liquid or liquid flow and generate a signal, the sensor comprising a component attached to a backing material; and an actuator operably coupled to the sensor, wherein the actuator is configured to actuate an alarm upon receiving the signal, or actuate an imaging device upon receiving the signal, or actuate both an alarm and an imaging device upon receiving the signal.

[0006] In some embodiments, the alarm generates a visual and/or audible alert. The visual and/or audible alert may comprise a discreet flashing light.

[0007] In some embodiments, an electrical property of the component changes when the component comes into contact with urine. The electrical property may be selected from the group consisting of a resistance and a capacitance.

[0008] In some embodiments, the device may further comprise a urinary catheter having an outer surface in contact with the component.

[0009] In some embodiments, the backing material has a funnel shape with a wide end of the funnel shape oriented toward a distal portion of the urinary catheter. The narrow end of the funnel shape may be secured to the outer surface of the urinary catheter.

[0010] The present disclosure further relates to devices and methods for reducing patient exposure to radiation during a fluoroscopic imaging procedure. In certain aspects of the method herein disclosed a patient is catheterized with a urinary catheter by advancing a distal portion of a urinary catheter through the urethra and into the bladder. An adhesive sensor is positioned in proximity to a portion of the urinary catheter that extends outwardly from the urethra of the patient. The sensor is configured to generate a signal in response to the sensor detecting a liquid or a liquid flow. Contrast agent is initially instilled through the urinary catheter and into the patient's bladder. After the patient's bladder is filled with contrast agent, the voiding portion of the VCUG examination can begin. When the patient starts voiding, a signal generated by the sensor in response to detection of liquid or liquid flow actuates the imaging device, causing the imaging device to begin taking fluoroscopic images of the patient.
Optionally, the sensor generates a signal that actuates an alarm that informs the radiologist that the patient has begun voiding, alerting the radiologist to manually begin taking fluoroscopic images of the patient. In certain aspects of the method, the alarm generates a visual or audio alert that is perceived by the radiologist. Optionally, the alarm is discreet to avoid distressing the patient.

In certain aspects of the method, the patient is a pediatric or neonatal patient. Optionally, the catheter is a Foley catheter. In some aspects of the method, the sensor is attached to a portion of the urinary catheter.

Certain aspects of the disclosure are directed to a device for reducing patient exposure to radiation during a medical imaging procedure. The device includes a sensor configured to detect liquid or flow of a liquid. The sensor is attached to an adhesive bandage that reversibly attaches the sensor to a surface. The device includes an actuator that activates an alarm or the imaging device upon the actuator receiving a signal from the sensor that a liquid or liquid flow has been detected. Optionally, the device has an alarm configured to emit a discreet audible alert or a discreet flashing light upon the alarm being activated by the actuator.

Certain aspects of the disclosure are directed to a kit for reducing patient exposure to radiation during a medical procedure. The kit includes an alarm and a disposable adhesive sensor configured to activate the alarm when the sensor detects a liquid or a liquid flow.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments are depicted in the accompanying drawings for illustrative purposes, and should in no way be interpreted as limiting the scope of the embodiments. Furthermore, various features of different disclosed embodiments can be combined to form additional embodiments, which are part of this disclosure.

FIGURE 1 illustrates an embodiment of a device for alerting a physician of patient voiding.

FIGURE 2 illustrates an embodiment of a urinary catheter.

FIGURE 3 illustrates a placement on a male patient of an embodiment of a device for alerting a physician of patient voiding.
FIGURE 4 illustrates a placement on a female patient of an embodiment of a device for alerting a physician of patient voiding.

FIGURE 5 illustrates a method of use in a voiding cystourethrogram of an embodiment of a device for alerting a physician of patient voiding.

FIGURE 6 illustrates a funnel-like shaped sensor for use in a voiding cystourethrogram, wherein the sensor has a backing and a component configured to detect a liquid or liquid flow.

FIGURES 7A and 7B illustrate an embodiment of the funnel-like shaped sensor of FIGURE 6 in open and closed configurations, respectively.

DETAILED DESCRIPTION

Certain aspects of the present disclosure are generally directed to devices for reducing patient exposure to radiation during VCUG. Each and every feature described herein, and each and every combination of two or more of such features, is included within the scope of the present disclosure provided that the features included in such a combination are not mutually inconsistent.

One difficulty with VCUG is that the radiologist cannot accurately predict when pediatric patients will start voiding, especially in younger children and infants who cannot follow direction. In addition, shy and nervous teenagers have a difficult time urinating on the fluoroscopic table while doctors, nurses, and radiology technicians are watching them. These factors significantly increase fluoroscopic times, which equates to unnecessary radiation for the radiosensitive young population. Furthermore, some of these pediatric patients with VUR require multiple VCUG examinations, which can cause high cumulative doses throughout their childhood and beyond.

Medical imaging studies have exponentially increased in utilization, producing higher levels of patient exposure to radiation. In 2006, the average annual effective dose per individual in the U.S. was 6.2 mSv, a figure that has almost doubled over the last 25 years. See Measurement NCoRPa. Ionizing Radiation Exposure of the Population in the United States: NCRP REPORT No. 160. 2009; 136. On average, radiation exposure for pediatric patients can be equivalent to 9 days to 6 months of background radiation during a single VCUG examination. Increased awareness of the doses and risks from medical

[0026] The current approach to limit radiation exposure associated with VCUG is to keep radiation dose as low as reasonably achievable by manipulating the fluoroscopic machine, tightly collimating the x-ray machine, decreasing fluoroscopic time, decreasing frame rate, utilizing pulsed imaging, etc. Nonetheless, the radiologist remains uncertain regarding when the pediatric patient will start urinating, the largest contributing factor for increased radiation dose. This leads to increasing the amount of unnecessary radiation by taking x-ray images in anticipation of the pediatric patient voiding. Sometimes this process of waiting for the patient to urinate may take over 30 minutes, leading to a substantial amount of radiation exposure.

[0027] The present disclosure is directed toward a device for reducing radiation exposure during VCUG. One aspect of the device is to reduce unnecessary ionizing radiation to patients (especially in radiosensitive pediatric and neonatal population) who are undergoing a VCUG. The device may include a sensor for detecting patient voiding and a means for alerting the radiologist when the patient begins voiding. The device may include a disposable adhesive sensor that can be placed on the Foley catheter or genital area to detect passage of urine or contrast material. Additionally or alternatively, the device may be configured to actuate the imaging device. Additionally or alternatively, the device may be configured to delay actuating the imaging device for a time period sufficient to allow a technician to remove the catheter from the patient before the imaging device begins to emit radiation. The device may be configured to allow a user to adjust the delay time period that is interposed between the device detecting patient voiding and the device actuating the imaging device.

[0028] FIGURE 1 depicts a device 100 for alerting a physician of patient voiding. The device 100 can include a sensor 102 for detecting patient voiding. The sensor 102 may be configured to generate a signal when the sensor 102 detects a liquid. The sensor 102 may include a sensing component 104 that changes electrical properties based on contact with a body fluid. For example, the resistance or capacitance of the component 104 may change
upon contact of the component 104 with a liquid. The liquid that activates the sensor 102 may be saline, a contrast agent, or a body fluid. Additionally or alternatively, the sensor 102 may include a transducer 106 configured to detect fluid flow. For example, the transducer 106 may be an ultrasonic or optical flow meter. The component 104 that changes electrical property on contact with a liquid or fluid (such as urine) thereby generates the signal. It is referred to herein interchangeably as either the sensing component, or simply as the component. The alarm 112 can be adapted to respond to the signal from the component 104 that voiding has begun. For example, the alarm 112 can include a switch that serves to receive the signal generated by the sensor 102 and activates the alarm 112 in response to receiving the signal from the sensor 102. The alarm 112 can include a base or motherboard that interfaces with the sensor 102. The base or motherboard of the alarm 112 can be battery powered.

[0029] The sensor 102 may include a bandage 108. The sensor 102 may be attached to a bandage 108 having an adhesive surface configured to removably couple the sensor 102 to a surface. The sensor 102 may include an adhesive 110 configured for securing the sensor 102 in proximity with a site of patient excretion. For example, the adhesive 110 may secure the sensor 102 in proximity with a patient's external urethral orifice. The adhesive 110 may gently and reversibly attach the sensor 102 to the patient's skin, allowing the sensor 102 to be removed with minimal patient discomfort. The adhesive 110 may secure the sensor 102 to at least a portion of the catheter used to access the patient's bladder. The adhesive 110 may secure the sensor 102 to both the patient's skin and the catheter used to access the patient's bladder. The adhesive 110 may secure the sensor 102 to a proximal portion of the catheter tubing that extends outward of the patient's urethra.

[0030] The sensor 102 may be electronically coupled to an alarm 112. The sensor 102 may be disposable or reusable. The alarm 112 may be disposable or reusable. The sensor 102 may be electronically coupled to the alarm 112 by an electrical conductor 114. The electrical conductor 114 may include a jack 113 that reversibly couples the sensor 102 to the alarm 112. The sensor 102 may be disposable and coupled to a reusable alarm 112 by a jack 113. After use, the disposable sensor 102 may be disposed of by removing the sensor 102 from the alarm 112 by disconnecting the jack 113 from the alarm 112. The alarm 112 can be reused with a second disposable sensor 102 by connecting the second disposable sensor 102
to the alarm 112 by a jack 113. Additionally or alternatively, the sensor 102 maybe electronically coupled to the alarm 112 through wireless or cordless technology. For example, the sensor 102 may be coupled to the alarm 112 through light, radio waves, microwaves, infrared radiation, bluetooth, or ultrasound.

[0031] The alarm 112 may include a display 116. The alarm may include a plurality of displays 116. The display 116 may be a light. The display 116 may be a light that illuminates or flashes or changes color in response to a signal from the sensor 102. The alarm 112 may include an audio speaker 120. The alarm 112 may include means for actuating an imaging device. The alarm 112 may be configured to generate a signal in response to the alarm 112 receiving a signal from the sensor 102. The alarm 112 may be configured to generate a signal that causes the imaging device to initiate the emissions of x-rays. The sensor 102 may be configured to generate a signal that directly or indirectly actuates the imaging device. The sensor 102 may be configured to generate a signal that actuates the alarm 112 or the imaging device when the sensor 102 detects a liquid. Additionally or alternatively, the sensor 102 may generate a signal that actuates the alarm 112, causing the alarm 112 to illuminate a display 116 or emit a sound from the audio speaker 120, which in turn alerts the radiologist to actuate the imaging device.

[0032] FIGURE 2 depicts a urinary catheter 200 that may be used to introduce contrast agent into the patient's bladder. The urinary catheter 200 used during the VCUG exam may be any urinary catheter, including but not limited to Foley catheters. The urinary catheter 200 has a distal portion 202 and a proximal portion 204. The patient may be catheterized with the urinary catheter 200 by advancing the distal portion 202 of the urinary catheter 200 through the patient's urethra and into the patient's bladder. Contrast agent may be passed into the patient's bladder by gravity drip following catheterization of the patient, as described in the following paragraphs.

[0033] The urinary catheter 200 may be a Foley catheter. The urinary catheter 200 may be a three-way Foley catheter. The distal portion 202 of the urinary catheter 200 may include an outlet opening 206 that fluidically communicates with an inflow port 210 at the proximal portion 204 of the urinary catheter 200. The inflow port 210 may be connected to the outlet opening 206 by an inflow lumen (not shown). An intravenous bag containing
contrast agent may be connected to the inflow port 210 of the urinary catheter 200. The contrast agent may flow into the catheter 200 at the inflow port 210, flow through the inflow lumen, and exit the catheter 200 at the outlet opening 206, thereby introducing contrast agent into the patient's bladder.

[0034] The urinary catheter 200 may include a balloon 214 at the distal portion 202 of the urinary catheter 200. The balloon 214 may remain deflated during the VCUG to allow fast removal of the catheter 200 from the patient once the patient begins voiding. Optionally, the balloon 214 may be inflated to help retain the distal portion 202 of the urinary catheter 200 within the patient's bladder after the patient has been catheterized with the urinary catheter 200. The balloon 214 may be fluidically connected to a balloon port 216 at the proximal portion 204 of the urinary catheter 200. The balloon 214 may be inflated after the balloon 214 enters the patient's bladder. The balloon 214 may be inflated by introducing sterile liquid at the balloon port 216 of the urinary catheter 200.

[0035] FIGURE 3 shows a placement of the device 100 on a male patient. The sensor 102 may be placed near the external orifice 300 of the urethra 302. The distal portion 202 of the urinary catheter 200 may be advanced through the urethra 302 and into the patient's bladder 304. Contrast agent may be introduced at the inflow port 210 of the urinary catheter 200, as discussed above, and may pass into the bladder 304 by flowing out of the outlet opening 206 of the urinary catheter 200. Urine and contrast agent exit the bladder 304 by flowing around (as depicted by small arrows in the figure inset) the external surface 306 of the urinary catheter 200, and ultimately touching the sensor 102. Liquid exiting the bladder 304 by flowing around the external surface 306 of the urinary catheter 200 drains onto the exam table and is collected by absorbent pads positioned around the patient.

[0036] The sensor 102 may detect at least a portion of the liquid that exits the bladder 304 by flowing around the external surface 306 of the urinary catheter 200. The sensor 102 may be positioned so that liquid exiting the bladder 304 by flowing around the external surface 306 of the urinary catheter 200 contacts the sensor 102 near the tip of the urethra 300. Additionally or alternatively, the sensor 102 may include a transducer 106 configured to detect liquid flow. The transducer 106 may be configured to generate a signal
when the transducer 106 detects the flow of liquid near the external orifice 300 of the patient's urethra 302.

[0037] The sensor 102 may be configured so that wetting the sensor 102 with urine or contrast agent causes the sensor 102 to generate a signal that actuates the alarm 112. The alarm 112 may be configured to discreetly alert the radiologist that the patient has begun voiding. The alarm 112 may discreetly alert the radiologist by illuminating a display 116 in response to the signal generated from the sensor 102 upon the sensor 102 detecting the patient has begun voiding. The urinary catheter 200 may be removed quickly once the patient starts voiding to allow an unobstructed view of the urethra 302 without the urinary catheter 200 in place.

[0038] FIGURE 4 depicts a placement of the device 100 on a female patient. As discussed, the distal portion 202 of the urinary catheter 200 may be advanced into the patient's bladder 304 and used to introduce contrast agent into the bladder 304. The sensor 102 may be secured in proximity to the external orifice 300 of the urethra 302. During voiding, urine or contrast agent flows out of the bladder 304 and exits through the external orifice 300 of the urethra 302, thereby wetting the sensor 102. Wetting of the sensor 102 may actuate the alarm 112.

[0039] FIGURE 5 illustrates a method of use of the device 100 on a pediatric patient 500. The patient 500 is positioned on an exam table 502 under a fluoroscopy machine 504. The alarm 112 may be placed in view of the radiologist 506. The radiologist 506 may view a fluoroscopy monitor 510 during the procedure. The patient 500 can be catheterized with a urinary catheter 200, and contrast agent may be introduced into the patient's bladder through a peripheral intravenous line 512 by gravity drip. The sensor 102 can be positioned near the external orifice 300 of the patient's urethra 302 as previously described. Once the patient 500 begins to void, liquid from the patient's bladder 304 may exit at the external orifice 300 of the urethra 302 and may contact the sensor 102.

[0040] The sensor 102 can be configured to actuate the alarm 112 when the sensor 102 detects that the patient 500 has begun voiding. The alarm 112 can be configured to illuminate a display 116 or emit sound from a speaker 120 upon actuation of the alarm 112 by the sensor 102. The radiologist 506 may then remove the urinary catheter 200 and manually
actuate the fluoroscopy machine 504 upon the radiologist 506 receiving a visual or audio alert from the alarm 112 in response to the signal generated by the sensor 102. The radiologist 506 may start taking the x-ray images upon receiving an alert from the alarm 112. Additionally or alternatively, the sensor 102 or the alarm 112 may be configured to automatically actuate the fluoroscopy machine 504 upon the sensor 102 detecting voiding by the patient 500. The sensor 102 or alarm 112 may be configured to signal the fluoroscopy machine 504 to begin taking x-ray images. The sensor 102 may be configured to delay automatically actuating the fluoroscopy machine 504 in order to give the radiologist 506 sufficient time to remove the urinary catheter 200 from the patient 500 without the radiologist 506 being exposed to radiation from the fluoroscopy machine 504. The sensor 102 may have a control interface (not shown) that allows the radiologist 506 to adjust the delay time period between the sensor 102 detecting patient voiding and the sensor 102 actuating the fluoroscopy machine 504.

[0041] FIGURE 6 shows a non-limiting, illustrative embodiment of the sensor 102 attached to the urinary catheter 200. The sensor 102 can be adapted to be positioned close to the external orifice 300 of the patient's urethra 302, as described above, in order to facilitate early detection of patient voiding. The sensor 102 can also be designed to allow the urinary catheter 200 to be quickly removed from the patient without requiring an adhesive tape to be pulled from the patient's skin. As shown in FIGURE 6, the sensor 102 can have a backing material 123 that forms a funnel-like shape with the wide end of the funnel oriented toward the distal portion 202 of the urinary catheter 200. The funnel-like shape of the sensor 102 can channel excreted urine onto the component 104, making the sensor 102 efficient and reliable at detecting patient voiding. Because liquids can flow in streams that have a narrow width and an unpredictable path, excreted urine may bypass sensors that are merely taped to the patient in the vicinity of the external orifice of the urethra.

[0042] The sensing component 104 that detects liquid (e.g., urine) can be positioned throughout the inner surface of the funnel-like shaped sensor 102. Examples of components 104 that can detect liquid are existing bedwetting alarms and moisture or liquid sensors. The component 104 can be positioned along or immediately adjacent to the distal edge 125 of the sensor 102. The outer surface of the urinary catheter 200 can lie on top of the component 104 so that liquid flowing down the outer surface of the urinary catheter 200 will
be detected by the component 104. In some variants, the sensor 102 is folded or wrapped around the urinary catheter 200 to maintain contact between the component 104 and the outer surface of the urinary catheter 200 so that the component 104 can detect liquid on the outer surface of the urinary catheter 200. In certain embodiments, an adhesive 108 (e.g., tape) can be used to secure the tip portion funnel-like shaped sensor 102 to the urinary catheter 200, as shown in the illustrated embodiment. In this way, the sensor 102 can be adapted to quickly detect patient voiding without requiring the sensor 102 to be taped to the patient's skin.

[0043] With continued reference to FIGURE 6, the component 104 can communicate with the alarm 112 through an electrical conductor 114 that is coupled to the component 104 through an outlet 115 of the sensor 102. In certain variants, the component 104 interfaces directly with the alarm 112 and serves as an actuator for the alarm 112. For example, a change in the electrical property of the component 104 can be directly included in the circuitry that controls activation of the alarm 112. In some embodiments, a transducer serves as an intermediary for communication from the component 104 to the alarm 112. The transducer can be an actuator that receives the signal from the sensor 104 and then actuates the alarm 112 or the fluoroscopy machine 504. As discussed, in some embodiments, the component 104 communicates with the alarm 112 using wireless communication. In some embodiments, the component 104 actuates the fluoroscopy machine 504 with or without delay, as discussed above.

[0044] FIGURE 7A illustrates a non-limiting embodiment of the sensor 102 in an open or unfolded configuration. FIGURE 7B shows the sensor 102 in a closed or folded configuration. As shown in FIGURE 7A, the sensor 102 can have a tapered or trapezoidal shape. A first lateral edge 117 of the sensor 102 can be secured to a second lateral edge 119 by an adhesive 110a (e.g., tape, hook and pile fastener), thereby defining an inner surface 127 and an outer surface 129 of a cone-like or funnel-like structure, as shown in FIGURE 7B. A base edge 121 of the sensor 102 can be secured to itself or to the urinary catheter 200 by an adhesive 110b. In some variants, the sensor 102 is folded into the closed configuration without the use of adhesive. The component 104 can be arranged in an undulating pattern along the inner surface 127 of the sensor 102, with peaks and troughs that extend substantially perpendicular to the longitudinal axis of the sensor 102, as shown in FIGURE 7A. The
component 104 can be arranged in other patterns as well, such as square waves that have peaks and troughs that are substantially parallel to the longitudinal axis of the sensor 102. In many embodiments, at least a portion of the component 104 is positioned along or adjacent to the distal edge 125 in order to facilitate early detection of urine flowing along the outer surface of the urinary catheter 200 that is in contact with the sensor 102.

[0045] Features, materials, characteristics, or groups described in conjunction with a particular aspect, embodiment, or example are to be understood to be applicable to any other aspect, embodiment or example described herein unless incompatible therewith. All of the features disclosed in this specification (including any accompanying claims, abstract and drawings), and/or all of the steps of any method or process so disclosed, may be combined in any combination, except combinations where at least some of such features and/or steps are mutually exclusive. The protection is not restricted to the details of any foregoing embodiments. The protection extends to any novel one, or any novel combination, of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or to any novel one, or any novel combination, of the steps of any method or process so disclosed.

[0046] While certain embodiments have been described, these embodiments have been presented by way of example only, and are not intended to limit the scope of protection. Indeed, the novel methods and systems described herein may be embodied in a variety of other forms. Furthermore, various omissions, substitutions and changes in the form of the methods and systems described herein may be made. Those skilled in the art will appreciate that in some embodiments, the actual steps taken in the processes illustrated and/or disclosed may differ from those shown in the figures. Depending on the embodiment, certain of the steps described above may be removed, others may be added. Furthermore, the features and attributes of the specific embodiments disclosed above may be combined in different ways to form additional embodiments, all of which fall within the scope of the present disclosure.

[0047] Although the present disclosure includes certain embodiments, examples and applications, it will be understood by those skilled in the art that the present disclosure extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses and obvious modifications and equivalents thereof, including embodiments which
do not provide all of the features and advantages set forth herein. Accordingly, the scope of the present disclosure is not intended to be limited by the specific disclosures of preferred embodiments herein, and may be defined by claims as presented herein or as presented in the future.
WHAT IS CLAIMED IS:

1. A device comprising:
   a sensor configured to detect a liquid or liquid flow and generate a signal, the
   sensor comprising a component attached to a backing material; and
   an actuator operably coupled to the sensor, wherein the actuator is configured
to actuate an alarm upon receiving the signal, or actuate an imaging device upon
receiving the signal, or actuate both an alarm and an imaging device upon receiving the
signal.
2. The device of claim 1, wherein the alarm generates a visual and/or audible
   alert.
3. The device of claim 2, wherein the visual and/or audible alert comprises a
   discreet flashing light.
4. The device of claim 1, wherein an electrical property of the component
   changes when the component comes into contact with urine.
5. The device of claim 4, wherein the electrical property is selected from the
   group consisting of a resistance and a capacitance.
6. The device of any one of claims 1 to 5 further comprising a urinary catheter
   having an outer surface in contact with the component.
7. The device of claim 6, wherein the backing material has a funnel shape with a
   wide end of the funnel shape oriented toward a distal portion of the urinary catheter.
8. The device of claim 7, wherein a narrow end of the funnel shape is secured to
   the outer surface of the urinary catheter.
9. A kit comprising:
   an alarm and
   a sensor configured to activate the alarm when the sensor detects a liquid or
   liquid flow.
10. The kit of claim 9, wherein the alarm and the sensor are contained within a
    common housing.
11. The kit of claim 9, wherein the sensor further comprises an adhesive patch for
    reversibly coupling the sensor to a surface.
12. The kit of claim 11, wherein the sensor and adhesive patch are disposable.
13. The kit of claim 9, wherein the sensor further comprises a wireless transmitter and the alarm further comprises a wireless receiver, and wherein the sensor is configured to activate the alarm via a wireless signal.
14. A method of reducing a patient's exposure to radiation during a voiding cystourethrogram procedure, the method comprising:
   catheterizing a urethra of the patient with a urinary catheter;
   advancing a distal portion of the urinary catheter through the urethra and at least partially into a bladder of the patient;
   positioning a sensor within a region where a proximal portion of the urinary catheter extends outwardly from the urethra, wherein the sensor is configured to generate a signal when the sensor detects a liquid or liquid flow;
   administering contrast agent into the bladder through the urinary catheter; and
   actuating an imaging device thereby exposing the patient to radiation after the sensor generates the signal.
15. The method of claim 14, wherein actuating the imaging device comprises actuating an alarm that generates a visual and/or audible alert, and wherein a medical practitioner manually actuates the imaging device after perceiving the alert.
16. The method of claim 14, wherein the signal actuates the imaging device.
17. The method of claim 14, wherein the patient is a pediatric or a neonatal patient.
18. The method of claim 14, wherein the urinary catheter comprises a Foley catheter.
19. The method of claim 14, wherein the sensor is attached to a portion of the urinary catheter.
Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

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

1. \( \square \) Claims Nos.:

   because they relate to subject matter not required to be searched by this Authority, namely:

   the subject matter listed in Rule 39 on which, under Article 17(2)(a)(i), an international search is not required to be carried out, including

2. \( \square \) Claims Nos.:

   because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. \( \square \) Claims Nos:

   because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

See Supplemental Box for Details

1. \( \square \) As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. \( \sqrt{\checkmark} \) As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. \( \checkmark \) As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

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

Remark on Protest

\( \checkmark \) The additional search fees were accompanied by the applicant’s protest and, where applicable, the payment of a protest fee.

\( \checkmark \) The additional search fees were accompanied by the applicant’s protest but the applicable protest fee was not paid within the time limit specified in the invitation.

\( \checkmark \) No protest accompanied the payment of additional search fees.
A. CLASSIFICATION OF SUBJECT MATTER

A61F 13/42 (2006.01)  A61B 5/20 (2006.01)  G08B 21/20 (2006.01)

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)


Keywords used: Catheter, tubing, urine, void, funnel and the like

PAMS NOSE, INTESS,

GOOGLE SCHOLAR: keywords used 'cystourethrogram sensor on catheter' and 'sensor, liquid, catheter' and 'VCUG, Pediatric, Radiation Dose'

Applicant and Inventor search performed

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category*</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
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Documents are listed in the continuation of Box C

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

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

Date of the actual completion of the international search

15 August 2016

Date of mailing of the international search report

15 August 2016

Name and mailing address of the ISA/AU

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Form PCT/ISA/210 (fifth sheet) (July 2009)
<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
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<td>X</td>
<td>US 2014/0012197 A1 (FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH) 09 January 2014 para 32, 51, 52, 54, 55, 57, 65, Fig. 2</td>
<td>1-2, 4-9, 11-12</td>
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<td>WO 2013/061 179 A1 (KIMBERLY-CLARK WORLDWIDE, INC.) 02 May 2013 page 13-22, lines 28-33, page 19 lines 1-9; page 21 lines 5-8; Fig. 2</td>
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<td>page 18 line 17 or page 19, lines 29-33</td>
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<td>WO 2008/02 1462 A2 (FRESENIUS MEDICAL CARE HOLDINGS, INC.) 21 February 2008 page 8, line 30 - page 9 line 14, page 10, lines 24-25, page 13, lines 19-22, page 14, line 5, page 16, lines 2-25, page 20, lines 13-18, Fig. 3</td>
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<td>US 419 1950 A (LEVIN et al.) 04 March 1980 col. 5 lines 19-27; col. 5 lines 19-28 or col. 6 lines 4-28; Fig. 1</td>
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<td>US 5 137033 A (NORTON) 11 August 1992 col. 3 lines 1-10; col. 3 lines 49-50, Fig. 4; Fig. 5</td>
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<td>EP 2738748 A1 (ADVANCE TECHNOLOGY LIMITED ) 04 June 2014 para 42-43, Fig. 5</td>
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Continuation of: Box III

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

This Authority has found that there are different inventions based on the following features that separate the claims into distinct groups:

- Claims 1-13 are directed to a sensor configured to detect a liquid. The feature of is a funnel shaped backing material for the liquid sensor is specific to this group of claims.

- Claims 14-19 are directed to a method of reducing a patient's exposure to radiation during a voiding cystourethrogram procedure. The feature of the imaging device being actuated by a sensor signal where the sensor is on a urinary catheter within a patient is specific to this group of claims.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

When there is no special technical feature common to all the claimed inventions there is no unity of invention.

In the above groups of claims, the identified features may have the potential to make a contribution over the prior art but are not common to all the claimed inventions and therefore cannot provide the required technical relationship. The only feature common to all of the claimed inventions and which provides a technical relationship among them is a sensor configured to detect a liquid.

However this feature does not make a contribution over the prior art because it is disclosed in: D1

Therefore in the light of this document this common feature cannot be a special technical feature. Therefore there is no special technical feature common to all the claimed inventions and the requirements for unity of invention are consequently not satisfied a posteriori.
This Annex lists known 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.

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Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.
This Annex lists known 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.

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