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(54) **WIRELESS URODYNAMIC MONITORING SYSTEM WITH AUTOMATED VOIDING DIARY**

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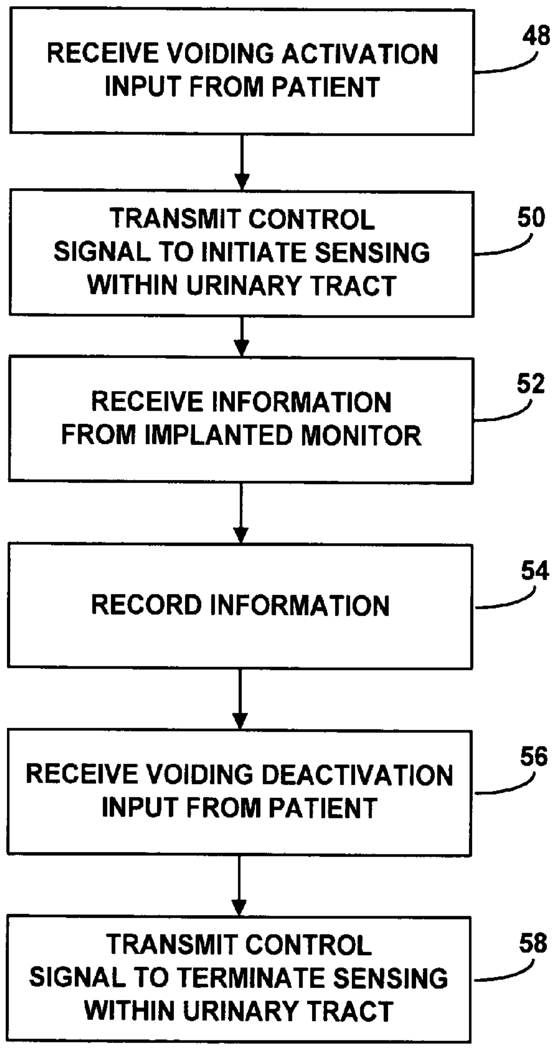
(52) **U.S. Cl.** **600/561**; 600/549

(57) **ABSTRACT**

The disclosure describes a wireless urodynamic monitoring system with an automated voiding diary feature. The system senses and records urodynamic information in response to a user command or in response to detection of the onset of a voiding event. The urodynamic information obtained over a series of voiding events forms an automated voiding diary that is useful in diagnosis of urological disorders. An implantable monitor obtains the urodynamic information and either records the information locally or transmits the information to an external controller via a wireless telemetry link. In some embodiments, the external controller may include a loop recorder for recording urodynamic information obtained by the implantable monitor over an extended period of time.



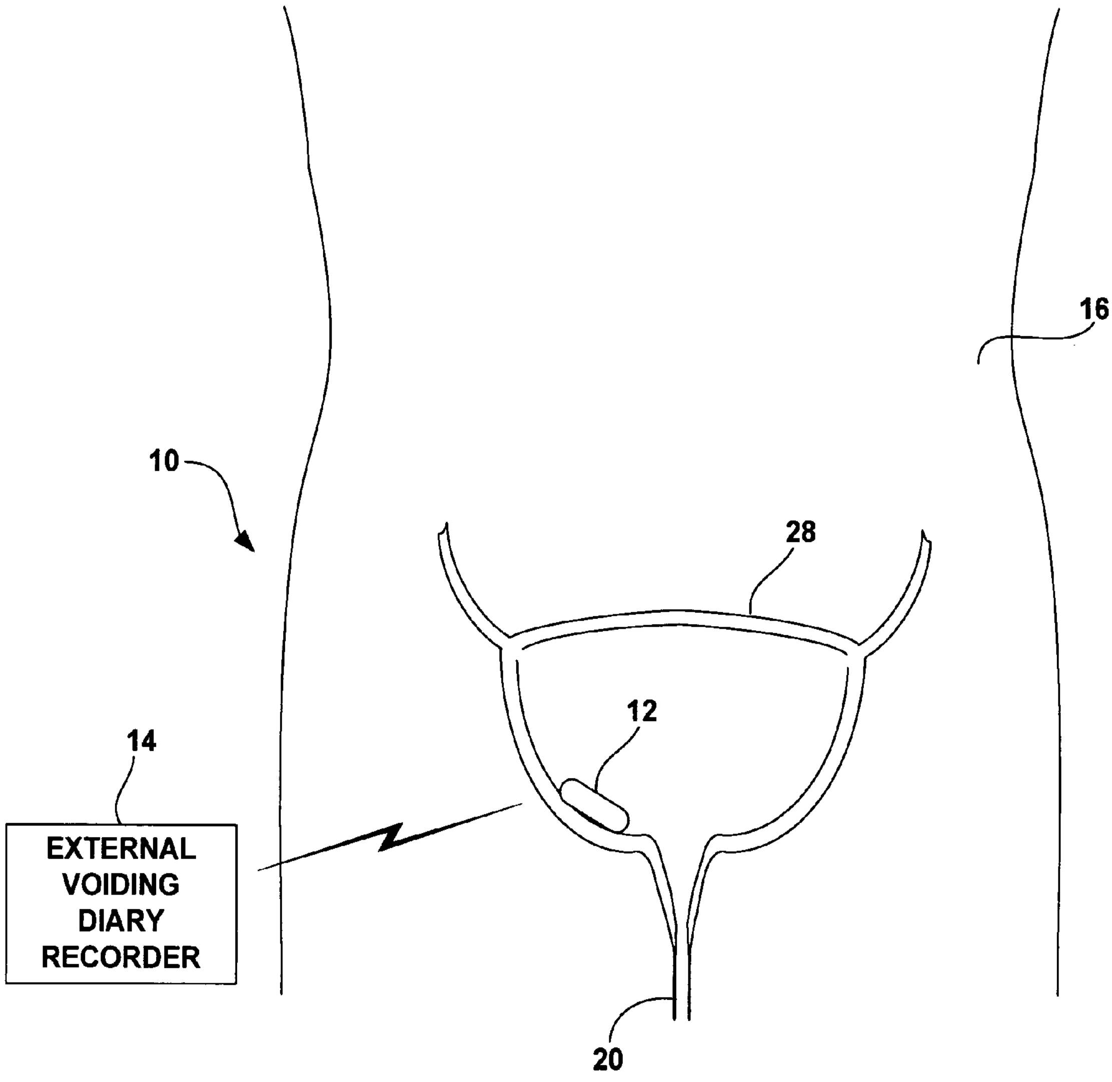


FIG. 1

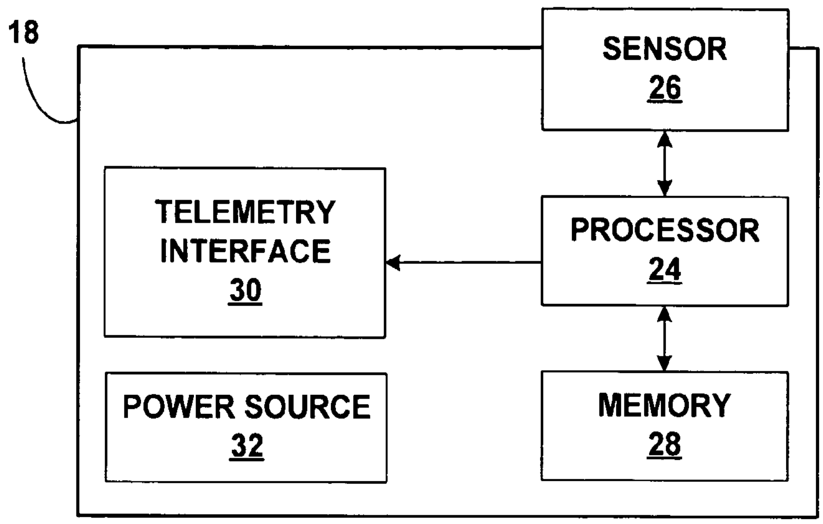

18
SENSOR
26
TELEMETRY
INTERFACE
30
PROCESSOR
24
POWER SOURCE
32
MEMORY
28

FIG. 2

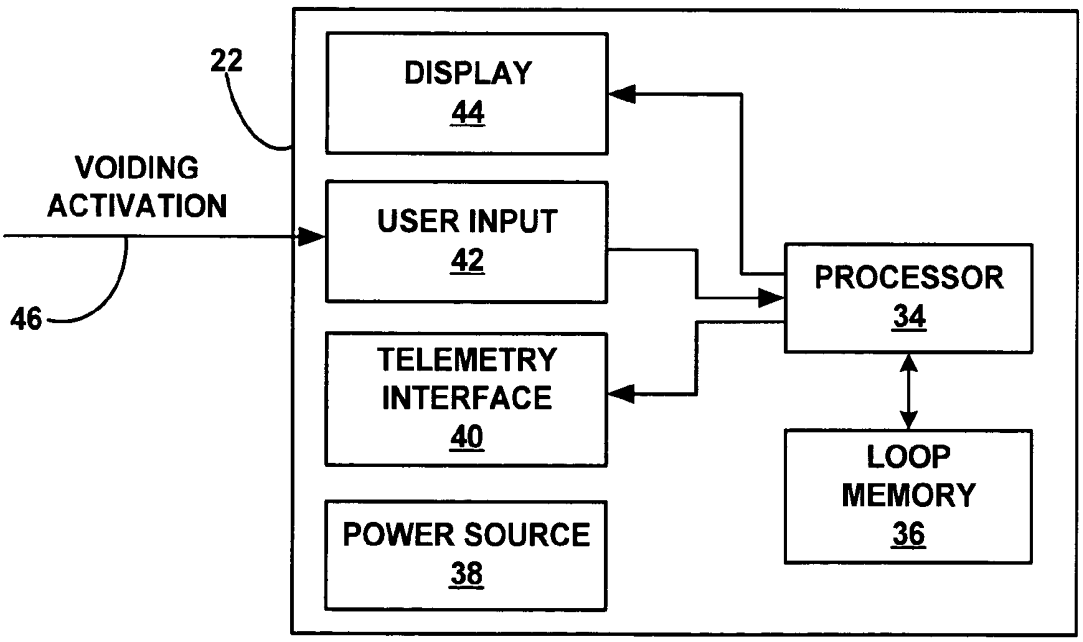

22
DISPLAY
44
VOIDING
ACTIVATION
USER INPUT
42
46
PROCESSOR
34
TELEMETRY
INTERFACE
40
LOOP
MEMORY
36
POWER SOURCE
38

FIG. 3

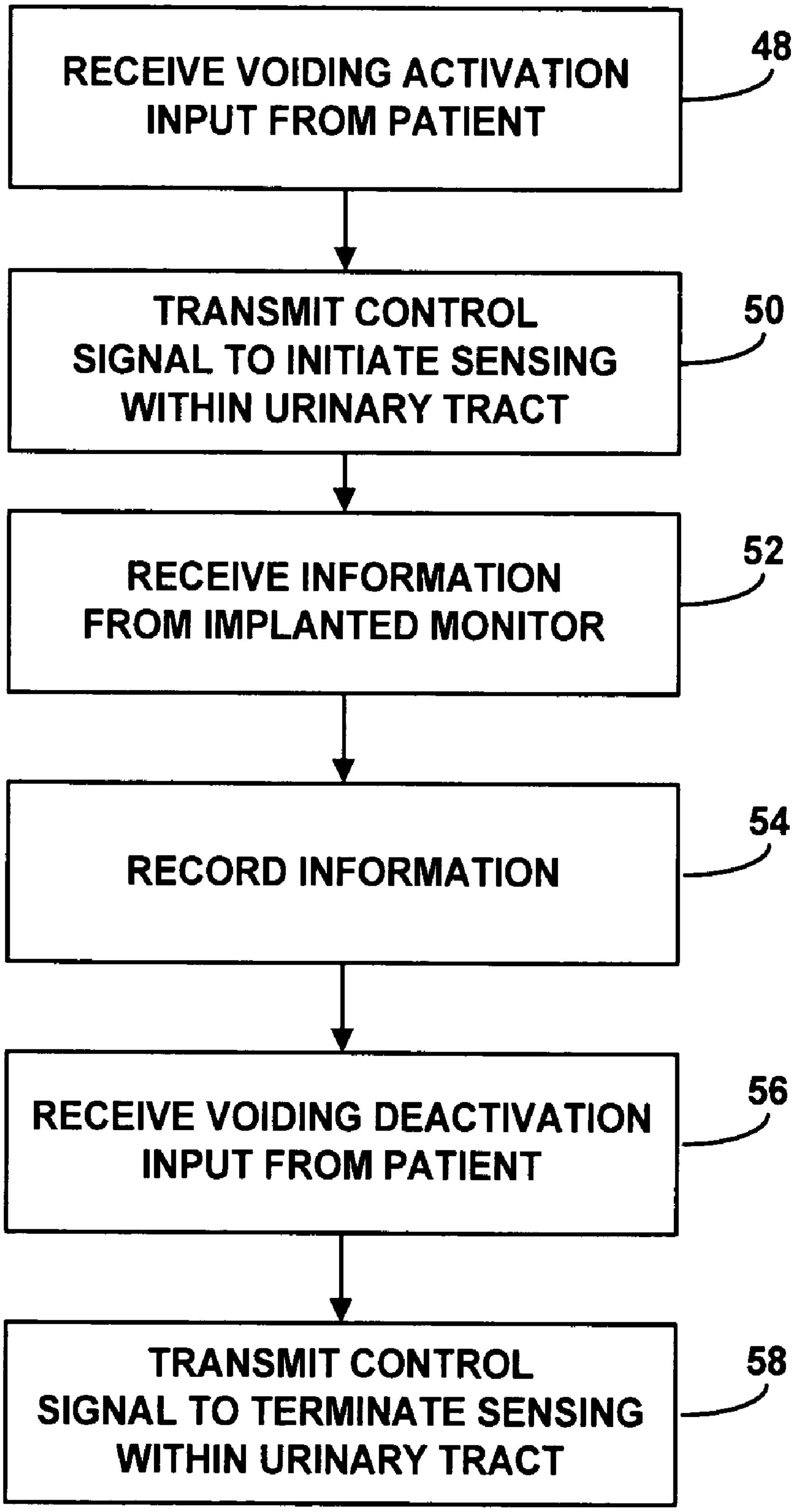

RECEIVE VOIDING ACTIVATION INPUT FROM PATIENT
48
TRANSMIT CONTROL SIGNAL TO INITIATE SENSING WITHIN URINARY TRACT
50
RECEIVE INFORMATION FROM IMPLANTED MONITOR
52
RECORD INFORMATION
54
RECEIVE VOIDING DEACTIVATION INPUT FROM PATIENT
56
TRANSMIT CONTROL SIGNAL TO TERMINATE SENSING WITHIN URINARY TRACT
58

FIG. 4

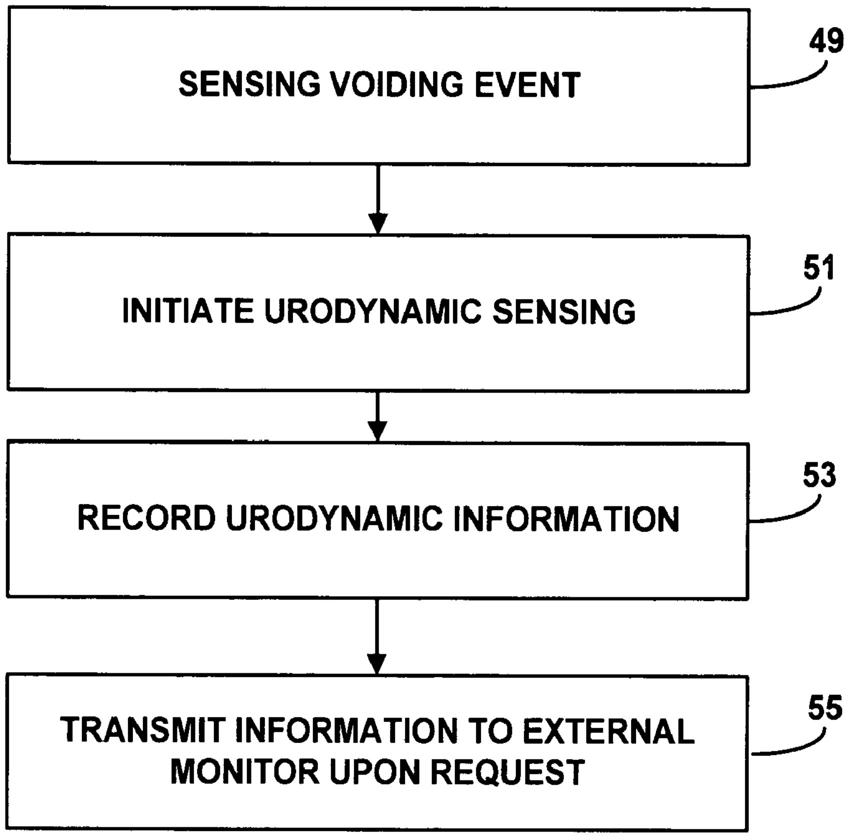

SENSING VOIDING EVENT
49
INITIATE URODYNAMIC SENSING
51
RECORD URODYNAMIC INFORMATION
53
TRANSMIT INFORMATION TO EXTERNAL MONITOR UPON REQUEST
55

FIG. 5

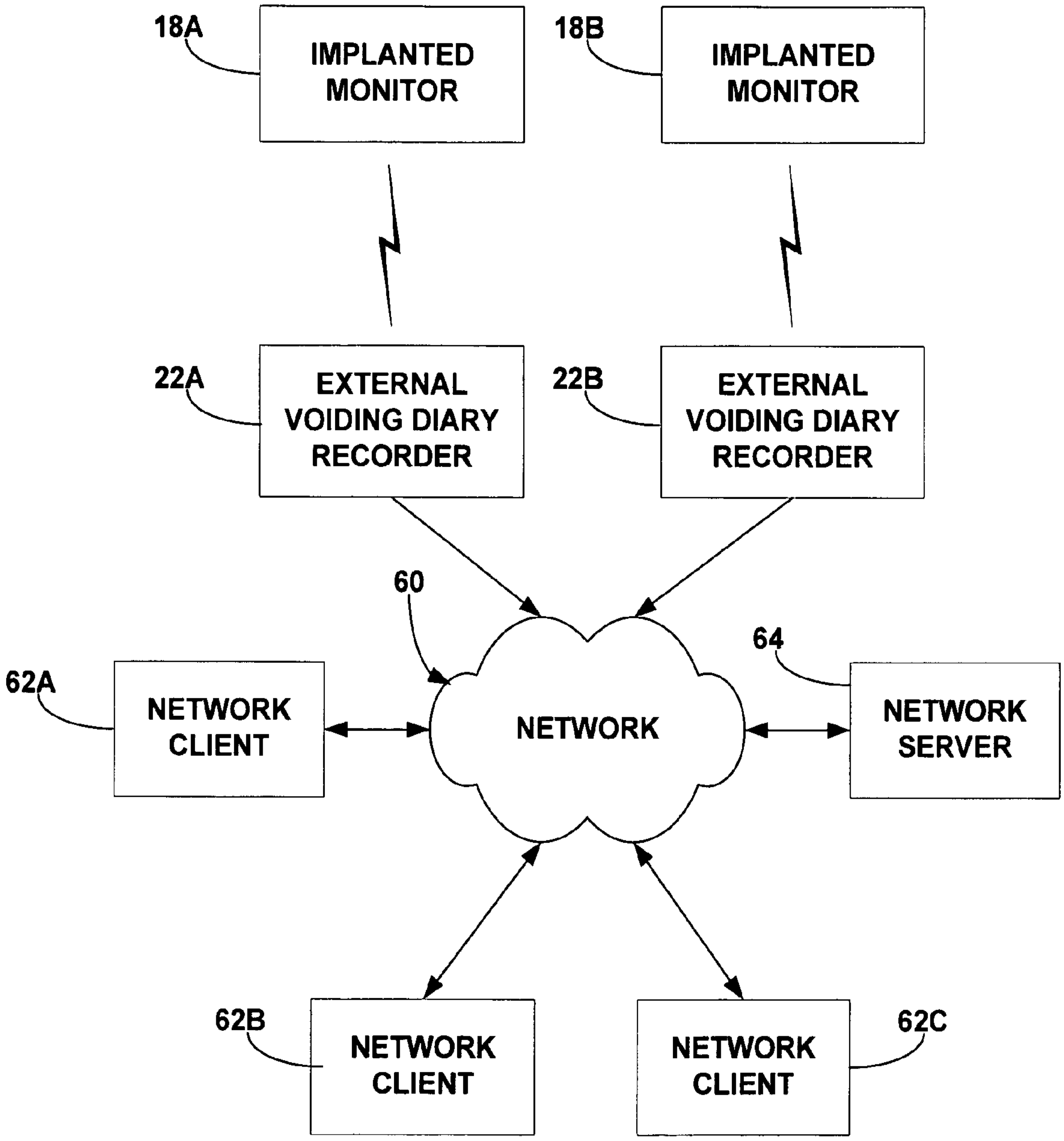

18A
IMPLANTED MONITOR
18B
IMPLANTED MONITOR
22A
EXTERNAL VOIDING DIARY RECORDER
22B
EXTERNAL VOIDING DIARY RECORDER
60
NETWORK
62A
NETWORK CLIENT
64
NETWORK SERVER
62B
NETWORK CLIENT
NETWORK CLIENT
62C

FIG. 6

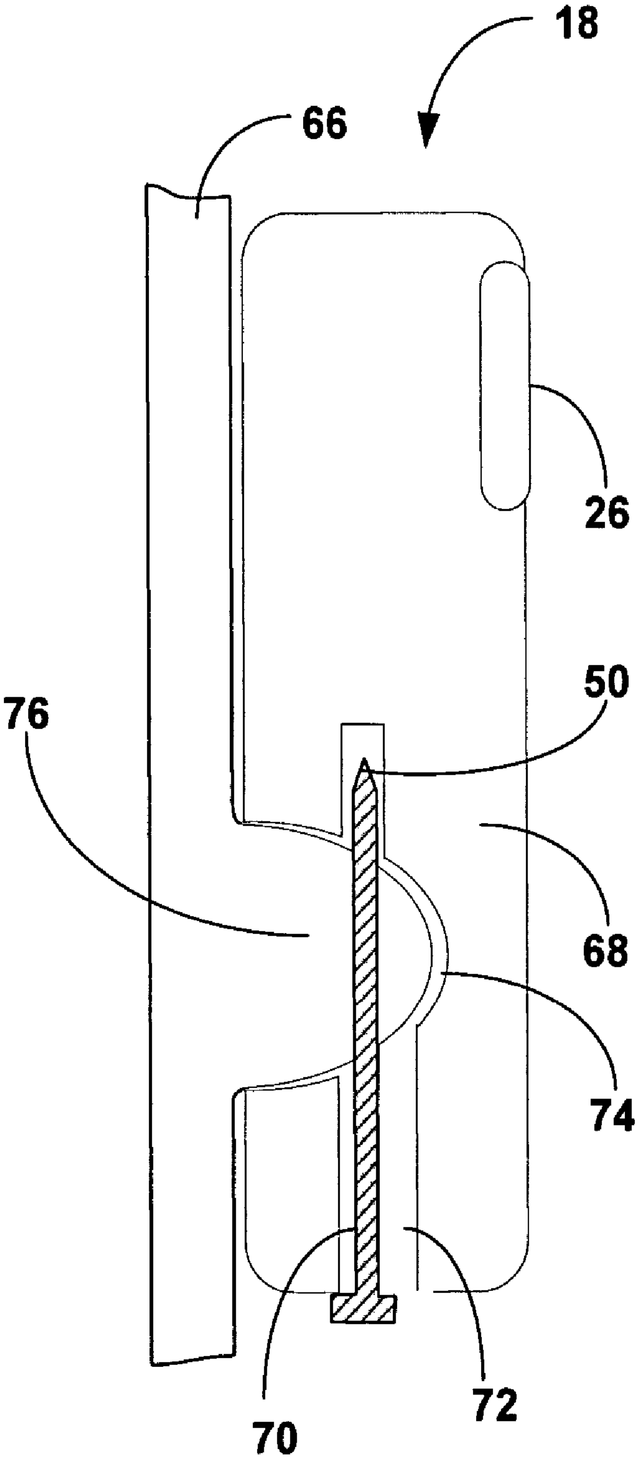


FIG. 7

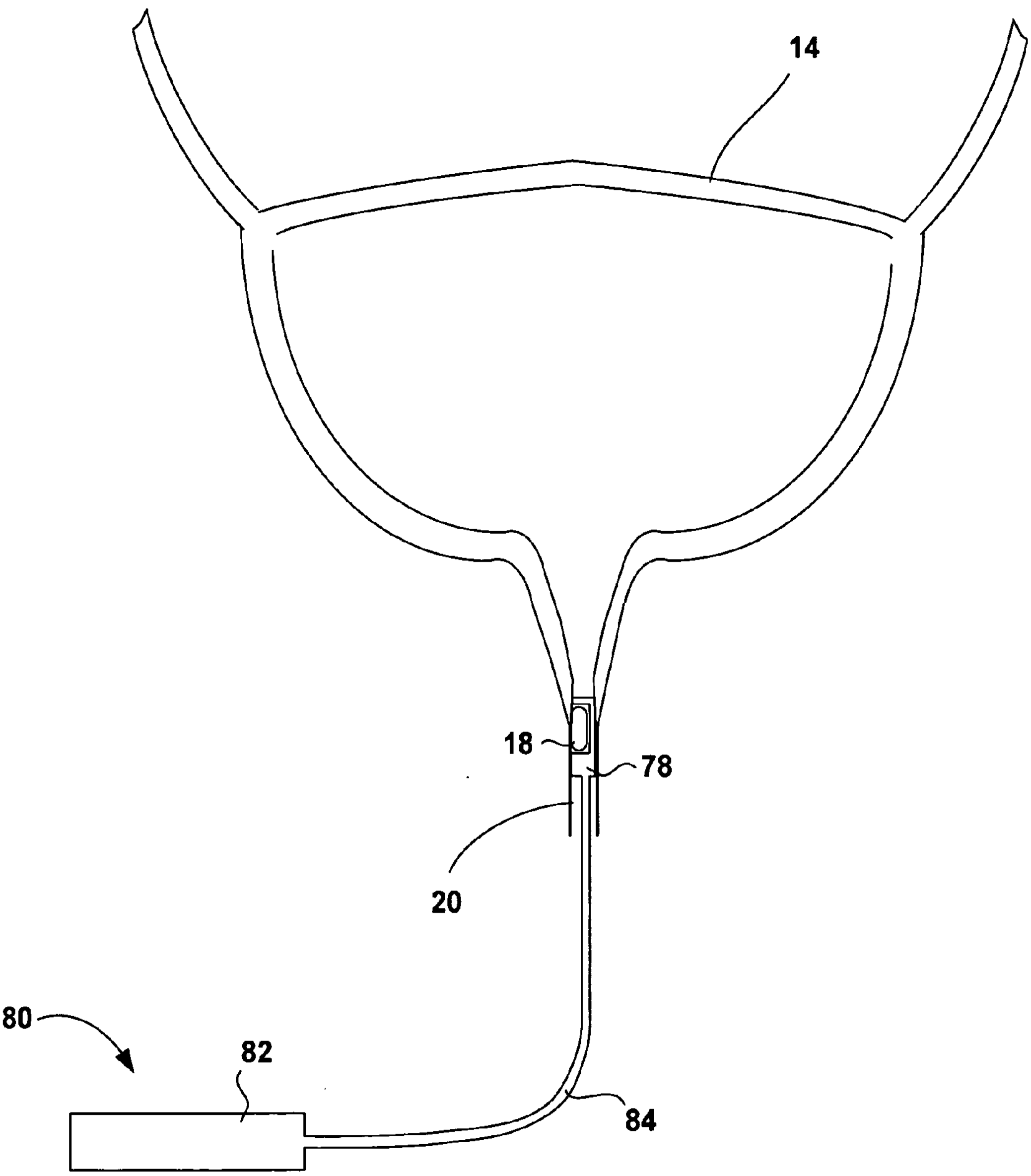


FIG. 8

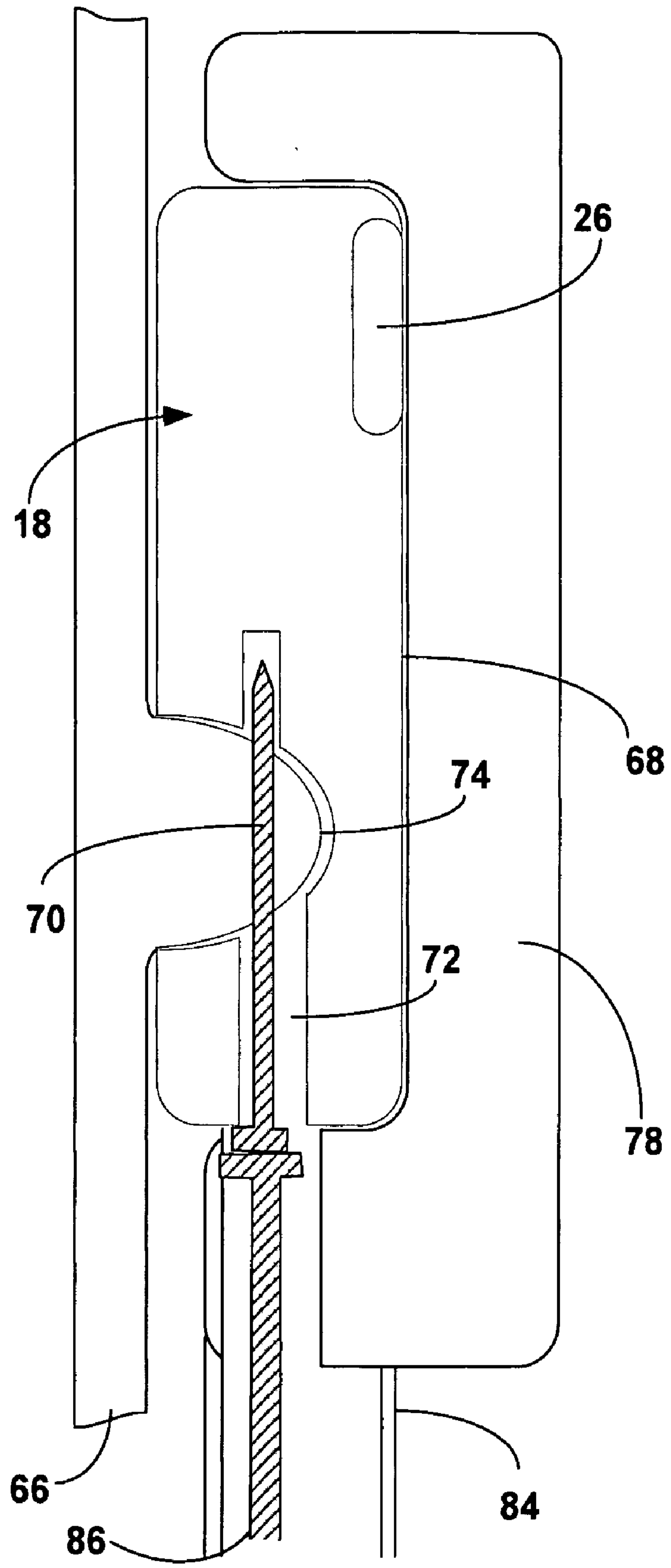


FIG. 9

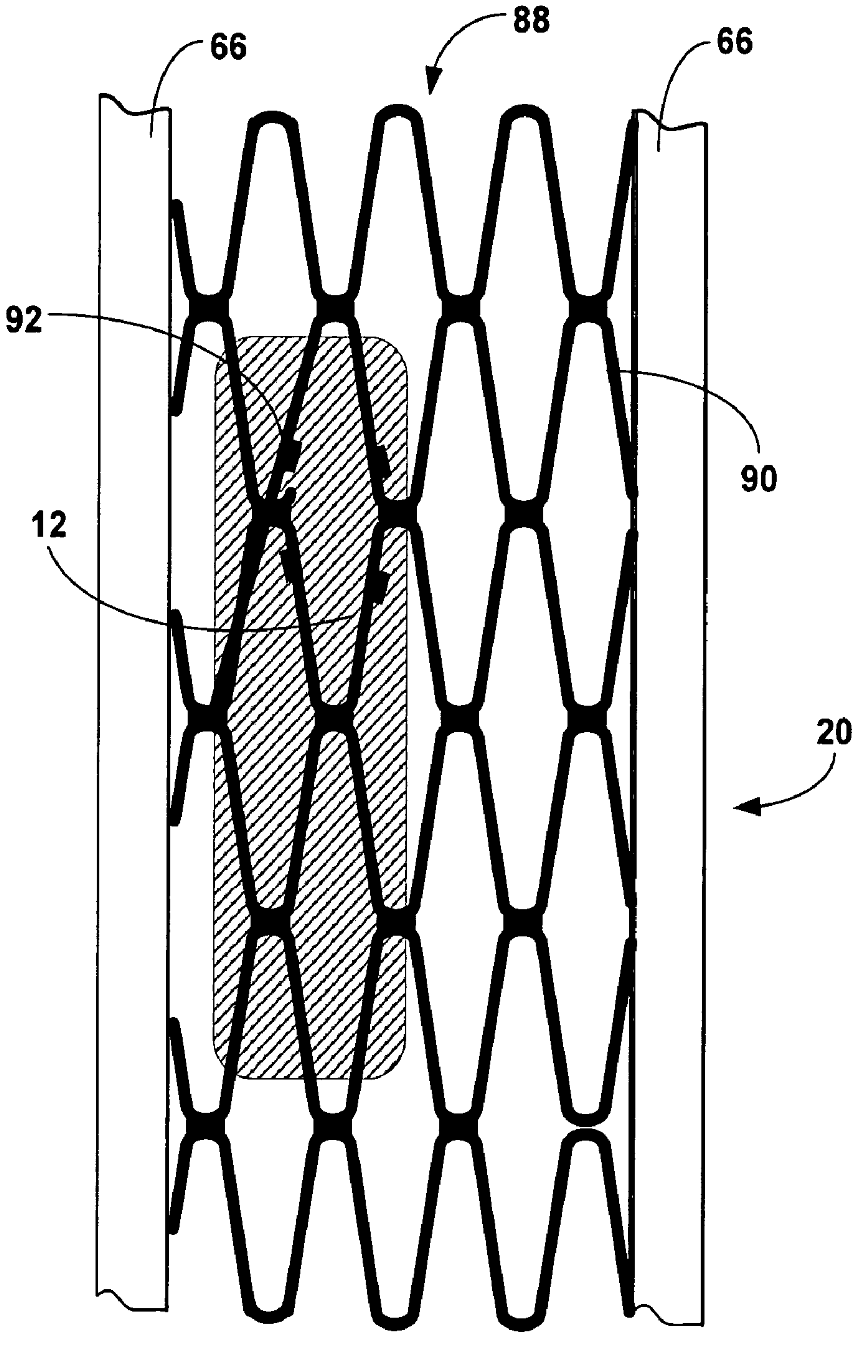


FIG. 10

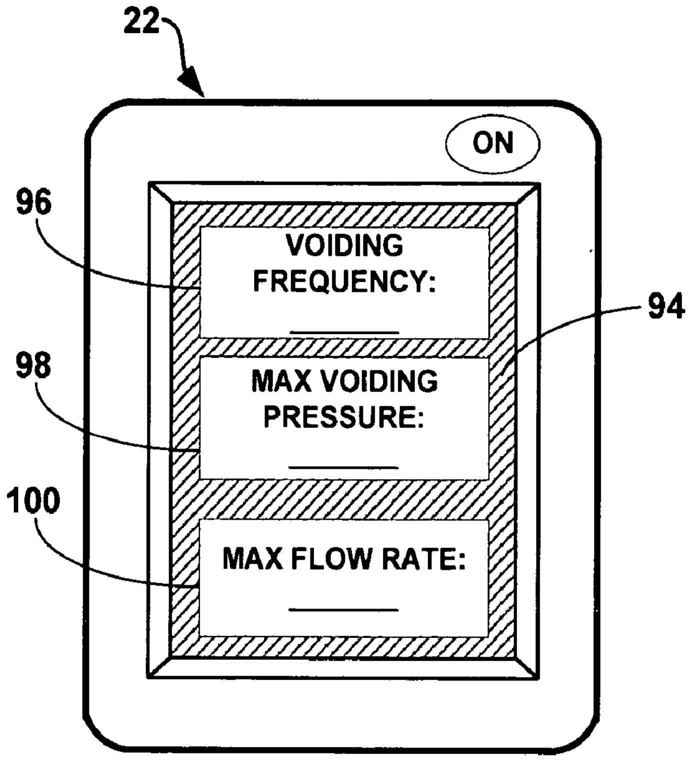

22
ON
96
VOIDING
FREQUENCY:
94
98
MAX VOIDING
PRESSURE:
100
MAX FLOW RATE:

FIG. 11

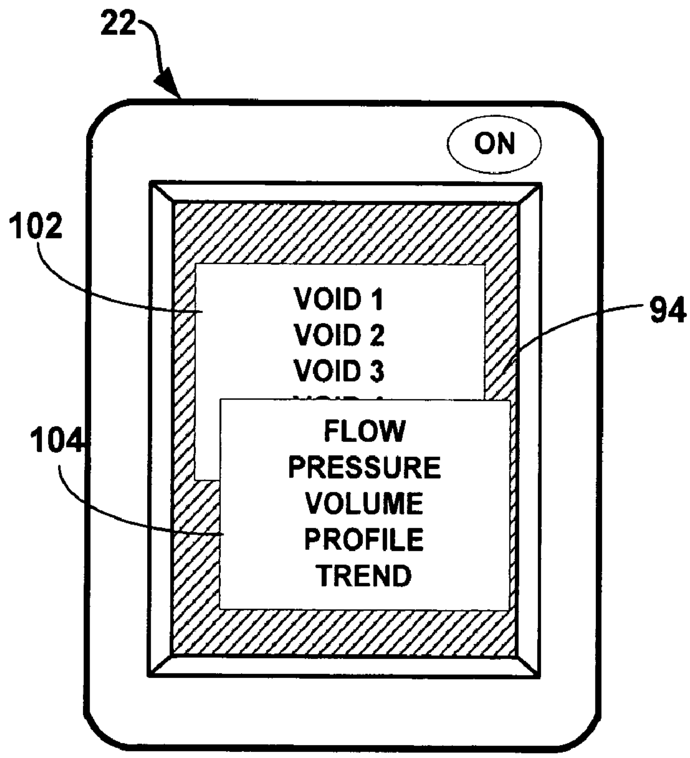

22
ON
102
VOID 1
VOID 2
VOID 3
94
104
FLOW
PRESSURE
VOLUME
PROFILE
TREND

FIG. 12

WIRELESS URODYNAMIC MONITORING SYSTEM WITH AUTOMATED VOIDING DIARY

[0001] This application claims the benefit of U.S. provisional application No. 60/589,442, filed Jul. 20, 2004, and U.S. provisional application No. 60/589,542, filed Jul. 20, 2004, the entire content of each of which is incorporated herein by reference.

FIELD OF THE INVENTION

[0002] The invention relates to medical devices and, more particularly, devices for monitoring urodynamic conditions.

BACKGROUND

[0003] Many people suffer from involuntary urine leakage, i.e., urinary incontinence. Others may suffer from blocked or restricted urine flow. Other urinary disorders include frequent urination, sudden urges to urinate, problems starting a urine stream, painful urination, problems emptying the bladder completely, and recurrent urinary tract infections. A physician uses a urodynamic test to study how a patient stores and releases urine. During the test, the physician obtains urodynamic information based on one or more physiological conditions within the urinary tract.

[0004] Different muscles, nerves, organs and conduits within the urinary tract cooperate to collect, store and release urine. A variety of disorders may compromise the urinary tract performance and contribute to incontinence or restricted flow. Many of the disorders may be associated with aging, injury or illness. For example, aging can often result in weakened sphincter muscles, which cause incontinence, or weakened bladder muscles, which prevent complete emptying. Some patients also may suffer from nerve disorders that prevent proper triggering and operation of the bladder or sphincter muscles.

[0005] Urodynamic sensing can reveal how well the bladder and sphincter muscles perform, and may help identify the causes of various urinary tract disorders. Urodynamic sensing can take the form of simple observation or precise measurement using monitors that sense physiological conditions such as urine pressure, flow, velocity, volume, and the like. Some monitors sense the occurrence and force of bladder contractions to identify abnormal bladder function. Other monitors may determine a volume of urine remaining in the bladder following urination. Hence, urodynamic sensing may focus on the ability of the bladder to empty steadily and completely.

[0006] Urodynamic testing ordinarily requires catheterization of the patient in order to place a monitor within the bladder or urethra. For this reason, urodynamic testing typically takes place within a clinical setting. In some cases, the presence of a catheter can disrupt the normal physiological function of the urinary tract. Although ambulatory catheterization is possible, it can be uncomfortable and may result in measurements that are not be representative of normal physiological function. In addition, the urinary catheter can be uncomfortable for the patient.

[0007] Various urodynamic testing systems are described in U.S. Pat. No. 4,873,990 to Holmes et al., U.S. Pat. No. 5,331,548 to Rollema et al., and U.S. Pat. No. 6,454,720 to Clerc et al. Siwapomsathain et al. describe a bladder monitor with wireless telemetry in Siwapornsathain et al., "A Telemetry and Sensor Platform for Ambulatory Urodynamics," Proceedings of the 2nd Annual International IEEE-EMBS Special Topic Conference on Microtechnologies in Medicine & Biology, Madison, Wis., 2002. J. Coosemans et al. describe an implantable bladder pressure monitor with wireless telemetry in "Datalogger for Bladder Pressure Monitoring With Wireless Power and Data Transmission," Katholieke Universiteit Leuven, Department ESAT-MICAS, Belgium, Belgian Day on Biomedical Engineering, 2003.

[0008] Table 1 below lists documents that disclose various techniques for urodynamic testing.

TABLE 1

Patent Number	Inventors/ Author	Title
4,873,990	Holmes et al.	Circumferential Pressure Probe
5,331,548	Rollema et al.	Method and system for on-line measurement, storage, retrieval and analysis of urodynamical data
6,454,720	Clerc et al.	System for measuring physical parameters with a medical probe
Not applicable	J. Coosemans et al.	Datalogger for Bladder Pressure Monitoring With Wireless Power and Data Transmission
Not Applicable	Siwapornsathain et al.	A Telemetry and Sensor Platform for Ambulatory Urodynamics

[0009] All documents listed in Table 1 above are hereby incorporated by reference herein in their respective entireties. As those of ordinary skill in the art will appreciate readily upon reading the Summary of the Invention, Detailed Description of the Preferred Embodiments and claims set forth below, many of the devices and methods disclosed in the patents of Table 1 may be modified advantageously by using the techniques of the present invention.

SUMMARY OF THE INVENTION

[0010] In general, the invention is directed to a wireless urodynamic monitoring system with an automated voiding diary feature. The system senses and records urodynamic information in response to a user command or in response to detection of the onset of a voiding event. The urodynamic information obtained over a series of voiding events forms an automated voiding diary that is useful in diagnosis of urological disorders. An implantable monitor obtains the urodynamic information and either records the information locally or transmits the information to an external controller via a wireless telemetry link. In some embodiments, the external controller may include a loop recorder for recording urodynamic information obtained by the implantable monitor over an extended period of time.

[0011] Various embodiments of the present invention provide solutions to one or more problems existing in the prior art with respect to prior art systems for urodynamic monitoring. These problems include the general inconvenience and discomfort experienced by the patient during the use of catheter-based urodynamic monitoring systems. Other problems relate to potential inconsistencies involved in the manual preparation of voiding diaries by individual patients. Further problems relate to the difficulty in the transfer and analysis of voiding diary information. Such problems can limit the collection and analysis of useful urodynamic information, and undermine the integrity and diagnostic efficacy of the information.

[0012] Various embodiments of the present invention are capable of solving at least one of the foregoing problems. When embodied in a system or method for wireless urodynamic monitoring, the invention includes features that facilitate automated formulation of a voiding diary. A wireless urodynamic monitoring system, in accordance with the invention, includes a wireless implantable monitor and an external controller. The implantable monitor and external controller can accompany the patient throughout a routine of normal daily activities.

[0013] The implantable monitor is configured for indwelling urodynamic monitoring within the bladder or urethra. The wireless implantable monitor obtains urodynamic information in response to a voiding event activation command entered into the external controller or automated detection of the onset of a voiding event. The monitor may be configured to transmit the information to the external controller. In this manner, the monitoring system selectively records urodynamic information obtained at the time of a voiding event.

[0014] In comparison to known techniques for monitoring urodynamic parameters, various embodiments of the invention may provide one or more advantages. For example, the invention facilitates the automated acquisition, transfer and analysis of voiding diary information. In addition, the use of a wireless urodynamic monitor can reduce patient inconvenience and discomfort, and facilitate urodynamic monitoring as the patient goes about his daily routine. Also, by acquiring urodynamic information automatically in response to either patient input or detection of the onset of a voiding event, a wireless monitoring system supports convenient recording of urodynamic information that is particularly relevant and useful in diagnosis of urological disorders. Automated formulation of a voiding diary also avoids potential inconsistencies in manual voiding diaries, which may rely on individual patient discipline.

[0015] The details of one or more embodiments of the invention are set forth in the accompanying drawings and the description below. Other features, objects, and advantages of the invention will be apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] **FIG. 1** is a schematic diagram illustrating a wireless urodynamic monitor and an external controller shown in conjunction with the bladder and urethra of a patient.

[0017] **FIG. 2** is a functional block diagram illustrating a wireless urodynamic monitor with a telemetry interface for communication with an external controller.

[0018] **FIG. 3** is a functional block diagram illustrating an external controller with a telemetry interface for wireless communication with an implanted urodynamic monitor.

[0019] **FIG. 4** is flow diagram illustrating operation of a urodynamic monitor and external controller in response to a voiding activation input from a patient.

[0020] **FIG. 5** is flow diagram illustrating operation of a urodynamic monitor and external controller in response to a sensed voiding event.

[0021] **FIG. 6** is a functional block diagram illustrating a network for communication of information obtained by wireless urodynamic monitors.

[0022] **FIG. 7** is a cross-sectional side view of a wireless urodynamic monitor attached to a tissue site within the bladder or urethra.

[0023] **FIG. 8** is a schematic diagram illustrating deployment of the monitor of **FIG. 7** within a patient's urinary tract with an endoscopic delivery device.

[0024] **FIG. 9** is a cross-sectional side view of the wireless urodynamic monitor and distal end of the endoscopic delivery device of **FIGS. 7 and 8**.

[0025] **FIG. 10** is a side view of a monitor with a fixation structure in the form of an expandable frame.

[0026] **FIG. 11** is a conceptual diagram of an external controller equipped to record and present information obtained from an implantable urodynamic monitor.

[0027] **FIG. 12** is another conceptual diagram of the external controller of **FIG. 11**.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0028] **FIG. 1** is a schematic diagram illustrating a wireless urodynamic monitoring system **10** including an implanted urodynamic monitor **12** and an external controller **14** shown in conjunction with a patient **16**. System **10** collects and records urodynamic information in response to a voiding event activation command. The voiding event activation command may be entered into external controller **14** by patient **16** to indicate the onset of a voiding event. Alternatively, the voiding event activation command may be generated automatically within monitor **12** or external controller **14** upon detection of urodynamic information indicating the onset of a voiding event. Implantable monitor **12** and external controller **14** cooperate to form an automated voiding diary containing urodynamic information obtained over a series of voiding events.

[0029] Urodynamic monitor **12** may be implanted within a patient bladder **18** or urethra **20** forming part of the patient's urinary tract. In **FIG. 1**, urodynamic monitor **12** is shown at a target location within bladder **18**, but alternatively may be implanted within urethra **20**. In some embodiments, multiple urinary tract monitors **18** may be placed within the urinary tract. Monitor **12** may be placed at a target location within the urinary tract by endoscopic delivery, e.g., using a catheter, cystoscope, endoscope, or the like, as will be described in greater detail. Monitor **12** may be implanted temporarily or chronically.

[0030] The target location may be within bladder **18** or within urethra **20**. As will be described in greater detail, monitor **12** may include any of a variety of fixation structures to securely position the monitor at a target tissue location within the urinary tract. Upon fixation of monitor **12**, the endoscopic delivery device may be withdrawn from the urinary tract of patient **16**. In this manner, monitor **12** can remain in a desired position for an extended period of time, and accompany patient **16** outside the clinic or hospital and throughout a routine of daily activities.

[0031] Urodynarnic information, as used herein, generally refers to physiological information characterizing or relating to the function of the bladder **18**, urethra **20**, or other segments of a patient's urinary tract in storing, releasing, and passing urine. The urodynamic information may include urine pressure, flow, velocity, temperature, impedance, or the like, as well as contractile activity of bladder **18**. A voiding event, as used herein, generally refers to a time at which a patient attempts to void urine from the bladder, feels discomfort in the bladder or urethra, or experiences involuntary urine leakage or other urinary incontinence symptoms. Each type of voiding event can provide important urodynamic information for evaluation of urological health. A voiding diary, in general, refers to a set of urodynamic information associated with particular voiding events.

[**0032**] Patient **16** may activate urodynamic monitor **12** to collect urodynamic information during or proximate to a urinary voiding event. For example, patient **16** may activate urodynamic monitor **12** by entering a voiding event activation command into external controller **14** to indicate the onset of a voiding event, such as an attempt to void urine from bladder **18**. In response, external controller **14** transmits a wireless command to urodynamic monitor **12**, which then captures one or more measurements of urodynamic parameters within bladder **18** or urethra **20** to form a set of urodynamic information. Alternatively, in some embodiments, urodynamic monitor **12** may automatically detect the onset of a voiding event, and automatically trigger the collection of urodynamic information.

[**0033**] In some embodiments, urodynamic monitor **12** transmits the urodynamic information to external controller **14**, e.g., as the information is obtained. External controller **14** generates a voiding diary that contains a record of voiding events and urodynamic information measured by urodynamic monitor **12** during the voiding events. In this manner, external controller **14** selectively records relevant information obtained at the time a patient experiences a voiding event, such as an attempt to void urine from the bladder. Hence, there is no need for the patient **16** to make a manual voiding diary. Also, the automated voiding diary contains objective urodynamic information, rather than subjective impressions from the patient.

[**0034**] In other embodiments, rather than immediately transmitting the urodynamic information to external controller **14**, monitor **12** may initially store the information internally for subsequent wireless transmission to external controller **14** or another device. Hence, in some embodiments, the urodynamic information may be stored within monitor **12**, and later transmitted to external controller **14** upon interrogation of the monitor. Interrogation may be initiated by the patient **16** by entering a command into external controller **14**. In further embodiments, monitor **12** may store the information internally on a persistent basis for later retrieval by external controller **14**, or upon explantation of the monitor.

[**0035**] Urodynamic monitor **12** is configured for indwelling urodynamic testing within the bladder **18** or urethra **20**. In this manner, monitor **12** can accompany patient **16** throughout a routine of normal daily activities. In some embodiments, multiple urodynamic monitors **12** may be implanted within the urinary tract of patient **16**. External controller **14** may take the form of a handheld, external recorder that is carried by patient **16**.

[**0036**] Urodynamic monitor **12** may obtain a variety of urodynamic information relating to physiological conditions within the bladder **18** or urethra **20** during a voiding event. For example, the physiological conditions may include one or more urodynamic conditions such as urine pressure, urine volume, urine flow, urine pH, temperature, bladder contraction, or urinary sphincter contraction. The urodynamic information may represent averages, trends, or instantaneous measurements, as well as information representing specific events during the course of voiding. As a further example, implanted monitor **12** may measure and record an indication of the residual volume of urine following a voiding event. Residual volume is another important parameter in urodynamic studies to measure the effectiveness of the voiding bladder condition. In some embodiments, urodynamic monitor **12** and external controller **14** may be configured as loop recorders to overwrite their respective memories with new information as the memory becomes full.

[**0037**] **FIG. 2** is a functional block diagram illustrating implantable urodynamic monitor **12** of **FIG. 1**. In the example of **FIG. 2**, monitor **12** includes a processor **24**, a sensor **26**, memory **28**, wireless telemetry interface **30**, and a power source **32**. Monitor **12** also may include an internal clock to track date and time of voiding events. In accordance with the invention, monitor **12** obtains urodynamic information via sensor **26** in response to a voiding event activation command, which may be initiated by a user or generated automatically upon detection of the onset of a voiding event.

[**0038**] Monitor **12** may be entirely self-contained, self-powered and integrated within a common housing using miniaturized integrated circuitry available to those skilled in the art. In some embodiments, for example, monitor **12** may be constructed in a manner similar to the monitors described in U.S. patent application Ser. No. 10/833,776, to Mark Christopherson and Warren Starkebaum, filed Apr. 28, 2004, entitled "Implantable Urinary Tract Monitor," the entire content of which is incorporated herein by reference.

[**0039**] Power source **32** may take the form of a small battery. An external source of inductively coupled power may be used, in some embodiments, to power some features of monitor **12**. For example, monitor **12** may include an inductive power interface for transcutaneous inductive power transfer to power higher energy functions such as telemetry. However, monitor **12** typically will include a small battery cell within the monitor housing. Alternatively, monitor **12** may include an inductive power interface in lieu of a battery.

[**0040**] Telemetry interface **30** permits wireless communication with external controller **14** for wireless transmission of information obtained by sensor **26**, as well as wireless reception of a voiding event activation command directing monitor **12** to collect physiological information during an attempt to void urine from the bladder. As a further alternative, the voiding event activation command may be applied by patient **16** in the form of a magnet swiped in proximity to monitor **12**, in which case the monitor will include appropriate sensing circuitry to detect the magnet. Accordingly, an optional magnet detector **33** is shown in **FIG. 3**.

[**0041**] Processor **24** controls telemetry interface **30** and handles processing and storage of information obtained by sensor **26**. Processor **24** controls operation of monitor **12** and may include one or more microprocessors, digital signal processors (DSPs), application-specific integrated circuits (ASICs), field-programmable gate arrays (FPGAs), or other equivalent logic circuitry. Memory **28** may include any magnetic, electronic, or optical media, such as random access memory (RAM), read-only memory (ROM), electronically-erasable programmable ROM (EEPROM), flash memory, or the like, or a combination thereof. Memory **28** may store program instructions that, when executed by processor **24**, cause the controller to perform the functions ascribed to it herein. For example, memory **28** may store instructions for processor **24** to execute in support of control of wireless telemetry interface **30** and control of, and processing of information obtained by, sensor **26**. Memory **28** may include separate memories for storage of instructions and urodynamic information.

[**0042**] Telemetry interface **30** may include a wireless radio frequency (RF) transmitter and receiver to permit bi-directional communication between monitor **12** and external controller **14**. In this manner, external controller **14** may transmit commands to urodynamic monitor **12** for collection of urodynamic information or collection of information stored in memory **28**, and receive status and operational information from the monitor. Telemetry interface **30** includes an antenna, which may take a variety of forms. For example, the antenna may be formed by a conductive coil or wire embedded in a housing associated with monitor **12**. Alternatively, the antenna may be mounted on a circuit board carrying other components of monitor **12**, or take the form of a circuit trace on the circuit board.

[**0043**] Battery power source **32** may take the form of a battery and power generation circuitry. Urodynamic monitor **12** typically may be used for a few days or weeks, and therefore may not require substantial battery resources. Accordingly, the battery within battery power source **32** may be very small. An example of a suitable battery is the Energizer **337** silver oxide cell, available from the Eveready Battery Company, of St. Louis, Mo., USA. The Energizer **337** battery is disc-shaped, and has a diameter of 4.88 mm and thickness of 1.65 mm. Another example battery is the QL003I3 milliamp cylindrical battery from Quallion, LLC, of Sylmar, Calif., USA, which has a diameter of approximately 2.9 mm and a length of approximately 13.0 mm.

[**0044**] In further embodiments, battery power source **32** may be rechargeable via electromagnetic induction or ultrasonic energy transmission, and includes an appropriate circuit for recovering transcutaneously received energy. For example, battery power source **32** may include a secondary coil and a rectifier circuit for inductive energy transfer. In still other embodiments, battery power source **32** may not include any storage element, and monitor **12** may be fully powered via transcutaneous inductive energy transfer, which may be provided by external receiver **14**.

[**0045**] Sensor **26** may be selected for any of a variety of urodynamic testing applications, and may include appropriate signal processing circuitry such as amplifier, filter, driver, and analog-to-digital conversion circuitry for presentation of sensed information to processor **24**. For urodynamic testing, sensor **26** may take the form of a pressure, flow, velocity, volume, temperature, impedance, or contractile force sensor.

[**0046**] Pressure, contractile force or other measurements may be used to detect bladder or urinary sphincter functions in order to automatically detect the onset of an attempt to void urine from bladder **18**. For example, an elevated pressure or force, or change in pressure or force, may indicate a contraction of the bladder muscle, which may be used to generate a voiding event activation command to trigger collection of urodynamic information for recording in a voiding diary. As a further example, if monitor **12** is implanted within urethra **20**, the voiding event may be detected by detecting the presence of urine in the urethra, e.g., by flow, pressure, temperature, or impedance sensing. Accordingly, in some embodiments, the use of two monitors **12** may be desirable, e.g., one in bladder **18** and one in urethra **20**. Hence, for automated detection, processor **24** may periodically sample and monitor the output of sensor **26**. In some embodiments, monitor **12** may transmit the periodically sampled information to external controller **14**, which then analyzes the information to detect a voiding event.

[**0047**] For urodynamic testing, sensor **26** may have a structure similar to sensors conventionally used for catheter-based urodynamic testing. For pressure measurements, for example, sensor **26** may include one or more diaphragm sensors, strain gauge sensors, capacitive sensors, piezoelectric sensors, or other sensors used in conventional catheter-based urodynamic testing to sense pressure. For bladder emptying, sensor **26** may include a conductive sensor to sense the presence of urine within the lower region of the bladder **18**.

[**0048**] For flow measurements, sensor **26** may comprise a pulsed Doppler ultrasonic sensor, or a laser Doppler flow sensor. Doppler shifting of the frequency of the reflected energy indicates the velocity of the fluid flow passing over a surface of sensor **26**. Consequently, in some embodiments, monitor **12** may include circuitry, such as a quadrature phase detector, in order to enable the monitor to distinguish the direction of the flow of fluid in addition to its velocity.

[**0049**] As a further example, sensor **26** may include any one or more thermal-convection velocity sensors. A thermal-convection velocity sensor may include a heating element upstream of a thermistor to heat urine within the urethra **16** such that flow rate may be measured according to the temperature of the heated fluid when it arrives at the thermistor. In other embodiments, flow rate may be determined from the output of a concentration or temperature sensor using Fick's techniques.

[**0050**] In some embodiments, sensor **26** may include multiple sensors of a given type, as well as multiple types of sensors, e.g., pressure, flow, bladder emptying, or the like. Accordingly, the urodynamic information obtained by monitor **12** may then include different types of physiological parameters associated with a voiding event. Alternatively, multiple monitors **12** may be deployed within bladder **18** or urethra. In this case, each monitor **12** may be configured with a different type or set of sensors **26** to collect a variety of different urodynamic parameters during a voiding event.

[**0051**] In response to a voiding event activation command, monitor **12** obtains urodynamic information from sensor **26** and either records the information in internal memory **28** carried by the monitor, or transmits the information directly to external controller **14** by wireless telemetry. In some embodiments, monitor **12** also may be capable of continuously or periodically performing urodynamic testing over an extended period of time, encompassing voiding events and measurements between voiding events.

[**0052**] By selectively obtaining urodynamic information associated with voiding events, however, monitor **12** is configured to support the generation of an automatic urinary voiding diary containing urodynamic information obtained over a series of voiding attempts. Again, in response to the voiding event activation command, monitor **12** commences sensing of one or more physiological conditions within bladder **18** or urethra **20**, and either records pertinent information internally, transmits the information directly to external controller **14**, or temporarily buffers and then transmits the information to external controller **14**, either directly or in response to an interrogation request by the external controller.

[0053] In embodiments in which information is stored internally within monitor **12**, the monitor may include functionality similar to the existing Medtronic Reveal™ implantable loop recorder, manufactured by Medtronic, Inc. of Minneapolis, Minn. The Reveal™ implantable loop recorder samples and records one or more segments of far field EGM or subcutaneous ECG signals.

[0054] Aspects of the Reveal™ loop recorder are disclosed in commonly assigned PCT publication WO98/02209, the entire content of which is incorporated herein by reference. In accordance with the invention, monitor **12** may be adapted to sample and record one or more segments of information pertaining to physiological conditions within the urinary tract. In some embodiments, the memory capacity of memory **28** in monitor **12** may be limited, and so the segments of information that are stored in memory can be written over with new information when the patient triggers storage and the memory is full.

[0055] The most recently stored segment or segments of information may be transmitted via uplink telemetry transmission from monitor **12** to external controller **14** on a continuous or periodic basis, or when a memory interrogation telemetry session is initiated by a medical care provider using the external controller. In other embodiments, external controller **14** may be configured to avoid overwriting, and instead retain previously sensed information when the memory with the external controller is full.

[0056] **FIG. 3** is a functional block diagram illustrating external controller **14** for communication with urodynamic monitor **18** of **FIG. 2**. In the example of **FIG. 3**, external controller **14** includes a processor **34**, memory **36**, power source **38**, telemetry interface **40**, user input **42** and display **44**. Memory **36** stores instructions for execution by processor **34**. In addition, memory **36** stores information received from monitor **12** incident to a voiding event, thereby forming an automated voiding diary for review by a physician. Memory **36** may include separate memories for storage of instructions and urodynamic information.

[0057] Processor **34** controls telemetry interface **40** to obtain urodynamic information from monitor **18**. Processor **34** also may control telemetry interface **40** to receive information from monitor **18** on a substantially continuous basis, at periodic intervals, or only upon receipt of a user activation command. Hence, external controller **14** may obtain on ongoing, up-to-date indication of the physiological conditions sensed by monitor **12**. More particularly, however, external controller **14** is configured to respond to a voiding event activation command **46** entered by patient **16** via user input device **42**. In response to the voiding event activation command **46**, external controller **14** generates an activation control signal and transmits the control signal to monitor **12** via telemetry interface **40**.

[0058] Urodynamic monitor **12** may be configured to collect information for a specified period of time following receipt of an activation control signal from external controller **14**, e.g., for a period of several minutes. Alternatively, external controller **14** may receive a voiding event deactivation command (not shown) from the user. In this case, external controller **14** transmits a deactivation control signal to urodynamic monitor **12**. Accordingly, monitor **12** may be configured to collect urodynamic information from the time an activation control signal is received to the time a deactivation control signal is received.

[0059] External controller **14** permits a user to receive urodynamic information obtained by a sensor carried by monitor **12** during the course of a voiding event. In addition, external controller **14** may process and record information obtained from monitor **12**, and present the information to a user via display **44** or other output media. In some embodiments, the information may include one or more advisories with respect to the presence or level of a urodynamic parameter. In addition, the recorded information may be transmitted from external device **14** to other external devices for presentation, archival or further analysis.

[0060] Advantageously, the recorder functionality of the external controller **14** serves to build a voiding diary. In particular, by permitting a patient **16** to activate sensing and recording coincident with a voiding event, external controller **14** is able to compile information specifically associated with one or more voiding events over an observation period. Consequently, a physician can view a more selective set of urodynamic information, which may be very useful in diagnosing symptoms such as incontinence, pain, or the like. In particular, a physician can parse through multiple entries in the voiding diary to identify changes in physiological conditions over time, or at different times of the day or night.

[0061] Wireless telemetry may be accomplished by radio frequency (RF) communication or proximal inductive interaction of external controller **14** with monitor **12**. Alternatively, telemetry interfaces **30**, **40** may be configured for monitor **12** and external controller **14** to support radio frequency (RF) communication with a sufficiently strong signal such that proximate interaction is not required. In addition to an RF or inductive telemetry interface **40**, in some embodiments, external controller **14** may include an additional RF or infrared interface for communication with other external devices, e.g., for transfer of urodynamic information.

[0062] External controller **14** may take the form of a portable, handheld device, like a pager or cell phone, that can be carried by patient **12**. External controller **14** may include an internal antenna, an external antenna protruding from the recorder, or an external antenna that extends from the recorder on a cable and is attached to the body of patient **12** at a location proximate to the location of monitor **12** to improve wireless communication reliability. Also, in some embodiments, external controller **14** also may receive operational or status information from monitor **12**, and may be configured to actively configure and interrogate the monitor to receive the information.

[0063] **FIG. 4** is flow diagram illustrating operation of a urodynamic monitor **12** and external controller **14** in response to a voiding event activation command from a patient. As shown in **FIG. 4**, external controller **14** receives a voiding event activation command from patient **16** (**48**). In response, external controller **14** transmits a control signal to monitor **12** instructing the monitor to initiate sensing of one or more physiological parameters of the urinary tract (**50**). Implanted monitor **12** transmits urodynamic information, based on the sensed physiological parameters. External controller **14** receives the urodynamic information from implanted monitor **12** (**52**). External controller **14** then processes the information received from monitor **12**, if necessary, and records the information in memory for evaluation by a physician or other care-giver (**54**).

[**0064**] Urodynamic monitor **12** may continue to collect urodynamic information for a specified period of time following receipt of the activation command. Upon expiration of the specified period of time, monitor **12** automatically terminates collection of urodynamic information. The specified time may be selected to correspond to the maximum expected duration of a voiding event, such as an attempt to void urine from the bladder, and may be on the order of several seconds to a few minutes.

[**0065**] Alternatively, as shown in **FIG. 4**, implanted monitor **12** may terminate collection of urodynamic information in response to a termination command received from external controller **14**. For example, a patient may enter a voiding deactivation command into external controller **14** (**56**), e.g., at the end of a voiding event. In response, external controller **14** transmits a control signal to instruct monitor **12** to terminate sensing of urodynamic parameters (**58**).

[**0066**] During a voiding event, monitor **12** may intermittently or continuously transmit urodynamic information to external controller **14**, e.g., in the form of measured parameters obtained at different sample times during the course of monitoring. Alternatively, monitor **12** may transmit information at the end of a monitoring period, either as measured parameters or processed values, such as average or trend data. Once the information is transmitted, monitor **12** waits for the next activation command for a subsequent voiding event.

[**0067**] **FIG. 5** is flow diagram illustrating operation of a urodynamic monitor **12** and external controller **14** in response to a sensed voiding event. In the example of **FIG. 5**, monitor **12** does not require a voiding event activation command from the patient **16**. Instead, monitor is configured to automatically sense a voiding event (**49**), e.g., by detection of an elevation or change in pressure or urine flow. Upon automated detection of a voiding event, urodynamic monitor **12** initiates sensing of physiological parameters (**51**), and records urodynamic information based on the sensed parameters (**53**). The urodynamic information may be recorded within memory in monitor **12**, and later transmitted to external controller **14** upon receipt of an interrogation request (**55**). Alternatively, the urodynamic information may be transmitted to external controller **14** as the information is obtained by monitor **12**.

[**0068**] **FIG. 6** is a functional block diagram illustrating a network **60** for communication of information obtained by one or more urodynanic monitors **12**. Two implanted urodynamic monitors **12**A, **12**B, e.g., in different patients, are shown for purposes of illustration. However, information for any number of monitors **12** and patients **16** may be accessed via network **60**. In particular, physicians or other medical personnel may view urodynamic information transmitted to external controllers **14**A, **14**B by implanted monitors **12**A, **12**B to evaluate urodynamic conditions. External controllers **14**A, **14**B are coupled to network **60** via wired or wireless connections, and transmit information obtained from monitors **12**A, **12**B to a network server **62** via the network.

[**0069**] Network server **62** may be equipped to analyze the information and generate appropriate reports or advisories for viewing by users via any of network clients **64**A, **64**B, **64**C (collectively **64**), coupled to network **60**. For example, network server **62** may generate web pages or other output that conveys voiding diary information obtained by monitors **12**A, **12**B. Hence, network clients **64** may access information on network server **62** using web browsers. In this manner, one or more users, such as physicians, may remotely view voiding diaries for one or more patients **16**. Network **60** may take the form of a local area, wide area or global computer network, such as the Internet.

[**0070**] In some embodiments, network server **62** may be configured to poll external controllers **14** to received information. Network server **62** also may be configured to transmit advisories by email, facsimile, text messaging, instant messaging or the like to network clients **64**, when voiding diary results are available for a particular patient. In this manner, the user associated with a network client **64** is able to remotely monitor information concerning a patient's condition, as obtained by the implanted monitor **12**, and act on that information, if appropriate.

[**0071**] The ability to formulate an automated voiding diary with a temporary or chronic implanted monitor **12**, combined with remote monitoring capabilities, can support a wide range of patient management capabilities, tight control of drug management, disease diagnostics, and chronic disease management. In addition, the ability to formulate a voiding diary while that patient is at home and going about daily living activities can provide much more accurate and meaningful data. For example, a pressure monitor in the bladder may be used to monitor bladder function during voiding events occurring over a period of several days, and over the course of several activities such as rest, eating, drinking, and exercise.

[**0072**] Implanted monitor **12** also may be used chronically for management of spinal cord injury patients who do not have bladder sensation. Rather than timed, intermittent catheterization, implanted monitor **12** would allow a spinal cord injury patient to monitor fullness and void only when necessary. In this case, monitor **12** could transmit a signal to external controller **14** when a particular level of bladder fullness is reached, thereby triggering an alarm or advisory for voiding.

[**0073**] **FIG. 7** is a cross-sectional side view of a urodynamic monitor **12** with a fixation structure. In the example of **FIG. 7**, monitor **12** is placed adjacent mucosal lining **66** within bladder **18** or urethra **20**. Monitor **12** includes a capsule-like housing **68**. A sensor **26** is exposed by housing **68** for interaction with the environment within bladder **18** or urethra **20**. A shaft **70** extends through an internal channel **72** in the capsule-like housing **68** of monitor 12. Monitor **12** defines a vacuum cavity **74** on a side of the housing **68** adjacent mucosal lining **66**. A vacuum port defined by channel **72** applies vacuum pressure to vacuum cavity **74** to draw a portion of mucosal tissue **76** into the cavity. The vacuum port is attached to a vacuum line (not shown) carried by an endoscopic delivery device. The vacuum line is coupled to an external vacuum source.

[0074] An elongated control rod (not shown in **FIG. 7**) may be applied via the endoscopic delivery device to drive shaft **70** into mucosal tissue **76**. Shaft **70** may have a sharpened tip **77** that facilitates partial or complete penetration of tissue **76**. Upon penetration of tissue **76** to secure monitor **12** relative to mucosal lining **66**, vacuum pressure is deactivated and the endoscopic delivery device is withdrawn from urethra **20**. Although shaft **70** is illustrated as penetrating tissue **76**, in some embodiments, the shaft may be spring-biased to pinch a fold of the tissue and thereby secure monitor **12** at a desired position.

[0075] In some embodiments, shaft **70** may be manufactured from degradable materials that degrade over time, e.g., in the presence of urine, to release monitor **12** from mucosal lining **66**. Alternatively, monitor **12** may release from mucosal lining **66** as mucosal tissue **76** sloughs away from mucosal lining **66**. In either case, once the mucosal tissue **76** is released by shaft **70**, monitor **12** detaches from mucosal lining **66** for passage through the urinary tract with urine flow or recovery with an endoscopic recovery device. Shaft **70**, vacuum cavity **74** and the vacuum port defined by channel **72** form a fixation structure.

[0076] In general, monitor **12** may make use of fixation structures that are configured and function in a manner similar to any of the fixation structures disclosed in U.S. Pat. Nos. 6,285,897 and 6,698,056 to Kilcoyne et al. The Kilcoyne et al. patents provide examples of fixation mechanisms for attaching monitoring devices to the lining of the esophagus, including suitable degradable materials. The fixation structures described in the Kilcoyne et al. patents may be suitable for attachment of monitor **12** within bladder **18** or urethra **20**. Examples include shafts, hooks, barbs, screws, sutures, clips, pincers, staples, tacks, and expandable frames. The contents of the Kilcoyne et al. patents are incorporated herein by reference in their entireties.

[0077] Although sensor **26** is depicted as having one or more surface components exposed to an environment within bladder **18** or urethra **20**, in some embodiments, monitor **12** may include a hollow lumen to allow urine flow through the monitor. In this case, monitor **12** may have an annular cross-section, in a plane perpendicular to urine flow, and sensor **26** may be oriented such that sensor components are exposed to the interior of the hollow lumen. This type of configuration for monitor **12** may be particularly useful within urethra **16**, and can be used to monitor flow rate, pressure, and timing of voiding, which may be advantageous in diagnosing benign prostate hyperplasia (BPH).

[0078] **FIG. 8** is a schematic diagram illustrating deployment of a monitor **12** within a patient's urinary tract. As shown in **FIG. 8**, an endoscopic delivery device **80** serves to position and place monitor **12** within the urinary tract of patient **16**. Delivery device **80** includes a proximal portion, referred to herein as a handle **82**, and a flexible probe **84** that extends from handle **82** for insertion into urethra **20**. Probe **84** is sized for passage through urethra **20** and may include a lubricating coating to facilitate passage.

[0079] Monitor **12** is coupled to a distal end **85** of delivery device **80** for delivery to a target location within the urinary tract. The target location may be within urethra **20** or within bladder **18**. In some embodiments, delivery device **80** may include appropriate guidewires or other steering mechanisms to permit placement of monitor **12** on a lateral wall of bladder **18**, as indicated by the position of monitor **12** depicted in **FIG. 1**.

[0080] Distal end **85** of delivery device **80** enters urethra **20** and extends into the urethra to the target location. The progress of distal end **85** may be monitored by endoscopic viewing or external viewing, e.g., with ultrasound or fluoroscopy. Monitor **12** is attached to the mucosal lining at the target location within bladder **18** or urethra **20**, and the distal end **85** of delivery device **80** releases the monitor. Upon placement of monitor **12**, flexible probe **84** and distal end **85** are withdrawn from urethra **20**. Monitor **12** may be activated prior to placement within the urinary tract, or activated remotely by wireless communication or passage of a magnet in close proximity to monitor **12** to activate a switch carried by the monitor.

[0081] **FIG. 9** is a cross-sectional side view illustrating positioning of monitor **12** of **FIGS. 7 and 8** within distal end **85** of an endoscopic delivery device **80**. As shown in **FIG. 8**, monitor **12** is held within a placement bay within distal end **85** of endoscopic delivery device **80**. In this example, a physician advances elongated control rod **86** to drive shaft **70** into mucosal tissue **76**. In general, elongated control rod **86** permits a physician to exert force to penetrate mucosal tissue **76**. Elongated control rod **86** is flexible and extends though flexible probe **84** to handle **82** so that the physician can manipulate the elongated control rod. Before advancing elongated control rod **86**, however, the physician activates a vacuum line to supply vacuum pressure to vacuum cavity **74** via channel **72** of monitor **12**.

[0082] **FIG. 10** is a side view of a monitor **12** with another fixation structure in the form of an expandable frame **88**. As shown in **FIG. 10**, the capsule-like housing of monitor **12** has a diameter that is substantially less than the diameter of expandable frame **88** when the frame is in a fully expanded state. Upon expansion, frame **88** engages the mucosal lining of the interior wall **66** of urethra **20**, much like a conventional stent used for restoring patency of blood vessels. In this manner, expandable frame **88** securely holds monitor **12** in place at a target location within the urethra **20**. Details of a similar expandable frame and monitor arrangement are described in the aforementioned Christopherson et al. application.

[0083] The capsule-like housing of monitor **12** is attached to a portion of a wire grid **90** forming expandable frame **88**. Monitor **12** may be welded, adhesively bonded, or crimped to one or more coupling points **92** on expandable frame **88**. Wire grid **90** may take the form of a grid, network, or mesh of elastic wires that form a substantially cylindrical frame, similar to a conventional stent useful in restoring blood vessel patency. Examples of suitable materials for fabrication of wire grid **90** include stainless steel, titanium, nitinol, and polymeric filament, which can be absorbable or nonabsorbable in vivo, as described in the above-referenced Kilcoyne patents.

[0084] Expandable frame **88** may be intrinsically elastic such that it is self-expandable upon release from a restraint provided by an endoscopic delivery device. Alternatively, in some embodiments, a balloon or other actuation mechanism may be used to actively expand frame **88** to a desired diameter. In each case, expandable frame **88** extends radially outward to engage the wall of a urethra **20**, and thereby place monitor **12** in contact with the lumen wall. In particular, upon expansion of frame **88**, monitor **12** is placed within the lumen defined by urethra **20**, and within the flow of urine through the urethra.

[**0085**] The position of monitor **12** within urethra **20** permits sensing of urodynamic parameters, such as pressure, flow rate, velocity, temperature, impedance, contractile force, and the like. In further embodiments, monitor **12** may include an ultrasonic imaging transducer to obtain snapshot ultrasound images of a region of interest during a voiding event. Monitor **12** senses the applicable physiological conditions and transmits information based on the sensed conditions to external controller **14**. In some embodiments, expandable frame **88** may be electrically coupled to monitor **12** and form part of an antenna to facilitate reliable wireless telemetry.

[**0086**] Monitor **12** is depicted in **FIG. 10** as being coupled to one side of expandable frame **88**, and therefore resides adjacent a wall of urethra **20**. In other embodiments, however, monitor **12** may be mounted to frame **88** such that monitor resides substantially centrally within urethra **16**. For example, monitor **12** may be cantilevered or otherwise supported by frame **88** with expandable struts that place the monitor centrally within the aperture defined by the frame. In this case, monitor **12** may be constructed with a hollow lumen for passage of urine flow, and a sensor associated with monitor **12** may be oriented inward toward the lumen to sense conditions of the urine such as urodynamic conditions or urinalysis characteristics.

[**0087**] **FIG. 11** is a conceptual diagram of an external controller **14** equipped to present voiding diary information to a user. External controller **14** includes a display screen **94** that presents urodynamic information associated with a particular voiding event. In the example of **FIG. 11**, display screen **94** presents the date and time **96** of the voiding event, a maximum voiding pressure **98** measured by monitor **12** during the course of the voiding event, and maximum flow rate **100** measured by monitor **12** during the course of a voiding event. A variety of additional urodynamic parameters may be presented on external controller **14**, as well as average, maximum, minimum and trend data over a voiding event or over a series of voiding events. The parameters depicted in **FIG. 11** are merely for purposes of illustration, and should not be considered limiting of the invention as broadly embodied herein.

[**0088**] **FIG. 12** is another conceptual diagram of external controller **14**, illustrating organization and selection of urodynamic information obtained from monitor **12**. For example, external controller **14** may present a list **102** of voiding events throughout a period of time, such as a day or several days. If display screen **94** is equipped as a touch-screen display, or external controller **14** includes other input media, such as buttons, keys, or the like, a user may select one of the voiding events and access a set **104** of urodynamic information for the selected voiding event. The set **104** of urodynamic information, in turn, may permit the user to select individual parameters, as well as profile or trend data, for presentation on display screen **94**. External controller **14** also may provide the capability to transmit the information to another device, e.g., via wireless or wired connection.

[**0089**] The preceding specific embodiments are illustrative of the practice of the invention. It is to be understood, therefore, that other expedients known to those skilled in the art or disclosed herein may be employed without departing from the invention or the scope of the claims. For example, the invention is not limited to deployment of a monitor at a particular location within the urinary tract. In various embodiments, a medical device may be located anywhere within the urinary tract where useful diagnostic information can be obtained.

[**0090**] In the claims, means-plus-function clauses are intended to cover the structures described herein as performing the recited function and not only structural equivalents but also equivalent structures. Thus, although a nail and a screw may not be structural equivalents in that a nail employs a cylindrical surface to secure wooden parts together, whereas a screw employs a helical surface, in the environment of fastening wooden parts a nail and a screw are equivalent structures.

[**0091**] Many embodiments of the invention have been described. Various modifications may be made without departing from the scope of the claims. These and other embodiments are within the scope of the following claims.

1. A system for forming a urinary voiding diary for a patient, the system comprising:

an implantable urodynamic monitor to generate urodynamic information based on a sensed physiological condition within a urinary tract of a patient in response to a voiding event activation command; and

an external controller to receive the urodynamic information from the monitor via wireless communication, and record the urodynamic information to form a voiding diary.

2. The system of claim 1, wherein the monitor terminates generation of the urodynamic information in response to a voiding event deactivation command.

3. The system of claim 1, wherein the monitor terminates generation of the urodynamic information upon expiration of a period of time following the voiding event activation command.

4. The system of claim 1, wherein the external controller includes a user input device to enter the voiding event activation command, and a wireless telemetry interface to transmit the voiding event activation command to the monitor.

5. The system of claim 1, wherein the monitor includes a wireless telemetry interface to receive the voiding event activation command.

6. The system of claim 1, wherein the monitor includes a magnet detector to detect proximity of a magnet to the monitor as the voiding event activation command.

7. The system of claim 1, wherein the monitor generates the voiding event activation command in response to detection of the onset of a voiding event.

8. The system of claim 7, wherein the monitor includes a sensor to detect the onset of the voiding event.

9. The system of claim 7, wherein the voiding event corresponds to at least one of an attempt to void urine from a bladder of the patient, a feeling of discomfort in the urinary tract, and involuntary leakage of urine.

10. The system of claim 1, wherein the monitor includes a memory to record the urodynamic information.

11. The system of claim 1, wherein the monitor includes a sensor configured to sense the physiological condition, and wherein the physiological condition includes at least one of pressure, flow, velocity, temperature, contractile force, and impedance.

12. The system of claim 1, wherein the external controller includes a display to present the urodynamic information to a user.

13. The system of claim 1, wherein the monitor includes a fixation element to fix the monitor within the urinary tract of the patient.

14. The system of claim 1, wherein the implantable urodynamic monitor generates urodynamic information for a plurality of voiding events over a period of time in response to a plurality of voiding event activation commands, and the external controller records the urodynamic information to form a voiding diary for the plurality of voiding events.

15. The system of claim 1, further comprising a plurality of the implantable urodynamic monitors generating multiple sets of the urodynamic information, the external controller recording the multiple sets of urodynamic information to form the voiding diary.

16. A method for forming a urinary voiding diary for a patient, the method comprising:

controlling an implantable urodynamic monitor to generate urodynamic information based on a sensed physiological condition within a urinary tract of a patient during a voiding event; and

generating a voiding diary based on the urodynamic information.

17. The method of claim 16, further comprising transmitting the urodynamic information to an external controller via wireless communication, and recording the urodynamic information in memory in the external controller to form the voiding diary.

18. The method of claim 16, wherein controlling the monitor includes transmitting a voiding event activation command to the monitor.

19. The method of claim 18, further comprising controlling the monitor to terminate generation of the urodynamic information upon expiration of a period of time following the voiding event activation command.

20. The method of claim 18, further comprising transmitting a voiding event deactivation command to the monitor to cause the monitor to terminate generation of the urodynamic information.

21. The method of claim 16, wherein controlling the monitor further comprises controlling the monitor to generate urodynamic information in response to user input indicating onset of a voiding event.

22. The method of claim 16, wherein controlling the monitor further comprises controlling the monitor to generate urodynamic information in response to detection of proximity of a magnet to the monitor.

23. The method of claim 16, wherein controlling the monitor further comprises controlling the monitor to generate urodynamic information in response to detection of the onset of a voiding event.

24. The method of claim 23, wherein the monitor includes a sensor to detect the onset of the voiding event.

25. The method of claim 16, wherein the voiding event corresponds to at least one of an attempt to void urine from a bladder of the patient, a feeling of discomfort in the urinary tract, and involuntary leakage of urine.

26. The method of claim 16, further comprising obtaining the sensed physiological condition from a sensor that senses at least one of pressure, flow, velocity, temperature, contractile force, and impedance.

27. The method of claim 16, further comprising transmitting the urodynamic information to an external controller via a wireless interface, and presenting the urodynamic information to a user via a display associated with the external controller.

28. The method of claim 16, wherein controlling the monitor includes controlling the monitor to generate urodynamic information for a plurality of voiding events over a period of time, and forming the voiding diary includes forming the voiding diary using the urodynamic information generated for the plurality of voiding events.

29. The method of claim 16, further comprising controlling a plurality of implantable urodynamic monitors to generate multiple sets of the urodynamic information, and forming the voiding diary based on the multiple sets of urodynamic information.

30-42. (canceled)

43. An implantable urodynamic monitor comprising:

a sensor to sense a physiological condition within a urinary tract of a patient; and

a processor to generate urodynamic information based on the physiological condition in response to a voiding event activation command indicative of an onset of a voiding event.

44. The monitor of claim 43, further comprising a wireless telemetry interface to transmit the urodynamic information to an external controller for formulation of a voiding diary based on the urodynamic information.

45. The monitor of claim 43, further comprising a wireless telemetry interface to receive the voiding event activation command from an external controller operated by the patient.

46. The monitor of claim 43, wherein the processor terminates generation of the urodynamic information in response to a voiding event deactivation command received from a user.

47. The monitor of claim 43, wherein the processor terminates generation of the urodynamic information upon expiration of a period of time following the voiding event activation command.

48. The monitor of claim 43, wherein the monitor includes a magnet detector to detect proximity of a magnet to the monitor as the voiding event activation command.

49. The monitor of claim 43, wherein the processor generates the voiding event activation command in response to detection of the onset of a voiding event.

50. The monitor of claim 49, wherein the monitor includes a sensor to detect the onset of the voiding event.

51. The monitor of claim 43, wherein the voiding event corresponds to at least one of an attempt to void urine from a bladder of the patient, a feeling of discomfort in the urinary tract, and involuntary leakage of urine.

52. The monitor of claim 43, further comprising a memory to record the urodynamic information.

53. The monitor of claim 43, wherein the sensor is configured to sense at least one of pressure, flow, velocity, temperature, contractile force, and impedance.

54. The monitor of claim 43, wherein the monitor includes a fixation element to fix the monitor within the urinary tract of the patient.

* * * * *

patsnap

专利名称(译)	无线尿动力监测系统，自动排尿日记		
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摘要(译)

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