URODYNAMIX TECHNOLOGIES LTD

URO-1000 URO-NIRS Bladder Monitor

User Manual

URO-1000 URO-NIRS Bladder Monitor

CAUTION: Federal (or United States) Law restricts this Device to sale by or on the order of a Licensed Physician

Manufactured by:

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	**Caution - Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous laser radiation exposure**

Caution: Portable and mobile RF communications equipment may affect medical electrical equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/ TV technician for help.

Caution: Changes or modifications to this equipment, not expressly approved by the manufacturer could void the user's authority to operate the equipment.

Rev. 1.5

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Introduction

The URO-1000 URO-NIRS Bladder Monitor by Urodynamix Technologies Ltd. is a non-invasive urodynamics device used to aid in the diagnosis of male patients with lower urinary tract symptoms (LUTS) caused by benign prostatic hyperplasia (BPH).

Urodynamix's URO-NIRS technology utilizes an optical sensor that is placed directly on the abdomen over the site of the bladder. The sensor is attached to a control unit. The URO-NIRS exam projects specific wavelengths of near infrared light onto the skin over the bladder to gather data about bladder health and function in a painless, easily administered and efficient manner.

The URO-1000 URO-NIRS Bladder Monitor measures and displays changes in oxygenated hemoglobin (HbO_2), de-oxygenated hemoglobin (Hb) and cytochrome (Cyt) over time during bladder filling and voiding. It is intended for integration into an OEM diagnostic system.

Theory of Operation

URO-NIRS technology is based on the principles of near-infrared spectroscopy (NIRS). NIRS is a non-invasive optical technique commonly used in medical diagnostics. The NIRS emitter projects specific wavelengths of near-infrared light onto the skin to illuminate the tissues and organs beneath. The NIRS light is absorbed differently depending on a variety of factors, including the concentrations of chromophores such as hemoglobin (the iron-containing oxygen-transport metalloprotein in red blood cells) and cytochromes (membrane-bound proteins) in the blood and/or muscles. Some of the light that is not absorbed is scattered and returns to the sensor, and these changes are analyzed to provide useful clinical information.

NIRS can be used for non-invasive assessment of the bladder through the intact abdominal wall in human subjects by detecting changes in blood hemoglobin concentrations associated with bladder function. By using URO-NIRS technology to continuously monitor and detect changes in the concentrations of chromophores in the detrusor muscle (the contraction of which causes urination), valuable information can be provided to the physician to indicate the physiological activity of the bladder.

Intended Use / Indications for Use

The URO-1000 Bladder Monitor is intended for non-invasive urodynamics testing to aid in the diagnosis of male patients with lower urinary tract symptoms caused by benign prostatic hyperplasia. It is intended to be integrated into an OEM system comprising, at minimum, a PC and uroflow meter.

Contraindications

Underweight subjects with a low initial body mass index (BMI) are contraindicated from tests using the URO-1000.

Obese subjects with a high initial body mass index (BMI) are contraindicated from tests using the URO-1000.

Components

The URO-1000 URO-NIRS Bladder Monitor consists of the following items:
1. URO-1000 Controller
2. Optical sensor cable
3. Single-use sensor patches
4. Serial and power cables

Figure 1 – URO-1000 URO-NIRS Bladder Monitor

URO-1000 Controller

The URO-1000 controller houses three near-infrared lasers and an optical signal detector. An onboard processor measures the changes in chromophore concentrations and transmits data to the OEM PC for display. An RFID reader mounted in the top panel is used to scan and validate the single-use sensor patches.

The front panel of the URO-1000 has three laser emitters, a signal detector port, laser status display and keylock power switch. The laser emitters and detector port are protected by a spring-loaded sliding connector guard to prevent removal of the optical sensor cable while the device is powered.

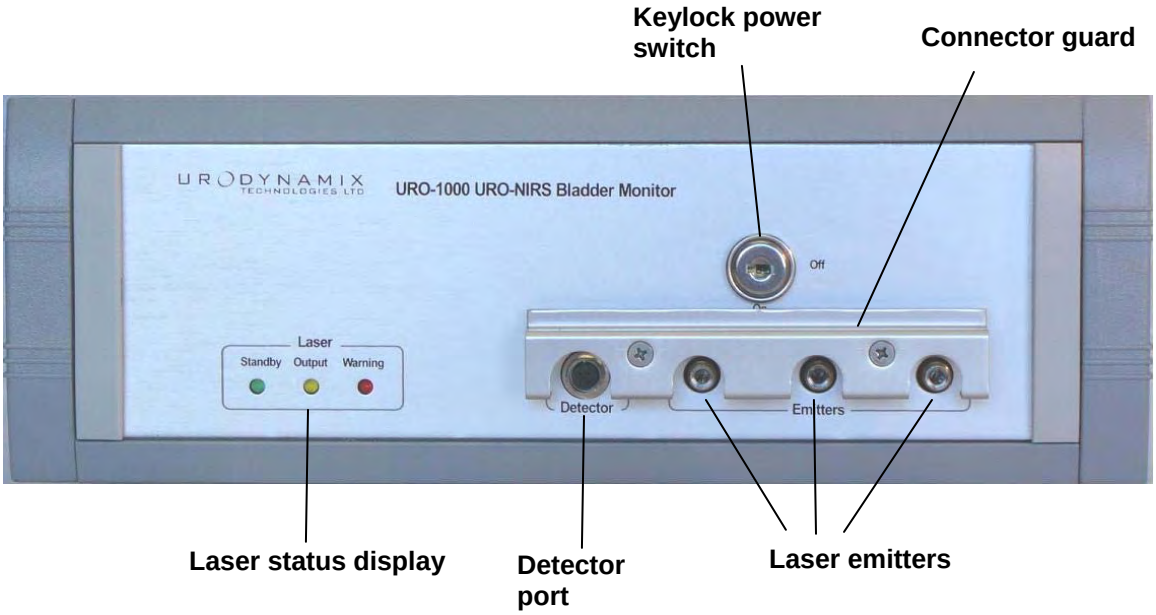


Figure 2 – URO-1000 Front Panel

The rear panel of the URO-1000 has a power cord receptacle, fuse housing, and USB and RS232 data output ports for connection to the OEM PC.

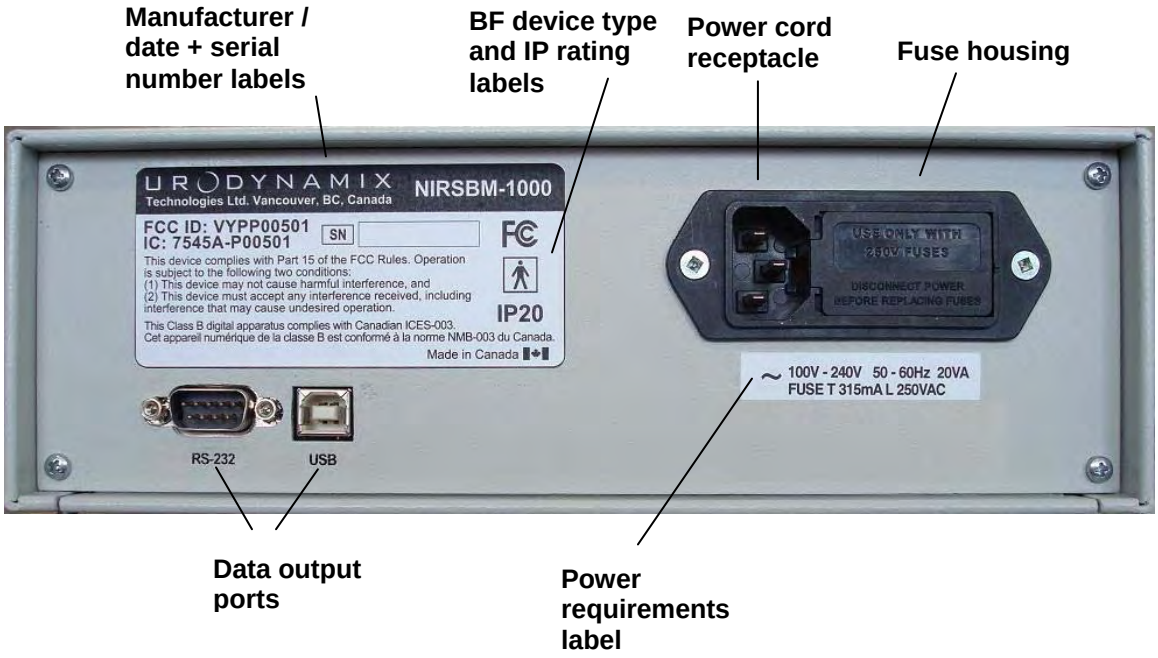


Figure 3 – URO-1000 Rear Panel

The top panel has an RFID scan area used to read and identify the single-use sensor patches. The URO-1000 becomes enabled when the user swipes a new unused sensor patch over the scan area.

Figure 4 – URO-1000 Top Panel

Optical Sensor Cable

The optical sensor cable carries laser light from the device to the patient and detects light absorbed in the patients' tissue. The detected light is converted to an electrical signal that is transmitted back to the URO-1000 for analysis.

The optical sensor cable has three fiber optic connectors that connect to the laser emitters on the URO-1000, and one detector connector that connects to the detector port. The optical sensor houses the optical emitter and detector, and fits into the single-use sensor patch for coupling to the patient.

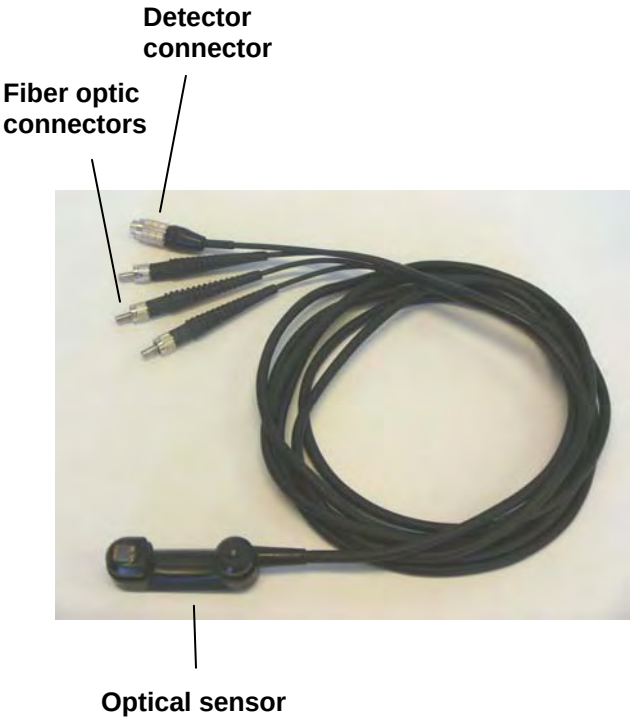


Figure 5 – Optical Sensor Cable

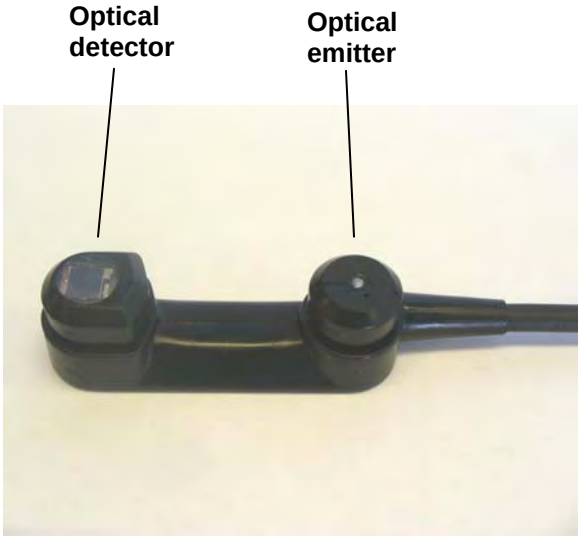


Figure 6 – Optical Sensor

Single-use Sensor Patch

The single-use sensor patch is used to couple the optical sensor to the patient. It also shields the sensor from ambient light.

The optical sensor fits into the sensor patch which has a medical grade peel-and-stick adhesive backing for adhering to the patient.

Each sensor patch contains an RF identification tag with a unique ID code. To prevent reuse, the URO-1000 becomes enabled only when a new sensor patch is swiped over the scan area of the controller unit. The same patch cannot be used to enable the system twice.

Figure 7 – Sensor Patch

Figure 8 – Sensor Patch with Optical Sensor Inserted

Technical Specifications

Product Classification

Protection against electric shock: **Class I, BF applied parts**
Protection against harmful ingress of water or particulate matter: **IP20**
Method of Sterilization or Disinfection: **Wipe with isopropyl alcohol swab (disinfect only - not to be sterilized)**
Mode of operation: **continuous**
Not suitable for use in an oxygen-rich environment.
Not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide

URO-1000 Controller

Electrical:	100 – 240VAC, 50 – 60Hz, 20VA Fuse: T 315mA L 250VAC
Dimensions:	260mm (length) x 250mm (width) x 100mm (height)
Weight:	2 kg
Operating temperature range:	0 to 40° C
Storage temperature range:	-40 to 70° C
Laser specifications:	Maximum Output Power: 2.2mW Class: 1 Wavelengths: 785nm, 808nm, 830nm Pulse duration: 4us Beam characteristic: Divergent

Optical Sensor Cable

Cable jacketing material:	Silicon rubber (latex-free)
Optical sensor material:	Polyurethane elastomer (latex-free)
Lengths:	10ft or 15ft
Operating temperature range:	0 to 35° C
Storage temperature range:	-40 to 70° C

Sensor Patch

Material: Thermoplastic elastomer compound (latex-free)

Adhesive: Medical grade, pressure-sensitive acrylic (latex-free)

Operating temperature range: 0 to 40° C

Storage temperature range: -40 to 40° C
Storage/transport restrictions: Do not expose patch to direct sunlight

Classification Standards

IEC 60601-1 : 1988 + A1:1991 + A2:1995
IEC 60601-1-2 : 2007
IEC 60825-1 : 2007

Verify proper operation before clinical use when connecting the URO-1000 Bladder Monitor to an external IT device.
• Any external IT device connected to the URO-1000 must be certified according to IEC60950.
• Compliance with IEC Standard 60601-1-1 system requirements is required for all combinations of equipment connected to the URO-1000.
• Any person connecting peripheral equipment to the data output port is configuring a medical system and is therefore responsible for compliance to system standard IEC Standard 60601-1-1 and the electromagnetic compatibility system standard IEC Standard 60601-1-2.

Electromagnetic Compatibility (EMC)

Guidance and manufacturer's declaration – electromagnetic emissions		
The URO-1000 is intended for use in an electromagnetic environment specified below. The customer or the user of the URO-1000 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 2	The URO-1000 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The URO-1000 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The URO-1000 is intended for use in an electromagnetic environment specified below. The customer or the user of the URO-1000 should assure that it is used in such an environment.			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1kV for input/output lines	± 2 kV for power supply lines ± 1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC6100-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the URO-1000 requires continued operation during power mains interruptions, it is recommended that the URO-1000 be powered from an interruptible power supply or a battery
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The URO-1000 is intended for use in an electromagnetic environment specified below. The customer or the user of the URO-1000 should assure that it is used in such an environment.			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the URO-1000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations (cellular/cordless) telephones and land mobile ratios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the URO-1000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the URO-1000.

[b] Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the URO-1000

The URO-1000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the URO-1000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the URO-1000 as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 KHz to 80 MHz $d = 1.17\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.17\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Safety

Laser Safety

During operation the URO-1000 Bladder Monitor emits invisible, divergent laser radiation from the emitter of the optical sensor. This radiation can cause damage to the eye if exposed. It is important to operate the system only with the optical sensor cable connected to the device and the sensor securely fastened to the patient.

	**Caution - Avoid any direct eye exposure to laser radiation**

Laser Radiation Delivery

The URO-1000 emits three wavelengths of near-infrared laser radiation (785nm, 808nm and 830nm) into the connected optical sensor cable through three laser emitters. The cable carries the light to the optical emitter and is injected into the patient's tissue. Light scattered back to the optical detector is converted to an electrical signal and transmitted back to the URO-1000. A laser safety interlock system in the device monitors the receiver signal and will shut down the laser emitters upon receiving improper signal.

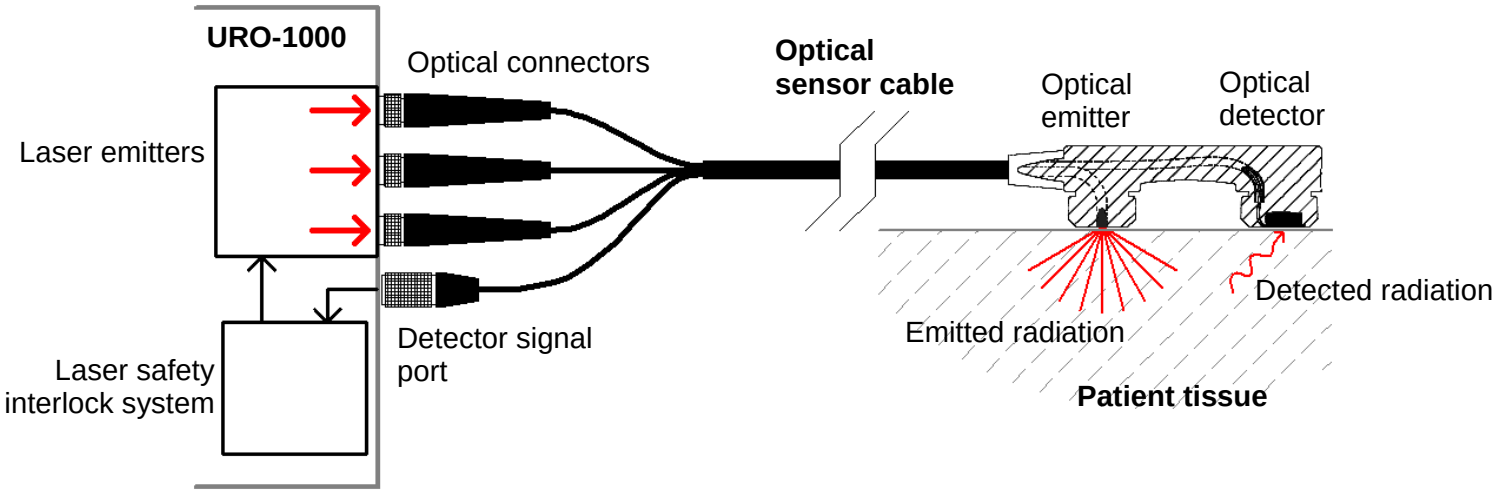


Figure 9 – Laser Radiation Delivery System

Laser Apertures

The URO-1000 emits invisible laser radiation from 3 apertures in the front panel as shown in the figure below:

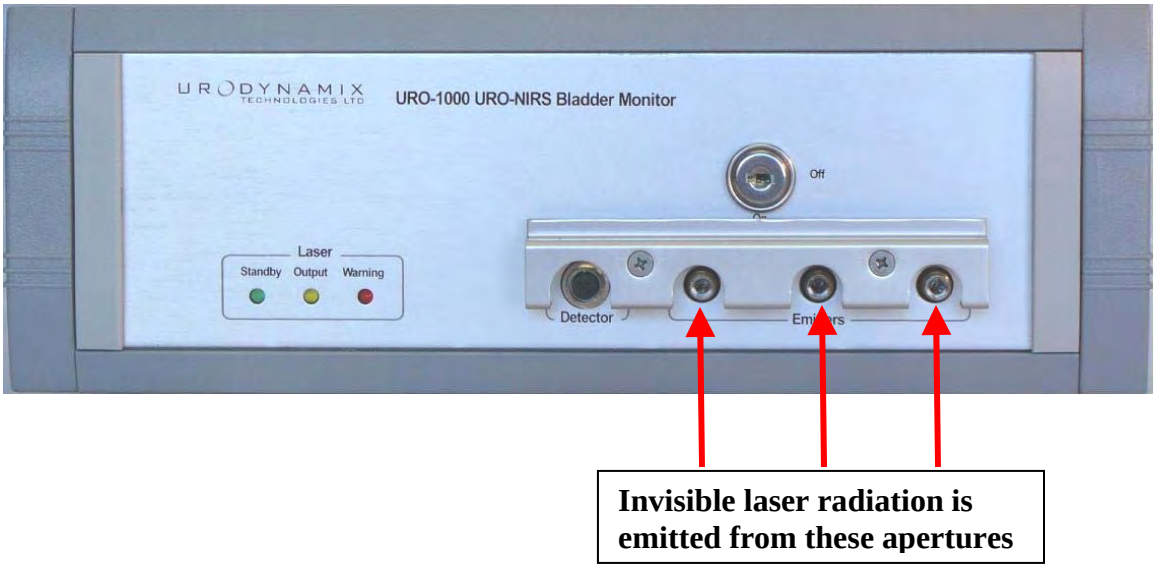


Figure 10 – URO-1000 Laser Apertures

⚠	**Caution - Do not look directly into the laser apertures of the URO-1000 when powered.**

⚠	**Caution - Do not operate the URO-1000 with the optical sensor cable disconnected**

The optical sensor emits invisible laser radiation from its emitter aperture.

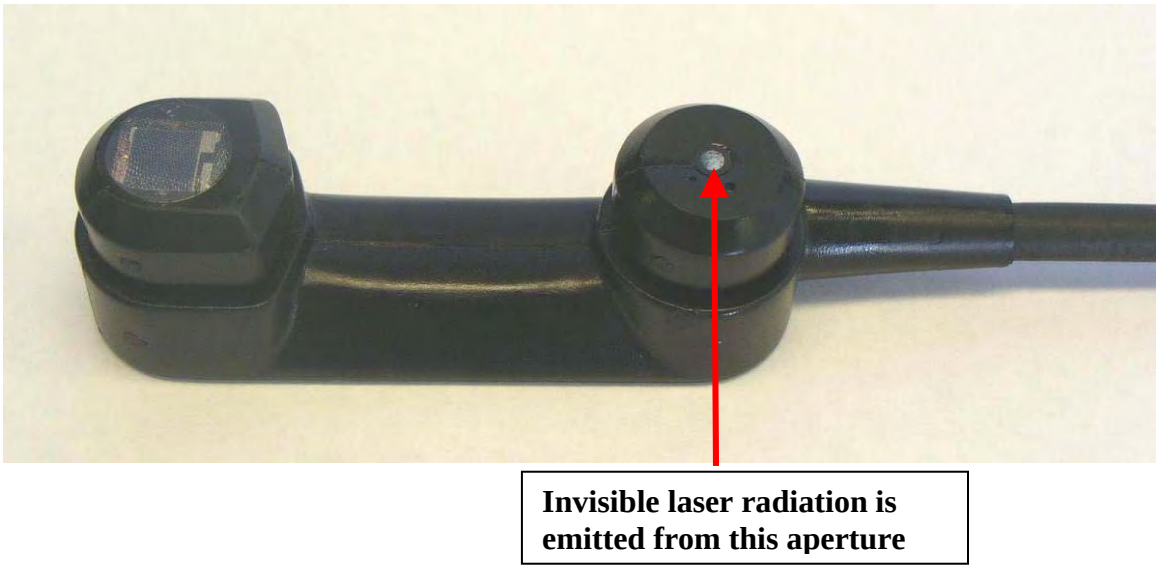


Figure 11 – Optical Sensor Laser Aperture

	**Caution - Do not look directly into the emitter of the optical sensor when the URO-1000 is powered.**

	**Caution - Do not operate the URO-1000 without the optical sensor and sensor patch securely fastened to the patient.**

Laser Status Indicators

The front panel of the URO-1000 has three laser status LEDs to indicate when the lasers are on. Only one LED will light at a time. The LEDs indicate the following:

Laser LED indicator	**Status**
Standby (Green)	The lasers are off and the device is not monitoring.
Output (Amber)	The lasers are on and the device is monitoring.
Warning (Red)	The lasers have been turned off automatically by the device due to detection of a loose sensor patch. The device will return to the 'Output' state if the patch is re-attached to the patient properly.

Laser Safety Interlock System

The URO-1000 has a software laser safety interlock system to detect conditions that could result in eye exposure to laser radiation. If the device detects such a condition it will immediately turn the lasers off.

If the system is used while the optical sensor cable is disconnected from the device, or if the cable becomes disconnected in mid-session, the software interlock will shut the lasers off and return the device to the 'Standby' state (see the section 'Laser Status Indicators' above).

If the sensor patch comes loose from the patient during a test session the software interlock will shut the lasers off and place the device in the 'Warning' state. The device will monitor the patch placement and automatically return to the 'Output' state if the patch is reattached properly.

Keylock Switch

The URO-1000 can only be turned on using the keylock switch on the front panel. To protect against unqualified operation, the key should be removed from the keylock switch when the device is not in use.

Use and Disposal of the Sensor Patch

The patient-applied sensor patch is a single-use item that is to be disposed after use. After each test session, remove the optical sensor from the used sensor patch and dispose of the patch according to hospital/clinic policy. **Do not re-use disposables**.

Use a new, clean sensor patch for each new test session. Sensor patches are supplied in individually sealed packages to maintain cleanliness. Do not use a sensor patch if its packaging appears compromised.

Cleaning the Optical Sensor Cable

The patient-applied optical sensor cable is to be cleaned **before and after each test session**.

Clean the optical sensor cable as follows:
Wipe the optical sensor end thoroughly with an isopropyl alcohol swab for 20 seconds.
Wipe the entire length of the sensor cable jacketing with a second isopropyl alcohol swab.

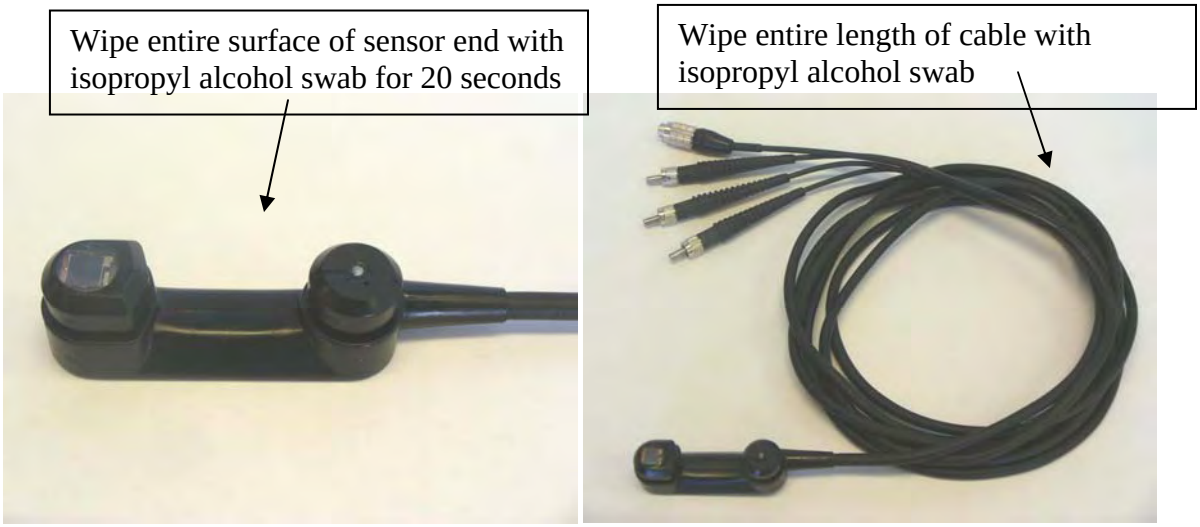


Figure 12 Cleaning the Optical Sensor End (left) and Complete Optical Sensor Cable (right)

Do not immerse any part of the sensor cable in liquids. Do not sterilize any part of the sensor cable. Do not use any other disinfectant or cleaning solution other than isopropyl alcohol. Do not apply heat to any part of the sensor cable.

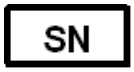
Use of Optical Sensor Cable

The optical sensor cable is intended for external use only.

	**Caution - Avoid direct contact between the optical sensor cable and open wounds or broken skin.**

Device Labels, Symbols and Indicators

The following labels / symbols appear on the of the URO-1000 enclosure:

Symbol	Description
	ATTENTION – consult documentation
	Device laser classification
	Laser hazard warning
	BF type applied parts
IP20	International protection rating against ingress of water and particulate matter
	Serial Number
	Alternating Current

USB	USB communication port
RS-232	RS-232 communication port

The following labels / symbols appear on the URO-1000 sensor patch:

Symbol	Description
	“Single Use Only” - “Do Not Reuse”

Operation

OEM Integration

The URO-1000 Bladder Monitor is intended to be integrated into an OEM urodynamics diagnostic system. The system is intended to collect and display a plot of uroflow and URO-NIRS concentration data together over time. The OEM is responsible for supplying the following items:

- System PC (desktop or laptop)
- PC compatible uroflow meter (connection to PC via RS-232 or USB)
- Software application for acquiring and displaying URO-1000 and uroflow meter data

The URO-1000 controller unit connects to the system PC via a serial connection (RS-232 or USB). The PC software application must be designed to acquire data from the URO-1000 controller device and uroflow meter, and plot the data on a graph vs. time. Please consult Urodynamix Technologies for technical details on communication with the URO-1000.

A typical URO-1000 integrated urodynamics system is set up as shown below:

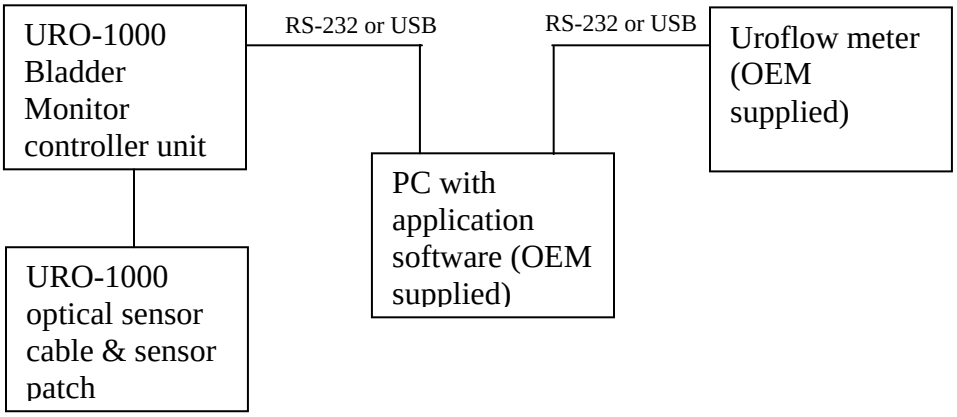


Figure 13 - Block Diagram of URO-1000 OEM Urodynamics Diagnostic System

A typical PC application data graph is shown below:

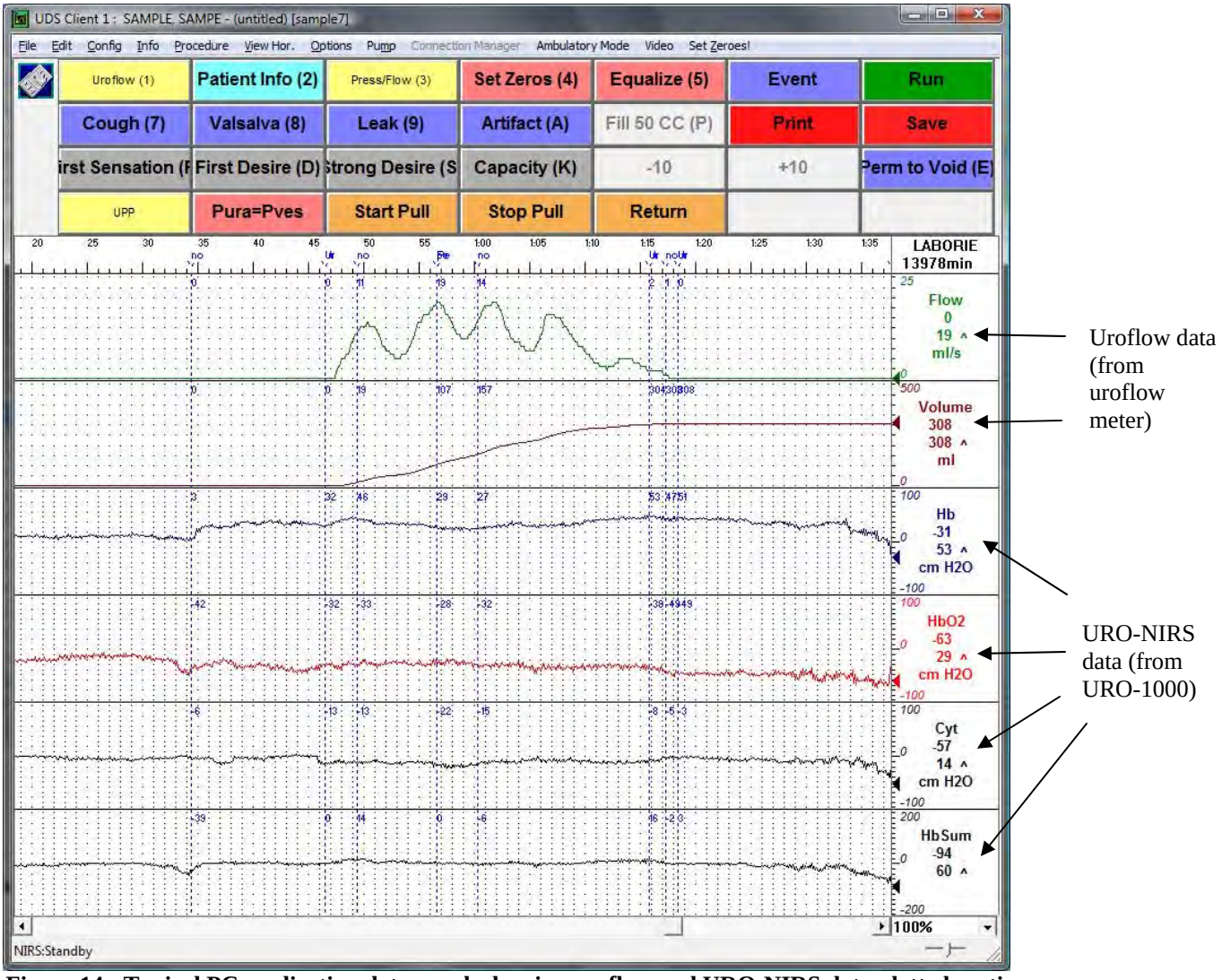


Figure 14 - Typical PC application data graph showing uroflow and URO-NIRS data plotted vs. time

The Uro-NIRS Exam

A typical URO-NIRS exam consists of the following sequence of events:

- The URO-1000 sensor patched is validated (see 'sensor patch validation' section below)
- The URO-1000 sensor is placed on the patient's abdomen
- Data collection is started on the URO-1000 and uroflow meter and logged on the PC
- The patient voids into the uroflow meter until he indicates his bladder is empty
- Data collection is stopped
- The URO-NIRS / uroflow data graph is analyzed by the physician

System Setup

Select a suitable workspace

The URO-1000 should be installed in a location that allows easy access to the front panel connectors, clear visibility of the laser status LED indicators, and is in close proximity to the patient. The RFID scan area on the top of the controller unit should be easily accessible.

Examination Room Lighting:

The optical sensor is sensitive not only to its emitted near-infrared light, but other light sources as well. Excessive ambient light in the examination room can prevent the device from initializing or result in data dropouts during test sessions. Natural light entering through windows or skylights is of particular concern.

Any windows in the examination room should be equipped with blinds to block out natural light during test sessions. Overhead fluorescent lighting has shown not to interfere with device operation.

Video Urodynamics:

The x-rays produced by video urodynamics systems are detectable by the URO-NIRS optical sensor. URO-NIRS test sessions that are run in conjunction with such urodynamics equipment will experience data loss for the duration of each x-ray.

Additionally, x-rays can prevent the URO-1000 from initializing when a test session is started. Allow the URO-NIRS test session to initialize and begin before using the video urodynamics equipment.

Connect power

Plug the supplied hospital grade AC power cable into the rear panel of the URO-1000. Plug the supplied PC power adapter into the power receptacle of the PC. Plug both power cables into a suitable wall outlet.

Connect the URO-1000 to the OEM PC

The URO-1000 can connect to the OEM PC via RS-232 or USB. Connect an RS-232 or USB cable to the appropriately labeled connector on the back panel of the URO-1000. Connect the other end to the PC.

The URO-1000 system PC is required to collect and display data from the URO-1000 quickly and reliably. For best results do not to use the system PC to run software other than the URO-NIRS application, especially during a test session.

Connect the Optical Sensor Cable

Remove the protective caps from the fiber optic connectors of the optical sensor cable and laser emitters of the URO-1000. Avoid touching the bare fiber optic connector ends.

Ensure the URO-1000 is turned off. The front panel of the URO-1000 has a spring-loaded connector guard to prevent removal or installation of the optical sensor cable while the device is powered. Pull the connector guard away from the front panel to expose the threaded laser emitters and detector port.

Install the optical sensor cable by screwing each of the three fiber optic connectors completely onto a laser emitter. The order is not important; any fiber optic connector may connect to any laser emitter. Similarly, fasten the detector connector to the detector port.

The optical sensor cable contains fine, fragile optical fibers that can break if the cable is mishandled. Broken optical fibers can degrade system performance or prevent the device from operating. To ensure long cable life, observe the following precautions:

- Do not yank, twist, or apply strain to the cable
- Do not bend the cable at sharp angles
- Do not step on or place heavy objects on the cable
- Gently coil the cable and store in a safe location when not in use

	**Caution - Operation of the URO-1000 with a damaged or insecurely connected optical sensor cable could result in harmful exposure to laser radiation.**

Sensor Patch Validation

The URO-1000 will not operate until it has scanned and identified a valid sensor patch. The software user interface will prompt for the patch to be validated at the start of each test session. Note that the patient name must be entered before validating the patch.

To validate a patch place it flat side down on the scan area on the top of the URO-1000 and follow the software instructions on the PC screen. Note that the patch does not need to be removed from its packaging to be validated.

Validating a patch will enable the URO-1000 device for operation and allow a test session to start. Once a patch has been scanned it will remain valid for the specified patient for a period of 4 hours. During this time the same patch can be rescanned to run multiple test sessions for the specified patient as necessary. The patch cannot be re-validated for another patient. Once the validation period has expired the patch will no longer be capable of enabling the URO-1000.

Sensor Patch Placement

Proper sensor patch placement is critical to the collection of good data. Before placing the patch on the patient, ensure that the optical sensor has been cleaned and inserted into the patch properly.

The sensor patch needs to be placed such that the emitted laser radiation can penetrate through to the bladder without being obstructed by the pubic bone.

To place the patch, peel off the adhesive backing and adhere it to the patient's lower abdomen just above the pubic bone as shown in the diagram below. Note that the patch needs to be oriented with the rounded portion at the bottom.

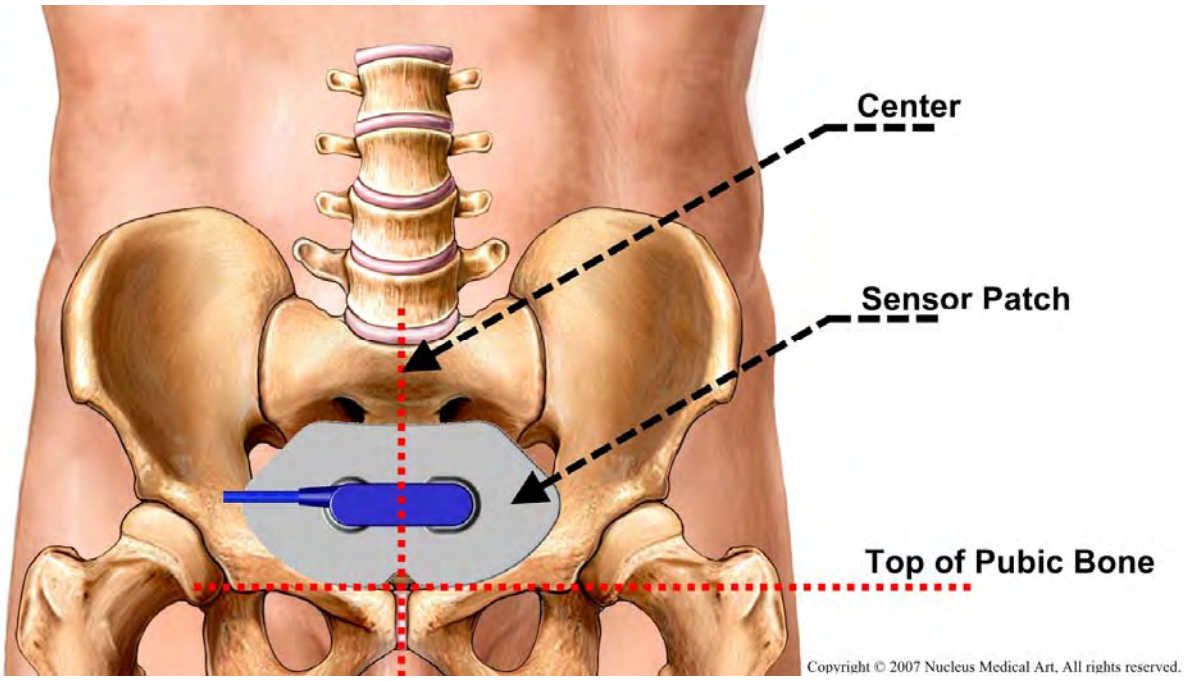


Figure 15 – Sensor Patch Placement

The sensor patch shields the optical detector from ambient background light. Ensure that the entire perimeter of the sensor patch adheres to the patient's skin and that there is nowhere external light can leak through to the optical detector. A high level of detected ambient light will result in poor data collection or prevent the device from operating.

It is important to keep the patient's movement to a minimum during the test session. Movement can introduce data artifacts and cause the patch to come loose resulting in data loss.

Maintenance

URO-1000 Controller Unit

The URO-1000 controller unit is **non-immersible**. It should be wiped down once a week with a clean cloth dampened with a cleaning solution such as soap and water or as per hospital cleaning instructions.

The URO-1000 controller device has no user-serviceable parts. Do not open the device for any reason. Return the device to Urodynamix Technologies if servicing is required.

This equipment has been tested and found to comply with electromagnetic compatibility requirements for medical devices. This testing shows the device provides reasonable protection against harmful interference in a typical medical installation. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices or is negatively impacted by other devices, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the devices.
- Increase the separation between the devices.
- Connect the equipment to an outlet on a different circuit.
- Contact the Service Center.

Optical Sensor Cable

Gently coil the cable and store in a safe location when not in use. The optical sensor cable should be visually inspected once a week for physical damage. Damaged cables should be replaced.

The cable should also be functionally tested on a weekly basis to ensure its performance has not degraded. The cable is tested using the supplied calibration analyzer tool. To test the optical sensor cable, connect it to the URO-1000 as usual and insert the sensor end into the calibration analyzer in the same manner as with the sensor patch. Use the ‘system check’ function in the PC software application to run the cable test. The software will report the test result (pass or fail). A cable that fails the system check test should be replaced.

Figure 16 Optical Sensor Inserted into Calibration Analyzer

System PC

Virus checking of the OEM system PC should be conducted regularly if it is connected to a network and no hospital/clinic-wide virus protection exists.

Storage Conditions

All URO-1000 system components should be stored in a clean, dry, room-temperature location. Do not place heavy objects on any of the system components.

The laser emitters of the URO-1000 should be covered with the supplied protective caps when the optical sensor cable is not connected. Likewise, the fiber optic connectors of disconnected optical sensor cables should have their protective caps installed.