UROSTYM®

Pelvic Floor Behavioural System

Owner's Manual

LABORIE USA
400 Avenue D, Suite 10
Williston, Vermont, USA 05495
Tel: 1.800.522.6743
Fax: 1.802.878.1122

LABORIE Headquarters
6415 Northwest Dr., Unit 10
Mississauga, Ontario, Canada L4V 1X1
Tel: +1.905.612.1170
Fax: +1.905.612.9731

LABORIE Europe/International
EC REP
Medical Measurement Systems B.V.
Colosseum 25
7521 PV Enschede
Netherlands
Tel.: +31.53.4803700
Fax: +31.53.4803701

Document Number: UST-UM07
Version: Version 38.00
Release Date: April 17, 2020

Laborie Medical Technologies Canada ULC
6415 Northwest Drive, Unit 10
Mississauga ON L4V 1X1
CANADA

CE 2797

ABOUT THIS MANUAL

As you read through the manual, you will find information on how to configure features in the **Urostym®** software, as well as information on care and maintenance of the **Urostym®**.

Throughout the manual you will also find specially marked sections that emphasize important reminders and information to help you understand the features of the system, as marked here:

	CAUTION Provides information users need to know in order to prevent minor injury or product damage.
	IMPORTANT Provides important information regarding use of device or software
	NOTE Provides useful information or reminders while operating the device or software.

CONTENTS

LIST OF FIGURES

LIST OF TABLES

1 INTRODUCTION

The Urostym® Behavioral Therapy System offered by Laborie Medical Technologies provides the most current protocols for pelvic floor retraining. Reports are quickly and easily generated — providing complete patient information for analysis, treatment, and results.

1.1 GENERAL DESCRIPTION

Along with the features of the standard Urostym® Pelvic Muscle Rehabilitation (PMR) and stimulation capabilities, the software contains animation features to help keep a child's or adult's attention to facilitate their responses and participation in the rehabilitation process.

1.2 MAIN FEATURES

Some of the basic features of the Urostym® unit include:

- Animation features
- Multi-channel unit (2 EMG, 1 Electrical Stimulation, 1 Manometry)
- Vaginal and anal Manometry
- Internationally recognized standard protocols that are fully customizable
- Computer-controlled probe detection for patient safety
- Soft-ramping stimulation for patient comfort
- Patient file preview for analysis
- Tone sound during uroflowmetry/EMG sessions that changes pitch with muscle activity
- Full color patient reports
- Stand-alone unit with laptop computer

Optional features include:

- A variety of low cost probes and surface electrode patches
- Uroflowmetry (voided volume and flow rate) with EMG (1 or 2 channels)
- Integration with most LABORIE Urodynamic systems to enhance your pelvic floor center

The following features are also supported in V7.0 and above:

- Urostym® standalone
- Electrical Stimulation
- Linking with UDS Unit
- Uroflowmetry (with UDS unit, Urocap™ or Uroflowmeter)
- Notification section
- PMR games
- Questionnaire section
- Pressure Manometry

1.3 CAUTIONS AND WARNINGS

READ CAREFULLY BEFORE USE

CAUTION

United States Federal Law restricts this device to sale or use by, or on the order of, a licensed physician.

GENERAL SYSTEM WARNINGS:

- Only technicians and physicians trained in Urodynamics should operate this device. The operator must read the Owner's manual entirely and refer to any additional training materials before using the device. Optional In-Service is available from LABORIE.
- The **Urostym®** system and associated devices are intended for indoor use only under the following *standard operating conditions*:
    - Temperature: +10° C to +40° C
    - Humidity: 30% to 75% relative humidity
    - Pressure: 70 kPa to 106 kPa
- And under the following *transport and storage conditions*:
    - Temperature: -29° C to +60° C
    - Humidity: uncontrolled to 85% relative humidity
- The computer (printer and monitor, if applicable) MUST be used with LABORIE's Line Isolation Transformer (LIT) in order to ensure safe operation and to meet safety regulations.
- **DO NOT USE** in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- **DO NOT USE** the **Urostym®** in the presence of a magnetic resonance imaging system as it may contain ferromagnetic objects that pose a risk to the patient in the presence of a magnetic core. The strong magnetic field produced by the MRI may cause disruption of the system.
- **DO NOT** re-use probes between patients, re-use of probes creates a risk of cross-infection and/or cross transmission of infectious disease(s) from one patient to another.
- The vaginal/rectal probes and the surface electrodes are delivered non-sterile and are intended for SINGLE PATIENT USE only. Probes must be cleaned between SINGLE PATIENT USES and disposed after single patient use is complete. Cleaning instructions for probes are provided in this manual.
- Simultaneous connection of a patient to high frequency surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.
- Application of electrodes near the thorax may increase risk of cardiac fibrillation.
- **DO NOT** apply stimulation crossing over the heart, across or through the head, directly on the eyes, covering the mouth, on the front of the neck (especially the carotid sinus), or from electrodes placed on the chest and the upper back.
- Operation in close proximity (1 meter) to shortwave or microwave therapy equipment may produce instability in the Stimulator output.

- DO NOT REPAIR the system by yourself or through an unauthorized party. Only LABORIE trained technicians may service the unit. Do not attempt to service system or any connected devise while system is in use with a patient.
- LABORIE equipment and accessories are licensed/approved by Government and Safety Agencies to work with LABORIE equipment and accessories ONLY.
- LABORIE equipment and accessories are warranted to work with LABORIE equipment and accessories ONLY.
- LABORIE is not responsible for loss of patient files or test data. We recommend backing up patient data on a regular basis.
- Any additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g. IEC 60950 for data processing equipment). Avoid altering or adding to UROSTYM™ medical electrical system. Any alteration to UROSTYM™ system by an unauthorized party transfers responsibility for meeting ME system requirements from LABORIE to the altering party. Anyone connecting supplementary equipment to medical electrical equipment configures a medical system and is therefore responsible for ensuring that the system complies with the requirements for medical electrical systems, encompassed in the IEC 60601 series."
- No modification of this equipment allowed.
- To prevent possible injury to the patient, ensure all castor wheels are locked during testing procedures (where applicable).
- Use the UDS system with LABORIE equipment and accessories ONLY.
- Device uses the general warning sign/symbol from EN ISO 15223 and ISO 7010. Descriptions of all symbols that appear on the device and the device label can be found at the back of this manual.
- Device does not have any protection against water ingress (IPX0).
- To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- To prevent tripping, all parts and accessories, including cables and cords, related to the Urostym® system should be kept appropriately tidy to ensure a safe environment.
- Any additional Multiple Portable Socket Outlets (MPSO) or extension cord shall not be connected to the system.
- Do not plug in any components or accessories supplied with the system directly into a wall outlet. Plug all components and accessories into the LIT. Failure to do so may result in damage to the system and void the system's electrical isolation.
- When a separate plug or appliance coupler is used as isolation means, the device shall remain readily operable.
- Session results are for informational purposes only and must not be used exclusively for diagnostic purposes.
- Local laws take priority over the above-mentioned requirements and warnings. If in doubt, consult your local LABORIE representative or the technical service department.

IMPORTANT INFORMATION

- Position the **Urostym®** unit close enough to keep the **Urostym®** Stop button within reach of the patient. Always place the unit to facilitate disconnection of device. Device operator must be able to disconnect the device quickly and safely in the case of emergency.
- LIT includes a circuit breaker that can easily reset in case of any short circuits or voltage surges.
- Connecting electrical equipment to a multiple socket outlet effectively leads to creating a medical electrical system and can result in a reduced level of safety. Only connect devices specified and approved by Laborie to GOBY™ multiple socket outlets. Connecting any device not approved by LABORIE to the ME system alters the functional integrity of the product creating a safety risk.
- Ensure that the stimulation probe is handled with care since there is no automatic stop to stimulation if the probe slips out while still in stimulation ramp up or ramp down phase.
- Always wear protective gloves.
- Patients should be examined for any signs of skin and/or mucosal irritation prior to use.
- The device must not be placed on the floor. It must be placed on a low cart or low shelf.
- To ensure patient safety, operator must not simultaneously touch patient and any part of non-medical electrical equipment that come into contact during routine calibration and maintenance after the removal of covers and connectors.
- Do not allow applied parts linked to a PATIENT CONNECTION, but not connected to the PATIENT, to contact other conductive parts including those connected to protective earth. Preserve the patient connection electrical isolation.

GENERAL SYSTEM SAFETY COMPLIANCE

- To prevent electric shock, patients and equipment operators are protected in single fault conditions since resultant leakage currents fall well below acceptable standards for open ground conditions. This specification is conformant to EN 60601-1 (class 1 B) and CSA-22.2 (class 2/2G) standards. It will not present any risk to the patient in either normal or ground fault conditions.
- The device meets and exceeds the insulation breakdown specifications for both EN 60601-1 and CSA 22.2 medical standards. Insulation is maintained by a combination of dielectric insulators and minimum physical separation (creep distances).
- Device uses approved wire for connection, and adheres to EN 60601-1 air clearance and creepage distance requirements.
- The **Urostym®** is a low-power electronic device for measurement purposes. Conforms to IEC EMC and EMI specifications for acceptable levels of radiated emissions.
- The system already incorporates the use of individually approved EMC devices (power supplies, etc). It is further improved at the design stage by shield cabling and inductor/choke placement to achieve the EMC conformance.

- The power entry module (connector for mains input) is rated as medical grade. It meets IEC standards for insulation. The location of the power entry module is also situated in the back (or recessed) so that access to the connection point is reduced.
- Software and firmware used in the final product are alpha tested in identical combination. Strict revision control and release control of Software and Firmware are established and followed.
- To maintain connection, software contains built-in algorithms that add checksum (CRC) protocol to data transmissions. In the event that the data received is not correct, a finite number of re-transmissions are performed (typical 3 times) before a message is prompted to the operator. While the communication scheme is purely digital, the quality of the signal was enhanced by providing our own shielded connection cables of tested length. Adheres to the PC standard for RS-232C pin-out specifications.

1.4 INTENDED USE

The **Urostym®** Biofeedback and Stimulation Device is used for treating urinary incontinence by way of perineal re-education. The **Urostym®** probes are non-implanted electrical devices applied to the pelvic floor musculature and surrounding structures for therapy in the treatment of urinary incontinence. The probes and patches are provided nonsterile for single (individual) patient use / disposable. The probes are for office or hospital use under the direction of a physician or other licensed healthcare professionals.

1.5 TARGET POPULATION

The target population for pelvic floor rehabilitation is extensive — both men and women of all ages may benefit from this form of treatment. Some of the dysfunctions that can be treated include:

- stress urinary incontinence
- urge urinary incontinence
- mixed urinary incontinence

Children who have the cognitive ability to listen to and follow instructions may benefit from pelvic floor therapy. Pediatric use of the **Urostym®** involves the use of EMG patches only, NOT probes.

1.6 CONTRAINDICATIONS

The **Urostym®** is contraindicated for any patient who is not a candidate for instrumentation. For example, probes should not be used with children. Patients who have implants or an implanted electronic device (like a cardiac pacemaker) should seek expert medical opinion before treatment.

DO NOT USE Urostym® if the patient:

- Has symptomatic UTI, fever
- Has fecal impactions
- Is too feeble, senile
- Has menorrhagia
- Has an infection of the bladder, vagina, rectum, or anus; or displays the symptoms of infection (such as itching, painful urination, sores, or fever)
- Is pregnant, suspected to be pregnant or thinks she is pregnant.

DO NOT USE the probes if the patient:

- Has an anatomy that would make proper probe insertion difficult or impossible.
- Has an infection of the bladder, vagina, rectum, or anus; or displays the symptoms of infection (such as itching, painful urination, sores, or fever).
- Is a child, or considered as a pediatric patient.

DO NOT USE stimulation if the patient:

- Is pregnant, suspected to be pregnant or thinks she is pregnant.
- Has colorectal or genitourinary cancer.
- Has infection of the bladder, vagina, rectum, or anus; or displays the symptoms of infection (such as itching, painful urination, sores, or fever).
- Has symptomatic UTI, fever
- Has fecal impactions
- Is too feeble, senile
- Has menorrhagia
- Has a pacemaker (patient should seek expert medical opinion before treatment)
- Has defibrillator
- Has a metal IUD

- Has rectal bleeding/swollen hemorrhoids (if using an anal probe)
- Has cardiac arrhythmia
- Had pelvic surgery in the last 6 months without primary surgeon's permission
- Has metal prosthetics in pelvic area (i.e., Hip implants)
- Has seizure disorders
- Has a pessary that contains metal. The pessary can be removed prior to start of session and replaced when session is complete.
- Has cancer in the pelvic region (colorectal or genitourinary cancer)
- Is a child, or considered a pediatric patient.

For more information, please refer to the Patient Care Guide in the appendix at the back of this manual.

2 CLEANING AND PREVENTATIVE MAINTENANCE

2.1 **UROSTYM®** UNIT

The **Urostym®** unit is **not immersible**. It should be wiped down with a clean cloth dampened with a cleaning solution as per your facility's cleaning instructions.

Performing regular maintenance of your **Urostym®** system will reduce the need for costly repairs.

The following schedule is recommended:

- At startup of the **Urostym®** unit, assess all components are functioning:
  - Make sure the system is powered on before the laptop.
  - Make sure the laptop shows a green indicator light for **Urostym®** (and UDS if integrated).
  - Check the function of the probes. Squeeze the Manometry vaginal probe with your gloved hand (before insertion) and check for a response on screen; if no response is observed then channel accessories are not properly connected. Check accessory connections and test again.
- Clean the ball inside the PC mouse at least once a year (if applicable).
- The EMG and stimulation function is factory calibrated and does not require recalibration on a regular basis. If the calibration is found to be inaccurate after performing a calibration, please contact Laborie Medical Technologies.
- (*EMG Uroflow Option only*) Calibrate only if the Uroflow transducer is off calibration. Check the calibration of the Uroflow transducer every 6 months.
- The Uroflow beaker should be rinsed and dried after use. Soap and water, or a mild detergent solution, can be used for cleaning.

Although the beaker is reusable, it will discolour over time and may need to be replaced.

When cleaning the funnel, maximum cleaning temperature should not exceed 80°C (176°F).

2.2 **UROCAP™** III UROFLOWMETER

The **Urocap™** may become dirty due to urine contamination and cleaning will be required.

ALWAYS WEAR PROTECTIVE GLOVES WHEN CLEANING THE EQUIPMENT TO PREVENT BIOLOGICAL CONTAMINATION.

The exterior surface of the unit should be cleaned using a damp cloth with alcohol, soap, or disinfectant detergent. Wipe the surface dry immediately and do not let any liquid leak into the shaft that holds the dish. The unit should be stored in a cool and dry area.

DO NOT SOAK THE **UROCAP™** III IN WATER. DO NOT IMMERSE IN WATER OR ANY OTHER LIQUIDS.

2.3 STIMULATION PROBES

Refer to original manufacturer for cleaning validation details.

Always wear protective gloves when cleaning to prevent biological contamination.

Standard water-soluble lubricants (like K-Y® or Surgilube®) are not appropriate for use with EMG probes. Always use conductive gels (such as LABORIE's ULT050 ultrasound gel) as lubrication.

The connection end of the cables must not come into contact with water.

Condoms or other covers must never be used with EMG probes

2.4 MANOMETRY PROBES

The following materials and equipment are recommended for manometry probe cleaning, as per LABORIE's cleaning validation test protocols:

- Cleaning Agent: CaviWipes™ and ENZOL®
- Disinfectant: Revital-Ox Resert™ HLD (Ready to use)
- High-Level Disinfectant: CIDEX® Activated Dialdehyde Solution & Revital-Ox Resert™ HLD (Ready to use)
- Soft lint-free cloth
- Tap water
- Basin
- Appropriate personal protective equipment

Any other cleaning and disinfectant products which have not been tested by LABORIE may not have the desired outcome, causing damage to the manometry probe materials and are therefore not recommended by the manufacturer.

Manometry probes are intended for single patient use only. Probes may NOT be used between patients. Manometry Probes are provided non-sterile and must undergo high level disinfection before use.

2.4.1 PRE-CLEANING

After the procedure, perform the pre-cleaning step by wiping the manometry probes with a CaviWipe until visibly clean (for at least 20-30 seconds).

2.4.2 CLEANING

Following drying of the device, follow the below instructions for correct cleaning procedure.

1. Immerse device in prepared ENZOL prepared to manufacturer's specifications (59.14 mL detergent + 7570 mL tap water) solution for one minute at 20-25°C
2. Use a soft, lint-free cloth while the device is immersed in detergent to remove any residues on the device
3. Rinse under warm tap water (24-30°C) for 60 seconds
4. Wipe dry with soft lint-free cloth

2.4.3 HIGH LEVEL DISINFECTION

Following cleaning of the device, please follow the below instructions for High-Level Disinfection procedure.

1. Prepare each disinfectant as per the manufacturer's instructions. Ensure disinfectant used is above minimum recommended concentration (MRC) prior to use.
2. When appropriate, pre-warm the disinfectant by using a water bath or incubator set above the minimum temperature requirement for the disinfectant. A warming pack, incubator or water bath may be used to maintain the desired temperature.
3. Submerge the manometry probes in the prepared disinfectants accordingly:
    a. Using Revital-Ox Resert HLD:

i. Submerge the device in the solution for 8 minutes at 20 ± 2℃.

ii. Cover the basin during disinfection procedure.

iii. Rinse with water for minimum of 1 minute

iv. Wipe dry with soft lint-free cloth

b. Using CIDEX® Activated Dialdehyde Solution

i. Submerge the device in the prepared solution for 45 minutes at 25 ± 2℃

Refer to LABORIE Cleaning Validation Documents for full details.

2.5 TREATING AND DISPOSING OF PRODUCTS AFTER USE

After use, discard the contaminated, plastic, single-use disposables and any packaging according to your institution's standard operating procedures on medical waste handling.

For end of life product waste electrical and electronic equipment should be collected separately and returned to the designated local recycling service.

Packaging waste should be collected separately for available national packaging collection and recycling services.

2.6 COMPUTER VIRUS PROTECTION

All computers purchased from LABORIE are virus-free before shipment and are installed with an Antivirus program. It is the customer's responsibility to correctly use and maintain the antivirus program to prevent virus problems. LABORIE is not responsible for any virus-related computer problems after point of delivery to the customer.

2.7 DATA BACKUP

Check the space available on the computer's hard disk at least every 6 months. Back up data from the UROSTYM® MDB file located in the Urostym® folder on the computer (*C:\Program Files\Laborie Medical Technologies\Urostym*) on external media like CDs, DVDs or USB flash drives.

3 DEVICE SETUP

To get up and running as quickly as possible, the following sections will outline the recommended setup procedures.

3.1 PERFORM AN EQUIPMENT CHECK

Verify that all ordered equipment and accessories have been received. Contact LABORIE if there are any discrepancies between ordered and received equipment. Inspect the equipment for any visible signs of damage or mishandling. Notify the carrier immediately if damage has been found. Carrying cases and cartons should be saved to provide a convenient and safe way to return the equipment should service be required.

Standard Equipment

- EQUIPMENT
- Urostym® Unit
- Computer Connection Cable (RS-232)
- Channel 1 Cable (STIM/BIO)
- Channel 2 Cable (EMG)
- Channel 2, non-shielded, EMG, UDS 94
- Vaginal Probe
- Anal Probe
- Virtual Software Key
- Urostym® Software CD
- Line Isolation Transformer (110V or 220V)
- LIT Output Power Cord
- Medical Grade Power Cord (110V or 220V)
- Cable, Snap-on Filter
- Cable, Urostym®, Channel 3 / Pressure Transducer
- Re-closable Fastener Strips

3.2 EQUIPMENT STATUS AND LIGHT SIGNALS

3.2.1 INDICATOR SIGNALS

Indicator LEDs provide important information on system readiness and device action. Please see illumination descriptions below.

Illuminations:

Power on: Please turn on the Urostym® using the power switch. See section 3.2.2 Device Guide for a layout overview of all command buttons, channels and switches.

During turn on, the Stop/Reset channel LED blinks six times then remains illuminated indicating the completion of a successful self test; the Urostym® is ready to use. Please note that during the self test Manometry, and EMG Channels blink six times then turn off; while, the SIM/Bio Channel briefly illuminates yellow then sustains green.

EMG & Manometry Activation: Selection of either EMG or Manometry functions in the application software will cause both channel LEDs to rapidly blink green signaling a 'Ready' state for information input.

Stimulation Activation: Selection of the Stimulation function in the application software will cause the channel LED to illuminate solid yellow for outputs over 4.5mA.

Please see Troubleshooting on page 88 for further information.

3.2.2 DEVICE GUIDE

Refer to Figure 1 and Figure 2 for an overview of controls and connections available on the **Urostym®.**

FRONT FACING CONTROL PANEL:

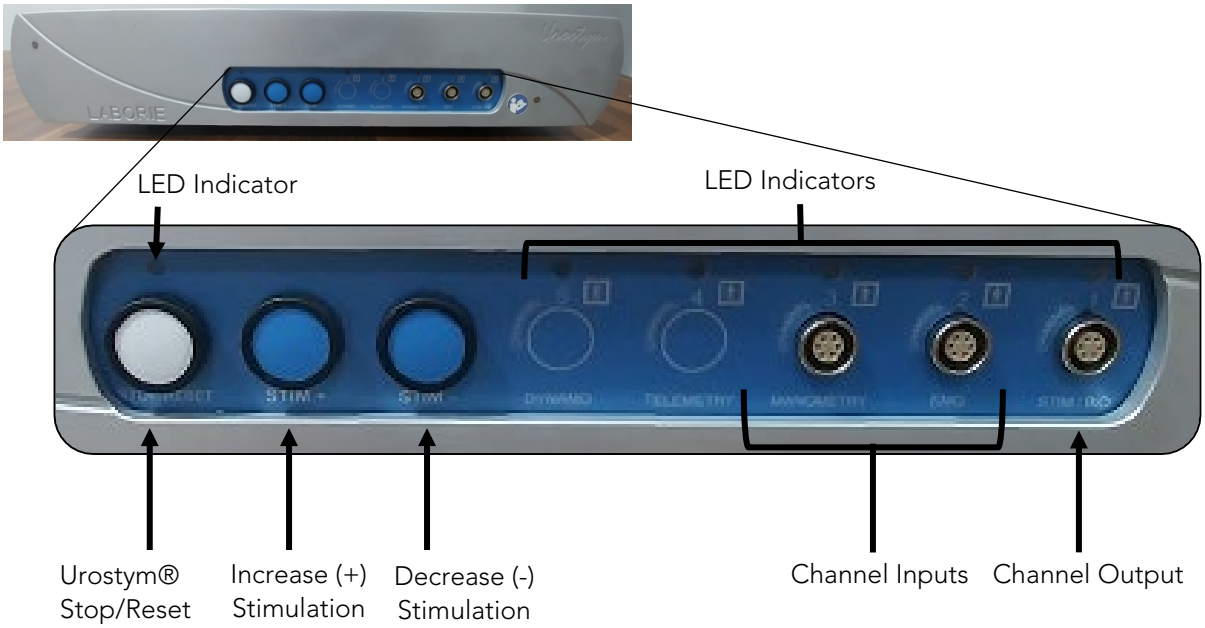


Figure 1: Urostym Device Guide – Font Facing Controls

Note: Please reference 6.2 **Urostym®** Connection Diagrams for Adult Patients, of the "PATIENT CARE GUIDE" for further information on **Urostym®** channels.

REAR FACING CONTROLS:

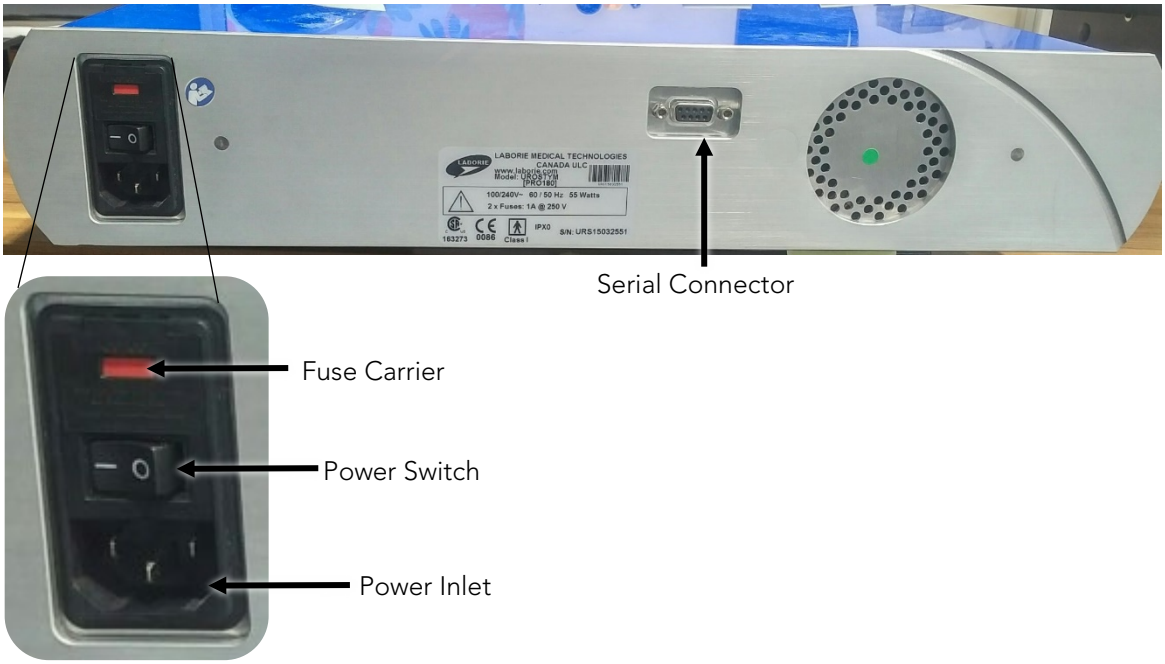
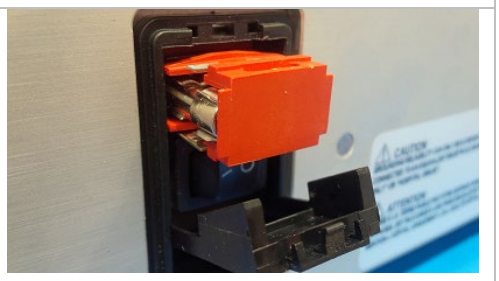
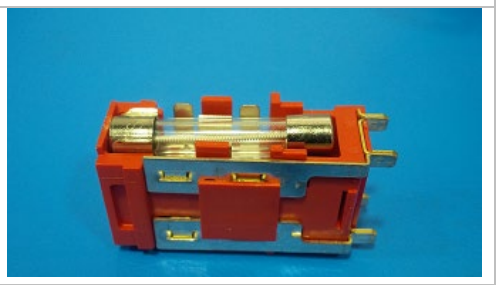


Figure 2: Device Guide – Rear Facing Controls

3.3 USER REPLACEABLE FUSE

STEP	IMAGE
1. Locate fuse housing on the rear panel of the Urostym®. Ensure the power switch is in the 'off' position.	
2. Using a non-conductive screwdriver, carefully open the fuse housing by pressing down lightly on the housing latch. Lower the housing panel to expose the red fuse carrier.	
3. Place the non-conductive screwdriver tip at the topmost edge of the fuse carrier and gently pry the carrier from the fuse housing. Grasp the loosened fuse carrier and remove from the housing entirely. Please note orientation of the fuse carrier.	
4. Remove fuses from the fuse carrier and insert replacements. Reinsert the fuse carrier into the housing and secure the housing panel latch.	

If the replacement fuse immediately burns out, move the power switch to the 'off' position and remove the power cord from the unit. Contact your LABORIE Service representative for further instruction.

Table 1: Replacing the Fuse

3.4 CART SET-UP

Utilize the provided reclosable fastener strips to secure laptop and printer as part of Urostym® cart configuration. Recommended adhesion positioning for laptop:

1. Apply re-closable fastener strips to the bottom of laptop.	
2. Flip laptop over so that the bottom of the laptop faces up. Locate two areas approximately ¼ and ¾ of the way along the laptop large enough to place the re-closable fastener strips so that they do not cover any vents or openings. Make sure both identified areas are clean so that a firm seal forms, if necessary use alcohol wipes to clean the laptop.	
3. Peel the protective cover away from one side of the re-closable faciner strip and place face down on the laptop in one of the two areas located above, hold the strip down for 30 seconds before releasing to ensure a frim seal forms. Repeat for the other piece re-closable fastener strip the second area notated above.	
4. Ensure the top of the Urostym® is clean and if necessary use alcohol wipes to clean the surface to ensure a firm seal. Peel the protective covering from the two reclosabel fastener strips and place the bottom of the laptop on the top of the Urostym® so that the centre of the laptop aligns with the centre of the Urostym®. Press down on the laptop for 30 seconds to ensure a good seal is formed.	
5. Ensure the laptop is secured to the Urostym® by attempting to slide the laptop along the Urostym®. If the laptop slides remove the laptop from the Urostym® and remove the re-closable fasteners applied. Clean the areas with alcohol wipes and retry the procedure from step 2.	

Table 2: Cart Setup - Securing the Laptop

Recommended adhesion positioning for printer:

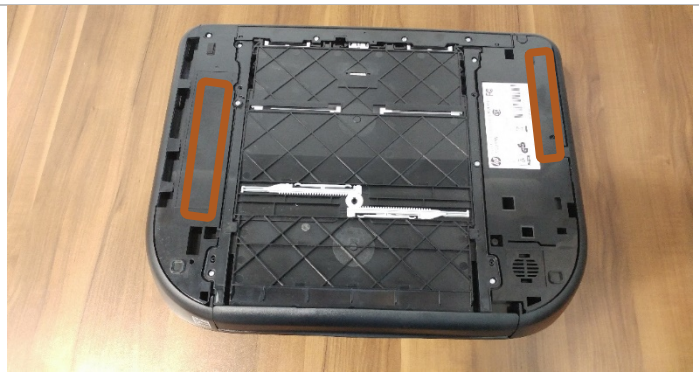
1. Apply re-closable fastener strips to the bottom of the printer.	
2. Flip printer over so that the bottom of the printer faces up. Locate 2 areas along the side of the printer large enough to place the re-closable fastener strips so that they do not cover any vents, gears or openings. Make sure all identified areas are clean so that a firm seal forms, if necessary use alcohol wipes to clean the printer.	
3. Peel the protective cover away from one side of the re-closable fastener strip and place face down on the printer in one of the areas located above, hold the tape down for 30 seconds before releasing to ensure a firm seal forms. Repeat for the second position notated above.	
4. Ensure the cart shelf is clean and if necessary use alcohol wipes to clean the surface to ensure a firm seal. Peel the protective covering from the re-closable fastener strips and place the bottom of the printer on the top of the cart shelf so that the back of the printer touches the back of the cart shelf. Press down on the printer for 30 seconds to ensure a firm seal forms.	
5. Ensure the printer is secured to the cart shelf by attempting to slide the printer along the shelf, if the printer slides remove the printer from the cart shelf, remove the pieces of Velcro tape from the printer and cart shelf, clean the areas with alcohol wipes and retry the procedure from step 2.	

Table 3: Cart Setup - Securing the Printer

3.5 WIRELESS PRINTER SETUP

3.5.1 BEFORE YOU BEGIN

Ensure the following:

● The wireless network is set up and working properly.

● The printer and the computers that use the printer are on the same network (subnet).

While connecting the printer, you might be prompted to enter the wireless network name (SSID) and a wireless password.

● The wireless network name is the name of your wireless network.

● The wireless password prevents other people from connecting to your wireless network without your permission. Depending on the level of security required, your wireless network might use either a WPA passphrase or WEP key.

If you have not changed the network name or the security passkey since setting up your wireless network, you can sometimes find them on the back or side of the wireless router.

If you cannot find the network name or the security password or cannot remember this information, see the documentation provided with your computer or with the wireless router. If you still cannot find this information, contact your network administrator or the person who set up the wireless network.

3.5.2 SET UP THE PRINTER ON YOUR WIRELESS NETWORK

To set up the printer on your wireless network use the Wireless Setup Wizard from the printer control panel display to set up wireless communication.

1. On the printer control panel display, from the Home screen, touch (Wireless).
2. Touch (Settings).
3. Touch Wireless Setup Wizard or Wi-Fi Protected Setup.
4. Follow the display instructions to complete the setup.

If you are already using the printer with a different type of connection, such as a USB connection, follow the instructions in Change the connection type on page 29 to set up the printer on your wireless network.

3.5.3 PRINT USING WI-FI DIRECT

With Wi-Fi Direct, you can print wirelessly from a computer, smart phone, tablet, or other wireless-capable device—without connecting to an existing wireless network.

Guidelines for Using Wi-Fi Direct

- Make sure your computer or mobile device has the necessary software.
    - If you are using a computer, make sure you have installed the HP printer software.
    - If you have not installed the HP printer software on the computer, connect to Wi-Fi Direct first and then install the printer software. Select Wireless when prompted by the printer software for a connection type.
- Make sure Wi-Fi Direct for your printer is turned on.
- Up to five computers and mobile devices can use the same Wi-Fi Direct connection.
- Wi-Fi Direct can be used while the printer is also connected either to a computer using a USB cable or to a network using a wireless connection.
- Wi-Fi Direct cannot be used to connect a computer, mobile device, or printer to the Internet.

To Turn On Wi-Fi Direct

1. On the printer control panel display, from the Home screen, touch (Wi-Fi Direct).
2. Touch (Settings).
3. If the display shows that Wi-Fi Direct is Off, touch the toggle button next to Wi-Fi Direct to turn it On.

To Change Connection Method

1. On the printer control panel display, from the Home screen, touch (Wi-Fi Direct).
2. Touch (Settings).
3. Touch Connection Method and then select Automatic or Manual.

To Print From a Wireless-Capable Computer (Windows)

4. Make sure you have turned on Wi-Fi Direct on the printer.
5. Turn on the computer's Wi-Fi connection. For more information, see the documentation provided with the computer.
6. From the computer, connect to a new network. Use the process you normally use to connect to a new wireless network or hotspot. Choose the Wi-Fi Direct name from the list of wireless networks shown such

as DIRECT-**- HP ENVY 5000 series (where ** are the unique characters to identify your printer). Enter the Wi-Fi Direct password when prompted.

NOTE: To obtain Wi-Fi Direct password, on the printer control panel display, from the Home screen, touch (Wi-Fi Direct).

7. Proceed to step 5 if the printer has been installed and connected to the computer over a wireless network. If the printer has been installed and connected to your computer with a USB cable, follow the steps below to install the printer software using the Wi-Fi Direct connection.
    a. Open the HP printer software.
    b. Click Tools.
    c. Click Device Setup & Software, and then select Connect a new device.
    d. When the Connection Options software screen appears, select Wireless.
    e. Select your HP printer from the detected printer list.
    f. Follow the onscreen instructions.
8. Print your document.

3.5.4 CHANGE THE CONNECTION TYPE

After you have installed the HP printer software and connected the printer to your computer or to a network, you can use the software to change the connection type (for example, from a USB connection to a wireless connection).

To Change From a USB Connection to a Wireless Network (Windows)

1. Open the HP printer software.
2. Click Tools.
3. Click Device Setup & Software.
4. Select Convert a USB connected device to wireless. Follow the onscreen instructions.

To Change From a Wireless Connection to a USB Connection (Windows)

Connect the printer and the computer with a USB cable. This USB port is at the rear of the printer.

NOTE: A USB connection between the computer and printer can only be used if these two devices are isolated from the patient environment to reduce the risk of electric shock to the patient. Laborie highly recommends that a wireless connection is used between the computer and printer at all times.

4 SOFTWARE INSTALLATION AND SETUP

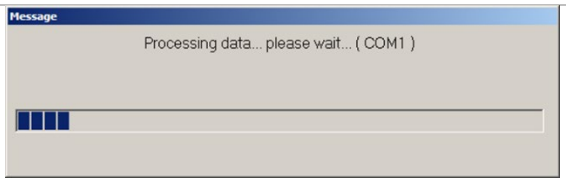
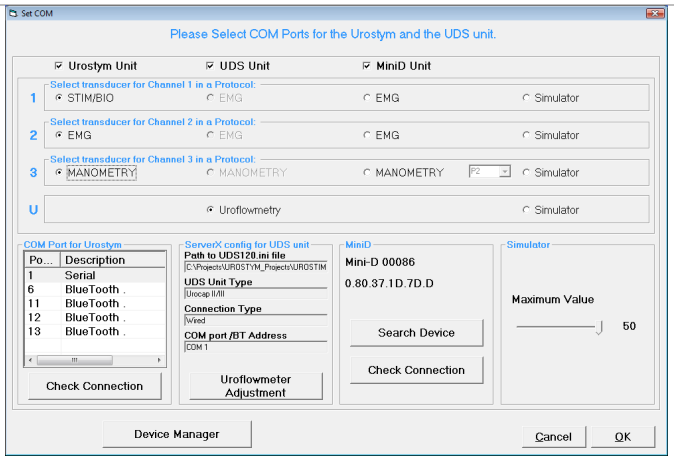
For information on how to install the **Urostym®** software please refer to the *Laborie System Installation Guide* in the Laborie Software CD/DVD for detailed information. Remember that the software is factory-installed and should only be re-installed if it has been accidentally removed.

4.1 SOFTWARE SETUP

Any of the **Urostym®** channels (channels 1, 2 or 3) can be connected (or mapped) to one of the following devices:

- **Urostym®** unit
- UDS unit: Triton, Dorado KT (not the **Urocap™**)

The Uroflowmeter can be connected to either the UDS unit or to the **Urostym®**.

STEP		IMAGE
1	Start the **Urostym®** software by double clicking the **Urostym®** icon on the computer desktop.	
2	Click the **Set COM** button on the **Urostym®** toolbar.	
3	Select the **Urostym®** Unit check box, if not already checked, and then select the COM port that was used to connect the **Urostym®** unit (with the RS232 cables or the Belkin USB to Serial) to the computer.	

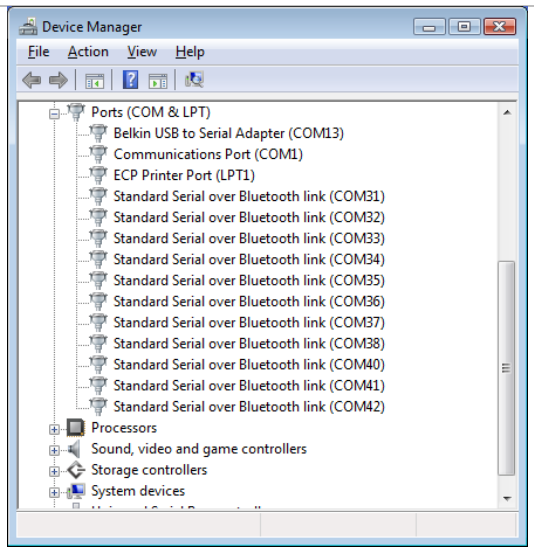
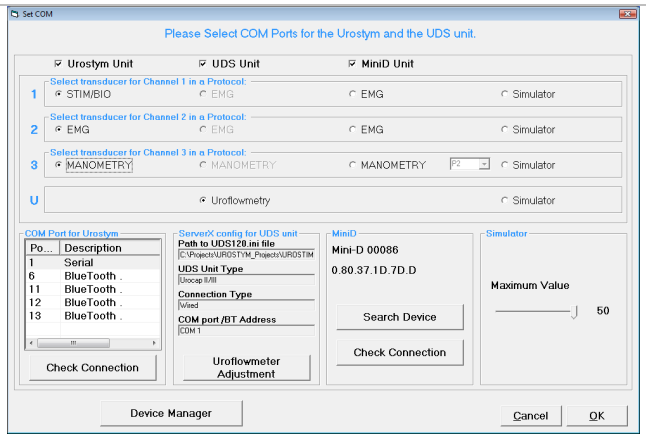
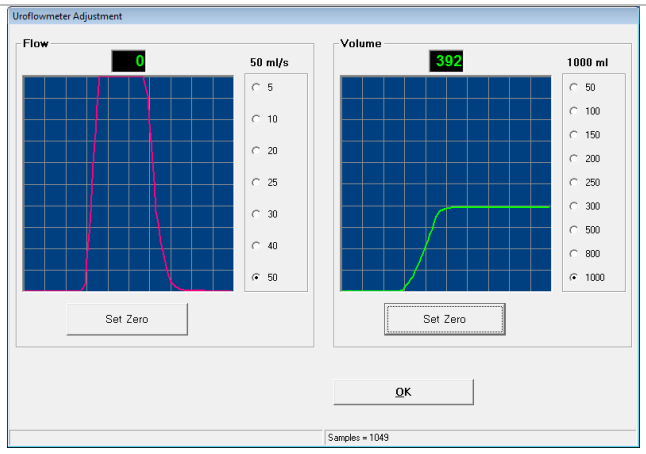
3b	To find available port(s) consult the Device Manager application by clicking the **Device Manager** button in the ***Set Com*** window and selecting the appropriate port.	
4	Click the **Check Connection** button and wait approximately 10 seconds. If the proper COM port was selected, the **Urostym®** connection indicator on the lower left of the **Urostym®** screen will change color to green. The COM Port for UDS section is for informational purposes only. *Configuration of UDS120 software should be performed with the UDS120 software according to the *Laborie Software Installation Guide*.	
5	If using a Uroflowmeter, click the **Uroflowmeter Adjustment** button to adjust the scale for the Flow and Volume channels.	
6	Click **OK** to save your scale selections.	

Table 4: Synergy Software Setup

If your system was installed by Laborie Medical Technologies, the default COM ports used by the **Urostym®** and wired **Urocap™** are COM1 and COM2 respectively.

4.1.1 SOFTWARE LOGIN

Once the software starts, you may be asked to enter a user name and password. This logon feature, in accordance to the Health Insurance Portability and Accountability Act (HIPAA), provides an extra layer of security for testing and when accessing patient test files.

Figure 3: Login Window

The user name and password used for logging on to the computer **must** be used in this logon screen too (Figure 3).

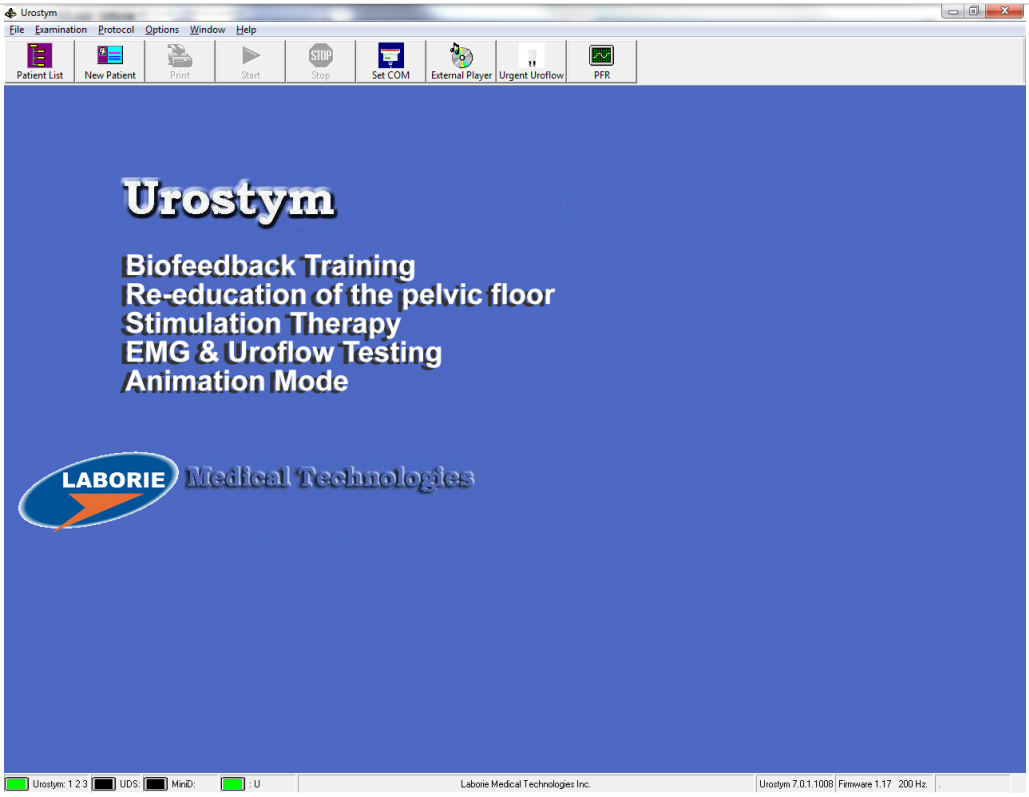
If a password is not available ask your system administrator to provide one for you.

A log file is created whenever someone starts the software and opens a file.

The software will shut down if an incorrect user name or password is repeatedly entered more than three times.

5 UROSTYM® SOFTWARE OVERVIEW

The main **Urostym®** window is composed of four different sections (Figure 4):



Main Menu Bar	The main menu bar provides quick access to all functions. It contains the following submenus: File, Examination, Protocol, Options, Window and Help.
Patient Toolbar	The Patient Toolbar buttons provide quick access to the most frequently used functions.
Patient List Button	The Patient List button provides quick and easy viewing of patient folders. These functions are also available through the main menu and the toolbar.
Status Bar	Along the bottom of the **Urostym®** welcome screen is a Status Bar that contains a **Urostym®** connection indicator, the UDS connection status, the Simulator connection status, the Clinic Name, the software version, the firmware version and the Notification indicator.

Figure 4: Urostym® Main Software Window

Mapped devices (also called connected devices) will be displayed in the status bar beside the device name. For example, on the bottom of the image above:

- Channel 1 is linked to the **Urostym®** unit
- Channel 2 (EMG1) and Manometry (transducer P4) are linked to the UDS unit
- Uroflowmeter is linked to the Simulator (pseudo device)

If a device is not linked, the indicator in the status bar is black; if the device is linked but not connected, the indicator is red; if the device is linked and connected, the indicator is green.

5.1 MAIN MENU BAR

The **Urostym®** menu structure provides easy access to all software functions.

5.1.1 FILE MENU

The **File** menu is a top-level menu that provides all functions relating to patient records.

New Patient	Creates a new patient folder. Fill in the required information in the empty patient folder.
Delete Patient	Deletes the currently selected patient folder. When selected, a message will appear asking for verification of deletion.
Delete Session	Deletes the currently selected session in the Previous Session Folder. When selected, a message will appear asking for verification of deletion.
Printer Setup	Select printers installed on your computer or change the printer's settings.
Print Report	Prints the selected Phase report.
Import Protocols	Allows for the exchange of protocols between different users. File exchange can only occur with files created by the same version of **Urostym®** software. Date and time of file creation will also be visible.
Import Patient File from i-LIST	Imports patient files from i-LIST database for easy selection.
Exit	Closes the **Urostym®** software.

5.1.2 EXAMINATION MENU

The **Examination** menu is a top-level menu that provides all the functions related to the examination session.

Start	Starts the selected session. Available in the patient folder when a session is selected from the Add New Session List.
Stop	Stops a running session. Available during an adjustment session or when an examination session is running.

5.1.3 PROTOCOL MENU

The **Protocol** menu is a top-level menu that provides all the functions related to Protocol programming.

Program a Protocol	Create, modify, copy, and/or delete a Protocol.
Program a Current	Create, modify, copy, and/or delete a Current.
Program an Envelope	Create, modify, copy, and/or delete an Envelope.
Program a Template	Create, modify, copy, and/or delete a Template.

5.1.4 OPTIONS MENU

The **Options** menu is a top-level menu that offers the option of activating or deactivating available features.

Show Hidden Protocols	View all protocols, including hidden protocols, in the Protocol list.
Animation Character and Background Music Options	Change the animation and background music settings.
Graph Configuration	Change graph appearance such as curves, colors, and widths. Graph configurations can be set at a global or local level.
Clinic Name	When clinic name is added in this section, it will be included on all printed reports.
EMG/Manometry Calibration	Calibration of Channels 1, 2 and 3.

5.1.5 WINDOWS MENU

The **Window** menu provides display all open windows. Use the list to switch to the desired window. Each window is identified by window title. Also, pressing **CTRL+F6** keys simultaneously will switch to another window.

5.1.6 HELP MENU

The **About Urostym®** menu option opens the window containing information about the software version, the firmware version, the support telephone numbers, and the website address.

5.2 PATIENT TOOLBAR

The Toolbar provides quick access buttons to frequently used functions. It contains some of the most common functions of the **Urostym®** software.

Patient List	The **Patient List** button switches the patient listing between the visible and the invisible modes. The first click prompts the patient list to appear; on the second click, the patient list disappears. **To show the Patient List:** • Click the **Patient List** button on the toolbar • **To hide the Patient List:** • When the patient list is visible, click the **Patient List** button to hide it -OR- Click the X button in the upper-right side on the Patient List form.
New Patient	The **New Patient** button is a shortcut for the **File > New Patient** function, which is also accessible through the File menu on the main menu bar.
Print	The **Print** button is a shortcut to print reports.

Start	The **Start** button is a shortcut to the Start function, which is also accessible through the Examination menu on the main menu bar.
Stop	The **Stop** button is a shortcut to the Stop function, which is also accessible through the Examination menu on the main menu bar.
Set COM	The **Set COM** button is a shortcut to the Map Devices and Com port setting that is performed when the **Urostym®** is initially set up.
External Player	The **External Player** button opens the Windows Media Player, which allows you to play CDs during a patient session or to build a music library with your choice of songs.
Urgent Uroflow	**To be used for new patients only.** Creates a new patient file with a unique ID, and adds all Uroflowmetry protocols to the *Session List* section. *For existing patients, please select that patient from the Patient List and proceed to adding the protocols in the sessions tab.*
PFR	**To be used for new patients only**. Creates a new patient file with a unique ID and adds all PFR protocols (PFR_EMG1EMG2AndManometry, PFR_EMG2AndManometry, PFR_EMG1AndEMG2, Alternating stimulation, and Continuous stimulation) to the *Session List* section. *For existing patients, please select that patient from the Patient List and proceed to adding the protocols in the sessions tab*

Table 5: Patient Toolbar Settings

5.3 PATIENT LIST AND PATIENT FOLDER

The purpose of the **Patient List** is to list the patient files in the database, which includes patient name, date of birth, and date of most recent session. Click the headers to sort the records or use the filters at the top of the screen to further organize files (Figure 5).

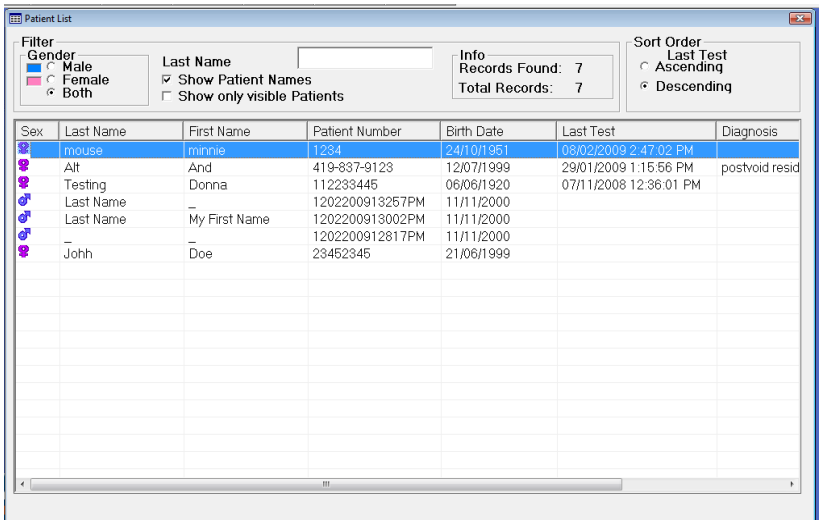


Figure 5: Patient List Window

A patient folder is the window displayed when you open a patient file or create a new patient file in the Patient List (Figure 6).

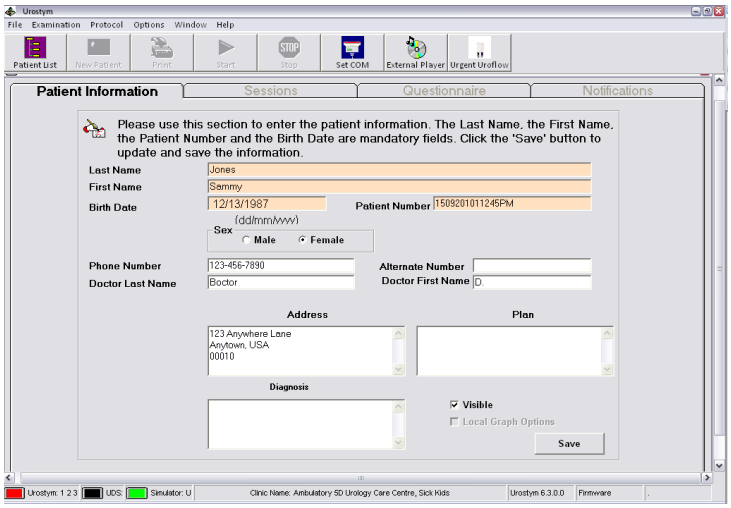


Figure 6: Patient List -Patient Information Tab

5.3.1 PATIENT INFORMATION TAB

The Patient Information tab is used to enter personal information about the patient.

Last Name*	the patient's last name
First Name*	the patient's first name
Birth Date*	the patient's date of birth
Patient Number*	the unique number used to identify the patient
Sex*	the patient's gender
Phone Number	the patient's contact phone number
Alternate Number	the patient's work phone number or an alternate contact number
Doctor Last/First Name	the doctor's name
Address	the patient's address
Plan	any relevant note(s) about the plans for treatment or a related subject
Diagnosis	any relevant note(s) about the patient or a related subject
Visible	select if the patient's name is to be included in the Patient Tree
Local Graph Options	select this option to set up specific graph configurations for this patient only
Save	Click this button to save any new or edited patient information

*Required Information

5.3.2 SESSIONS TAB

The Sessions tab contains information about a patient's treatment sessions (). The *Session List* contains treatments selected for the patient. The **Used** column indicates the number of times a specific session has been used on this patient.

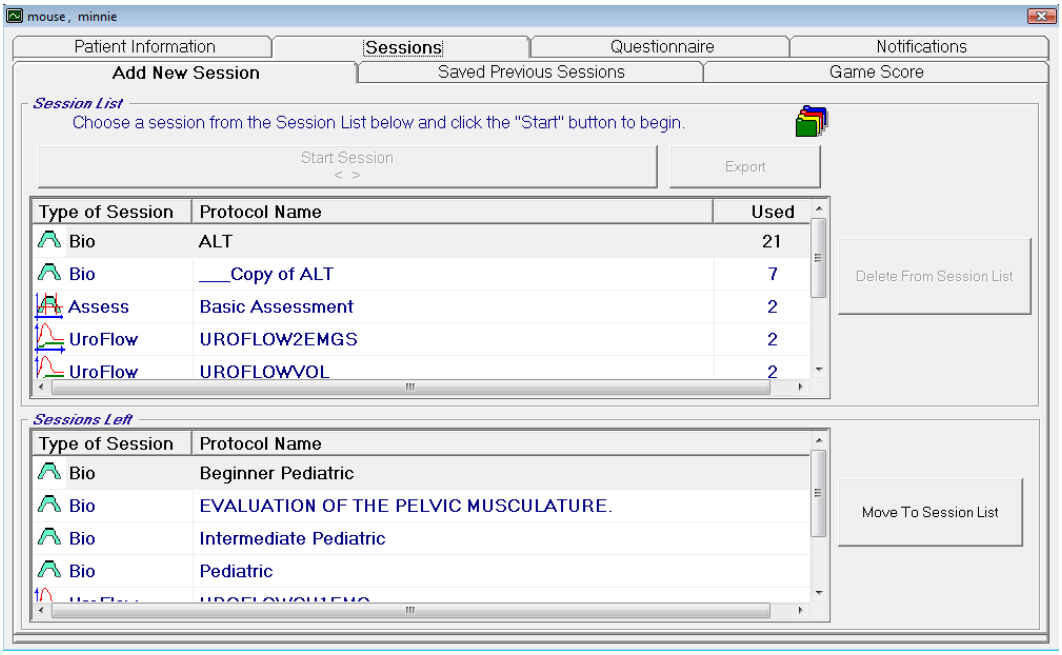


Figure 7: Patient List- Sessions Tab

To add a new session to the Session List:

1. Click a session from the ***Sessions Left*** listing at the bottom half of the screen. The session is highlighted in the listing.
2. Click the **Move To Session List** button.
3. Double-click any session in the ***Session List*** (or in the ***Sessions Left*** list) to see the Protocol information for that particular session.

If necessary, click the **Export** button to set up the file (containing the protocols from the Session List) for use by another user. The file can then be imported by another user with the same version of **Urostym®** software.

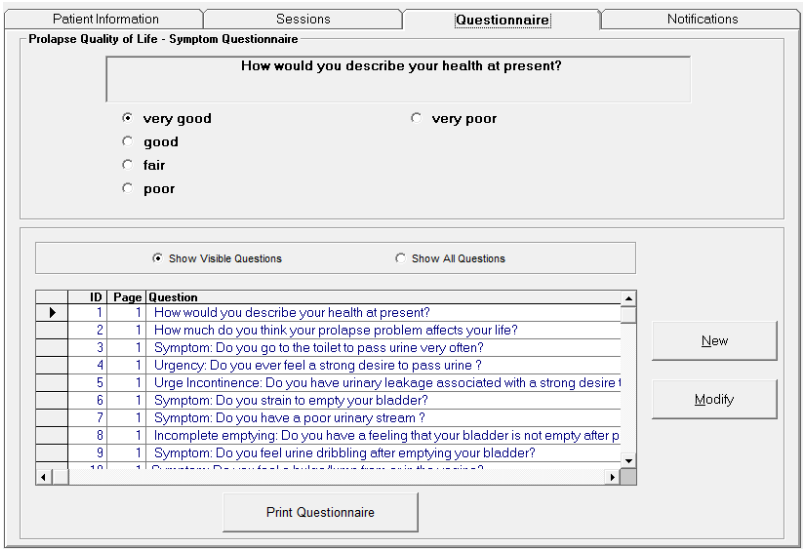
Saved Previous Sessions contains information on protocols used in previous visits.

Game Score contains information on the results of a patient's participation in the **Urostym®** video games.

5.3.3 QUESTIONNAIRE TAB

The Questionnaire tab contains some of the most commonly used patient questionnaires such as: *The Prolapse Quality of Life Symptom and Activities Questionnaires, The Kings' Health Symptoms and Activities Questionnaires* and the *Urogenital Distress Inventory Questionnaire*.

Select either a specific questionnaire for each patient or use all of them.

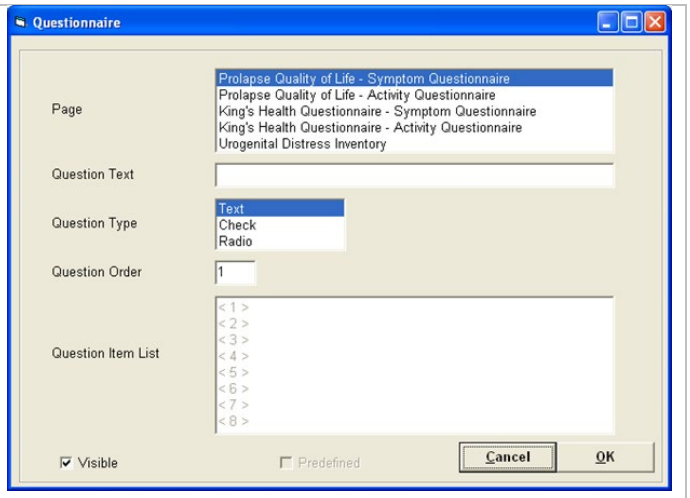


Select to have all questions in a questionnaire visible or select to display a specific number of questions. To select specific questions click the **Modify** button to open the *Questionnaire* dialog box. Select the question that you would like to display and check the *Visible* option at the bottom of the dialog box.

Figure 8: Patient List – Questionnaire

TO ADD QUESTIONS:

1	Click the **New** button to open the *Questionnaire* form (Figure 8).
2	Select the *Page* where you would like to add the question.
3	Type the question in the *Question Text* line.
4	Select the *Question Type*.
5	Select the *Question Order*.
6	Add the choices in the *Question Item List*.



7	Select the *Visible* box if you want the question to appear at all times in the questionnaire.
8	Click **OK** to add the newly created question to the *Questionnaire* Tab. • You can add as many questions as you like. • If you select to have a question in the *Check* or *Radio* format, you can have up to eight choices for the answers. • To make the question visible in the *Questionnaire* tab you will need to select the *Visible* check box. • Once you have created a question, it cannot be deleted or changed. If you do not want to include this question in the questionnaire, remove the check mark from the *Visible* check box.
9	Click the **Modify** button to:

	• change the *Question Order* (for example, if you want to move a question from the third spot in the list to the fifth spot) • make the question *Visible* or not • change the page where the question appears
10	Click the **Print Questionnaire** button to obtain a printout of the questionnaire for a selected patient.

Table 6: Questionnaire – Adding Questions

5.3.4 NOTIFICATIONS TAB

Click the ***Notifications*** tab in the patient file to add notes to a patient's file (). The contents of the note can be added by typing in the Notifications text box. The notification icon will be visible in the lower right corner of the **Urostym®** program on the date you have chosen.

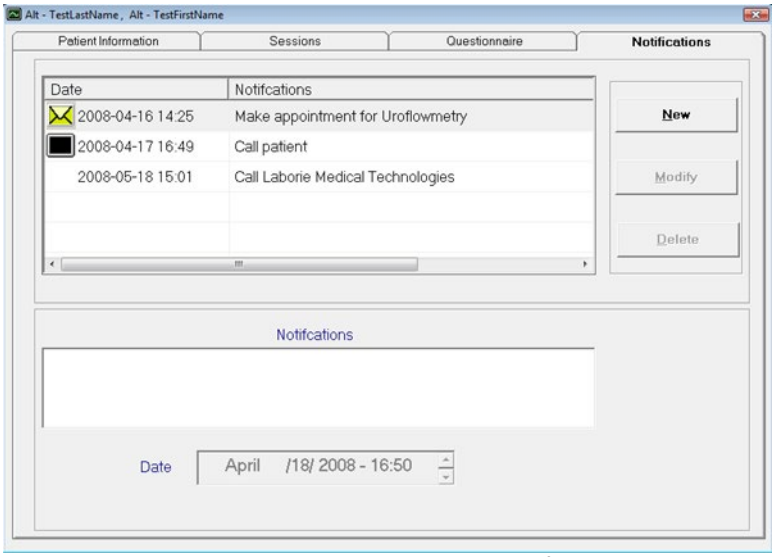


Figure 9: Patient List - Notifications Tab

Click the **New** button to add a new note/message to the listing and to enter the date the notification should become visible.

To edit a note, select the note requiring changes and then click the **Modify** button.

To remove a note, select the note to be removed and then click the **Delete** button.

6 ADVANCED FEATURES

6.1 DELETE A PATIENT FOLDER

1. Open the desired folder.
2. Click File > Delete Patient
3. Confirm deletion by clicking yes in the resulting window

Deleting a patient folder also deletes all related treatment sessions for this specific patient. Verify the selection of the patient folder to delete is correct before deleting.

6.2 DELETE A PREVIOUS PATIENT SESSION

1. Click the ***Sessions*** tab in the patient file. Click the ***Saved Previous Sessions*** tab to view the list of sessions saved with the patient's file.
2. Click on the line containing the session to be deleted.
3. On the main menu bar click **File > Delete Session**.
4. Click **Yes** to delete.

6.3 CONFIGURING GRAPH APPEARANCE

With this feature, you can set the color, line width, background, and grid properties of the graph area.

To access the Graph Configuration window, Click Options on the menu bar and select Graph Configuration (Figure 10).

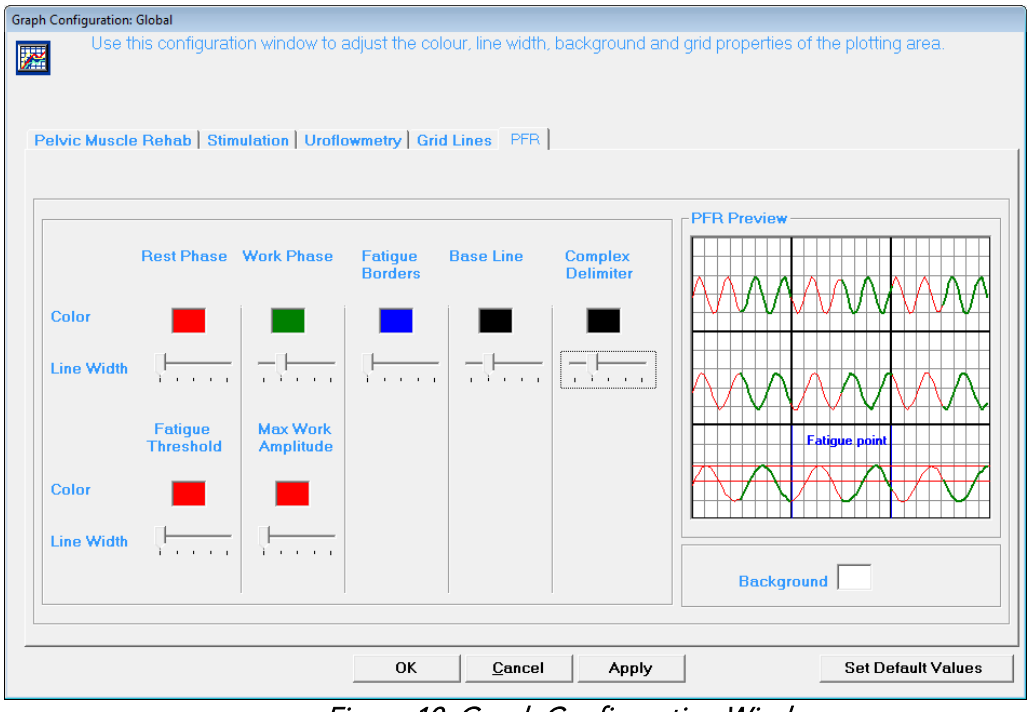


Figure 10: Graph Configuration Window

The Graph Configuration window contains five tabs:

- Pelvic Muscle Rehab
- Stimulation
- Uroflowmetry
- Grid Lines
- PFR

6.3.1 PELVIC MUSCLE REHAB TAB

This tab allows you to set the appearance of the PMR screens. Lines and curves in the graph area for Channels 1, 2, and 3 can be modified to suit your preferences. A preview screen is available to help visualize your selections as you apply line widths and colors.

Line Width: Move the slider pointer of the desired curve to modify the drawing width. Move it to the left for a narrower width or to the right for a wider width.

Line Color, Template Color, BG (background) Color: Double-click the desired colored rectangle to display the color dialog box. The dialog box allows you to choose a color for each channel line, for the template and for the background of each channel.

Fill in Curve Area: Select this option to fill in the area under the PMR curve with the selected line color.

6.3.2 STIMULATION TAB

Select this tab to set the appearance of the stimulation screen. A preview screen is available to help visualize your selections as you apply line widths and colors. Double-click the desired colored rectangles to display the color dialog box. The dialog box allows you to choose a color for the specific section.

6.3.3 UROFLOWMETRY TAB

Select this tab to set the appearance of the Uroflowmetry screen. You can modify the Volume and Flow curve colors, as well as the appearance of the channel curves and base line to suit your preferences. A preview window is available on the right-hand side of the screen to help visualize what your selections will look like on screen.

If you choose to print your reports in color, the curves will be printed with the selected colors.

6.3.4 GRID LINES TAB

This tab allows you to set the color and style for the Grid Lines of the plotting area.

Color: Double-click the desired colored rectangle to display the color dialog box. The dialog box allows you to choose a color for the line.

Draw Style: Select the desired style to draw the grid lines in the plotting area. The default style is Solid, but you can also choose a Dash, Dot, Dash-Dot or Dash-Dot-Dot style.

- **To set draw style:** Click the color box in the screen.
- Select the Draw Style from the listing.
- Click **OK** to apply your modifications.

6.3.5 PFR TAB

This tab allows you to set the color and style for the appearance of the PFR session curves. A preview window is available on the right-hand side of the screen to help visualize what your selections will look like on screen.

SET DEFAULT VALUES BUTTON

To restore default value settings, click the **Set Default Values** button to open the confirmation screen. Click **Yes** to go back to the default settings.

6.4 PROGRAMMING A PROTOCOL

Click Protocol to display the menu for programming a protocol (Figure 11).

If information is changed during Protocol creation, then you **must click** *Update Phase*, *OK*, and *Yes* when prompted to save the information.

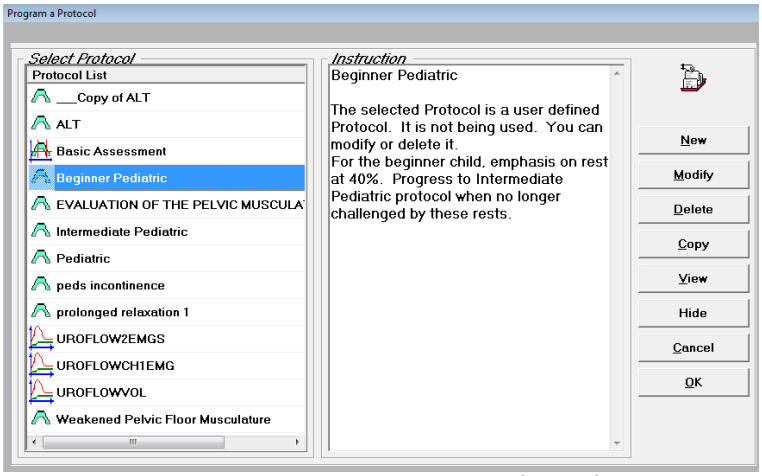


Figure 11: Protocol Window

6.4.1 VIEW INFORMATION ABOUT A PROTOCOL

1. Double-click the selected Protocol item from the **Protocol List.**
2. View Sequence information.
3. View Phase information.

6.4.2 ADD NEW PROTOCOL

1. Click the Protocol button on the toolbar.
2. Click the New button on the right-hand side to open the *Protocol Information* window.

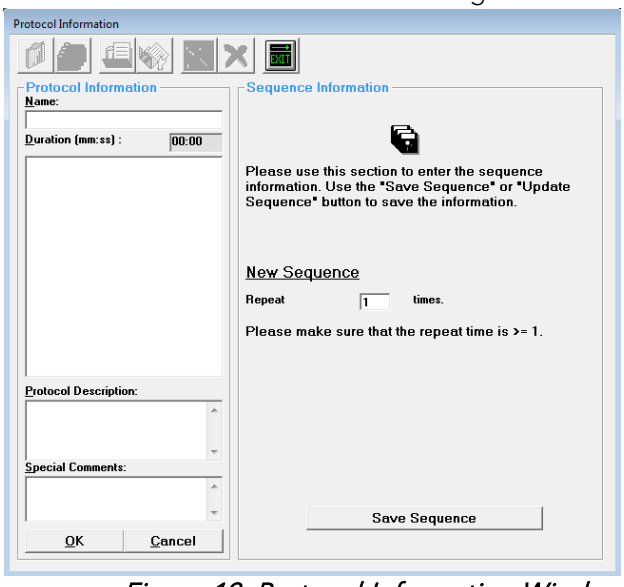


Figure 12: Protocol Information Window

The window contains the following information:

- Name: Protocol Name
- Duration: Protocol Length (using HH:MM). The max value is 30 minutes.
- Protocol Description: Protocol Description
- Special Comments: Comment related to the Protocol

3. Enter the Protocol information. (The Protocol name **must** be entered.)
4. Click the **Save Sequence** button.
5. Add new *Sequences* and *Phases* for the Protocol.
6. Click OK.

6.4.3 COPY INFORMATION FROM A PREDEFINED PROTOCOL

This option will allow you to copy a predefined Protocol and modify it without altering the original Protocol. The name of the new Protocol will automatically be called "Copy of…." followed by the name of the original Protocol. The duration, name, description, and recommendation of the Protocol can be modified.

1. Click the **Protocol** button on the toolbar.
2. Select the protocol to copy from the *Protocol List*.
3. Click the **Copy** button on the right-hand side.
4. Click **OK.**

6.4.4 MODIFY INFORMATION IN A USER-DEFINED PROTOCOL

1. Click the **Protocol** button on the toolbar.
2. Select the Protocol that you want to modify from the **Protocol List.**
3. Click the **Modify** button.
4. Modify information such as: *Name*, *Duration*, *Protocol Description*, and *Special Comment*.
    - Double-click the Sequence node on the **Protocol Tree** to modify the Repeat information.
    - Double-click the Phase node in **Protocol Tree** to modify the Phase information. Click **OK**.

A Protocol can only be modified if:

- It is a user-defined Protocol.
- It is not in any patient's Sessions List.
- It has not been used in any Session for any patient.

6.4.5 DELETE A USER-DEFINED PROTOCOL

1. Click the **Protocol** button on the toolbar.
2. Select the Protocol that you want to delete from the **Protocol List**.
3. Click the **Delete** button.
4. Verify that the Protocol selected for deletion is the correct one.
5. Click **Yes** to delete.

6.4.6 HIDE A PROTOCOL

This function allows you to keep selected protocols hidden from the protocol listing. To hide the protocol, click the protocol name in the list and click the **Hide** button. To view hidden protocols, click **Options** > **Show Hidden Protocols**.

6.5 PROGRAMMING A SEQUENCE

Important Sequence Terminology to remember:

- **Sequence No:** (*Sequence Number*) The order of the *Sequence* in the *Protocol*
- **Repetition:** How many times the particular *Sequence* will be repeated in the *Protocol*
- **Protocol Phase No**: *(Protocol Phase Number)* The order of the *Phase* in the *Protocol*
- **Sequence Phase No**: *(Sequence Phase Number)* The order of the *Phase* in the *Sequence*
- **Total Phase No**: *(Total Phase Number)* Total number of *Phases* in the *Protocol*
- **Work Time**: Duration of the work *Phase*
- **Rest Time**: Duration of the rest *Phase* (Note: During the *Session*, **Rest Time** will always appear as a countdown clock on the screen)
- **Channel No:** *(Channel Number)* The channel being used (channel 1, 2 or 3)
- **Channel Type:** PMR (channels 1,2, and 3) or stimulation (channel 1)

To create a Sequence, define the repetition of a Phase or a set of Phases. Sequences must be created before Phases can be created.

The buttons at the top of this window help save, modify, and delete Sequences and Phases.

Phases can be added to an existing Sequence. To do this, you **must first select** the Sequence you wish to modify, and then highlight the Phase within that Sequence to which you wish to add a Phase. The *New Phase* will be added immediately following the highlighted Phase.

6.5.1 VIEW INFORMATION ABOUT A SEQUENCE

Select the sequence from the Protocol Tree to view the information about the sequence (Figure 13).

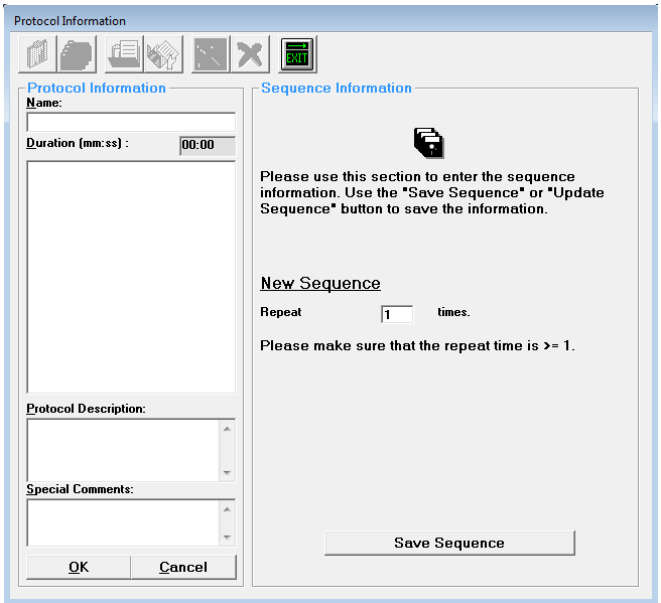


Figure 13: Protocol Information Window – Sequence

6.5.2 ADD A NEW SEQUENCE

1. If a desired sequence already exists, select the Sequence in the Protocol Tree to which you want to add a new Sequence.

2. If a sequence does not yet exist, click the flashing **New Sequence** button on the toolbar. 

3. Enter the **Repeat Times** and click the **Save Sequence** button. The new Sequence is added to the Protocol Tree.

6.5.3 MODIFY INFORMATION IN A SEQUENCE

1. Double-click the Sequence that you want to modify in the *Protocol Information* section.

2. Modify the information in the *Sequence Information* section.

3. Click **Update Sequence**.

6.5.4 DELETE A SEQUENCE

1. Select the Sequence that you want to delete in the *Protocol Information* section.

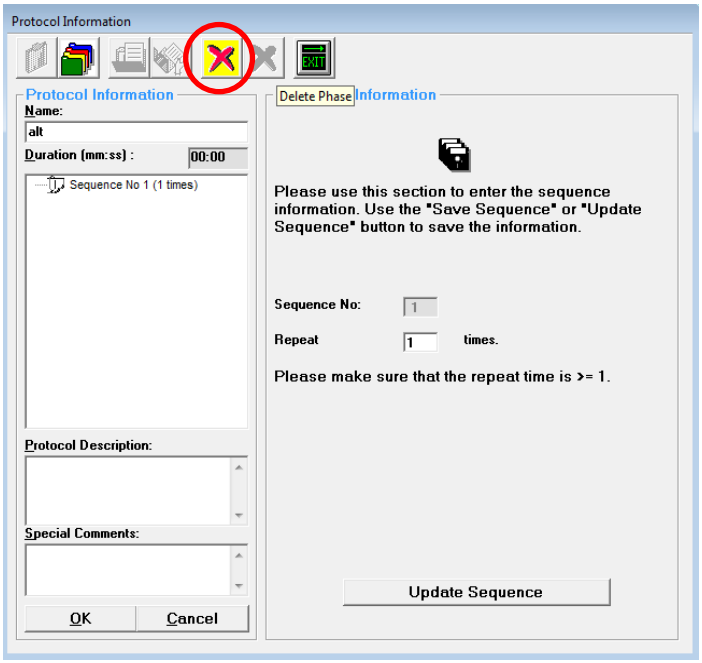


Figure 14: Protocol Information Window – Delete icon

2. Click the **Delete Sequence** button on the toolbar.

3. Click **Yes**.

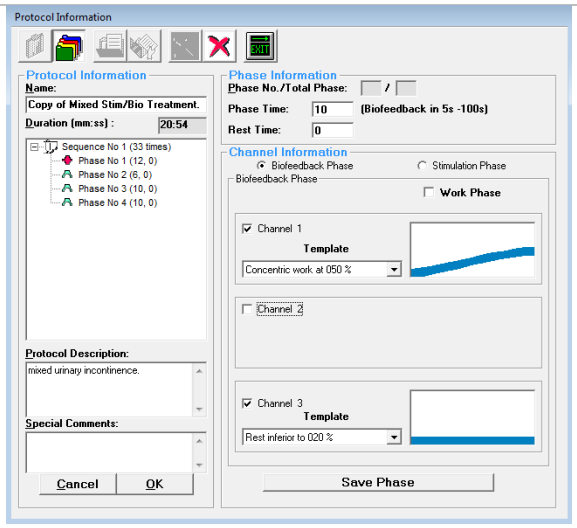
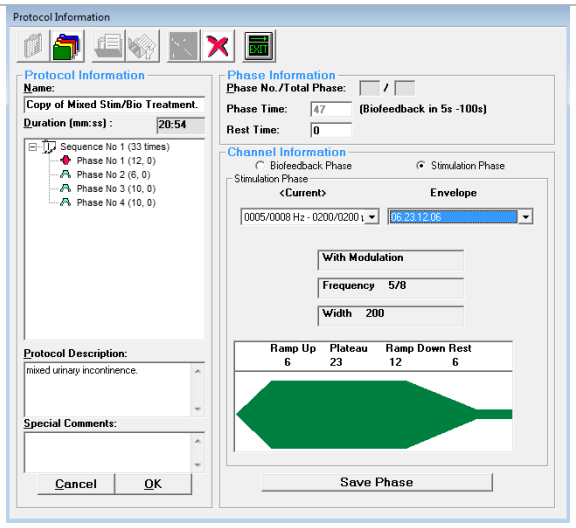
6.6 PROGRAMMING A PHASE

To view information about a phase:

1. Click the plus sign (+) beside the Sequence in the *Protocol Information* section.
2. Double-click the Phase you want to view.

6.6.1 ADD NEW PHASE

Add a new Phase to the listing in the sequence (Table 7).

1	Select the Phase or Sequence in the *Protocol Information* after which you want to add a new Phase.	
2	Click the **New Phase** button on the toolbar. 	
3	Enter the Phase information such as *Phase Time** and *Rest Time***.	
4	Select the type of phase.	
4a	For PMR : Select the Work Phase check box if phase is considered to be a work phase; specify what channels are to be used in the phase by checking off the appropriate channel check box; in selected channels select a template. Recommended use of channels: • Channel 1: For pelvic floor muscles; sensor: whether internal probe or surface electrodes • Channel 2: For abdominal muscle group; sensor: surface electrodes • Channel 3: For pelvic floor muscles; sensor: internal Manometry probe	
4b	For Stimulation: select a Current and an Envelope. Stimulation must be used only on Channel 1.	
5	Click **Save.**	

* The **Phase Time**: Work time of the Phase.
The **Rest Time: Rest time of the Phase. Appears as a countdown clock

A Work Phase can be one of action (attempt to contract the pelvic floor) or relaxation (attempt to rela
the pelvic floor).

Table 7: Adding a New Phase in the Sequence

6.6.2 MODIFY INFORMATION ABOUT A PHASE

1. Click the plus sign (+) beside the Sequence on the *Protocol Tree*.
2. Double-click the Phase that you want to modify.

6.6.3 MODIFY PHASE TIME AND REST TIME

1. Click the combo box to select a different **Template** for the PMR channel, and/or **Current** and **Envelope** for the stimulation channel.
2. Click **Update Phase.**
3. Double-click the Phase that you just modified.

6.6.4 DELETE A PHASE

1. Select the Phase that you want to delete from the *Protocol Information* section.
2. Click **Delete > Phase** on the menu bar
3. Click **Yes**.

6.7 PROGRAMMING CHANNELS

The Table 8 contains the recommended setup for channels.

Mode	Channels	Accessory
Pressure PMR (Manometry)	Use Channel 3 **only**	Anal/Vaginal Manometry probe
PMR	Use Channels 1 and/or 2	Anal/Vaginal EMG probe; Surface electrodes
Stimulation	Use Channel 1 **only**	Anal/Vaginal EMG probe; ELE625 Surface electrodes

Table 8: Channel Setup

6.7.1 PROGRAMMING A STIMULATION CHANNEL

Important Stimulation Terminology to remember:

- Current: Current used in the electrical stimulation *Session*.
- Envelope: Displays the way in which electrical stimulation will be administered
- Frequency: Current frequency
- Modulation: Current uses a modulated frequency (for example: current fluctuates between two predetermined frequencies)
- Pulse Width: Current pulse width, sometimes referred to as bandwidth
- Plateau Value: Maximum current intensity in a stimulation envelope
- Ramp Up Time: In a stimulation *Envelope*, time allocated for the current to ramp up (in seconds) to the Plateau value
- Plateau Time: In a stimulation *Envelope*, time allocated for current remaining at maximum intensity (plateau period)
- Ramp Down Time: In a stimulation *Envelope*, time allocated for current to ramp down to 0
- Rest Time: In a stimulation *Envelope*, time allocated for resting (no current) within the *Phase*

Only Channel 1 can be programmed for stimulation mode.

1. Select the Stimulation Phase radio button to choose the **Stim** mode.
2. Under **Current,** click the combo box and select a Current from the standard list.
3. Click the **Envelope** combo box to choose one Envelope from the standard list.

6.7.2 PROGRAMMING A PMR CHANNEL

Important **PMR Terminology** to remember:

- **Average Contraction:** Average value of the patient's contraction
- **Effort**: The percentage of time a patient is able to remain within the template goal line during a particular phase.
- **Max Contraction**: Maximum value of the patient's contraction
- **Template**: PMR profiles that appear on the screen during the patient *Session*. The *Template* acts as a goal line or target area the patient must attempt to reach.

When programming a phase, Channels 1, 2, and 3 can be programmed for PMR mode.

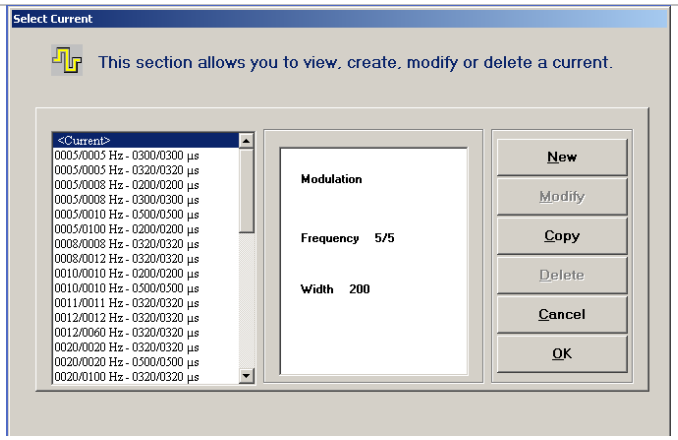
1. Select the PMR Phase radio button to choose the PMR mode.
2. Specify the channels to be used in the phase
3. Click the combo box under **Template for each selected channel** and choose one Template from the standard list.
4. Enter all Phases and channel information as directed by the on-screen instructions.
5. Click **Update Phase** to add it into the Protocol Tree.

6.8 PROGRAMMING A CURRENT

6.8.1 VIEW INFORMATION ABOUT A CURRENT

1. Click Current on the main menu bar to display list.
2. Select current to view. Selected current information is displayed in the picture box.

6.8.2 ADD A NEW CURRENT

1	Click the current button on the toolbar to display current list.	

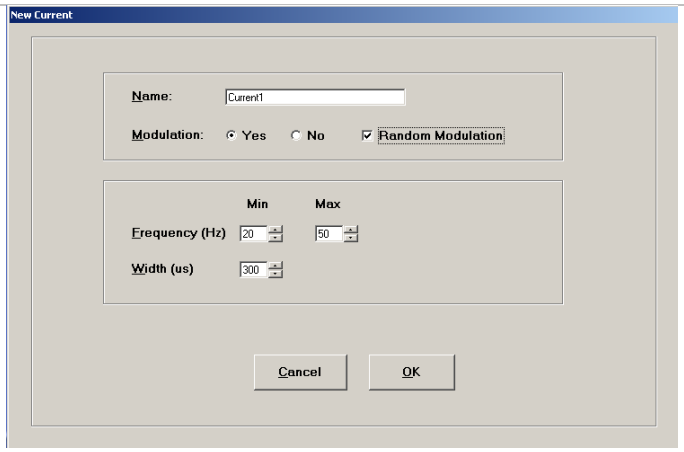
2	Enter a name for the new current. NOTE: Do not add any punctuation character to the name	
3	Click the up and down arrow buttons to increase or decrease the value of Frequency and Bandwidth and click OK. NOTE: The valid frequency range is 5-200 Hz. The valid pulse width range is 200-500us	

Table 9: Adding a New Current

When defining Current with modulation in Frequency, two values are displayed on screen. These are Min Frequency and Max Frequency. The Min and Max Frequencies should have different values and the Min Frequency must be less than the Max Frequency.

If you select **Random Modulation**, you are selecting to have a shuffled set of modulation sequences. For example, a set can contain a specific sequence with a set time between pulses. If you select to have random modulation, the time between pulses can be shuffled to provide a more effective type of treatment.

6.8.3 MODIFY INFORMATION ABOUT A USER DEFINED CURRENT

1. Select the current you want to modify from the Current List.
2. Click the Modify button.
3. Modify the current informations including Modulation, Frequency, and Width.
4. Click OK.

Only user-defined currents that have never been used in a patient session may be modified.

6.8.4 COPY CURRENT INFORMATION

To copy the information from one current setup to another:

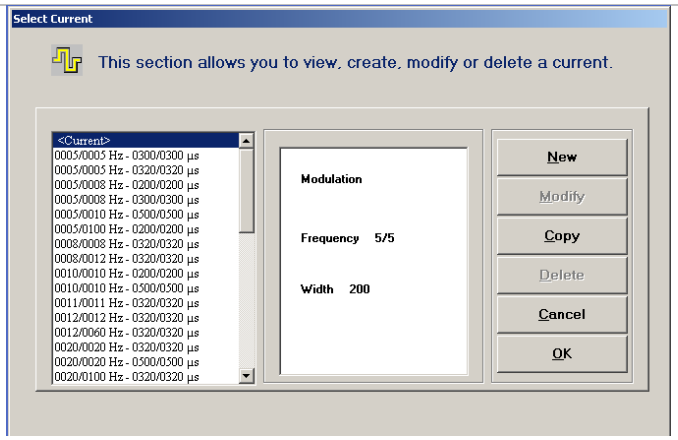
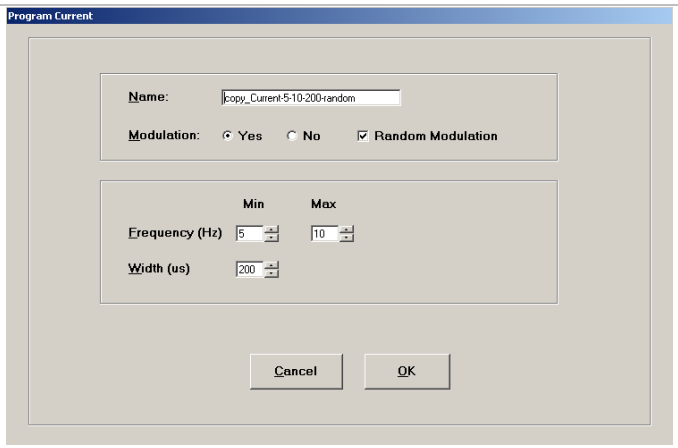
1	Select the Current you want to copy.	
2	Click the copy button to open the Program Current window.	
3	Verify that the information is correct. If desired, change the name. Click OK when complete.	

Table 10: Copying Setup - Current

6.8.5 DELETE A USER DEFINED CURRENT

1. Select the current you wish to delete from the Current List.
2. Click the Delete button.
3. Click Yes in the resulting window to confirm deletion.

6.9 PROGRAMMING AN ENVELOPE

When programming a stimulation Envelope, you may include current ramping (*Ramp-Up, Ramp-Down, Plateau)* and rest time within each stimulation Phase.

6.9.1 VIEWING INFORMATION ABOUT THE ENVELOPE

1. Click Envelope on the main menu bar to display the envelope list.
2. Select the Envelope you want to view from the list.

6.9.2 ADD A NEW ENVELOPE

1. Click Envelope on the main menu bar to display the envelope list.
2. Click New.

3. Enter the name of the new Envelope and click UP/DOWN buttons to increase or decrease section times in the envelope.
4. Click OK.

6.9.3 MODIFY INFORMATION IN A USER DEFINED ENVELOPE

1. Select an Envelope that you want to modify from the **Envelope List**.
2. Click **Modify** to display envelope information.
3. Modify Envelope information including Ramp-Up, Plateau, Ramp-Down and Rest Time (in seconds).
4. Click **OK**.

6.9.4 COPY AN ENVELOPE

1. Select the Envelope to copy.
2. Click the **Copy** button to display the information window.
3. Verify the information is correct.
4. If desired, change the name.
5. Click **OK** when complete.

6.9.5 DELETE A USER DEFINED ENVELOPE

1. Select an Envelope that you want to delete from the **Envelope List.**
2. Click the **Delete** button. A confirmation message will appear.
3. Click **Yes**.

6.10 PROGRAMMING A TEMPLATE

A Template is a PMR profile that illustrates the contraction or relaxation to be performed by the patient.

6.10.1 VIEW INFORMATION ABOUT A TEMPLATE

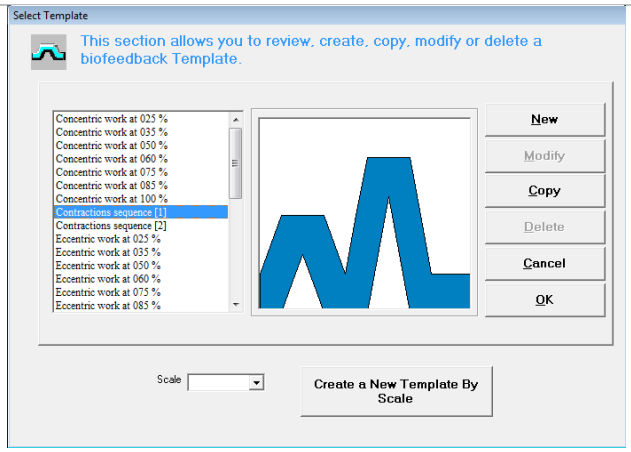
1	Click Template on the main menu bar to display the Template list.	
2	Select a template to view.	

Table 11: Viewing Template Information

Create new Templates by clicking the **Create a New Template By Scale** button. Select a pre-configured Template to add to the Template list and/or change the scale value as necessary. A new pre-configured template will be created and added to the list.

You can also create a "No Template" Template by typing the number "0" into the *Scale* box and clicking the **Create a New Template By Scale** button.

6.10.2 ADD A NEW TEMPLATE

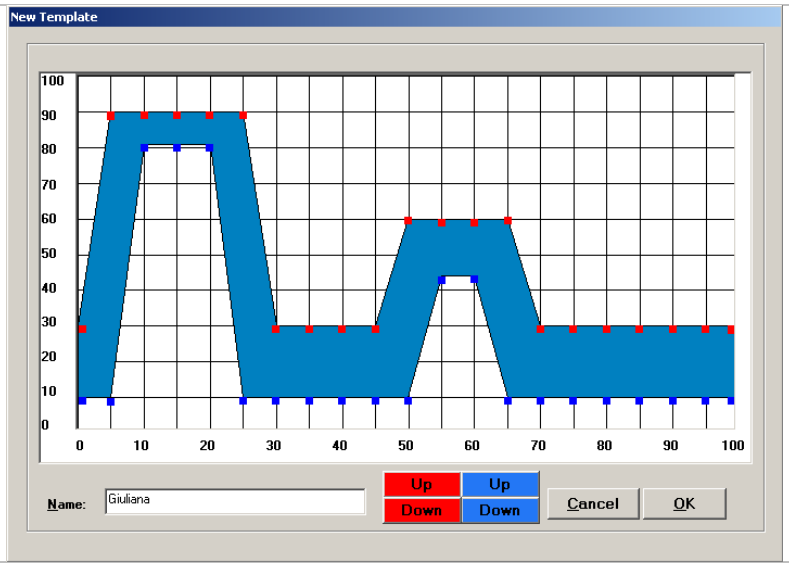
1	Click Template on the main menu bar to display the Template list.	
2	Click New Template.	
3	Using the grid, drag and drop the red or blue points to the desired position to draw the new template.	
4	Click OK.	

Table 12: Adding a New Template

6.10.3 MODIFY INFORMATION IN A USER DEFINED TEMPLATE

1. Select the Template to be modified from the **Template List.**
2. Click the **Modify** button.
3. Drag and drop the red and blue points to make the desired changes to the Template.
4. Click **OK**.

6.10.4 COPY A TEMPLATE

1. Select the Template you want to copy.
2. Click the **Copy** button.
3. Verify that the information is correct.
4. If desired, change the name.
5. Click **OK** when complete.

6.10.5 DELETE A USER DEFINED TEMPLATE

1. Select a Template that you want to delete from the **Template List**.
2. Click the **Delete** button.
3. Click the **Yes** button to confirm.

6.11 VIEWING STATISTICS OF A SESSION

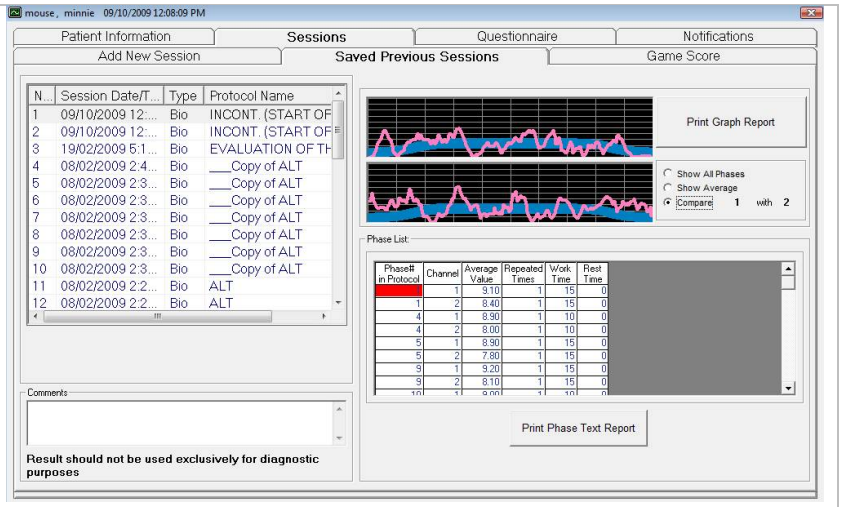
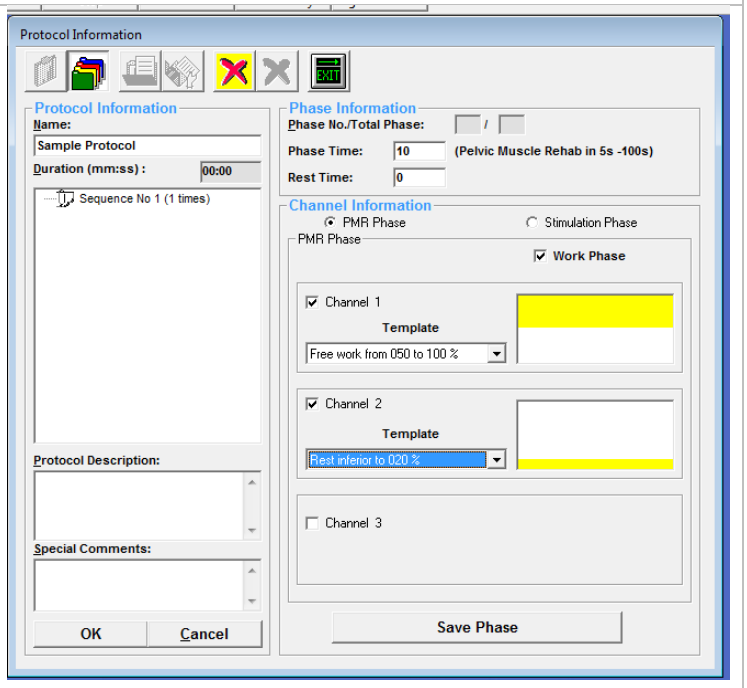
1	When the session is complete, click YES in the resulting message box.	
2	The statistics of the session will be highlighted.	
3	Double-click the image to resize the phase and / or bar graph; this allows for easier viewing. Placing the cursor over a line produces the mA reading.	
4	Select Show Average next to the graph (it averages the phase report). OR Select *Compare* when two of the same reports are available for comparison	

Table 13: Viewing Session Statistics

7 PROTOCOL SETUP

7.1 SAMPLE PMR PROTOCOL SETUP

1.	On the main menu bar, click **Protocol > Program a Protocol**.
2.	Click the **New** button.
3.	Name the Protocol. (*for example:* Freework Bio Treatment) Click the **Save Sequence** button.
4.	Type any desired information in the Protocol Information and Special Comments sections.
5.	Under the *Phase Information* section, set the *Phase Time* to 10 seconds and the *Rest Time* to 0 seconds.
6.	Under *Channel Information* select **PMR Phase**.
7.	Select the *Work Phase* check box.
8.	Select the *Channel 1* check box and select **Freework 50 to 100%** from the drop down list under "Template".
9.	Select the *Channel 2* check box and select **Rest Inferior to 20%** from the drop down list under "Template".
10.	Click the **Save Phase** button.
11.	Under the *Protocol Information* section, highlight *Phase No 1*.
12.	Click the flashing **New Phase** button
13.	Leave the *Phase Time* at 10 seconds and leave the *Rest Time* at zero.
14.	Under *Channel Information* select **PMR Phase**.
15.	Select the *Work Phase* check box.
16.	Select the *Channel 1* check box and select **Rest Inferior to 20%** from the drop-down list under "Template".
17.	Select the *Channel 2* check box and select **Rest Inferior to 20%** from the drop-down list under "Template".
18.	Click the **Save Phase** button
19.	Under the *Protocol Information* section double-click *Sequence No 1*.



20.	Under the *Sequence Information* section, set the *Repeat Time* to 15.
21.	Click the **Update Sequence** button
22.	Under the *Protocol Information* section, you may add a *Protocol Description* and *Special comments* in the designated fields.
23.	Click **OK**.

Table 14: Sample PMR Protocol Setup Instructions

7.2 SAMPLE ELECTRICAL STIMULATION PROTOCOL SETUP

1.	On the main menu bar, click **Protocol > Program a Protocol**.
2.	Click the **New** button.
3.	Name the Protocol. (*for example:* Stimulation Treatment) Click the **Save Sequence** button.
4.	Type any desired information in the Protocol Information and Special Comments sections.
5.	Under the *Phase Information* section, set the *Rest Time* to 30; the stim envelope set the *Work Time*.
6.	Under *Channel Information* select **Stimulation Phase** radio button.
7.	Under the *Current* section, select the **50/50Hz – 300/300µs** template, and under the Envelope section, select the **03.10.02.00** template.
8.	Click the **Save Phase** button.
9.	Under the *Protocol Information* section, highlight *Sequence No 1*.
10.	Under the *Sequence Information* section, set the *Repeat Time* to 30 and click the **Save Sequence** button.
11.	Click OK to confirm and exit.

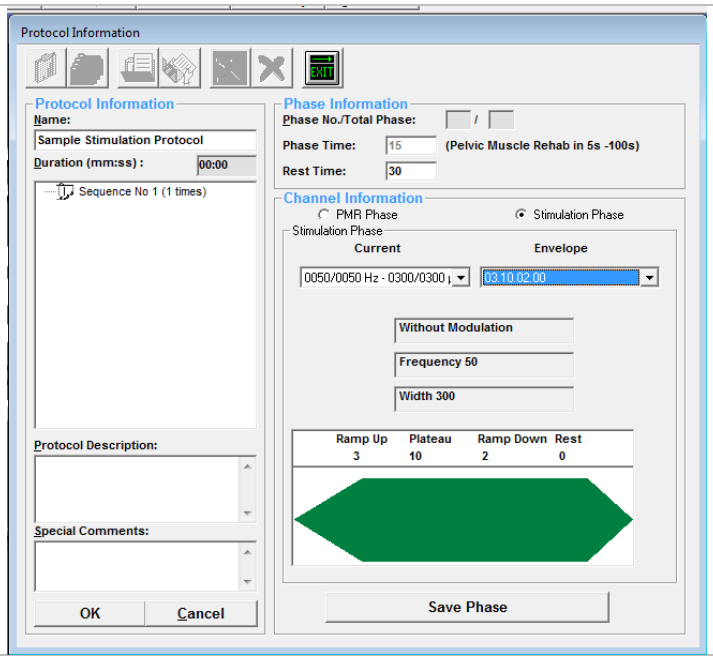


Table 15: Sample Electrical Stimulation Protocol Setup Instructions

7.3 SAMPLE PMR AND ELECTRICAL STIMULATION PROTOCOL SETUP

The following instructions outline the creation of a simple PMR and Electrical Stimulation Protocol.

7.3.1 CREATE A PMR SEQUENCE

1. On the main menu bar, click **Protocol** > **Program a Protocol**.
2. Click the **New** button.
3. Name the Protocol. (for example: Freework Bio Treatment)
4. Click the **Save Sequence** button.
5. Type any desired information in the Protocol Information and Special Comments sections.
6. Under the *Phase* Information section, set the Phase Time to 10 seconds and the Rest Time to 0 seconds.
7. Under Channel Information select **PMR Phase**.
8. Select the *Work Phase check* box.
9. Select the *Channel 1* check box and select **Freework 50 to 100%** from the drop-down list under "Template".
10. Select the *Channel 2* check box and select **Rest Inferior to 20%** from the drop-down list under "Template".
11. Click the **Save Phase** button.
12. Under the *Protocol Information* section, Double-click Sequence No. 1.
13. Under sequence information, set the Repeat Time to 30 and click **Update Sequence**.

7.3.2 CREATE A STIMULATION SEQUENCE

1. Under the Protocol Information section, highlight Sequence No. 1.
2. Click the **New Sequence** button.
3. Under the Sequence Information section, Click the **Save Sequence** button.
4. Under the *Phase Information* section, set the Rest Time to 30 seconds
5. Under the *Channel Information* section select the *Stimulation Phase* radio button.
6. Select **50/50Hz - 300µs** from the drop-down list under "Current" and **03.10.02.00** from the drop-down list under "Envelope".
7. Click the **Save Phase** button.
8. Under the *Protocol Information* section, double-click *Sequence No 2*.
9. Under the *Sequence Information* section, set the *Repeat Time* to 15.
10. Click **Update Sequence**.
11. Click **OK** to confirm and exit.

8 USING THE **UROSTYM®** SOFTWARE

Once you have made the connections to the correct Com ports, you can begin using the **Urostym®** software for PMR or Stimulation sessions.

8.1 CREATING A NEW PATIENT RECORD

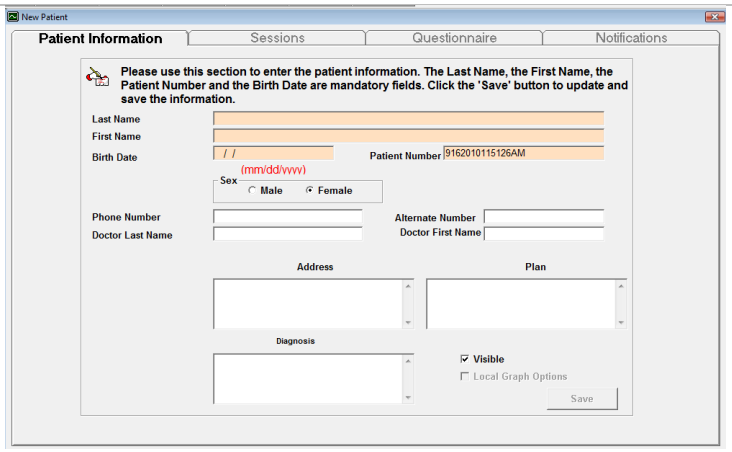
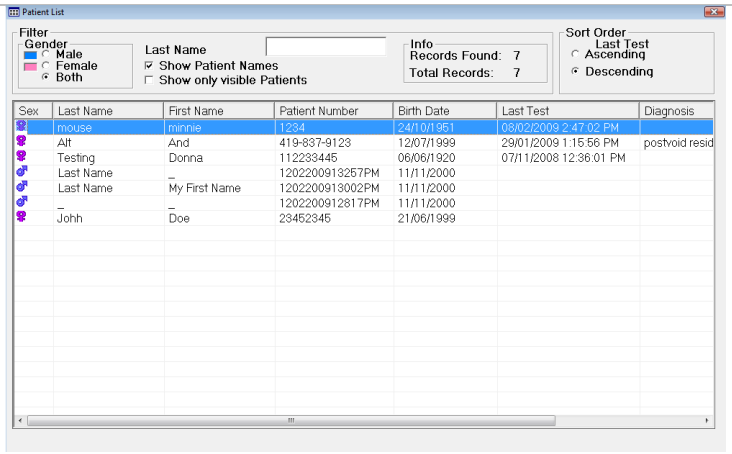
1	Select the menu option **File > New Patient**, click the **New Patient** button from the toolbar, *OR* press CTRL+N on the keyboard.	
2	Enter the Last Name, the First Name, the Patient Number, and the Birth Date in the boxes under the *Patient Information* tab. Remember to also select the gender of the patient. All other information is optional.	
3	Once all relevant information is added click the **Save** button to store the new information into the database.	

Table 16: Creating a new Patient Record – Instructions

8.2 CREATING A NEW SESSION

To create a new session, you must add a new session to the session list.

1	Open a patient folder
2	Click the **Add New Session** tab under the **Sessions** tab.
3	Select a Session from the ***Sessions Left*** listing.
4	Click the **Move To Session List** button.

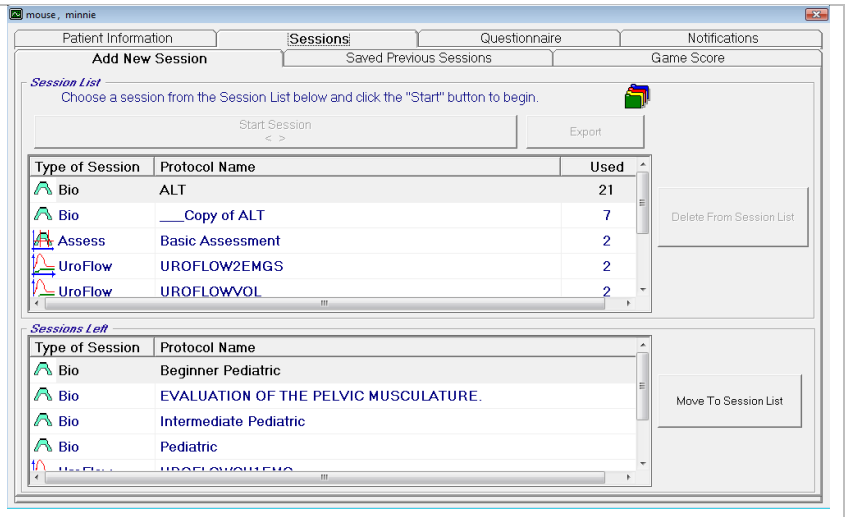


Table 17: Creating/Adding a New Session

8.3 STARTING A SESSION ACQUISITION

8.3.1 SESSION ADJUSTMENT

When starting a PMR session the **Adjustment Session** screen appears (Figure 15). When starting a stimulation session, the **Transducer Detection** window appears followed by the **Stimulation Adjustment** screen. For a session including PMR and stimulation, the PMR adjustment screens will appear first then the transducer detection and stimulation adjustment screen.

PMR ADJUSTMENT

The PMR adjustment screen allows you to evaluate the electrical activity of a muscular contraction. When asking the patient to carry out a maximum contraction, the contraction will act as a reference to test the muscle at 3/5 of its maximum strength and then adjust the channel scale accordingly.

The adjustment screen contains a preview window that allows you to see what the template will look like during the session. A maximum of ten templates are listed in the preview area.

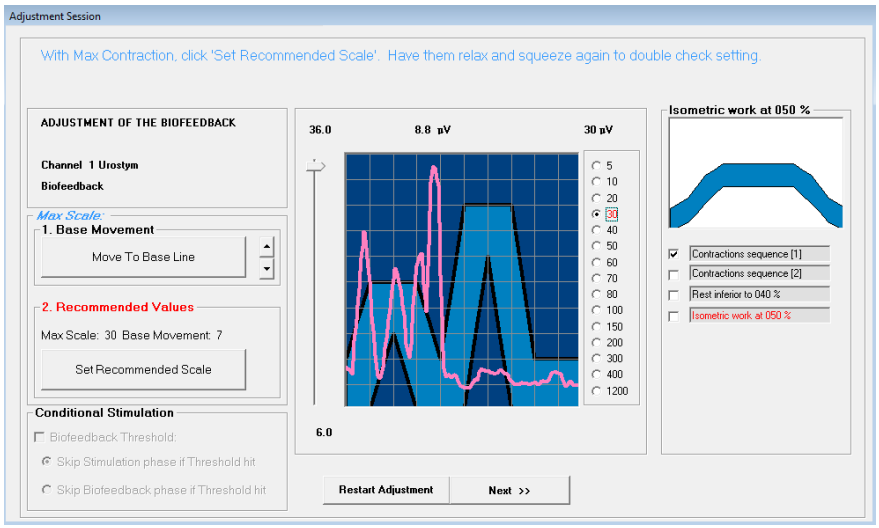


Figure 15: Adjustment Session Window

- Max Scale: Recommended Values: Several parameters are available. Choose a scale for the sensitivity level with the slider or the buttons. For example: When 200μV is chosen, the base line will be 0 μV and the maximal scale will be 200μV.
- Set Recommended Scale: Clicking this button sets the height to an ideal of 5% from the top and 10% from the bottom of the graph.
- Restart Adjustment: Restarts the adjustment.
- Next: When there are several PMR channels programmed in the Protocol, the Next button will independently adjust the Min and Max contraction value for the next channel. Upon reaching the last channel, clicking the Next button will launch the session.
- Stop (On the Toolbar): This button cancels the session and brings you back to the Patient Folder screen.

1. Ask the patient to relax the targeted muscle group as much as possible.
2. Click the **Move to Base Line** button.
3. Ask the patient to perform a strong contraction of the targeted muscle group.
4. Click the **Set Recommended Scale** button.
5. Ask the patient to relax again and contract maximally the targeted muscle group. Make sure the maximum contraction is within the graph area. If it is not, start over at Step 1.
6. Proceed to the next screen.

STIMULATION MODE

In a stimulation session, the **Stimulation Adjustment** screen allows for the adjustment of the current's intensity level prior to launching the session and *it must be adjusted to each individual's need or sensitivity*.

Transducer detection will generate a small test current (up to 9 mA depending upon Probe detection signal strength). This is a normal testing/safety occurrence and may or may not be sensed by the patient.

When starting a stimulation session, the **Urostym®** software runs a transducer detection test to verify that the **Urostym®** unit has been properly connected. The transducer detection applies to Channel 1 since it is the only channel capable of providing electrical stimulation (Figure 16).

If the connection was not properly established, and after performing the transducer detection, a window will appear showing the connection status as **OFF.** Make sure the probe and cables are properly connected, and then retest the connection.

After performing the transducer detection, the connection indicator on the status bar will change from green to red if the unit is powered off or if the **Urostym®** unit has not been properly connected. If this occurs, turn the device off, verify your connections, turn the device on again and restart the software.

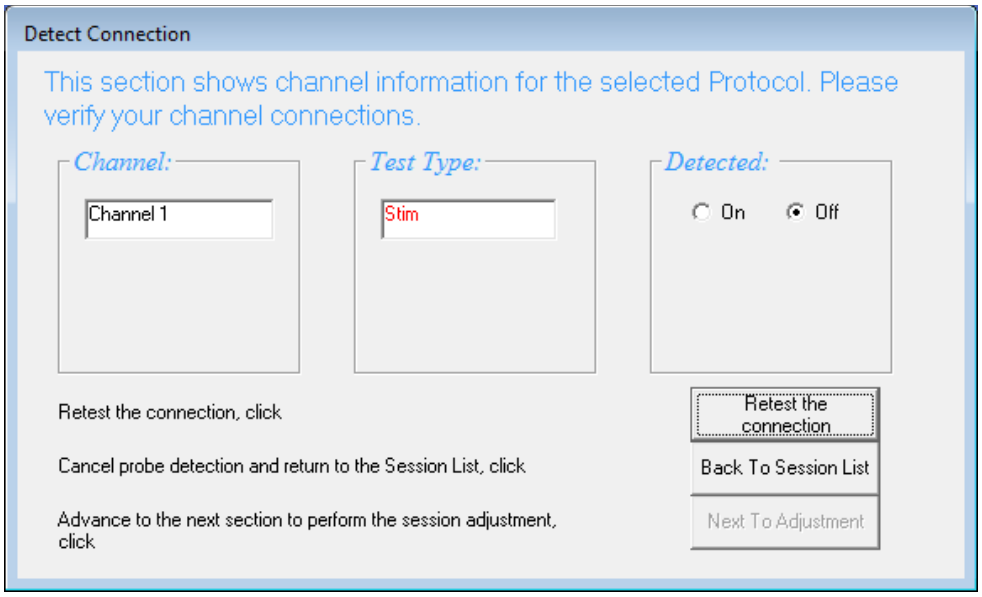


Figure 16: Detection Connection Window

Screen Buttons include:

- Retest the Connection: click this to begin the transducer detection sequence again
- Back to Session List: click this to cancel the Session and return to the Patient Folder
- Next To Adjustment: click to go to session adjustment

The **Session Adjustment** window appears (Figure 17). For Firmware 1.17 or later the maximum stimulation value is displayed (25 mA for anal probes or 70 mA for vaginal probes).

Figure 17: Session Adjustment Window

Screen Buttons include:

- Restart Adjustment: This button allows you to retest the channel connection.
- Next: If a Protocol has multiple Phases, this button will allow you to adjust the current's intensity level for the next Phase. Upon reaching the last Phase in the Protocol, clicking the Next button will start the session.
- Stop (on the Toolbar): This button cancels the session and brings you back to the Patient Folder screen.

The current's intensity is adjusted by pressing the plus (STIM+) and minus (STIM-) buttons on the **Urostym®** unit. If you have Firmware 1.12 or later, you can click the blue **Stim+** or **Stim-** buttons on the computer screen as well. The **Phase No. (Phase Number), Channel,** and **Intensity** degree are displayed on the window.

As you adjust the Stim+ or Stim- buttons, the change in the current's intensity level will be reflected in the vertical line height. This vertical line has a range of 0 to 25 mA for anal probes and 0 to 70 mA for vaginal probes and patch electrodes.

NOTES:

- For Firmware 1.15 or later: Press and hold the **Stim+** button to increase the stimulation signal by 0.5 mA per 1 second. Press and hold the **Stim-** button to decrease the stimulation signal by 0.5 mA per 1 second.
- Minimum time for increments/decrements is 0.5 sec; maximum time is 2.0 sec. To change time increments please contact the Laborie support team at 1-800-333-1039.

During the session, the current's intensity can only be adjusted when in the plateau period of a stimulation envelope. For safety reasons, current intensity may not be adjusted during ramping or resting.

The WHITE Stop button on the front panel of the **Urostym®** is a safety feature allowing for rapid stop of current delivery. Position the unit close enough to keep the button within reach of the patient.

8.4 SESSION ACQUISITION

The session acquisition can be started after adjustments are completed. Click **Next** to start session acquisition.

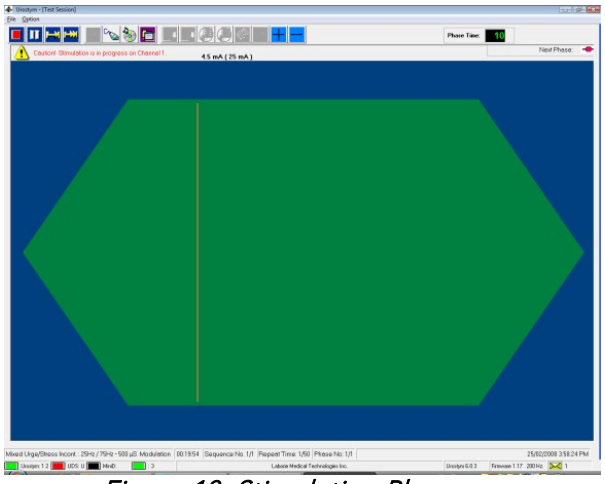


Figure 18: Stimulation Phase

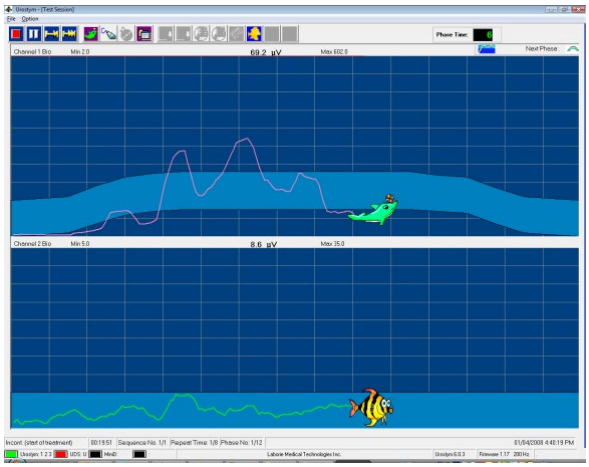


Figure 19: PMR Phase

The Session Screen contains the following toolbar options:

	**STOP / START**: Starts the session. If the session has already started, click this button to stop the session. Once you click the button to stop the session, a dialog box will appear. Select one of the options to either exit the session completely or to continue the procedure.
 	**PAUSE / RESTART** Pauses the session (when colored green) or restarts the session (when colored red).

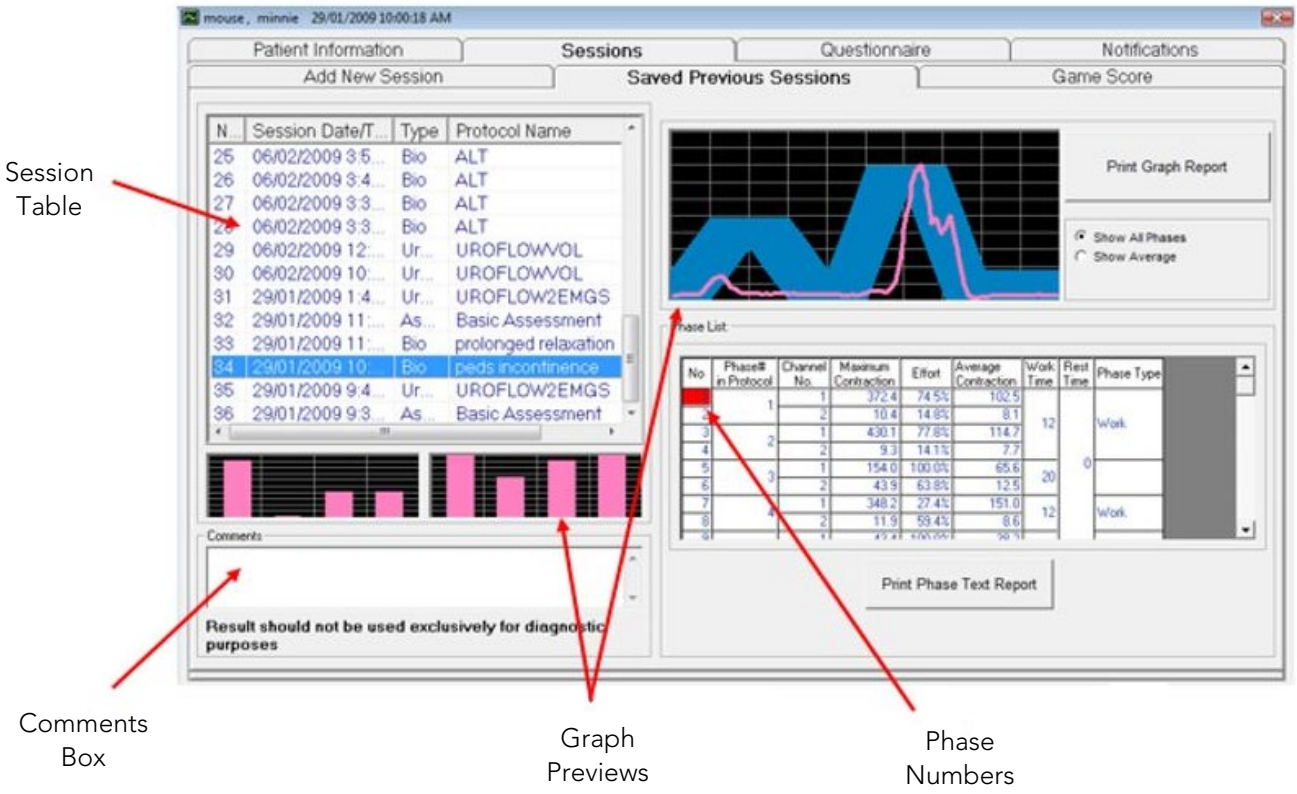
	**SKIP PHASE:** Skips the current Phase and proceeds to the next Phase.
	**SKIP SEQUENCE:** Skips the current Sequence and proceeds to the next Sequence. If there is only one Sequence, this will end the session.
	Changes the default screen to the Animation screen.
	Displays graph curves.
	Background Music is ON.
	Opens the **Animation Character and Background Music Option** window for: • Selecting a different character for Channel 1 and/or Channel 2 • Changing background music • Enabling or disabling the response character • Changing number of circles
 	Audio feedback for Channel 1 and Channel 2 during Uroflowmetry.
	Increase or decrease the current's intensity.

Table 18: Session Screen – Toolbar Options Overview

For a PMR phase, the Work Phase icon  is displayed below the Phase Time clock at the top-right of the screen.

8.5 REVIEW A SESSION

To view the results of a session click the ***Sessions*** tab in the patient file. Click the ***Saved Previous Sessions*** tab to open the following window.



- COMMENTS BOX: allows you to add notes to a selected session. Information added here will appear on the printed report.
- SESSION TABLE: Click a session on the left side of the window to view the phase list of that session.
- GRAPH PREVIEW: Click the graph to open the Graph Preview window. Place the cursor on a wave in the graph to view the mA or H2O measurement.
- PHASE LIST: .If you click on a particular phase number (that is highlighted red) under *Phase List*, the graph will display the results for viewing and/or printing for this particular phase.

GRAPH PREVIEW

- The EMG and Manometry complexes can be individually viewed by clicking the **Next** and **Prev** buttons. Note that only PMR phases are viewable in this window.
- To view a close-up of a stimulation phase it will need to be selected from the *Phase List* in the main saved sessions tab.

Click OK to close the window.

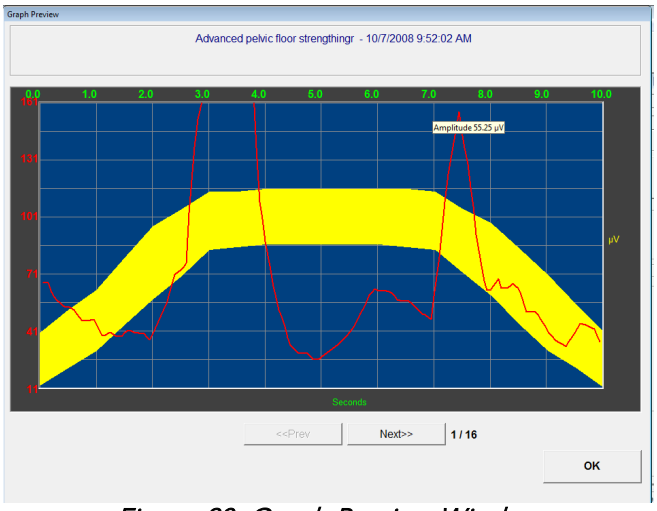


Figure 20: Graph Preview Window

GRAPH PREVIEW

- Double-click the bar graphs on the bottom-left side of the screen to open the *Graph preview* window.

Click the **OK** button to close the window or click the **Print** button to print the graph.

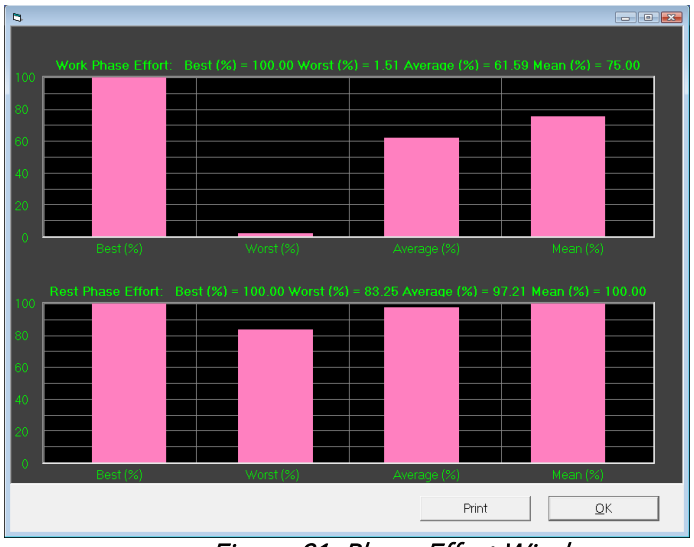


Figure 21: Phase Effort Window

When reviewing a saved session, three options are available:

i) **Show All Phases:** This option shows all the saved Phases in the **Phase List**.
ii) **Show Average:** This option calculates and displays the average value of all the repeated Phases within the current Protocol. Click the grid of the **Phase List** to review each individual Phase recorded in the database.
iii) **Compare *<test 1>* with *<test 2>*:** This option calculates and displays the average values for two compared PMR sessions. (*<test1>* and *<test2>* represent the numbers in the text box). The two PMR session comparisons must be based on the same Protocol.

8.6 SETTING A LAG TIME OR A VOIDING SEGMENT AND INSERTING RESIDUAL VOLUME

When performing Uroflowmetry sessions with EMG, you can select to have either a lag time or a Voiding Segment for calculations and reports. The Lag Time, or Voiding Segment, and PVR are set in the Graph Preview window.

- Lag Time for **Urostym®** is the time from the start of pelvic floor relaxation to the start of flow.
- Voiding Segments are portions of the graph that will be used for calculations and provide results in reports. **This is useful to avoid miscalculations if, for example, a patient touched the beaker either before or after a Uroflowmetry test and it may have been recorded on the graph.**
- Post Void Residual (PVR) values can be typed into the PVR box and are included in all reports and review screens.

To set a lag time:

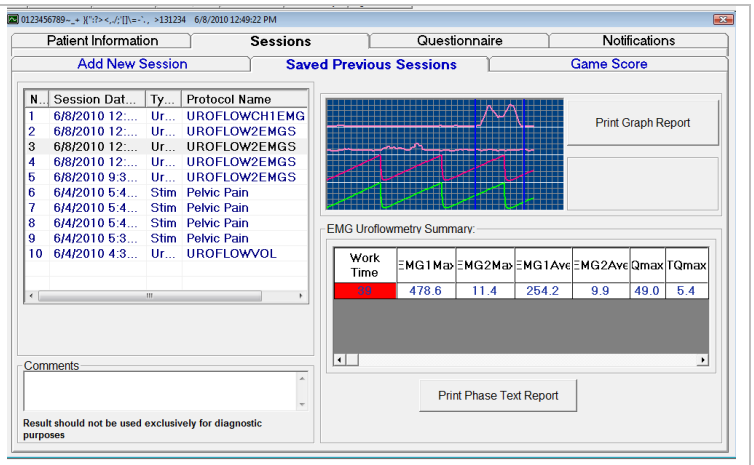
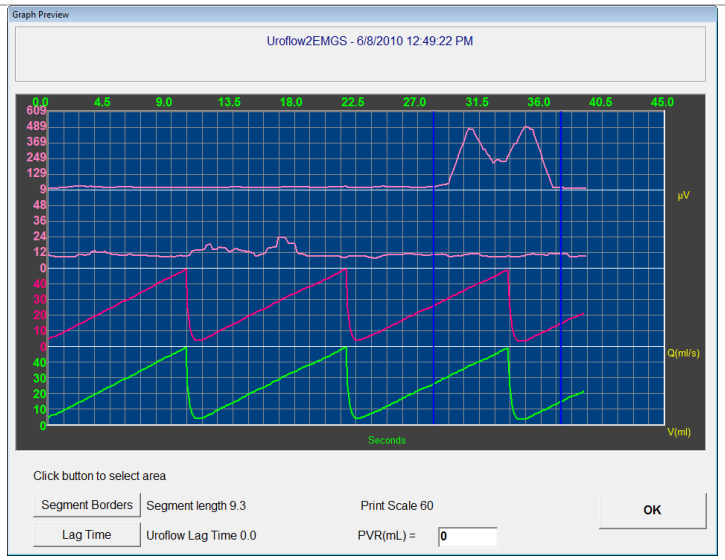
1	Double-click the Graph Preview window for a Uroflowmetry session with EMG channel(s) to open the enlarged Graph Preview window.	
2	In the Graph Preview window, select the *Lag Time* area by first clicking the **Lag Time** button. Then click on the graph where the lag time starts, and while holding down the left mouse button, drag the cursor from the left border to the right border of the desired area.	
3	Release the mouse button when desired area is selected. Add a **PVR** value if needed.	
4	Close the window by selecting **OK** and then click the **Print** button on the toolbar or the **Print Phase Text Report** button on the Patient folder.	

Table 19: Selecting Lag Time

To select a voiding segment:

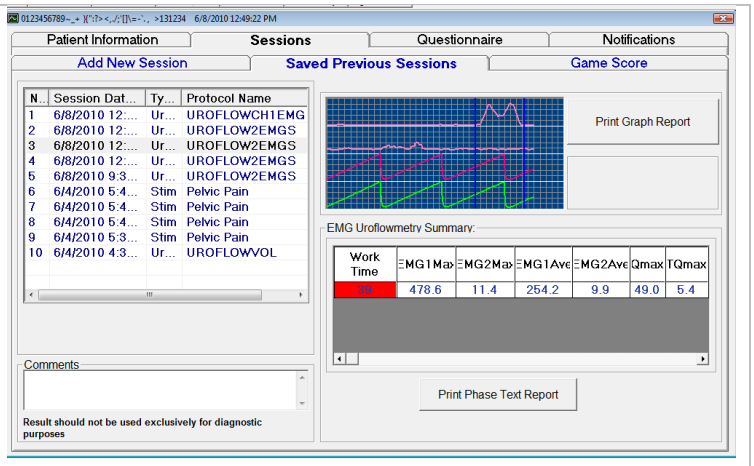
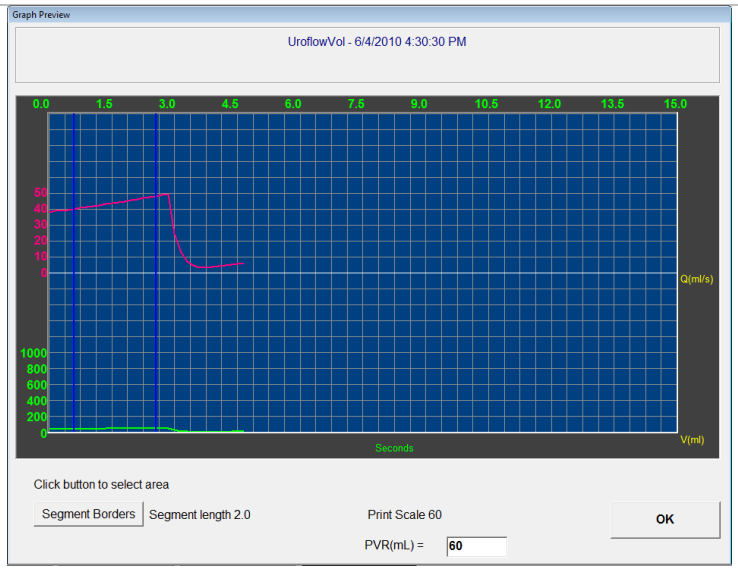
1	Double-click the Graph Preview window for a Uroflowmetry session with EMG channel(s) to open the enlarged Graph Preview window.	
2	In the Graph Preview window, select the *Segment* by first clicking the **Segment Borders** button. Then click on the graph where the desired segment for use in calculations starts, and while holding down the left mouse button, drag the cursor from the left border to the right border of the desired area. The selected segment allows for removal of artifacts from the voiding picture.	
3	Release the mouse button when desired area is selected. Add a **PVR** value if needed.	
4	Close the window by selecting **OK** and then click the **Print** button on the toolbar or the **Print Phase Text Report** button on the Patient folder	

Table 20: Selecting a Voiding Segment

The Lag Time, Segment, PVR value, and EMG Uroflowmetry information will be printed on the report as well as visible in the saved session window.

8.7 PFR SESSION FUNCTIONS

PFR sessions contain their own set of additional features and functions along with the features and functions of the general session protocols.

8.7.1 PFR SESSION BUTTONS

Additional PFR session buttons include:

	Click the red Pause button to temporarily stop a session. The button color then changes to green. Click the green Pause button to continue the session.
	Click to stop a session.
	Click to set the Manometry channel (if available) to zero without deleting the current session's data. The Manometry calibration will be set to the current Manometry reading.
	Click to restart the session; also deletes the current session's data. Click yes or no to confirm the restart.

Table 21: PFR Session Button Overview

8.7.2 PFR SUMMARY IN PATIENT FILE

Under the *Saved Previous Sessions* tab the **PFR Summary** is displayed when a PFR session is selected ().

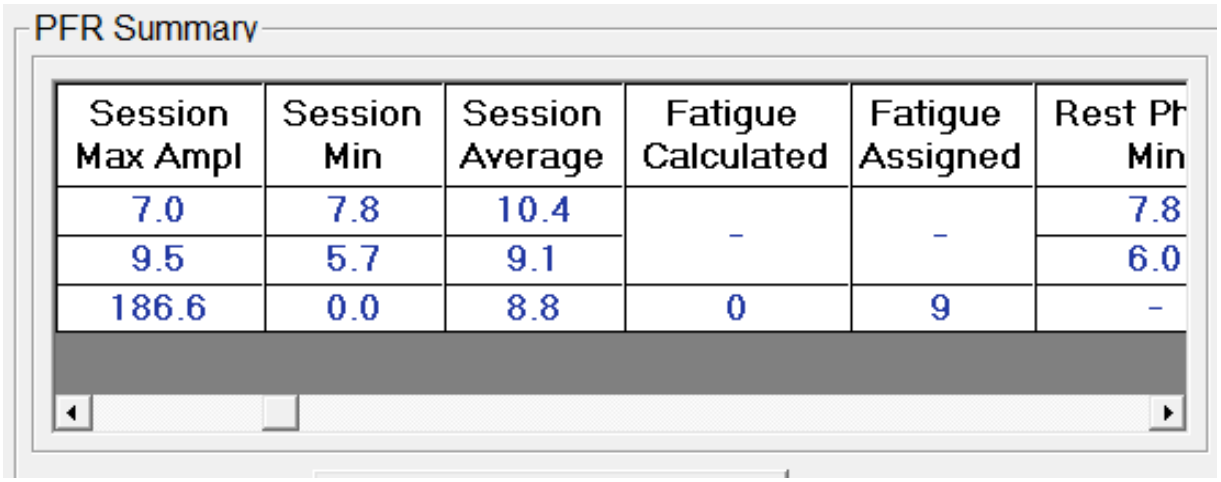


Figure 22: PFR Summary

The session parameters and the calculated *Fatigue* value are displayed.

8.7.3 PFR REPORT PREVIEW

Double-click the graph window in the summary tab to view an enlarged curve graph containing the complexes captured during a test.

The preview contains *Work Time* information, allows for EMG and Manometry max scale changes, *Zoom* for specific complex ranges, and displays the *Fatigue Point* as calculated by the software. The *Fatigue Point* can be changed to a desired location by clicking on the displayed pint and dragging it to the desired location on the graph. (as illustrated in the following diagram)

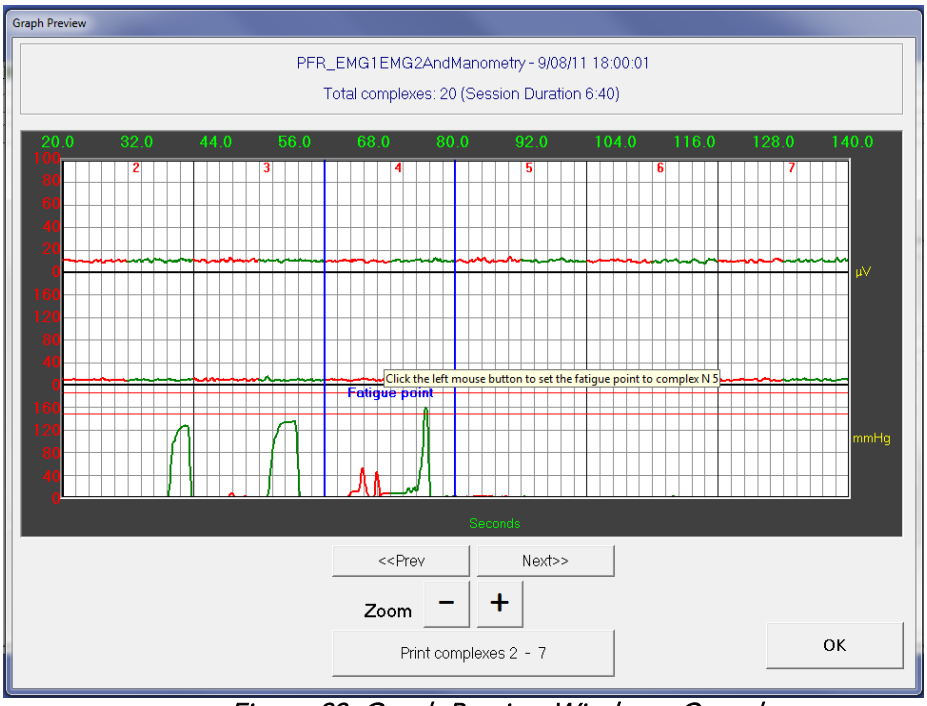


Figure 23: Graph Preview Window - Complexes

Use the control buttons on the bottom of the window to page through complexes and to select the print ranges and report types.

8.7.4 PFR REPORTS

When the **Print complexes** button is clicked in the *Graph Preview* window, a *PFR Print Report Configurator* window appears (Figure 24). Select the type(s) of report(s) to print as well as what type of information to include in a printout.

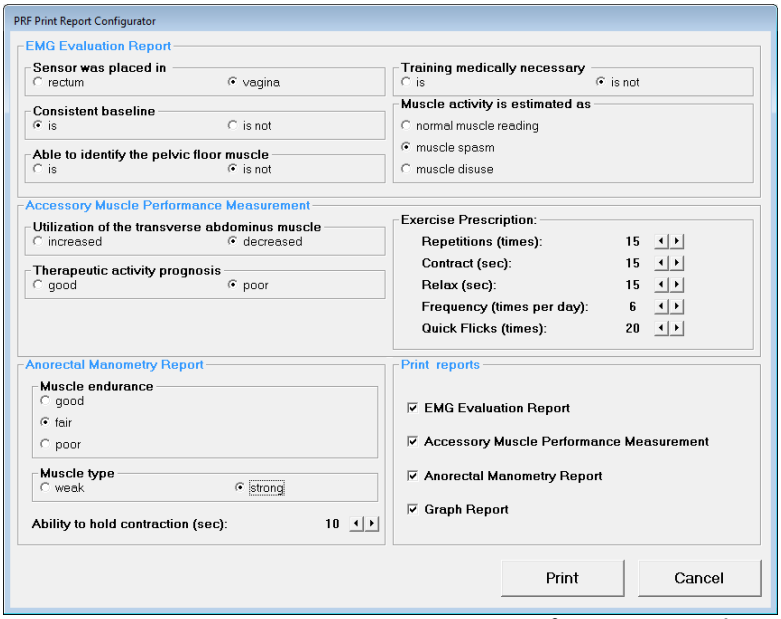
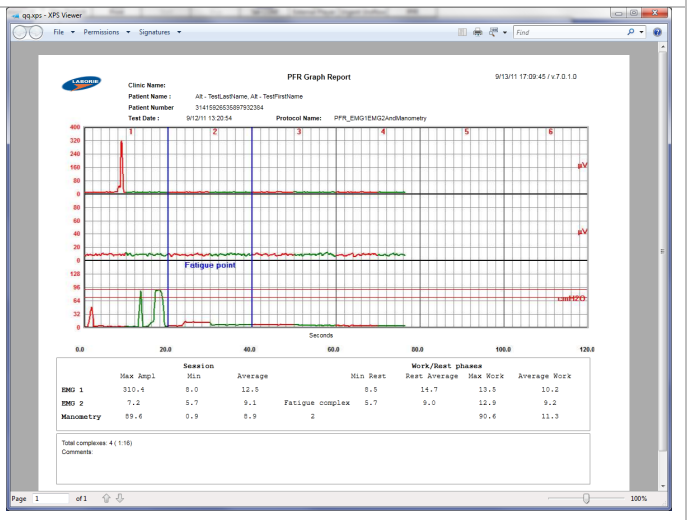
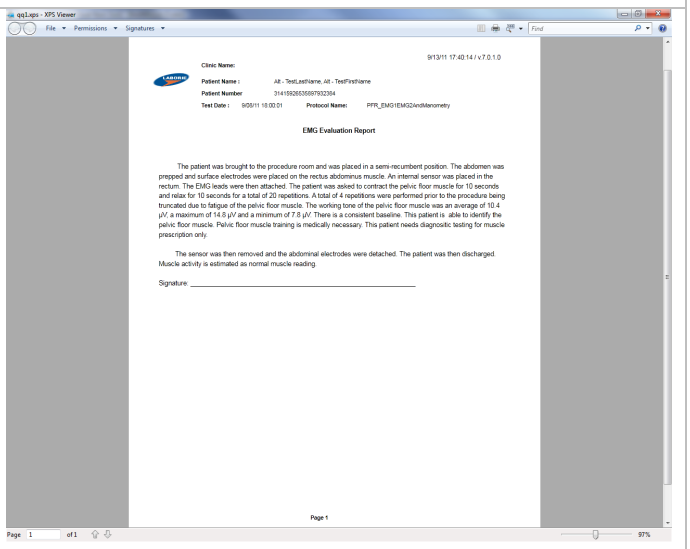
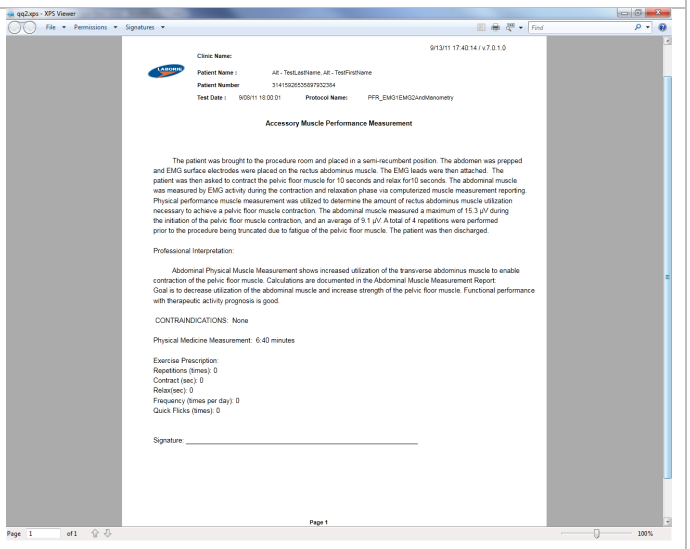


Figure 24: PRF Print Report Configurator Window

REPORT TYPE	SAMPLE PRINTOUT
Graph Report Automatically contains: • PFR graphs with selected complexes and their numbers • Units of measure • Work time and total complexes • All parameters listed in the summary table • Comments	
EMG Evaluation Report Automatically contains: • total repetition • average value of work phases • maximum value of work phases • minimum value of work phases Selection of: • sensor placement • muscle reading • baseline consistency • PFR identification • Medically necessary training • Muscle activity	
Accessory Muscle Performance Measurement Automatically contains: • total repetition • average value of work phases • maximum value of work phases • session duration Selection of: • transverse abdominus muscle use • prognosis of therapy • exercise prescription	

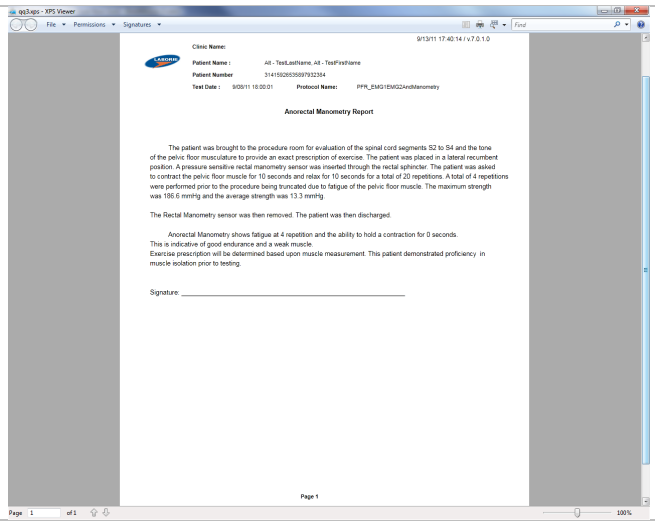
Anorectal Manometry Report Automatically contains: • total repetition • average value of work phases • maximum value of work phases • fatigue point calculated by the software Selection of: • muscle endurance evaluation • muscle type evaluation • muscle contraction holding ability	

Table 22: Report Types and Samples

8.7.5 PFR REPORTS IN ILIST REPORTER

If the **Urostym®** is linked to *i-LIST Office Reporter* and when a PFR session is complete, the i-LIST Reporter generates a report. The report contains PFR session information and the graphs with the number of repetitions.

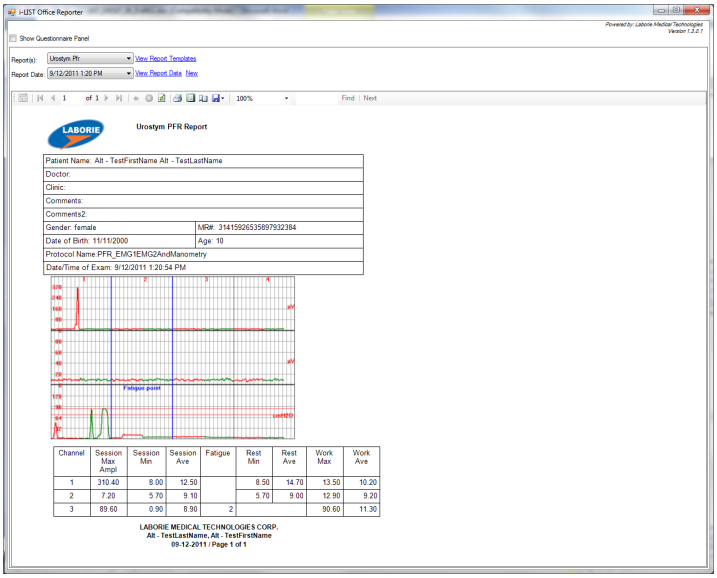


Figure 25: iList Office Reporter

8.8 CHANGING FLOW/VOLUME MAX SCALE FOR UROFLOWMETRY SESSIONS

You can change the Flow/Volume maximum scale for completed sessions. The Max Scale appears on the right in the Graph Preview window.

To change the Flow/Volume Max Scale:

1. Open a patient file and click the ***Sessions*** tab.
2. Click the ***Saved Previous Sessions*** tab.
3. Select the Uroflowmetry session for viewing.
4. Click the Preview Picture box in the session to open the Graph Preview window.
5. In the Graph Preview window, click either the **Q (ml/s)** or **V (ml)** label to open the Set Uroflowmetry Scales.
6. Select new scale(s) and then click the **OK** button - the new Max Scales will be applied.

8.9 CHANGING THE EMG MAX SCALE FOR UROFLOWMETRY SESSIONS WITH EMG CHANNELS

You can change the EMG maximum scale(s) for saved or previous sessions. The Max Scale is changed in the Graph Preview window.

To change the EMG Max Scale:

1. Open a patient file and click the ***Sessions*** tab.
2. Click the ***Saved Previous Sessions*** tab and select the Uroflowmetry session with EMG channel(s).
3. Click the *Preview Picture* box to open the *Graph Preview* window.
4. In the *Graph Preview* window, click the **mV** label to open the *Set EMG Scales*.
5. Select new scale(s) and then click the **OK** button.
   Result: The new Max Scales will be applied.

8.10 CHANGING THE UNIT OF MEASURE FOR MANOMETRY

Pressure values can be displayed in either mmHg or cmH2O.

To change the unit of measure:

1. Click Options > EMG/Manometry Calibration.
2. Select the preferred unit of measurement for Manometry.
3. Click OK.

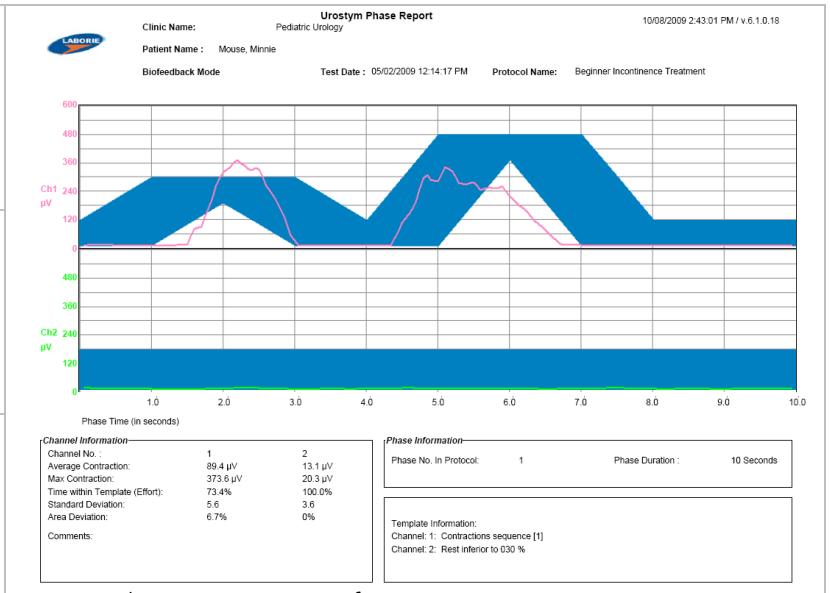
9 PRINTING SESSION REPORTS

Depending on printer capabilities and settings, **Urostym®** reports can be printed in color or in black and white.

After opening a *Saved Previous Session* under a selected *Patient Folder*, all previous sessions are loaded into the **Sessions Table** by date and time.

Select the session you wish to print from the **Sessions Table**.

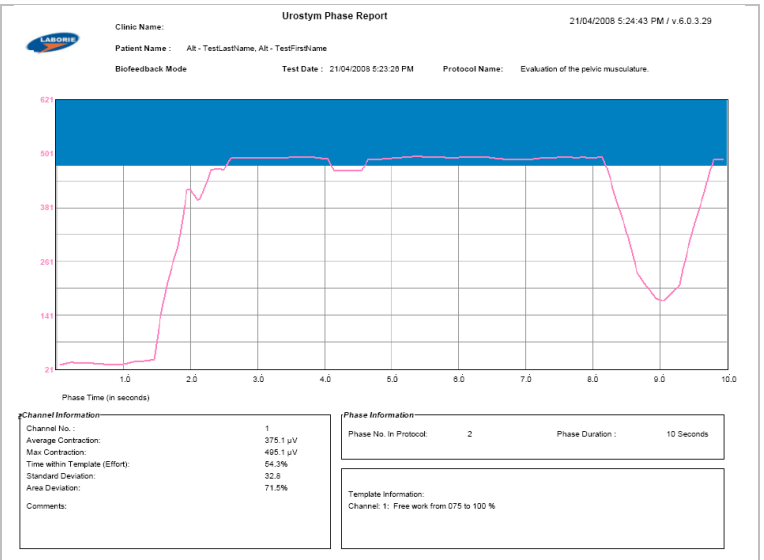
9.1 INDIVIDUAL PHASE REPORTS

1	Select the **Show All Phase** option to load all saved information.	
2	Choose one item from the **Phase List** to display the graph of the selected channel.	
3	Click the Print button of the toolbar.	

Example printout: Report for Beginner Incontinence Treatment

Table 23: Printing Phase Reports

9.2 REPORT AVERAGE

1	Select the **Show Average** option. The summary information of the repeated channels is loaded into the **Phase List**.	
2	Choose one item from the **Phase List** to display the graph of the selected channel.	
3	Click the Print button of the toolbar.	

Example printout: Average Report with Evaluation of Pelvic Musculature Protocol

Table 24: Printing Report Average

9.3 COMPARISON REPORTS

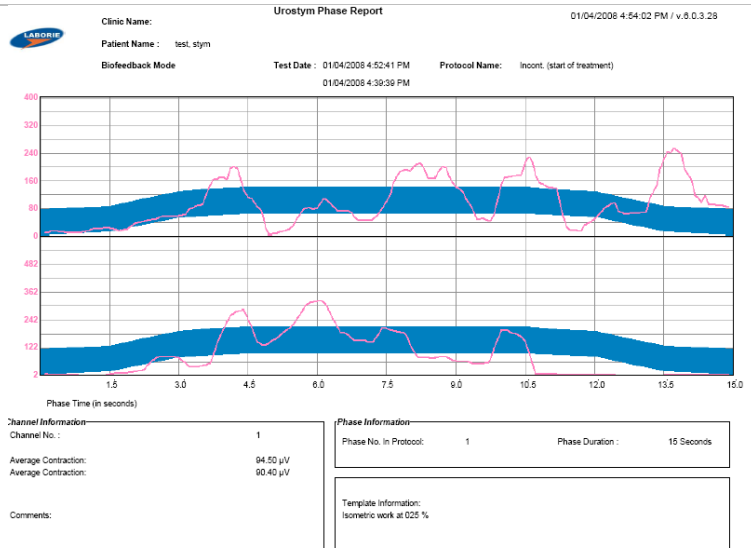
1	Select a PMR session	 *Example printout: Comparison Report for Incontinence start of treatment*
2	Select another PMR session to compare with the first. (Remember that this will only work if both PMR sessions use the same protocol.	
3	Select the **Compare *<1>* with *<2>*** option located at the bottom of the graph.	
4	Click the Print button on the toolbar.	

Table 25: Printing Comparison Reports

9.4 PRINT PHASE TEST REPORT

1	Select a PMR session	**Urostym Phase Report** 21/04/2008 5:29:58 PM / v.6.0.3.29 **Clinic Name:** **Patient Name :** Alt - TestLastName, Alt - TestFirstName **Test Date :** 18/04/2008 5:19:39 PM **Protocol Name:** Incont. (start of treatment)
2	Click the **Print Phase Text Report** button.	

No	Phase# in Protocol	Channel No.	Maximum Contraction	Effort	Average Contraction	Work Time	Rest Time	Phase Type
1	1	1	37.3	84.4%	34.9	15	0	Work
2	1	2	14.3	98.0%	11.2	15	0	Work
3	2	1	36.9	43.4%	34.9	10	0	
4	2	2	14.1	98.5%	11.0	10	0	
5	3	1	36.3	25.3%	34.5	15	0	Work
6	3	2	13.1	100.0%	11.5	15	0	Work
7	4	1	37.7	34.3%	35.6	10	0	
8	4	2	12.8	100.0%	10.7	10	0	
9	5	1	38.0	33.3%	35.0	15	0	Work
10	5	2	14.3	99.5%	11.2	15	0	Work
11	6	1	37.4	59.6%	34.8	10	0	
12	6	2	15.3	96.0%	11.3	10	0	
13	7	1	37.0	90.5%	34.8	15	0	Work
14	7	2	15.0	98.5%	11.4	15	0	Work
15	8	1	39.1	49.5%	35.2	10	0	
16	8	2	12.6	100.0%	10.7	10	0	
17	9	1	36.9	25.8%	35.2	15	0	Work
18	9	2	15.5	97.0%	11.4	15	0	Work

Example printout: Phase Text Report for Incontinence end of treatment

Table 26: Printing Phase Test Reports

9.5 USING I-LIST OFFICE REPORTER FOR **UROSTYM®** REPORTS

If i-LIST Office reporter software is installed on the computer, the test results will open in a new window (Figure 26).

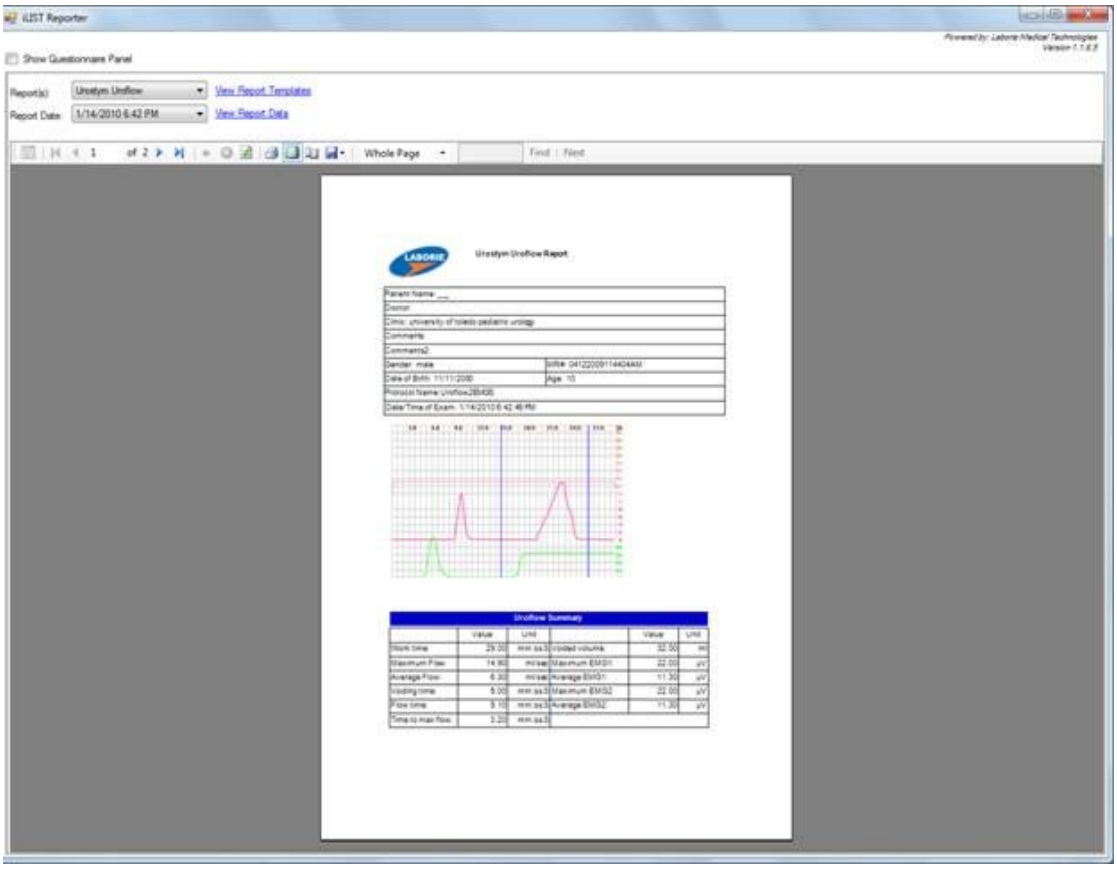


Figure 26: iList Reporter

Click the print button on the toolbar to print a report. Note that PVR information added to a test file in **Urostym®** will be printed on the i-LIST report.

Refer to the *i-List Office Reporter Owner's Manual* for more information on selecting items to include in the printed reports.

10 ANIMATION AND PEDIATRIC APPLICATIONS

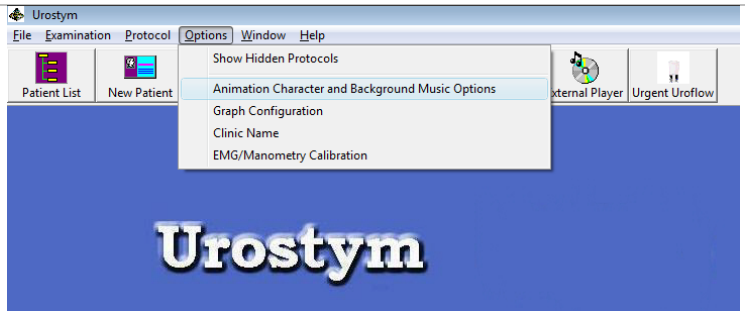
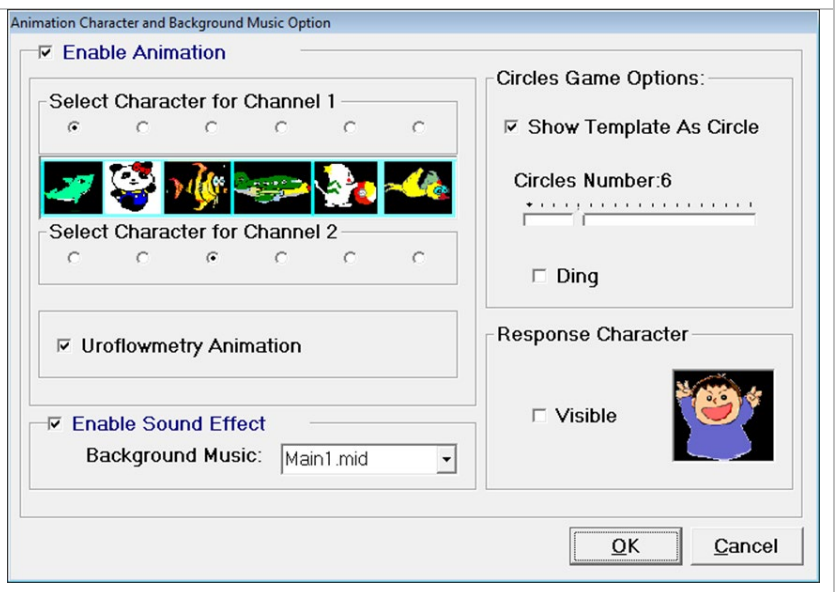
The short attention span of children works well with the Laborie **Urostym®**. Pre-defined sessions and the ability to create individualized sessions of various lengths allow for stimulating sessions to maintain a child's attention. Both the animation and video game options excite and delight children. Couple this with the feature of **Score Keeping** from session to session and it serves to motivate for self-improvement. Children are encouraged to do better each time.

For evaluation of the voiding pattern, a Uroflow with 2 channel EMG offers assessment of both the pelvic and abdominal involvement along with the corresponding flow pattern. A full bladder is recommended as Uroflowmetry is best with greater than 100cc volume. The **Auto Flow** feature helps those with "shy bladder" as it keeps up to 5 seconds available prior to the start of voiding, dispensing with a long period of time up to voiding. Should **Lag Time** be desired, **Auto Flow** may not be advisable due to the 5 second limit.

The starting point in Pediatrics is Uroflowmetry with one or both channels of EMG. Select one or all of the following for the **Patient Session List**:

1. **Uroflow -** ([**UroflowVol**] with EMG 1 or 2 channel or without)
2. **Evaluation of Pelvic Floor Musculature. –** ([**UroflowCh1EMG**] one channel, 10 minutes long)
3. **Pediatric** - ([**Uroflow2EMG**] 2 Channels, 10 minutes)

10.1 SETTING ANIMATION CHARACTERS AND BACKGROUND MUSIC

1	Start the **Urostym®** software by double-clicking the **Urostym®**.exe icon on the desktop	
2	Before a session is started, click Options and select Animation Character and Background Music Options. OR	
	During a session, click the **Option** menu and select **Music Sprites Option**.	

3	Click to: • Enable animation and music • Select your preferred animation character for channels 1 and 2 • Enable sound effect • Select your preferred background music • Enable or disable the response character • Change the number of circles displayed (for single channel protocols only) • Select to have a "Ding" sound that signals when a prize in the game is caught (for single-channel protocols only)
4	Click **OK** to save your choices. -OR- Click **Cancel** to exit the screen.

Table 27: Set Animation Characters and Background Music

10.2 SCREEN FUNCTIONS

BUTTON	FUNCTION
	Stop a session
	Pause a session
	Skip to next Phase
	Skip to next Sequence
	Animation mode.
	Regular mode. (No characters or rings)
	Graph curves display.
	Graph curves removed.
	Background music ON.
	Background music OFF.
	• Select a different character for Channel 1 and/or Channel 2 • Change background music • Enable or disabled response character • Change number of circles
	Start PMR Game

Table 28: Screen Functions - Overview

10.3 PMR PROTOCOL SETUP FOR PEDIATRIC TESTING

The following instructions outline the creation of a simple PMR Protocol that could be used with pediatric patients using two EMG channels.

1	On the main menu bar, click **Protocol > Program a Protocol**.
2	Click the **New** button and name the Protocol. (*for example:* Pediatric PMR Treatment)
3	Click the **Save Sequence** button. Any **Protocol Description** and/or **Special Comments** may also be added at this time in the appropriate fields.
4	Under the *Phase Information* section, set the **Phase Time to 5 seconds** and the **Rest Time to 0 seconds**
5	Select **PMR Phase** and select the *Work Phase* check box.
6	Select the Channel 1 check box. Select, for example, **Freework 50 to 100%** from the drop-down list under Template.
7	If a second channel is desired, select the Channel 2 check box and select for example, **Rest Inferior to 20%** from the drop-down list under Template.
8	Click the **Save Phase** button.
9	Under the *Protocol Information* section, highlight *Phase No 1*.
10	Click the flashing **New Phase** button.
11	Under *Phase Information*, set the *Phase Time* to 10 seconds and the *Rest Time* to 0 seconds.
12	Select **PMR Phase** and select the *Work Phase* check box.
13	Select the Channel 1 check box.
14	Select **Rest Inferior to 30%** or **Rest Inferior to 40%** from the drop-down list under Template. If a second channel is desired, select the Channel 2 check box and Select **Rest Inferior to 30%** or **Rest Inferior to 40%** from the drop-down list under Template.
15	Click the **Save Phase** button.
16	Click **Update Sequence** and then click **OK**.

Table 29: PMR Pediatric Protocol Setup Instructions

The Work Phase is often kept short with pediatric patients since the emphasis is typically placed on pelvic floor relaxation. The countdown clock is not visible during a rest phase.

10.3.1 IMPORTANT NOTES REGARDING PEDIATRIC PATIENTS

- Children must often be taught how to relax the pelvic floor as well as how to contract (tighten) it.
- When performing Uroflowmetry with EMG monitoring, the **sound feature**  provides audio feedback. With the contraction of the targeted muscle groups, the tone increases; and with relaxation, the tone decreases.
- Only surface electrodes are used with pediatric patients.

10.4 STARTING A SESSION WITH ANIMATION

1. Click Options and select Animation character and Background Music Options.
2. Select Enable Animation and then select the animation for each channel at the top of the screen.
3. Click OK.
4. Choose a patient file in the *Patient Tree.*

   - OR -

5. Create a *New Patient* file.
6. Go to the *Sessions* tab.
7. Start a PMR session from the *Sessions List.*

10.5 STARTING A SESSION USING VIDEO GAMES

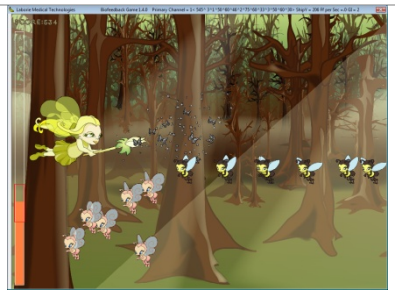
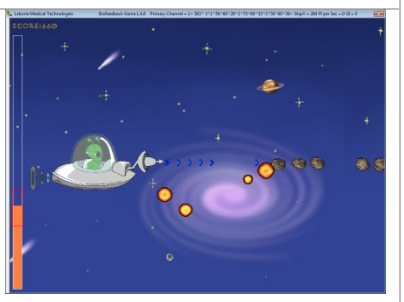
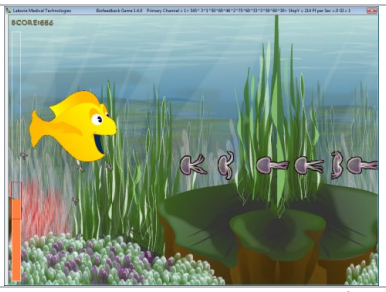
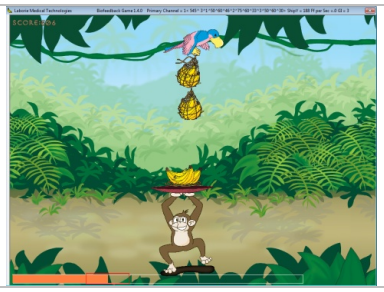
1	Begin a PMR session.	
2	Once you have completed the adjustment screens and the session screen is visible click the **Start Game** icon on the toolbar.	
3	When in game mode, the PMR template is displayed as objects (bees, asteroids, jellyfish or bananas) crossing or dropping from the screen.	   

Table 30: Starting a Session – Video Games

Contracting the pelvic floor muscles will make the main character travel up (contraction) and down (relaxation) in these games. The goal is to contract or relax the target muscle group in such a way that the Character can have successful contact with the moving objects.

In the Monkey Dance game, contracting the pelvic floor muscles makes the monkey move to the right, relaxation makes the monkey move to the left. Abdominal activity will also affect the size of the tray; for example, increased abdominal activity makes the tray smaller.

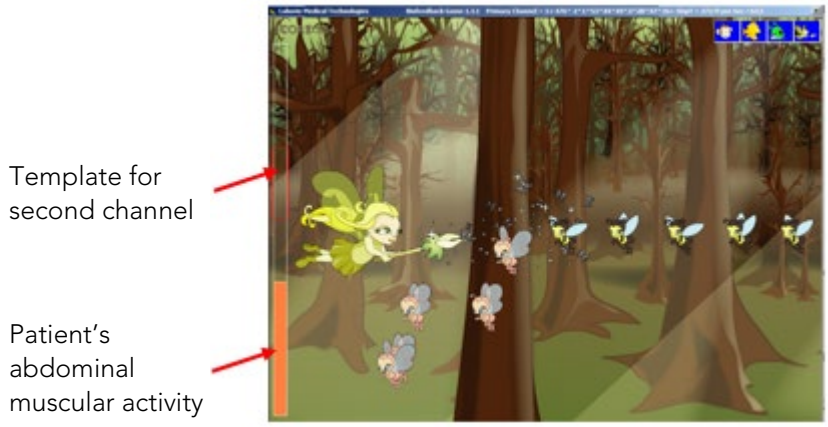


Figure 27: PMR Template – Channels

When using a protocol that includes Channel 2 (abdominal muscles), the template for Channel 2 will appear as a bar graph either on the side or bottom of the screen. The rectangular outline of the bar graph represents the template for the second channel, the solid color represents the patient's abdominal muscular activity. The goal is to keep the muscle activity within the template. Increased abdominal muscle activity will increase the solid color bar within the template area.

You can change the color of the bar graph by double-clicking it and selecting a new color from the color selection window.

10.5.1 WAIT TIE DISPLAY

During a Rest Time, a *Wait* message with countdown time will be displayed in the middle of the screen.

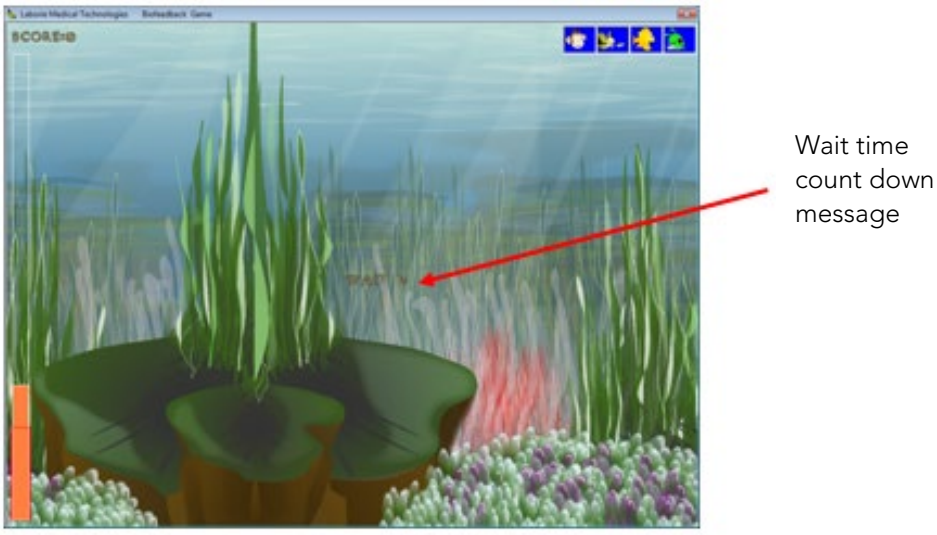


Figure 28: Resting Countdown

10.5.2 GAME SCORES

To review the Game Score records look in the ***Game Score*** tab located in the Patient folder. Click the grid headers to sort the records by score or by date.

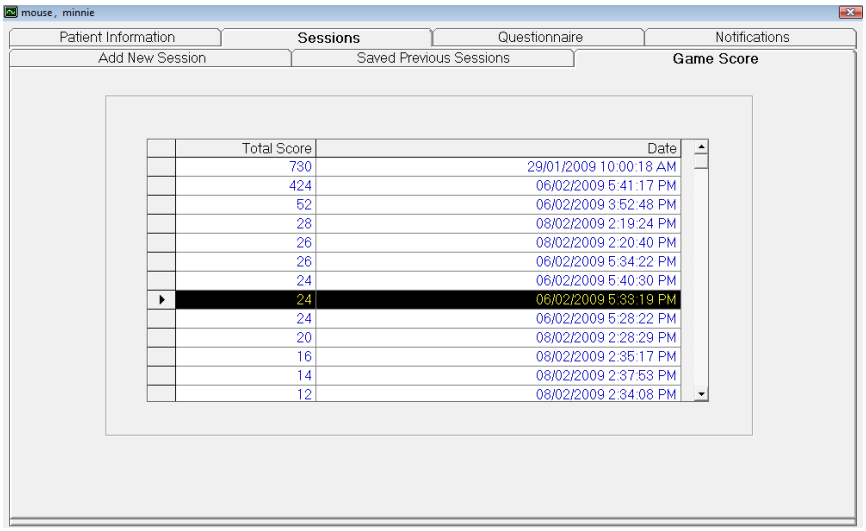


Figure 29: Game Score Tab

The scores are carried over from session to session. They act as a motivational tool and can help judge the progress of the patient over time. As each subsequent treatment session is successful, the score increases.

10.5.3 GAME CONTROLS

CONTROLS	RESULT
Contraction of pelvic floor	The Fairy, UFO, or Fish moves up (vertical) The Monkey moves right (horizontal)
Relaxation of pelvic floor	The Fairy, UFO, or Fish moves down The Monkey moves left
Fn+End button on the keyboard or the **End** button on an extended keyboard	Slows down background image speed
FN+Home button on the keyboard or **Home** button on an extended keyboard	Speeds up background image speed
Delete button on the keyboard	Slows down the target speed (bees, asteroids, jellyfish or bananas)
Insert button on the keyboard	Speeds up the target speed (bees, asteroids, jellyfish or bananas) appearing on screen

Table 31: Game Score Controls - Overview

IMPORTANT: Increasing the target speed makes the game more difficult. LABORIE does not recommend adjusting the speed of targets during the study; where possible determine target speed before beginning testing. Do not use the speed change feature while training is in progress with a patient. If speed adjustment is required during the study, notify the patient and use the indicated controls to decrease or increase speed. Wait for all targets traveling at the previous speed to clear the screen before resuming training.

11 EMG AND UROFLOW SESSIONS

Important Uroflowmetry Terminology to remember:

- Flow: Urine flow rate (in ml/sec)
- Volume: Voided volume (in ml)
- Uroflow Lag Time: Time from the start of pelvic floor relaxation to the start of flow (in seconds)

There are three predefined Uroflowmetry Protocols:

UROFLOWMETRY PROTOCOL	CHANNELS RECORDED
UroflowCh1EMG	Flow, Volume, EMG on Channel1 uses one EMG channel (pelvic muscle)
Uroflow2EMGS	Flow, Volume, EMG on Channel1, EMG on Channel2 uses two EMG channels (pelvic and abdominal)
UroflowVol	Flow, Volume does not use any EMG channels

Table 32: Uroflowmetry Protocols

All Uroflowmetry Protocols have the following pre-defined conditions:

- All Uroflowmetry Protocols have a single Sequence made up of a single Phase. The Phase has a 30 second work time and no rest time. The Sequence is repeated 50 times for a total of 1500 seconds (25 minutes).

Remember to position the beaker so that it is flat on the Uroflowmeter and to place the Uroflowmeter directly under the commode chair's funnel. Nothing must touch the beaker or Uroflowmeter during testing.

11.1 STARTING A UROFLOWMETRY SESSION

1	Choose a patient file from the Patient Tree or create a new patient file.
2	In the Add New Session tab, select either **UroflowCh1EMG** *or* **Uroflow2EMGS** *or* **UroflowVol (the Type of Session is UroFlow).**
3	Click **Move To Session List.**
4	Click the flashing **Start** button on the toolbar. The **PMR Adjustment Screen** will appear if the selected protocol is either **UroflowCh1EMG** or **Uroflow2EMGS**. In this window, you can set the base line and set the recommended scale for the selected session.
5	Select Max Scale for EMG channels (if desired).
6	Select **Flow** and **Volume** scales, appropriate for age of patient, on the Uroflowmetry Adjustment form.

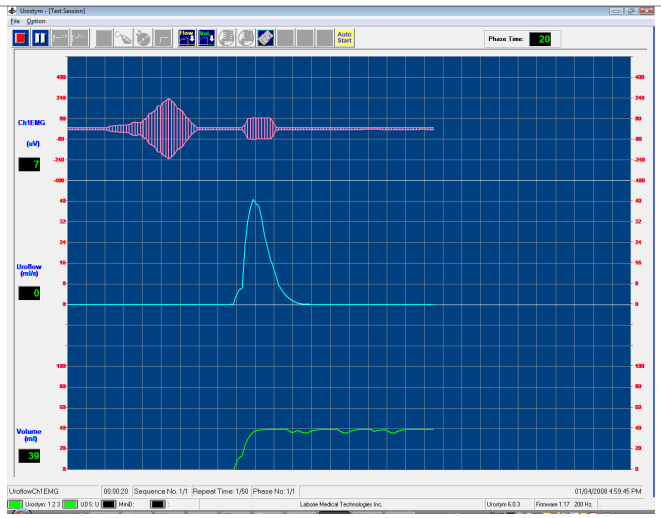
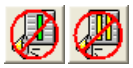
<table>
<tr><td>7</td><td>Click the Set Zero buttons to set the Uroflow volume and flow channels to zero.</td><td colspan="3">  </td></tr>
<tr><td>8</td><td colspan="4">Click the Next button.</td></tr>
<tr><td>9</td><td colspan="4">Use the following buttons as required:</td></tr>
<tr><td></td><td>  </td><td>EMG sound is ON. Click the icon to turn the sound OFF.</td><td>  </td><td>EMG sound is OFF. Click the icon to turn ON the sound.</td></tr>
<tr><td></td><td>  </td><td>Click the red Pause button to temporarily stop a session.</td><td>  </td><td>Click the green Pause button to continue the session.</td></tr>
<tr><td></td><td>  </td><td>Click the Stop button to stop a session.</td><td>  </td><td>Uroflowmeter is connected.</td></tr>
<tr><td></td><td>  </td><td>Uroflowmeter is not connected.</td><td>  </td><td>Click to set Flow channel to zero.</td></tr>
<tr><td></td><td>  </td><td>Click to set Volume channel to zero.</td><td></td><td></td></tr>
</table>

Table 33: Starting a Uroflowmetry Session – Instructions

11.2 CHANGE VOLUME SCALE DURING A SESSION

The Volume scale can be set to 50, 100, 150, 200, 250, 300, 500, 800, and 1000 ml.

1. Click **Option** > **Volume Scale** to open the Set Uroflowmetry Scales window.
2. Select one of the scale values for the individual patient.
3. Click **OK** when finished.

11.3 CHANGE THE VOLUME AND FLOW SCALE IN A SAVED SESSION

1. Click the picture box in the *Patient Folder* under the ***Saved Previous Sessions*** tab to enlarge the graph.
2. Click either the *Q(ml/s)* or *V(ml)* label on the *Graph Preview* window.
3. Select one of the scale values.
4. Click **OK** to finish.

11.4 AUTO-START

Use of AutoStart is not recommended if you wish to monitor pelvic floor activity BEFORE actual voiding begins, or if you wish to calculate Lag Time measurements. AutoStart allows for a buffer of 15 seconds prior to void.

You can select to have the Uroflow session start automatically when urine flow is detected by selecting the **Auto Start** button on the toolbar ().

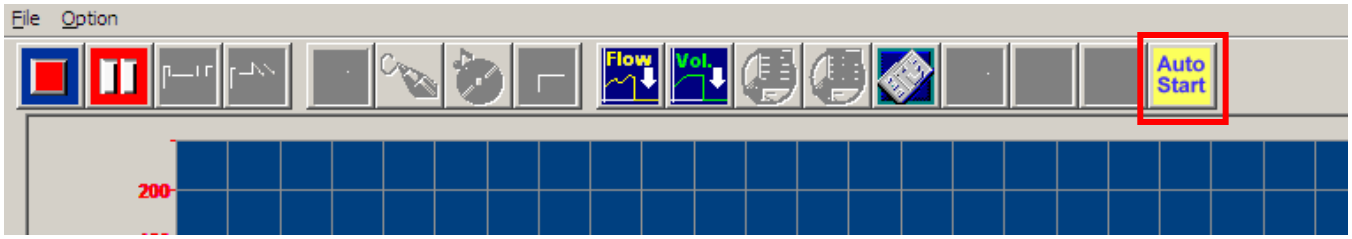


Figure 30: Tool Bar – Auto Start

When selecting AUTOSTART, keep in mind the time buffer is 15 seconds, consider if this amount of time allows for full evaluation of pelvic and accessory muscles use prior to voiding. In that case, do not select.

Once the beaker has settled, the session automatically starts if an increase in volume is detected. The session will automatically stop 50 seconds after the urine flow stops. In pediatrics, the **lag time** feature may be affected when *Auto Start* is used as this allows for a maximum of 15 seconds done before start of flow. Should **lag time** be greater, it will not be on the screen for measurement.

11.5 URGENT UROFLOW

It is intended for new patients, those not already entered in the system. Once selected, three sessions are available: *Uroflow2EMG*, *Uroflow1EMG* and *Uroflow/Vol*.

Important points to remember about urgent Uroflow:

- If using EMG, quickly place on the patient.
- As this is Urgent, and to bypass adjustment screens, select **Next** and **Next** to obtain the testing phase.
- Allow patient to void.
- At end of testing, select the ***Saved Previous Sessions*** tab to access the voiding graph. Click on the graph to enlarge and address the scaling for *EMG* and *Flow/Volume* by selecting from the right margin: *uV* and *Q (ml/sec)*. See page 41 for more information.
- The patient's name and all mandatory fields are indicated or held by a dash and simulated dates; these must be changed or repopulated with accurate patient information.
- If the patient is already in the system, do not use Urgent Uroflow. Select the patient name and start the desired Uroflow session prior to the patient's arrival. Do as instructed in step 2 by selecting **Next** and **Next** to get to the voiding screen. Follow with steps 3 and 4 for completion.

11.6 ANIMATION OPTION FOR UROFLOWMETRY

With the animation option enabled, the animation character will be visible on-screen once the Flow value exceeds the value that is selected on the flow scale.

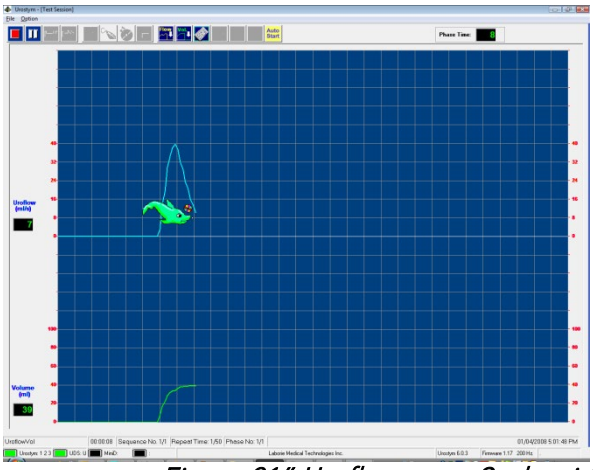


Figure 31" Uroflowmetry Scale with Animation

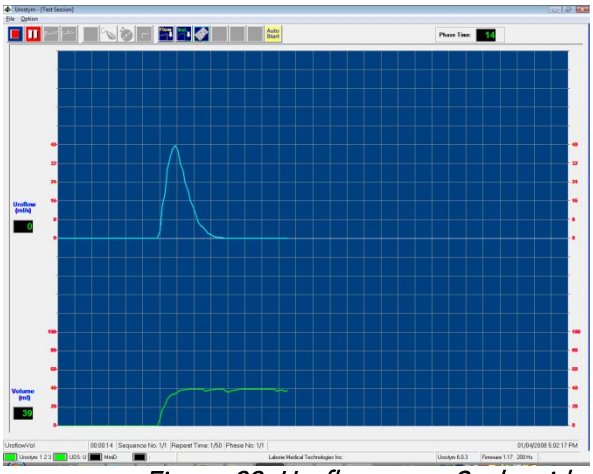


Figure 32: Uroflowmetry Scale without Animation

For example, if 5 ml/s is selected on the uroflowmetry scale the animation character will appear as soon as a 5 ml/s flow rate is attained. If animation is disabled, the curve will be drawn without animation.

12 CALIBRATION

12.1 CALIBRATE **UROCAP™** USING **UROSTYM®** CHECKDB UTILITY

If the UDS120 software is not installed on the computer, the **Urocap™** transducer can be calibrated through the ***Urostym®*** *CheckDB* utility.

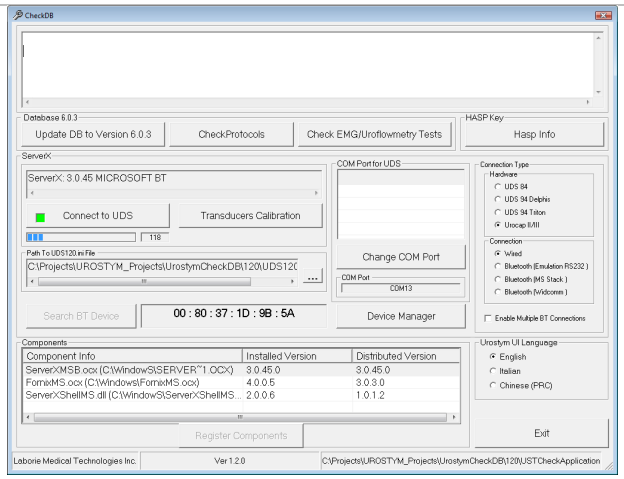
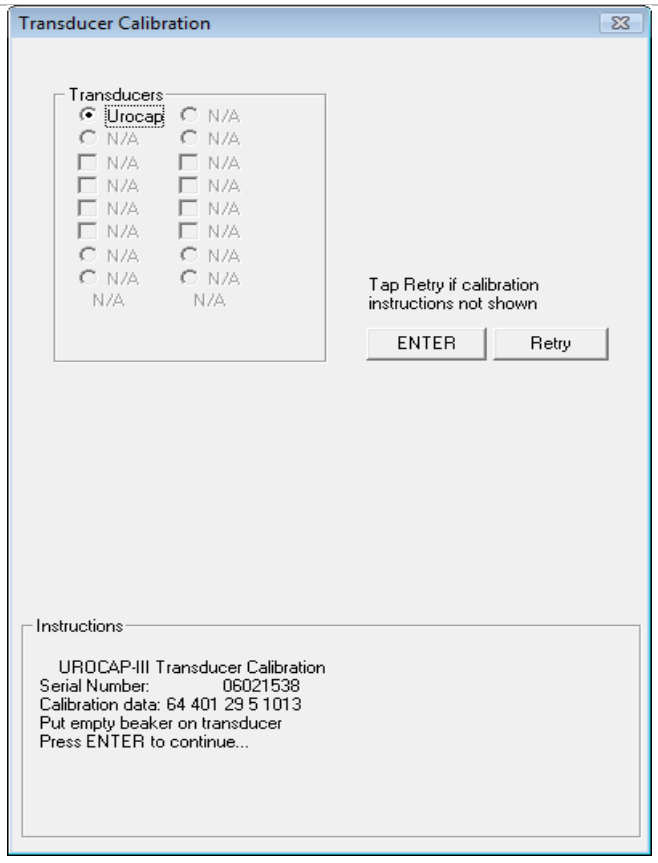
1	Open the default calibration utility located in the `C:\Program Files\Laborie Medical Technologies\`**`Urostym®`**`\Utilities` folder.	
2	Run the *CheckDB* utility.	
3	Click the Connect to UDS button.	
4	Click the **Uroflowmetry Transducer Calibration** button.	
5	Select the ***Urocap™*** option and follow the instructions displayed at the bottom of the screen to complete calibration.	

Table 34: Check DB Utility – Calibrating the Urocap™

To produce an even flow it is best to use a small hand held funnel. By keeping the water level constant in the funnel as you are pouring, the flow will be relatively constant. If you do not have access to a funnel, a paper or foam cup with a hole in the bottom will suffice.

To verify your calibration, choose a Uroflow protocol, set zeroes, and pour using the same pouring procedure as the calibration. The unit should provide you with the same volume reading as during calibration.

12.1.1 CALIBRATING EMG/MANOMETRY

To calibrate channels 1, 2, and 3:

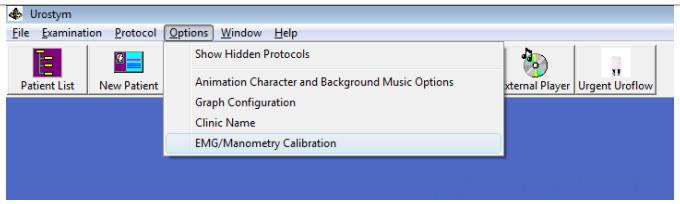
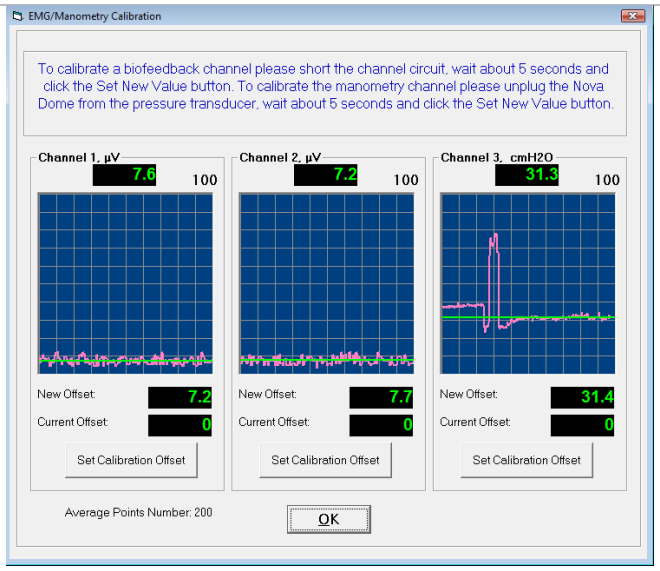
1	1. Click Options > EMG/Manometry Calibration.	
2	From the resulting screen, you can calibrate the channels by following the on-screen instructions. To short the channel circuit: • For Channel 1 or 2: Connect the cable for surface electrodes into the channel you wish to calibrate. • Use the "shorting tool" provided with the unit and connect the leads from the shorting tool into the EMG headstage. Alternate methods: • Take the patient leads and hold the metal portion of the snaps down on an available metal surface like an I.V. pole. • Another method is to undo a paperclip, shape it into the letter "W" and place the top points of the letter "W" into the center holes of all three leads. • For Channel 3: have the transducer cable connected, with NO transducer in place.	
3	Once you are finished with calibration, click **OK**	

Table 35: Calibrating Urostym® Channels

13 TROUBLESHOOTING

The following table explains common errors or problems, possible causes, and solutions. If these actions do not resolve the current situation, please contact Laborie at the number listed on the front inside cover of the manual.

SYMPTOM(S)	POSSIBLE CAUSE(S)	CHECK/CORRECTIVE ACTION(S)
No Power? *or* Stop/Reset Light OFF?	Power cord unplugged	• Check the power cord installation at both the **Urostym®** power entry module and the power outlet. • Plug the power cord into the outlet or power entry module.
	Power switch in the OFF position	• Check to see if the power switch is in the ON position • Turn the power switch ON
	AC outlet not receiving voltage	• Connect another appliance to the outlet to verify the voltage • Plug the power cord into another outlet
	Blown fuses	• Check the two fuses in the power entry module at the back of the **Urostym®** unit  • Replace blown fuses
No Communication between the **Urostym®** and the PC?	Communication cable unplugged	• Check the Communication cable installation at both the PC Communication port and the **Urostym®** Communication port • Plug the Communication cable into the port
	Incorrect Communication port setting	• Change the setting to the Communication port being used with the Set COM Port button

SYMPTOM(S)	POSSIBLE CAUSE(S)	CHECK/CORRECTIVE ACTION(S)
Channel 1 does not respond. Patient experiences no sensation with Channel 1 yellow indicator LED illuminated?	Poor patient contact due to excess hair, dry skin, adipose tissue	• Check the patient contact with the probe or the surface electrodes • Ensure proper patient contact with the probe or the surface electrodes • Ensure Laborie lubricant (ULT050) is on probe
	Channel 1 cable not properly connected	• Check all cable connections. Make sure cables are plugged in securely.
	Channel 1 cable defective	• Connect Channel 2 cable into Channel 1 and check to see if Channel 1 is responding • Return the defective cable to Laborie Medical Technologies for repair
Channel 2 does not respond. No data/signal received from sensor with Channel 2 green blinking indicator LED illuminated?	Poor patient contact due to excess hair, dry skin, adipose tissue	• Check the patient contact with the surface electrodes • Ensure proper patient contact with the surface electrodes
	Channel 2 cable not connected properly	• Check all cable connections • Make sure cables are plugged in securely.
	Channel 2 cable defective	• Connect Channel 1 cable into Channel 2 and check to see if Channel 2 is responding • Return the defective cable to Laborie for repair
Channel 3 does not respond. No data/signal received from sensor with Channel 3 green blinking indicator LED illuminated?	Poor positioning or inflation of probe	• Check the patient contact with the Manometry probe; hold in place to prevent loss • Ensure proper patient contact with the Manometry probe at level with pelvic floor muscle

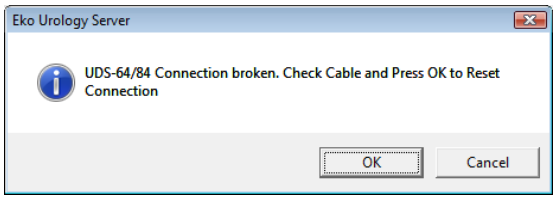
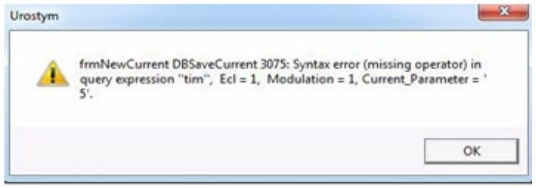
SYMPTOM(S)	POSSIBLE CAUSE(S)	CHECK/CORRECTIVE ACTION(S)
	Manometry probe air leak	• Inject 1 cc of air into the Manometry probe and dip the probe in a container of water. Look for bubbles in the water • Replace the Manometry probe
Error message appears: 	UDS unit turned off	Turn on the UDS unit
Error message appears: 	Incorrect characters used in current /envelope/template name	Names for currents, envelopes, and/or templates cannot contain punctuation characters, such as commas or apostrophes, etc....
Probe disconnects from the system and stimulation stops	Stimulation current greater than 10.5 mA	For safety reasons, the software will not allow the stimulation current to go higher than 10.5 mA.

Table 36: Troubleshooting Instructions

Note: The Laborie Urostym is designed to be used as a stand-alone system, with the only mains power supply connection going through the Laborie medical-grade power supply (LIT). Do not connect it to any other devices unless the whole system is outside the patient environment or the other device is also using a medical grade power supply.

14 APPENDICIES

Appendix A: Specifications

SYSTEM SPECIFICATIONS

Upon request, LABORIE will make available any circuit diagrams, component part lists, and other technical documentation directly related to the **Urostym®**.

Model	**Urostym®**
Dimensions	44cm (17") x 25cm (9.8") x 9.3cm (3.6") [L x W x H]
Weight	1.7kg (3.8 lb.)
Cable length	182cm (6')
Channels	3 (Input) Channel 1 – Stimulation/PMR Channel 2 – PMR Channel 3 – Manometry 1 (Output) Channel 1 - Stimulation
Sampling Rate	Max. 20 pts/sec.
Operating Conditions	Temperature: +10°C to +40°C Humidity: 30% to 75% relative humidity (non-condensing) Pressure: 70 kPa to 106 kPa
Transport and Storage Conditions	Temperature: -29°C to +60°C Humidity: uncontrolled to 85% relative humidity
Power Supply	Input: 100-240 V~, 50-60Hz, 55W Fuse: 2X1A, 250V
Pressure Transducer (TRA168)	Cable Length: 4.0ft/1.2m Measurement Range: 0 to 200 cmH2O Tolerance: +/- 4% relative to reading or +/- 5 cmH2O, whichever is greater
Line Isolation Transformer (LIT030, LIT055)	LIT030 Input: 120V~, 50/60Hz, 1000VA Output: 120V~, 50-60Hz, 1000VA LIT055 Input: 230-240 V~, 50/60Hz, 1000VA Output: 230-240 V~, 50/60Hz, 1000VA
Fuse	Breaking capacity: 35A Voltage rating: 250Vac Current rating: 1A

	Response time: Slow Series: MDL

Table 37: Urostym Specifications

INPUT CHANNELS

Channel (1,2,3)	Range	Tolerance
PMR	0-600 µV	±10% FS
Manometry	0-250 cmH_2O (0-184mmHg)	±10% FS

Table 38: Input Channels – Range and Tolerance

OUTPUT CHANNELS

Channel (1)	Range		Tolerance
Stimulation (Biphasic)	Current	0 – 25 mA (Rectal Probe) 0 – 70 mA (Vaginal Probe/Surface Electrodes)	(1) ±20 %FS
	Frequency	5 – 200 Hz	+/- 10 % FS
	Pulse Width	200 – 500 µs	+/- 5 % FS

(1) The Urostym® is a current source device. Stimulation Output is calibrated at a nominal load of 500 ohms. Distortion might occur at low impedances as well as high impedances.

Table 39: Output Channels – Range and Tolerance

The values listed in the table below are the maximum values that the Urostym® unit will supply. Laborie Medical Technologies strongly recommends staying within the specified ranges.

Calculations of the Maximum Power Density, Maximum Current Density and Maximum Charge per Pulse:

*This is for the Anal probe 2.75 cm^2, thus the maximum value for power and current maximum 25mA for this probe.

** Is for the Vaginal probe 15.7 cm^2 with maximum current 70mA for this probe.

*** Is for the ELE625 patch electrodes 25 cm^2 with maximum current 70mA for this patch.

Maximum Power Density:

P = power; F = frequency; θ = total length of pulse; U= volts; I = current; R = resistance; U = IR and *U = .025A x 500Ω and **U/***U = .070A x 500 Ω

For a periodic signal Pmax = rms (U^2 x F x θ) /R using U= 12.5 R= 500Ω θ = 1ms and with F = 200Hz

*Pmax = (12.5^2x 200x .001) / 500

*Pmax = 31.25 / 500 = .063 Watts and .063W/2.75cm^2 = .023 W/cm^2

And

**Pmax = (35^2x 200x .001) / 500

**Pmax = 0.49 Watts and 0.49W/ 15.7 cm^2 = .031 W/ cm^2

***Pmax = (35^2x 200x .001) / 500

***Pmax = 0.49 Watts and 0.49W/ 25.0 cm^2 = .002 W/ cm^2

Maximum Current Density = Imax / Minimum electrode area

= *25mA / 2.75 cm^2 = 9.0mA/cm^2

With = **70mA / 15.7cm^2 = 4.5mA/ cm^2

= ***70mA / 25cm^2 = 2.8mA/ cm^2

Maximum Charge per Pulse = Imax x θ (total =1ms or)

= *25mA x . c = .025A x .001 = 25 µC

With = **70mA x .0 = .070A x .001 = 70 µC

= ***70mA x .0 = .070A x .001 = 70 µC

Pmax as a function of impedance for the patch electrodes is calculated as rms (U^2 x F x θ) /R/S using U= 12.5 θ = 1ms and with F = 200Hz; S = 25 cm^2

***Pmax = (35^2x 200x .001) /25/ R = 9.8/R

CLASSIFICATION

MDD Directive 93/42/EEC	Class IIa Equipment
IEC-60601-1	Class I Equipment, Type BF Applied Parts
FDA 510K	Class II
Canadian Medical Device Regulation	Class II
Degree of protection	IPX0 Equipment: no protection against ingress of objects or water
Mode of Operation	Continuous

Table 40: Urostym®

Appendix B: Symbols and Labeling

SYMBOLS

EC REP Authorized Representative in the European Community (5.1.2)[1]: Indicates the manufacturer's device representative in the European Community.	SGS SGS certification - certified to U.S. and Canadian safety standards.	Date of Manufacture (5.1.3)[1]: Indicates the date of device manufacture.	Manufacturer (5.1.1)[1]: Indicates the device manufacturer.	Consult Instructions for Use (5.4.3)[1]: Manufacturer recommends consultation of Instructions for Use.	Read Operator's Manual (M002)[4]: Indicates user must refer to Owner's/Operator's Manual.
REF Catalogue Number (5.1.6)[1]: Indicates the device model or catalogue number.	SN Serial Number (5.1.7)[1]: Indicates unique device serial number for device traceability.	Type BF Applied Part (Table D.1, 20)[2]: Identifies a type BF applied part complying with IEC 60601-1.	Not for general waste. This product is designated for separate collection at an appropriate collection facility in accordance with WEE Directive. Dispose of in accordance to local regulations.	Non-ionizing electromagnetic Radiation (5140)[5]: Radio Frequency (RF) Transmitting Device Indicates presence of RF transmitters.	Do Not Immerse
Humidity Limitation (5.3.8)[1]: Indicates the humidity range to which the medical device can be safely exposed.	Temperature Limit (5.3.7)[1]: Indicates the temperature limit to which the medical device can be safely exposed.	Atmospheric Pressure Limitation (5.3.9)[1]: Indicates the atmospheric pressure range to which the medical device can be safely exposed.	MAX System Safe Working Load	MAX 2kg Safety Label, Safe Working Load 2kg	Safety Label, No Pushing (P017)[3]: To prohibit pushing against a specified device.
Importer (3725)[4]: Indicates the entity that imports the medical device.	(01) 0 0627825 00601 9 (11) 200304 (21) URSYYMMZZZZ GS1 DataMatrix for Unique Device Identification: (01) Global Trade Item Number (11) Date of Manufacture (21) Serial Number	1. EN ISO 15223-1 Medical Devices – Symbols to be used with medical device, labels, labelling and information to be supplied – Part 1: General Requirements. 2. CAN/CSA-C22.2 No. 60601-1:14 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. 3. BS EN ISO:2012+A6:2016 Graphic symbols – Safety colours and safety signs – Registered safety signs (ISO 7010:2011). 4. ISO 7000:2014 – Graphic Symbols for Use on Equipment – Registered Symbols. 5. IEC 60417 – Graphic Symbols for Use on Equipment. NOTE: Sterility symbols are applicable to consumbale devices only. Refer to consumable device instructions for use for complete symbol and instructional overview.			

Table 41: Symbols Glossary

Appendix C: Electromagnetic Compatibility (EMC)

Standards to which conformity is declared:

IEC 60601-1-2:2014 (Ed.4)	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
IEC 60601-2-10:2012	
IEC 60601-2-40:2016	
CISPR 11: 2010	Industrial, scientific and medical (ISM) radio-frequency equipment – Electromagnetic disturbance characteristics – Limits and methods of measurement
CISPR 22: 2008	Information technology equipment – Radio disturbance characteristics – Limits and methods of measurement
IEC 61000-3-2: 2009	Limits for harmonic current emissions (equipment input current =16 A per phase)
IEC 61000-3-3: 2013	Limits – Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current =16 A per phase and not subject to conditional connection
IEC 61000-4-2: 2008	Testing and measurement techniques –Electrostatic discharge immunity test
IEC 61000-4-3: 2010	Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test. Ed 3.2.
IEC 61000-4-4: 2012	Testing and measurement techniques – Electrical fast transient/burst immunity test
IEC 61000-4-5: 2005	Testing and measurement techniques - Surge immunity test
IEC 61000-4-6: 2003+A1:2004+A2:2006	Testing and Measurement Techniques – Immunity to Conducted Disturbances, Induced by Radio-Frequency Fields.
IEC 61000-4-8: 2009	Testing and measurement techniques – Power frequency magnetic field immunity test
IEC 61000-4-11: 2004	Testing and measurement techniques – Voltage dips, short interruptions and voltage variations immunity tests

1. These limits are designed to provide reasonable protection against harmful electromagnetic or other interference in most installations. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful electromagnetic or other interference, 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 **Urostym®**
    - Increase the separation between **Urostym®** and affected equipment
    - Connect the non-medical system equipment into an outlet on a circuit different from that to which the **Urostym®** is connected.
    - Consult the dealer or experiences technical personnel for help.

Changes or modifications not expressly approved by LABORIE could void the user's authority to operate the equipment.

2. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation.

TABLES OF GUIDANCE AND DECLARATION REGARDING ELECTROMAGNETIC IMMUNITY

- The use of accessories, transducers, and cables other than those specified by LABORIE may result in increased EMISSIONS or decreased IMMUNITY of the Urostym®
- The Urostym® needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this EMC section.
- The following connectors have applied the ESD testing exemption:
    - None
- Pins of connectors identified with the ESD warning symbol should not be touched and connections should not be made to these connectors unless ESD precautionary procedures are used.
- Ensure ESD precautionary measures such as proper grounding, use of antistatic straps, use of antistatic sprays or solutions for wiping, and antistatic floor mats and table mats are in place.
- It is strongly recommended that all staff involved receive an explanation of the ESD warning symbol and training in ESD precautionary procedures.
- The minimum contents of an ESD precautionary procedure training should include:
    - An introduction to the physics of electrostatic charge.
    - The voltage levels that can occur in normal practice and the damage that can be done to electronic components if they are touched by an operator who is electrostatically charged.
    - An explanation should be given of methods to prevent build-up of electrostatic charge and how and why to discharge one's body to earth or to the frame of the equipment or bond oneself by means of a wristband to the equipment or the earth prior to making a connection.
- Portable and mobile RF communications equipment can affect the Urostym®.
- This equipment/system is intended for use by health care professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the equipment or shielding the location.
- The equipment should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.

IEC 60601-1-2: 2014 - TABLE 1 REQUIREMENTS

Urostym® is intended for use in the electromagnetic environment specified below. The customer or the user of the **Urostym®** should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic environment – guidance
RF Emissions CISPR 11	Group 1	The **Urostym®** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The **Urostym®** 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. **Warning:** This equipment/system is intended for use by health care professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re- orienting or relocating the device or shielding the location.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Complies	

Table 42: Electronic Emissions

IEC 60601-1-2:2014 – TABLE 2 REQUIREMENTS

The **Urostym** is intended for use in the electromagnetic environment specified below. The customer or the user of the Urostym should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV Contact ±2kV, ±4kV, ±8 kV and ±15kV Air	±8 kV Contact ±15 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	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±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 UT = 120/230 Vac	0% UT (100 % dip in UT) for 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 70% UT (30% dip in UT) for 25 cycles 0% UT (100% dip in UT) for 5 seconds	<5% UT (>95 % dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power Frequency Magnetic Field (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Table 43: Electromagnetic Immunity

IEC 60601-1-2: 2014 – TABLE 4 REQUIREMENTS

The **Urostym®** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Urostym®** should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6Vrms for ISM bands	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the**Urostym** including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.17\sqrt{p}$ 150kHz to 80Hz $d = 1.17\sqrt{p}$ 80 MHz to 800 MHz $d = 2.3\sqrt{p}$ 800 MHz to 2.7 GHz 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 known RF transmitting devices and equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

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 for radio (cellular/cordless) telephones and land mobile radios, 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 equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the equipment.

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

Table 44: Electromagnetic Immunity – Radio Frequency Communications

IEC 60601-1-2: 2014 – TABLE 6 REQUIREMENTS

Recommended separation distances between portable and mobile RF communications equipment and the Urostym®.

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

⚠ WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Aquarius system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (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 separation distance for 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.

Table 45: Separation Distances

Appendix D: End User Software License Agreement

Find licenses and terms for LABORIE products and services in the following locations:

End User License Agreement: http://www.laborie.com/eula/

Terms and Conditions: http://www.laborie.com/terms-and-conditions/

Appendix E: Protocol Setup

The following chart outlines the most common protocol setups:

PROTOCOL NAME	TYPE OF SESSION	INTENDED FOR
Evaluation of the Pelvic Musculature	Pelvic Muscle Rehabilitation (PMR) Ch 1, EMG probe (adult use only) or perineal patches	All patients (adult and pediatric) Can be used to evaluate muscle strength, coordination, and endurance Appropriate for anyone needing to regain pelvic floor muscle control
Incontinence (start of treatment)	PMR Channel 1, EMG probe (adult use only) or perineal patches Channel 2, abdominal patches	All patients (adult and pediatric) Appropriate for anyone needing to regain pelvic floor muscle control Easy treatment for beginners
Incontinence (end of treatment)	PMR Channel 1,EMG probe (adult use only) or perineal patches Channel 2, abdominal patches	All patients (adult and pediatric) Appropriate for anyone needing to regain pelvic floor muscle control Challenging treatment
Stress Incontinence	Electrical stimulation Channel 1, EMG probe or perineal patches Frequency 50 Hz, band width 250µs	Adult patients only Appropriate for stress urinary incontinence (targets fast twitch muscle fibers with high frequency current)
Urge Incontinence	Electrical stimulation Channel 1, EMG probe or perineal patches Frequency 20 Hz , band width 320µs	Adult patients only Appropriate for urge urinary incontinence (targets slow twitch muscle fibers with low frequency current)
Mixed Stim/Bio	PMR and electrical stimulation Channel 1, EMG probe or perineal patches Frequency modulation 25Hz/75Hz, band width 500µs	Adult patients only Used to treat stress, urge, or mixed incontinence, urgency and frequency Fluctuates between phases of stimulation and phases of PMR Targets slow and fast twitch muscle fibers by modulating between high and low frequencies

PROTOCOL NAME	TYPE OF SESSION	INTENDED FOR
Mixed Urge/Stress	Electrical stimulation Channel 1, EMG probe Frequency modulation 25Hz/75Hz, band width 500µs	Adult patients only Used to treat stress, urge, or mixed incontinence, urgency and frequency Targets slow and fast twitch muscle fibers by modulating between high and low frequencies
Uroflow2EMGS	Uroflowmetry and EMG Channel 1, perineal patches Channel 2, abdominal patches	Adult or pediatric patients with dysfunctional voiding patterns
UroflowCh1EMG	Uroflowmetry and EMG Channel 1, abdominal or perineal patches	Adult or pediatric patients with dysfunctional voiding patterns
UroflowVol	Uroflowmetry	Anyone needing Uroflowmetry testing
PFR	Pelvic Floor Rehabilitation. EMG and Manometry.	Adult patients only. Used to treat urge urinary incontinence. Could be used to treat faecal incontinence and pelvic pain. It is often used with men as it is not possible to add the vaginal probe.

Table 46: Protocol Setup

PREDEFINED PROTOCOLS

The following are predefined protocols stored in the **Urostym®** database. These protocols **CANNOT** be deleted or modified, but they may be hidden.

PROTOCOL NAME	PROTOCOL DURATION (S)	TREATMENT TYPE‡
Evaluation of the pelvic musculature	665	PMR
Incont. (start of treatment)	1200	PMR
Incont. (end of treatment)	1220	PMR
Stress Incontinence.	1200	Stimulation
Urge Incontinence.	1200	Stimulation
Mixed Urge/Stress Incont.	1200	Stimulation
Mixed Stim/Bio Treatment.	1254	StimBio
Stress Urinary Incontinence	1360	StimBio
Urge Urinary Incontinence	1360	StimBio
Mixed Urinary Incontinence	1360	StimBio
Pediatric	600	PMR
Weakened Pelvic Floor Musculature	600	PMR

PROTOCOL NAME	PROTOCOL DURATION (S)	TREATMENT TYPE‡
Evaluation of the Pelvic Musculature (Manometry)	420	PMR
Pelvic Pain	1800	Stimulation
Urinary Retention	1080	Stimulation
UroflowVol	1500	Uroflow
Uroflowch1EMg	1500	Uroflow
UroflowEMGs	1500	Uroflow
Assessment EMG	200	PMR
Assessment Manometry	200	PMR
Beginner Incontinence Treatment	600	PMR
Beginner Pediatric	600	PMR
Evaluation of the Pelvic Musculature (Manometry)	420	PMR
Evaluation of the pelvic musculature.	665	PMR
Incont. (end of treatment)	1220	PMR
Incont. (start of treatment)	1200	PMR
Intermediate Pediatric	600	PMR
Manometry, Incontinence End of Treatment	1220	PMR
Manometry, Incontinence Start of Treatment	1200	PMR
Mixed Stim/Bio Treatment.	1254	StimBio
Mixed Urge/Stress Incont.	1200	Stim
Mixed Urinary Incontinence	1360	StimBio
Pediatric	600	PMR
Pelvic Pain	1800	Stim
Quick Flicks	300	PMR
Stress Incontinence.	1200	Stim
Stress Urinary Incontinence	1360	StimBio
Urge Incontinence.	1200	Stim
Urge Urinary Incontinence	1360	StimBio

PROTOCOL NAME	PROTOCOL DURATION (S)	TREATMENT TYPE‡
Urinary Retention	1080	Stim
Uroflow2EMGS	1500	UroFlow
UroflowCh1EMG	1500	UroFlow
UroflowVol	1500	UroFlow
Weakened Pelvic Floor Musculature	600	PMR
PFR	400	PMR

‡ Treatment Protocol Types:
Stimulation: The *Protocol* is comprised of one or of several electrical stimulation *Phases/ Sequences.*
PMR: The *Protocol* is comprised of one or of several PMR *Phases/Sequences.*
Bio/Stim: The *Protocol* is comprised of one or of several stimulation and PMR *Phase/Sequences.*
Uroflow: This is a Uroflowmetry Protocol and is comprised of one Phase/Sequence with or without EMG PMR capabilities.

Table 47: Predefined Protocols

Appendix F: Glossary

14.1 TERMS USED IN URODYNAMIC TESTING

Protocol: In the **Urostym®** software, a *Protocol* refers to a treatment session used to treat a specific pathology. *Protocols* placed in patient *Sessions List* consist of one, or several, stimulation and/or PMR S*equences* and *Phases*.

Phase: A *Phase* represents a group of actions (acquisition and/or stimulation), which unfold in a given time (P*hase* length). A *Phase* can be active (Work Phase) or passive (Rest Phase). A Work Phase can be one of action (such as an attempt to contract the pelvic floor) or relaxation (such as an attempt to relax the pelvic floor).

PMR Terminology:

- **Average Contraction:** Average value of the patient's contraction
- **Effort**: The percentage of time a patient is able to remain within the template goal line during a particular phase.
- **Max Contraction**: Maximum value of the patient's contraction
- **Template**: PMR profiles that appear on the screen during the patient *Session*. The *Template* acts as a goal line or target area the patient must attempt to reach.

Sequence: A *Sequence* represents a group of *Phases* that unfold in a sequential manner.

Sequence Terminology:

- **Sequence No:** The order of the *Sequence* in the *Protocol*
- **Repetition:** How many times the particular *Sequence* will be repeated in the *Protocol*
- **Protocol Phase No**: The order of the *Phase* in the *Protocol*
- **Sequence Phase No**: The order of the *Phase* in the *Sequence*
- **Total Phase No**: Total number of *Phases* in the *Protocol*
- **Work Time**: Duration of the work *Phase*
- **Rest Time**: Duration of the rest *Phase* (Note: During the *Session*, **Rest Time** will always appear as a countdown clock on the screen)
- **Channel No:** The channel being used (channel 1, 2 or 3)
- **Channel Type:** PMR (channels 1,2,and 3) or stimulation (channel 1)

Stimulation Terminology:

- **Current:** Current used in the electrical stimulation *Session*.
- **Envelope**: Displays the way in which electrical stimulation will be administered
- **Frequency:** Current frequency
- **Modulation**: Current uses a modulated frequency (for example: current fluctuates between two predetermined frequencies)
- **Pulse Width**: Current pulse width, sometimes referred to as bandwidth
- **Plateau Value:** Maximum current intensity in a stimulation envelope
- **Ramp Up Time**: In a stimulation *Envelope*, time allocated for the current to ramp up (in seconds) to the Plateau value
- **Plateau Time**: In a stimulation *Envelope*, time allocated for current remaining at maximum intensity (plateau period)
- **Ramp Down Time**: In a stimulation *Envelope*, time allocated for current to ramp down to 0
- **Rest Time**: In a stimulation *Envelope*, time allocated for resting (no current) within the *Phase*

Uroflowmetry Terminology:

- **Flow:** urine flow rate in ml/sec
- **Volume**: Voided volume (in ml)

- **Uroflow Lag Time**: Time from the start of pelvic floor relaxation to the start of flow (in seconds)

14.2 COMMON ACRONYMS

- ALPP: Abdominal leak point pressure
- BOOI: Bladder outlet obstruction index[i]
- BCI: Bladder contractility index
- BPH: Benign prostate hyperplasia
- BVE: bladder voiding efficiency
- CLP: Cough leak point pressure
- CMG: Cystometrogram
- DLPP: Detrusor leak point pressure
- DSD: Detrusor sphincter dyssynergia
- EMG: Electromyogram
- FUL: Functional urethral profile length
- ICS: International Continence Society
- IH2O: Rate of fluid infusion during
- ISD: Intrinsic sphincter dysfunction (or deficiency)
- IUD: Intrauterine device
- LinPURR: linear passive urethral resistance (*Nomogram available in UDS120 software*)
- LPP: Leak point pressure
- LUTS: Lower urinary tract symptoms
- MCC: Maximum cystometric capacity
- MUCP: Maximum urethral closure pressure
- MUP: Maximum urethral pressure
- NGB: Neurogenic bladder Pabd Abdominal pressure
- Pabd: Abdominal pressure
- Pclo: Closure pressure
- Pdet: Detrusor (or subtracted) pressure
- Pura: Urethral pressure
- Pves: Intravesical pressure
- PVR: Post-void residual
- SUI: Stress urinary incontinence
- UDC: Uninhibited detrusor contraction
- UPP: Urethral pressure profile
- URA: Urethral resistance factor - Nomogram
- UTI: Urinary tract infection
- VH2O: Volume infused during CMG
- VLPP: Valsalva leak point pressure
- VS: Valsalva
- VUR: Vesico-ureteral reflux

ANNEX: PATIENT CARE GUIDE

1 INTRODUCTION TO URINARY INCONTINENCE

About thirteen million Americans, 38% of females and 19% of males, are plagued by urinary incontinence. Studies show prevalence ranges from 1.5% to 5% in the male population ages 15-64, and 10% to 30% in women of the same age.

Although such a large proportion of the population experiences urinary incontinence, the majority of those individuals do not seek care. Due to the sensitive nature and social stigma associated with this disorder, patients are often embarrassed to discuss the condition with their physician. Surveys have indicated that less than half of the community-dwelling population with incontinence seeks treatment for their symptoms. As the Agency for Health Care Policy and Research (AHCPR), now the Agency for Healthcare Research and Quality, guidelines for urinary incontinence suggest, prevalence of incontinence does increase with age, but should not be considered a normal part of aging.

Although studies show women are unaware of the current treatments for incontinence or assume treatment is ineffective, the AHCPR guidelines suggest that treatment of urinary incontinence is effective in most people - around 80 per cent of urinary incontinence can be cured completely. Urinary incontinence is a symptom rather than a disease. It may be related to any of the following conditions:

- Pregnancy or childbirth
- Birth defects
- Pelvic surgery
- Injury to the pelvic region or spinal cord
- Neurological diseases
- Multiple sclerosis
- Polio infection
- Degenerative changes associated with ageing
- Pelvic Organ Prolapse (POP)
- Constipation
- Other bowel symptoms
- Chronic cough (from smoking, chronic bronchitis or asthma)
- Hormonal changes
- Drugs
- Recurrent Urine Tract Infection (UTI)
- Childhood bedwetting
- Some types of prostate surgery
- Stroke, Parkinson's disease
- Urinary retention
- Diabetes
- Persistent straining to empty the bladder or bowel with or without constipation
- Persistent heavy lifting
- Lack of regular exercise

1.1 TYPES OF INCONTINENCE

There are different types of urinary incontinence:

Stress urinary incontinence (SUI): consists of urine leakage with increased intra-abdominal pressure. Increased pressure in the abdominal cavity pushes down on the bladder. When pressure in the bladder exceeds urethral pressure, urine is lost unless the bladder outlet is adequately closed to prevent leakage. Increases in intra-abdominal pressure may occur with laughing, coughing, or sneezing, or during physical exertion such as bending, lifting, or exercise. Although urine loss is typically small, the amount of leakage depends on the degree of exertion along with the severity of the pelvic floor weakness. With strenuous activities such as exercise or heavy lifting, urine loss may be large enough to soak the outer clothes.

Although pelvic floor weakness is more common during pregnancy, after childbirth and after the age of 40, SUI can happen to women of any age. One in three women experience SUI at some point in their lives.

Causes that contribute to the weakening of the pelvic floor:

- **Pregnancy**: carrying the increasing baby weight in the pelvis over 40 weeks puts extra stress on the pelvic floor. Also, during pregnancy the hormone *relaxin* softens the muscles of the pelvic floor to ready the pelvis for birth. Around 50% of post-partum women suffer from SUI.

- **Childbirth**: with vaginal delivery, it is possible the nerves of the pelvic floor become stretched and bruised. After delivery, this contributes to the pelvic floor work improperly and the muscles may not respond as well. A **Danish study** (http://www.vaginalweights.org/urinary_stress_incontinence.html) of more than 2000 women found those who had a tear or episiotomy had a three-fold risk of developing urinary incontinence.

- **Obesity**: this means there is increased pressure on abdominal muscles, which in turn puts increased pressure on the pelvic floor. A British study by Dallosso et al in 2002 (Dallosso et al: Dallosso, HM, McGrother, CW, Matthews, RJ, & Donaldson, MMK. The association of diet and other lifestyle factors with overactive bladder and stress incontinence: a longitudinal study in women. BJU International 2003 92 (1), 69.) found that women who were overweight were nearly twice as likely to have SUI as someone of normal weight. (A BMI of 20-25 is normal weight; 26-30 is overweight; 30+ is obese.)

- **Hysterectomy**: may cause damage to the pelvic floor. There is now a resulting change in the supporting ligaments along with a change in pelvic contents. Hormonal changes also contribute to a weakening of pelvic floor muscles.

- **Smoking**: having a chronic cough puts pressure on the pelvic floor and makes SUI worse. Chronic coughers have a low success rate in PFT.

- **Chronic Cough**: places repeated pressure upon the pelvic floor muscles. Chronic coughers have a low success rate in PFT.

- **Menopause**: after menopause estrogen levels are lower, which may mean muscle pressure around the urethra is weaker and leaks are more likely to occur. The urethra may be less elastic and less able to close completely. Postmenopausal women are also more likely to be overweight and have had a hysterectomy.

- **Medication:** some types of medication can affect the pelvic floor. Examples are alpha-blockers used to treat high blood pressure, some antidepressants and sedatives, and some muscle-relaxant drugs.

Things that can damage the sphincter muscle:

- A pelvic fracture
- Bladder neck surgery
- Radical prostatectomy (for men)

Urge urinary incontinence (UUI): also known as *overactive bladder (OAB)* or *detrusor overactivity* is defined as the involuntary loss of urine associated with a strong desire to void. When bladder fullness is perceived, an individual senses a sudden urge to urinate and is unable to delay voiding. Urine loss is typically moderate to large and often occurs on the way to the bathroom. An involuntary contraction of the bladder detrusor muscle occurs prematurely during filling and forces urine through the urethra. An individual with urge incontinence is unable to inhibit this contraction or close the urethra adequately and urine leakage results..

People with UUI may also:

- Need to empty the bladder more frequently than normal (*more than eight times a day*)
- Void smaller volumes
- Get up in the night several times to pass urine
- Feel the bladder does not empty completely

- Leak when hearing running water.

Often, voiding frequency is increased in an effort to keep the bladder empty and avoid the sudden urge to urinate. Urge incontinence predominately occurs in older adults.

Mixed urinary incontinence (MUI): is a combination of stress urinary incontinence and urge urinary incontinence and occurs in 40% of incontinent people.

Overflow urinary incontinence (OUI) usually happens when there is a blockage (such as a narrowing in the urethra), so the bladder does not empty completely. When the bladder refills, it puts pressure on the obstruction, which gives way slightly and results in a small leak of urine. Overflow urinary incontinence is less common in women than SUI.

Functional Incontinence: Urinary leakage associated with impairment of cognitive or physical functioning, psychological unwillingness or environmental barriers to the toilet. Example: Elderly with impaired mobility and distant toilet.

1.2 EFFECTS OF EXERCISE

The AHCPR advocates the selection of the least invasive treatment with the fewest potential adverse effects as a first course of treatment of urinary incontinence. For many types of urinary incontinence, behavioral techniques meet these criteria. Suggested *behavioral techniques* include toilet assistance, bladder retraining, timed voiding, diet and fluid management, positive affirmations and pelvic muscle exercise with or without augmentation by PMR, electric stimulation, or vaginal weight training. Behavioral techniques are most effective with motivated patients who wish to avoid medication, surgical intervention, or the need for protective garments. Inquiries of medical practices using pelvic floor therapy report a 75 to 80% success rate.

Pelvic muscle exercises began in 1948 when Dr Arnold Kegel developed a program of progressive pelvic floor contractions in combination with PMR training to treat women with urinary incontinence. Various researchers over the past 50 years have implemented their own exercise protocols, but the exercise itself has remained the same. The goal of pelvic muscle exercise is to isolate and strengthen the pelvic floor, or levator ani musculature. Often patients do not know how to squeeze the pelvic floor appropriately without also using nearby muscles or accessory muscles.

2 PELVIC FLOOR ANATOMY & FUNCTION

The pelvic floor muscles are a group of muscles that attach to the base of the bony pelvis, including the levator ani musculature. They provide support to the pelvic organs and control of the outlets. Quality of support depends on anatomical position, resting tone, volume or cross-sectional area of musculature, and integrity of the fascia.

The pelvic floor is composed of *two types of muscle fibers*: 30% fast-twitch and 70% slow-twitch fibers. At rest, slow-twitch fibers are activated through toning to provide support to pelvic viscera. These fibers are primarily responsible for setting the resting tone. Pelvic floor muscle tone may vary with hormonal status such as during menstrual cycle, pregnancy, and menopause and can be influenced by the lumbar and pelvic musculoskeletal system. Resting tone may be classified as hypotonic, normal, or hypertonic. Typically, persons experiencing incontinence have hypotonic or underactive muscle tone, which indicates insufficient functional activity of the pelvic floor muscles. Of note is the fact that children are often treated for the opposite (hypertonic) muscles.

Fast-twitch fibers are activated during increases in intra-abdominal pressure in an effort to quickly close the urethra and provide greater resistance in anticipation of increased pressure from the bladder. With contraction, the urethra, vagina, and rectum are compressed and pelvic organ displacement is prevented. Contracting the pelvic floor enhances closure of the urethra. With this closure, pressure in the urethra is elevated and leakage is avoided. Contraction also helps maintain urethral position during increases in intra-abdominal pressure. When patients perform a contraction prior to activities that raise intra-abdominal pressure, stress incontinence can be avoided. *Pelvic floor contraction also reflexively inhibits the detrusor muscle, which lessens or represses the incidence of urge incontinent episodes.*

3 TREATMENT OF INCONTINENCE

3.1 PMR

PMR uses a device that records electromyographic (EMG) information of the pelvic floor utilizing either surface electrodes or a vaginal or rectal probe. PMR teaches the patient how to improve control of the external sphincter by contracting the pelvic floor muscles. Visual and auditory stimuli such as graphs, color, and sound provide information (feedback) regarding the patient's performance. The feedback shows the patient what alteration is needed, thereby increasing their awareness. A trained clinician continually monitors performance and provides verbal cues to enhance or alter performance. With increased awareness of performance, the patient is encouraged to make small changes in order to increase motor control of the pelvic floor muscles. PMR training is most appropriate for those who are cognitively intact with neurologically intact musculature and motivated to comply with the program.

The PMR instrument displays the electrical signals of the pelvic floor muscles in a graphic form with optional color and auditory capabilities. A system with two or more channels is preferable in order to monitor the activity of potential compensatory muscle groups such as the abdominals or gluteals.

The EMG graph displays data such as resting tone, strength and endurance.

- *Resting* tone is the amount of tension/ tone that resides in the musculature when the muscle is inactive. A strong muscle has more tone than a weak muscle at rest.
- *Strength* is recorded by the maximum pressure or the peak of the waveform.
- *Endurance* is the average muscle contraction measured across the waveform. Endurance can be measured by the period of time a contraction is sustained or the maximum number of repetitions that can be performed.

Temporal characteristics include contractibility or rate of the rise of the contraction and time to release.

The EMG signal of the second channel monitors the accessory muscle activity and should remain quiet with little activity.

PMR provides visual and/or auditory stimuli to facilitate motor learning. With a visual image of muscle activity on the display and verbal cueing, the patient is assisted in identifying a correct pelvic floor contraction. Once the contraction is isolated consistently, an individualized exercise program is developed. The therapist utilizes basic exercise and motor learning principles to facilitate neuromuscular re-education.

Principles used in general strength training can be applied to pelvic muscle exercise. The principles include specificity of training, overload, and reversibility. Training effects are highly specific to the methods employed; therefore, an exercise program should include training of both fast-twitch and slow-twitch muscle fibers. Fast-twitch fibers are trained with quick burst-like contractions interspersed with relaxation, while slow-twitch fibers are targeted with less intense endurance contractions of longer duration. Overload principles suggest a muscle must be continually worked beyond its normal limit to gain strength. An exercise program must be continually modified in order to account for improvements in strength and endurance. The principle of reversibility applies to the muscle's ability to return to its prior level of function with cessation of exercise.

Patients must continue the prescribed program in order to maintain the desired effect.

Principles of motor learning are helpful when re-educating the pelvic floor muscles. When instructed to contract the pelvic floor, many individuals also recruit the abdominal, gluteal, or thigh muscles. As the skill acquisition proceeds, the individual is able to free accessory muscles and perform a more fine-tuned movement with less effort.

During an initial PMR training session, the focus is to increase the patient's *awareness of pelvic muscle activity* and inhibition of accessory muscle use. The patient practices the skill while utilizing visual information and verbal cueing from the therapist. Verbal cueing decreases as proficiency of the task increases. PMR training provides constant awareness of performance via visual and verbal feedback; therefore, acquisition of the skill is accelerated.

3.2 ELECTRICAL STIMULATION

If the patient is having difficulty with voluntary contraction or isolation of the pelvic muscles as seen in muscle wasting or weakness, *electrical stimulation* may be an appropriate adjunct to training. With urge suppression training the resultant pelvic floor contraction serves to inhibit the detrusor.

Electrical stimulation provides contraction of the pelvic muscles with an external device. The patient may also be instructed to squeeze as the stimulator elicits contraction of the pelvic muscles thus creating an active rather than passive exercise. Repeated contractions heighten a patient's awareness of contractility and increase strength and recruitment. Electrical stimulation aids in the identification of the pelvic floor musculature and thus increases awareness of the muscles to target with the exercises.

3.3 INDIVIDUAL TREATMENT

Exercise prescription for pelvic muscle exercises should be individually tailored for the patient. Once the patient has demonstrated the ability to isolate pelvic floor contraction in the supine position, training may progress to the seated and standing positions. Each successive position provides additional gravitational demands on the pelvic muscles. These include variables such as body weight; active muscle recruitment to maintain posture; fascial and ligamentous support; and pelvic organ position. The training program must also address the specific functional needs of the patient. If leakage occurs when lifting a patient's 10-pound infant, training should simulate this activity. The therapist is limited only by his or her own creativity when it comes to functional training.

3.4 BEHAVIOR MODIFICATION

No matter how productive a training session may seem, if the patient is not compliant with their home exercise program, no improvement in muscle strength, coordination, or symptoms will result. It is the therapist's responsibility to collaborate with the patient to develop an exercise program that fosters adherence. The therapist determines the appropriate exercise parameters, but should consider the context of the patient such as work schedule, familial duties, community responsibilities, etc. Establishing specific exercise times such as during daily commutes to and from work, and at lunch break may be easier to integrate, rather than instructing your new patient to exercise their pelvic floor five times per day for the rest of their life. If the patient is an active part of the process, they will be more likely to be compliant. Ask what works best for them and their schedules.

PMR serves as an effective training tool that provides patients with the knowledge and skills to successfully exercise the pelvic muscles and manage their urinary incontinence symptoms. Medical management of this disorder is limited by the incontinent patient's hesitancy to seek care. Guidelines have been established by the AHCPR in an attempt to educate health care providers and advance the timely diagnosis and treatment of urinary incontinence. It is our responsibility as health care professionals to increase public awareness in order to encourage individuals to seek treatment and reduce the psychosocial and economic costs of this manageable disorder.

3.5 TARGET POPULATION

The target population for pelvic floor rehabilitation is extensive — both men and women of all ages may benefit from this form of treatment. Some of the dysfunctions that can be treated include:

- stress urinary incontinence
- urge urinary incontinence
- mixed urinary incontinence

Children who have the cognitive ability to listen to and follow instructions may benefit from pelvic floor therapy as well.

Those who respond best to pelvic floor re-education/rehabilitation (PFR) include:

- Patients who are motivated to comply with the program, are cognitively intact, and are capable of following instructions.
- Patients who have a pelvic floor that is neurologically intact.
- Patients who suffer from urge incontinence.

- Patients who experience mild stress incontinence - including men with post-prostatectomy incontinence (PPI) after a suitable period of healing.
- Patients who suffer from mixed incontinence (combination of urge and stress incontinence).
- Patients who do not want medication or surgery.
- Patients in pre-natal training.
- Patients in pre-prostatectomy training.

Some use PFR while waiting for surgery or as a psychological bridge to surgery by allowing them to feel they have exhausted all possible options.

AVOID:

- Patients who want a quick fix with little effort.
- Patients who do not have the time.
- Patients with cognitive impairment.

3.6 DESIGNING A TREATMENT PLAN

Pelvic floor strengthening may have two phases:

i. A PMR phase and an electrical stimulation phase *or*
ii. A PMR phase *only* (if they are able to isolate their muscles and simply need strengthening practice.

3.6.1 PMR PHASE

PMR is a technique employed to improve pelvic floor strength by learning to control/contract the proper muscle groups through increased awareness. A computer monitor is used to visualize these contractions. An EMG or pressure Manometry probe is used (vaginally or anally) along with surface patch electrodes (abdominally). The patient is asked to squeeze the probe while keeping abdominal muscles relaxed.

CONTRAINDICATED FOR PATIENTS WHO:

- Have symptomatic UTI, fever
- Have fecal impactions
- Are too feeble, senile
- Have heavy menses

DO NOT USE the probes if the patient's anatomy would make proper probe insertion difficult or impossible

DO NOT USE the probes if the patient has an infection of the bladder, vagina, rectum, or anus; or displays the symptoms of infection (such as itching, painful urination, sores, or fever).

3.6.2 STIMULATION PHASE

Stimulation is a technique by which current is used to stimulate or inhibit *(as seen in urinary retention or pelvic pain therapy)* the pelvic floor muscles. This is done through the EMG probe or through special surface patch electrodes. Stimulation is to occur within a comfort zone for the patients who are asked to report when they feel a tingling/tugging sensation.

CONTRAINDICATED FOR PATIENTS WHO:

- Have symptomatic UTI, fever
- Have fecal impactions
- Are too feeble, senile
- Have heavy menses

- Have a pacemaker (patient should seek expert medical opinion before treatment)
- Metal IUD's
- Have rectal bleeding/swollen hemorrhoids (if using an anal probe)
- Have cardiac arrhythmia
- Had pelvic surgery in the last 6 months without primary surgeon's permission
- Have metal prosthetics in pelvic area (i.e., Hip implants)
- Have seizure disorders
- Have a pessary that contains metal. The pessary can be removed prior to start of session and replaced when session is complete.
- Have cancer in the pelvic region (colorectal or genitourinary cancer)
- Pregnancy or suspected pregnancy

DO NOT USE the probes if the patient's anatomy would make proper probe insertion difficult or impossible

DO NOT USE the probes if the patient has an infection of the bladder, vagina, rectum, or anus; or displays the symptoms of infection (such as itching, painful urination, sores, or fever).

4 PATIENT EDUCATION

4.1 PRIOR TO TESTING

- The first visit takes about one hour, and subsequent visits will last 30-45 minutes.
- Recommended clothing:
    - Men, children: long T-shirts, loose, easy-to-remove bottom clothing
    - Women: loose dress or loose, easy-to-remove bottom clothing
- The goal of pelvic muscle training is to isolate the pelvic floor muscle, specifically the levator ani.
- A Pelvic Floor Strengthening session lasts approximately 30 minutes and is repeated once a week for 4 to 8 weeks, lasting typically for 6 weeks.
- Patients must perform daily pelvic floor exercises at home in between each session. Give them homework and have them report on their homework when they return. Use the voiding diaries to note improvement during the course of treatment. Recommend daily bowel movements to aid in the ease of pelvic floor exercise.
- It may take 3 to 4 weeks to notice changes in symptoms. Improvement may be noticed to continue for up to 6 months following a course of PFR with continued home Pelvic Floor Exercises (PFE's). It is not uncommon to return for a 'tune up' session or two sometime later.
- Discontinuing home exercises will result in a return of urinary symptoms
- If electrical stimulation is used, it will not be painful

4.2 PATIENT POSITIONING

1. Electrical stimulation provided by probes requires supine or side-lying in order to hold the probe in proper alignment with the pelvic floor muscles. The gynecology chair or the exam table offer ease in positioning.
2. Consider comfort: Lounger chair, couch, bean bags for kids, video chair for kids, etc.
3. Ease of viewing: patients need to be able to see the video screen easily and without glare from lighting.
4. Consider anatomical limitations: prolapse, handicaps, etc.
5. Standing, laying, sitting are all possible positions for PMR exercises. Consider the diagnosis and treat accordingly: stress with lifting requires they lift during therapy while using Knack technique to prevent leaking.

4.3 SESSION ROOM SETUP

- Room Environment: Dim the lights: overhead fluorescent lighting places glare on the screen. Dim, indirect lighting is relaxing.
- Privacy: Keep a "Do Not Disturb" sign on the door to indicate privacy.
- Music: Load the computer's music library with tunes appropriate for the patient population. Adults may enjoy and prefer meditation music while children may prefer their own music.
- Props: A rubber ball (soft to be held between the knees); elastic bands to exercise hip abductors and adductors; foot stool for comfortable seating while voiding; free standing toilet paper holder and trash receptacle; books and articles to promote self-care and interest; artwork for the wall appropriate for your clients; changing area that has clothes hooks and a mirror; a bell to call nurse when micturition complete, and so on.

4.4 PATIENT HOMEWORK

Everyone should have homework assignments. A means of keeping track of the daily assignments is best as this provides the basis for lifestyle modification. Patients are in charge of their bladder and this includes daily exercise sets for improved ***muscle tone, endurance, and strength.***

- *Go easy in the beginning*. Encourage them to go easy in the beginning, just as in any new endeavor, as this is ultimately about progress.
- Base assignments on their abilities during the PMR session. They may need to practice lying down if they are obese, or have prolapse without the aid of a pessary. Eventually, follow with sitting and finally standing. However, if the patient is suffering from SUI then standing, walking, or jumping would be the better choice for practice. Consider the age, abilities, and reason for PMR.
- Bowel Management must be stressed. The most helpful approach to pelvic floor rehabilitation includes a daily bowel movement. *Constipation* must be treated and avoided. Please note: Pelvic floor rehabilitation often treats *fecal incontinence* as the pelvic floor muscle includes the rectal sphincter as well.

4.4.1 HOMEWORK EXAMPLES

- For weak muscles perform these exercises three times a day:
  - 5 quick contractions, then a 20 second relax (repeat 5-7 times)
  - 5 second hold for endurance followed by a 10 second rest (repeat 5 - 7times)
- For strong muscles perform these exercises three times a day:
  - 5 quick contractions, then a 20 second relax (repeat 8-10 times)
  - 5 second hold for endurance followed by 10 second rest (repeat 8-10 times)
- No increasing of the target during the first week;
- Drink recommended volume of water (8 ounces 6-8 times a day)
- Eat plenty of fresh fruit, vegetables and cereals to avoid constipation.
- If you experience urgency that makes you rush to the toilet, drink less caffeine (tea, coffee and cola) and drink more water.
- Regular exercise - walk as much as possible.
- Wear clothes that are easy to manage.
- If you have to get up more than once during the night to pass urine (nocturia) then it is advisable not to drink any fluid within three hours of going to bed.
- Involve your family in understanding the problems so that embarrassment is not so much of a problem.
- Get someone else to do heavy lifting and avoid strenuous exertion in general.
- Drinking alcohol is likely to worsen any type of urinary incontinence because it is a diuretic and stimulates the kidneys to produce more urine.
- Bowel management – stress the importance of maintaining a 3 or 4 on Bristol Stool Scale

4.5 EFFECTS OF FLUIDS

- Large fluid intake: if you drink more than 1500ml a day, it will likely worsen SUI because the volume of the bladder increases and puts more pressure on the pelvic floor. It also will worsen UUI because you pass smaller amounts of urine more frequently.

- Not enough fluids: cutting down too much will make your urine more concentrated, which irritates your bladder and worsens UUI. It also decreases the effective capacity of your bladder.
- Caffeinated drinks: caffeine is a diuretic, which means it makes your kidneys make more urine, so you pass more water. Caffeine also irritates the detrusor (bladder) muscle. Tea, coffee, cola and chocolate all contain caffeine.
- Carbonated drinks: if you drink carbonated drinks daily, you're more likely to have SUI and UUI. This is possibly because the most popular carbonated drinks are colas, which contain caffeine and citric acid.
- Alcohol: alcohol is a diuretic and makes your kidneys to produce more urine, which will worsen urinary incontinence.

4.6 PREVENTING URINARY INFECTIONS

- Urinate after bathing or after sexual intercourse.
- Drink plenty of fluids in order to keep the urine light in color and to wash any germs out of the bladder.
- Empty the bladder every 3 to 4 hours during the day. Holding back urination causes normal bacteria to multiply.
- For females, correct wiping is from front to back; especially after a bowel movement.
- For females, stay away from bubble baths as this is often irritating to the genital area by removing the normally protective secretions for the urethra. Avoid the use of soap in the genital area until reaching puberty – this means washing the genital area with warm water.

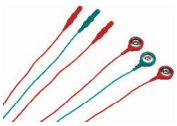
5 EQUIPMENT OVERVIEW

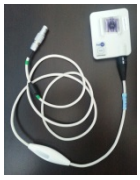
5.1 SURFACE ELECTRODES AND PRESSURE PROBES

*Indicates item not for use with pediatric patients

Probes Non-Sterile, Single Patient Use

PRODUCT	Description
Channel 1 Cable Stimulation/PMR* (part number CAB 896) 	Length: 10ft. Used in Adult Pelvic Floor Therapy when a probe is employed for both EMG and/or stimulation.
Channel 2 Cable EMG (part number CAB906) 	Length: 10ft. EMG headstage labeled for Channel 2 but may also be used on Channel 1 in Pediatrics and for Adults who do not use a probe for stimulation/PMR.
Vaginal Probe Classic* (part number PRB450) 	Length: 4inches/10cm. Reusable for individual patient. Useful for both PMR and Electrical Stimulation. Vaginal probe will deliver up to 70mAmp of Stimulation.
Anal Probe* (part number PRB055) 	Length: 3.25inches/8.3cm. Slender. Reusable for individual patient. Useful for both for PMR and Electrical Stimulation. The anal probe is set to deliver up to a max of 25mAmp of Stimulation.
Vaginal Atrophic Probe* (part number PRB085) 	Length: 3 inches/ 8cm. Slender Vaginal probe. Useful for both PMR and Electrical Stimulation. Capable of stimulation to a max of 70mAmp. For use with vaginal atrophy.
Vaginal Tampon Probe* (part number PRB425) 	Length: 2inches/5cm. Short Vaginal probe. Useful for both PMR and Electrical Stimulation. Capable of stimulation to a max 70vAmp.
EMG surface electrodes – 3/pack pre-wired	Surface electrodes that offer excellent transmission of EMG activity in a soft patch with superior adhesive qualities. Useful for PMR only. The ability to

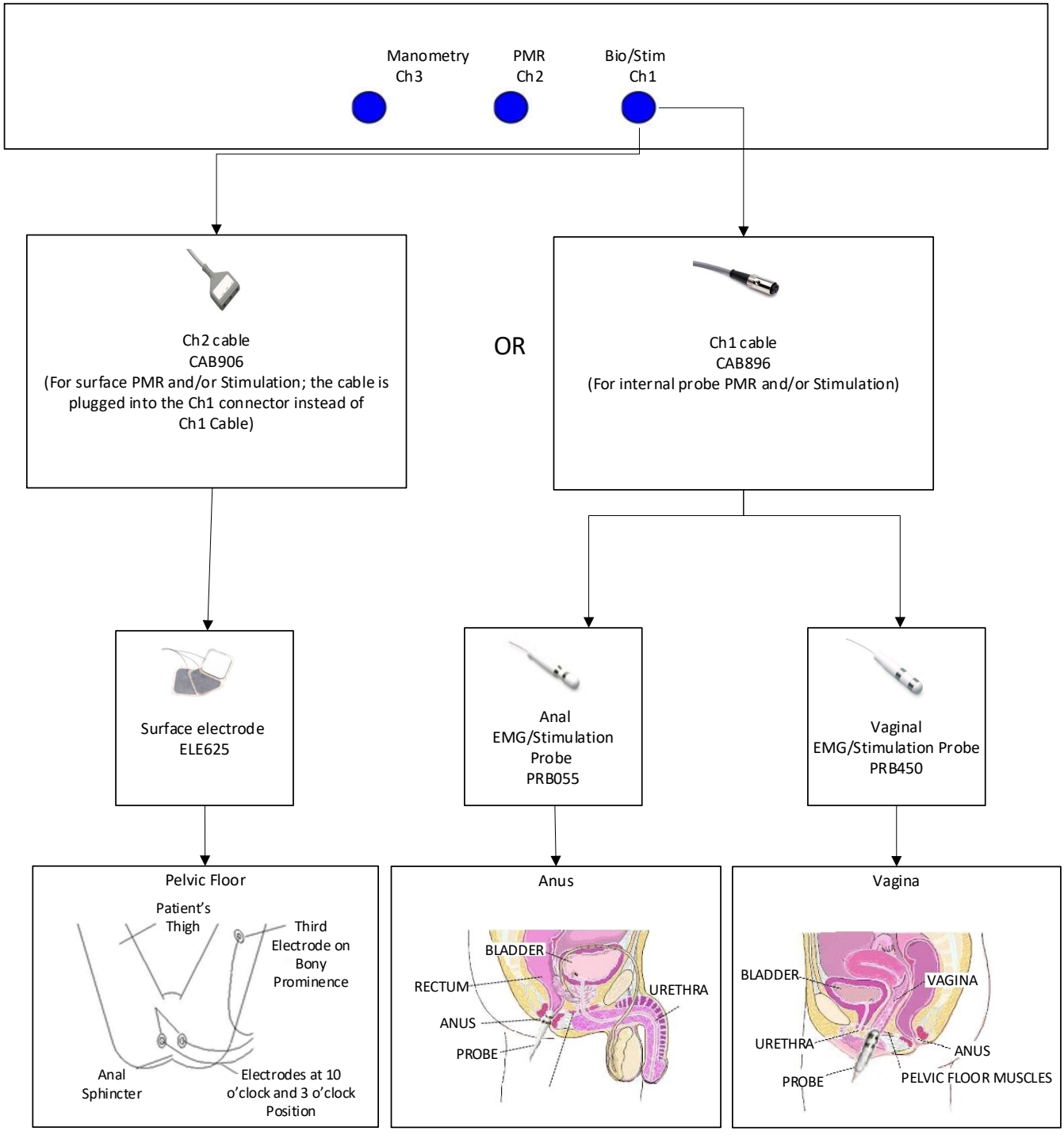
PRODUCT	Description
(part number ELE428) 	dispose of the patch with the wire leads after each use ensures optimal hygiene. Recommended for both pediatric and adult PMR sessions.
Surface Electrodes / stimulation – reusable 4/pack (part number ELE625) 	Dual purpose patches useful for PMR and capable of stimulation. Reusable on the same patient. Used for pelvic or abdominal accessory muscles. After use store on enclosed plastic film. Lifetime depends on care and storage.
Package of 3 Surface Electrodes (part number ELE425) 	Useful for PMR. Recommended for abdominal or accessory muscle measurement, used with EMG leads, ELE350
EMG Leads Red and Green (reusable) (part number ELE350) 	Length: 10inches. For use with ELE 425 for PMR. Life expectancy with cleaning between uses is approximately 6 months to 1 year. Two sets are recommended.
Beaker (part number DIS173) 	Plastic with measurements embossed onto the clear surface. For Uroflowmetry

For Manometry * NOTE: for PMR only – no stimulation	
PRODUCT	Description
Channel 3 Manometry Cable (part number TRA168) 	Length: 4.0ft. /1.2m Connects to **Urostym®** Channel 3.
Pressure transducer cartridge + Luer Lock Plug DIS130 	Used for recording direct muscle pressure. Connects to pressure tubing.
Vaginal Manometry Probe (part number PRB113) 	Length: 4.25 inches (11cm). Used for monitoring direct muscle pressure with TRA168. Latex free, micro-porous, supple, air filled probe. Air is inserted / removed with a 10cc syringe. Lubricate before insertion.
Vaginal Pressure Tubing (part number PRB080) 	Length: 30 inches / 77cm. Used with TRA168 for direct muscle pressure measurement Requires 10cc syringe to inflate with 5cc of air. For use with Vaginal Manometry Probe only.
Anal Manometry Probe (part number PRB108) 	Length: 2.25inches/ 6cm. Used for recording direct muscle pressure. Latex free, supple, micro-porous, air filled probe. Lubricate before insertion.
Anal Pressure Tubing (part number PRB078) 	Length: 48 inches / 122cm. Pressure tubing for use with anal Manometry probe only.

Annex, Table 1: Surface Electrodes and Pressure Probes

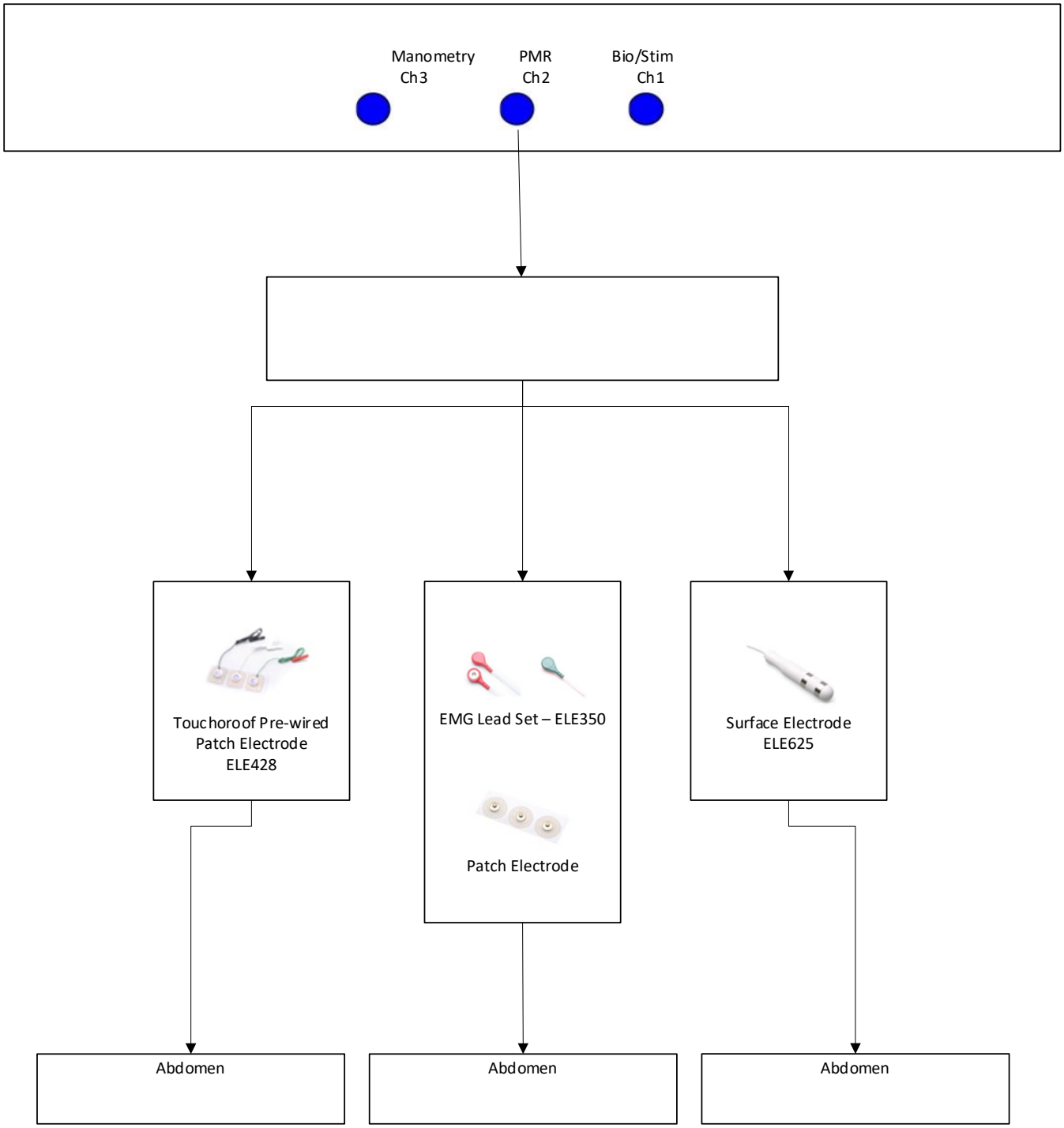
5.2 **UROSTYM®** CONNECTION DIAGRAMS FOR ADULT PATIENTS

Channel 1 Connection: Stimulation and Electrical PMR



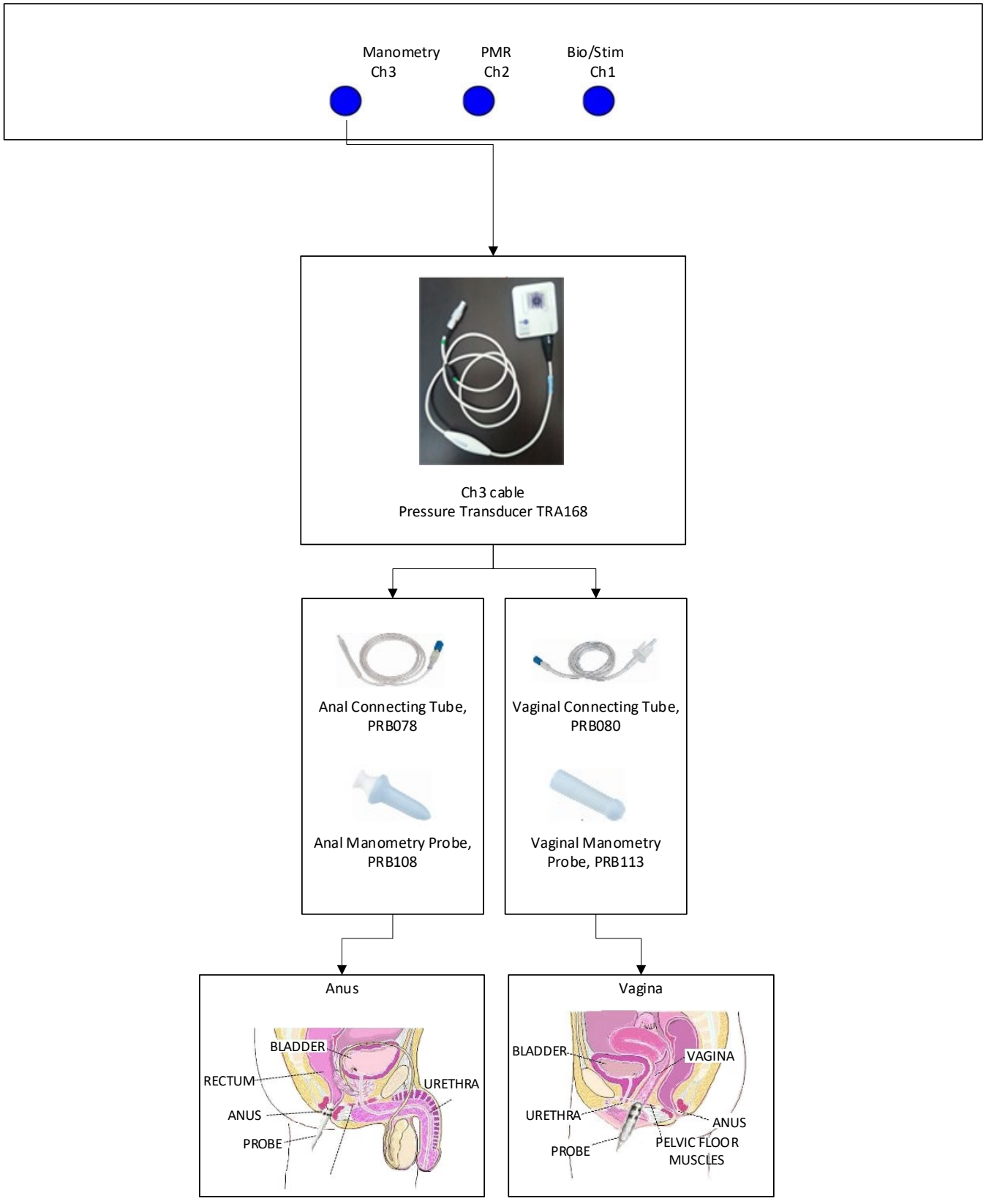
Annex, Figure 1: Channel 1 Connection - Stimulation and Electrical PMR

Channel 2 Connections: Electrical PMR



Annex, Figure 2: Channel 2 Connections - Electrical PMR

Channel 3 Connections: Manometry PMR



Annex, Figure 3: Channel 3 Connections - Manometry PMR

5.3 PROBE AND SURFACE ELECTRODE PLACEMENT

5.3.1 SURFACE ELECTRODES

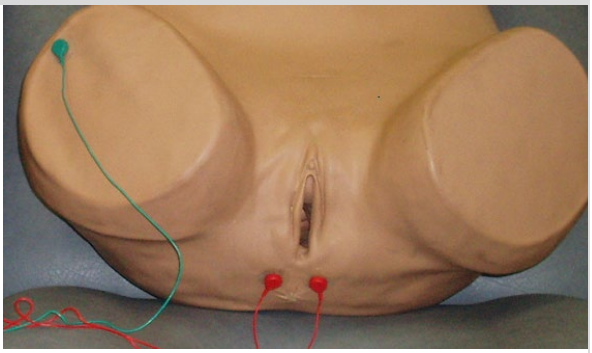
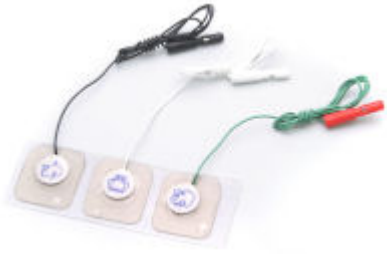
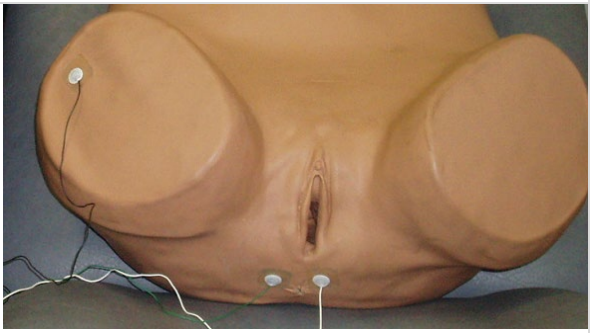
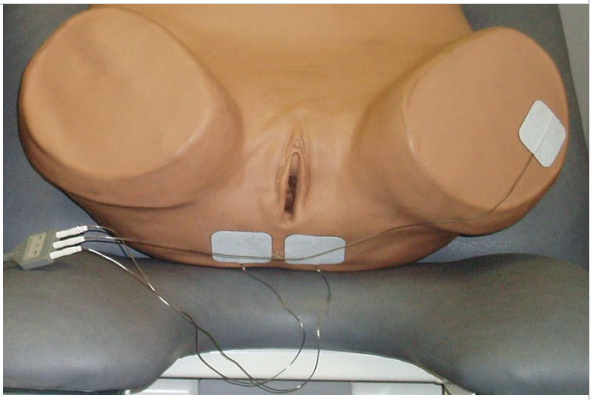
EMG values will vary according to: tissue impedance, electrode placement, contact medium and grounding.

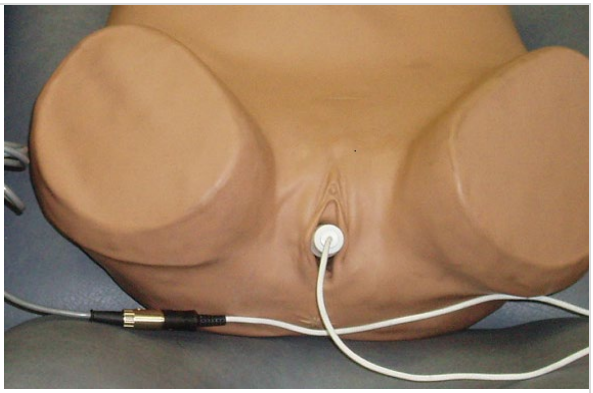
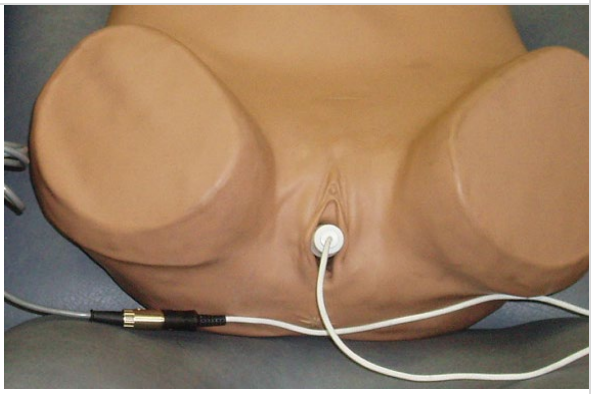
5.3.2 VAGINAL/ANAL EMG PROBES

Graphic values will vary according to: intra-cavity electrolyte balance, probe placement and contact medium. Please use conductive lubricant such as ultrasound gel.

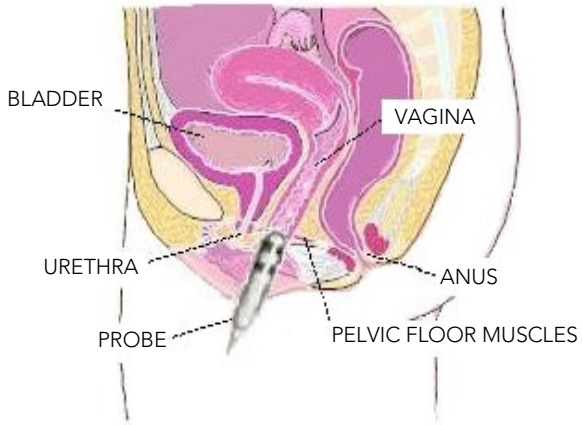
Pelvic floor (connects to channel 1 of the Urostym® unit)

- Two surface electrodes are placed on the peri-anally, at the 10 o'clock and 2 or 3 o'clock positions. The third electrode is placed on a bony prominence (knee or hip bone) or fleshy inner thigh.

Product	Patient Setup
PF: ELE425 electrodes 	
PF: ELE428 electrodes 	
PF: ELE625 electrodes 	

PF: PRB450, or PRB085 or PRB425  or  or 	
PF: PRB055 	

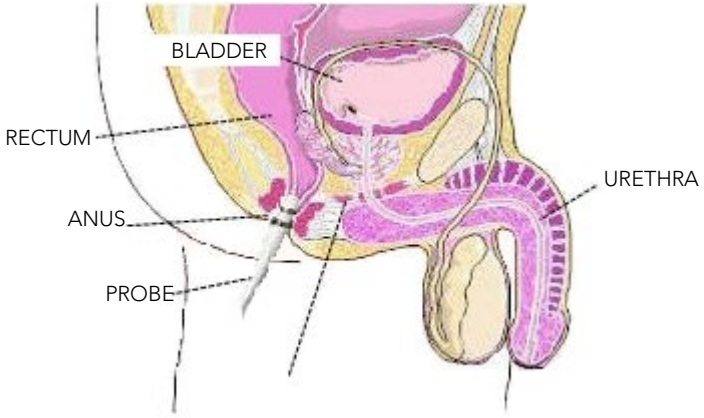
Annex, Table 2: EMG Probe Setup



Annex, Figure 4: Probe Insertion - Female

Note:

- The metal rings are in line with the pelvic floor muscles.
- It is necessary to hold the probe in place to maintain positioning.
- Maximum setting of 70 mAmp.



Annex, Figure 5: Probe Insertion - Male

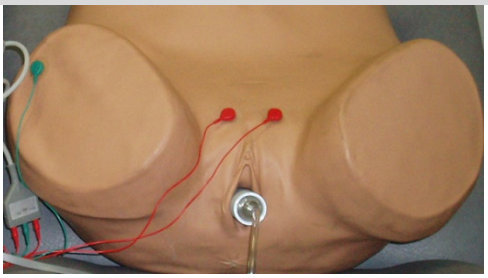
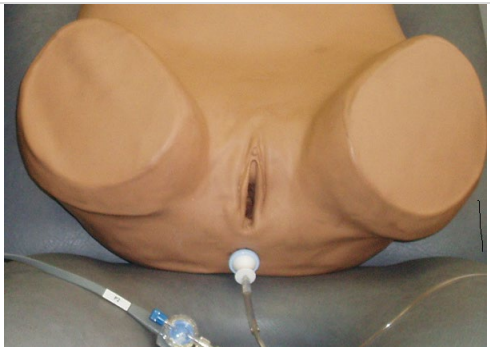
Note:

- Anal probe placement for men or women.
- Maximum stimulation = 25mA, rectal tissue is more sensitive
- Hold the probe in alignment with pelvic floor muscle.

If probe use is contraindicated, Laborie's 50mm X 50mm surface electrode patches (ELE625) may be used to provide electrical stimulation. Smaller patches must NEVER be used for stimulation.

5.3.3 VAGINAL/ANAL MANOMETRY PROBES

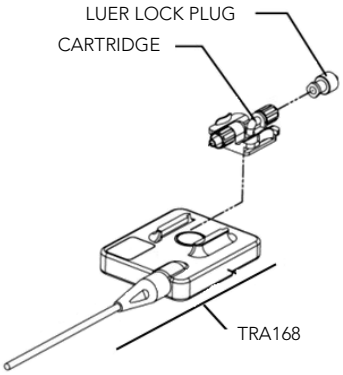
Manometry is defined as providing a true measure of pelvic floor strength, Manometry may be performed with an anal probe on males, and a vaginal probe on females. The anal probe may be employed in the female with atrophic vaginitis and other anatomical limitations.

Product	Patient Setup
PF: PRB113 	
PF:PRB108 	

Annex, Table 3: Manometry Probe Setup

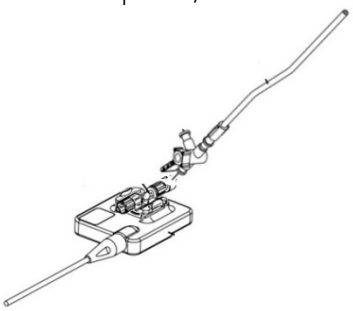
1. Position patient in side-lying or other comfortable position for insertion.
2. Take each cartridge out of its package, and remove the protective covers from the back and from the connector ends.

3. Gently squeeze both sides of the cartridge and slide it over the TRA168 transducer until it clicks into place.



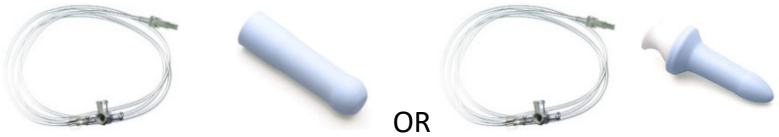
Annex, Figure 6: Transducer Setup

4. Attach pressure tubing, with an attached stopcock, to the lower (male) end of the cartridge.



Annex, Figure 7: Pressure Tubing and Transducer Setup

5. Connect the pressure tubing to the corresponding Vaginal/Anal Manometry Probe.



OR

Annex, Figure 8: Probe and Pressure Tubing Setup

6. Spread a light coating of lubricating gel on the probe to ease insertion.
7. Carefully insert the lubricated probe.
8. Use a syringe to inflate the probe with 3 cc's of air for vaginal probe. The anal probe requires 1cc of air. Confirm it is not too hard or too soft.

Annex, Figure 9: Inflate Probe

9. Hold the probe in position during therapy.

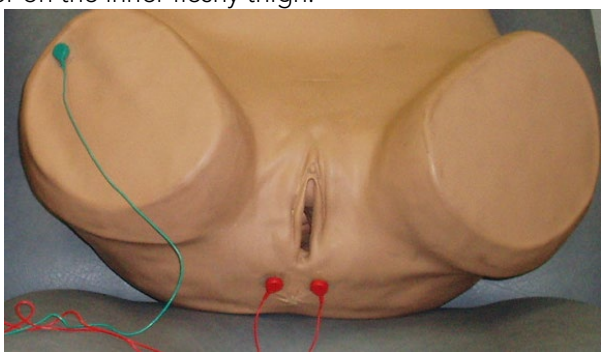
NOTE: Do not move the cartridge during tests; movement of the cartridge may affect readings.

10. After use, clean the probe with soap and water and store dry.

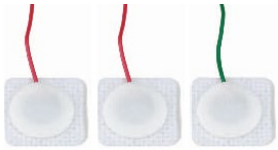
Abdomen

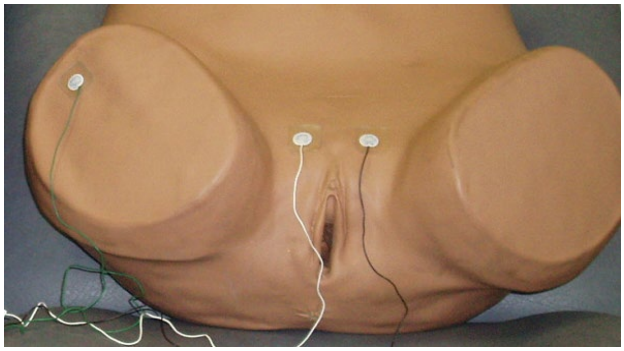
- Apply two surface electrodes to the right or left abdomen, near the level of the hip. Apply the third, ground electrode, to the hip bone region or on the inner fleshy thigh.

Abd: ELE425 electrodes

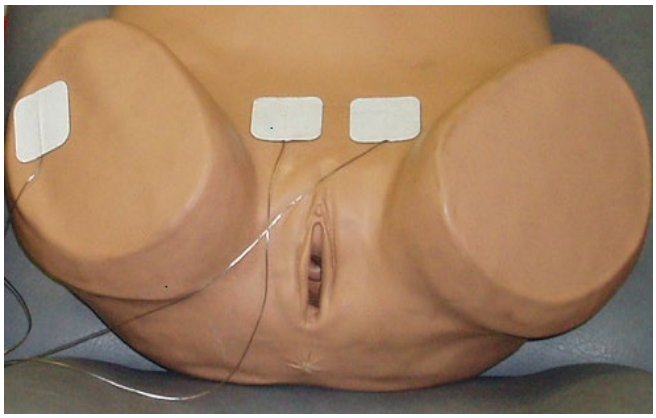


Abd: ELE428 electrodes





Abd: ELE625 electrodes



Annex, Table 4: EMG Setup

5.4 BEGINNING THE PELVIC FLOOR STRENGTHENING PROGRAM

- Document any failed treatment (such as Kegel exercises for 6 weeks) before starting PMR.
- Review and document patient symptoms during each session.
- Assign pelvic floor home exercises to be performed 2-3 times daily: repetitions and relaxations for long squeezes and short squeezes based upon the individual's demonstrated ability during each therapy session.
- Patients are typically placed in a semi-reclined position or on their side. The probe is inserted (by clinician or patient) using an ultrasound gel. *Note: standard water-soluble lubricants are not adequate and should not be used.* The probe is inserted properly when the "curve" or narrowing in the probe is at the point of

exiting the body. *** ALWAYS verify probe positioning before starting stimulation. Starting the stimulation when the probe is not inserted properly may be painful.*

- If you are unable to use a probe with a particular patient, surface patch electrodes may be used perianally instead. These may be patients who refuse the probe or have severe Prolapse. In this case, the ELE625 surface electrodes are better for this population.

5.5 SELECTING PROTOCOLS BASED ON DIAGNOSIS

5.5.1 STRESS URINARY INCONTINENCE

Protocol Name	Stimulation	PMR
Incont. (start of treatment)		Y
Incont. (end of treatment)		Y
Stress Incontinence.	Y	
Mixed Urge/Stress Incont.	Y	
Mixed Stim/Bio Treatment.	Y	Y
Mixed Urinary Incontinence	Y	Y
Stress Urinary Incontinence	Y	Y
Weakened Pelvic Floor Musculature		Y
Manometry, Incontinence Start of Treatment		Y
Manometry, Incontinence End of Treatment		Y
Quick Flicks		Y

Annex, Table 5: Stress Urinary Incontinence Protocols

5.5.2 URGE URINARY INCONTINENCE

Protocol Name	Stimulation	PMR
Incont. (start of treatment)		Y
Incont. (end of treatment)		Y
Mixed Urge/Stress Incont.	Y	
Mixed Stim/Bio Treatment.	Y	Y
Mixed Urinary Incontinence	Y	Y
Weakened Pelvic Floor Musculature		Y
Urge Incontinence.	Y	
Urge Urinary Incontinence	Y	Y
Manometry, Incontinence Start of Treatment		Y
Manometry, Incontinence End of Treatment		Y

Annex, Table 6: Urge Urinary Incontinence Protocols

5.5.3 MIXED URINARY INCONTINENCE

Protocol Name	Stimulation	PMR
Incont. (start of treatment)		Y
Incont. (end of treatment)		Y
Mixed Urge/Stress Incont.	Y	
Mixed Stim/Bio Treatment.	Y	Y
Mixed Urinary Incontinence	Y	Y
Weakened Pelvic Floor Musculature		Y
Urge Incontinence.	Y	
Urge Urinary Incontinence	Y	Y
Manometry, Incontinence Start of Treatment		Y
Manometry, Incontinence End of Treatment		Y
Quick Flicks		Y

Annex, Table 7: Mixed Urinary Incontinence Protocols

5.5.4 URINARY RETENTION

Protocol Name	Stimulation	PMR
Urinary Retention	Y	
Pediatric		Y
Beginner Pediatric		Y
Intermediate Pediatric		Y
Uroflow2EMGS (a diagnostic tool useful for treating Urinary Retention)		Y

Annex, Table 8: Urinary Retention Protocols

5.5.5 PELVIC PAIN

Protocol Name	Stimulation	PMR
Pelvic Pain	Y	
Pediatric		Y
Beginner Pediatric		Y
Intermediate Pediatric		Y

Annex, Table: Pelvic Pain Protocols

5.5.6 FECAL INCONTINENCE

Protocol Name	Stimulation	PMR
Incont. (start of treatment)		Y
Incont. (end of treatment)		Y

Stress Incontinence.	Y	
Mixed Urge/Stress Incont.	Y	
Mixed Stim/Bio Treatment.	Y	Y
Mixed Urinary Incontinence	Y	Y
Stress Urinary Incontinence	Y	Y
Weakened Pelvic Floor Musculature		Y
Urge Incontinence.	Y	
Urge Urinary Incontinence	Y	Y
Manometry, Incontinence Start of Treatment		Y
Manometry, Incontinence End of Treatment		Y

Annex, Table 9: Fecal Incontinence Protocols

5.5.7 CONSTIPATION

Protocol Name	Stimulation	PMR
Mixed Urge/Stress Incont.	Y	
Mixed Stim/Bio Treatment.	Y	Y
Mixed Urinary Incontinence	Y	Y
Urge Urinary Incontinence	Y	Y
Pediatric		Y
Beginner Pediatric		Y
Intermediate Pediatric		Y

Annex, Table 10: Constipation Protocols

5.6 HOW TO MEASURE SUCCESS

1. **Transformation from wet to dry**, or from depressed to empowered, requires a comprehensive approach: mental, physical, spiritual and emotional.
2. **Routine**, consistent use of voiding / bladder diaries.
3. **Diet and fluid intake** guidance and handouts for home use and completion; use to measure success over time.
4. **Quality of Life** (QOL) assessment which takes into account the amount and number of 'accidents' per day. This assessment is used with each visit to chart success.
5. Notice the amount of **effort** needed to complete the selected protocol. Over time effort will be less as tone and strength improve — indicating the need for a more challenging protocol.
6. Note when **fatigue** starts while performing the protocol. Is it at the beginning, middle or the end of the protocol? Fatigue is measured by increasing use of accessory muscles, for instance squeezing gluteal and/or abdominal muscles, or holding their breath to complete a phase or to reach the goal.
7. Note the patient's change of positioning during 'effort'/ work. Do they start to employ accessory muscles to aid in their success? Have they started to hold their breath to succeed? See *Fatigue* section below.
8. As with any muscle-building endeavor, make it easy and not impossible in the beginning to allow for success, which rewards a patient's efforts. They will want to return and they will do their homework, too! *Not really a measurement of success but a key to achieving success!*
9. Review their homework chart with every visit. Encourage and praise their efforts.

5.7 FATIGUE

Consider ending therapy sessions when the patient shows signs of fatigue. Muscle **Fatigue** may be noted in one or all of the following ways:

- When the ability to hold the long contraction starts to diminish.
- When the ability to perform quick flicks of equal heights starts to fall.
- When use of accessory muscles (abdominal and/or gluteal) increases.

5.8 PEDIATRIC PELVIC FLOOR THERAPY

Dysfunctional elimination syndrome (DES) denotes an abnormal pattern of elimination for the child characterized by urinary and bowel incontinence and withholding.[ii] (along with history of UTIs). The child's efforts to stay dry or to avoid voiding results in high muscle tone, and limited voidings (which eventually results in incontinence)

The cause is not well defined but may include delayed developmental control, effects of environmental/ social factors, UTI and learned behavior. There is controversy over the use of disposable diapers and delayed toilet training. Here culture and education play their roles.

The main goal is to restore a normal micturition pattern, reduce or relax pelvic floor activity, eliminate incontinence, UTI, and constipation. DES management requires a combination of cognitive, behavioral and physical approaches. The support and encouragement of the family members is built into the combination of approaches.

5.8.1 STEPS TO INITIATING THERAPY WITH CHILDREN

Items needed:

- Two sets of surface electrodes for the pelvic floor and the abdomen.
- Empty beaker placed on the Uroflow transducer.
- Bladder ultrasound probe, ultrasound gel, tissues for cleaning 'jelly belly'.
- Step stool for short legs while seated on the commode chair.
- A toilet seat insert for smaller children.
- Two minute timer to 'slow down time for voiding'.
- Softer rubber balls: four-inch and six-inch diameter balls.
- Toilet paper and receptacle.
- Privacy screen/ curtain.
- Rewards basket to pick from at completion of study.
- Cups for water (should they come with an empty bladder).
- Protocol selected for sessions: Uroflow / 2 EMG, beginner pediatric.
- Voiding, stool, fluid and diet charts.
- Give or display a copy of the Bristol stool chart (*example on page - 136 -*) and fiber foods list.
- Instructions on obtaining a voiding history.
- Instruction on PMR homework and voiding practices for home.
- School excuse for appointments.
- Instructions for school nurse / teacher to allow for timed voidings in school.
- Alarm or watch choices, for example Potty MD™.

5.8.2 BASIC APPROACH

Keeping mindful of the fear associated with visits to the doctor, have a set of electrodes available to 'show and tell', and to place on and off a doll or their own arm. If there is an initial visit planned without treatment sessions, send a set of electrodes home with the parents to position on their child's 'bottom' as will be performed in the actual session. This is also the time to instruct on the routine needed for the start of all sessions:

- The younger children are invited to bring their favorite stuffed animal as a guest.
- Provide a selection from a rewards basket for cooperation at session's end.
- Make it fun and enjoyable. There has been much stress for these children related to voiding and overall behavior.
- Remind parents to have the child arrive with a full bladder.
- If siblings must come, they and the parents may enjoy time together in the waiting area.

5.8.3 FIRST SESSION

If time and the child allows (with their full bladder), you may take a pre-voiding measurement of the bladder volume using a bladder scanner or ultrasound probe. Take this opportunity to apply the surface electrodes to the peri-anal region. Apply to the pelvic floor region and not onto the gluteal region. Apply the second set of electrodes to the lower abdomen. The ground is placed on a hip bone or inner thigh for both sets of electrodes.

When ready to void:

- Select the Uroflow/2EMG protocol.
- Perform the adjustment screen (scaling for relaxed and max contraction) for each channel.
- Set the volume and flow selections appropriate for the child's age.
- Once screens are completed, it is time for the child to sit on the commode chair and void.
- Position the screen for their viewing.

You may wish to select the audible icon for either channel 1 or 2. The audible selected is dependent upon the child's EMG picture. Are the channel 1 muscles employed more than channel 2 or is it the opposite? If you note high use of the abdomen to 'push' during voiding, channel 2 could be chosen to highlight the need to 'calm' this area during voiding. Should the pelvic floor muscles be overactive, creating the saw-tooth or intermittent voiding picture, highlight channel 1 as audible to aid in relaxation emphasis and to create the 'bell curve'.

If they have a "shy bladder" at this time, start a PMR session while they are positioned on the commode chair and provide a cup of water for drinking as well.

There is no rule for the order of protocols. The goal is to address their voiding picture by increasing awareness of muscle use. Awareness of the need for relaxation is key to improved voiding, including providing relaxation techniques such as deep breathing using the 2 minute timer. PMR sessions are selected to heighten their awareness with emphasis on relaxation. Here the goal is to increase the time at toileting. Often these children take less time than needed to void thus leaving the toilet when not completely empty.

Note the voiding position as well as a girl's wiping practice. Note the color and aroma of urine.

Perform a post-void residual (PVR) measurement immediately after voiding. It may be necessary to ask the child to void again based upon this measurement. This is called 'double voiding'.

Please note PVR measurements in the Comments section of the Uroflow report. You may wish to give the child a record of the voiding graphic in order to work toward improvement.

Second and Subsequent Sessions

The child and family are now aware of the 'game plan'. They bring in diet, fluid, voiding and stool records. Rewards are visible with stars or stickers on their charts.

Uroflowmetry is first, otherwise start with the assessment and/or PMR sessions appropriate for the child. If they have high 'relaxation' (tone) or difficulty relaxing, use the protocols which allow for success in both relaxation and contractions. If they have "giggle incontinence", for example, use the protocols that emphasize quick contractions.

Giggle Incontinence, defined as urine lost when laughing or with stress efforts, requires a quick flick protocol which emphasizes the quick squeeze muscles. Combine this with instructions for home on the Knack technique: squeeze before laughter and any other stress related effort. They must employ the quick squeeze muscles in their homework, too.

Review the voiding curve and the contraction / relaxation picture with them. Ask them what is their practice when voiding at home and school. Do they take enough time? Enlighten them to the change that is required for greater and greater improvement.

Check a PVR after the voiding. Compare to previous PVR measurements. Is there improvement? Go on to the PMR sessions next. Keep in mind their attention span and employ the video games near the end of the sessions.

5.8.4 PMR SESSIONS

Is there a recommended position for PMR? With children, the most important emphasis is on their comfort and building their confidence with the visit, so they may sit or stand. Much depends on the diagnosis and on their ability to perform in the position of their choosing. Use this time to experiment with the position that allows for the most relaxed outcome. Have them help you to find this optimal position. You will note the easiest position for relaxation is seated. And boys are encouraged to sit to void during these sessions in order to aid in their relaxation efforts.

Since seated is usually the optimal position, employ props such as a rubber ball to aid in identification of the pelvic floor. This allows them to squeeze the ball between their knees for contraction and to release the ball for relaxation. Props are helpful initially to aid in identification. Another recommendation is to ask them to squeeze as if holding back 'gas'.

5.8.5 HOW MANY SESSIONS?

The number of sessions and the spacing between sessions is determined by both the patient's progress (or lack thereof) and the clinician's evaluation of parent support / understanding for home practice. There is no firm recommended number of sessions as each child and their situation varies.

Generally speaking, 5 to 8 sessions are the common amount needed; however, some will only need to see the voiding picture once and they understand it while others may need more time. Consider stressors at home and school should you note a regression during sessions.

The overall picture of progress – be it slow or fast – can be seen by factors such as: improved relaxation during Uroflowmetry or PMR sessions, improving (decreasing) PVR, and decreasing incidence of UTI's.

5.8.6 WHEN IS GRADUATION?

This requires a multifaceted review of behaviors and outcomes.

- You will note improved (decreasing) PVRs
- Improved understanding and relaxation during voiding.
- There is a decrease or elimination of UTIs.
- There are no reports of leakage
- Timed voiding is now a daily practice at school and at home.
- Fluid intake has improved
- Increased fiber intake.
- There may also be a report of improvement in the night time record of dryness as well!
- Bowel management is appropriate.

Should the need for a 'tune-up' visit occur at some later time; this is ok.

5.8.7 UROFLOWMETRY

Uroflowmetry is a non-invasive screening tool used as an indicator of lower urinary tract function that measures the flow rate and volume over time. Combining Uroflowmetry with the measurement of post void residual (PVR) urine is useful in the evaluation of bladder outlet obstruction and voiding dysfunction.

Uroflowmetry combined with EMG monitoring of the pelvic floor and abdominal muscles provides a clear portrait of both pelvic and abdominal muscle involvement during voiding.

Accurate Uroflowmetry requires a voiding volume of at least 60 cc in pediatrics and 150cc in adults (but <600 cc). Interpretation includes a description of the flow pattern. Normal flow pattern is a smooth, bell shaped curve. Age, sex and volume affect the flow rate. Spikes and /or quick fluctuations may be the result of muscle straining, contracting or even beaker movement. The EMG picture aids in determining the influence of muscles upon voiding.

Dysfunctional (immature) voiding is common in children; however, there are also cases of dysfunctional voiding in adults with and without obstructional etiology. Use of EMG monitoring with the Uroflow is highly recommended for the complete picture.

For the evaluation of Uroflowmetry, the International Continence Society has recommended the following definitions from Abrams, Blaivas, Stanton, & Andefson, 1988 [iii]:

- Voided volume: Total volume of urine expelled from the bladder.
- Flow time: The time over which measurable flow actually occurs.
- Residual urine volume (PVR): The total volume of urine remaining in the bladder after voiding.
- Maximum Flow Rate (Qmax) The maximum measured value of the flow rate in ml/sec.
- Time to maximum flow: The elapsed lime from the onset of flow to the point of maximum flow
- Continuous urinary flow: A constant urinary stream without interruptions.
- Mean flow rate (Qmean): Volume voided divided by flow time. The average flow rate is only interpretable if flow is continuous without aberrancy, either at the initiation or termination of voiding.
- Flow pattern: Subjective description of the regularity of voiding. The flow pattern must be described when the flow time and average flow rate are measured
- Intermittent flow: Flow pattern in which interruptions of varying duration occur between episodes of voiding.

The average flow rates vary depending on age and sex [iv]:

	Males	Females
Ages 4 – 7	10 mL/sec.	10 mL/sec.
Ages 8 - 13	12 mL/sec	15 mL/sec
Ages 14 – 45	21 mL/sec	18 mL/sec
Ages 46 – 65	12 mL/sec	15 mL/sec
Ages 66 – 80	9 mL/sec	10 mL/sec

Annex, Table 11: Flow Rates

Normal values for Uroflowmetry [v]

Males	< 40 years old >22 ml/sec 40-60 years old >19 ml/sec >60 years old >13 ml/sec
Females	<50 years old >25 >50 years old > 18

Annex, Table 12: Normal Values

5.9 DEFINITIONS USEFUL WITH PELVIC FLOOR MUSCLE REHABILITATION (PFR)

Anal Sphincter: Two rings of muscles, internal and external, surrounding the rectum and anus which helps to control passage of bowel movements.

Anus: Muscular opening at the end of the rectum and is the outlet for solid waste.

Behavioral Therapy: Treatment that uses conditioning and awareness to change behavior. This may be done with PMR, bladder training, electrical stimulation, habit training, pelvic muscle exercises and prompted voidings.

Benign Prostatic Hyperplasia (BPH): Condition characterized by the benign growth of the prostate, often resulting in voiding difficulties due to the obstruction. Also known as benign prostatic hypertrophy.

Bladder: Muscular organ located in the pelvis for temporary storage of urine.

Bladder Training: Exercises that focus on changing urinary habits and patterns. A person is encouraged to hold (resist or inhibit urgency to void) urine for increasingly longer periods of time, until the comfortable voiding interval is increased. This technique is used in the treatment of urge incontinence, interstitial cystitis, and frequency.

Colon: Lower portion of large intestine leading to the rectum.

Conservative Approach or Treatment: Any non-surgical technique to treat incontinence.

Constipation: Hard, dry, firm bowel movements that are difficult to pass and less frequent than twice a week; may contribute to voiding difficulties.

Cystocele: Bulging of the bladder into the anterior vaginal wall.

Diuretic: Any drug, food or beverage that promotes increased urine excretion.

Electrical Stimulation: Application of an electrical current to stimulate a muscle contraction. It also serves to help identify muscles to those lacking in sensation. This is accomplished with vaginal or rectal probes or surface electrodes.

Encopresis: Uncontrolled bowel movements or smears of feces into underwear or inappropriate places by an individual over the age of four.

Enuresis: Involuntary loss of urine; during sleep termed 'nocturnal'.

Episiotomy: Surgical incision into the perineum between the vagina and anus to ease childbirth through the vagina.

Estrogen: Hormone contributing to female sexual characteristics, produced in the female ovaries and male testicles, in adrenal glands and fat.

Fecal Impaction: A hard mass of stool packed in the rectum rather than passing through normally. Impaction can contribute to incontinence.

Fecal Incontinence: Accidental and involuntary loss of liquid or solid stool or gas from the anus.

Frequency: Voiding more than 8 times in a twenty-four hour period.

Functional Incontinence: Physical disability or mental confusion leading to inability to void in appropriate places

Hormone: Chemical substances made in endocrine glands and essential for human biological processes.

Hysterectomy: Surgical removal of the uterus

Incontinence: Loss of urine.

Kegel Exercises: Pelvic muscle exercise to decrease or eliminate incontinence.

Mixed Urinary Incontinence: A combination of urge and stress incontinence.

Overflow Incontinence: Temporary inability to void, followed by uncontrollable urine flow, associated with over distension of the bladder.

Pelvic Diaphragm : The levator ani muscle group.

Pelvic Muscles: General term referring to the muscles of the pelvic diaphragm and urogenital diaphragm as one unit, sometimes referred to as the pelvic floor muscles.

Pelvic Muscle Exercises (PMEs): Repetitive exercises of the Pubococcygeal muscles also referred to as Kegel or *pelvic floor exercises.*

Pelvic Muscle Weights: Small weights placed in the vagina to offer resistance for the muscles to contract against.

Perineum/Perineal Muscles: Area of muscle and tissue between the vagina or scrotum and anus.

Pessaries: Devices for women placed intravaginally to treat pelvic relaxation or prolapse of pelvic organs.

PMR: A technique in which a person learns to consciously control involuntary responses such as heart rate, brain waves, and muscle contractions, by having these responses electronically monitored and noted through sound, graphs, or on a screen. In terms of pelvic floor rehabilitation, computerized equipment is used to monitor and record progress.

Prostate: Firm, muscular gland that surrounds the urethra in males.

Prostatectomy: Removal of all or part of the prostate gland.

Prostatitis: Infection of the prostate; acute or chronic.

Rectocele: A bulging of the rectum into the posterior vaginal wall.

Rectum: Final several inches of the intestines below the colon and above the anus.

Reflex Incontinence: Loss of urine due to hyperactivity of the bladder muscle and/or involuntary urethral relaxation in the absence of the sensation associated with the desire to urinate. This occurs in neurogenic disorders.

Scheduled Toileting: Fixed schedule of voiding; for example, every 2 to 4 hours. Also known as timed voiding or prompted voiding.

Sphincter: Circular muscle that tightens and relaxes to control the flow of urine from the urethra. There are internal and external urethral and anal sphincters.

Stress Incontinence: Loss of small amounts of urine with increased intra-abdominal pressure during coughing, sneezing, laughing, jumping and running.

Urethra: Tube connecting the bladder to the outside for the passage of urine.

Urge Incontinence: Sudden leaking of relatively large amounts of urine when the bladder muscle contracts, overcoming the contractions of the pelvic muscles.

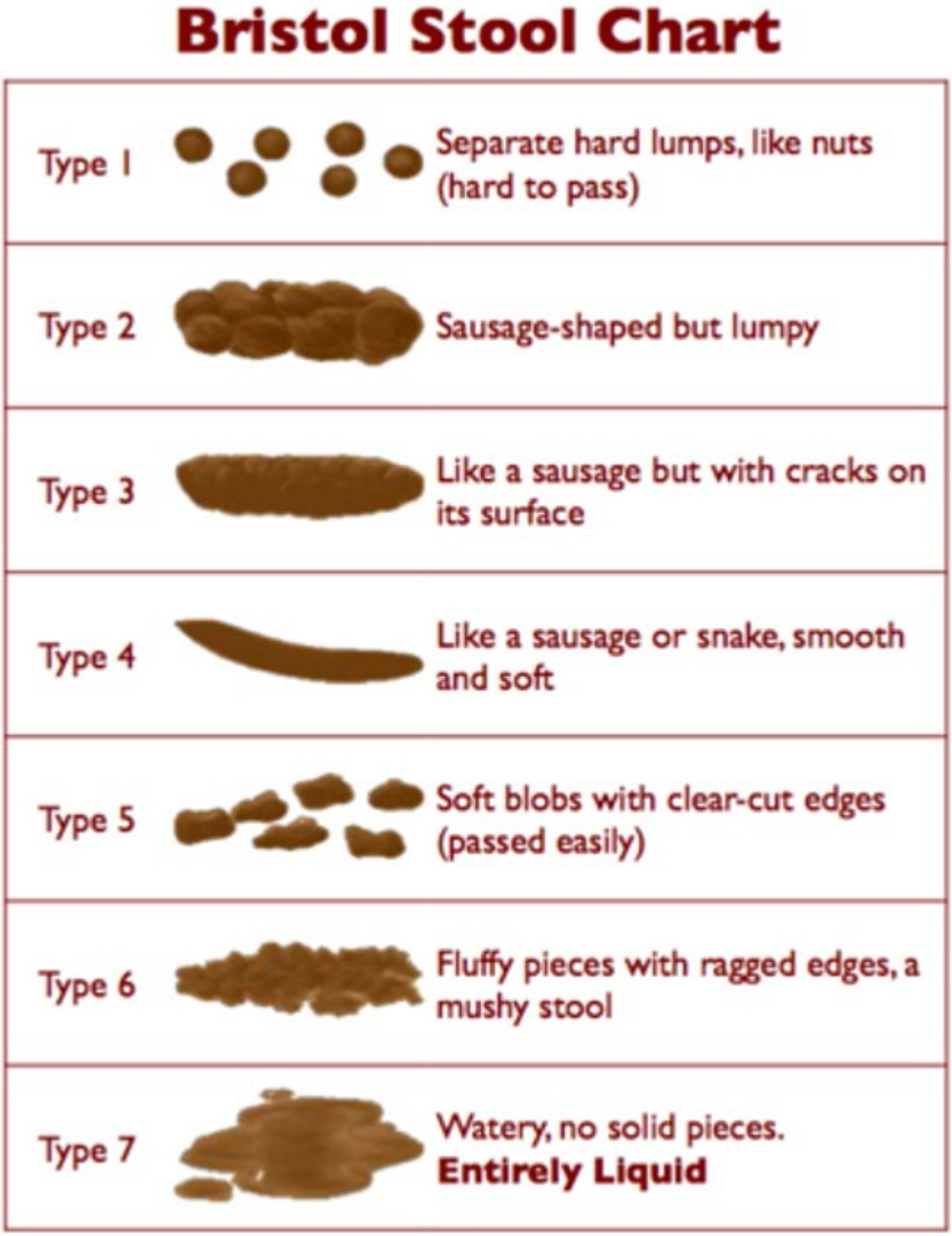
Urinary Retention: Inability to empty the bladder, which may lead to bladder and kidney damage.

Urinary Tract Infection (UTI): Inflammation of the Urinary tract.

Uterine Prolapse: Descent of the uterus into the vaginal canal.

Valsalva Maneuver: The action of closing the airway and straining down on the abdominal muscles (such as straining during bowel movements).

5.10 BRISTOL STOOL CHART [vi]



Reprinted courtesy of Lewis, SJ, and Heaton, KW. University Dept. of Medicine, Bristol Royal Infirmary, UK.

Annex, Table 13: Bristol Stool Chart

REFERENCES

1. AHCPR Clinical Practice Guideline, *Urinary Incontinence in Adults*: Acute and Chronic management, No. 2, 1996 Update, Publication # 96-0682, US Dept. of Health and Human Services, Rockville, Maryland
2. Brown, C., *Pelvic Floor Rehabilitation*: A Practical Approach, Chapter 30, The Urinary Sphincter, edited by Corcos, J and Schick, E: Dekker, NY 2001
3. Burgio, K: *Staying Dry*. The John Hopkins Press Ltd., London, 1989
4. Carrière, B., Markel Feldt, C: *The Pelvic Floor*, Theime, New York, 2006
5. Carrière, B., *Fitness for the Pelvic Floor*, Thieme, Stutgart-New York,2002
6. Chalker R, Whitmore KE: *Overcoming Bladder Disorders*, New York, Harper Perennial, 1991
7. Chiarelli, P.: *Women's Waterworks*. www.womenswaterworks.com, copyright 2005
8. Corcos, J, Schick, E: *The Urinary Sphincter*, Dekker, NY 2001
9. Hulme, J.A.: *Beyond Kegels*
10. Newman, D. K., *The Urinary Incontinence Sourcebook*, Lowell House, 1997
11. Wise, D., Anderson, R.: *A Headache in the Pelvis*
12. http://www.netdoctor.co.uk/womenshealth/sui/ui_005139.htm Lessening the Burden By Amy U. Altman, MPT
13. Dallosso et al: Dallosso, HM, McGrother, CW, Matthews, RJ, & Donaldson, MMK. The association of diet and other lifestyle factors with overactive bladder and stress incontinence: a longitudinal study in women. BJU International 2003 92 (1), 69.

PEDIATRICS

1. Branzei, S., Grossology and You, Price Stern Sloan, 2002
2. Bennett, H., Waking Up Dry: A Guide to Help Children Overcome Bedwetting. American Academy Of Pediatrics; 1st Ed., 2005
3. Cho, S. The Gas We Pass: The Story of Farts. Kane/Miller, 1st Ed.,1994
4. Mercer, R.: Seven Steps to Nighttime Dryness: A Practical Guide for Parents of Children with Bedwetting, Brookeville Media Llc; First Printing edition 2004
5. Goodman, S.E. Gee Whiz! It's all about PEE. Viking Juvenile, 2006
6. Goodman, S.E. The Truth about Poop. Viking Juvenile, 2004

[i] A Cannon. AW Thomas, E Bartlett, J Ellis-Jones, L Chambers and P Abrams. BLADDER CONTRACTILICITY AND VOIDING EFFICIENCY IN MEN WITH BLADDER OUTLET OBSTRUCTION TREATED CONSERVATIVELY AND BY TURP. Bristol Urological Institute, Bristol, United Kingdom. Informally discussed posters, ICS 2000 Tampere.

[ii] Koff SA, Wagner TT, Jayanthi VR (1998) The relationship among dysfunctional elimination syndromes, primary vesicoureteral reflux and urinary tract infections in children. J Urol 160:1019–1022.

[iii] Abrams P, Blaivas JG, Stanton SL, Andersen JT. The standardisation of terminology of lower urinary tract function. The International Continence Society Committee on Standardisation of Terminology. Scand J Urol Nephrol Suppl. (1988) 114:5-19

[iv] http://adam.about.com/encyclopedia/Uroflowmetry.htm

[v] Walsh, PC. et al. Campbell's Urology. Saunders, 8th Ed., 2002

[vi] Lewis SJ, Heaton KW (1997). "Stool form scale as a useful guide to intestinal transit time". *Scand. J. Gastroenterol.* **32** (9): 920–4. PMID 9299672.