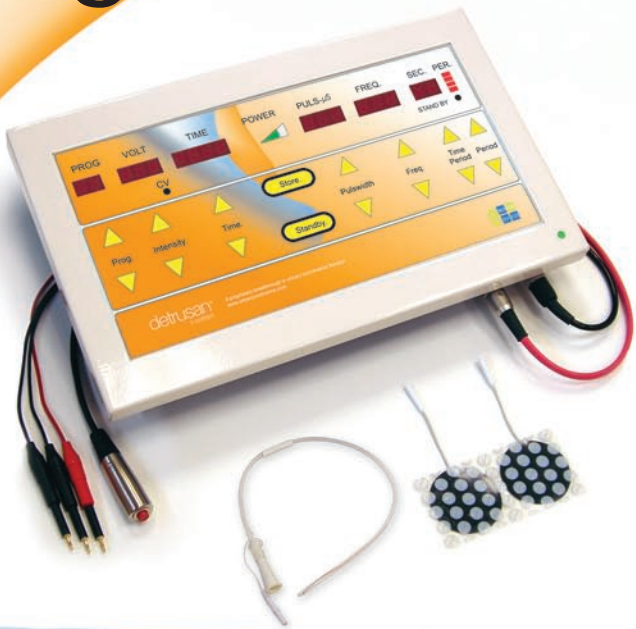
clinician guide



detrusan®

b cont•fident

A proprietary breakthrough in urinary incontinence therapy!

www.urinarycontinence.com

Preface

detrusan® Urinary Incontinence Treatment System

Urinary Incontinence (UI) can be treated using a variety of clinical and non-clinical procedures. Clinical treatments can range from medication to surgery while non-clinical methods typically include diet modification, pelvic floor exercises or biofeedback.

detrusan® is an extraordinary device that offers perhaps the most effective treatment for bladder function restoration on the market. It is based on using natural, electrical stimulation to exercise the muscles in and around the bladder.

detrusan® was designed to take advantage of decades of clinical research. Its patented technology enables stimulation protocols optimized for specific conditions including urinary incontinence and lower spinal cord injury. This remarkable device includes a built-in computer with extensive hardware and software features conveniently enabling all of the necessary functions within a single unit.

The ***detrusan®*** system includes patented disposable catheters, or ***detrusets®***, that have been clinically engineered to provide optimal delivery of electrical stimulation into the bladder, lower spine and pelvic floor. Use of ***detrusets®*** in conjunction with the ***detrusan®*** 500 electrical stimulation unit allows many patients to regain control of their bladder functions in a safe and comfortable manner. In short, the ***detrusan®*** system offers one of the most efficacious platforms for the treatment of Urinary Incontinence on the market today.

b cont•fident!

Table of Contents

Part 1: The Device and Its Accessories

Part 2: Clinical Considerations

Part 3: Therapy Administration

Necessary Equipment and Accessories

Accessories Included in the detrusan® Package:

Product Code	Quantity	Description
185_0550CE	1	***detrusan®*** 500 base device
185_5600CE	1	***detrusan®*** Clinician Guide
185_5607	1	Biomedical System Calibration Certification
185_5252	1	Emergency Stop Switch
185_5251	1	Universal Extension Cable
185_5302	3	Reduction Adapters 4 mm to 2 mm
185_5301	1	Patient Cable for ***detruset®*** Catheters
185_5201	1	Power Cord
NA	1	***detrusan®*** Training Video (DVD)
NA	1	***detrusan®*** Digital Treatment Kit (CD)

Additional Accessories Available at EMED®:

Product Code	Description
185_5001	***detruset®*** Electrotherapy Catheter CH8
185_5002	***detruset®*** Electrotherapy Catheter CH10
185_5003	***detruset®*** Electrotherapy Catheter CH12
185_5400	Ground Electrodes 2" x 2" (4 pc)
CL-150	***detruset®*** Urinary Catheter Clamp

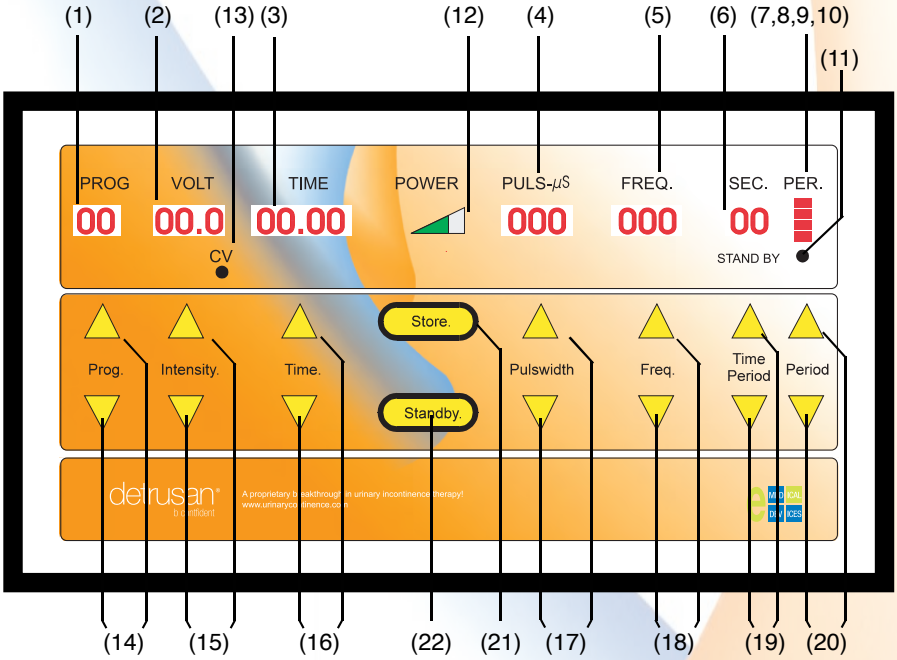
Additional Accessories Sold Separately:

Description

- Water-soluble, disinfecting lubricant (non-anesthetic)
- Catheterization site disinfecting solution
- 60 mL Syringe
- 150 mL of 0.9% (NaCl) sterile saline solution

Panel Displays and Indicators

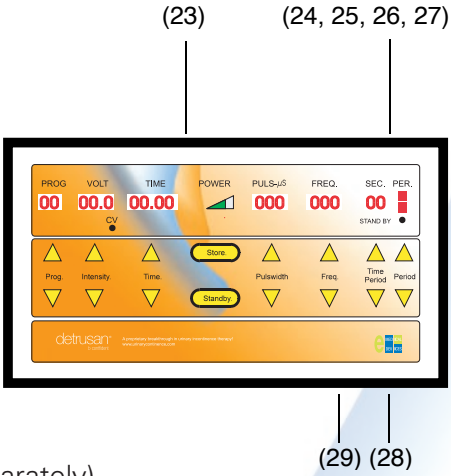
1 Display "Program Number"
2 Display "Intensity"
3 Display "Time of Treatment"
4 Display "Impulse Width"
5 Display "Impulse Frequency"
6 Display "Period"
7 Display "First Rest"
8 Display "Second Rest"
9 Display "Third Rest"
10 Display "Fourth Rest"
11 Display "Stand By"
12 Intensity LED
13 Control Voltage LED
14 Program Select Keys
15 Intensity Inc/Dec Keys
16 Treatment Time Inc/Dec Keys
17 Impulse Width Inc/Dec Keys
18 Impulse Frequency Inc/Dec Keys
19 Time Period Inc/Dec Keys
20 Rest, Phase of Stimulation, Phase of Feedback Select Keys
21 Store Program Key
22 Stand By Select Key

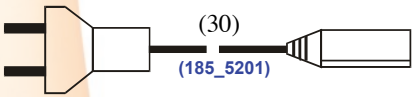


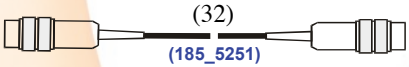
Connections, Switches and Cables

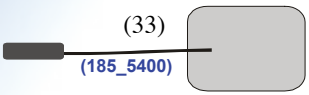
detrusan® 500 Base Unit Connections

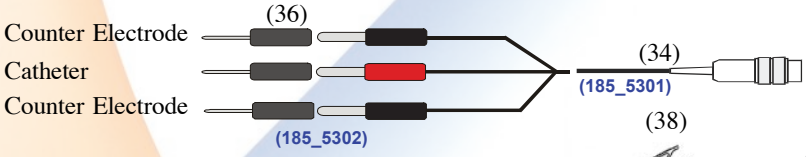
23 Serial Number
24 Power Connection
25 Fuse Box
26 Fuse Carrier
27 Main Switch
28 Stimulation Emergency Stop Switch
29 Extension Probe/Patient Cable Accessories
30 Power Cable (sold separately)
31 Emergency Stop Switch
32 Universal Extension Cable
33 Counter Electrode (sold separately)
34 Patient Cable
35 ***detruset®*** Catheter
36 Reduction Adapter
37 ***detruset®*** Female Electrical Lead
38 ***detruset®*** Catheter Clamp (sold separately)

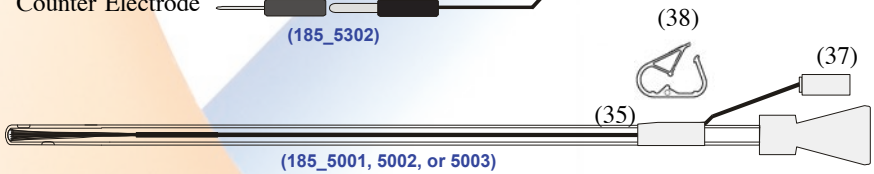












Technical Specifications

MEDICAL APPLIANCE CLASS	876.5320
SAFETY CLASS	MODERATE
FDA 510(k) NOTIFICATION	K994109
VOLTAGE	220 V / 50 Hz ±10%
FUSES	2 x 1.15 AF
DIMENSIONS	L=432 x B=280 x H=90 mm
WEIGHT	3.5 kg (7.72 lbs)
ENVIRONMENTAL CONDITIONS	TEMPERATURE: -10°C to +40°C
HUMIDITY	30 - 77%
PULSE SHAPE	Biphasic, symmetrical rectangular pulse
PULSE WIDTH	10 - 400 µsec
PULSE FREQUENCY	1 - 100 Hz
INTENSITY	0 - 127 V at 500 Ω - max.80 mA
TYPE OF STABILIZING	Constant Voltage
MAX PULSE POWER	32 µC Singlepulse, 62 µC Doublepulse (AC)
STIMULATION / REST	0 - 60 sec
NUMBER OF PROGRAMS	100

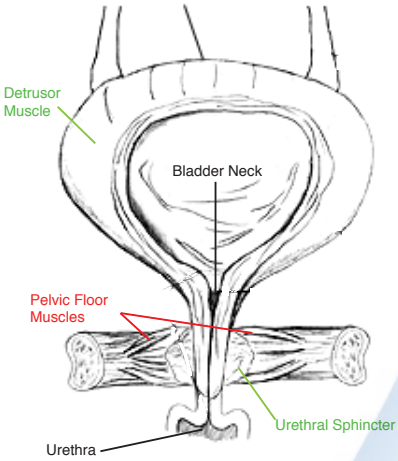
Reference

At a static voltage above 500 V, the microprocessor switches to "ERROR" mode and the display screens are no longer fully illuminated. This is necessary to protect both the patient and the operator against program malfunction during treatment. Once it is in this state, the unit will need to be reset by a staff member who has been trained using the ***detrusan®*** 500 device.

The warranty of this product is VOID if service or repair is performed by personnel NOT authorized, in writing, by EMED® Corporation. In case of injury to the user or patient from improper repair, service or tampering by persons WITHOUT written authorization from EMED® Corporation, EMED® is absolved of all responsibility.

The Continence Mechanism

The muscular mechanism controlling Urinary Continence is both complex and counteractive. The figure to the right provides an elementary illustration of the key muscle groups that are activated during a typical Urinary Continence cycle of bladder filling and voiding: namely the detrusor, urethral sphincters and pelvic floor muscles.



As a properly functioning bladder fills, the detrusor relaxes (or is inhibited) allowing the bladder to expand providing additional volume for urine storage. Meanwhile, the urethral sphincters and pelvic floor muscles constrict to essentially seal the urethra and contain the urine within the bladder. During voiding, however, the exact opposite effect is observed. As the detrusor becomes stimulated, it constricts the bladder forcing the urine out. While the urine is expelled from the bladder, the sphincters and pelvic floor muscles relax allowing it to pass freely through the urethra.

Urinary Incontinence typically results from a malfunction within the afore-mentioned mechanism causing involuntary constriction or relaxation of the bladder muscles and undesired urine retention or leakage. Successful treatment of Urinary Incontinence, therefore, involves re-training these muscle groups to establish proper functionality. One method that has provided consistent positive results in the re-training of bladder muscles is electrical stimulation.

Electrical Stimulation

Electrical stimulation of the bladder involves delivering pulsate or continuous doses of electricity to the muscles and their surrounding tissue. This can be accomplished using either anal or vaginal probes, or intravesical catheters. Anal and vaginal probes deliver electrical stimulation to the pelvic floor muscles while intravesical catheters are indicated to stimulate *all* of the muscle groups within the continence mechanism. Although probes have provided the more traditional means of bladder electrostimulation with consistent success, studies have shown that Intravesical Electrostimulation (IVES) through urinary catheters offers increased efficacy over the conventional probe technique in both male and female patients because it entails the stimulation of both the muscle tissue of the bladder as well as specific receptors within the bladder wall (1). Therefore, because muscle movement requires the integration of muscle tone, muscle activation, and sensory feedback, intravesical electrostimulation, enhances proprioception of the bladder muscles.

The ***detrusan®*** electrical stimulation system offers perhaps the most efficacious treatment platform for Urinary Incontinence on the market because it facilitates IVES with EMED® Corporation's proprietary urinary catheters, or ***detrusets®***, designed specifically for the optimization of electrical stimulation to the bladder. Please review the subsequent sections in this manual for treatment protocols or contact EMED® Corporation directly for more information.

Indications

The ***detrusan®*** incontinence treatment system is designed for acute, ongoing or chronic treatment of Urge, Stress or Mixed Urinary Incontinence. The system is indicated to improve urethral sphincter closure, pelvic floor strength, and inhibition of the detrusor muscle through reflexive mechanisms.

Indication

- Sphincter Insufficiency
- Stress Incontinence
- Urge Incontinence
- Mixed Incontinence
- Detrusor areflexia
- Residual Urine in Absence of Obstruction

Symptomatic

- Weakening of Urinary Beam
- Sensation of Residual Urine
- Urinary Retention
- Overflow Incontinence
- Urinary Tract Infection (UTI)

Contra-Indications

Do **NOT** use this device:

- If the patient has a cardiac pacemaker or implantable defibrillator.
- If the patient is pregnant or suspects she may be pregnant.
- If the patient has an infection such as itching, painful urination sores or fever.
- If the patient has been diagnosed with colorectal or genitourinary cancer.
- If the patient's anatomy makes proper probe insertion difficult or impossible.
- If the patient exhibits any skin or mucosal irritation prior to treatment.

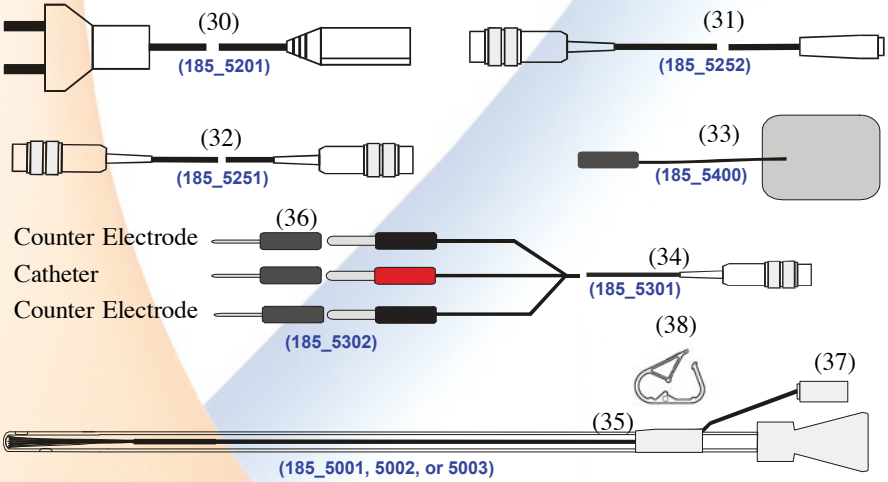
Warnings

- ***detrusets®*** are sterile, single-use devices. **NEVER** reuse or resterilize as doing so may result in urinary tract infections or patient cross-contamination and reduced therapeutic efficacy. EMED® / INNOVAMED do **NOT** accept any responsibility for the transfer of infections or diseases that result from the reuse of ***detrusets®***.
- Do **NOT** use the ***detrusan®*** 500 device in the presence of high frequency radio equipment to avoid possible malfunction of the stimulation device due to electromagnetic interference.
- Do **NOT** use the ***detrusan®*** 500 base device in the presence of magnetic resonance.
- Patients should **NOT** use ***detrusan®*** while under the influence of alcohol or any other judgment-impairing medications.
- ***detrusan®*** should **NOT** be used while the patient is wet or standing or submerged in water (i.e. while bathing).
- ***detrusan®*** must **NOT** be connected to more than one patient at a time. Doing so can result in tissue burn.
- ***detrusan®*** is designed with effective patient safety protection guards that require the unit to be connected to an adequate physical ground that should be available at any hospital or clinic.
- As with other electrical stimulation therapies, optimal treatment requires stimulation to be conducted near the limit of the patient's tolerance. However, ***detrusan®*** must **NOT** be used above the comfort threshold of any patient. Such thresholds are subjective, patient-dependent, and must be respected by the clinician administering the therapy. Patients should be instructed to stop the stimulation program by using the Emergency Stop Switch (item 31 on Page 12) in event that sensation becomes uncomfortable or intolerable.
- Water soluble lubricants may have a disinfectant effect and can be useful to facilitate insertion of Intravesical Catheters in both male and female patients. However, Anesthetic Lubricants should **NOT** be used as they may inhibit the patient's ability to feel the applied electrical current.

(Continued on Page 12)

Warnings (Continued from Page 11)

- Do **NOT** use this device near any source of heat (i.e. stove, oven, radiator, heaters, etc.). This unit must also be protected against direct sun, rain, wind and dampness.
- Do **NOT** use this device with improper voltage sources that exceed or do not meet the power input specifications as this may damage the unit. This unit must be connected to a proper power supply as indicated in the "Technical Specifications" section of this Clinician Guide using only a nationally certified (UL) and approved power (main) cable. The power source (wall socket) must be equipped with a physical ground.
- Do **NOT** insert or remove catheters that are connected to the ***detrusan***® 500 stimulation device as this can result in electric shock. Prior to treatment, catheters should be inserted into the patient while the device is powered "OFF" and the Patient Cable, item 34, remains disconnected. After catheter insertion, the Patient Cable, item 34, should be connected and the stimulation device can be powered "ON" as directed. Once treatment is finished, first power the stimulator "OFF," then disconnect the Patient Cable, item 34, from the device. Lastly, remove catheter from the patient per standard urinary de-catheterization protocol.
- Do **NOT** disconnect Ground Electrodes, item 33, from the patient or the device while it is powered "ON" or delivering electrical stimulation.



Therapy Protocols

Basic Programs

Incontinence often manifests as a combination of symptoms. ***detrusan®*** has been designed to encompass paradigms that ensure proper coverage of a wide spectrum of stimulation parameters. The result is the optimal treatment platform for a various symptoms and conditions. In this section, we will discuss treatment of specific UI conditions using the ***detrusan®*** system.

CAUTION: The following statements are empirical and should **NOT** be considered statements fact. These recommendations are the result of hundreds of cases wherein ***detrusan®*** was used clinically and are not intended to be strict guidelines for its use but rather a point of reference to facilitate clinical approaches to specific prognoses and treatment of patients.

The ***detrusan®*** 500 electrical stimulator offers 12 basic preset stimulation programs compiled specifically for the treatment of Urge (1 - 4), Stress (5 – 8) or Mixed Urinary Incontinence (9 – 12). These programs were optimized based on the work of clinicians in various countries and they optimize stimulation parameters including voltage, frequency and pulse width.

Urge Urinary Incontinence

Urge Urinary Incontinence (UUI) is commonly characterized by the involuntary contraction or over-activity of the Detrusor muscle. Hence successful treatment of UUI entails relaxation (or inhibition) of the Detrusor to restore normal bladder functionality. Program Numbers 1 through 4 of the ***detrusan®*** 500 stimulator accomplish this by applying continuous pulses of low-frequency electricity while accounting for the patient's sensitivity to the applied electrical current by varying the Pulse Width. Specific parameters for Program Numbers 1 through 4 are provided in the Table of Therapy on Page 15.

Stress Urinary Incontinence Stress

Urinary Incontinence (SUI) occurs as the result of weakening of the urethral sphincters and pelvic musculature. Programs 5 through 8 of the ***detrusan®*** 500 are optimized for the treatment of SUI for patients with extreme sensitivity to low sensitivity, respectively, because they apply cyclical pulses of high-frequency electricity that strengthen these muscle groups and help to restore normal functionality. Again, please refer to the Table of Therapy on Page 15 for more specific program information.

(Continued on Page 14)

Mixed Urinary Incontinence

Mixed Urinary Incontinence (MUI) is a combination of both Urge and Stress Incontinence. For that reason, the parameters for treatment used by the ***detrusan®*** 500 electrical stimulator are a combination of those for both Urge and Stress Incontinence. For instance, Program Numbers 1 through 4 use low frequency stimulation (5 - 10 Hz) to treat UUI and Program Numbers 5 through 8 use high frequency stimulation (50 Hz) to treat SUI. Program Numbers 9 through 12 were compiled specifically for the treatment of MUI and use two cycles of stimulation that alternate between the low frequency settings of Programs 1 through 4 and the high frequency settings of Programs 5 through 8. The Table of Therapy on Page 15 offers a more comprehensive review of the treatment parameters.

Therapy duration

In general, ***detrusan®*** therapy will result in perceptible and measurable improvements early on in the process. However, in some cases such as Severe Spinal Cord Injuries, Incontinence derived from brain lesions, or a combination of multiple patient issues, no immediate results are detected. In these cases, if there are no obvious results after 10 treatment sessions, then the damage may be of a severity that will prevent successful treatment with ***detrusan®***.

Patient Sensitivity

As with other types of Electrical Stimulation, patient sensitivity is subjective and clinicians in charge of administering this therapy should exercise care and should respect the feedback and limits of the patient.

The first program (1, 5 and 9) of each group was designed for patients with high sensitivity to stimulation. The second program (2, 6 and 10) was made for patients with medium sensitivity. The third program (3, 7 and 11) of each group was programmed for low sensitivity and the fourth program (4, 8 and 12) for very low sensitivity.

It is typical to observe reduced patient sensitivity to the applied stimulation as the series of treatment sessions progresses and the optimal program within each treatment regime is that with the highest Program Number therein. A patient that started on one level within a specific group may switch to other levels in the same group. Refer to the Table of Therapy on Page 15 for more specific program information.

Table of Therapy

Program 1
- High Patient Sensitivity
- Frequency: 10 Hz
- Pulse Width: 50 µs

Program 2
- Above Average Patient Sensitivity
- Frequency: 10 Hz
- Pulse Width: 100 µs

Program 3
- Normal Patient Sensitivity
- Frequency: 5 Hz
- Pulse Width: 150 µs

Program 4
- Low Patient Sensitivity
- Frequency: 5 Hz
- Pulse Width: 200 µs

Number of Sessions per Week: 4 - 5
Total Number of Weeks: 1
Total Number of Sessions: 4 - 5

Urge

Program 5
- High Patient Sensitivity
- Frequency: 50 Hz
- Pulse Width: 50 µs

Program 6
- Above Average Patient Sensitivity
- Frequency: 50 Hz
- Pulse Width: 100 µs

Program 7
- Normal Patient Sensitivity
- Frequency: 50 Hz
- Pulse Width: 250 µs

Program 8
- Low Patient Sensitivity
- Frequency: 50 Hz
- Pulse Width: 350 µs

Number of Sessions per Week: 3
Total Number of Weeks: 3
Total Number of Sessions: 8 - 10

Stress

Program 9
- High Patient Sensitivity
- Frequency: 50 Hz, 10 Hz
- Pulse Width: 50 µs

Program 10
- Above Average Patient Sensitivity
- Frequency: 50 Hz, 10 Hz
- Pulse Width: 100 µs

Program 11
- Normal Patient Sensitivity
- Frequency: 50 Hz, 5 Hz
- Pulse Width: 250 µs

Program 12
- Low Patient Sensitivity
- Frequency: 50 Hz, 5 Hz
- Pulse Width: 350 µs

Number of Sessions per Week: 3
Total Number of Weeks: 3
Total Number of Sessions: 8 - 10

Mixed

Ongoing Clinical Research

Other Applications

EMED® Corporation is researching the use of ***detrusan®*** technology for additional clinical applications. Preliminary positive results have been shown for the treatment of:

Pelvic Pain, Incomplete Urinary Bladder Emptying, Prostate Enlargement, Spina Bifida, Fecal Incontinence; and in the pre and post-operative treatment of patients undergoing Spinal Surgery, Colorectal Surgery, Prostatectomy, and a wealth of other surgeries involving the urinary tract.

Since these conditions frequently result in Urge, Stress or Mixed Urinary Incontinence, the 12 basic programs have been used for their treatment with positive results.

EMED® pledges to continuously update our customers with more specific information regarding these conditions and treatment recommendations as they become available. We encourage clinicians to offer suggestions and feedback from their own experience with ***detrusan®***.

CAUTION: ***detrusan®*** should **NOT** be used to treat Interstitial Cystitis as the pathology of this condition is not considered in its design.

Procedural Overview

A *detrusan®* therapy session can be successfully administered using the following general steps:

1. Place the ground electrodes in the patient in accordance with diagnostic requirements.

2. Catheterize the patient using the appropriate ***detruset®*** catheter and per standard urinary catheterization protocol.

3. Connect the Patient Cable, Emergency Stop Switch cable and main power cable to the ***detrusan®*** 500 stimulation device.

4. Determine the voltage tolerance threshold of the patient.

5. Implement the appropriate electrostimulation treatment program.

6. Disconnect the ***detruset®*** catheter and ground electrodes from the stimulator.

7. De-catheterize the patient.

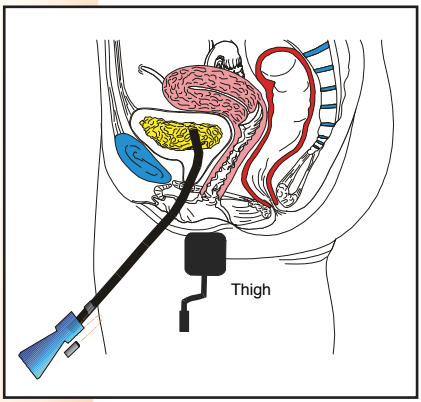
Each of these steps will be examined more thoroughly in subsequent sections of this Clinicians Guide.

Step 1:
Ground Electrode Placement

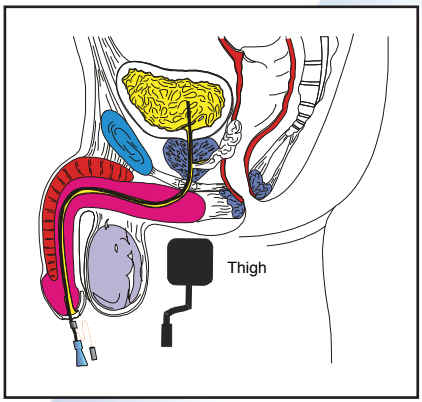
The first step of the ***detrusan®*** treatment process is to place the ground electrodes on the patient while he or she is still sitting upright. To do so, remove the protective film from the adhesive side of each electrode and place the electrodes directly onto the patient's skin, adhesive side down, in the appropriate position.

NOTE: Positioning of the ground electrodes is crucial to ensure adequate electrical stimulation and is dependent on the diagnosed condition. We will now guide you through ground electrode placement for some of the most common conditions.

Ground Electrode Positioning:
Incontinence Treatment



When treating Urinary Incontinence in female patients, place both ground electrodes on the inner thigh for Stress Incontinence or near the vulva in the case of Urge Incontinence. In either case, the electrodes should be positioned approximately 3 inches (8cm) apart.



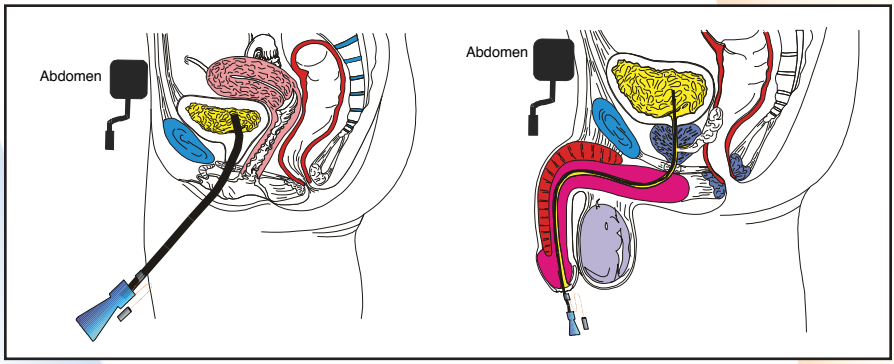
When treating Stress or Urge Urinary Incontinence in male patients, place both ground electrodes on the inner thigh approximately 3 inches (8cm) apart.

(Continued on Page 19)

Step 1:
Ground Electrode Placement

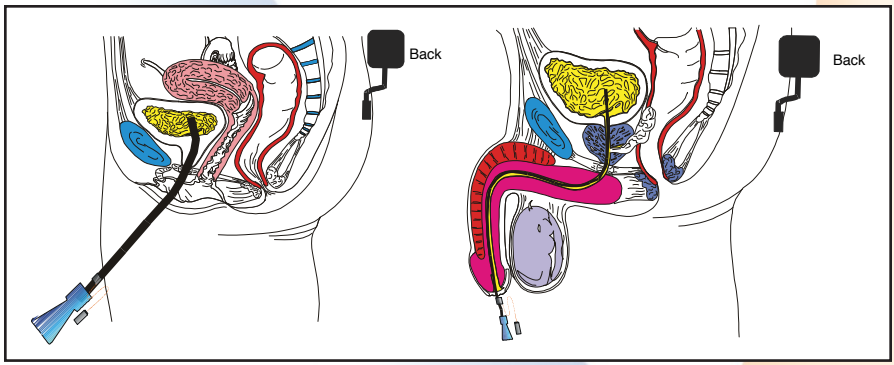
(Continued from Page 18)

Ground Electrode Positioning:
Weak Detrusor Treatment



For the treatment of a weak Detrusor muscle in both female and male patients as indicated by incomplete bladder emptying, place the counter electrodes directly on the abdomen, above the Symphysis, approximately 3 inches (8 cm) apart as shown in the figures above.

Ground Electrode Positioning:
Lower Spinal Cord Injury Treatment



For Lower Spinal Cord Injury treatment in both female and male patients, place the ground electrodes directly on the lower back above the L4 vertebrae approximately 3 inches (8cm) apart. This will provide electrical stimulation directly to the nerves connecting the bladder and the spine.

Step 2: Patient Catheterization

The next step of the ***detrusan®*** treatment process is to catheterize the patient. However, prior to catheterization, please ensure that:

- There are no signs of skin or mucosal irritation at or near the catheterization site.
- The ***detruset®*** catheter packaging has not been compromised and that it is in its original, sterile state.
- The ***detruset®*** urinary catheter is **NOT** connected to the ***detrusan®*** 500 stimulation device.
- The cap of the ***detruset®*** catheter, if applicable, is carefully secured in place to prevent urine leakage during insertion.
- The patient's bladder is at least 80% full to facilitate electrical stimulation. To accomplish this, instruct the patient **NOT** to void within 2 to 3 hours of the therapy session, if possible. If avoiding voidance is not a viable option or if the patient's bladder is insufficiently full then refer to Step 7 on Page 21.

Once the above have been confirmed, please follow the steps provided below to catheterize the patient:

1. If you have not already done so, guide the patient into the Lithotomy position.
2. Disinfect the catheterization site using any standard disinfectant solution.
3. Apply a water-soluble, disinfecting lubricant to the tip of the ***detruset®*** urinary catheter to facilitate insertion.

   WARNING: Do **NOT** use anesthetic lubricants as they can hinder the patient's ability to apperceive stimulation.
4. "Set" the ***detruset®*** catheter per standard urinary catheterization protocol.
5. Once inserted, carefully ensure that the catheter has reached the bladder by checking for detectable urine flow within the catheter.

(Continued on Page 21)

Step 2: Patient Catheterization

(Continued from Page 20)

6. If there is detectable urine flow within the ***detruset®*** catheter, proceed to Step 8. If there is minimal or no detectable urine flow within the catheter and it has assuredly reached the bladder, proceed to Step 7.

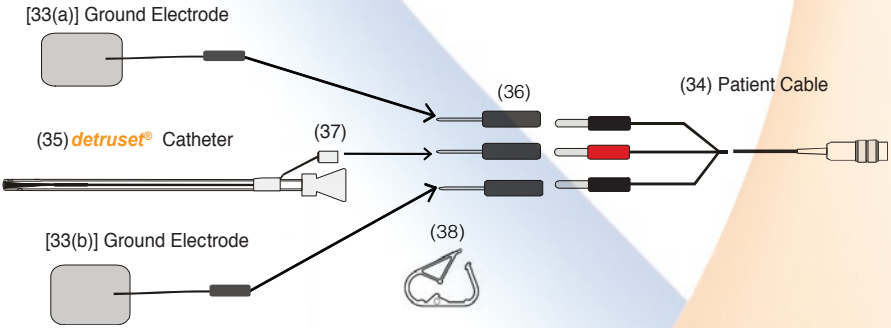
7. If there is insufficient urine volume within the bladder, use the 60 mL syringe to inject up to 100cc of 0.9% (NaCl) sterile saline solution directly through the ***detruset®*** catheter and into the bladder. The saline solution will act as "artificial urine" and provide the proper electrical conductivity to facilitate bladder stimulation.

8. After adequate bladder volume has been determined or established, secure the pinch clamp (38) onto the catheter to avoid urine spillage during treatment.

9. Secure the external portion of the catheter a assembly under the patient's thigh using adhesive tape, if necessary.

10. Connect the female ends of both ground electrodes (33) (a) and (b) and the Female Electrical Lead (37) of the ***detruset®*** urinary catheter (35) to the corresponding male ends of the three Reduction Adapters (36).

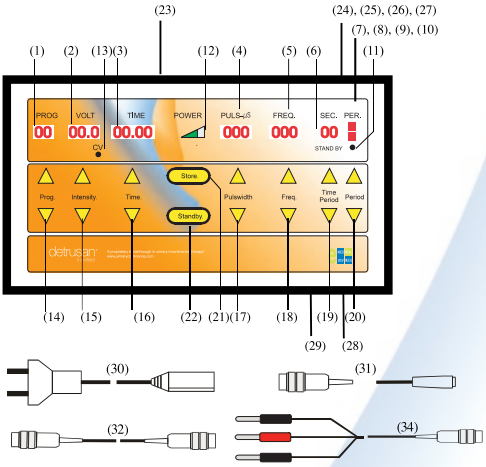
11. Connect the Reduction Adapters (36) to the Patient Cable (34). The leads from each ground electrode should be placed on a **black** lead of the Patient Cable and that from the ***detruset®*** should be placed on the **red** lead as shown in the figure below.



Step 3: Cable Connection

Now that the ground electrodes are in place and the patient has been catheterized, it is safe to connect the Patient Cable, the Emergency Stop Switch cable, and the main power cable to the ***detrusan®*** 500 stimulator using the following steps:

WARNING: Never connect or disconnect cables to the stimulator or insert or remove catheters from the patient while the device is delivering stimulation. Wait until stimulation ceases and LED Displays (1) through (6) read zero values before performing any of these operations.



1. Connect the ***detrusan®*** 500 base unit to the appropriate power source by running the Power Cable (30) from the outlet to the Power Connection (24) socket on the device. **NOTE:** The power source must be equipped with a physical ground.

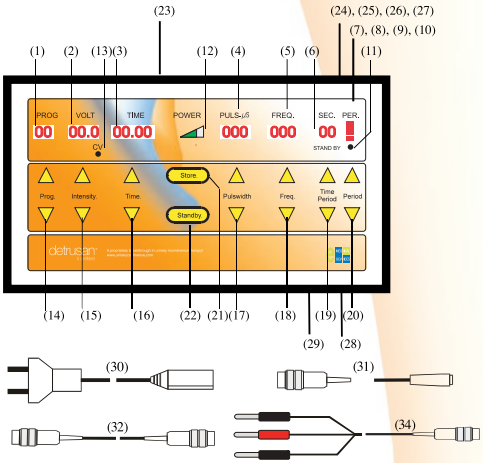
2. Connect the Patient Cable (34) to the Patient Cable socket (29).

3. Connect the Emergency Stop Switch (31) to the Stimulation Power Emergency Stop Switch socket (29). **NOTE:** When the Emergency Stop Switch (31) is not connected to the device, "SEcurit" will read across display windows (2) and (3).

4. Hand the patient the Emergency Stop Switch (31) and explain that by pressing the red button, they can interrupt the stimulation immediately. This gives them complete control should sensation become intolerable at any time during the treatment. When the Emergency Stop Switch (31) is activated, "SEcurit" will read across display windows (2) and (3). The device will then revert to the start condition and be ready to resume treatment. **NOTE:** The device will automatically revert to "Stand By" mode after 10 minutes of inactivity.

Step 4: Patient Stimulation Threshold Determination

After connecting all necessary cables to the device, it is now safe to power the ***detrusan®*** 500 stimulator by turning the Main Switch (27) to the "ON" position. The system will go through a self-test routine and "dETruSan 500" will display across windows (1) through (6) (this routine should last approximately 5 seconds). The unit will select the pre-saved treatment parameters from the stimulation program used most recently. **NOTE:** This same self-test routine will also be performed every time the unit is activated from the "Stand By" position.



Once the self-test routine has finalized, determine the patient's voltage tolerance threshold by using the following steps:

1. Select the appropriate program by pressing the Prog. Increase/Decrease (14) keys until the desired program number reads across the Prog. LED (1). Refer to the Therapy Protocols on Pages 19 and 20 and the Table of Therapy on Page 15 for specific program information and indications for the treatment of some of the most common Urinary Incontinence conditions. If the specific UI condition is not listed in the Table of Therapy, please contact EMED® for treatment program recommendations

   NOTE: Once the program number has been selected, the voltage [as read by the Volt LED (2)] will remain 0 and no stimulation will be released from the ***detrusan®*** 500 device.

2. Gradually increase or decrease the stimulation voltage using the Intensity Increase/Decrease keys (15) until the limit of the patient's tolerance has been attained.

   WARNING: Stimulation tolerance thresholds are subjective and patient-dependent and should be respected by the clinician administering the therapy.

3. After the patient's tolerance limit has been established, record the voltage in the Clinician's Treatment Log. **NOTE:** This limit may change from session to session due to the patient's increased sensitivity.

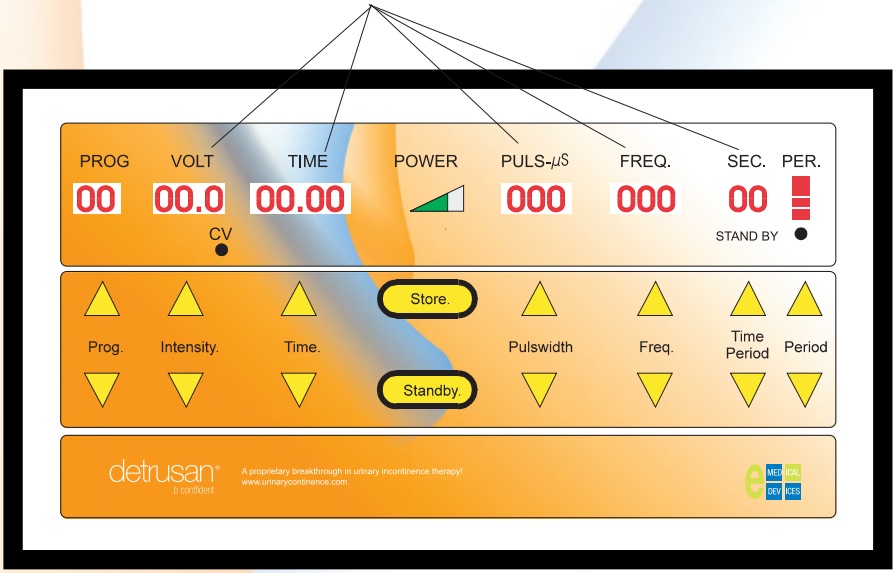
Step 5: Electrostimulation Therapy Implementation

After the desired program has been selected and the patient's voltage tolerance threshold has been established, the ***detrusan®*** 500 stimulator will proceed through the treatment program.

WARNING: Do **NOT** adjust the voltage (intensity) settings while the stimulator is in a rest cycle as the patient will be unable to indicate tolerance toward the new voltage setting. Also, use caution when changing the voltage setting under the low frequency cycle of Programs 9 through 12 as patients' voltage tolerance limits are typically higher at low frequency but will be drastically reduced during the high frequency cycle of the program.

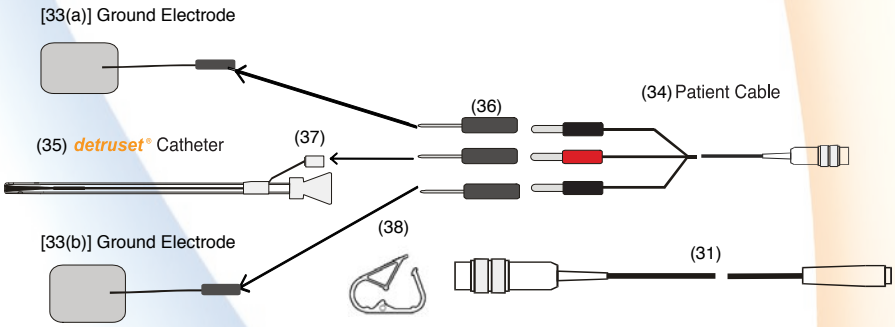
The ***detrusan®*** 500 stimulator will "beep" to indicate that the treatment session has finished. At this time, all LED displays, with the exception of Program Number Indicator, will show zero values as illustrated in the picture below. It is now safe to commence disconnection of the cables from the stimulator and to de-catheterize the patient.

All of the LED displays windows indicated here will show zero values upon completion of the therapy session. The value shown in the Program Number Indicator will remain the same



Step 6: Cable Disconnection and De-Catheterization

1. After the stimulator has finalized its treatment session, power the ***detrusan®*** 500 "OFF" using the Main Power Switch (1) at the rear of the device.
2. Disconnect the Patient Cable (34) and the Emergency Stop Switch cable (31) from the stimulator.
3. Disconnect the Reduction Adapters (36) from the ***detruset®*** catheter (35) and both Ground Electrodes (33) (a) and (b) from the Patient Cable (34).



4. Disconnect the Ground Electrodes (33) (a) and (b) and ***detruset®*** catheter (35) from their respective Reduction Adapters (36).
5. Remove the Ground Electrodes from the patient. If the electrodes are multi-use, replace the protective cover and store for future use. Otherwise, discard the electrodes.
6. De-catheterize the patient per standard urinary catheter removal protocol.

   WARNING: ***detrusets®*** are single-use urinary catheters. **NEVER** reuse ***detruset®*** catheters as this can result in patient cross-contamination and/or infection.
7. Discard the catheters in compliance with bio-hazardous waste disposal procedures.

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