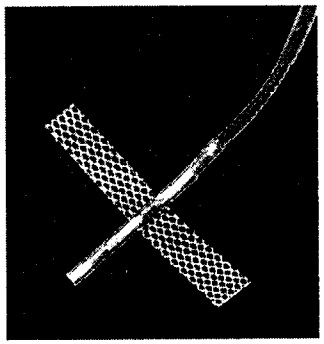

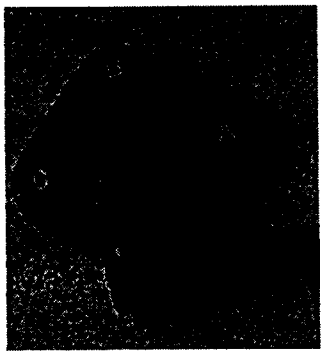

NeuroControl Corporation VOCARE Bladder System

Implantable Functional Neuromuscular Stimulator

PACKAGE INSERT

NEUROCONTROL CORPORATION

Humanitarian Device. Authorized by Federal law for use in providing urination on demand with low residual volumes of urine to complete spinal cord injured individuals. The effectiveness of this device for this use has not been demonstrated.

Caution: *Federal Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).*

NeuroControl Corporation VOCARE Bladder System
Implantable Functional Neuromuscular Stimulator

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Humanitarian Device. Authorized by Federal law for use in providing urination on demand with low residual volumes of urine to complete spinal cord injured individuals. The effectiveness of this device for this use has not been demonstrated.

***Caution:** Federal Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).*

DEVICE DESCRIPTION

The NeuroControl *VOCARE Bladder System* is a radiofrequency powered motor control neuroprosthesis which consists of both implanted and external components. The *VOCARE Bladder System* delivers low levels of electrical stimulation to a spinal cord injured patient's intact sacral spinal nerve roots in order to elicit functional contraction of the muscles innervated by them. The NeuroControl *VOCARE Bladder System* consists of the following subsystems:

- The **Implanted Components** include the Implantable Receiver-Stimulator and Extradural Electrodes.
- The **External Components** include the External Controller, External Transmitter, External Cable, Transmitter Tester, Battery Charger and Power Cord.
- The **Surgical Components** include the Surgical Stimulator, Intradural Surgical Probe, Extradural Surgical Probe, Surgical Test Cable, and Silicone Adhesive.

INDICATIONS FOR USE

The NeuroControl *VOCARE Bladder System* is indicated for the treatment of patients who have clinically complete spinal cord lesions (ASIA classification) with intact parasympathetic innervation of the bladder and are skeletally mature and neurologically stable, to provide urination on demand and to reduce post-void residual volumes of urine.

CONTRAINDICATIONS

The NeuroControl *VOCARE Bladder System* is contraindicated for patients with the following characteristics:

- poor or inadequate bladder reflexes
- active or recurrent pressure ulcers
- active sepsis
- implanted cardiac pacemaker

WARNINGS

The NeuroControl *VOCARE Bladder System* may only be prescribed, implanted, or adjusted by clinicians who have been trained and certified in its implementation and use.

Magnetic Resonance Imaging (MRI): Do not expose patients to MRI. There are potential effects of induced currents and radio frequency heating of the *VOCARE Bladder System* when exposed to magnetic fields and radio frequency fields associated with MRI systems which may result in patient injury.

PRECAUTIONS

X-rays, diagnostic ultrasound: X-ray imaging, and diagnostic ultrasound have not been reported to affect the function of the Implantable Receiver-Stimulator or Extradural Electrodes. However, the implantable components may obscure the view of other anatomic structures.

Therapeutic ultrasound, therapeutic diathermy, and microwave therapy: Therapeutic ultrasound, therapeutic diathermy, and microwave therapy should not be performed over the area of the Implantable Receiver-Stimulator or Extradural Electrodes as it may damage the *VOCARE Bladder System.*

Electrocautery: Do not touch the Implantable Components of the *VOCARE Bladder System* with electrocautery instruments. Do not use electrocautery within 1 cm of the electrode metal contacts.

Antibiotic prophylaxis: Standard antibiotic prophylaxis for patients with an implant should be utilized to protect the patient when invasive procedures (e.g., oral surgery) are performed.

Drug Interactions: Anticholinergic medications, or other medications which reduce the contraction of smooth muscle, may reduce the strength of bladder contraction achieved using the *VOCARE Bladder System.* Anticholinergic medications should be discontinued at least three days prior to evaluating patients for the *VOCARE Bladder System* and prior to implantation surgery so that bladder reflexes and response to electrical stimulation can be accurately evaluated. In addition, long-acting neuromuscular blocking agents must not be used during surgery.

Prior procedures (such as bladder neck surgery or bladder augmentation) ***or conditions*** (such as severe urethral damage, stricture, or erosion) may affect patient suitability for the *VOCARE Bladder System* or clinical outcome. Patients with bladder augmentation may not be candidates for this procedure unless they can still achieve appropriate bladder pressures through reflex contractions. Patients should be thoroughly evaluated and counseled regarding the effect of any prior procedures or conditions.

Post-operative incontinence may occur following posterior rhizotomy, which is typically performed in conjunction with implantation of the *VOCARE Bladder System*. While rhizotomy generally abolishes reflex incontinence, some patients may still experience stress incontinence. Patients should be evaluated for open bladder neck pre-operatively and counseled regarding the factors that may increase the risk of stress incontinence.

Bowel motility may be affected by the rhizotomy procedure and by use of the *VOCARE Bladder System*. Patients should be advised that the rhizotomy may decrease the response to suppositories and digital stimulation of the rectum. Conversely, use of the *VOCARE Bladder System* for bladder management may affect bowel motility. Patients may need to adjust the frequency and/or method of their bowel management routine postoperatively.

The ***rhizotomy*** procedure typically performed in conjunction with implantation of the *VOCARE Bladder System* may cause loss of erectile function and ejaculation in men who had these responses before surgery.

Spinal instability may result from the laminectomies required during implantation and rhizotomy surgery. Patients should be evaluated carefully for added risk factors, such as significant osteoporosis or scoliosis.

Studies have not been conducted on the use of the NeuroControl *VOCARE Bladder System* in pregnant women.

Post-operatively, the patient should be advised to check the condition of his or her skin over the *VOCARE Bladder System* Receiver-Stimulator and leads daily for signs of redness, swelling, or breakdown. If skin breakdown becomes apparent, patients should contact their clinician immediately. The clinician should treat the infection aggressively, taking into consideration the extra risk presented by the presence of the implanted materials.

Unintended Stimulation: While there have been no reports of *VOCARE Bladder System* activation or malfunction due to electromagnetic interference (such as retail anti-theft detectors, airport metal detectors, or other electronic devices) testing has not been conducted to rule out the possibility of this occurring. Patients should be advised to notify their clinician if they experience **unintended** stimulation when the *VOCARE Bladder System* is **not** in use. If possible, patients should note when and where the stimulation occurred.

Keep it dry: The user should avoid getting the external components, cables, and attachments of the *VOCARE Bladder System* wet.

The patient and caregiver should be advised to ***inspect the external cables and connectors*** daily for fraying or damage and replace components when necessary.

To avoid possible interference, patients with electric wheelchairs should be advised to ***turn off their wheelchair controller*** prior to turning on the *VOCARE Bladder System* External Controller.

External Defibrillation: The effect of external defibrillation on the *VOCARE Bladder System* is unknown.

Patients should be advised to turn off the *VOCARE Bladder System* External Controller when not in use. ***The External Transmitter can become hot*** if the *VOCARE Bladder System* is left on for extended periods of time.

ADVERSE EVENTS

Devices similar to the *VOCARE Bladder System* have been implanted in patients in Europe, Australia, Asia and the US. Published reports (Brindley 1994a) describe relevant adverse events including implant infection (1%), exposure of the implanted components via dehiscence or ulceration (1%), and component failures (Brindley 1994b). These complications have occurred in relatively small numbers of patients. No failures of extradural electrodes have been reported to date.

About 30% of patients (Brindley 1990) have noticed an increase in sweating over the lower part of the body and/or undesirable changes in the pattern of their lower limb reflexes. These changes have never been permanent and have returned to preimplant status within three months to a year.

A clinical study in the US involved 23 devices (using extradural electrodes) implanted in 23 patients and 13 cumulative implant years (median implant duration = 1.2 years, range approximately 1 month to 2 years). Key adverse events (AEs) reported from this clinical trial include temporary anterior nerve root damage which resolved within 3 months (two cases), incomplete rhizotomy (one case), pathological fracture of L2 vertebra with resulting nerve compression (one case), and post-operative stress incontinence not present preoperatively (two cases).

Possible adverse events include:

- Device malfunction or electrode/lead breakage
- Spinal nerve root damage
- Infection
- Incomplete rhizotomy
- Skin breakdown
- Post-operative incontinence

CLINICAL STUDIES

Devices similar to the *VOCARE Bladder System* have been implanted in patients in Europe, Australia, Asia and the US. Published reports indicate that approximately 90% of patients with this implant use it for voiding and the majority have significant decrease in infection rate and improvement in continence (Brindley et al. 1986, 1990a).

A US clinical trial has been conducted, with results available from 23 complete spinal cord injured individuals implanted at 6 centers. The purpose of the trial was to prospectively demonstrate that the NeuroControl *VOCARE Bladder System* enables patients to urinate on demand with low residual volumes of urine. The study also evaluated other quality of life measures affected by the *VOCARE Bladder System.*

Design and Patients: A multi-center trial was conducted at 6 US sites using a common protocol. Patients were implanted with the VOCARE Bladder System combined with posterior rhizotomy. Patients were evaluated in the clinic to determine if the *VOCARE Bladder System* enabled them to urinate on demand with reduced residual volumes of urine. Patients also kept diaries to record voided volumes, incontinence episodes, and methods of bladder management. Patients served as their own controls, with comparisons made between post-operative and pre-operative function as well as between function with the *VOCARE Bladder System* ON and OFF post-operatively. Data were gathered pre-operatively, and at 3, 6, and 12 months post-operatively.

Of the 23 patients implanted with the VOCARE Bladder System, all were at least one year post-injury at the time of enrollment. All had histories of bladder complications, usually UTI's, autonomic dysreflexia, and reflex incontinence. Seventy percent were male, median age 40 years (range 14-67). All patients had clinically complete spinal cord injuries with 26% quadriplegic and 74% paraplegic patients.

Methods: Evaluations were conducted at baseline pre-operatively (23 patients), post-operatively at 3 months (23 patients), at 6-months post-op (21 patients) and at 12-months post-op (9 patients). Key measures included demonstration of voiding on demand with measurement of resulting residual volumes of urine. Secondary measures included evaluating the effect of the *VOCARE Bladder System* on incontinence, use of urinary catheters, use of medications, and urinary tract infections.

Table 1. Primary Effectiveness Measures (n=#)

	Pre-Op (n=23)	3 Month (n=21)	6 Month (n=20)	12 Month (n=12)
Patients who can micturate on demand >200 ml (100% of attempts)				
VOCARE Bladder System **ON**	NA	19/21 (90%)	18/20 (90%)	11/12 (92%)
VOCARE Bladder System **OFF**	4/23 (17%)	0/21 (0%)	1/20 (5%)	1/12 (8%)
Patients w/PVR < 50 ml				
VOCARE Bladder System **ON**	NA	17/21 (81%)	17/20 (85%)	9/12 (75%)
VOCARE Bladder System **OFF**	3/23 (13%)	1/21 (.5%)	0/20 (0%)	1/12 (8%)

Results: The NeuroControl *VOCARE Bladder System* enabled patients with complete spinal cord injury to urinate on demand with low post-void residual (PVR) volumes of urine.

Results of secondary endpoint studies indicate that patients eliminated the need for intermittent and indwelling catheters (68%), became more continent [(13/20)65%], reduced the need for anticholinergic medication [15/17 (88%)], eliminated episodes of autonomic dysreflexia [8/8 (100%)], and reduced the incidence of reported urinary tract infections (78%).

INDIVIDUALIZATION OF TREATMENT

For optimal outcome, the following elements should be considered when selecting candidates for the NeuroControl *VOCARE Bladder System*:

- Prior to implant, patients should show reflex bladder contraction with an increase in detrusor pressures over baseline of at least 35 cm H_2O in women and 50 cm H_2O in men during cystometry. This ensures that parasympathetic preganglionic neurons from the conus medullaris to the bladder are intact. Anticholinergic medication should be discontinued at least three days in advance of testing for most accurate results.

- A cystourethrogram should be performed to evaluate the bladder neck for risk of post-operative stress incontinence.

- Candidates for the *VOCARE Bladder System* should be in good health and be able to understand the operation of the *VOCARE Bladder System.*

- Spinal fixation hardware may interfere with the implantation and rhizotomy laminectomy sites. Hardware should be evaluated and its partial removal considered.

DIRECTIONS FOR USE

Specific Directions for Use can be found in the Clinician and User Manuals.

PATIENT COUNSELING INFORMATION

It is important that patients who are candidates for the NeuroControl *VOCARE Bladder System* be counseled regarding use and expectations for the device. The following should be considered in this counseling:

- Patients should be counseled regarding the reasons for and consequent advantages and disadvantages of the posterior rhizotomy procedure performed in conjunction with implantation of the *VOCARE Bladder System,* including loss of sacral sensation, decreased response to digital stimulation and suppositories, and (if present) loss of reflex erection and ejaculation in males.

- Patients with poor hand function or inability to transfer to a toilet seat should be counseled regarding their options and limitations for urine collection.

- Patients should be counseled on the importance of reporting problems which may compromise their health or the implant to their physician. Problems include skin breakdown, infections, changes in performance of the *VOCARE Bladder System* (function or sensation), etc.

- Patients should be counseled that there is a possibility of post-operative stress incontinence and should be advised regarding the risk factors for stress incontinence such as weight gain, postural changes, and weak or open bladder neck.

- The patient should be trained in the proper maintenance of the *VOCARE Bladder System.* A clinician should explain the operation and maintenance of the *VOCARE Bladder System* as described in the Clinician Manual and the Patient Manual.

- Patients should be trained in an alternative "back-up" method of bladder emptying in the event the *VOCARE Bladder System* is not producing adequate bladder emptying.

- Patients should be educated to recognize urine flow patterns or problems that might indicate improper function of the *VOCARE Bladder System.*

HOW SUPPLIED

The *VOCARE Bladder System* Implantable Receiver-Stimulator and the Extradural Electrodes are supplied in dual STERILE peel-pack packages. The Intradural and Extradural Probes and Test Cable are supplied in dual STERILE peel-pack packages. The Intraoperative Stimulator is provided non-sterile and is intended for use outside the sterile field. External Component Kits are provided for patients and replacement components can be obtained from NeuroControl Corporation.

For more information:

NeuroControl Corporation - USA
Valley View, Ohio
TOLL FREE 800-378-6955
FAX: 216-912-0129

NeuroControl Corporation - Europe
Brussels, Belgium
PHONE: +32 (0)2 375.51.63
FAX: +32 (0)2 375.89.06

NeuroControl Corporation - Asia Pacific
Melbourne, Australia
PHONE: +61 3 9256 6170
FAX: +61 3 9222 1809

www.neurocontrol.com

NEUROCONTROL CORPORATION

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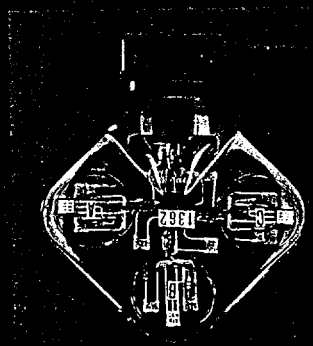
THE NEUROCONTROL VOCARE BLADDER SYSTEM

User Manual



Dedicated to Creating an Independent Lifestyle

NEUROCONTROL CORPORATION

NeuroControl Corporation
VOCARE Bladder System

USERS MANUAL

December 1998

Humanitarian Device. Authorized by Federal law for use in providing urination on demand with low residual volumes of urine to complete spinal cord injured individuals. The effectiveness of this device for this use has not been demonstrated.

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NeuroControl Corporation
8333 Rockside Road
Valley View, OH 44125
1-800-378-6955

NeuroControl Corporation
VOCARE Bladder System

USERS MANUAL
MODEL NUMBER 1645-1

December 28, 1998

This manual was adapted from "Sacral Anterior Root Stimulator Implant: Notes for Patients" by GS Brindley, MD, Honorary Director, MRC Neurological Prostheses Unit, London.

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1.0 INTRODUCTION

This manual is intended to provide information for the safe use of the *VOCARE Bladder System* for you, your family, your caregivers, and your doctor.

The purpose of this manual is to help you understand the *VOCARE Bladder System*:

- what the *VOCARE Bladder System* is intended to be used for,
- who the *VOCARE Bladder System* is intended to be used by,
- where the *VOCARE Bladder System* is implanted,
- how to operate the *VOCARE Bladder System*, and finally,
- the general procedures you must go through in order to have the *VOCARE Bladder System* work successfully and reliably, including a procedure known as a rhizotomy

In general, you should be in reasonably good health and be able to understand how to operate the *VOCARE Bladder System*. You will be trained by your doctor using the information in this manual. Call Dr. _____ at_____ if you, your attendant, or a family member need help in understanding how to use your *VOCARE Bladder System* or if you have an emergency. You can also get help between the hours of 8:30 AM and 5:00 PM Eastern Standard Time by calling NeuroControl Corporation Customer Service at 1-800-378-6955.

What is the *VOCARE Bladder System* intended to be used for?

The *VOCARE Bladder System* is an implanted sacral anterior root stimulator that will allow individuals with complete spinal cord injury to urinate on demand leaving only a small amount of urine in the bladder.

Who can use the *VOCARE Bladder System*?

The *VOCARE Bladder System* is intended to be used by skeletally mature individuals (those who have stopped growing) who have complete spinal cord injuries and are neurologically stable. Patients must also have a bladder that will contract when it is filled (bladder reflexes).

How is the *VOCARE Bladder System* implanted?

Some of the *VOCARE Bladder System* components are implanted internally while other components are used externally. The Implantable Receiver Stimulator is implanted just below the skin (similar to a pacemaker). The Extradural Electrodes are implanted internally at the base of your spine where the nerves exit the spinal cord. The remaining components are used externally. Each component will be described in greater detail later in this manual. Figure 1 below shows where the *VOCARE Bladder System* is implanted in your body.

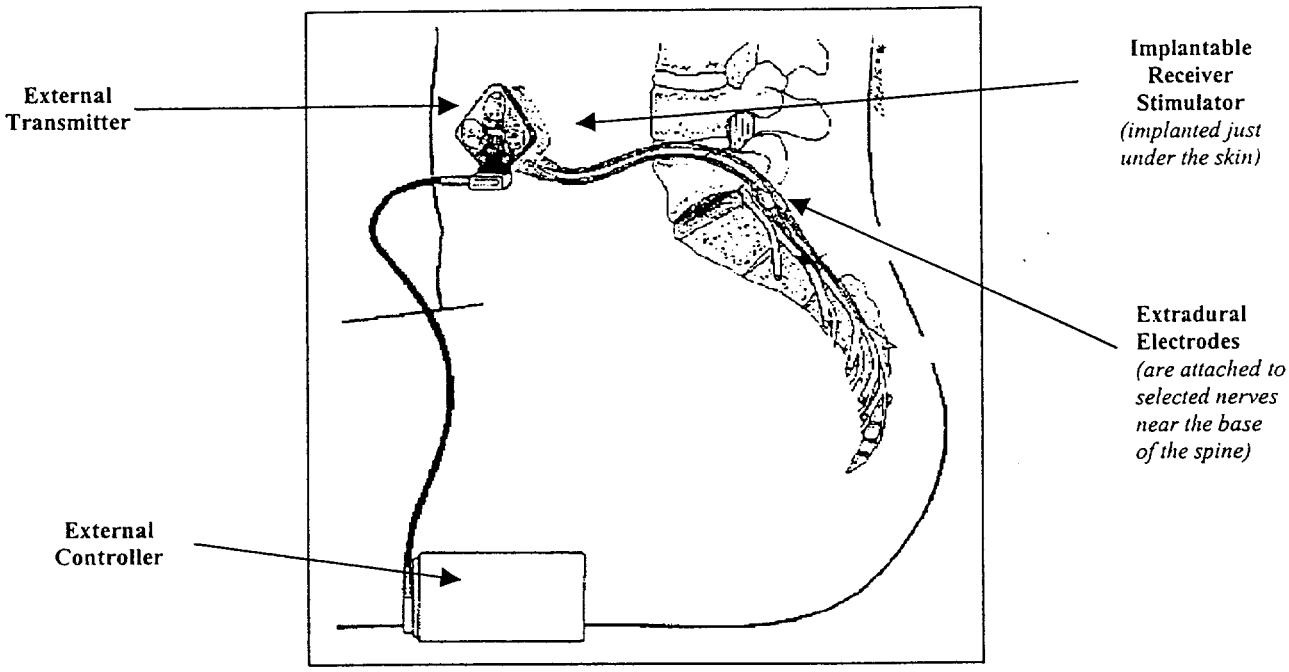

FIGURE 1

During the surgery to implant the *VOCARE Bladder System*, you will typically undergo a surgical procedure called a rhizotomy in which the nerves carrying sensation impulses from the bladder, anus, and penis are cut. This procedure is performed to eliminate reflex incontinence and autonomic dysreflexia. However, it also has some disadvantages including loss of erectile function and ejaculation in men who had these responses before surgery. The rhizotomy procedure is described in more detail later in this manual.

2.0 IMPORTANT INFORMATION

INDICATIONS:

The NeuroControl *VOCARE Bladder System* is indicated for the treatment of patients who have clinically complete spinal cord lesions (ASIA Classification) with intact parasympathetic innervation of the bladder and are skeletally mature and neurologically stable, to provide urination on demand and to reduce post-void residual volumes of urine.

CONTRAINDICATIONS: ***(Patients in whom the* VOCARE Bladder System *should not be used):***

Patients who have one or more of the following characteristics are not candidates for the *VOCARE Bladder System*:

- poor or inadequate bladder reflexes
- active or frequent pressure ulcers
- active infection
- implanted cardiac pacemaker

WARNINGS :

The *VOCARE Bladder System* is a prescription device and is safe only when used under your doctor's supervision. You should use the *VOCARE Bladder System* only after you have received special training and counseling by your doctor.

Magnetic Resonance Imaging (MRI): Testing has not been completed on the effects of MRI on the *VOCARE Bladder System* and its users. Exposure to MRI could cause injury to you or damage to the *VOCARE Bladder System*. MRI should not be performed on patients with the *VOCARE Bladder System* at this time.

PRECAUTIONS :

- X-rays and ultrasound have not been reported to affect the function of the Implantable Receiver-Stimulator or Extradural Electrodes. However, your doctor's ability to see the tissue behind the implants may be blocked.

- Therapeutic ultrasound (physical therapy) should not be performed over the area of the Implantable Receiver-Stimulator or Extradural Electrodes since it may damage the *VOCARE Bladder System*.

- Therapeutic diathermy (physical therapy) should not be performed over the area of the Implantable Receiver-Stimulator or Extradural Electrodes since it may damage the *VOCARE Bladder System*.

- Microwave therapy should not be performed over the area of the Implantable Receiver-Stimulator or Extradural Electrodes since it may damage the *VOCARE Bladder System.*

- The Implantable Components of the *VOCARE Bladder System* should not be touched with electrocautery instruments (instruments used during surgery to cut tissue or to stop bleeding). Electrocautery should not be used within 1 cm of the metal electrode contacts. Prior to any subsequent surgeries, you should notify your surgeon that the *VOCARE Bladder System* has been implanted.

- You should notify and talk to your doctor **before** you have dental, ENT (ear, nose, and throat) or other "high risk" medical procedures. You may need to take antibiotics to prevent infection that could spread to your implanted *VOCARE Bladder System.*

- Certain medications like anticholinergics (such as Ditropan or Oxybutynin which help control spasms of the bladder) may cause the strength of bladder contractions to be decreased using the *VOCARE Bladder System.* Your doctor will tell you to stop these medications before surgery so that the bladder reflexes and effect of the electrical stimulation can be evaluated. Patients who continue to take these anticholinergic medications may have a decreased response to the stimulation.

- Bladder surgery such as bladder neck surgery or bladder augmentation may affect your candidacy for the *VOCARE Bladder System* or the performance of the System for you. Your doctor will evaluate you and tell you if you have conditions that may affect the performance of your *VOCARE Bladder System.*

- Some leakage of urine (postoperative incontinence) can occur after implantation of the *VOCARE Bladder System.* Part of the surgery involves the cutting of nerves that cause the bladder to leak urine when it is filled (reflex incontinence). While this procedure generally stops this reflex, some patients continue to experience some leaking during exertion, coughing, etc. (stress incontinence). Your doctor will evaluate your bladder and tell you about any factors that increase the risk of this stress incontinence.

- It is important to understand that implantation of the *VOCARE Bladder System* may affect your bowel routine. The movement of stools through your body (known as bowel motility) may be different after your surgery. Your body's response to suppositories and digital stimulation may be less effective because of the rhizotomy surgery. Use of the *VOCARE Bladder System* to empty your

bladder may affect the rate of movement of stool through the colon to the rectum.

- The rhizotomy procedure typically performed in conjunction with implantation of the *VOCARE Bladder System* may cause loss of erectile function and ejaculation in men who had these responses before surgery.

- The surgery to implant your *VOCARE Bladder System* involves partial removal of a portion of one or more bones in your back. After surgery, your spine may become unstable, causing abnormal or excessive movement of some portion of the spine (usually near the level of the injury) due to the loss of this bone. This instability is usually related to the initial injury of your spinal cord, but could become worse following surgery. Your doctor will evaluate you for risk factors that may contribute to this problem prior to implanting your *VOCARE Bladder System.*

- It is important to understand that the *VOCARE Bladder System* has not been tested in pregnant women.

- Check your skin daily for any signs of redness, swelling, or sores especially in the areas where the *VOCARE Bladder System* Receiver-Stimulator or Electrodes are located. Call your doctor immediately if you notice any change in your skin condition.

- It is important to stay healthy and to notify your doctor immediately if you become sick, get an infection, experience any unusual sensations or muscle contractions, or notice any change in how your bladder stimulation works.

- It is important to notify your doctor if you experience **unintended** stimulation when the *VOCARE Bladder System* is **not** in use. While there have been no reports of *VOCARE Bladder System* activation or malfunction due to electromagnetic interference (such as from retail anti-theft detectors, airport metal detectors, or other electronic devices), testing has not been conducted to rule out the possibility of this occurring. If possible, note when and where the stimulation occurred when reporting this information to your doctor.

- It is essential that you or your caregiver be familiar with an alternative method of emptying your bladder (such as catherization). If you have any problems with your *VOCARE Bladder System*, you should be prepared to use this alternative method.

- It is important to turn off the *VOCARE Bladder System* when you are not using it. If it is left "on" for long periods of time, the External Transmitter could become hot.

- If you turn "on" the *VOCARE Bladder System* while in an electric wheelchair, your wheelchair may move unpredictably. You or your attendant should always turn "off" your electric wheelchair before you use the *VOCARE Bladder System.*

- The effect of external defibrillation (devices which deliver an electrical shock to the heart when it has stopped beating regularly) on the *VOCARE Bladder System* is unknown.

- Avoid getting the external components, cables, and attachments of the *VOCARE Bladder System* wet because this may cause damage to the device. Call your doctor if you get the *VOCARE Bladder System* wet.

- While recharging the batteries for your *VOCARE Bladder System*, you will be **unable** to use the device to empty your bladder. If you need to empty your bladder during the charging period, you may stop the recharging process and use the *VOCARE Bladder System*. You may continue to charge the *VOCARE Bladder System* after you are finished. If you find that you need to use your *VOCARE Bladder System* when your batteries are "dead" (completely discharged), recharging the batteries for approximately 30 minutes should enable you to use the *VOCARE Bladder System* for one use.

- You need to take good care of your *VOCARE Bladder System*. Your doctor will review the procedures with you. You should inspect the *VOCARE Bladder System* cables and connections for any visible signs of frayed wires or damage daily and call your doctor to report any damage.

- **You should not open the *VOCARE Bladder System* External Controller to expose the internal circuits. Do not open the Battery Charger.**

3.0 How Does The *VOCARE Bladder System* Work?

Functional Electrical Stimulation (FES) is a method used to provide function to otherwise paralyzed muscles. The *VOCARE Bladder System* uses FES to stimulate the nerves which connect the spinal cord to the bladder. The *VOCARE Bladder System* is designed to be used by people with complete spinal cord injuries to allow them to urinate when they decide to ("on demand") leaving only a small amount of urine in the bladder.

In order to achieve control of the bladder, electrical signals normally travel from the brain down the spinal cord to the nerves that control this system. In the case of spinal cord injury, this path is broken. The brain still sends the signals, but they do not reach the bladder. (See Figure 2 below.)

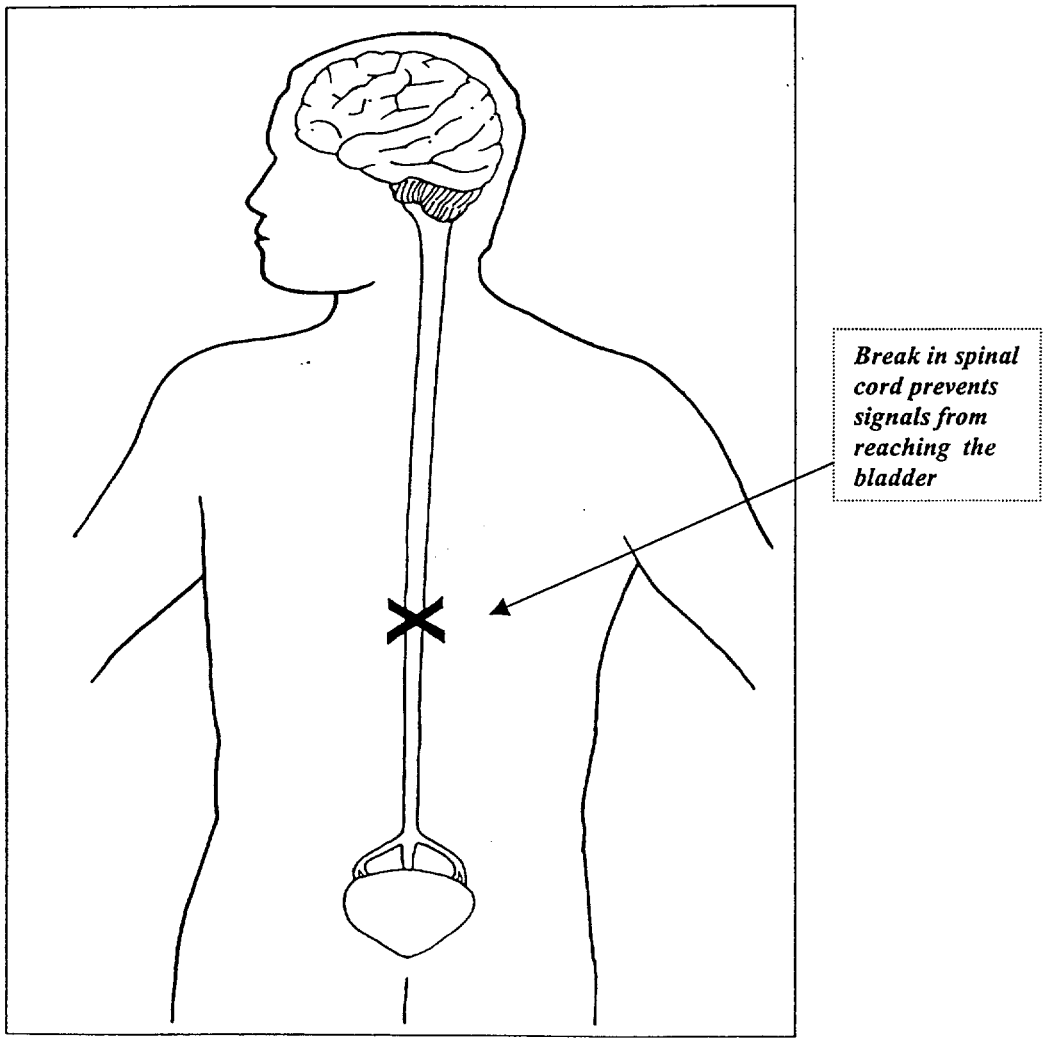

Figure 2

Using **FES**, the *VOCARE Bladder System* sends low levels of electrical energy directly to the nerves below the spinal cord injury that control the bladder. If these nerves are healthy, the electrical signals will cause the muscle of the bladder to contract.

What are the sacral nerves?

The nerves that connect the spinal cord to the bladder are located at the lower end of the spine in an area called the "sacrum". The nerves that exit the spinal cord through the sacrum are called **sacral nerves**.

How is the VOCARE Bladder System used to empty the bladder?

Two things must happen for a person to empty their bladder. First, the pressure inside the bladder must increase. Second, the valve at the bottom of the bladder must open to allow the urine to flow out. This valve is known as the **external urethral sphincter**.

In most situations, stimulation of the sacral nerves causes the bladder to be squeezed and increases the pressure inside it. But, during stimulation, the external urethral sphincter stays closed. To open the sphincter, the stimulation must be turned off.

The *VOCARE Bladder System* is designed to send the electrical signals (stimulation) in bursts, with gaps of no stimulation between them. In the gaps between the bursts of stimulation, the bladder is still squeezed but the external urethral sphincter has relaxed. Urine empties out of the bladder in spurts during these gaps. An illustration of the bladder and sphincter is provided in Figure 3 below.

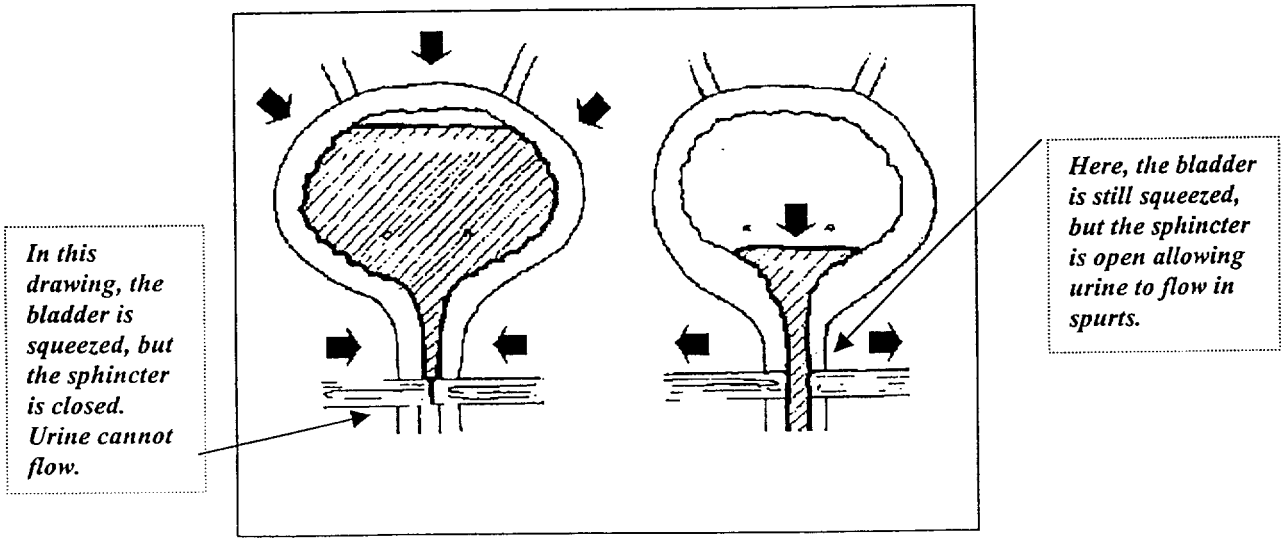

Figure 3

WHAT IS A RHIZOTOMY?

A **rhizotomy** is a surgical procedure in which some nerves are permanently cut. For use of the *VOCARE Bladder System*, some of the nerves that carry sensation impulses *from* the bladder *to* the spinal cord may be cut.

A rhizotomy is usually performed during the same operation in which your *VOCARE Bladder System* is implanted. Combining the *VOCARE Bladder System* with a rhizotomy can have the following benefits:

- Removes the reflexes from the bladder which can cause a dangerous rise in blood pressure (a condition known as **autonomic dysreflexia**)
- Removes the reflex contractions of your bladder (which may cause **reflex incontinence**) and movement of urine from the bladder into the kidneys, decreasing the risk of kidney damage
- Improves the ability of the bladder to contain urine (known as **bladder capacity**)
- Improves the flow of urine

Disadvantages of the rhizotomy procedure are:

- Loss of reflex erections (those from physical touch) in men who have these types of erection
- Loss of reflex ejaculation (from physical touch) in men who have this type of response
- Loss of sensation or "feeling" (if present) in the regions controlled by the sacral nerves (such as the anus and buttocks). Because the *VOCARE Bladder System* is intended for patients with complete spinal cord injuries, this sensation has already been lost.
- A decrease in movement of stool through your body (known as bowel motility)

HOW DOES THE *VOCARE BLADDER SYSTEM* AFFECT LEAKAGE OF URINE?

Leakage of urine, known as **incontinence**, can be caused in several ways. A common problem in spinal cord injury is large unpredictable leaks. This results from a reflex that causes the bladder to contract when there is urine in your bladder, called **reflex incontinence**. Small leaks, resulting from bending forward or coughing, may also occur and are known as **stress incontinence**.

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The NeuroControl *VOCARE Bladder System* may improve continence because it empties the bladder more completely. Combining the implantation of your *VOCARE Bladder System* with a procedure known as a rhizotomy, described above, can further improve continence. The rhizotomy can improve continence because it removes reflex contractions of your bladder.

4.0 PARTS OF THE *VOCARE BLADDER SYSTEM*

Your *VOCARE Bladder System* is made up of **implanted** and **external** components.

IMPLANTED COMPONENTS

The implanted components include the **Implantable Receiver-Stimulator** and two **Electrodes**. Figure 4 below shows the Implantable Receiver-Stimulator along with one (of the two) Electrodes.

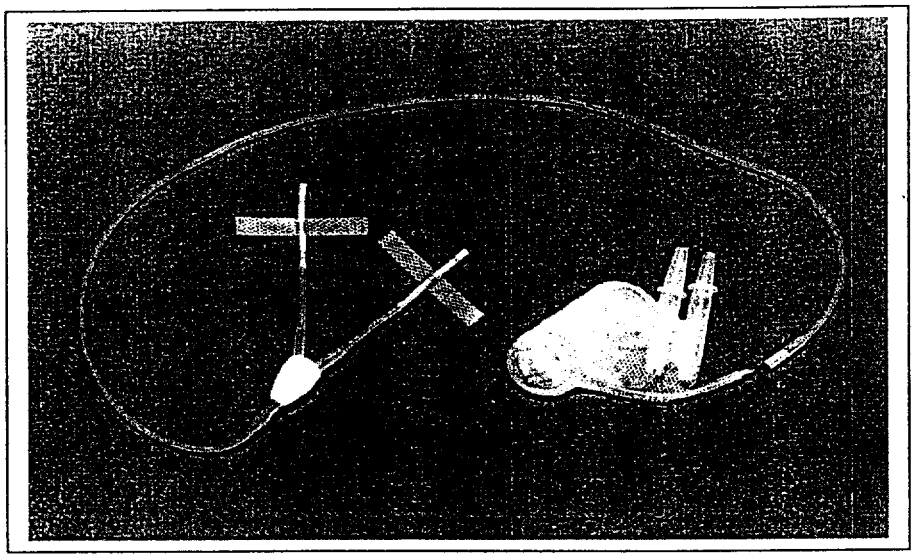


Figure 4

- Implantable Receiver-Stimulator

The Implantable Receiver-Stimulator is implanted under the skin of your abdomen by your surgeon. It receives signals from the external components (see discussion below) and sends an electrical signal to the nerves, which control the bladder. Figure 5 gives a closer view of the Implantable Receiver-Stimulator.

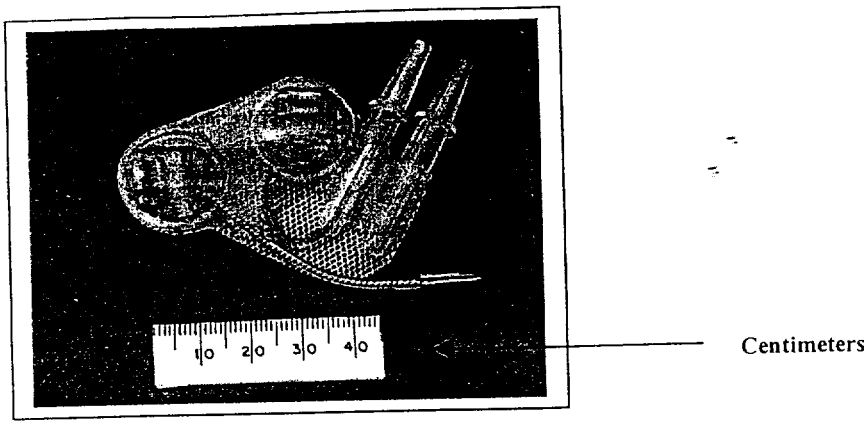


Figure 5

- Electrodes and Leads

One **Electrode** and its **Lead** are pictured below in Figure 6. The electrical signals produced by the Receiver-Stimulator are carried along the leads to the electrodes. The electrodes are attached to the sacral nerves.

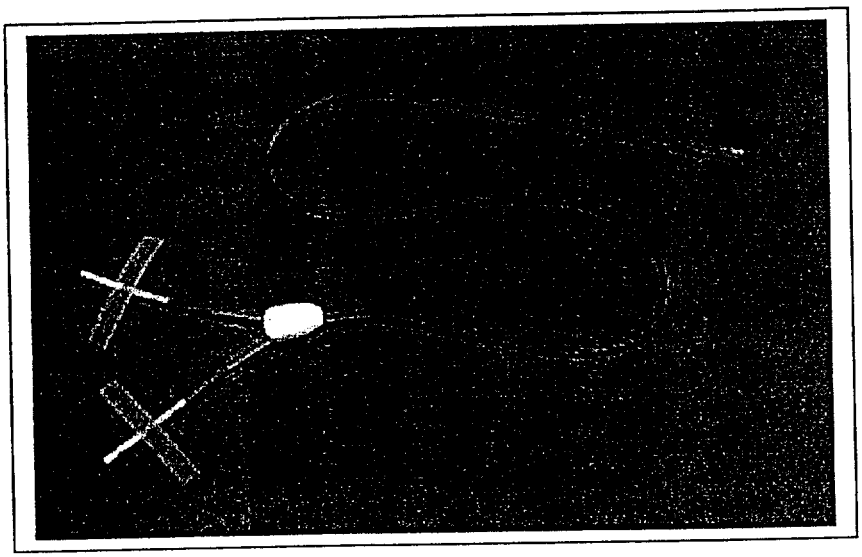


Figure 6

EXTERNAL COMPONENTS

The external components allow you to operate and control the *VOCARE Bladder System*. The external components consist of the **External Transmitter**, the **External Controller** and its **Cable**, the **Battery Charger and Power Cord**, and a small **Transmitter Tester**, which can be used to test whether or not the External Transmitter is working correctly. Figure 7 below shows the External Transmitter, External Controller, the External Cable, and Transmitter Tester. Figure 8 shows the Battery Charger and Power Cord.

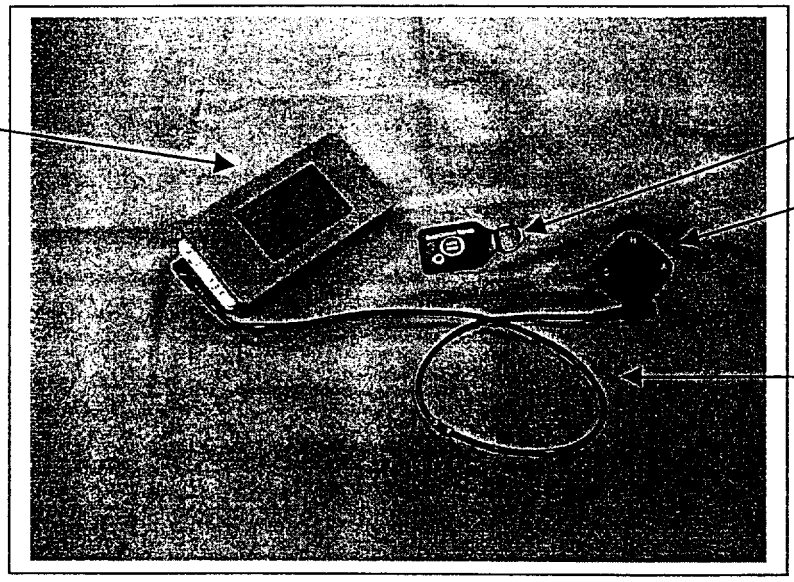


Figure 7

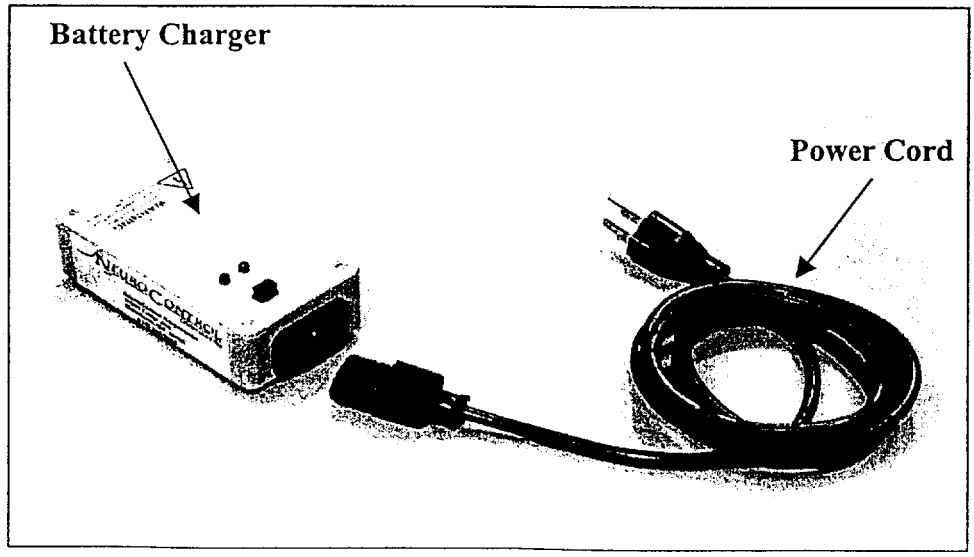


Figure 8

- External Controller

The External Controller allows you to turn your *VOCARE Bladder System* on and off and to select the bladder mode. It is adjusted by your doctor specifically for your bladder management needs. There are two switches on the top of the External Controller. One switch is used to turn the *VOCARE Bladder System* OFF (marked as O) and ON (marked as I). The second switch should usually be in Position 1 for your bladder routine. Your doctor may provide alternate bladder settings using Position 2 or Position 3. Figure 9 gives you a close up view of these switches.

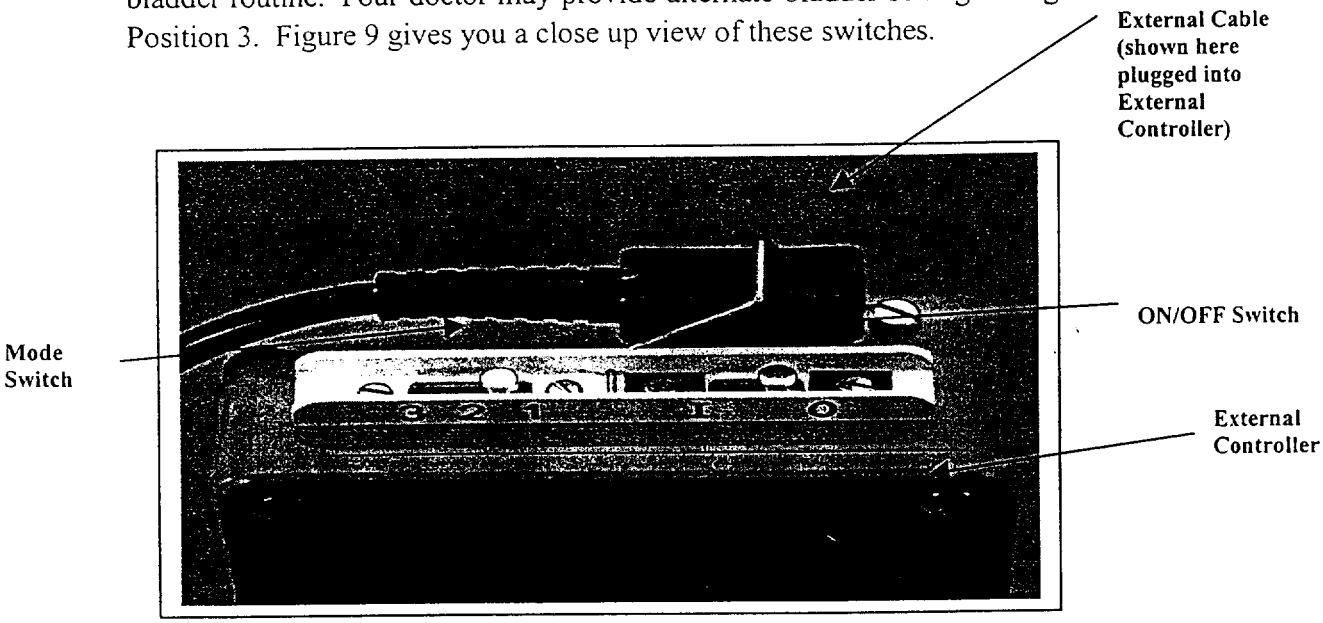


Figure 9

- External Transmitter

The External Transmitter sends a radio signal from the External Controller through your skin to the Implantable Receiver-Stimulator. The External Transmitter is held over the site of your Implantable Receiver-Stimulator whenever you want to use the *VOCARE Bladder System*. You can either hold it over by hand or use a medical adhesive product to hold it on. The External Transmitter is labeled with the letters "A" , "B", and "C" which identify the individual stimulation "channels" (similar to channels on a radio). The letters "A" and "B" will help you identify how to place the transmitter over your skin. The implanted parts of your *VOCARE Bladder System* only have two channels ("A" and "B"). The "C" channel is not used. The "C" channel is used in other European models of the *VOCARE Bladder System*. The External Transmitter is shown below in Figure 10.

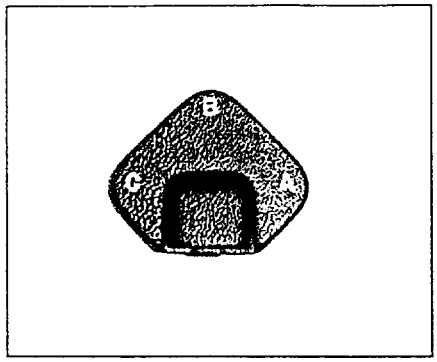


Figure 10

- Battery Charger and Power Cord

The Battery Charger and Power Cord (see Figure 11 below) are used to recharge the batteries in the External Controller. The Power Cord is used to connect the Charger to an electrical outlet. The free end of the External Cable is plugged into the Battery Charger to charge the batteries. *The External Transmitter must be removed from the External Cable before plugging the External Cable into the charger.*

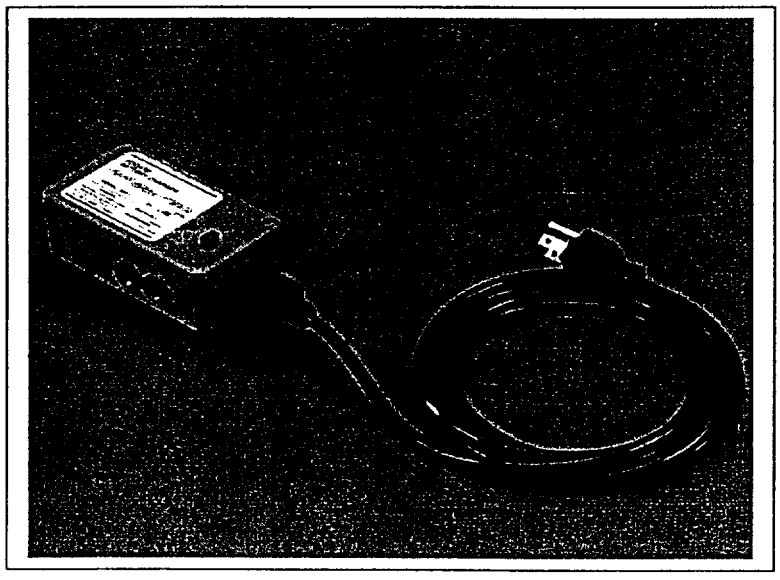


Figure 11

- Transmitter Tester

The Transmitter Tester is used to test if the External Transmitter is working correctly. The Transmitter Tester is pictured in Figure 12 below.

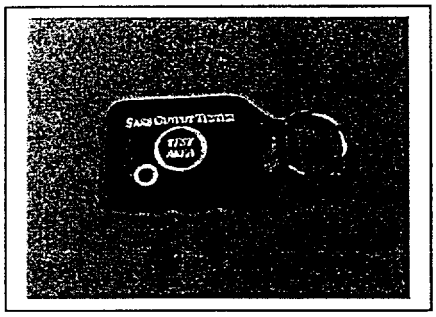


Figure 12

5.0 OPERATING THE *VOCARE BLADDER SYSTEM*

To use the *VOCARE Bladder System* effectively, you will need to have an approximate "schedule" for using the device to empty your bladder. For example, you might use the *VOCARE Bladder System* in the morning, at lunch time, in the mid afternoon, in the evening, and before you go to bed. You and your doctor will decide on a schedule that is best for you.

In order to operate the *VOCARE Bladder System, you must first position the External Transmitter.*

PLACING THE EXTERNAL TRANSMITTER

- The External Transmitter must be placed on the skin so that the "A" and "B" of the External Transmitter lie over the corresponding receiver channels of the Implantable Receiver-Stimulator. (Please refer to Figure 13 below.)

- You may be able to feel the Implantable Receiver-Stimulator under the skin. Your doctor will help you learn where the receivers are and how to position the External Transmitter.

- During the first six weeks after implantation, the implant may move slightly, but after six weeks, its position is usually very stable.

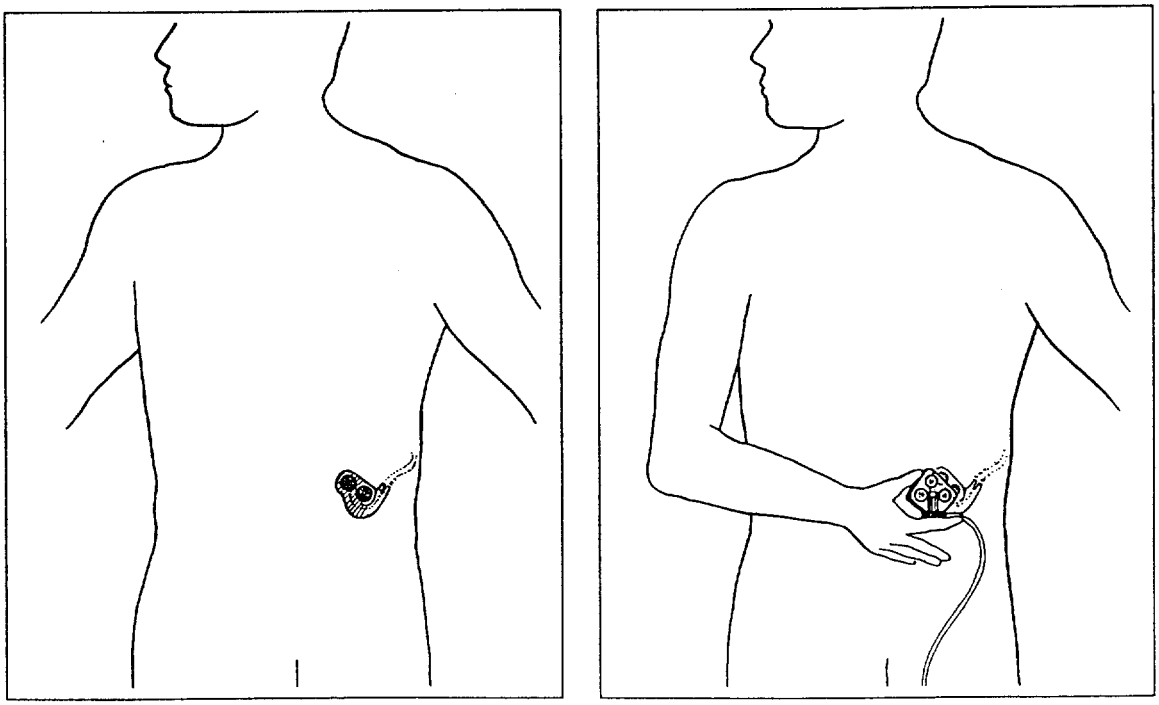


Figure 13

BLADDER EMPTYING

- Position yourself to begin your voiding program. *This may involve a transfer to a commode, placement of a urinal, or assistance from a personal care attendant. Refer to HELPFUL HINTS below for help in positioning.*

- You will usually select the Position "1" of the 3-position switch, move the on-off switch to the "I" (ON) position, and place the External Transmitter over the Implantable Receiver-Stimulator.

- You should expect urine to come out in spurts between the bursts of stimulation. Keep the External Transmitter in position until the spurts have stopped, or nearly stopped. *Note: You may need to turn the External Controller OFF, wait two minutes and then turn the VOCARE Bladder System back ON again. Waiting for a period of two minutes will enable your bladder to rest before beginning another series of stimulation. This may help you empty your bladder completely.*

Remember to switch off the External Controller when you are finished. If you forget, your batteries may be drained.

Caution: If your urine flow pattern changes or you do not think you are emptying your bladder completely, contact your physician immediately. If you cannot contact your physician, use an alternative or back-up method (such as Intermittent Catheterization) to empty your bladder.

Helpful Hints

Using the *VOCARE Bladder System* in a wheelchair

- While sitting in a wheelchair, a man can empty his bladder into a condom catheter and legbag or male urinal and a female can empty her bladder into a female urinal.

  If you are a man, you may not empty your bladder completely if your wheelchair cushion is pressing against your urethra (the opening through which urine passes). You may be able to relieve this pressure if you sit further forward on the cushion, you lean to one side, or if you reduce the height of the center of the cushion.

6.0 CARE AND MAINTENANCE OF THE *VOCARE BLADDER SYSTEM*

CHARGING THE BATTERIES IN THE EXTERNAL CONTROLLER

- Disconnect the External Controller Cable from the External Transmitter by holding onto the molded plug, not the cable. This will avoid damage to the cable. Plug the cable into the Charger. Figure 14 below shows you how the External Controller is connected to the Battery Charger.

- Connect the Battery Charger to the wall outlet with the Power Cord.

- There are yellow and green lights on the charger. If the charger is supplied with current from the wall outlet but the External Controller is not connected, only the green light will be on.

- If the External Controller is connected and the batteries are being charged, only the yellow light will be on.

- When the batteries are fully charged, the yellow and green lights should be almost equally bright.

- Moderate overcharging will not harm the batteries.

- Once a week, you should recharge the batteries for the entire night (8-10 hours).

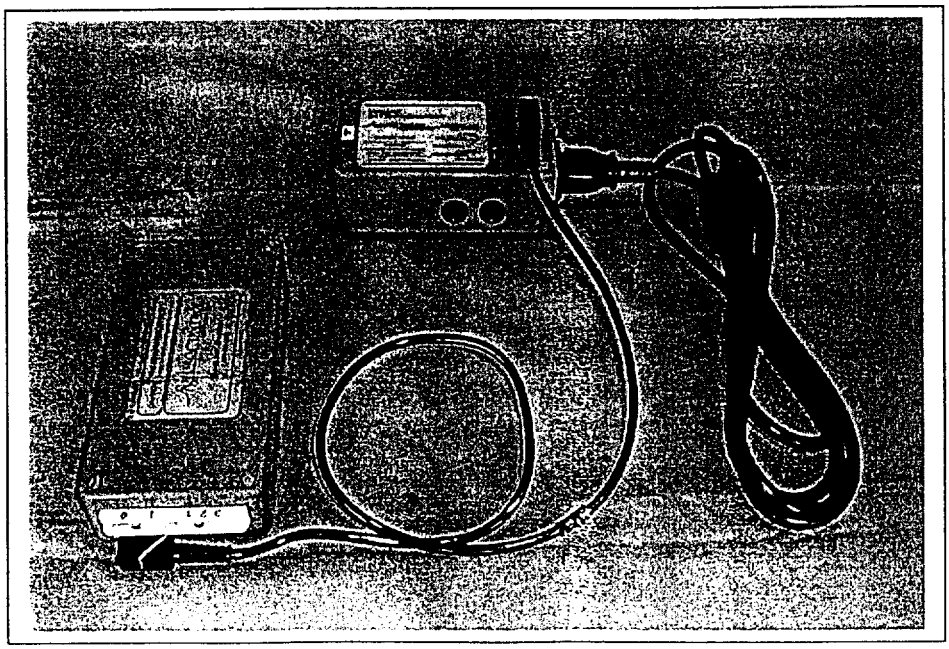


Figure 14

CLEANING

The outside cover of External Controller can be cleaned with a damp cloth. **Do not wash or submerse the External Controller for cleaning**. For heavier dirt or stains, a mild detergent such as dishwashing soap may be used for cleaning. Remove the soap with a damp cloth. Tape residue may be cleaned off the External Transmitter with rubbing alcohol. The cables should be wiped clean with mild detergent. Allow all items to air-dry completely before using.

INSPECTING CABLES

You should inspect the External Cable and the Power Cord for cracking or breaks in the insulation. If the insulation on either of your cables is cracked or broken, contact NeuroControl Customer Service at 1-800-378-6955 for a replacement cable.

SERVICE MAINTENANCE

If you find that the External Controller needs charging more than once per week, the internal batteries will need to be changed. The unit should be returned to NeuroControl Corporation to ensure proper installation.

7.0 TROUBLESHOOTING

If you have any questions or concerns with the *VOCARE Bladder System* or need assistance, call your Doctor or NeuroControl Corporation at 1-800-378-6955. This is an international toll free number and may be reached, outside of the U.S., by calling your local AT&T operator and asking to be connected to this number.

IF YOUR *VOCARE BLADDER SYSTEM* DOES NOT APPEAR TO FUNCTION PROPERLY

- If you think that the External Controller or External Transmitter is not working properly, you should first make sure the External Controller has enough charge. Connect the External Controller to the Battery Charger and check the lights as described in the section on battery charging on Page 18.

- If the External Controller is charged, you can test it by using the Transmitter Tester.

- Turn on the External Controller and place the Transmitter Tester opposite each of the transmitters (one at a time). If they are transmitting properly, a light on the Transmitter Tester will go on and off. Remember that it may take several seconds for the Transmitter Tester to begin flashing.

- If you cannot get a "transmitter tester" response from any of the transmitters, the External Controller is not working properly. Contact your Doctor or NeuroControl Corporation at 1-800-378-6955.

- If your *VOCARE Bladder System* seems to work sometimes but not other times, check the External Cable. You may have a loose connection.

IF YOU CANNOT EMPTY YOUR BLADDER

If you think that a large amount of urine is left in your bladder after trying to empty it, you should use an alternative or back-up method to empty your bladder (such as catheterization) until the problem has been corrected. **You should also contact your physician immediately.**

IF THE EXTERNAL CONTROLLER IS ACCIDENTALLY DROPPED IN WATER

If you have dropped your External Controller in water, contact NeuroControl Corporation at 1-800-378-6955 for instructions.

OTHER PROBLEMS

If you have any other problems with your *VOCARE Bladder System*, you should contact your doctor or NeuroControl Corporation at 1-800-378-6955.

OTHER REASONS TO CONTACT YOUR PHYSICIAN

If you suspect that you have a urinary tract infection you should contact your doctor. Signs and symptoms of a urinary tract infection include one or more of the following: fever; general tiredness and weakness; foul smelling, cloudy, or bloody urine; and increased leaking of urine.

8.0 Product Specifications

IMPLANTABLE RECEIVER-STIMULATOR (MODEL 1635-1)

Output:	2 Independent output channels Biphasic, capacitively coupled waveform (See waveform below)
Carrier Frequency:	Channel A - 7MHZ Channel B - 9 MHZ
Physical Dimensions:	8 x 5 x 0.85 cm 12g
Packaging:	1 Receiver stimulator in steam sterile double bag

EXTRADURAL ELECTRODES (MODEL 1640-1 for Clear Electrode, MODEL 1641-1 for White Electrode)

Stimulating Area (Cathodic):	35 mm^2 total
Return Area (Anodic):	74 mm^2 total
Physical Dimensions:	44 cm connector to bifurcation length 7 cm bifurcation to distal anode length 4g
Packaging:	2 extradural electrodes (1 white core, 1 clear core) in sterile double bag

EXTERNAL CONTROLLER (MODEL 1637-1)

Power Source:	(5) - 9 Volt rechargeable NiCd batteries
Operating Life:	8 hours (with typical stimulation settings)
Front Panel Controls:	3 Position mode selection switch On/Off toggle switch
Connections:	5 Contact receptacle
Physical Dimensions:	16 x 8 x 3 cm 420 g
Typical Output Control:	Amplitude 0-40 V Pulse Duration 24-720 µs Pulse Frequency 8-46Hz Bladder Gap Duration 2-14sec Bladder Burst Duration 1-7sec Alternate Gap Duration 5-35sec Alternate Burst Duration 2-17sec

EXTERNAL CABLE (MODEL 1638-1)

Physical Dimensions:	75 cm length
Connectors:	5 Contact molded plugs Interchangeable ends

EXTERNAL TRANSMITTER (MODEL 1636-1)

Output:	7 MHz-Channel A 9 MHz-Channel B
Physical Dimensions:	7.5 x 6.2 x 1.1 cm 19 g
Connection:	5 Contact receptacle

TRANSMITTER TESTER (MODEL 1642-1)

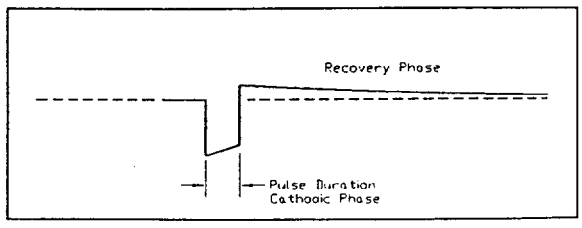
Visual indicator of stimulus pulse output from External Transmitter

BATTERY CHARGER (MODEL 1639-1) AND POWER CORD (MODEL 1670-1)

Power Output:	Full charge, 14 mA Trickle Charge, 4 mA
Input:	120/240 VAC 50 - 60 Hz
Indicators & Connections:	Amber charging indicator Green charge complete indicator 5 Contact connector receptacle
Physical Dimensions:	12.6 x 6.5 x 5.2 cm 290 g

ENVIRONMENTAL CHARACTERISTICS FOR ALL COMPONENTS

Transport and Storage:	Temperature -40°C to +70°C Relative Humidity 10 to 90% Pressure 500 to 1060 hPa



9.0 *VOCARE BLADDER SYSTEM* GLOSSARY

Autonomic Dysreflexia – Reflexes from the bladder which can cause a rise in blood pressure.

Bladder Capacity- The amount of urine that the bladder can hold.

External Urethral Sphincter– A valve at the bottom of the bladder which needs to open for urine to empty out of the bladder.

Functional Electrical Stimulation (FES) – A method by which electrical signals provide function to otherwise paralyzed muscles.

Incontinence – Leakage of urine.

Reflex Incontinence- Large unpredictable leakage of urine resulting from a reflex that causes the bladder to contract when there is urine in it.

Rhizotomy –The selective cutting of nerves.

Sacral Nerves – Nerves which travel through a lower part of the spine called the sacrum.

Stimulation – electrical signals which cause the contraction of muscles.

Stress Incontinence – small leaks of urine from bending forward or coughing.

10.0 INDEX