A STRATEGIC ANALYSIS OF DEVELOPMENT OPPORTUNITIES FOR NEOCONTROL PELVIC FLOOR THERAPY SYSTEM IN CANADA

by

Payam Shahi
M.Sc. Electrical & Computer Engineering, Concordia University 2005
B. Sc. Electrical & Computer Engineering, Shahid Beheshti University 1998

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Name: **Payam Shahi**

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Supervisory Committee:

_____

Dr. Mark Selman
Senior Supervisor
Director,
Learning Strategy Group,
Faculty of Business Administration

_____

Dr. Mark Moore
Second Reader
Lecturer,
Faculty of Business Administration

Date Approved: _____

Abstract

Urinary incontinence is an important health problem that affects millions of Canadians and many millions of people in all age groups worldwide. It is a demoralizing and costly problem with widespread human, social and financial implications. There are various types of treatments available to improve and control incontinence.

The NeoControl Pelvic Floor Therapy System provides a non-surgical, non-invasive therapy for treatment of urinary incontinence. Unlike other treatments, NeoControl exercises all the muscles of the pelvic floor to rebuild strength by repeating a painless and easy procedure.

The number of Canadians suffering from incontinence is growing because the population is aging. NeoControl and its technology is a new way of treatment, which has not been introduced to the Canadian marketplace to date.

This project investigates the opportunity to introduce the NeoControl Pelvic Floor Therapy System to the Canadian marketplace. The study presents an estimate for the demand for the therapy, a strategic evaluation of the market using Porter's Five Forces Framework, and a description of the target markets. The project concludes with a financial analysis of a proposed business to import and distribute the device into Canada.

Keywords: Urinary Incontinence, NeoControl Pelvic Floor Therapy System, Porter's Five Forces Framework

Dedication

I would like to dedicate this thesis to my father (Javaty), who had taught me to be patient and tolerant. It is also dedicated to my mother (Heshmat) and my brother (Raham) who have supported and encouraged me in all aspects of life.

I also would like to thank my lovely wife, Atoosa Mionji, who has given me limitless energy to tackle difficulties along the way. Without her support, I would have not been able to succeed in the EMBA program.

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I would also like to thank my partner Hamid Vaziri who has brought up the idea of distributing the NeoControl device in Canada.

Table of Contents

List of Figures

List of Tables

Glossary

Bladder	A sac that temporarily retains urine and discharges from the urethra
Catheter	A tubular device inserted into the urethra to withdraw urine
ExMI	Extracorporeal Magnetic Innervations
Kegel's exercises	Repetitive contractions to increase the tone of the pelvic floor muscles
Micturition	The desire to urinate
Pelvic Floor Muscle	Muscles that connect the pubis bone at the front to the tailbone at the back.
Prostate gland	A partly muscular, partly glandular body, situated about the base of the male urethra, that secretes the fluid which is a major constituent of ejaculatory fluid
Rectum	Straight part of the intestine before the anus
SUI	Stress urinary incontinence
Sphincter	A ring-like muscle that normally maintains constriction of a body passage or orifice and that relaxes as required by normal physiological functioning
UUI	Urge urinary incontinence
Ureter	A duct that carries urine away from a kidney to the bladder
Ureteritis	Inflammation of the ureter
Urethra	The canal which carries urine from the bladder to outside the body and, in males, also carries ejaculatory fluid
Urinary Incontinence	Loss of bladder control
Urinary system	The organs of the urinary tract — the kidneys, ureters, bladder and urethra

Urologist	A physician specializing in the urinary and urogenital tract
UTI	Urinary tract infection

1: Introduction

In response to the growing population of older patients with incontinence, pharmaceutical companies are developing new treatments for urinary conditions. There have been many innovations in the development of new drugs, electrical devices, and physical exercises to stop and control incontinence. Before recommending a treatment for incontinence, health care providers determine the nature and cause of the patient's incontinence. Based on the results, physicians choose the best treatment for the patient.

One of the latest therapies for incontinence, which is quite new to the Canadian marketplace, is a device known as NeoControl. The device offers treatment with a high level of comfort without introducing any side effects to the patients. It is simply an office chair fitted with magnets in its seat. The device does not require health care providers to analyse and monitor the treatment. The instructions are simple and easy to follow.

According to the NeoControl manufacturer, there are 20 published clinical studies available on the NeoControl therapy system and 17 published studies available on Extracorporeal Magnetic Innervation (ExMI) technology, on which the NeoControl therapy system is based. Within each study, a group of incontinent people were treated by the NeoControl therapy system, and the treatment success was measured by various methods. In most of the studies, more than 60% of the patients became dry and the rest saw improvement in their incontinence condition. There are 43 other clinical and non-clinical studies awaiting publication (NeoControl Website 2011) (NeoControl News 2011) (NeoControl Publication 2011).

The NeoControl therapy system has been successful in the European and United States markets. Since 2000, physiotherapists and family doctors have prescribed NeoControl therapy in many European countries such as France, Italy, and Spain. The NeoControl therapy system has been placed in the offices of physiotherapists and family doctors in Europe. Also, the NeoControl therapy system is available in European drug stores and retirement residences as an alternative treatment for incontinence. European insurance companies have recognized the value of the treatment offered by NeoControl therapy and agreed to fully cover the treatment costs. This has meant that incontinent people frequently use this treatment to improve their incontinence. In the United States market, the NeoControl treatment is not covered by any insurance companies. However, because of the large population and the size of the market, NeoControl therapy has found its place as an alternative treatment for incontinence. The treatment is available in physiotherapist and family doctor offices as well as spas, beauty salons, retirement centres, hospitals, and medical clinics.

Based on the recent information by Statistics Canada, there are approximately 5 million seniors (over 70 years of age) living in Canada in 2011 and about 60% of them have symptoms of stress, urge, or mixed urinary incontinence (Statistics Canada 2011). There are a few treatments available in the market for seniors to improve their urinary incontinence. The NeoControl therapy system provides a comfortable and easy to use treatment that has the potential to compete with or replace some of the existing treatments.

The following investigates business development opportunities to become an exclusive distributor of the NeoControl therapy system in Canada and deliver treatment through continuing and special care retirement centres. The distributor will import and install the NeoControl device and market treatment for a fee through continuing and special care retirement centres. The main intent is to get a foothold in the incontinence treatment market and target patients using electrical stimulation treatment. The Canadian exclusive distributor will own the NeoControl devices and will support centres to sell the

NeoControl treatment to their residents. Demand evaluation, possible financial implication analysis and distribution channels assessment are the most important aspects of this study.

2: Project Objectives

The objective of this project is to analyse the possible introduction of the NeoControl therapy system to Canadian retirement centres as an alternative treatment for urinary incontinence. To date, the NeoControl therapy system has not been brought to Canada.

This study investigates the development opportunity to create and establish a market for this technology throughout Canada, and prepares a strategic business case to import, distribute, and support the NeoControl therapy system.

After a brief explanation of urinary incontinence and its available treatments, the NeoControl device and ExMI technology will be discussed in detail.

This study:

- provides an analytical review of the incontinence treatment market and examines internal and external factors influencing its success. This includes the assessment of the NeoControl therapy system and its distribution in Canada using Michael Porter's "Five Forces Framework" and strengths, weaknesses, opportunities, and threats (SWOT) analysis.
- measures the Canadian market size and determines the key success factors in a growing market.
- introduces target markets and provides recommendations and strategies to penetrate the marketplace with minimum risks.
- evaluates potential sales and anticipates annual operating expenses, development profits, and returns.

3: Clinical Overview

People who have an incontinence problem have trouble stopping the flow of urine from the bladder. Incontinent people have both health and social problems. Some of their problems include:

- social embarrassment: They become depressed and limit their activities away from home, often becoming socially isolated. Many of them are too embarrassed to talk to their health care provider about their condition.
- physical health conditions: infections, skin imitations, and sleep disturbances are some of the problems caused by incontinence.
- special care: Past research shows that the major reason for people going into nursing homes is incontinence. Approximately 60% of elderly people who live in nursing homes are affected. However, incontinence is not an inevitable consequence of aging.

Some products and exercises have been developed that work to improve urinary incontinence. It is clear that finding the right treatment is not a simple task. The patient needs to consult with health care providers and try different products/exercises. In the following section, different types of incontinence along with the existing treatments are discussed in detail.

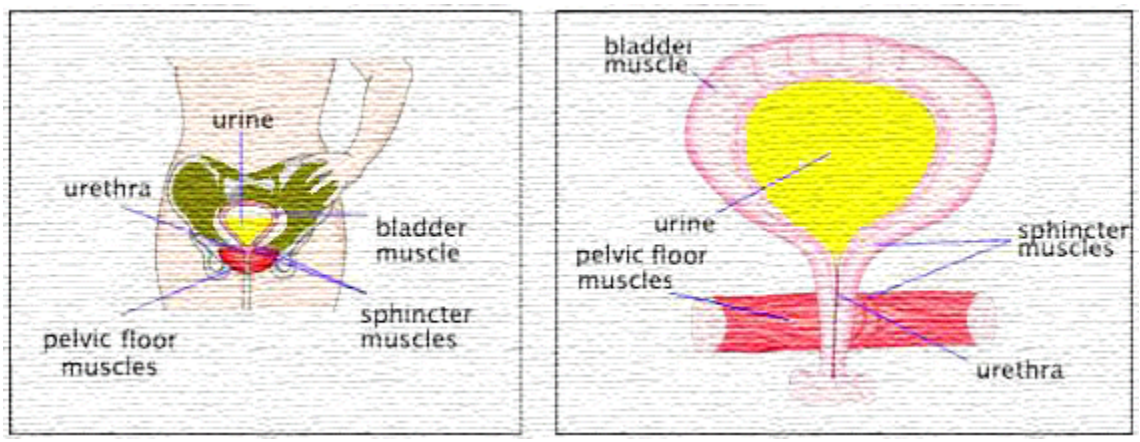
3.1 Types of Urinary Incontinence

In general, urinary incontinence is defined as the involuntary loss of urine that can be demonstrated objectively. It occurs when the pressure within the bladder exceeds that within the urethra during the filling phase. Incontinence is a symptom with a wide variety of causes. Actions like

coughing, laughing, lifting and sneezing could make intra abdominal pressure higher than urethral resistance. It is caused by weakening of the pelvic floor muscles and structural muscles.

Figure 3.1 demonstrates the high-level picture of bladder control system (NKUDIC 2011). There are many reasons why an individual may leak urine. Sometimes it is caused by an illness, in which case bladder control returns when the illness goes away. Being unable to have a bowel movement or taking certain medicines also may make it hard to control the bladder. Sometimes incontinence is an ongoing problem. Diseases such as arthritis make it hard to get to the bathroom in time and can make it even harder to control urine leakage.

Figure 3.1 (Left) Bladder Control System (Right) Bladder and Sphincter Muscles (NKUDIC 2011)



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There are several types of urinary incontinence. Many people have more than one type of incontinence. The common types of incontinence are discussed in the following.

3.1.1 Stress Incontinence

This is the involuntary leakage of any amounts of urine in response to increased pressure on the bladder, for instance when a person laughs, coughs, sneezes, bends, or lifts heavy objects. The major reason for stress incontinence is weakness or injury to the muscles of the pelvis or the sphincter. The

underlying causes include physical changes due to pregnancy, childbirth, or menopause. Stress incontinence commonly occurs in women who have had a number of children, possibly as a result of damage to the pelvic floor during vaginal delivery. However, women who have never had children may also suffer from this condition. In men, the most common factor leading to stress incontinence is the surgical removal of the prostate gland to treat prostate cancer. Other factors that may cause stress incontinence include:

- illnesses that cause chronic sneezing
- smoking, which can cause frequent coughing
- diabetes, which can cause excess urine production and nerve damage
- excess consumption of caffeine or alcohol
- medications that cause a rapid increase in urine production

Stress incontinence is seen mainly in women and is present in about 35% of incontinent seniors.

3.1.2 Urge Incontinence

This is a sudden uncontrollable desire to urinate regardless of how much urine is in the bladder. Urgency, frequency, and urination at night are common in people with this condition, which is due to disruption of signals between the bladder and the brain. Urge incontinence occurs because of over-activity of the bladder muscle. It is also caused by a problem with a weakened pelvic floor muscle, with the nerves that control the muscle, or both. It is a frequent type of incontinence in both men and women. Other causes include:

- conditions that can affect bladder nerves, such as stroke, dementia, Alzheimer's disease and Parkinson's disease
- diabetes

- previous surgery for stress incontinence
- anxiety and stress

Urge incontinence is the most common type of incontinence (60-70%) in seniors.

3.1.3 Mixed Incontinence

This term describes people who suffer from both urge incontinence and stress incontinence.

3.1.4 Overflow Incontinence

Overflow leakage of urine occurs when there is an obstruction in the bladder. The obstruction leads the bladder to overfill and incontinence results when the bladder contracts. Usually, the person does not know why she/he leaks urine and frequent leakage is common. In the majority of cases, this is more prevalent in men than in women. Overflow incontinence accounts for 10 to 15% of urinary incontinence.

3.2 Treatment Options

There are many treatments for urinary incontinence. Some treatment techniques, such as surgery, are invasive. Others introduce soft techniques that lead to controlling and stopping urinary incontinence. In the following, the popular treatments for different types of incontinence are discussed.

3.2.1 Behavioural Techniques

This type of treatment includes the following techniques to gradually improve urinary incontinence:

- dietary changes: Patients are advised to avoid caffeine-based and carbonated beverages, juices, chocolate, highly spicy foods, and alcohol.

- bladder training: Certain techniques are taught to patients to "hold on" for increasing amounts of time and to void at regular, scheduled intervals. These techniques teach patients to resist the urge to void and gradually expand the intervals between voiding.
- weight loss: Losing extra pounds, especially in the abdomen, can relieve pressure on the bladder and pelvic floor muscles.

Studies show that low-intensive behaviour therapy intervention for urinary incontinence is effective and should be considered as a first-line treatment for all people of all ages (ICUD 2009). The treatment is safe and is practical for all patients with different types of incontinence. It is not invasive and has the lowest impact on patients. Table 3.1 contains detailed information for behavioural treatment. As a general rule, behavioural treatments should be started before any other types of incontinence treatments. This treatment often requires multiple visits to a health care provider. Treatment duration could be between 2 and 6 months, depending on the patient's medical conditions.

Table 3.1 Treatment by Behavioural Techniques Summary of Facts

Treatment Method	Behavioural Techniques
Effectiveness Based on Gender	Male/Female
Incontinence Type Efficacy	Stress/Urge/Mixed/Overflow (ICUD 2009)
Approximate Usage	15% (Graham Swanson 2002)
Invasiveness	Low
Risks	Low
Treatment Duration	2 to 6 months (depends on the patient's medical conditions)
Pros	- Practical - Conservative approach - Minimum impact on patients
Cons	- Time-consuming treatment - Requires active patient participation - Caregivers are needed if patient has physical or mental limitations

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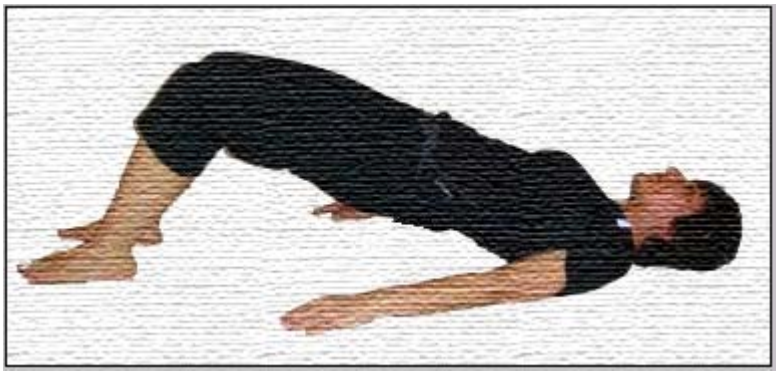
3.2.2 Pelvic Muscle Exercise (Kegel)

This type of treatment includes pelvic muscle rehabilitation by doing certain exercises, biofeedback therapy, and vaginal weight training. These techniques are recommended to strengthen the muscles around the vagina and urethra. Pelvic muscle exercises involve contracting the muscles of the urethra, vagina, and rectum for a period of time and then relaxing them (Figure 3.2). However, these exercises can be very difficult, or even impossible, for some patients to perform correctly. Either because of extreme weakness of their pelvic muscles or difficulty in identifying the correct muscles to exercise, these patients are unable to perform manual pelvic floor exercise therapy. For women, pregnancy, childbirth, and being overweight can weaken the pelvic muscles. For men, prostate surgery can weaken pelvic muscles. Fortunately, pelvic muscles are just like other muscles and exercises can make them stronger. Patients can also exercise almost anytime and anywhere without lying down. To exercise the pelvic floor muscles, the patient needs to pull in or squeeze the pelvic muscles as if he/she is going to stop urine flow. Then, they should hold this squeeze for about 10 seconds and rest for other 10 seconds.

Figure 3.2 *Kegel's exercise: Contract Pelvic Floor Muscle for Five Seconds and Relax the Muscles for Five Seconds.*



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Kegel's exercises offer a more practical and intense approach to improve stress and urge urinary incontinence problems. Treatment duration is slightly less than that for behavioural treatment. Usually, a patient's condition improves between 4 and 5 months. Often, people who are not having success with pelvic muscle exercises have simply either not performed the exercises correctly or for a long enough time. Special incontinence clinics or trained physical therapists can help people who have trouble doing the Kegel's exercises on their own. Kegel's exercise is not considered as an invasive or risky treatment, as it recommends only pure muscle movements to strengthen the muscles around the urethra. Table 3.2 summarizes Kegel treatment specification.

Table 3.2 Treatment by Pelvic Muscle Exercising (Kegel) Summary of Facts

Treatment Method	Pelvic Muscle Exercise (Kegel)
Effectiveness Based on Gender	Mostly Female
Incontinence Type Efficacy	Stress/Urge/Mixed (ICUD 2009)
Approximate Usage	5% (Graham Swanson 2002)
Invasiveness	Low
Risks	Low
Treatment Duration	4 to 5 months (depends on the patient's participation)
Pros	- Set of simple exercises - Conservative approach - Doable everywhere - Healthy approach
Cons	- Requires active patient participation - Day to day assistance is needed if patient has physical movement problems - Exercises should be done properly otherwise the treatment will not work

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Pelvic muscle exercises are very similar to other exercises used in strength training. Patients should focus on isolating their pelvic muscles, so that contractions are in these muscles and not in other areas. The good way of distinguishing the pelvic floor muscles from other muscles is to contract the muscles to stop urine passing during voiding. Patients are expected to fully understand the instructions

and execute them properly. The advantage of this approach is that it offers only a simple set of painless exercises, which patients should follow. This treatment is offered mostly to women after giving birth to strengthen their pelvic floor muscles. Kegel's exercise treatment is the healthiest way to improve stress, urge or mixed urinary incontinence.

3.2.3 Medication

Urinary incontinence can also be treated with medications. The most effective medications are anticholinergics, topical estrogen, and imipramine. Many medications for women's urinary incontinence have a drying effect on the body, which causes the common side effects of dry eyes, dry mouth, and constipation. In addition, some medications cause nausea. Taking medication to treat urinary incontinence is often a balancing act between the positive benefits of the medication and the negative side effects.

Treatment using medication may be useful alone or in conjunction with behavioural treatment, particularly if behavioural methods do not fully restore continence. Combining behavioural and medication therapy sometimes works better than either treatment alone. The type of medicine depends on the patient's medical conditions and incontinence type. Medication treatment requires close monitoring, especially for the dosage and scheduling. This treatment is for both men and women, and it can improve all types of incontinence. Medication therapy may have possible side effects such as confusion, agitation, dry mouth, and an irregular heart rhythm. Treatment duration is between 2 and 3 months, and it can be longer, based on the patient's medical conditions. Table 3.3 summarizes medication treatment specification. Medicines commonly used to treat incontinence include:

- anticholinergics: This category of medicines is helpful to treat urge and overflow incontinence. Medicines in this category include oxybutynin, tolterodine, darifenacin, solifenacin, and trospium.

- imipramine: This category of medicines is used to treat stress, urge, and mixed incontinence.

Table 3.3 Treatment by Medication Summary of Facts

Treatment Method	Medication
Effectiveness Based on Gender	Male/Female
Incontinence Type Efficacy	Stress/Urge/Mixed/Overflow (ICUD 2009)
Approximate Usage	10% (Graham Swanson 2002)
Invasiveness	Low
Risks	Medium
Treatment Duration	2 to 3 months (depends on the patient's medical conditions)
Pros	- Quicker treatment - Can be used concurrently with other treatment methods
Cons	- Has possible side effects - Applicable to certain patients (patients with medical conditions may not be able to use the prescribed medicines)

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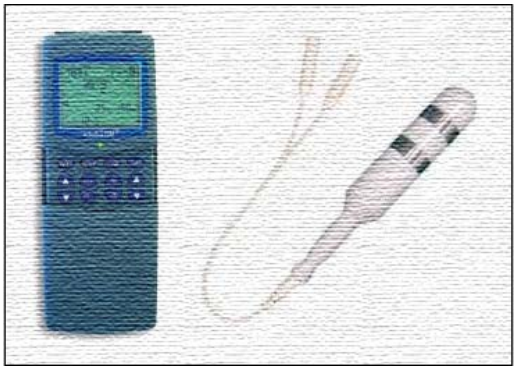
3.2.4 Electrical Stimulation

This treatment activates natural nerves in pelvic floor muscles without active patient participation. This treatment has no significant side effects and it exercises only the correct muscles to prevent urine leakage. The treatment consists of intermittent electrical stimulation of the pelvic floor nerve and muscle tissues using a tampon-shaped exerciser inserted into the patient's vagina, or a smaller exerciser inserted into the patient's rectum (Figure 3.3). The treatment is the application of electrical current to the pelvic floor muscle to provide a passive contraction that increases awareness of pelvic floor muscle contractions in general. Applying a low-grade electrical current to pelvic floor muscles stimulates the pelvic muscle to contract. Muscle contraction resulting form this treatment is a useful addition to pelvic floor exercises in the rehabilitation of weakened pelvic muscles. It can be very

beneficial for both men and women who are unable to contract these muscles on command, as it may teach the correct action. The electrical currents transmitted by the device stimulate and contract the same muscles as Kegel's exercises.

Figure 3.3 Electrical Stimulation Device



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Electrical treatment is recommended for patients with severe incontinence for whom other alternative treatments have not been effective. This treatment has been remarkably effective; it does not have any side effects and may be accompanied by only some temporary pain. Using electrical stimulation device teaches patients to contract their pelvic muscles themselves. This treatment can be administered twice weekly in 20-minute sessions for 2 to 3 months. This treatment is recommended to patients with uncomplicated and mild stress, urge or mixed incontinence who have never undergone surgery. Patients with irritated or sensitive skins cannot use this treatment as it may increase the irritation. This treatment is popular in Canada. According to the result of a survey (Graham Swanson 2002), almost 40% of the Canadians who are suffering from stress, urge or mixed incontinence are using electrical stimulation treatment. Table 3.4 summarizes electrical treatment specification.

Table 3.4 Treatment by Electrical Stimulation Summary of Facts

Treatment Method	Electrical Stimulation
Effectiveness Based on Gender	Male/Female
Incontinence Type Efficacy	Stress/Urge/Mixed (ICUD 2009)
Approximate Usage	40% (Graham Swanson 2002)
Invasiveness	Medium
Risks	Low
Treatment Duration	2 to 3 months (depends on the patient's medical and physical conditions)
Pros	- Quicker treatment - Can be used concurrently with other treatment methods - Teaches patients to contract pelvic muscles - Has no side effects whatsoever - Apply to the pelvic muscle directly - Can be used on a temporary or long-term basis
Cons	- Requires active patient participation. - Applicable to certain patients (those with irritated or sensitive skins cannot employ this treatment)

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3.2.5 Surgery

This treatment improves stress urinary incontinence in most women. If necessary, surgical procedures can be combined with other treatments to give the best results. For example, Kegel's exercises can be practices after the surgery to correct pelvic floor muscles support problem. The type of surgery depends on the patient's age, lifestyle, medication history, and general health. Potential risks associated with the surgery include:

- injury to the bladder, bowel, or blood vessels
- bleeding
- infection of the urinary tract or wound infections
- urinary problems after the procedure (difficulty urinating or urge symptoms)

Time to recover is needed after the surgery. Hospital stay is mandatory for a few days. Surgery is not usually recommended if other options are feasible. For instance, if a patient has mixed incontinence, surgery will not help with his/her urge incontinence. A patient may need medications or physical therapy to treat the urge incontinence (ICUD 2009).

Surgical treatment is the last option recommended by medical doctors. All kinds of urinary incontinence can be treated by surgery. Surgery can increase the storage ability of the bladder and decrease the pressure within the bladder. This treatment is reserved for patients who are severely affected by their incontinence and have an unstable bladder and a poor ability to store urine. Augmentation cystoplasty is the most often performed surgical procedure for severe stress, urge and mixed incontinence. In this surgery, a segment of the bowel is added to the bladder to increase bladder size and allow the bladder to store more urine. This procedure can also increase the risk of developing tumours. Surgery is recommended only if more conservative treatments have been tried and have failed to resolve the issue. Around 30% of incontinent Canadians are treated by surgical treatments (Graham Swanson 2002). Table 3.5 summarizes surgical treatment specification.

Table 3.5 Treatment by Surgery Summary of Facts

Treatment Method	Surgery
Effectiveness Based on Gender	Male/Female
Incontinence Type Efficacy	Stress/Urge/Mixed/Overflow (ICUD 2009)
Approximate Usage	30% (Graham Swanson 2002)
Invasiveness	High
Risks	High
Treatment Duration	1 week for recovery (depends on the patient's medical conditions)
Pros	- Fastest treatment - High success rate (60 to 90%)
Cons	- Has possible side effects - May cause trouble emptying the bladder after the surgery

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4: NeoControl – A New Form of Treatment

Behavioural therapies, Kegel's exercises, electrical stimulation, medication therapy and surgical treatments have been prescribed for more than 50 years by physiotherapists and family doctors. Neotonus Company invented the NeoControl therapy system as a new form of treatment for urinary incontinence in 1998. The NeoControl therapy system utilizes ExMI technology to provide a new approach which has complemented old treatments. The NeoControl therapy system provides treatment with no side effects, no pain, no disrobing, and no contact with the skin. Basically, NeoControl provides a treatment which is affordable and easy to use by most patients, especially people with special physical disabilities. It integrates the advantages of the older treatments while avoiding their disadvantages. For instance, Kegel's exercises strengthen pelvic floor muscles through the repetition of a simple set of practices. After one month of practice, the patient will clearly recognize the control over pelvic floor muscles. The patient needs to participate in all practice sessions and follow the exact instructions in order to gain control over pelvic floor muscles. The NeoControl therapy offers the same practice with no need for patient participation. The patient need only sit on the NeoControl chair for 10 sessions of 20 minutes each. This treatment can be used by patients with physical or mental disabilities. The NeoControl treatment applies the treatment to only the pelvic floor muscles. This decreases potential side effects on other parts of the body and prevents further complications. Medication therapy is an example of a treatment that causes side effects because the treatment is applied to the whole body. Although electrical stimulation therapy is widely used in Canada, some incontinent patients are still reluctant to use this treatment. They complain of discomfort or irritation because a probe must go into the vagina or anus.

Treatment methods are recommended by family doctors, physiotherapists, urologists, or medical doctors in hospitals. After the type of incontinence is determined by the family doctor, or an urologist, a suitable treatment will be recommended based on the patient's medical condition and the type of incontinence involved. Physiotherapists offer behavioural therapy, Kegel's exercises, and electrical stimulation. Urologists and surgeons provide treatments such as medication therapy and surgery. It is challenging to introduce a new treatment in an established medical segment. Although there are many published and unpublished papers available to prove the usefulness of the NeoControl therapy, it has not yet been accepted by the Canadian Physiotherapy Association. Bringing this treatment to Canadian retirement facilities and motivating them to promote this new form of treatment by sharing profits seems to be a promising approach.

As indicated earlier, there are 20 published papers available on the NeoControl therapy system. One study shows that out of 50 patients who received NeoControl therapy treatment, 17 (34%) were dry and used no pads, 16 (32%) were using not more than 1 pad per day, and 17 (34%) were using more than 1 pad per day after receiving the NeoControl treatment. Treatment reduced the frequency of leak episodes per day from 2.6 to 1.0. This research was not a placebo-controlled study because the patients were aware of the strong and obvious contractions of the pelvic floor muscles during the treatment (Niall 2000).

Another study was performed to evaluate the efficiency and applicability of the NeoControl therapy system. Twenty four patients were treated for eight weeks. Twelve patients suffered from urge incontinence, and in twelve patients a mixture of urge and stress incontinence was present. In 58% of the patients an objective improvement of the incontinence was observed. Three patients were completely dry. 71% of the treated patients noticed a subjective improvement. The NeoControl therapy system was recognized as effective and easy-to-perform treatment in this study (Chandi 2006).

One clinical study has shown that 50% of the women patients who completed six weeks of this treatment are reported to be completely cured, and an additional 30% are reported to have significant improvement in their conditions (Almeida 2004).

Non-surgical treatments are very popular in Europe, but currently there is less enthusiasm for conservative therapies in North America. Urologists are more likely to advise surgical treatment, but patients are naturally reluctant to consider surgical treatments until incontinence symptoms are severe.

NeoControl treatment should be recommended by health care providers after they have examined patients to ensure the type of the incontinence. The NeoControl therapy system is recommended for patients with the stress, urge, or mixed incontinence.

This section explains the NeoControl device and elaborates its functionality and technology. In the end, a comparison table (Table 4.1) indicates the advantages of using NeoControl in comparison with other available treatments.

4.1 ExMI Technology

Extracorporeal Magnetic Innervation (ExMI) technology employs powerful and pulsed electromagnetic fields to induce natural contractions of the pelvic floor muscles. With this technology, there is no need for direct contact, probes, patches, or other electrodes. Patients remain comfortably seated and fully clothed throughout the duration of the treatment. Electromagnetic stimulation is painless and harmless.

ExMI technology was developed by the Neotonus Company in 1997 and was approved by the US Food and Drug Administration (FDA) in June 2000 for the treatment of stress, urge, and mixed urinary incontinence (FDA endorsement 2000). The company's first product to utilize ExMI technology was the NeoControl Pelvic Floor Therapy System. The Neotonus Company has been acquired by KitAlpha Company in February 2010.

The ExMI technology and its associated products have not been introduced and brought to Canada to date. Since NeoControl holds FDA approval, an import certificate needs to be issued by the Health Canada to import and distribute the device in the country. The device has been accepted as a new way of treatment for urinary incontinence globally. However, further examinations indicate that NeoControl has more applications, such as for erectile dysfunction, and haemorrhoids (NeoControl Website 2011). These applications have not yet been approved by the Food and Drug Association.

Figure 4.1 illustrates the waves created by the NeoControl device and where they strike the pelvic floor muscles. Simply, ExMI technology stimulates nerves in the pelvic floor area, which causes contractions of the pelvic floor and sphincter muscles.

Figure 4.1 ExMI Technology (ExMI technology 2011)

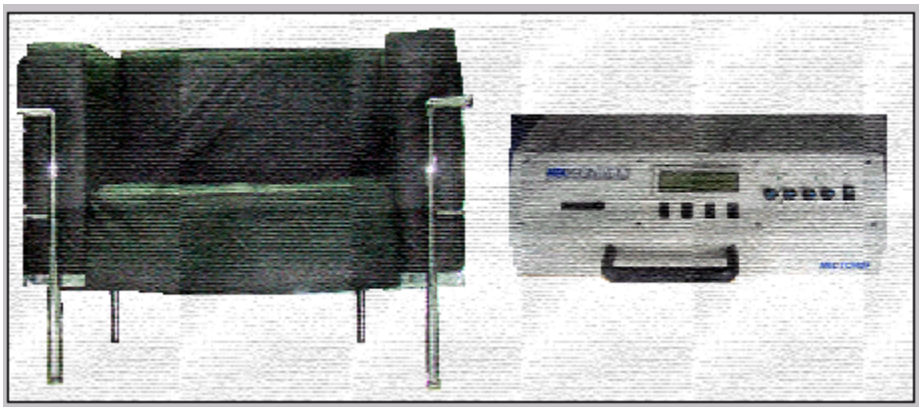
Created by the author

4.2 NeoControl Pelvic Floor Therapy System

The NeoControl pelvic floor therapy system is a non-surgical, non-invasive therapy for the treatment of stress, urge, and mixed urinary incontinence. For patients whose incontinence is caused by a weakening of their pelvic floor muscles, the NeoControl therapy system can offer unique therapeutic benefits. Unlike other therapy options, NeoControl exercises all of the muscles in the pelvic floor to

rebuild strength and endurance and restore bladder control. NeoControl accomplishes this while the patient sits fully clothed in a comfortable chair (Figure 4.2).

Figure 4.2 NeoControl Pelvic Floor Therapy System



Created by the author

Electromagnets have been designed and built into the seat of the NeoControl chair to create a small, effective magnetic field. These electromagnets are not as big as a small pineapple. The relationship between magnetic fields and electric current induces activity in nerves and muscles. When muscles contract, it is actually the electric signals from the nerves that trigger the contraction and coordinate the activity. NeoControl induces these natural patterns of activity in nerves and muscles by using electromagnetic stimulation.

When the patient is sitting fully clothed on the chair, the muscles of the pelvic floor are positioned directly above the magnetic field. By adjusting the strength of the field, the nerves and muscles of the pelvic floor are induced to contract by the pulsed magnetic fields. The rate and strength of the pelvic floor contractions can be adjusted to optimal settings using controls, like tuning the frequency and volume on a radio. This exercising of the muscles builds strength and endurance, helping the patient to regain bladder control. The pelvic floor muscles contract and relax with each magnetic pulse, creating a physical exercise like any other muscular workout, except the brain is not directing the

contraction. One way to think of NeoControl is as an automatic Kegel's exercise machine. A treatment session takes less than 20 minutes and is typically done once or twice a week for eight weeks.

While the NeoControl therapy system restores control over these functions, long-term benefits are also dependent on patients' willingness to change behavioural habits such as diet, weight control, and exercise.

The NeoControl therapy system provides treatment once a NeoCard is inserted into the device. NeoCards are manufactured by the NeoControl supplier for the distributors. Once a NeoControl device is purchased, a bundle of NeoCards are available which enable the device for unlimited treatment for a year. New NeoCards must be purchased separately to enable the device for the following years.

Before receiving NeoControl treatment, a patient needs to be fully examined by a health care provider to identify the type of the incontinence. Once it has been determined that the patient is suffering from stress, urge, or mixed incontinence and the cause of the incontinence is weakened pelvic floor muscles, then NeoControl treatment can be recommended. Once a patient completes a series of the NeoControl treatments and regains continence, a health care provider can provide advice on proper voiding habits and exercise that can help ensure long-term freedom from the worries of urinary leakage.

After approval by the Canadian government, the NeoControl therapy system will be an available treatment for incontinent patients in continuing and special care retirement centres in Canada. Incontinent patients who know their incontinence type can be recommended by the retirement centre to use the treatment.

4.3 NeoControl System Advantages / Disadvantages

Table 4.1 illustrates the benefits that patients receive by using NeoControl therapy system.

Table 4.1 Treatment by NeoControl Therapy System Summary of Facts

Treatment Method	NeoControl Pelvic Floor Therapy System
Effectiveness Based on Gender	Male/Female
Incontinence Type Efficacy	Stress/Urge/Mixed (NeoControl Website 2011)
Invasiveness	Low
Risks	Low
Treatment Duration	Less than 2 months
Pros	- Pain free - No side effects - No skin contact - Fast treatment - High rate of success (50 to 80%) - Non-invasive - Non-surgical - Easy and comfortable treatment - No patient participation - Can be used concurrently with behavioural techniques - Can be applied to the pelvic muscle directly - Practical for all ages - No recovery period - No probing - Other clinical applications (NeoControl Website 2011) • Erectile dysfunction • Vagina tonus • Orgasm problems • Hip fracture prevention (Note: Other clinical applications have not been granted FDA approval. NeoControl's manufacturer is in the process of obtaining FDA approval for these applications, which will create new markets in the future.)
Cons	- Specific to improvement of pelvic floor muscles - Not applicable to treat overflow incontinence
(Created by the author)	

5: Overall Treatments Comparison

There are many factors to be considered by incontinent people and health care providers, when it comes to choosing a suitable treatment. Obviously, the type of incontinence and the treatment appropriateness are critical to the patient. For instance, Kegel's exercises are widely used by women to strengthen their pelvic floor muscles after giving birth. The exercises are recommended to patients who are not physically or mentally restricted. Kegel's exercise can be recommended to patients suffering from stress, urge or mixed incontinence. Like other treatments, medication therapy has its own limitations. If a patient has sensitivity to a certain type of medication which is typically prescribed for incontinent people, then the patient would not be able to use that medication as a treatment for incontinence.

In this section, vital criteria that are considered by patients and health care providers to treat incontinence are discussed. These criteria are the critical factors when it comes to a health care provider choosing a treatment for a patient.

5.1 Evaluation Criteria

In this section, 10 criteria are discussed. Each criterion is evaluated as "low", "medium", or "high" for each criterion.

5.1.1 Invasiveness

This factor measures the invasiveness of the treatment. By definition, an invasive procedure is one which penetrates or breaks the skin or enters the body cavity. In the list of available treatments

discussed, only surgery is considered to be highly invasive. Electrical treatment is slightly invasive because a tampon-shaped exerciser is inserted into the patient's body. The NeoControl is not an invasive approach. Table 5.1 summarizes the invasiveness measurement for all type of treatments.

Table 5.1 Treatment Invasiveness Comparison Table (Lowest is the best)

	Invasiveness
Behavioural Techniques	Low
Kegel's Exercises Therapy	Low
Medication Therapy	Low
Electrical Therapy	Medium
Surgery	High
NeoControl	Low

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5.1.2 Risk

This factor measures the treatment safety and evaluates the potential complications ranging from infections to death after termination of the treatment. Risks and complications can include medication reaction, bleeding, infection, etc. Again, surgical treatment is the riskiest approach to treat incontinence; other treatments are much more secure and safe. The NeoControl is a low risk therapy. Table 5.2 summarizes the risk measurement for all type of treatments.

Table 5.2 Treatment Risks Comparison Table (Lowest is the best)

	Risks
Behavioural Techniques	Low
Kegel's Exercises Therapy	Low
Medication Therapy	Medium
Electrical Therapy	Low
Surgery	High
NeoControl	Low

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5.1.3 Treatment Duration

This factor measures the treatment length. Presumably, patients prefer faster treatment, but there are always trade-offs between treatment speed and involved risks. Unlike surgery, which is a fast treatment, behavioural and Kegel's exercise therapies are considered to be the most time-consuming treatments. The NeoControl requires a moderate amount of time for the treatment (1 to 2 months). Table 5.3 summarizes treatment duration for all type of treatments.

Table 5.3 Treatment Duration Comparison Table (Lowest is the best)

	Treatment Duration
Behavioural Techniques	High
Kegel's Exercises Therapy	High
Medication Therapy	Medium
Electrical Therapy	Medium
Surgery	Low
NeoControl	Medium

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5.1.4 Patient Participation

This factor measures the level of patient participation required by each type of the treatments. For instance, Kegel's exercises require patients to repeat the same set of simple exercises properly. Hence, patients are required to fully participate in the exercises. Surgery does not need patients participation, as the surgeon performs the procedure. NeoControl requires patients to sit on the chair and relax each session for 20 minutes. The level of participation is considered to be fairly low. Table 5.4 summarizes anticipated patient participation for all type of treatments.

Table 5.4 Patient Participation Comparison Table (Lowest is the best)

	Patient Participation
Behavioural Techniques	High
Kegel's Exercises Therapy	High
Medication Therapy	Medium
Electrical Therapy	Medium
Surgery	Low
NeoControl	Low

Created by the author

5.1.5 Side Effects

This factor measures the probability of potential side effects after using each type of treatment. Surgeries have the highest side effects. Medication may cause some inconvenience for patients, because the whole body consumes the medication. NeoControl has no side effects. Table 5.5 summarizes the level of side effects for all type of treatments.

Table 5.5 Treatment Side Effects Comparison Table (Lowest is the best)

	Side Effects
Behavioural Techniques	Low
Kegel's Exercises Therapy	Low
Medication Therapy	Medium
Electrical Therapy	Low
Surgery	High
NeoControl	Low

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5.1.6 Recovery Time

This factor indicates if the treatment requires recovery time. Recovering from any treatment is greatly dependent upon the type of the treatment. Behavioural techniques, Kegel's exercises, and electrical therapy do not need recovery time, because at any time patients can stop treatment without any

possible side effects. Conversely, surgeries require recovery time. NeoControl does not need recovery time. Table 5.6 summarizes anticipated recovery time for all type of treatments.

Table 5.6 Treatment Recovery Time Comparison Table (Lowest is the best)

	Recovery Time
Behavioural Techniques	None
Kegel's Exercises Therapy	None
Medication Therapy	Low
Electrical Therapy	None
Surgery	High
NeoControl	None

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5.1.7 Procedure Self-Monitoring

This factor measures the level of required self monitoring a patient should have over the course of the treatment. Obviously, behavioural techniques and Kegel's exercises require the highest level of monitoring. Surgery and NeoControl require minimum monitoring. Table 5.7 summarizes required procedure monitoring for all type of treatments.

Table 5.7 Treatment Procedure Self-Monitoring Comparison Table (Lowest is the best)

	Procedure Self-Monitoring
Behavioural Techniques	High
Kegel's Exercises Therapy	High
Medication Therapy	Medium
Electrical Therapy	Medium
Surgery	Low
NeoControl	Low

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5.1.8 Cost

This factor measures the costs of each treatment. Physiotherapists offer electrical therapy for, on average, $50 per session. A full electrical treatment includes 10 sessions. They also offer Kegel's exercises for, on average, $45 per session. There is no minimum or maximum number of sessions required for Kegel's exercises. A full cost of medication therapy starts, on average, at $350. All of these treatments are partially covered by the provincial health care systems. Patients with severe incontinence condition may be recommended to have surgery. BC Provincial health care plans provide full coverage for surgery to treat all types of incontinence and provide limited coverage for other available treatments. Private insurance companies offer a greater range of coverage for existing treatments. For instance, BC health care plans cover costs of physiotherapy care up to $125 per calendar year if the patient has an income of no more than $28k per year. However, extended health care providers cover costs of physiotherapy care up to $1000 per year. The coverage varies based on the province where the patient is located and on the patient's level of income. NeoControl therapy has not been covered by either provincial care plans or any private insurance companies because the treatment is quite new to Canada and no one has yet brought it to their attention. According to the Health Canada, any Canadian distributor of medical devices that offers medical treatment could submit an application to obtain insurance coverage for the treatment. The Health Canada processes and responds to applications within a year. Until then, NeoControl will be offered without insurance coverage to customers. This can introduce a serious barrier for incontinent people to actually use the treatment in the first year of the operation. In the chapter 9 and 10, development strategies will be discussed to tackle this issue. Table 5.8 summarizes the treatment cost information for all type of treatments.

Table 5.8 Treatment cost comparison table (Lowest is the best)

	Service Provider	Health Canada Coverage (%)	Extended Health Coverage (%)	Cost to Patient (%)	Cost Level to Patient
Behavioural Techniques	Physiotherapist	30	80	20 to 70	Medium
Kegel's Exercises Therapy	Physiotherapist	30	80	20 to 70	Medium
Medication Therapy	Medical Doctor/ Urologist	60	90	10 to 40	Low
Electrical Therapy	Physiotherapist	30	80	20 to 70	Medium
Surgery	Surgeon	100	70	0	None
NeoControl	Retirement Facilities	0	0	100	High

Created by the author (Health Canada 1 800 663-7100, Green Shield Extended Health care provider (April 2011))

5.1.9 Procedure Ease

This factor measures the ease of each treatment. Ease means the level of comfort that patients maintain when pursuing each treatment. The NeoControl and behavioural techniques provide the highest level of comfort for the patients. Table 5.9 summarizes the level of easiness for all type of treatments.

Table 5.9 Treatment Ease Comparison Table (Highest is the best)

	Procedure Easiness
Behavioural Techniques	High
Kegel's Exercises Therapy	Medium
Medication Therapy	Medium
Electrical Therapy	Medium
Surgery	Low
NeoControl	High

Created by the author

5.1.10 Success Rate

This factor measures the success rate of each treatment in general. Health care providers usually start their treatments with by first recommending low-risk methods like behavioural techniques and Kegel's exercises. Riskier treatments are recommended if no improvement is made to the patient's condition. Of existing treatments, surgery and NeoControl have the highest rate of success. Table 5.10 summarizes the level of success for all type of treatments.

Table 5.10 Treatment Success Comparison Table (Highest is the best)

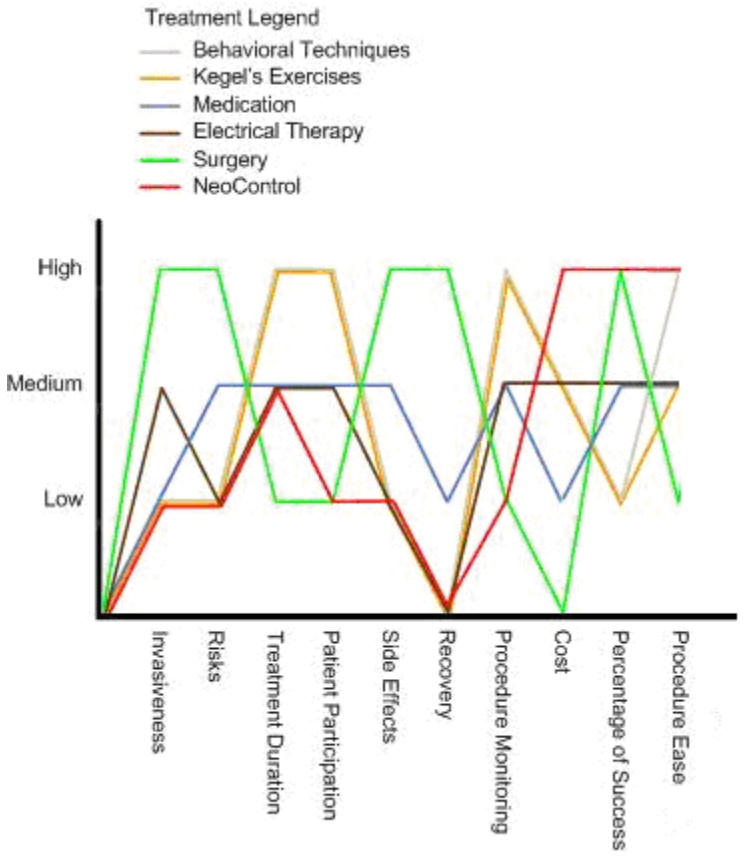
	Treatment Success
Behavioural Techniques	Low
Kegel's Exercises Therapy	Low
Medication Therapy	Medium
Electrical Therapy	Medium
Surgery	High
NeoControl	High

Created by the author

5.2 Treatment Evaluation

Figure 5.1 gives a value curve for each available treatment. For the first eight criteria, lower is more attractive, and for the last two criteria, higher is more attractive. A treatment method with high levels of risk and potential side effects is not considered as a desirable treatment to the patient. However, based on the patient's condition, a risky and invasive treatment may be recommended by the health care provider if that is the only way of making an improvement in the patient's incontinence condition.

Figure 5.1 Treatment Value Curve



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If each treatment is graded by these criteria, the most attractive treatment for incontinent people can be determined. Table 5.11 summarizes the grading rules. With the current grading rules, every treatment method can be graded. For example, medication therapy gets grade "2" for being a non-invasive approach. NeoControl is given "3" for being an easy treatment. However, the grading rules do not reflect the significance of each criterion. In order to emphasize the importance of each criterion, a weight is assigned to each one. While such weighting is necessarily somewhat subjective, the weights assigned, in the views of the author and based on his experience in talking to people about the issues, the relative significance of each criterion in the decision-making process about which treatment to use. Lack of invasiveness, lack of side effects, ease of the procedure for the patient and success rates are given the greatest weight in the decision while treatment duration, amount of recovery time and the amount of

monitoring of the treatment process required by the patient are the least significant criteria in this process. Table 5.12 summarizes weights for the criteria.

Table 5.11 Treatments Grading Rules

	Criteria	
Possible impacts	**Invasiveness** **Risks** **Treatment Duration** **Patient Participation** **Side Effects** **Recovery** **Procedure Monitoring** **Cost**	**Procedure Ease** **Percentage of Success**
None	3	0
Low	2	1
Medium	1	2
High	0	3

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Table 5.12 Treatments Weight Scales

	Possible Weight		**Possible Weight**
Invasiveness	4	**Recovery**	1
Risks	3	**Procedure Monitoring**	2
Treatment Duration	2	**Cost**	3
Patient Participation	3	**Procedure Easiness**	4
Side Effects	4	**Percentage of Success**	4

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Table 5.13 summarizes the criteria and the treatment methods to determine the most demanding treatment. The total grade is calculated by multiplying each criterion weight by its grade. As shown in the table 5.13, the NeoControl has the highest total grade. This presents a basic evaluation of the existing treatments and the NeoControl therapy.

Table 5.13 Treatments Grading Snapshot

	Behavioural Techniques	**Kegel's Exercise**	**Medication**	**Electrical Therapy**	**Surgery**	**NeoControl**
Invasiveness (weight=4)	2 (Low)	2 (Low)	2 (Low)	1 (Medium)	0 (High)	2 (Low)
Risks (weight=3)	2 (Low)	2 (Low)	1 (Medium)	2 (Low)	0 (High)	2 (Low)
Treatment Duration (weight=2)	0 (High)	0 (High)	1 (Medium)	1 (Medium)	2 (Low)	1 (Medium)
Patient Participation (weight=3)	0 (High)	0 (High)	1 (Medium)	1 (Medium)	2 (Low)	2 (Low)
Side Effects (weight=4)	2 (Low)	2 (Low)	1 (Medium)	2 (Low)	0 (High)	2 (Low)
Recovery (weight=1)	3 (None)	3 (None)	2 (Low)	3 (None)	0 (High)	3 (None)
Procedure Monitoring (weight=2)	0 (High)	0 (High)	1 (Medium)	1 (Medium)	2 (Low)	2 (Low)
Cost (weight=3)	1 (Medium)	1 (Medium)	2 (Low)	1 (Medium)	3 (None)	0 (High)
Procedure Easiness (weight=4)	3 (High)	2 (Medium)	2 (Medium)	2 (Medium)	1 (Low)	3 (High)
Percentage of Success (weight=4)	1 (Low)	1 (Low)	2 (Medium)	2 (Medium)	3 (High)	3 (High)
Total Grade= ∑grade*weight	**44**	**40**	**46**	**47**	**39**	**61**

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6: Market Analysis

The global market of urinary incontinence devices is expected to grow at an annual rate of approximately 4% between 2008 and 2016, reaching about $2 billion by the end of 2016 (Market Research 2008). The urinary incontinence market is one of the most under-penetrated medical markets. About 30% of women worldwide are urine incontinent, yet about two thirds of cases are estimated to remain undiagnosed (Marketstrat 2009). This is a huge market share to capture by introducing a new medical device that offers a safe and reliable treatment for incontinent people. Although a wide variety of treatment options are available, ranging from medication and exercise to surgery, patients largely remain unaware of these options or feel too uncomfortable to seek medical help. This is by far the biggest restraint in the urinary incontinence device market. However, changing demographics and campaigns to raise awareness of urinary incontinence treatments are expanding market opportunities in this segment. (Marketstrat 2009)

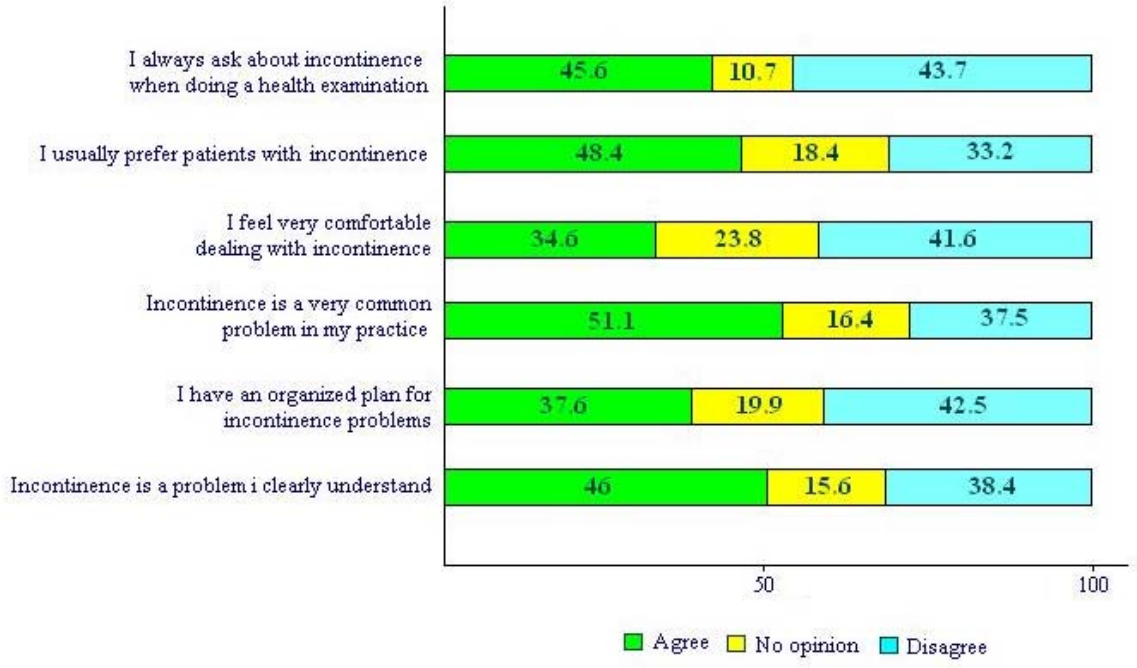
With a growing number of elderly around the world and increasing rates of chronic conditions that lead to incontinence, the demand for minimally invasive, cost-effective urinary incontinence devices such as NeoControl is going to increase in the foreseeable future.

Prevalence surveys found that 25% of clients who were receiving home care services in southern Ontario were incontinent of urine. The rate of urinary incontinence in acute care hospitals has been estimated at 35%. This rate increases to 50% to 70% in long-term care facilities (Mohide 1998) (Brocklehurst 1993).

6.1 Relevant Market and Customer Overview

Many health care professionals consider incontinence as part of the aging process. In approximately 70% of patients, urinary incontinence can be either resolved or improved (Seim 1996). Urinary incontinence is often not addressed because of lack of awareness on the part of health care professionals and clients. One study (Eriksen 1990) found that more than 50% of cases of incontinence were inadequately managed. Even when a problem had seen identified, available treatments were not discussed in almost half of the cases. In a survey of Canadian urologists, gynecologists, physiotherapists, occupational therapists, social workers, and visiting nurses, there are varying levels of skills and willingness to participate in the care of patients with urinary incontinence. Figure 6.1 illustrates the findings of a Canadian national survey (Canadian Survey 2002) which was sent to a sample of family

Figure 6.1 Survey Outcome about Urinary Incontinence Awareness (Canadian Survey 2002)



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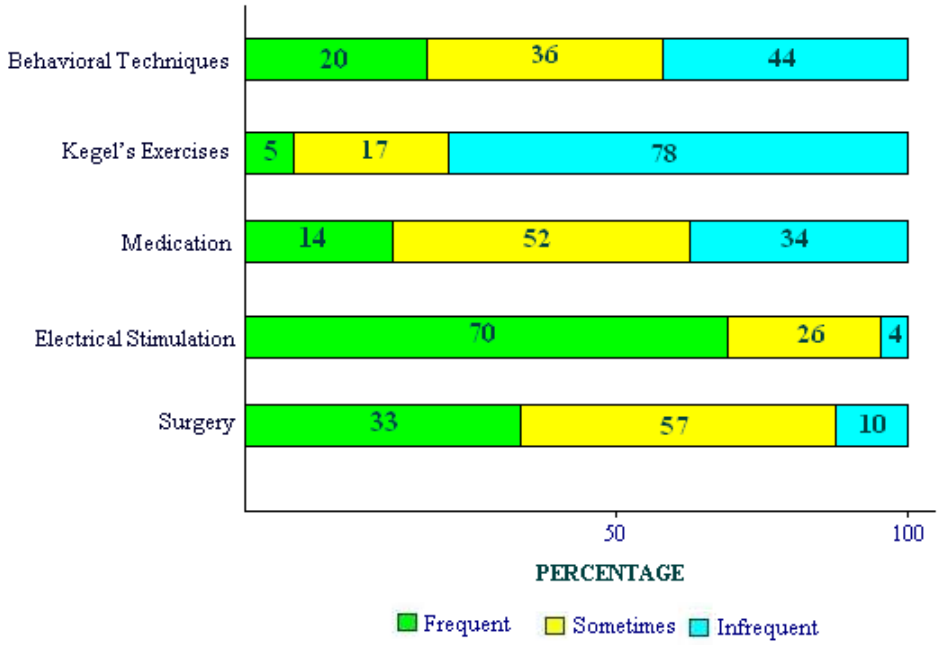
physicians throughout Canada. Although more than half of family physicians believed that urinary incontinence was common in their practices, less than 50% indicated that they clearly understood incontinence and less than 40% had an organized plan for urinary incontinence problems. Only 34.6% felt very comfortable dealing with incontinence (Graham Swanson 2002). Family physicians, as the front line of health workers, are expected to diagnose and manage most incontinence problems. This study emphasized that many Canadian family physicians feel unprepared to deal effectively with urinary incontinence and less than half of them ask their patients during health examinations whether incontinence is a problem.

The manufacturer of NeoControl has conducted seminars in various countries to improve awareness of incontinence and available treatments, especially the NeoControl therapy system. Participants are usually from non-profit organizations, senior residences, and medical clinics. The intent is to raise awareness about incontinence and at the same time advertise the NeoControl device and expand the market. For the Canadian marketplace, informative and marketing seminars will be conducted for the targeted organizations. Target markets are discussed in detail in section 6.2.

Figure 6.2 shows the treatment usage by a sample of patients across Canada (Graham Swanson 2002). Although the success rate of surgery is the highest amongst the available treatments, electrical stimulation is the treatment patients frequently use to improve their urinatary condition. As indicated in the past chapters, NeoControl is a very similar treatment to electrical stimulation. When NeoControl is introduced in the marketplace, it is expected that most patients will replace electrical stimulation with NeoControl therapy treatment because it is more comfortable.

Figure 6.2 Survey Outcome about Frequency of Using Different Treatments (Graham Swanson 2002)



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6.2 Market Segmentation and Targeting

Urinary incontinence is common in older people and associated with considerable morbidity. Older people are most likely to delay seeking help to improve their incontinence, and symptoms are often poorly managed in primary and secondary care. Therefore, the primary market to advertise NeoControl therapy system is the locations where there is a high density of the seniors.

Within the senior population in Canada, demographic trends continue to vary considerably across provinces. The number of Canadian seniors more than doubled between 1981 and 2005. Most of Canada's population (84.9%) resides in Ontario, Quebec, Alberta, and British Columbia. Table 6.1 shows the distribution of seniors across provinces in Canada. It also shows senior population growth from 1981 and projected to 2026.

Between 1981 and 2005, there was a small shift in the distribution of the total population and in the population of seniors across the provinces and territories. Projections indicate that between 2004 and

2026 the distribution of seniors across the provinces will change very little. The most noticeable change is a projected increase from 8.1 to 9.5% in the share of Canadian seniors located in Alberta (Statistics Canada 2005).

Table 6.1The Distribution of Seniors Across Provinces of Canada (Statistics Canada 2005)

	1981	1991	2001	2005	2026
Newfoundland and Labrador	44,051	55,746	63,348	67,745	135,200
Prince Edward Island	14,952	17,100	18,627	19,451	35,500
Nova Scotia	92,896	114,286	127,546	133,571	246,600
New Brunswick	70,969	89,522	99,605	104,711	196,900
Quebec	573,209	782,272	965,160	1,045,661	1,922,600
Ontario	874,099	1,205,305	1,489,294	1,608,698	3,079,400
Manitoba	122,197	147,690	157,191	158,589	263,200
Saskatchewan	116,533	141,050	148,067	147,102	220,900
Alberta	164,981	232,851	310,537	340,553	767,000
British Columbia	301,208	428,680	539,635	586,756	1,164,000
Yukon Territory	779	1,123	1,764	2,153	6,000
Northwest Territories with Nunavut	1,410	0	0	0	0
Northwest Territories	0	1,213	1,682	2,000	6,800
Nunavut	0	438	606	788	1,800
Total	**2,377,284**	**3,217,276**	**3,923,062**	**4,217,778**	**8,045,900**

Table created by the author

Canadian seniors have various residency options. Independent apartments and suites within communities specialized for seniors are the most used living options in Canada. Senior communities provide special care such as nursing, assisted living and other services to senior people.

In 2005, Canada had more than 4 million seniors located in all provinces (Statistics Canada 2005). Based on the recent information by Statistics Canada, there are approximately 5 million seniors living in Canada in 2011 (Statistics Canada 2011).

Statistics Canada's research and other studies on urinary incontinence indicate that approximately 60% of seniors above 70 years of age have symptoms of stress, urge, or mixed urinary incontinence (Graham Swanson 2002) (Statistics Canada 2011)

In the following discussion, the two major care facilities which lodge almost a quarter of the seniors in Canada are examined. These care facilities will be considered to be the first target markets. NeoControl therapy systems will be sold to these care centres, and they will offer the treatment to their incontinent patients. During this process, the Canadian distributor will provide maintenance for the NeoControl devices. There are benefits for these communities to offer NeoControl treatment to their customers. These benefits are the main drivers that would motivate them to adopt NeoControl therapy system. The benefits include:

- Create a competitive advantage: Adopting a new treatment will give these communities an advantage in comparison with other facility centres. This may lead to more customers in the future. Offering free treatment sessions for the new customers will encourage incontinent customers to try the treatment and assess its success. This competitive advantage may not be visible in the first year of the operation. But in the following years, once the value of the treatment is realized, then offering the NeoControl treatment will be an advantage for the retirement centres.

- Make marginal profit: The Canadian distributor will share profit with the communities who are participating in the launch of the NeoControl therapy system. This will provide them with an annual profit that increases their revenue. Care facilities will take 8% of the treatment sales per month as their commission.

- Purchase fewer incontinence products: Based on the results of a survey conducted by the author in December 2010, special care centres in BC spend approximately $80,000 annually to purchase incontinence products such as pads, diapers, liners, and pull-on style disposal

underwear. Facility centres are seeking ways to lower these costs. The NeoControl therapy can help them by reducing the need to purchase incontinence products.

- Less assistance needed: The amount of care required by older people with incontinence and its associated economic cost are substantial. By offering a treatment to manage incontinence problem, the cost of the additional efforts by the caregivers can be avoided.

6.2.1 Continuing Care Retirement Residences and Communities

Continuing care retirement residences and communities provide separate housing for seniors who are able to live independently, who require help in an assisted-living facility, or who require more intensive care in a nursing home. These residences and communities appeal to seniors because they can enjoy an independent lifestyle with the expectation that they will be able to stay in the same community, with their spouse, as their health deteriorates in their last years. Table 6.2 shows the number of continuing care centres in different provinces in Canada. There are currently 2745 continuing care retirement centres and communities in Canada (Retirement Homes 2011). The centres' capacities differ based on their locations and services offered. The average number of seniors in each centre is calculated using data from a survey conducted by the author in December 2010. As illustrated in Table 6.2, there are 601,170 continent seniors living in this type of centres. These individuals are considered to be the NeoControl customers of the future.

Table 6.2 The Distribution of Continuing Care Centres Across Major Provinces in Canada and the Target Market

	Alberta	**British Columbia**	**Ontario**	**Quebec**
Total Number of Registered Retirement Residences	287	243	844	1371
Average Capacity per residence	150	300	400	400
Total Number of Seniors in the Residences	43,050	72,900	337,600	548,400
Urinate Incontinent Seniors on Average	60%	60%	60%	60%
Total Number of Urinate incontinent Seniors on Average	25,830	43,740	202,560	329,040
Target Number of NeoControl Customers	**601,170**			

Created by the author

6.2.2 Special Care Retirement Residences and Communities

Special care retirement residences and communities offer special care to patients suffering from Alzheimer's disease or other mental or physical disabilities. With Alzheimer's or dementia, individuals sometimes lose the ability to understand the subliminal cue that tells them they need to go to the toilet. With Alzheimer's disease, it becomes a case of the caregiver always providing that direction. Special care centres spend more than $80,000, on average, annually to purchase incontinence related products such as pads, diapers, and gowns. Additionally, caregivers spend around 25% of their time daily dealing with their patients' incontinence problems (results of survey conducted by the author; Appendix A). NeoControl therapy system can help these centres to avoid spending money on incontinence products and also provide an easy way to treat patients suffering from Alzheimer's disease or other mental or physical disabilities.

Table 6.3 The Distribution of Special Care Centres Across Major Provinces in Canada and the Target Market Estimation

	Alberta	**British Columbia**	**Ontario**	**Quebec**
Total Number of Special Care Retirement Residences	19	16	166	29
Average Capacity per residence	50	100	200	50
Total Number of Seniors in the Residences	950	1,600	33,200	1,450
Urinate Incontinent Seniors on Average	60%	60%	60%	60%
Total Number of Urinate incontinent Seniors on Average	570	960	19,920	870
Target Number of NeoControl Customers	**22,320**			

Created by the author

Table 6.3 gives the number of special care centres existing in each province of Canada. The average capacity for each special care centre depends on its location and services. The average capacity numbers are calculated using data from a survey conducted by the author in December 2010. As illustrated in Table 6.3, there are 22,320 continent seniors living in this type of centre.

6.3 Market Size and Trends

Continuing care and special care retirement residences and communities are considered as the primary target markets for introduction of the NeoControl therapy system. As previously outlined, there are 623,490 incontinent seniors living in both types of centres.

The next phase is to tackle drugstore chains. The goal would be to install the NeoControl device as a service in such chains, in the same manner as diagnostic devices. Diagnostic devices currently available in drugstores include blood pressure and heart beat monitoring devices; these only diagnose health conditions and do not provide any treatment. NeoControl is a candidate to become a widely used

treatment by seniors in public locations such as drugstores and hotels. NeoControl has already been widely used in public locations in Europe. Considering that retail and social factors are different in European market, NeoControl chair is still a possible nominee in future drugstore layouts in Canada. Similar devices in size and usage in public such as Dr Scholl's footmapping machine have already been installed in London Drugs. However, Dr Scholl's device is a diagnostic tool. The use of "treatment devices" in drugstores in Canada requires further analysis.

Another possible means of expanding the business is to target physiotherapist's offices. A detailed plan needs to be drafted to approach physiotherapists. A serious problem is that they currently provide other treatments to incontinent people and may see NeoControl as a threat. However, at this stage of the rollout, most of the continuing and special care retirement centres are offering NeoControl therapy as an alternative treatment. In order to obtain buy in from physiotherapists and urologists, seminars and conferences will be held to raise awareness about NeoControl and its success in retirement centres.

An ongoing analysis of the senior residences will be commissioned by the distributor's sales force to estimate the prevalence of incontinent seniors by gender, age, residence, mental awareness, and mobility/immobility in the future. The outcome will help to define the target market more precisely. Statistics and reports provided by the Health Canada's Division of Aging and Seniors are available to the public. Unfortunately, the most recent statistics are from about a decade ago; hence, the current population density of incontinent seniors in Canada is not properly reflected. However, the information is reliable and can be used as a baseline for future analysis.

6.4 Treatment Cost

The manufacturer of the NeoControl offers the device to its exclusive distributors for $20,000 (Canadian Dollar). In addition, there is a variable cost to manufacture treatment cards. Treatment cards (NeoCards) are offered by the NeoControl manufacturer. They are necessary, since without them the

device will not provide treatments. Each card will enable the device to function for ten 20-minutes sessions. When each device is purchased, an extra variable cost of $3,000 is charged for delivery of 20 pre-programmed NeoCards for one year of service. Patients need to buy a NeoCard to receive a full 10-sessions treatment. The distributor can order half treatment NeoCards as well. In that case, 40 pre-programmed NeoCards for one year of service will be manufactured. Ordering any combination of full and half treatment NeoCards is possible.

A one-time licensing fee is required to register the device by the Health Canada. The NeoControl therapy system must receive a Canadian license before it can be imported and sold in the Canadian market. According to the information provided by the Health Canada, the process of obtaining the Canadian license for the NeoControl therapy system will be expedited because it has FDA approval and it has passed many tests over the past years in the various countries. The registration and licensing process will take 4 to 6 months and will cost a one time fee of $3,000.

The NeoControl device is a robust system, which requires minimum levels of service and maintenance. The warranty offered by the manufacturer covers everything for five years. There is no maintenance fee envisaged for NeoControl during the warranty period.

Undoubtedly, the device needs insurance for safety reasons. Insurance companies provide insurance coverage only for medical devices carrying both FDA-approval and the Canadian Medical Device Active License (MDAL) certificate. Insurance fees vary based on the potential radiation risks involved in the treatment. Insurance quotes which the author collected in January 2011 indicated that the maximum insurance fee per year per device is not more than $2,000. Table 6.4 shows the costs for one NeoControl device over the course of three years. Other costs such as marketing, advertising and other expenses are not incorporated into this table. Those costs will be shown on the pro forma statement presented at the end of this chapter.

Table 6.4 Total Costs of One NeoControl Device Over 3 Years

	Year 1	**Year 2**	**Year 3**
Fixed Cost	$20,000	0	0
Maintenance Fee	$1,000	$1,000	$1,000
Insurance	$2,000	$2,000	$2,000
Total Costs and Expenses	$23,000	$3,000	$3,000

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6.5 The Selling Cycle

Tables 6.2 and 6.3 gave the number of continuing and special care retirement residences in Canada. In order to monitor the behaviour of NeoControl customers and evaluate the treatment acceptance by seniors, it has been decided to install one device in a popular retirement centre in each province. This will open up a communication channel to analyse potential issues and collect customers' feedback.

The first year of the business will be dedicated to measuring customer reaction to the NeoControl treatment. More devices will be purchased and installed in the provinces with the highest success rates. The projection for the next three years is illustrated in Table 6.5. The assumption in this projection is that after the first year, retirement centres and their customers will report no serous issues with the treatment. The number of devices is based on the average capacity of the centres and the average number of incontinent people in each retirement residence.

Table 6.5 NeoControl Installation Projection Over 3 Years

	Total Number of Continuing and Special Care Retirement Centres	**Year 1**	**Year 2**	**Year 3**
Alberta	306	1	5	8
British Columbia	259	1	5	8
Ontario	1010	1	5	15
Quebec	1400	1	5	15
Total Number of Installed NeoControl Devices		4	20	46

Created by the author

The projection is subject to change based on the feedback received from the retirement centres. People living in a province may not accept the NeoControl treatment simply because of their cultural beliefs or treatment preferences. Being successful in a province does not mean that the same treatment will be acceptable in other provinces. After the second year of operation, the distributor will have a better understanding of the treatment acceptance in different regions and will be able to adjust the projection accordingly.

6.6 Treatment Pricing

One complete NeoControl treatment includes 10 sessions. Patients take two sessions per week to complete the treatment. Treatment should be repeated every 10 months to reinforce strength in pelvic floor muscles. The number of required sessions for returning patients is half of the full treatment.

Currently, medical clinics in Europe and the United States offer NeoControl therapy at different prices. In European countries, NeoControl is 100% covered by insurance companies. In the United States patients pay in full for the treatment.

The cost of the NeoControl treatment varies country by country. In European countries, medical clinics offer NeoControl treatment in a range of 30 to 40 Euros per session. In the United States, the treatment is about $40 to $50 per session. Proposing an appropriate price for NeoControl treatment in Canada can guarantee its success. The price should be affordable to most seniors living in continuing and special care retirement residences.

There has not been any effort to obtain insurance coverage for the NeoControl treatment from the Health Canada or any other private insurance provider in Canada. Non-profit organizations such as the Canadian Continence Foundation (www.canadiancontinence.ca) and Canadian Nurse Continence Advisors (www.cnca.ca) can play a vital role in supporting the treatment and lobbying to obtain insurance coverage. These organizations are meant to enhance the quality of life for people experiencing incontinence by helping them or their caregivers to seek and access treatment options. These organizations and the distributor can lobby collaboratively to demonstrate the value of the NeoControl treatment through conferences and exhibitions. Non-profit organizations have monthly or bi-monthly group meeting to demonstrate their support to their community. The Canadian distributor's representative can participate in those meeting to get to know the influential stakeholders and to introduce the NeoControl treatment to them and to collect their feedback. These organizations have brochures and advertisements on websites to raise awareness of the incontinence problem. Informative booklets are also published by these non-profit organizations to communicate available treatments for incontinence. The distributor must introduce the NeoControl therapy system to the non-profit organizations and obtain their support. NeoControl may then be included in their advertisements as an alternative therapy for incontinent patients. These activities may or may not result in insurance coverage

for the NeoControl treatment in the future. Until then, NeoControl will be offered without insurance coverage.

In order to come up with a best price for each NeoControl treatment session, all associated costs and maintenance fees need to be analysed. According to tables 6.2, 6.3, and 6.4, and the number of sessions required to have a full treatment, it has been determined to offer NeoControl treatment for $65 per session. This means that a full treatment for patients will be $650. Returning customers will receive a discount of $10 per session. As indicated before, patients need to repeat this treatment every 10 months for 5 sessions to maintain their pelvic floor muscle strength. This half treatment for returning customers will be $275. Care facilities will take 8% of the monthly sale as their commission.

7: Business Structural Analysis

This section provides information on the business model for importing and distributing the NeoControl therapy system in Canada. It provides positional analysis for the device and its distribution using Porter's Five Forces model. A SWOT analysis for the business and recommendations to increase its attractiveness are also given.

7.1 Business Model

The intent is to penetrate the Canadian incontinence treatment market to compete with any electrical stimulation treatments. In chapter 5, it was shown that the NeoControl therapy system can compete with the electrical stimulation therapy.

The business model is to obtain an exclusive distribution license from the NeoControl manufacturer to import and install NeoControl devices in continuing and special care retirement centres in Canada. The distributor will help these care facilities to market and sell treatment to their residents.

Competitors are any other electrical stimulation therapies available in Canada.

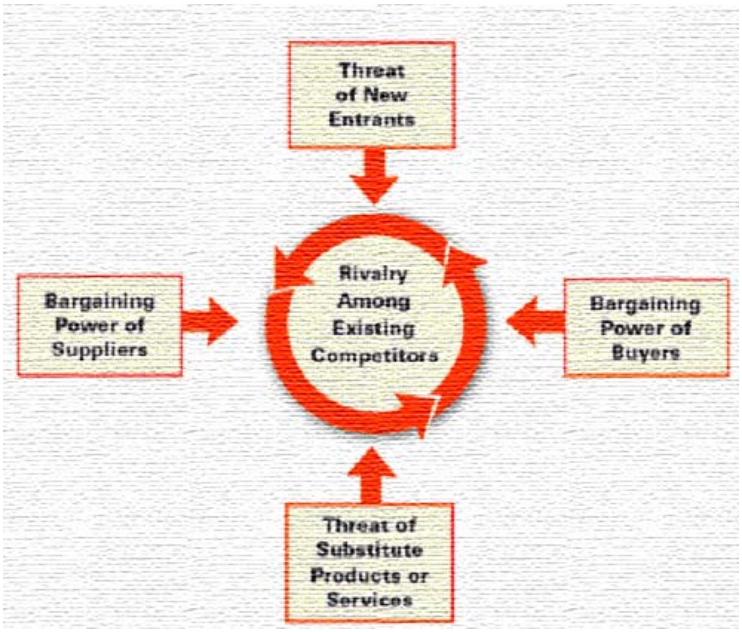
Substitutes are other available treatments in the market, such as behaviour therapy, Kegel's exercises, and medication therapy.

7.2 Porter's Five Forces Analysis

Porter's model (Figure 7.1) can be used in the initial diagnosis of the market to develop a detailed strategy for market penetration. It examines: new entrants to the industry, substitutes products,

supplier power, buyer power, and competitive rivals in the in market. The following sections provide more detailed information on each of these forces.

Figure 7.1 Porter's Five Competitive Forces that Shape Strategy (Porter 2008)



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7.2.1 Threat of New Entrants

The threat of new entry will depend on the extent to which there are barriers to entry. Barriers to entry vary based on the incontinence treatment type. There are barriers to entry if a firm aims to invent a new medical device to treat incontinence. Electrical stimulation and ExMI technologies have been available to the medical industry for more than a decade. There is a possibility that some ventures are trying to manufacture similar devices using these technologies to provide services to incontinent people. In that case, there will be important barriers which could stop firms from entering this industry. Barriers to duplication include research and development (R&D) costs, required infrastructure costs, and related efforts to obtain FDA approval. In addition, the NeoControl manufacturer and many other electrical

stimulation manufacturers hold patent protection for their products. Therefore, such devices can not be duplicated openly.

A comprehensive exclusive distributor agreement between the Canadian distributor and the NeoControl manufacturer is signed to authorize the Canadian distributor to be the only authorized company to sell and support the NeoControl therapy system in Canada. This will secure the Canadian distributor's position in the market. Therefore, the threat of new entrants has been evaluated as low.

7.2.2 Threat of Substitute Products and Services

A threat from substitutes exists if there are alternative products for the same purpose. Substitutes could potentially attract a significant proportion of market volume and hence reduce the potential sales volume for existing players.

There are a few alternative treatments for urinary incontinence, which have been discussed in the past chapter. In general, medication, Kegel's exercise, and surgery are advised depending on the patients' condition. In practice, all other treatments, which as previously outlined are covered by insurance, could be used as substitutes by patients. Therefore, threat of substitute for NeoControl has been evaluated as high.

7.2.3 Bargaining Power of Suppliers

A threat from a supplier exists when a provider of inputs is able to determine the price and terms of the supply. Suppliers can exert power over firms by raising prices or reducing the quality of purchased goods and services. Currently, there are many suppliers manufacturing electrical stimulation devices in North America. These suppliers do not have a lot of bargaining power because their products are fairly similar. The distributors and customers do not rely too much on one electrical stimulation manufacturer because they could easily find another one. With regards to the NeoControl device, there is only one manufacturer which makes the product and provides maintenance and support. Hence, the

bargaining power of this supplier is extremely high. There are other reasons for this evaluation, including the following:

- Presently, NeoControl distributors are scattered in various countries, so their bargaining power is low. When the NeoControl buyers are located in the same region, they can share information and resources through seminars and workshops. This will reduce the power of the supplier.
- There is no other device that offers exactly the same service. This has placed the NeoControl manufacturer in a strong position to enforce prices and rules on its distributors.

7.2.4 Bargaining Power of Buyers

The bargaining power of buyers determines how much customers can impose pressure on margins and volumes. The Canadian distributor has two sets of customers:

- The first group of customers are the continuing and special care retirement centres. The bargaining power of retirement centres is high because switching to an alternative product/service is relatively simple. Retirement centres can invite medical doctors to offer Kegel's exercises or electrical stimulation therapy on site.
- The second group of customers are patients residing in the retirement centres and their families who may be involved in choosing a treatment. They have no bargaining power on the treatment price because there are numerous patients interested in receiving such a treatment.

7.2.5 Rivalry among Existing Competitors

Rivalry describes the intensity of competition between existing companies which offer the same products or services. Rivalry between the NeoControl therapy system and electrical stimulation therapy is fairly low because the type of service that NeoControl offers is quite different. The distinctive ExMI technology employed in the NeoControl therapy system distinguishes it from other treatments.

The first of Canada's aging baby boomers are poised to turn 65. Given the aging population of Canada, the demand for alternative treatments will be increased which results in low rivalry between competitors.

7.3 Recommendations and Success Factors

Porter's five forces analysis can reveal insights into the potential attractiveness of the business. After the analysis of current and potential states of the five competitive forces, different options can be considered to influence these forces to increase attractiveness. Table 7.1 summarizes the Porter's five forces analysis with respect to the NeoControl therapy system. At first glance, the business does not seem to be attractive owing to the high level of bargaining power of suppliers and customers, and the high threat from substitutes. However, there are ways to reduce the power of these competitive forces.

Table 7.1 The Porter's Five Forces NeoControl Analysis Summary and the Recommendations

	Level	Recommendations to Reduce the Threat
Threat of new Entrants	Low	• Create a brand image (loyalty as a barrier to entry) • Sign an exclusive distribution agreement which reflects the Canadian distributor's interests • Tie up with suppliers and distributors (Increase switching costs)
Threat of Substitute Products and Services	High	• Study customer preferences • Emphasize NeoControl differentiation
Bargaining Power of Suppliers	High	• Create a partnership with the sole supplier • Increase dependency between the supplier and the distributor
Bargaining Power of Buyers	High	• Increase loyalty • Deal directly with customers (remove intermediaries)
Rivalry among Existing Competitors	Low	• Avoid price competition • Emphasize NeoControl differentiation • Focus on different market segments • Communicate and establish relationships with competitors

Created by the author

While industry analysis along with the proposed recommendations shows that the NeoControl business can be offered as an alternative treatment and potential risks can be mitigated, this alone does not provide sufficient justification to proceed. An analysis comparing estimated demand and revenue with estimated costs is needed to determine the potential viability of the business.

In chapter 10, a detailed set of strategies to reduce the bargaining power of suppliers, customers and the threat of substitutes will be explained.

7.4 SWOT Analysis

This section provides a SWOT analysis of the NeoControl distribution business in Canada. SWOT is a strategic planning method, which is used to evaluate the strengths, weaknesses, opportunities, and threats involved in a business venture. It involves specifying the objective of the business venture and identifying the internal and external factors that are favourable and unfavourable to achievement of that objective.

Identification of SWOTs is essential because subsequent steps in the process of strategic planning are derived from the SWOT analysis. In the following, each aspect of the NeoControl distribution business is discussed.

7.4.1 Strengths

The strengths of distributing the NeoControl therapy system in Canada include the following:

- The NeoControl therapy system provides a FDA-approved treatment for stress, urge, and mixed incontinence.
- The manufacturer has maintained patent protection since November 28, 1994. Patent protection expires every five years and the manufacturer is responsible for renewing the patent protection upon its expiration. Patent agreement is extended to all of its exclusive distributors. This prevents competitors from entering the market with products that have the same features and design as the NeoControl.

As part of protection granted through a patent you can stop competitors from entering the market with products that contain designs or aspects of your own invention. This gives a near-monopoly on the product, installing you as the sole beneficiary of all profits generated from the invention.

- The manufacturer signed an exclusive distribution agreement with the proposed Canadian distributor company; this prevents other companies from entering the Canadian market and offering the same treatment.
- The NeoControl therapy system provides a differentiated, easy to use, non-invasive, and affordable treatment.
- The NeoControl therapy system is supported by 20 published studies from different universities reporting its success (NeoControl news 2011)
- The NeoControl treatment requires patients to continue treatment to maintain the strength of their pelvic floor muscles. This establishes a long-term relationship with customers and provides a non-stop stream of revenue.
- The Canadian distributor can benefit from the NeoControl manufacturer's extensive global distribution experience.

7.4.2 Weaknesses

The weaknesses of distributing the NeoControl therapy system in Canada include the following.

- There are other available treatments that can be used as substitutes, for example, Kegel's exercises and electrical stimulation therapy.
- There is no insurance coverage for at least the first year of distribution.
- There is a high fixed cost to purchase and install each NeoControl device in the retirement facilities.

7.4.3 Opportunities

The future opportunities for the NeoControl distribution business in Canada include the following:

- convert non-customers to customers. There are a number of incontinent people who are not using any treatment to control and improve their urinary situation. Based on the outcome of the survey conducted by the author (Appendix A), on average, 28% of the patients from 36 special care retirement residences are not receiving any incontinence treatment. Instead, they use incontinence products on a daily basis to manage their situation.
- attract incontinent people who are using other treatments (mostly electrical therapy, and Kegel's exercises, and medication) by presenting and advertising the product in the care facilities.
- possibly obtain FDA approval for other clinical applications of NeoControl such as erectile dysfunction, vagina tonus, haemorrhoids, and cellulites. This would expand the target market in the future.

7.4.4 Threats

The potential threats for the NeoControl distribution business in Canada include the following.

- There are a number of safety issues surrounding medical devices that emit electric and magnetic fields radiation. This has become a topic of considerable scientific scrutiny during the past two decades. The NeoControl therapy system uses ExMI magnetic radiation throughout the treatment. This might create a barrier for some patients who are afraid of magnetic radiation and are unable to determine the legitimacy of the treatment. ExMI is the first and only technology of its type approved by the Food and Drug Administration's (FDA) Centre for Devices and Radiological Health (CDRH). The most obvious benefit of ExMI is the fact that these magnetic fields can enter the body, affect pelvic floor muscles, and exit without side effects. It utilizes

highly focused magnetic pulses to reach deep into the body and effectively treat the target muscles. There is no scientific controversy around ExMI technology, since it is approved by the FDA, which guarantees the device safety

- Obtaining insurance coverage for the NeoControl treatment from government health care systems or private health care providers will benefit patients and ultimately lead to more frequent repetition of the treatment. Insurance coverage is also a form of endorsement of the NeoControl treatment. Without insurance coverage, NeoControl's viability remains questionable.

8: Operational Analysis

For an organization to operate successfully in the market requires a number of resources such as sales, marketing, human resources, a management team, and financial capital. These allow the organization to perform its desired functions in an efficient and cost-effective way. In the case of the NeoControl distribution business, the operational plan will provide insight into which resources the company will need in order to execute the proposed strategy and to become a successful provider in the incontinence treatment industry.

8.1 Management Team

For a small start-up business such as the NeoControl distribution business, the management team can be very small. Founders can act as business owners while performing other critical tasks such as sales and marketing.

In the case of the NeoControl business, there are two founders with varied expertise. The first founder has been in the pharmaceutical industry for more than 25 years and has extensive experience in business development and distributing medical devices globally. Currently, he is working for one of the largest medicine manufacturer companies in Europe as Managing Director. His passion is extended to medical devices which offer treatment to incontinence patients. He has an established business relationship with the CEO of the NeoControl manufacturer. His involvement in the NeoControl distribution in the Middle East and his experience is an asset for this start-up company. The second founder has been in technology and marketing industries for more than 15 years. He has been involved in software marketing in North America and has significant experience in business analysis and project management.

The first owner will initially take on the role of CEO, responsible for strategic planning and business development with the supplier and for the growth and sales policies of the company. In the early stage of the business, the CEO will be responsible for financial management and transaction oversight for the business.

The second owner will initially take on the role of COO, responsible for developing and executing the strategies, and expanding the relationship with non-profit organizations, insurance companies and continuing and special care retirement centres. He will be responsible for meeting the expectations of the customers and for executing the operational plan.

During the early stages of the business it is feasible that the business founders run the company alone. After the initial phase, company owners will need to closely monitor business growth and development strategies and review existing capabilities. It may be important to hire sales consultants or to partner with other distributors in order to become successful.

8.2 Human Resources

The NeoControl distribution business is expected to have a few sales consultants to help sell the treatment to retirement centres. More consultants will be needed in the second and third years of the operation, as more chairs are purchased. Once the number of installed chairs exceeds 10, a customer service department will also be required. It will be important to have experts in customer service to learn more about the needs of the customers and what must be changed to enhance the relationship with the continuing and special care retirement centres. Effective recruiting and personnel policies will also need to be developed as the number of staff grows. Also, compensation plans, health care, profit sharing, and vacation allotments for each year need to be planned.

8.3 Partnership Agreement

There will be one partnership agreement between the NeoControl Canadian distributor and the sole NeoControl manufacturer. This agreement grants exclusive distribution rights to the Canadian distributor company to import and distribute the NeoControl therapy system into Canada. As part of this agreement, the manufacturer will share its distribution experience in other countries with the Canadian partner to expedite the market opening. In the partnership agreement, the manufacturer will sell a minimum of 20 chairs per year to the Canadian distributor except for the first year. The chair prices and its costs are fixed. The manufacturer is responsible for providing service and support for malfunctioning devices. The Canadian distributor can terminate the partnership agreement anytime after the second year if it is determined that the Canadian market is not satisfactory. In this case, the Canadian distributor pays a $30,000 termination penalty to the manufacturer. The manufacturer will agree to avoid cancelling the contract within the first five years of operation.

There will be a profit sharing agreement with each of the continuing and special care retirement centres. The agreement will guarantee that 8% of the monthly treatment sales revenue is given back to the centre as an incentive to continue selling the NeoControl treatment. The agreement remains in place until the NeoControl device is removed from the centre. Removal of the chair can be requested by either the centre or the distributor at any time. The distributor owns all the chairs and is committed to provide support and maintenance to the care facilities.

8.4 Financial Capital

The initial $200,000 inflow of cash is expected to come from a business loan; it will finance the first 12 months of operation as well as the initial purchase of four NeoControl devices. For the second year, $600,000 is required to expand the business and install more NeoControl devices in the retirement centres. The capital assets of the business reflect only the cost to purchase the NeoControl devices and the initial costs of the business operations. Revenue generation is not expected to begin until the end of the second year. In the third year, $1,100,000 inflow of cash will be required to install 46 new NeoControl devices in 46 centres across Canada. After three years of operation, the distribution business will be able to reach the breakeven point, providing that the Canadian distributor is able to obtain insurance coverage for the NeoControl treatment from the Health Canada or private insurance companies.

9: Financial Analysis

In this chapter, a financial analysis will be performed on the distribution of the NeoControl therapy system to continuing and special care retirement centres. The estimated expenses and revenue per calendar year are shown, to evaluate the viability of the business. Also, a pro forma income statement will be presented to summarize the calculations for the first three years of the operation.

It must be acknowledged that the calculations presented are preliminary. They illustrate the potential opportunity to introduce a new treatment to incontinent patients. The projected demand and price are subject to change, depending on economic and demographic circumstances.

9.1 Expenses

In the process of establishing the NeoControl distribution business, the Canadian distributor will incur a number of expenses. Capital expenditure will be required to purchase the NeoControl devices and the NeoCards. Fixed and variable operational expenses will be incurred on a monthly basis to operate the business. The fixed expenses consist of advertising, office expenses, salaries, and general expenses such as insurance, permission fees, and overheads. The variable expenses are related to the number of NeoCards required in each phase of the project.

9.2 Potential Revenue

With the potential costs and selling cycle calculated and tabulated, the next step is to transfer this data into a table that shows the potential revenue for each year. The average capacity for each continuing and special care centre varies, based on its location and services offered. The financial projections target 10% of the incontinent population of each care centre for the first year. The projection grows to 20% and 30% for the second and the third years of operation. This projection is applicable when insurance coverage for the NeoControl treatment is not available. The NeoControl treatment demand is price elastic. More patients are expected to receive the NeoControl treatment when either a public or a private insurance company covers part of the treatment costs. Patients are paying less when a treatment has insurance coverage. It is difficult to estimate the exact responsiveness of treatment demand when the cost to the patient is reduced. The projection is estimated to grow by 10% when the Health Canada or any private insurance company cover the costs of the NeoControl treatment. Under the assumption of insurance coverage, the projections target 20% in the first year, 30% in the second year, and 40% in the third year of the operation.

The rate of patients who will return to repeat the treatment is expected to be approximately 50%. As mentioned earlier, full treatment cost for new patients is $650 and $275 for returning patients. The following sections explain the projected revenue for each province, assuming that there will be no insurance coverage offered for three years.

9.2.1 Alberta

There are approximately 90 incontinent seniors on average living in each continuing retirement centre in Alberta. Table 9.1 shows the yearly revenue that will be generated by having one NeoControl device in a continuing retirement centre. Table 9.2 shows the total revenue generated by executing the

installation projection plan shown in Table 6.5. The sales targets are 10%, 20%, and 30% of the retirement centre incontinent customers, because there is no insurance coverage for the treatment.

Table 9.1 Projected Revenue in Alberta over Three Years for One NeoControl Device

	Year 1 (target 10%)	**Year 2 (target 20%)**	**Year 3 (target 30%)**
New Customer Target	9	18	27
Returning Customers (50% of existing customers)	0	5	12
Revenue Collected from New Customers	$5,850	$11,700	$17,550
Revenue Collected from Existing Customers	0	$1,375	$3,300
Total Provincial Revenue	$5,850	$13,075	$20,850

Created by the author

Table 9.2 Total Revenue per Year from the Installation of 14 devices in 14 centres in Alberta over Three Years

	Year 1		**Year 2**		**Year 3**	
	New Chair(s)	**Existing Chair(s)**	**New Chair(s)**	**Existing Chair(s)**	**New Chair(s)**	**Existing Chair(s)**
Total Number of Chair(s)	1	0	5	1	8	6
Revenue	$5,850	0	$29,250	$13,075	$ 46,800	$86,225
Total Revenue	**$5,850**		**$42,325**		**$133,025**	

Created by the author

In the following, the same calculations are presented using the higher sales targets of 20%, 30%, and 40%. Here, the assumption is that the Health Canada or private insurance companies cover the costs of the treatment by at least 50%.

Table 9.3 Projected Revenue in Alberta over Three Years for One NeoControl Device (treatment with insurance coverage)

	Year 1 (target 20%)	**Year 2 (target 30%)**	**Year 3 (target 40%)**
New Customer Target	18	27	36
Returning Customers (50% of existing customers)	0	9	18
Revenue Collected from New Customers	$11,700	$17,550	$23,400
Revenue Collected from Existing Customers	0	$2,475	$4,950
Total Provincial Revenue	$11,700	$20,025	$28,350

Created by the author

Table 9.4 Total Revenue per Year from the Installation of 14 devices in 14 centres in Alberta over Three Years (treatment with insurance coverage)

	Year 1		**Year 2**		**Year 3**	
	New Chair(s)	**Existing Chair(s)**	**New Chair(s)**	**Existing Chair(s)**	**New Chair(s)**	**Existing Chair(s)**
Total Number of Chair(s)	1	0	5	1	8	6
Revenue	$11,700	0	$58,500	$20,025	$ 93,600	$128,475
Total Revenue	**$11,700**		**$78,525**		**$222,075**	

Created by the author

9.2.2 British Columbia

There are approximately 180 incontinent seniors on average living in each continuing retirement centre in British Columbia. Table 9.5 shows the yearly revenue that will be generated by having one NeoControl device in a continuing retirement centre. Table 9.6 shows the total revenue generated by executing the installation projection plan shown in Table 6.5. The sales targets are 10%, 20%, and 30% of the retirement centre incontinent customers, because there is no insurance coverage for the treatment.

Table 9.5 Projected Revenue in British Columbia over Three Years for One NeoControl Device

	Year 1 (target 10%)	**Year 2 (target 20%)**	**Year 3 (target 30%)**
New Customer Target	18	36	54
Returning Customers (50% of existing customers)	0	9	23
Revenue Collected from New Customers	$11,700	$23,400	$35,100
Revenue Collected from Existing Customers	0	$2,475	$6,325
Total Provincial Revenue	$11,700	$25,875	$41,425

Created by the author

Table 9.6 Total Revenue per Year from the Installation of 14 devices in 14 centres in British Columbia over Three Years

	Year 1		**Year 2**		**Year 3**	
	New Chair(s)	**Existing Chair(s)**	**New Chair(s)**	**Existing Chair(s)**	**New Chair(s)**	**Existing Chair(s)**
Total Number of Chair(s)	1	0	5	1	8	6
Revenue	$11,700	0	$58,500	$25,875	$93,600	$170,800
Total Revenue	**$11,700**		**$84,375**		**$264,400**	

In the following, the same calculations are presented using the higher sales targets of 20%, 30%, and 40%. Here, the assumption is that the Health Canada or private insurance companies cover the costs of the treatment by at least 50%.

Table 9.7 Projected Revenue in British Columbia over Three Years for One NeoControl Device (treatment with insurance coverage)

	Year 1 (target 20%)	**Year 2 (target 30%)**	**Year 3 (target 40%)**
New Customer Target	36	54	72
Returning Customers (50% of existing customers)	0	18	36
Revenue Collected from New Customers	$23,400	$35,100	$46,800
Revenue Collected from Existing Customers	0	$4,950	$9,900
Total Provincial Revenue	$23,400	$40,050	$56,700

Created by the author

Table 9.8 Total Revenue per Year from the Installation of 14 devices in 14 centres in British Columbia over Three Years (treatment with insurance coverage)

	Year 1		**Year 2**		**Year 3**	
	New Chair(s)	**Existing Chair(s)**	**New Chair(s)**	**Existing Chair(s)**	**New Chair(s)**	**Existing Chair(s)**
Total Number of Chair(s)	1	0	5	1	8	6
Revenue	$23,400	0	$117,000	$40,050	$187,200	$256,950
Total Revenue	**$23,400**		**$157,050**		**$444,150**	

Created by the author

9.2.3 Ontario

There are approximately 240 incontinent seniors on average living in each continuing retirement centre Ontario. Table 9.9 shows the yearly revenue that will be generated by having one NeoControl device in a continuing retirement centre. Table 9.10 shows the total revenue generated by executing the installation projection plan shown in Table 6.4. The sales targets are 10%, 20%, and 30% of the retirement centre incontinent customers, because there is no insurance coverage for the treatment.

Table 9.9 Projected Revenue in Ontario over Three Years for One NeoControl Device

	Year 1 (target 10%)	**Year 2 (target 20%)**	**Year 3 (target 30%)**
New Customer Target	24	48	72
Returning Customers (50% of existing customers)	0	12	30
Revenue Collected from New Customers	$15,600	$31,200	$46,800
Revenue Collected from Existing Customers	0	$3,300	$8,250
Total Provincial Revenue	$15,600	$34,500	$55,050

Created by the author

Table 9.10 Total Revenue per Year from the Installation of 21 devices in 21 centres in Ontario over Three Years

	Year 1		**Year 2**		**Year 3**	
	New Chair(s)	**Existing Chair(s)**	**New Chair(s)**	**Existing Chair(s)**	**New Chair(s)**	**Existing Chair(s)**
Total Number of Chair(s)	1	0	5	1	15	6
Revenue	$15,600	0	$78,000	$34,500	$234,000	$227,550
Total Revenue	**$15,600**		**$112,500**		**$461,550**	

In the following, the same calculations are presented using the higher sales targets of 20%, 30%, and 40%. Here, the assumption is that the Health Canada or private insurance companies cover the costs of the treatment by at least 50%.

Table 9.11 Projected Revenue in Ontario over Three Years for One NeoControl Device (treatment with insurance coverage)

	Year 1 (target 20%)	**Year 2 (target 30%)**	**Year 3 (target 40%)**
New Customer Target	48	72	96
Returning Customers (50% of existing customers)	0	24	48
Revenue Collected from New Customers	$31,200	$46,800	$62,400
Revenue Collected from Existing Customers	0	$6,600	$13,200
Total Provincial Revenue	$31,200	$53,400	$75,600

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Table 9.12 Total Revenue per Year from the Installation of 21 devices in 21 centres in Ontario over Three Years (treatment with insurance coverage)

	Year 1		**Year 2**		**Year 3**	
	New Chair(s)	**Existing Chair(s)**	**New Chair(s)**	**Existing Chair(s)**	**New Chair(s)**	**Existing Chair(s)**
Total Number of Chair(s)	1	0	5	1	15	6
Revenue	$31,200	0	$156,000	$53,400	$468,000	$342,600
Total Revenue	**$31,200**		**$209,400**		**$810,600**	

9.2.4 Quebec

The average capacities of retirement centres average in Ontario and Quebec are identical, as shown in Table 6.2. In addition, the number of projected new NeoControl devices in the course of three years is the same. Therefore, the projected revenue per year for Quebec will be as same as the Ontario revenue.

9.2.5 Summary of Projected Consolidated Revenue

Table 9.13 summarizes the consolidated revenue for each province with the assumption that the treatment cost is not covered by the Health Canada or any private insurance companies.

Table 9.13 Projected Consolidated Revenue in Targeted Provinces over Three Years

	Year 1	**Year 2**	**Year 3**
Alberta	$5,850	$42,325	$133,025
British Columbia	$11,700	$84,375	$264,400
Ontario	$15,600	$112,500	$461,550
Quebec	$15,600	$112,500	$461,550
Total Revenue	$48,750	$351,700	$1,320,525

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Table 9.14 summarizes the consolidated revenue for each province with the assumption that the treatment cost is covered by the Health Canada or any private insurance companies.

Table 9.14 Projected Consolidated Revenue in Targeted Provinces over Three Years (treatment with insurance coverage)

	Year 1	Year 2	Year 3
Alberta	$11,700	$78,525	$222,075
British Columbia	$23,400	$157,050	$444,150
Ontario	$31,200	$209,400	$810,600
Quebec	$31,200	$209,400	$810,600
Total Revenue	$97,500	$654,375	$2,287,425

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9.3 Pro Forma Income Statement

The calculations above have only showed expected revenues for the targeted provinces. As such, the calculations have omitted any of the costs related to running a business such as administration, depreciation, cost of capital, advertising, and other expenses. The pro forma income statement is used to show the future revenues and costs, including depreciation and operating expenses, and how these affect net income. For comparison purposes, the income statement shows the outlook for the next three years. The costs and revenues shown below are those from Tables 9.1 to Table 9.14 calculated for the targeted provinces. There are two, separate pro forma income statements. Figure 9.1 is the pro forma income statement where there is no insurance coverage for the treatment, and the sales targets are 10%, 20%, and 30%. Figure 8.2 is the pro forma income statement where there is insurance coverage for the treatment by the Health Canada or other private insurance companies. As indicated earlier, sales targets grow to 20%, 30%, and 40% when insurance coverage is available. The analysis shows that within three years, the Canadian distributor will reach the breakeven point if the Canadian distributor obtains insurance coverage for the treatment from the first year of operation.

Figure 9.1 Pro Forma Income Statement for the First Three Years (With no insurance for the treatment)

	Year Ended December 31		
	Year 1	Year 2	Year 3
	(4 Devices)	(20 Devices)	(46 Devices)
Summary of Operations			
Net sales	$ 48,750	$ 351,700	$ 1,320,525
Alberta	$ 5,850	$ 42,325	$ 133,025
British Columbia	$ 11,700	$ 84,375	$ 264,400
Ontario	$ 15,600	$ 112,500	$ 461,550
Quebec	$ 15,600	$ 112,500	$ 461,550
Capital cost of chairs	$ 92,000	$ 472,000	$ 1,130,000
Gross Profits	$ (43,250)	$ (120,300)	$ 190,525
Operating Expenses	$ 68,900	$ 315,136	$ 750,642
Owners' drawings	$ 10,000	$ 50,000	$ 50,000
Payroll	$ 10,000	$ 50,000	$ 120,000
Advertising	$ 20,000	$ 50,000	$ 100,000
Administration	$ 2,000	$ 20,000	$ 50,000
Utilities	$ 5,000	$ 5,000	$ 5,000
Insurrance	$ 2,000	$ 10,000	$ 50,000
Interest	$ 1,000	$ 10,000	$ 50,000
Overhead	$ 1,000	$ 5,000	$ 20,000
Research and Devlopment	$ 2,000	$ 12,000	$ 50,000
Revenue Sharing (8% of Sale)	$ 3,900	$ 28,136	$ 105,642
NeoCards Costs	$ 12,000	$ 75,000	$ 150,000
EBITDA	$ (112,150)	$ (435,436)	$ (560,117)
Depreciation & Amortization (20% per year)	$ 16,000	$ 96,000	$ 280,000
Pre-tax Income (EBIT)	$ (128,150)	$ (531,436)	$ (840,117)
Provision for Income Tax (40%)	$ -	$ -	$ -
Net Income	$ (128,150)	$ (531,436)	$ (840,117)

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Figure 9.2 Pro Forma Income Statement for the First Three Years (With insurance for the treatment)

	Year Ended December 31		
	Year 1	Year 2	Year 3
	(4 Devices)	(20 Devices)	(46 Devices)
Summary of Operations			
Net sales	$ 97,500	$ 654,375	$ 2,287,425
Alberta	$ 11,700	$ 78,525	$ 222,075
British Columbia	$ 23,400	$ 157,050	$ 444,150
Ontario	$ 31,200	$ 209,400	$ 810,600
Quebec	$ 31,200	$ 209,400	$ 810,600
Capital cost of chairs	$ 92,000	$ 472,000	$ 1,130,000
Gross Profits	$ 5,500	$ 182,375	$ 1,157,425
Operating Expenses	$ 72,800	$ 354,350	$ 875,994
Owners' drawings	$ 10,000	$ 50,000	$ 50,000
Payroll	$ 10,000	$ 50,000	$ 120,000
Advertising	$ 20,000	$ 50,000	$ 100,000
Administration	$ 2,000	$ 20,000	$ 50,000
Utilities	$ 5,000	$ 5,000	$ 5,000
Insurrance	$ 2,000	$ 10,000	$ 50,000
Interest	$ 1,000	$ 10,000	$ 50,000
Overhead	$ 1,000	$ 5,000	$ 20,000
Research and Devlopment	$ 2,000	$ 12,000	$ 50,000
Revenue Sharing (8% of Sale)	$ 7,800	$ 52,350	$ 182,994
NeoCards Costs	$ 12,000	$ 90,000	$ 198,000
EBITDA	$ (67,300)	$ (171,975)	$ 281,431
Depreciation & Amortization (20% per year)	$ 16,000	$ 96,000	$ 280,000
Pre-tax Income (EBIT)	$ (83,300)	$ (267,975)	$ 1,431
Provision for Income Tax (40%)	$ -	$ -	$ 572
Net Income	$ (83,300)	$ (267,975)	$ 859

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10: Roll Out Strategy

The rollout strategy for the NeoControl therapy system in Canada is to place one NeoControl device in a continuing or a special retirement residence in each province for the first year. Preferably, a well-known centre with the largest population in the region will be chosen. Each retirement centre will purchase NeoCards from the distributor on a regular basis to provide treatment to their patients. Each NeoCard will activate the NeoControl device to provide either a full treatment or a half treatment. Returning patients purchase a half treatment NeoCard to receive 5 sessions. As indicated earlier, the cost of a full treatment is $650 for 10 sessions and the cost of a half treatment is $275 for 5 sessions. More NeoControl devices will be purchased and installed in the continuing and special care retirement centres if the roll out in the first year is successful.

As shown in the Figure 9.1, if a distributor targets only 10% of the retirement centre customers in the first year and targets 20% and 30% in the following years, the business will be very unprofitable. The major reason is that the senior density in the Canadian retirement centres is low. Also, there is a high fixed cost to purchase and maintain each NeoControl device. Lack of insurance coverage is another reason for being unprofitable. If the Canadian distributor obtains insurance coverage before opening the market, sales target is expected to increase by an additional 10% of the retirement centre customers for each year. In this case, Canadian distributor will reach the breakeven point after three years of operation.

Obtaining insurance coverage from the Health Canada and private insurance companies is the key to success of the NeoControl distribution business in Canada. The following steps are recommended to execute this rollout strategy:

1. Obtain the Canadian licence for the NeoControl device.

2. Establish relationships with non-profit organizations to introduce the NeoControl therapy concept.
3. Start negotiation to obtain insurance coverage from the Health Canada and from private insurance companies.
4. Start negotiation with one of the largest continuing retirement centres in each targeted provinces and arrange a profit-sharing agreement to offer NeoControl treatment in their centres.
5. Reduce the supplier power by arranging a partnership with the sole manufacturer of the NeoControl device. This will enable the Canadian distributor to increase its distribution success rate.
6. Start with a minimum number of NeoControl devices to evaluate treatment acceptance before purchasing and installing more devices.
7. Avoid negotiating with physicians and urologists to prescribe NeoControl therapy. There is a potential that patients who are receiving electrical stimulation therapy from physiotherapists might replace this electrical stimulation with NeoControl therapy. This will pose a threat to the physiotherapists. Medical doctors are expected to show less resistance after patients accept the NeoControl therapy system as an alternative treatment. Raising awareness before approaching medical doctors is the key factor in the success of this rollout strategy.
8. Conduct a survey to collect information from continuing and special care retirement centres and their customers. This will provide a baseline for adjustment of the rollout strategy.

11: Conclusion

This project investigates the development opportunity for establishing a market in Canada for the NeoControl Pelvic Floor Therapy System, which is a new generation of urinary incontinence therapy. Throughout the analysis, the potential target market is assessed based on competition with the most popular treatment option currently used in Canada, which is electrical stimulation therapy.

There are two proposed target markets for the NeoControl pelvic floor therapy system. One is the continuing care retirement residences and the other is special care retirement residences. The NeoControl therapy as a new entrant provides the latest treatment alternative especially for patients who are not using other available treatments.

Among the existing treatments in Canada, the electrical stimulation therapy is the competitor. However, they do not offer the same method of treatment. The NeoControl therapy provides a comfortable, easy to use, and more effective treatment to the incontinent patients. Given the size of the target market and the different treatments now available to patients, NeoControl therapy could gradually position itself as a successful alternative in the market.

In order to capture the target market, insurance coverage from either the Health Canada or a private insurance company is required. As a result, the distributor can reach the break even point within three years of operation. With an initial investment of $1.9 million, the company would be able to purchase 70 NeoControl devices and install them in the continuing and special care retirement centres. The distribution business will be highly unprofitable if the insurance coverage is not provided.

Appendices

Appendix A – Incontinence Survey

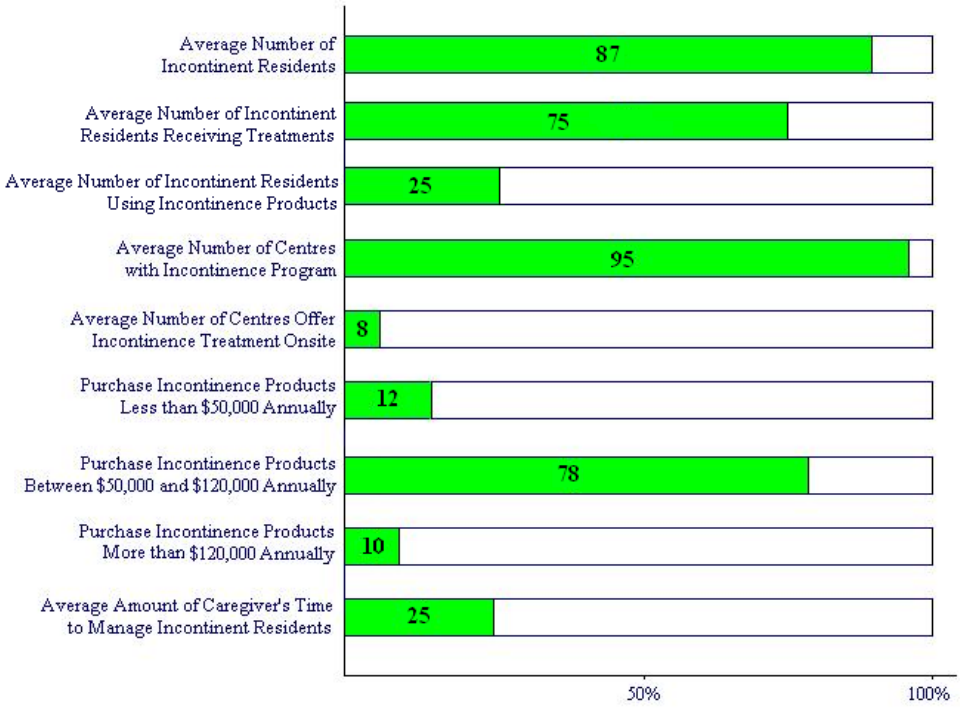
Methodology

An incontinence survey was conducted online among a sample of special care retirement centres in Canada. The online survey was conducted between December 10th and 20th, 2010. The estimated completion length was two minutes. A total of 180 email invitations were sent, of which 36 responded (20%). Figure 11.1 shows the survey outcome.

Demographics

Among survey respondents, 12% of the centres were from Alberta, 56% from British Columbia, 15% from Ontario, and 17% from Quebec.

Figure 11.1 Survey Outcome about Frequency of Purchasing Incontinence Products in Canadian Special Care Retirement Centres



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