ADVANCED MEDICAL TECHNOLOGY

UPTC
UNIVERSAL PAIN TECHNOLOGY CANADA, INC.

SpineMED®
decompression system

Model S200U/S200UC

OPERATIONAL INSTRUCTION MANUAL

Serial No.: Table: #_____
Serial No.: Cervical: #_____

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SpineMED® Patent #7201729

UNIVERSAL PAIN TECHNOLOGY CANADA, INC.

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Introduction to Universal Pain Technology Canada and the SpineMED®

For the past 20 years, health care clinics throughout the world have been able to deliver a non-invasive procedure for pain as a result of herniated, bulging, degenerative discs, facet syndrome and failed back surgery. This non-surgical decompression* of discs has been shown to be effective in reducing pain and improving the functional activity levels of patients. Fortunately, the collection of experiences during this lengthy clinical history, now provide a solid foundation for the improvements in the design and application of disc decompression.

Universal Pain Technology Canada was formed by a group of professionals from North America, whose years experience with non-surgical disc decompression systems is unprecedented. Since the 1980s, this group has been engaged in delivering and reviewing the results of decompression and patient satisfaction. Recognition of the continued benefit of this procedure for the patients, has served as motivation to work diligently on the engineering and manufacture of an enhanced disc decompression device and the development of an effective procedure protocol.

The SpineMED® System (S200U/S200UC) that is now in your possession is the new generation decompression system by Universal Pain Technology Canada. The advances made have culminated in a simplified, comfortable and efficient method of stabilizing the patient during decompression while providing an accurate method of spinal joint distraction. In partnership with the clinicians, the Universal Pain Technology Canada team has established a protocol that gives the most consistent and reproducible effectiveness possible with disc decompression available today. Together the technology and the knowledge of application create the SpineMED® System.

In the history of the manufacturing of medical technology, it has been demonstrated that the effectiveness of a device is only a part of the procedure. How the professional uses the technology is crucial to its success. It is the belief of UPTC that the delivery of a standardized system of training and support is an integral part of the SpineMED® System and ensures the best possible outcomes.

Initial training, online education and support are provided in the set-up and continue throughout the operational phase of the S200U/S200UC. Monitoring of the sessions, acts as a means of continuous quality control. During the learning stage, the use of a method of standardized data collection allows for the SpineMED® coordinator to view at any time a patient's procedure plan and outcome. Any changes required are offered to the clinician by direct feedback or via e-mail. Upon completion of the training and testing, certification for use of the S200U/S200UC is issued to the professional Operator.

Universal Pain Technology Canada and its established network of resources will continuously strive to provide the clinicians and the patients with the resources required to attain maximum effectiveness, patient comfort, safety and efficiency of use for the clinician. Ongoing clinical studies and customer feedback will provide the knowledge for necessary changes in the future.

This manual will serve as a guide for the health professionals who will be using the SpineMED® System (S200U/S200UC) and the SpineMED® Protocol for the Lumbar and Cervical Spine. It is important that every Clinician and Operator of the SpineMED® System read all of the instructions and warnings contained in this Manual, prior to operation of the device.

*Spinal Decompression that is, unloading due to non-surgical distraction and positioning.

⚠ CAUTION: FEDERAL LAW (CANADA/USA) RESTRICTS THIS DEVICE TO USE BY OR ON ORDER OF A PHYSICIAN, CHIROPRACTOR, PHYSICAL THERAPIST OR PRACTITIONER LICENSED TO USE THIS DEVICE. THIS EQUIPMENT MUST BE OPERATED/UTILIZED UNDER THE DIRECT SUPERVISION OF A LICENSED HEALTHCARE PRACTITIONER.

1. Therapeutic Guidelines and Protocol

1.1 Review of Underlying Principles of the SpineMED® Procedure

To be competent as clinicians working with the SpineMED® System, it is essential to know the functional anatomy of the spine and the surrounding tissues. This portion of the manual will serve to highlight the principles that are significant to the delivery of SpineMED® Decompression. The more detailed review of the material required for learning will take place during the training sessions once your SpineMED® System is installed. It is recommended by UPTC that clinicians be trained and certified prior to treatment of patients with the SpineMED® System.

The knowledge of how a normal disc operates as a shock absorber, how it remains healthy, and, how it behaves under immense pressure, will provide you with the foundation of the SpineMED® protocol. This information describes how the benefits of the design of this particular system and the protocol for disc decompression; ultimately provide pain relief for the patient.

The evolution of disc decompression has taken place over a long period of time, and after a great deal of investigation. The scientific reference articles and studies are strongly recommended, and are found in the Clinic Resource CD. Optimal effectiveness is quickly reproducible when there is a consistency and accuracy in the application technique with each patient. There is a routine that must be followed and not varied with each patient. Although certain patients will require modification in the delivery of the distraction, the basic principles apply. During the training and learning stage, careful review of the results of each patient with an experienced Universal Pain Technology Canada professional is extremely valuable.

1.2 Indications and Contraindications for Patients of SpineMED® Procedure

A) The Indications

SpineMED® is an inherently safe procedure; however, it must be performed on a spinal column that is anatomically structurally stable. The standardized medical and physiotherapy assessments completed prior to the patient entering into the procedure provide the screening necessary for confirming the condition of the spine. It is strongly recommended that prior to the SpineMED® procedure, the patient have the results of a current spinal X-Ray (i.e. no less than 3 months old). If there are recent MRI or CAT Scan diagnostics available, then it is up to the Clinician whether an x-ray is essential.

B) Candidates

a. The patient presenting with clinical and/ or radiological evidence of a herniated, bulging or degenerative disc is ideal.

b. The patient clinically presenting with buttock, leg and foot pain as a result of Lumbar spinal dysfunction, or shoulder, arm and hand pain as a result of Cervical spinal dysfunction.

c. The patient presenting with classic nerve root involvement of Sciatica Radiculopathy.

d. Patients with lateral stenosis and central stenosis may respond if severe secondary changes are not present in the vertebra and if the stenosis is not due to a structurally narrow spinal canal.

e. Patients presenting with a pain pattern and clinically findings suggestive of facet syndrome.

f. Patients presenting with back pain or neck pain and have degenerative disc findings, which have been to other therapy numerous times, and were compliant with exercise programs, but have not experienced pain relief.

g. Patients who have failed back surgery.

1.3 Guidelines for Patient Selection for SpineMED® Procedure

A) The maximum patient weight safe working load is 325 lbs. (147 Kg.).

B) Patients with lateral stenosis and central stenosis may respond if severe secondary changes are not present in the vertebra. The definition of stenosis also becomes an issue. When the diagnosis of stenosis results from an actual structural narrowing of the spinal canal, in this situation, positive results are less likely. However, if the diagnosis is present as a result of disc bulge, positive results can be expected.

C) The SpineMED® can be used post spinal surgery and following failed spinal surgery. The use of SpineMED® in conjunction with percutaneous discectomy is not contraindicated. Clinical trials have demonstrated that the dual approach seems to offer an advantage especially in those patients who have more than one level of disc herniation in which only the major segment was percutaneously excised.

Patients with a history of previous laminectomy may undergo the SpineMED® procedure when the extent of surgical excision has not compromised the vertebral articulations and ligamental structures. The guideline is that previous surgery is not contraindicated unless there is hardware; i.e. wire mesh, screws, rods, etc., that have been implanted in the spine. The procedure can be undertaken after 6 to 12 months following the removal of the hardware to allow complete healing. The health care professional and the Doctor will assess the time frame.

D) A patient with recurrent back or neck pain with little to no clinical findings presents a challenge and often becomes a chronic pain patient with secondary gain issues. If the patient continues to be motivated to alleviate the pain and does not want to continue on with the use of pain medication, SpineMED® is a choice that can be presented to the patient. The success rate with these patients is surprisingly high.

E) Although not a contra-indication, it is important to know if a patient is on narcotics for pain relief prior to undergoing the procedure. A patient who has a long history of using narcotics will be unable to accurately report a response to the procedure, and depending on the drug, the patient is at risk for experiencing rebound pain.

F) It is necessary for patients with a history of narcotic use, to first discontinue narcotic medication prior to beginning the procedure. If the patient has been on narcotics for a short time and requires strong medication because of the pain level, the SpineMED® procedure can begin while still taking narcotics for pain. In this scenario the narcotic use should be closely monitored and curtailed as quickly as possible.

1.3.1 Contraindications

The SpineMED® Procedure should not be administered if any of the following apply to the patient:

A) Pathological lesions or congenital deformities of the vertebral column that disrupt the integrity and stability of the vertebral and ligamental structures.

B) Fractures; i.e. compression fractures within one year.

C) Patients with lateral stenosis and central stenosis may respond if severe secondary changes are not present in the vertebra.

D) Neoplasm, spinal tumors; both metastasis and primary.

E) Spina bifida or pars defect.

F) Spondylolisthesis Grade 2 and greater.

G) Osteoporosis with more than 45% bone loss.

H) Progressive pathological or inflammatory process of the spinal joints or muscles.

I) Inflammatory diseases involving the Spine; i.e. Active Rheumatoid Arthritis or Ankylosing Spondylitis.

J) Connective tissue disease; i.e. Scleroderma.

K) Cauda Equina Syndrome, which is a result of pressure on the cauda equina, presenting with bowel and bladder dysfunction.

L) Post-surgical patient with hardware implants, including, but not limited to; rods, screw, metal mesh implants in the spine.

M) Post-surgical patients who have had spinal surgery and healing of tissue is still required. (The period of time post spinal surgery will vary between 6 months to a year).

N) Pregnancy

O) Patients under 15 years of age.

1.4 Patient Instruction Prior to Undergoing the SpineMED® Procedure

Patients are instructed to read the Patient Handbook and to speak to the Clinician about any questions or concerns. It is highly recommended that a patient complete a clinic visit and observe the session in progress, if possible.

The patient must have available for their use an acceptable Lumbar support that they must bring with them to the first session. The support serves primarily to prevent the patient from participating in movements or activity, which will have a negative effect on the healing that is taking place, and to offer some support to the Lumbar Spine. All patients undergoing the SpineMED® procedure are advised to wear a Pelvic Support Belt following each SpineMED® session. This is especially important if the patient must travel any distance or may be subject to acceleration or deceleration forces in transit. Pelvic Belts should also be worn when any postural strain is felt or anticipated as well as whenever the patient engages in activities that may invoke Lumbar flexion or rotational movements during the period of time they are on a course of SpineMED® sessions. Also, many patients find that wearing a Pelvic Support Belt, especially after a SpineMED® session, adds to their comfort level and assists them in maintaining a regular regime of sessions, further facilitating their recovery.

The patient is told that the commitment to the procedure is vitally important and that participation in strenuous activities and exercise during this time of healing will have a definite negative effect upon the results of the procedure. There cannot be enough encouragement given to the patient to comply too the suggested protocol and the “DO” and “DON’T” instructions contained in the Patient Handbook. It is their part of the program, which will have a direct effect on the outcome of the program. Patients are asked to consider this as a time of healing like one would following an injury to any joint.

Sessions are administered with patients fully clothed. However, comfortable, two-piece clothing that can be separated at the waist and loosened at the wrist would be the most practical and comfortable. To avoid bending immediately after each session, it is advisable to wear shoes that slip-on, rather than lace up.

1.5 Standard Protocol for the SpineMED® Procedure

A) Completion of medical screening and review of previous medical records and radiological reports. Minimal requirement is an X-Ray taken no longer than 3 months ago. The Medical Screening Form and radiological records must be faxed or sent to the SpineMED® Clinic, prior to the patient commencing the procedure.

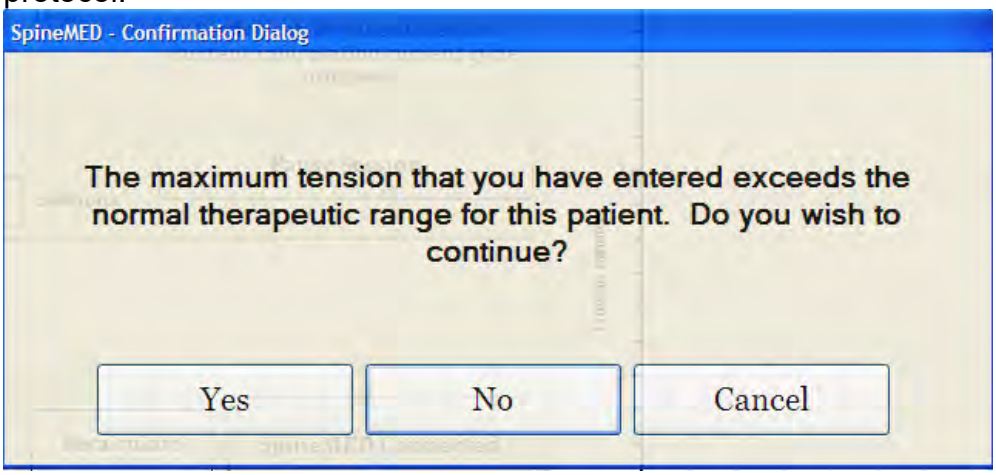
B) The patient must review the Patient Handbook prior to beginning the procedure and is encouraged to have any concerns dealt with prior to the sessions starting.

C) The patient will require a minimum of 20 sessions, which are administered daily, for a minimum of 5 days each week. With each session, there is a cumulative effect. Each SpineMED® session takes approximately 30 minutes, with total time for the session taking 60 to 90 minutes, inclusive of adjunct modalities.

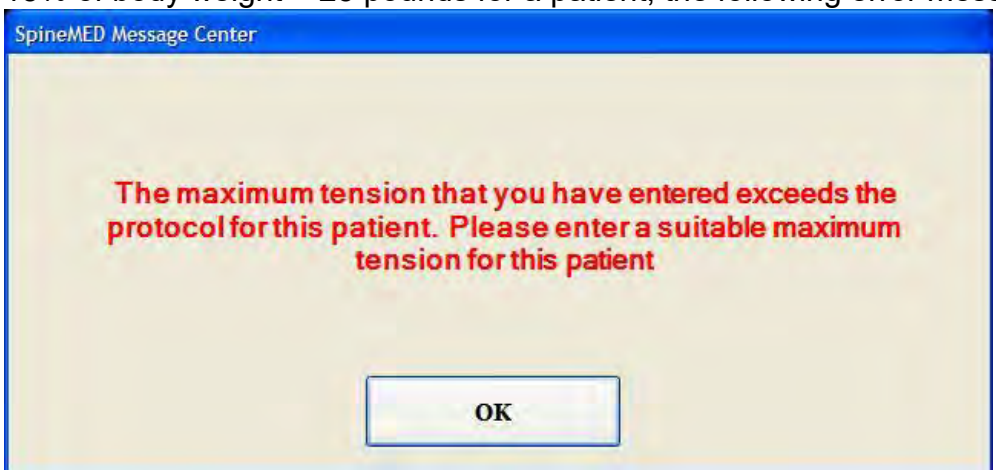
D) The clinician reviews the Medical Screening Form, medical records and radiological report at the first session. A standardized Physical Therapy Assessment is then completed. It is important to review all the clinical information and confirm the patient is an appropriate candidate.

E) Maximum Tension is calculated based on the patient's body weight. Starting Tensions should be 15% of Body weight. (*i.e. 160 lb. X 15% = 24 lb.) Gradual increase of distraction forces are based on patient response to the session plus the general guideline of 3-5 lbs. /session. Maximum distraction tensions of 15% of body weight + 25 lbs. is applicable to all patients. Most patients will find a comfortable plateau of tensions at approximately 15% of body weight + 15 to 20 pounds. It is very rare that tensions of 15% of body weight + 15 pounds is exceeded for any patient. The SpineMED® will enter the calculated Maximum Tension for the first session; however, the Operator can modify this value. Software will prevent user from entering Maximum Tensions above 15% of body weight + 25 lbs.

F) The SpineMED® software will alert the Operator in the event that they attempt to increase the Maximum Tension beyond 15% of body weight + 15 pounds. The following message will appear, to confirm that the Operator does wish to exceed the typical protocol:

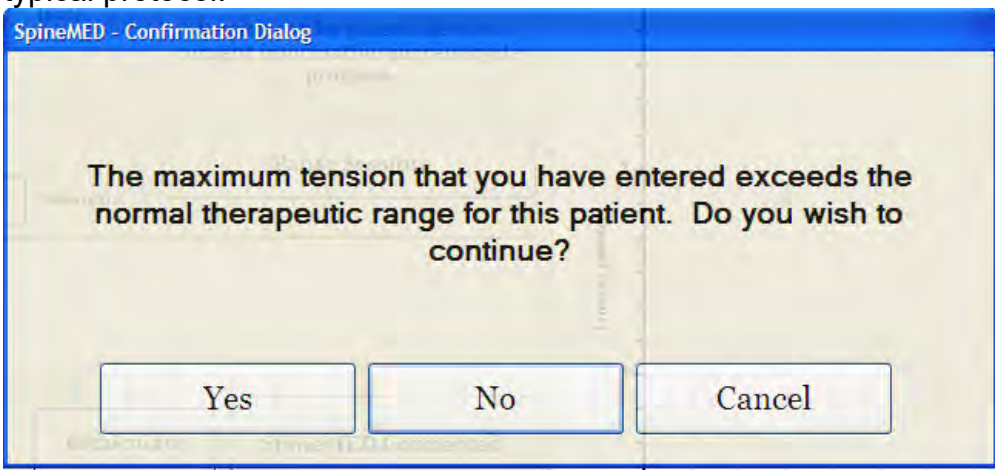


The SpineMED® software will also prevent the Operator from exceeding the maximum recommended tensions for the patient being treated. If the Operator attempts to exceed 15% of body weight + 25 pounds for a patient, the following error message will appear:



G) Calculation of distractive force to be used for patients undergoing Cervical procedure. Maximum Tension for Cervical procedure is calculated based on the patient's gender. Starting Tensions should be 4-5 lbs. for females and 5-6 lbs. for males. Tensions should be increased by 1-2 lbs. daily, until optimum tensions are reached. The SpineMED® software will prevent User from entering Maximum Tensions above 20 lbs. for females and 25 lbs. for males. Most male patients will reach a tension plateau of 15 lbs., while females will typically reach 12 lbs. The SpineMED® software will calculate the Maximum Tension for the first session; however, the Operator can modify this value.

The SpineMED® software will alert the Operator in the event that they attempt to increase the Maximum Tension beyond 15 lbs. for females and 18 lbs. for males. The following message will appear, to confirm that the Operator does wish to exceed the typical protocol:



The SpineMED® software will also prevent the Operator from exceeding the maximum recommended tensions for the patient being treated. If the Operator attempts to exceed 20 lbs. for a female patient or 25 lbs. for a male patient, the following error message will appear:

H) Settings for variable Pelvic angles to target specific spinal segments are programmable. The guidelines for targeting specific Lumbar segments are as follows:

DISTRACTION ANGLES:

- L5-S1 ..... 0 degrees
- L5-S1, L4-L5 ..... 5 degrees
- L4-5..... 10 degrees
- L4-L5, L3-L4..... 15 degrees
- L3-4..... 20 degrees
- L3-L4, L2-L3..... 25 degrees
- L2-3 and above ..... 25 degrees

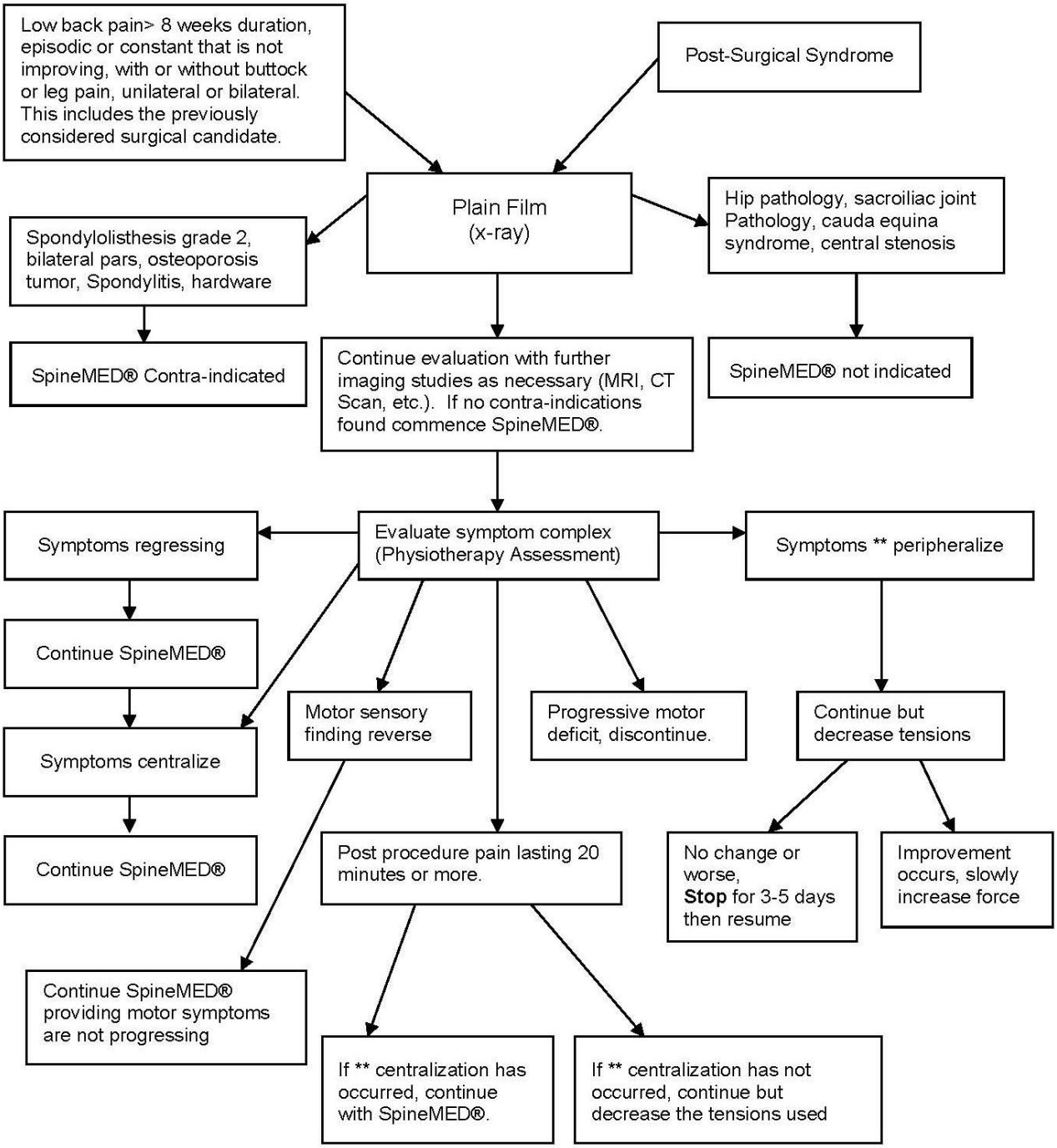
I) Settings for variable Cervical angles to target specific spinal segments are programmable. The guidelines for targeting specific Cervical segments are as follows:

DISTRACTION ANGLES:

- C1-C2..... 0 degrees
- C1-C2, C2-C3 ..... 3 degrees
- C2-C3..... 7 degrees
- C2-C3, C3-C4 .....10 degrees
- C3-C4.....14 degrees
- C3-C4, C4-C5 .....17 degrees
- C4-C5.....21 degrees
- C4-C5, C5-C6 .....24 degrees
- C5-C6.....28 degrees
- C5-C6, C6-C7 .....30 degrees
- C6-C7.....30 degrees
- C7-T1.....30 degrees

Each standard Lumbar session consists of the following *** Patient to sign release form before procedure started*	DURATION
Completion of self-reported V.A.S. for pain Scale	5 min.
Infrared heat application to tissue surrounding the area to be treated.	15 min. to 30 min.
Lumbar decompression with SpineMED® S200U/S200UC *For details see Section 5*	30 min.
Cryotherapy or conventional Ice Pack	10 min.
Pain Control Device—Interferential Current Unit	15 min.
Application of Lumbar Support	Continuous
Post Procedure completion of self reported V.A.S and Oswestry	Variable
Reinforcement of DO and DON'T after the Procedure	

1.6 Procedure Algorithm and Flowchart for SpineMED® Procedure



**Centralization – the movement of symptoms from a distal to more proximal location i.e. movement of symptoms from the leg to the buttock to the lower back.

**Peripheralization – the movement of symptoms from a proximal to a more distal location i.e. movement of symptoms from the back to the buttock to leg.

1.7 Recommended Adjuncts to the SpineMED® Procedure

Non-Steroidal Anti-Inflammatory Drugs (NSAID):
To relieve associated localized soft tissue inflammation and irritation during a SpineMED® session, it is important to select an NSAID agent that also possesses a significant analgesic component. Clinical studies have shown evidence that intradiscal pressures are reduced to negative levels during disc decompression, creating diffusion gradients in excess of 200 mm/Hg. across Vertebral End Plates. Therefore, it has been proposed that this diffusion gradient facilitates migration of serum levels of anti-inflammatory compounds into intervertebral spaces and to the site of the intervertebral lesions.

It is recommended that each candidate for the SpineMED® procedure be prescribed a concomitant NSAID. A therapeutic dosage regime should be started 48 hours prior to the first SpineMED® session in order to develop effective serum levels of anti-inflammatory activity to reduce discomfort from the initial mobilization of irritated Lumbar structures. The agent should be continued throughout the sessions and for approximately two weeks thereafter. To reduce gastric irritations, all NSAID's should be taken with food.

Calcium Supplements:
Calcium is an essential element in the process of skeletal muscle relaxation. This function is especially important for the "strut" (paravertebral) muscles that have a tendency to react with spasms to Lumbar stimuli. Clinical studies have indicated that patients seem to benefit with reduced incidence of spasms when they have a daily intake greater than 800 mg. of elemental Calcium. The preferred source of elemental Calcium is that from the organic salts such as Calcium Lactate or Calcium Gluconate (if allergic to Lactate).

1.8 Patient DO and DON'T

Optimal results are achieved when patients follow the DO and DON'T of the SpineMED® Program.

DO	DON'T
DO rest for at least 1 or 2 hours after each session	DON'T bend forward for the first few hours after a session
DO be aware of your sitting, standing, and lying posture	DON'T twist your back
DO wear your SpineMED® low back support as instructed	DON'T lift heavy objects (over 20 lbs./ 9 Kg.)
DO wear shoes without laces and use a long handled shoe horn if necessary	DON'T wear high-heel shoes
DO report to the Therapist any change in your symptoms at your next visit	DON'T walk long distances after a session
	DON'T try to engage in those activities that you avoided before the procedure, too soon after even though you feel relief

1.9 Post SpineMED® Procedure Protocol

A) Exercise program: At an appropriate time, approximately 4 weeks following completion of the procedure, an exercise program, specific to the patient's condition will be introduced. It will include stretches to promote flexibility through proper alignment of the healing tissue, stabilization and strengthening exercises and range of motion exercises. Throughout the course of the procedure, the client will be instructed in proper body mechanics, posture, and the correct way of using the affected structure to avoid re-injury.

B) Experience has shown that patients undergoing procedure for Posterior Facet Syndromes may resume full activities immediately following remission of their symptoms. However, those who have achieved remission from more serious Lumbar or Cervical dysfunction that involve Intervertebral Discs such as herniations and/or Degenerative Disc Disease, need to realize that their Lumbar/Cervical structures and tissues need time to heal. Follow up of post program patients indicate that this resolution period requires at least one to two months, before individuals can safely engage in body contact sports or strenuous work and recreational activities. This depends on the severity of the underlying lesions and needs to be discussed with the Clinician.

C) In the immediate post procedure period when a patient is in remission and relieved of pain, there is a tendency to return to a level of activity at work or play that is too strenuous. If this is done, the patient is at risk of experiencing a relapse. Therefore, it is especially important to allow time for resolution and healing of decompressed Lumbar/Cervical Discs and the surrounding structures and tissues.

D) Following a course of SpineMED® sessions, patients in remission should be cautioned to slowly increase their exercise program. If their low back pain has caused them to restrict their activities in the past, their muscle strength might be decreased. In some cases, muscles are smaller (atrophied) and weak as a result of nerve compression. For at least one-month post session, exercises that cause flexion, extension or rotation of the Lumbar/Cervical Spine need to be started in a gradual and cautious manner.

E) After patient has completed a minimum of twenty sessions, there should be regular follow-up by one of the SpineMED® Health Care professionals at four weeks for re-assessment and instruction of an exercise program. A review of patient's exercises should be completed within 2 months or earlier, if required. Individual issues can be addressed. The Health Care professional should perform a 6 month and one year follow-up at the SpineMED® clinic.

F) The majority of patients that recover through the SpineMED® procedure generally remain in remission. Some individuals whose lifestyle or work environment exposes them to higher risk factors have found that a maintenance program consisting of occasional sessions is necessary. The Clinician will determine this, and the schedule of these sessions will be decided upon at that time. Generally these sessions are performed at one or two week intervals. The purpose of the maintenance sessions is to serve as a measure of protection against disabling exacerbation of low back pain syndrome. Patients in this category develop their own rhythm of maintenance visits that keeps them free from problems.

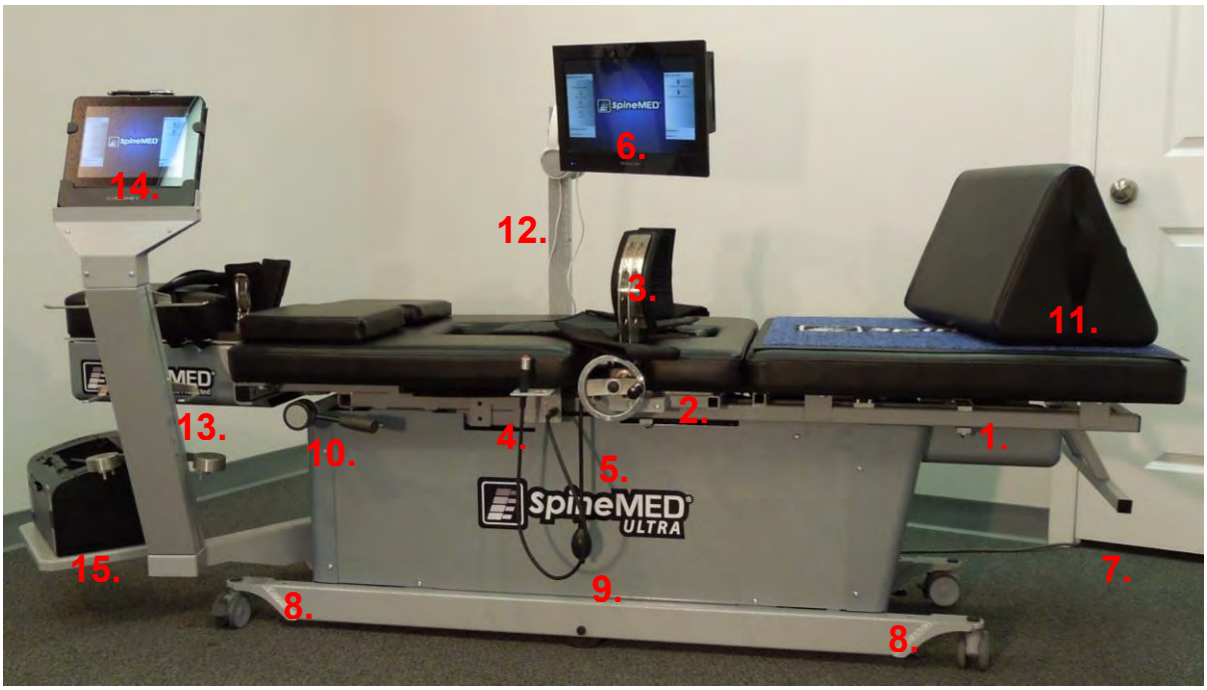
2. Description of the SpineMED® System S200U/S200UC

Components may differ from those shown in this Operational Manual.

2.1 Intended Use of the SpineMED®

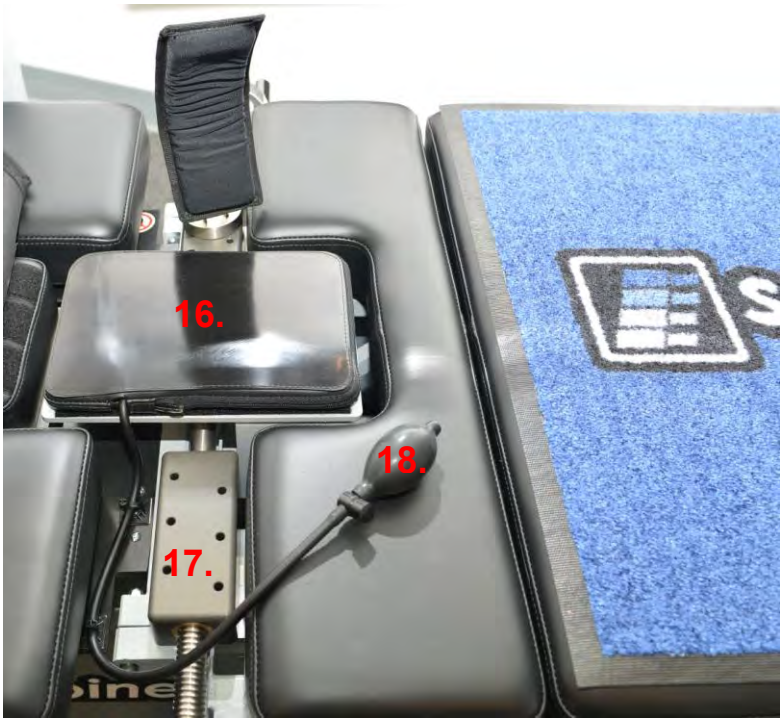
The SpineMED® System provides a program of sessions for relief from pain for those patients suffering with low back pain, neck pain or Sciatica. Each session consists of a physician prescribed protocol period on the SpineMED® and is designed to provide static, intermittent, and cycling distraction forces to relieve pressures on structures that may be causing low back pain, neck pain or Sciatica. It relieves pain associated with herniated discs, bulging or protruding discs, Degenerative Disc Disease, Posterior Facet Syndrome, and Sciatica. It achieves these effects through decompression of intervertebral discs, that is, unloading due to distraction and positioning.

2.2 Structural Design – Components and Features of the SpineMED® S200U/S200UC



A) The Table consists of:

1. A powered, moveable lower Table section
2. A tilting section incorporated into the lower moveable section, which allows tilting of the Pelvis during distraction
3. Pelvic Restraints
4. Patient Hand Held Electrical Emergency Switch (aka Emergency/Panic Switch)
5. Crank Handle to adjust the Pelvic Restraints against the patient
6. Patient Monitor with incorporated CD/DVD Player for patient entertainment
7. Grab Handle for moving Table
8. Screw for lowering Table Feet
9. Inflating Bulb for Lumbar Air Bladder
10. Slack Adjustment Indexing Lever
11. Adjustable Knee Bolster Support Cushion
12. Headphones and Holder
13. Cervical Unit (detailed in later section)
14. Touchcomputer
15. Printer



16. Infrared Heating Pad and incorporated Lumbar Air Bladder/Lordosis Support
17. Pelvic Restraint Adjustment Rail Assembly
18. Inflating Bulb for Lumbar Air Bladder

B) The Cervical Unit consists of:

1. A powered, moveable Cervical Head Cradle
2. A tilting section to adjust the angle of distraction
3. Adjustable Occipital Restraint System
4. Adjustable Head Strap

2.3 Details of Individual Components of the SpineMED® System

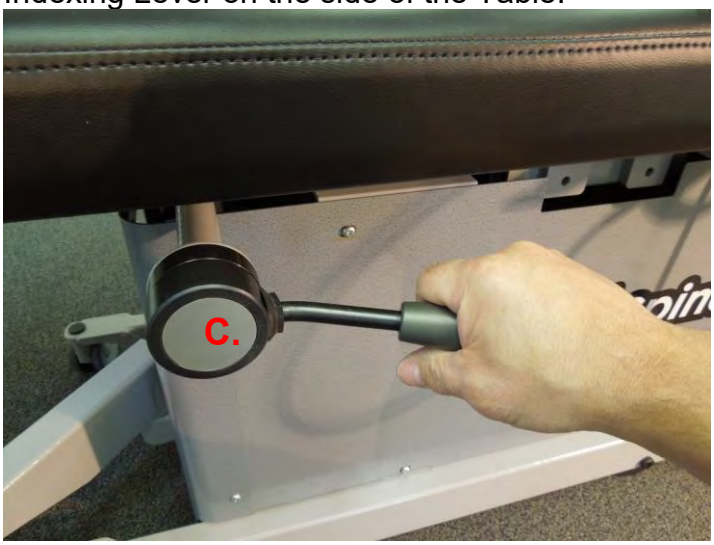
A) Pelvic Stabilization System:

Pelvic Restraint Mechanism: The proprietary SpineMED® Pelvic Restraints secure and stabilize the patient to the lower, moveable section of the Table. The Pelvic Restraints are removable for patient loading/unloading and are adjustable through an Acme Screw System. The adjustments required to secure the Pelvic Restraints in place, are done through the Crank Handle on the side of the device. Pelvic Restraints are positioned immediately above the Superior Iliac Crests on both sides of the Pelvis, and then tightened to hold the Pelvis securely and comfortably.

B) Upper Body Restraint

The Upper Body Restraint system is designed to provide maximal efficient stabilization of the trunk for the distraction that takes place in the Lumbar Spine. The integrated Upper Body Restraint is constructed of nylon fabric with integral foam padding for comfort. The Upper Body Restraint consists of two arm components attached to a back panel, which are designed to capture the ribcage under the lower margin. The Upper Body Restraint arms are comfortably secured around the patients lower rib margin.

C) Slack in the Upper Body Restraint is removed by turning the Slack Adjustment Indexing Lever on the side of the Table.



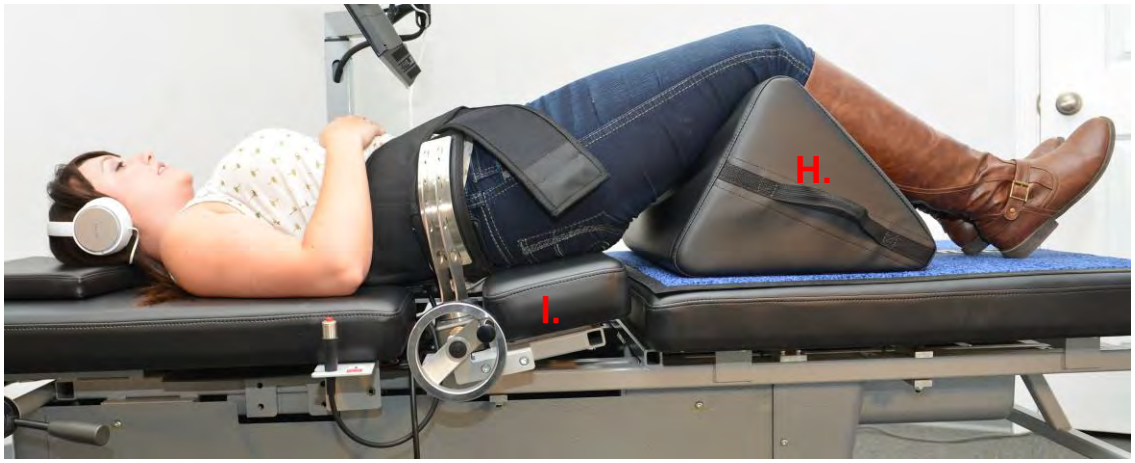
D) The Patient Hand Held Electrical Emergency Switch (also referred to as Emergency/Panic Switch) is designed to be held by the patient during the procedure but may also be located wherever it can easily be accessed by the patient, such as across the patient's abdomen or clipped to Upper Body Restraint. This switch will immediately discontinue the session when pressed, and provides the patient with full control of the session.

E) Printer: The Printer is a standard Laser Printer, which provides a variety of patient and device history reports. It is located on bottom shelf of Touchcomputer Arm, and connects to the Touchcomputer and Power Supply within the Table.

F) UPTC Proprietary Software: The UPTC Software, which was designed specifically for the SpineMED® System - S200U/S200UC, controls the entire operation of the SpineMED® System. This software controls the process and permanently stores individual patient records.

G) Infrared Heating Pad: Has been clinically substantiated to produce radiant heat to depths of 25-35 mm. Traditional heating pads, which provide only topical, conductive heat, only penetrate beyond the epidermis (2-3 mm). This form of heat is applied prior to and during the SpineMED® to relax the muscles and the surrounding tissue by stimulating blood flow and enhancing circulation. The pre-procedure infrared is administered through a mobile, external unit, while the integrated Infrared Heating Pad is utilized during the session. The incorporated Lumbar Air Bladder/Lordosis Support is located beneath the Infrared Heating Pad and is adjusted with the inflatable Air Bladder Bulb. The Infrared Heating Pad will produce a maximum surface temperature of 29.5°C at a 23°C ambient temperature. If the heat from the Infrared Heating Pad becomes uncomfortable for the patient, the Infrared Heating Pad can be turned off by depressing the “Turn Off Infrared Heat” button on the Lumbar Session Settings screen.

H) Adjustable Knee Bolster Support Cushion: Is a patented adjustable cushioned wedge knee support that allows the knees to be elevated and bent, providing additional comfort. The Knee Bolster Support Cushion is designed to be “adjustable” to three different heights by simply rotating the support.

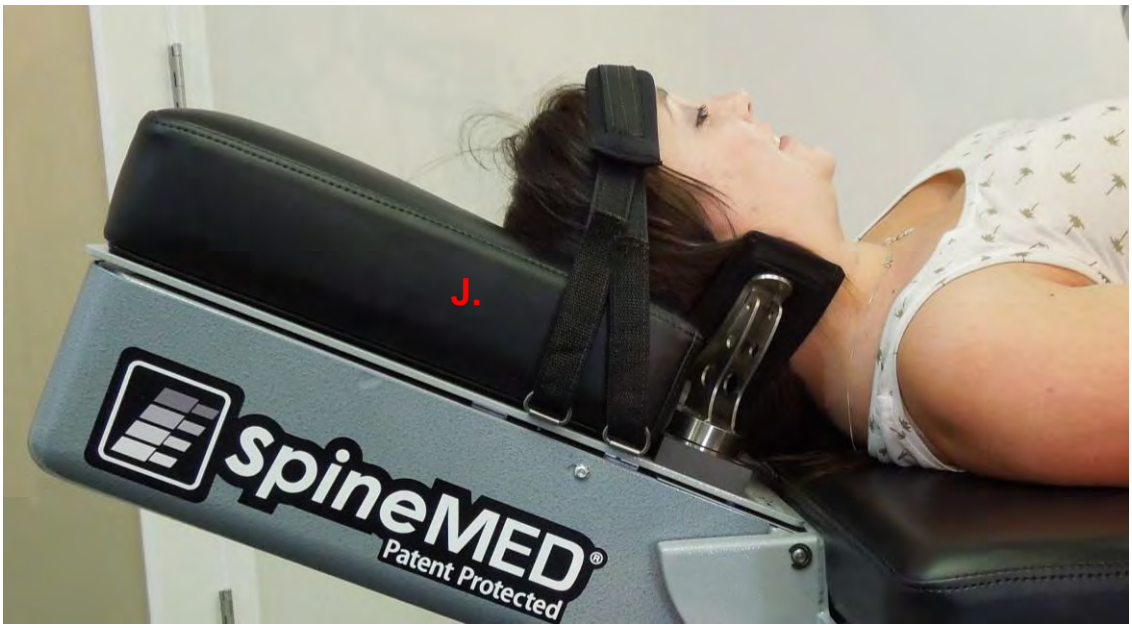


I) The tilting section of the moveable lower Table section pivots from 0 to 25 degrees to tilt the Pelvis during distraction. The settings required for the angle of the Pelvis during distraction are entered into the Touchcomputer on the Patient Procedure Screen. The angles of the pull on the Pelvis vary from 0 to 25 degrees and the angle determines the level of the Lumbar Spine where the distraction force primarily takes place. See Section 5 for procedure details.

PROCEDURE ANGLES:

- L5-S1 ..... 0 degrees
- L5-S1, L4-L5 Multiple Level ..... 5 degrees
- L4-L5..... 10 degrees
- L4-L5, L3-L4 Multiple Level..... 15 degrees
- L3-L4..... 20 degrees
- L2-L3, L1-L2..... 25 degrees

J) The tilting section of the Cervical Unit pivots from 0 to 30 degrees to tilt the Cervical Spine during distraction. The settings required for the angle of the neck during distraction are entered into the Touchcomputer on the Patient Procedure Screen. The angles of the pull on the neck vary from 0 to 30 degrees and the angle determines the level of the Cervical Spine where the distraction force primarily takes place. See Section 5 for procedure details.



PROCEDURE ANGLES:

- C1-C2..... 0 degrees
- C1-C2, C2-C3 ..... 3 degrees
- C2-C3..... 7 degrees
- C2-C3, C3-C4 .....10 degrees
- C3-C4.....14 degrees
- C3-C4, C4-C5 .....17 degrees
- C4-C5.....21 degrees
- C4-C5, C5-C6 .....24 degrees
- C5-C6.....28 degrees
- C5-C6, C6-C7 .....30 degrees
- C6-C7.....30 degrees
- C7-T1 .....30 degrees

2.4 Operational Design

A) The SpineMED® System S200U/S200UC

The SpineMED® System is computerized, and controlled via touch screen menus. The SpineMED® has several key systems incorporated into its design for reliability and patient safety. A Voltage Regulator incorporated into the Table, protects the electrical components from power surges and adverse power fluctuations. Replaceable fuse protection is also part of the Mains Voltage System. In the event of power failure, an internal UPS (Uninterruptible Power Supply) System with a minimum 30-minute capacity will continue the safe operation of the device to a controlled termination of the current session, while the SpineMED® System will emit an audible warning to notify the Clinician of the power failure. The patient is provided with a Patient Emergency/Panic Switch, which will immediately terminate the current session, and return the Table to the home position at a controlled rate.

B) Software Functions

- Complete control of the operation of the SpineMED® through touch screen menus to administer session to patients on the device. Control of program period consisting of cycles of maximum and minimum forces over a session period.

- Procedure Basic Data Field Storage: 1) Operator Name; 2) Patient ID #; 3) Patient Name; 4) Date; 5) Time of Procedure; 6) Graph of Procedure Cycles; 7) Daily 0-10 VAS Pain Index; 8) Patient Procedure History; 9) Procedure Comments; 10) Operating Physician

- Report Sorting: Report generation of complete patient history with this particular SpineMED® System, including a “Trend Line Graph” of the individual sessions.

C) Lumbar Operation

- Force measurements in Pounds

- Typical operation will consist of a series of two force phases per cycle, which typically consist of a 60 second “Hold Time” distraction phase (high force), and a 30 second “Relax Time” relaxation phase (low force) over a modifiable number of cycles for an approximate period of 30 minutes. A graph of this operation would show a beginning force of zero pounds, which is slowly built up to the maximum force. The Touchcomputer will gradually increase the force tensions to the preset Maximum Tension over a specific number of cycles, termed the "Progressive Cycles", which is preset at 3 cycles. The maximum (Hold Time) and minimum (Relax Time) phases in the cycles repeat through the session of 30 minutes, and at the end of the session, force is gradually diminished to zero pounds over the "Regressive Cycles" period, which is preset at 2 cycles.

- Time Length of Maximum (Distraction/Hold Time) Force Cycle - preset to 60 seconds

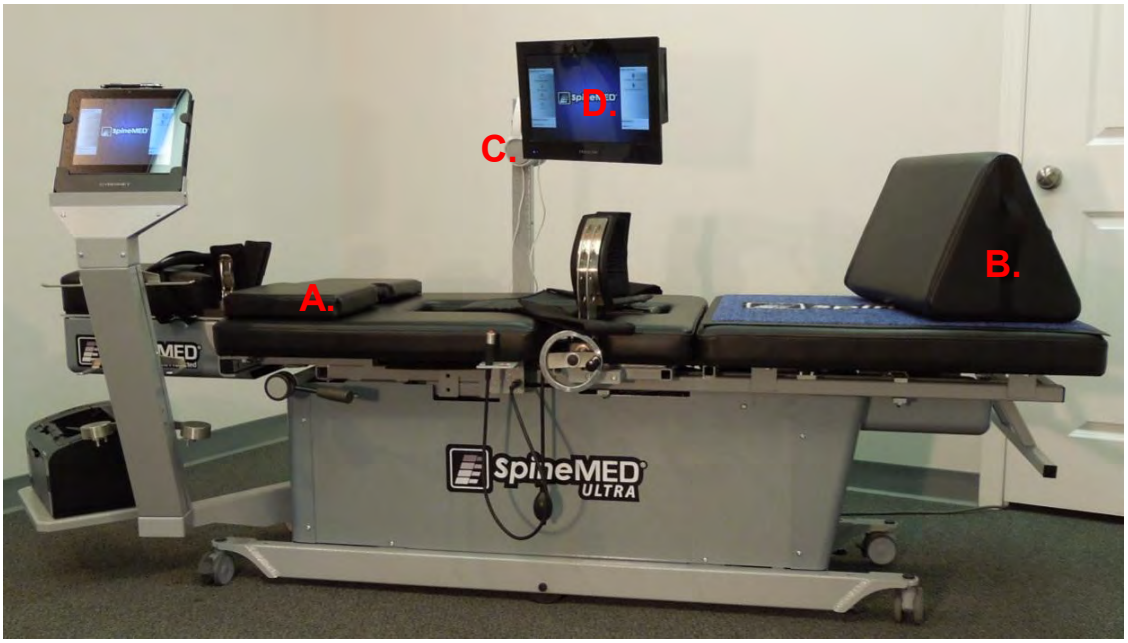
- Time Length of Minimum (Rest/Relax Time) Force Cycle - preset to 30 seconds

- Maximum force applied: 10 to 100 lbs.
- Minimum force applied is to be automatically calculated as 50% of Maximum force with an upper limit of 25 lbs.
- Progressive Cycles preset to 3 cycles
- Regressive Cycles preset to 2 cycles
- Emergency/Panic Switch: Switch operable by patient to immediately discontinue application of all tensions.

D) Cervical Operation

- Force measurements in Pounds
- Typical operation will consist of a series of two force phases per cycle, which typically consist of a 60 second “Hold Time” distraction phase (high force), and a 30 second “Relax Time” relaxation phase (low force) over a modifiable number of cycles for an approximate period of 30 minutes. A graph of this operation would show a beginning force of zero pounds, which is slowly built up to the maximum force. The Touchcomputer will gradually increase the force tensions to the preset Maximum Tension over a specific number of cycles, termed the "Progressive Cycles", which is preset at 2 cycles. The maximum (Hold Time) and minimum (Relax Time) phases in the cycles repeat through the session of 30 minutes, and at the end of the session, force is gradually diminished to zero pounds over the "Regressive Cycles" period, which is preset at 1 cycle.
- Time Length of Maximum (Distraction/Hold Time) Force Cycle - preset to 60 seconds
- Time Length of Minimum (Rest/Relax Time) Force Cycle - preset to 30 seconds
- Maximum force applied: 2 to 30 lbs.
- Minimum force applied is to be automatically calculated as 50% of Maximum force with an upper limit of 7.5 lbs.
- Progressive Cycles preset to 2 cycles
- Regressive Cycles preset to 1 cycle
- Emergency/Panic Switch: Switch operable by patient to immediately discontinue application of all tensions.

2.5 Accessories



A) Head Cushion: An adjustable, 3-way padded pillow is provided to comfortably support the patient's head during a session.

B) Adjustable Knee Bolster Support Cushion. A patented, 3-way adjustable cushioned wedge knee support that allows the knees to be elevated and bent, during the session for comfort and stability of the Pelvis. By simply rotating the Knee Bolster Support Cushion, the overall height can be tailored to accommodate individual patient comfort.

C) Patient Headphones. A headphone system is incorporated into the SpineMED® to provide sound to the patient from the Patient Monitor with incorporated CD/DVD Player.

D) Patient Monitor with incorporated CD/DVD Player: To play music and/or video programming for patient.

2.6 Installation and Space Requirements

Universal Pain Technology Canada will arrange transportation of the SpineMED® System. The Table and Cervical Unit arrive in one crate. It is important to consider the location for the SpineMED® System prior to its arrival. The Table weighs 440 lbs. (199.5 Kg.). The Cervical Unit increases the weight of the Table to 495 lbs. (224.5 Kg.).

It is preferred that the SpineMED® System, have a room of its own. The minimum recommended size for a room is approximately 6' x 9' (1.82m x 2.74m). It is beneficial to the success of the program and individual session, if the patient is in a quiet, dimly lit room, where there is no other activity/distraction noise.

At the time of installation, there will be a qualified technician from Universal Pain Technology Canada, who is responsible for the set-up and installation of the SpineMED® System.

There is an Installation Form, which will be filled out by the technician and signed, to confirm that the function of the SpineMED® System has been tested to manufacturer's specifications.

A) Moving the Table. The Table is fitted with casters to allow movement of the device if necessary, however, the Table is designed to be in a fixed, stationary position through the employment of the adjustable leveling feet located at each corner of the lower frame. To facilitate moving the Table, disengage the leveling feet by turning the screw assembly counter-clockwise until the feet are free from the floor surface. The casters also have a locking mechanism, which can be released by lifting on the locking tab.

B) Connection and Disconnection of Cervical Unit: It may be necessary to remove the Cervical Unit for relocation or transportation. There are four bolts (2 each side) that secure the Cervical Unit to the Table frame. Removal of these bolts and disconnection of the wiring harness will allow removal of the Cervical Unit from the Table.

2.7 SpineMED® Power On Procedure

A) At all times, with the exception of when the SpineMED® is in storage or being shipped, you must ensure the Main Supply Power Switch (#1 - Figure 2.7A) is left in the ON position, with the power cord attached to a suitable 120V power outlet. This is to maintain a full charge in the UPS (Uninterruptible Power Supply) System. If the SpineMED® System is to be unplugged from the wall outlet, or if the Main Supply Power Switch is turned off, the UPS (Uninterruptible Power Supply) System (#1 – Figure 2.7B) must be turned off to prevent the batteries from discharging. Excessively depleting the batteries can cause irreparable damage to the UPS (Uninterruptible Power Supply) System. Be sure to turn off the Main Supply Power Switch (#1 – Figure 2.7A) before unplugging the SpineMED® System from the wall outlet to prevent fuse failure.

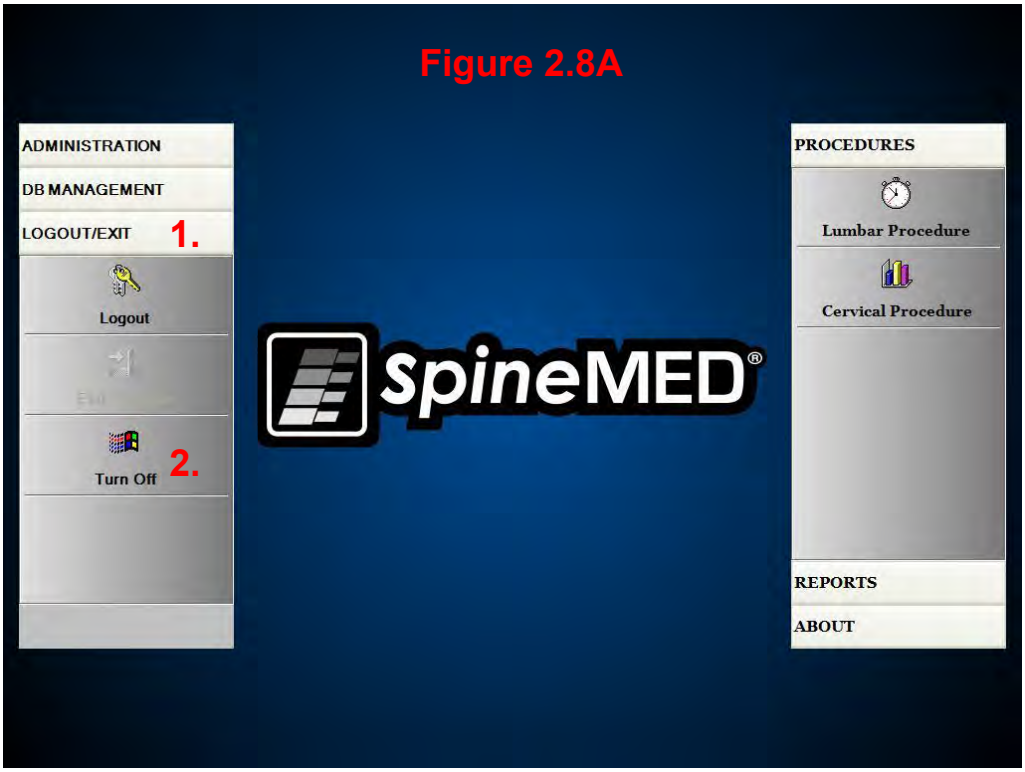
B) With the SpineMED® System plugged into a 120V outlet, ensure the UPS (Uninterruptible Power Supply) System (#1 - Figure 2.7B) is turned on and receiving power.

C) The Touchcomputer must now be powered on, by depressing the small “Power” button located on the bottom right corner of the Touchcomputer (#1 – Figure 2.7C and Figure 2.7D).

D) The Touchcomputer will go through the boot sequence and automatically load the SpineMED® program.

2.8 SpineMED® Shutdown Procedure

A) On the Main Menu in the SpineMED® software, select LOGOUT/EXIT (#1 - Figure 2.8A).



B) On the LOGOUT/EXIT screen, select TURN OFF (#2 – Figure 2.8A).

C) It is imperative that you wait for the Touchcomputer to completely shut down before powering off the SpineMED® System. Once the Touchcomputer has shut down, turn off the SpineMED® System by turning off the UPS (Uninterruptible Power Supply) System power. Press and hold ON/OFF Power button (Figure 2.7B) for a few seconds until a beep is heard. The power to UPS (Uninterruptible Power Supply) System will now be off.

D) The Main Supply Power Switch (#1 – Figure 2.7A) should be left in the ON position to maintain power to the UPS (Uninterruptible Power Supply) System to maintain a full battery charge in the UPS (Uninterruptible Power Supply) System.

3. SpineMED® Software Operation

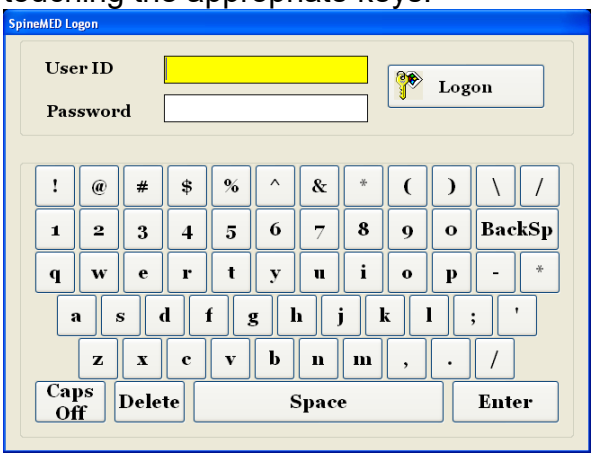
The SpineMED® System operates on a proprietary software application designed specifically for this device and utilizes a touch screen interface with a digital keyboard to input data into the Touchcomputer. The appropriate letters or numbers imaged on the screen are selected by simply “touching” the screen with a finger over the desired selection.

3.1 Operator Logon Screen

A) Once the SpineMED® has been powered on and completed the boot sequence, the Operator will be presented with the Logon Screen.

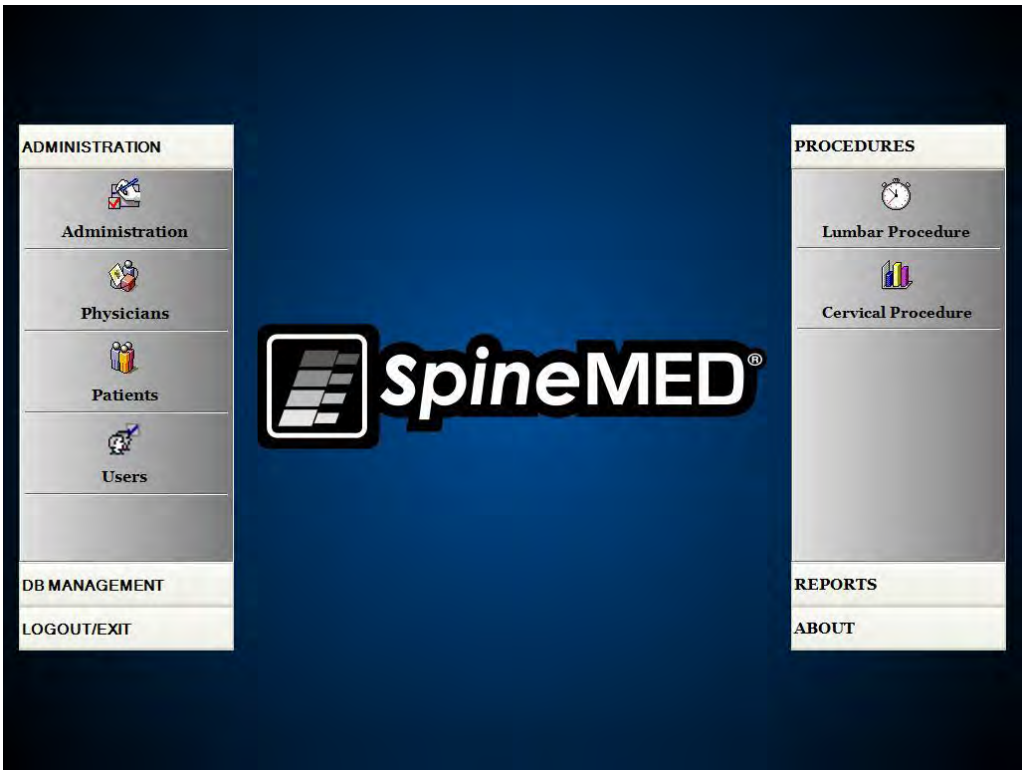
B) Enter the User ID by touching the appropriate keys. If no data appears in the User ID field, ensure there is a blinking cursor in this field by touching the white data area beside the User ID title.

C) After entering the User ID, the cursor should be blinking in the Password field. If it is not, touch the white data field beside the Password title. Enter the password by touching the appropriate keys.



D) Press the “Logon” button to logon to the system and move to the Main Menu Screen.

3.2 Main Menu



The Main Menu provides access to a number of general categories, which contain separate sub-menus.

A) Administration. The “Administration” button will bring up a sub-menu to allow administration of four separate functions: 1) Device Administration Module; 2) Physicians Administration Module; 3) Patients Administration Module; 4) Users Administration Module.

i. Administration Module: The Administration Screen allows the Clinic Manager to modify clinic information in the SpineMED® System.
ii. Physicians: The “Physicians” button will open the Physicians Screen, where Physician records can be added or edited.
iii. Patients: The “Patients” button will bring up the Patients Screen, where new patients can be entered into the system, or to modify a current patient’s personal data.
iv. Users: The “Users” button will open the Users Screen, where new Users can be added, or current Users can be edited.

B) Database Management: The “Database Management” button will bring up three sub-menus allowing administration of: 1) A database backup function: 2) A database restore function: 3) A database export function.

i. Backup DB: The Backup DB function allows for internal, external and offsite backup of the internal SpineMED® database. Clicking on this button will bring up a menu to allow the location of the backup. It is recommended that an internal backup be done at the end of each office day. Using a USB External Drive, it is recommended that a backup be saved to an external drive for offsite storage at least once per week.

ii. Restore DB: The Restore DB function allows for the restoration of the internal database from the internal backups or from an external backup copy (on USB Drive).

iii. Export DB: The Export DB function allows for the exporting of all session data for all patients to an Excel spreadsheet.

C) Logout/Exit: The “Logout/Exit” button will bring up two sub-menus allowing: 1) Logout; 2) Turn Off

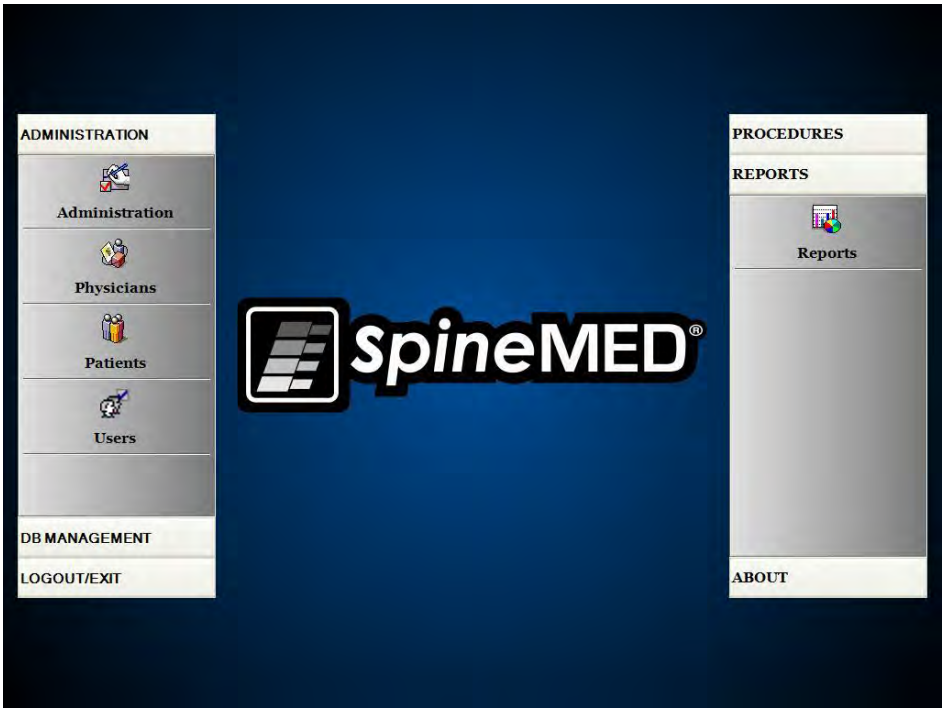
i. Logout: The “Logout” button is used to change current User operating the device. Clicking this button will log off the current User, and open the Logon Screen to allow a new User to Logon.

ii. Turn Off: The “Turn Off” button simply turns off the device, which begins with the exit of the SpineMED® software, and powering down of the Touchcomputer.

D) Procedures: The “Procedures” button will bring up a sub-menu to allow access to two separate functions: 1) Lumbar Procedure Module; 2) Cervical Procedure Module

i. Lumbar Procedure Module: The “Lumbar Procedure” button will bring up the Lumbar Procedure Screen, where the SpineMED® is controlled to administer individual Lumbar sessions.

ii. Cervical Procedure Module: The “Cervical Procedure” button will bring up the Cervical Procedure Screen, where the SpineMED® is controlled to administer individual Cervical sessions.

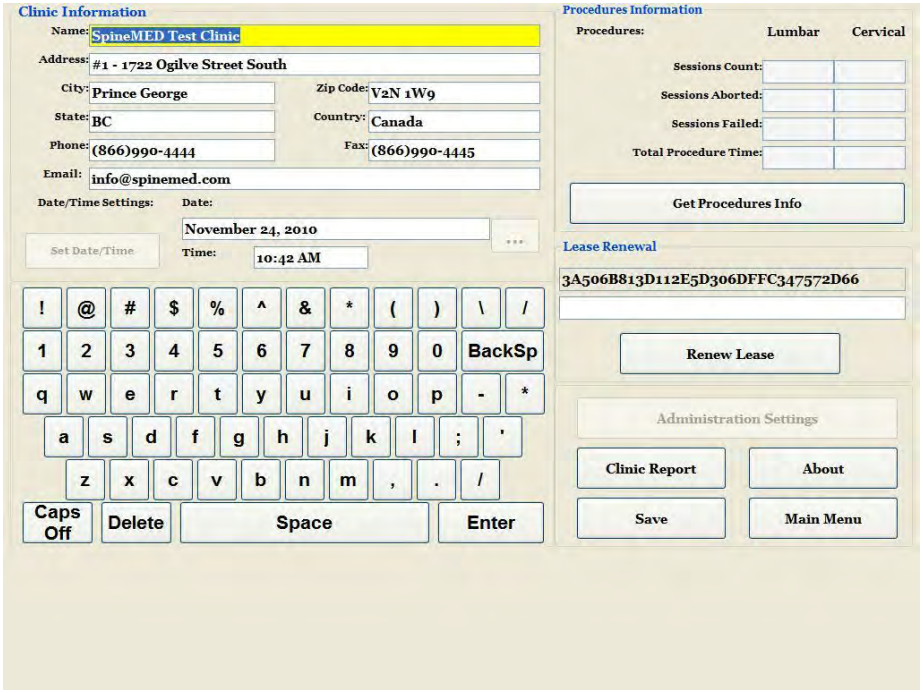


E) Reports: The “Reports” button will bring up a sub-menu to allow access to the Reports Module where individual patient reports can be generated.

F) About: The “About” button will display the current software version installed on the SpineMED® System.

3.3 Administration Menu Screen

Users with Doctor's ID's and Passwords can only access the Administration Menu. The administration function is to modify clinic information, which is printed on the various reports, modify date and time, obtain device statistics, and enter in new lease codes.



A) Clinic Information: To change any information about the Clinic, simply modify the fields and press the "Save" button to store your changes.

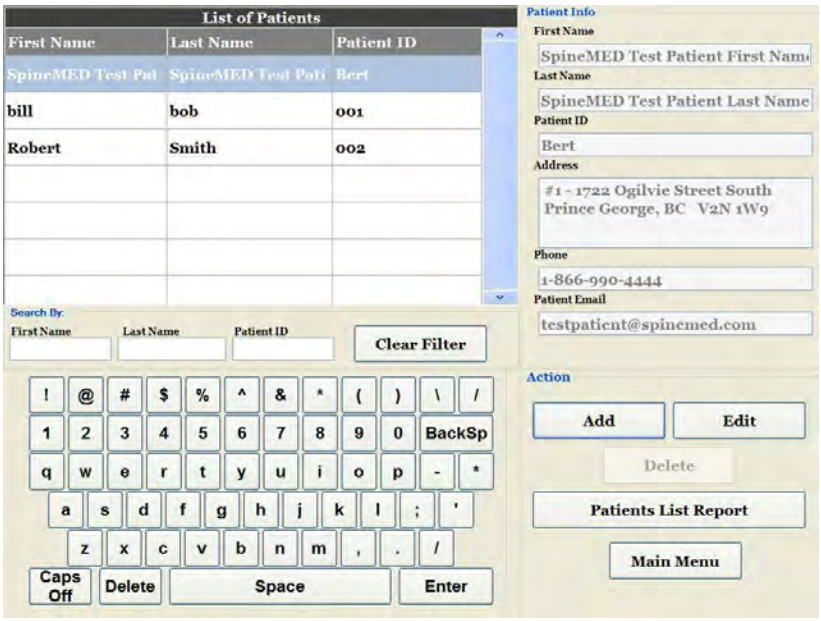
B) About: The "About" button will display the software version currently installed in this SpineMED® System.

C) Get Procedures Info: Pressing this button will calculate all of the procedure statistics for the device.

D) Clinic Report: This function will create a report outlining all of the clinic information stored in the SpineMED®.

E) Set Date/Time: Pressing the "…" button will open a calendar window that will allow you to set the current date. Simply enter in the current time in "12:00 AM" format, and press the "Set Date/Time" button to store the time and date.

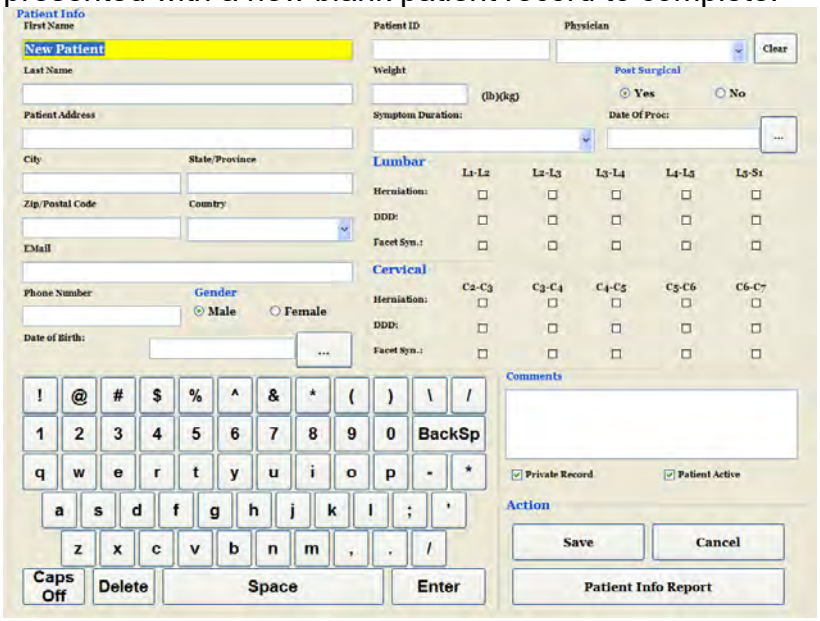
3.4 Patients Menu Screen



The Patients Screen is used to enter new patients into the Touchcomputer, and to modify existing patient's personal data.

3.4.1 Enter New Patient

A) To create a new patient in the system, click on the "Add" button. You will be presented with a new blank patient record to complete.

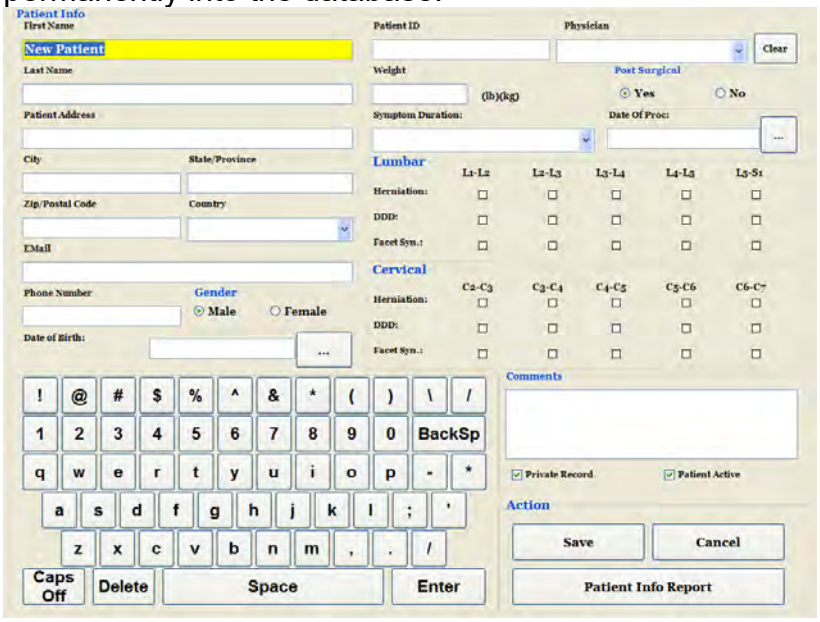


B) Enter the patient's personal information:

- First Name
- Last Name
- Home Street Address
- City, State/Province, Zip/Postal Code
- Country

- Email address
- Telephone Number with area code
- Date of Birth in MM/DD/YYYY format
- Gender: Male/Female
- Patient ID: Social Security number or other unique number (the system will only accept a specific number once)
- Attending Physician
- Weight (in pounds)
- Post Surgical: yes/no if patient has had previous spinal surgery
- Date of TX (Date of assessment/first session)
- Symptom Duration (length of time patient has had symptoms)
- Pathology: Cervical or Lumbar pathology. Multiple fields can be selected for Disc Herniation, Disc Degeneration and Facet Syndrome for the specific diagnosed levels i.e. L5-S1
- Private Record: Checking this box will eliminate this patient's procedure records from being exported from the SpineMED®
- Patient Active: Un-checking this box will eliminate this patient record from being available in the Patient List which is displayed in the Procedure Screen

C) When all data has been entered, touch the "Save" button to store this patient permanently into the database.



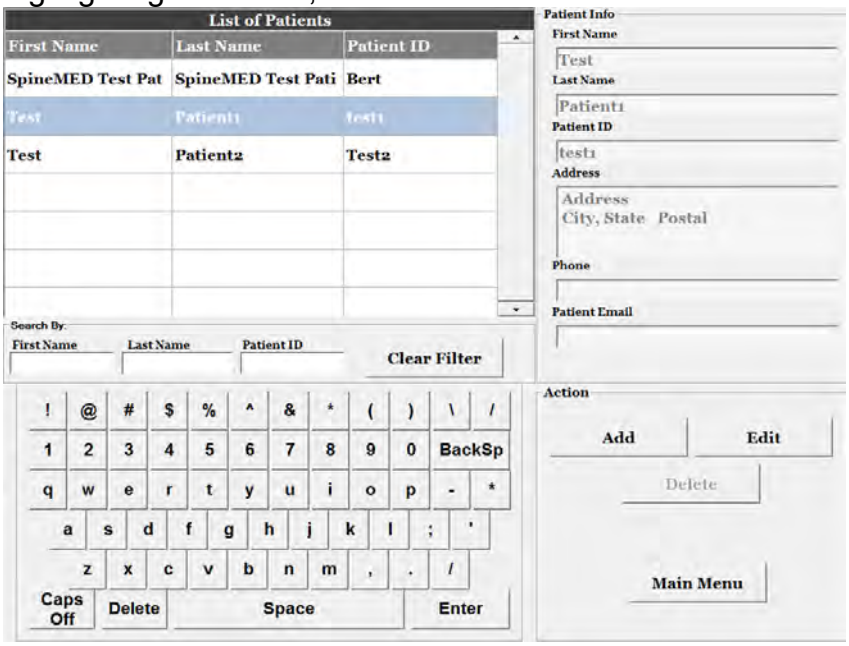
D) Touch the “Main Menu” button to return to the Main Menu Screen.

3.4.2 Modify Existing Patient’s Information

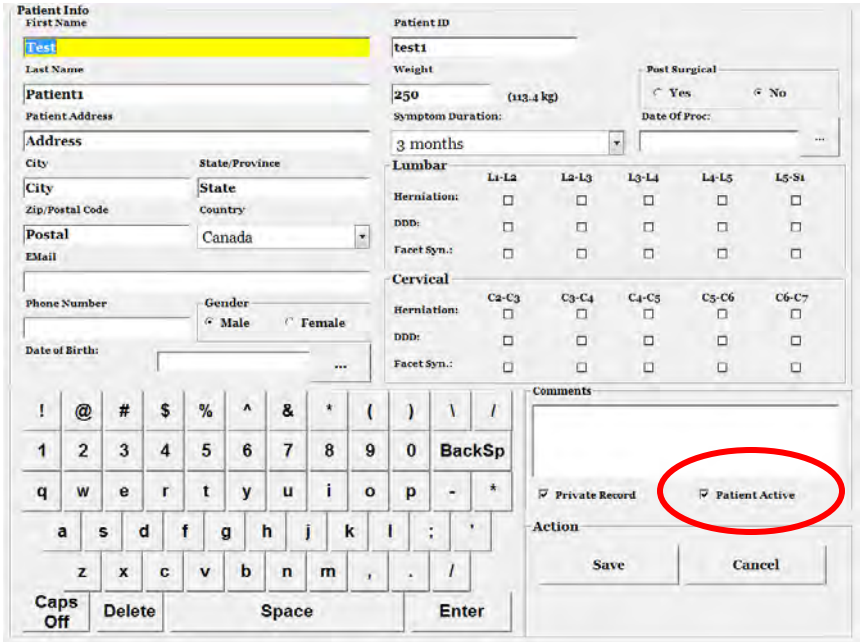
Select the patient to modify information for, by scrolling up or down to the appropriate patient name or enter in their first name, last name or patient ID into the “Search By” fields for the auto search function. Select the particular patient by highlighting the name, and then click on the “Edit” button to open this record. Modify the fields as necessary, and be sure to press the “Save” button to save your changes to this record. Touch the “Main Menu” button to return to the Main Menu Screen.

3.4.3 Archive or Restore Existing Patient Record

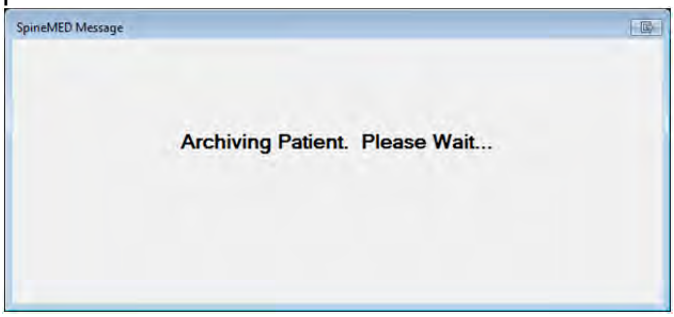
A) From Main Menu Screen, select Patients. Select the patient record scrolling up or down to the appropriate patient name or enter in their first name, last name or patient ID into the “Search By” fields for the auto search function. Select the particular patient by highlighting the name, and then click on the “Edit” button to open the record.



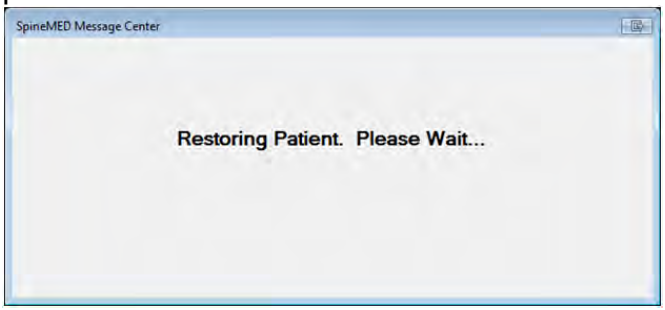
B) Click the Patient Active check box



i. If the patient is being modified from “Active” to “Inactive” this will archive all the patient’s data.



ii. If the patient is being modified from “Inactive” to “Active” this will restore all the patient’s data.



iii. An archived patient will not be visible anywhere in the application except here. The patient will have to be restored to “Active” to view reports or continue with SpineMED® sessions.

3.5 Physician Menu Screen

The Physician Menu is used to add, modify and delete referring Physician records in the SpineMED® database.

3.5.1 Enter New Physician

A) To create a new physician in the system, click on the “Add” button. You will be presented with a new blank physician record to complete.

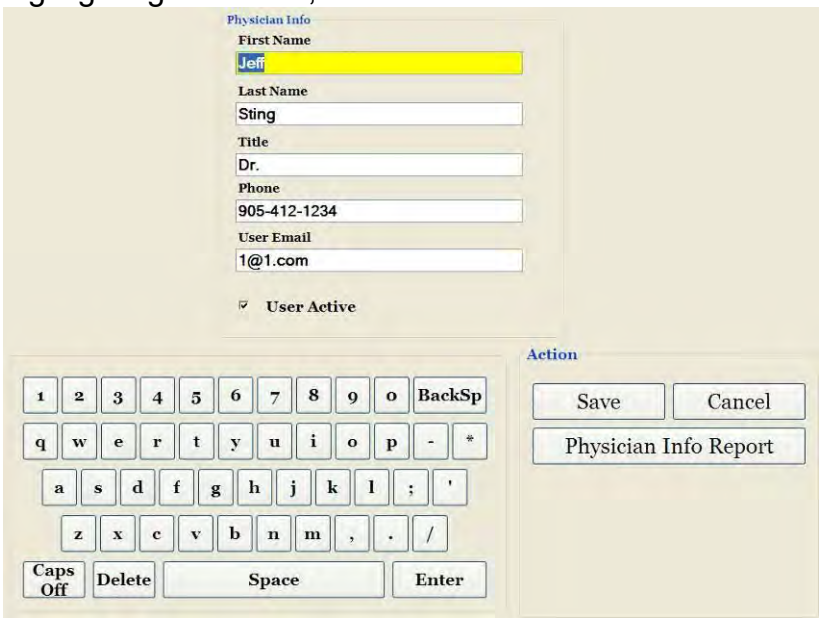
B) Enter the physician’s personal information:

- First Name
- Last Name
- Title
- Phone
- Email address

When all data has been entered, touch the “Save” button to store this physician record permanently into the database. You will be returned back to the Physician Main Screen.

3.5.2 Edit Existing Physician's Information

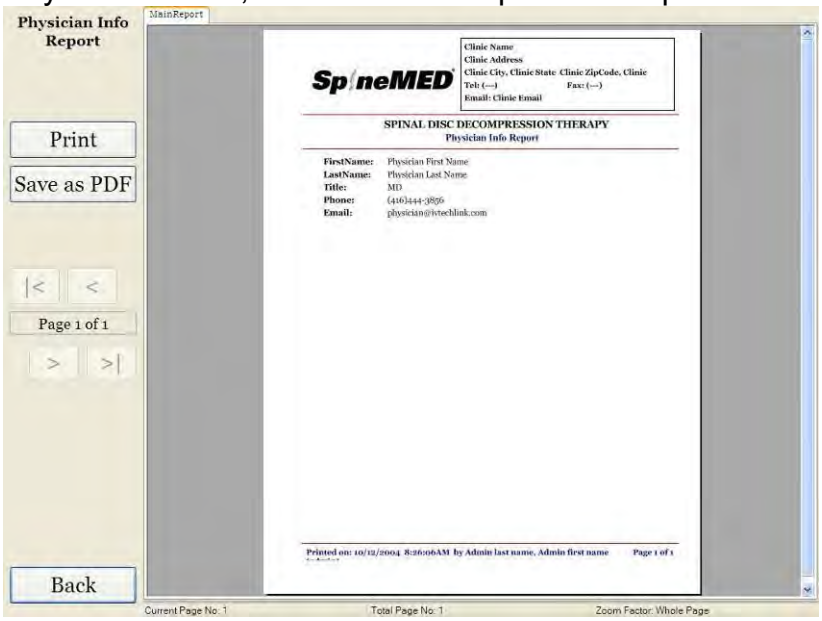
Select the physician record to modify, by scrolling up or down to the appropriate physician name or enter in their first name, last name or phone number into the "Search By" Fields for the auto search function. Select the particular physician record by highlighting the name, and then click on the "Edit" button to open this record for editing.



Modify the fields as necessary, and press the "Save" button to save your changes to this record. You will be brought back to the main Physician Screen.

3.5.3 Physician's Info Report

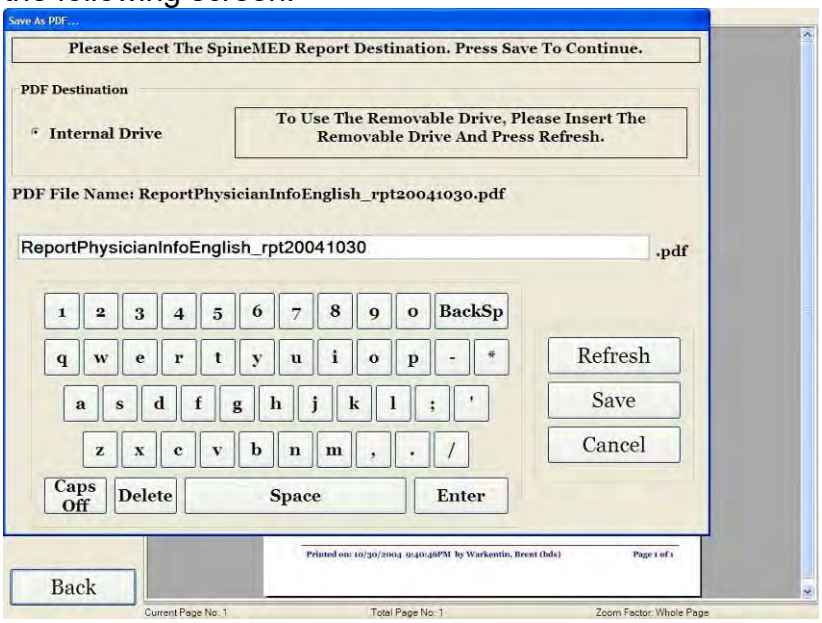
Touching the "Physician Info Report" button will generate a report of this particular Physician record, which can be output to the SpineMED® Printer, or create a PDF file.



A) Print: Pressing the "Print" button will output the displayed report to the SpineMED® Printer.

B) Back: Pressing the “Back” button will bring you back to the Edit Screen.

C) Save as PDF: Pressing the “Save as PDF” button, will output the displayed report to a PDF file, which can be saved internally or to an external drive. You will be prompted with the following screen.



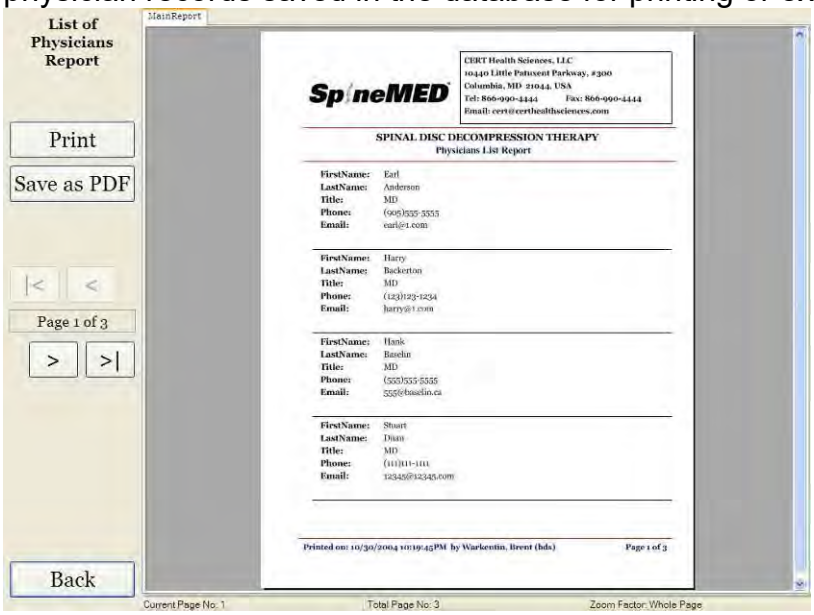
D) Refresh: Pressing the “Refresh” button will refresh the available Drives: for example, if you’ve inserted a USB key drive into the front USB port of the server, pressing the “Refresh” button will add it to the menu of available drives. You can also modify the file name by selecting the text in the file name field and modifying the selected text.

E) Save: Pressing the “Save” button will save the file to the selected drive.

F) Cancel: Pressing “Cancel” button will return you to the Physician Edit Screen.

3.5.4 Physician's List Report

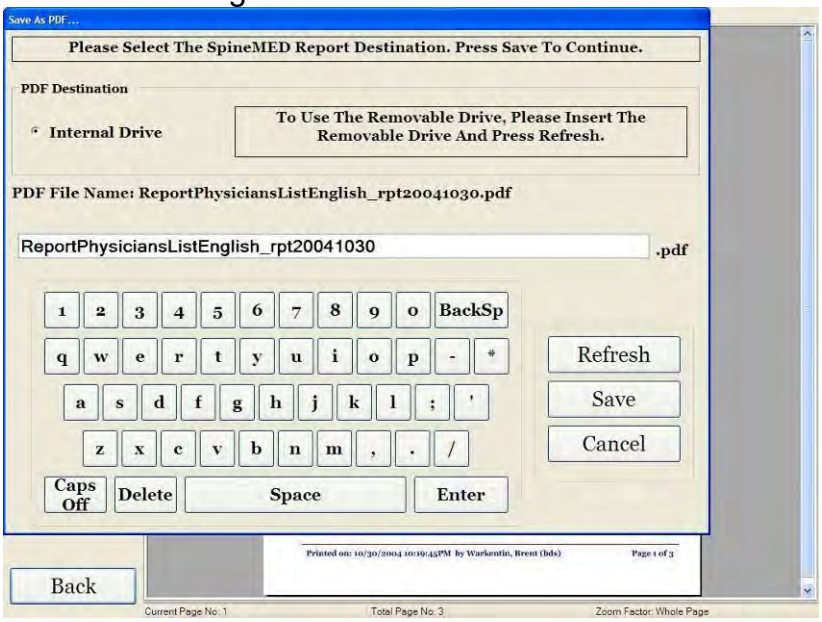
Touching the "Physician List Report" button will bring you to a screen with a list of physician records saved in the database for printing or exporting as a PDF file.



A) Print: Pressing the "Print" button will output the displayed report to the SpineMED® Printer.

B) Back: Pressing the "Back" button will bring you back to the Edit Screen.

C) Save as PDF: Pressing the "Save as PDF" button, will output the displayed report to a PDF file, which can be saved internally or to an external drive. You will be prompted with the following screen.



D) Refresh: Pressing the “Refresh” button will refresh the available Drives: for example, if you’ve inserted a USB key drive into the front USB port of the server, pressing the “Refresh” button will add it to the menu of available drives. You can also modify the file name by selecting the text in the file name field and modifying the selected text.

E) Save: Pressing the “Save” button will save the file to the selected drive.

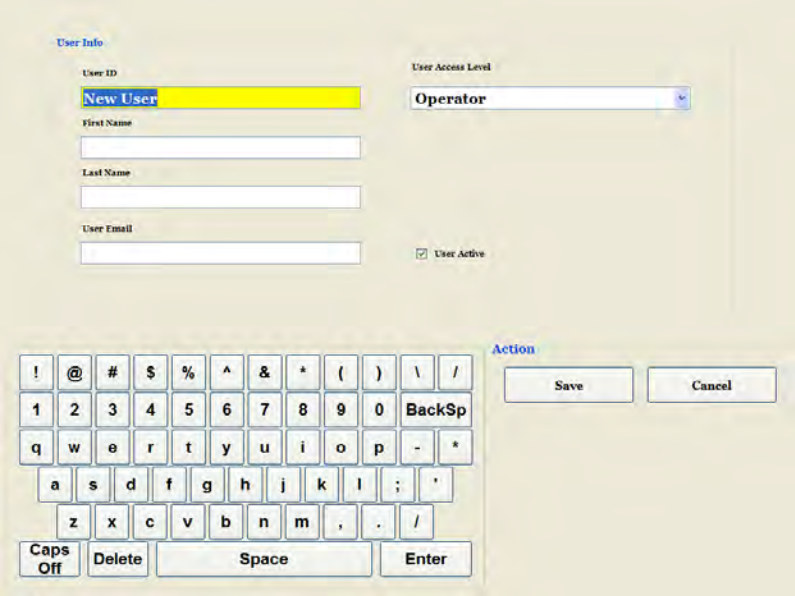
F) Cancel: Pressing “Cancel” button will return you to the Physician Edit Screen.

3.6 Users Menu

The Users Screen is used to Add or Edit the various Operators of the SpineMED® through their User ID’s and Passwords.

3.6.1 Enter New User

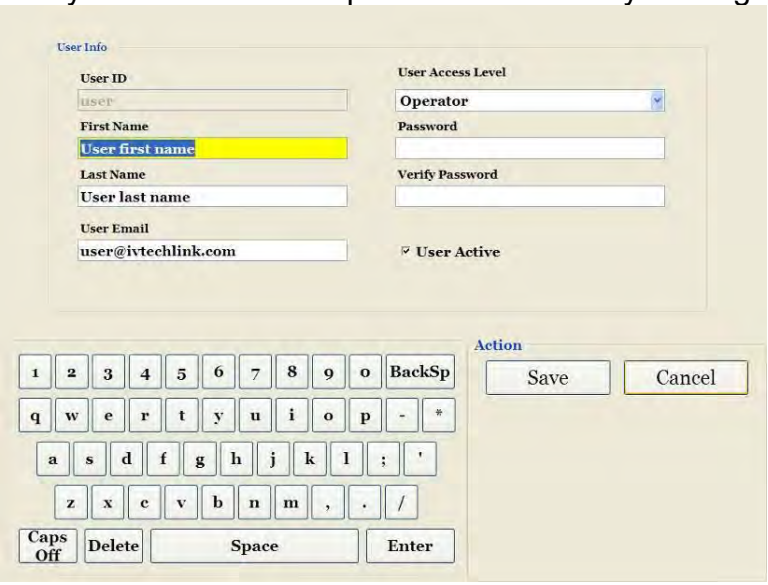
A) To create a new User in the system, click on the “Add” button. You will be presented with a new blank User record to complete.



B) Enter the User’s personal information:

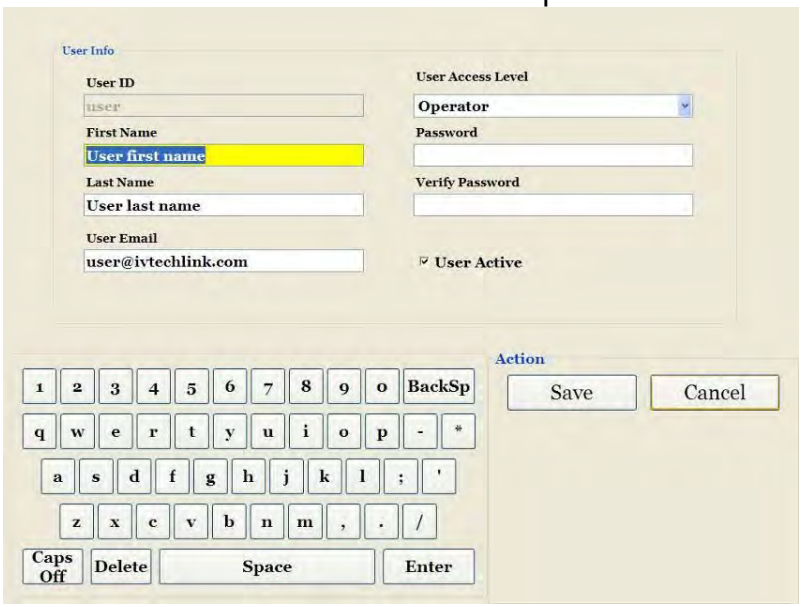
- First Name
- Last Name
- Email address
- Access Level: Operator or Physician

As a device administrator, you have the ability to enter in and modify User records, but you do not have the ability to enter in the User’s password. When all data has been entered, touch the “Save” button to store this User record permanently into the database. You will be returned back to the User Main Screen. The User will have the ability to enter their new password when they first logon to the SpineMED®.



3.6.2 Edit Existing User's Information

Select the User record to modify, by scrolling up or down to the appropriate User name or enter in their first name, last name or phone number into the "Search By" Fields for the auto search function. Select the particular User record by highlighting the name, and then click on the "Edit" button to open this record for editing.



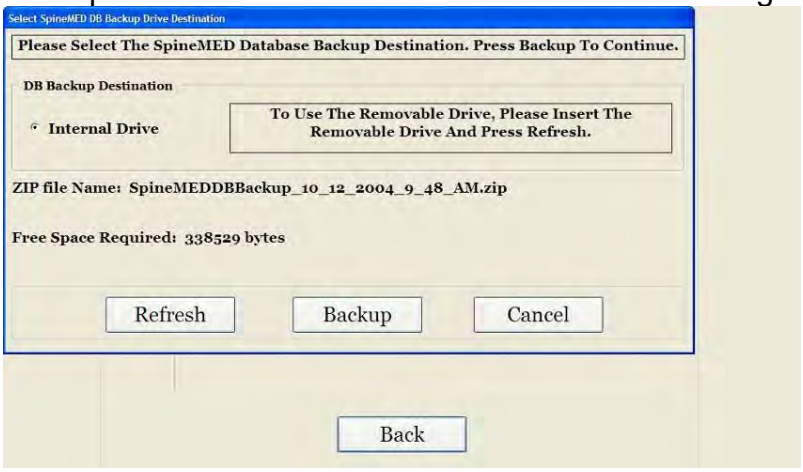
Modify the fields as necessary, and press the "Save" button to save your changes to this record. You will be brought back to the main User Screen.

3.7 Database Management

The Database Management functions allow maintenance and management of the internal SpineMED® Database.

3.7.1 Backup Database

Pressing "Backup Database" button will allow backup of the database to the internal drive, or an External USB Drive. It is recommended that an internal backup be done at the end of each office day. Using a USB External Drive, it is recommended that a backup be saved to an External Drive for offsite storage at least once per week.



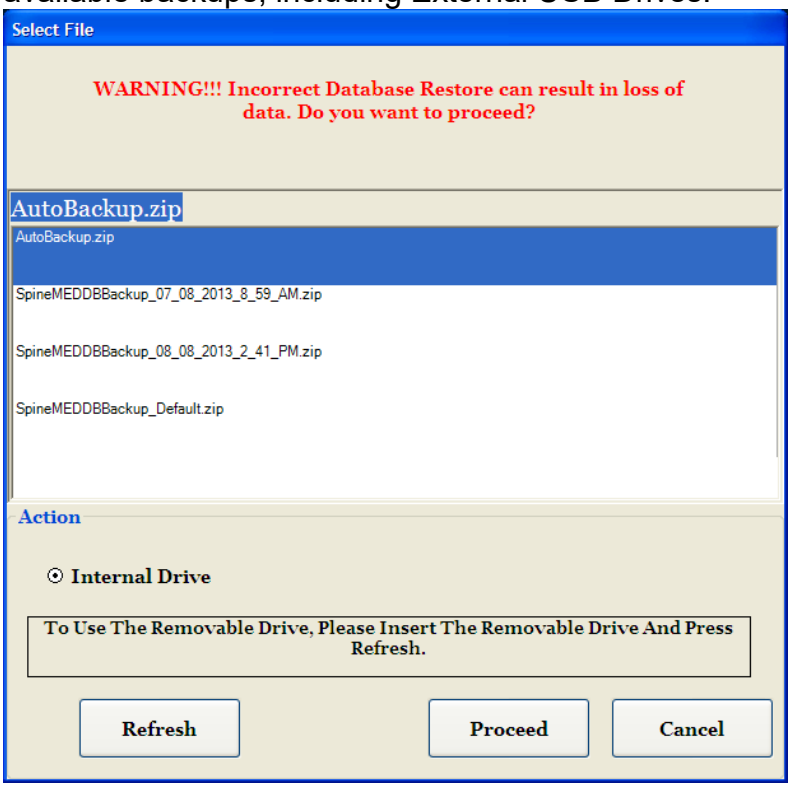
A) Refresh: Pressing the “Refresh” button will refresh the list of available drives attached to the Touchcomputer for backup purposes.

B) Backup: Pressing the “Backup” button will backup the database to the internal drive. Simply select “Backup” on the screen as the Internal Drive is the default location to store a backup file. To create a backup file on an External USB Drive, simply insert the USB Drive into the USB port on the bottom right side of the Touchcomputer. The screen should change, and indicate the presence of the USB Drive. If not, press the “Refresh” button for the Touchcomputer to check for the Drive, and then press the “Backup” button. Pressing the “Backup” button will initiate the backup procedure for either the Internal Drive or External USB Drive Backup.

C) Cancel: Pressing the “Cancel” button will abort the backup procedure and bring you back to the DB Management Menu.

3.7.2 Restore Database

Pressing the “Restore Database” button will allow a restore of the database from a list of available backups, including External USB Drives.



A) Refresh: Pressing the “Refresh” button will refresh the list of available backups attached to the Touchcomputer for backup purposes.

B) Proceed: Highlight the most recent Backup File, and press the “Proceed” button to initiate the Backup Restore Function, using the highlighted file. If restoring from an External USB Drive, insert the USB Drive and select a suitable backup file from the list.

C) Cancel: Press the “Cancel” button to abort the Restore Function, and to return to the DB Management Screen.

3.7.3 Export Database

Pressing the “Export Database” button will allow exporting of all session data for all patients to an Excel spreadsheet.

A) Insert an External USB Drive into SpineMED® Touchcomputer and select “Export Database” button.

B) Window will automatically open to save “.TSV” file. Name the file and save on the External USB Drive.

C) When database export is completed message box “Data export completed” will appear. Press “OK”.

D) To open the Export DB file, complete the following steps:
   i. Insert the External USB Drive into your computer.
   ii. In Excel select “Open” and make sure file type is set to “All Files”.
   iii. Open the saved file (ending with “.tsv”).
   iv. Text Import Wizard will open. Select “Next” twice, then “Finish”. Exported data is now open in Excel.

3.8 Logout/Exit

A) Logout: Pressing the “Logout” button will logoff the current User and allow another User to Logon to the SpineMED®.

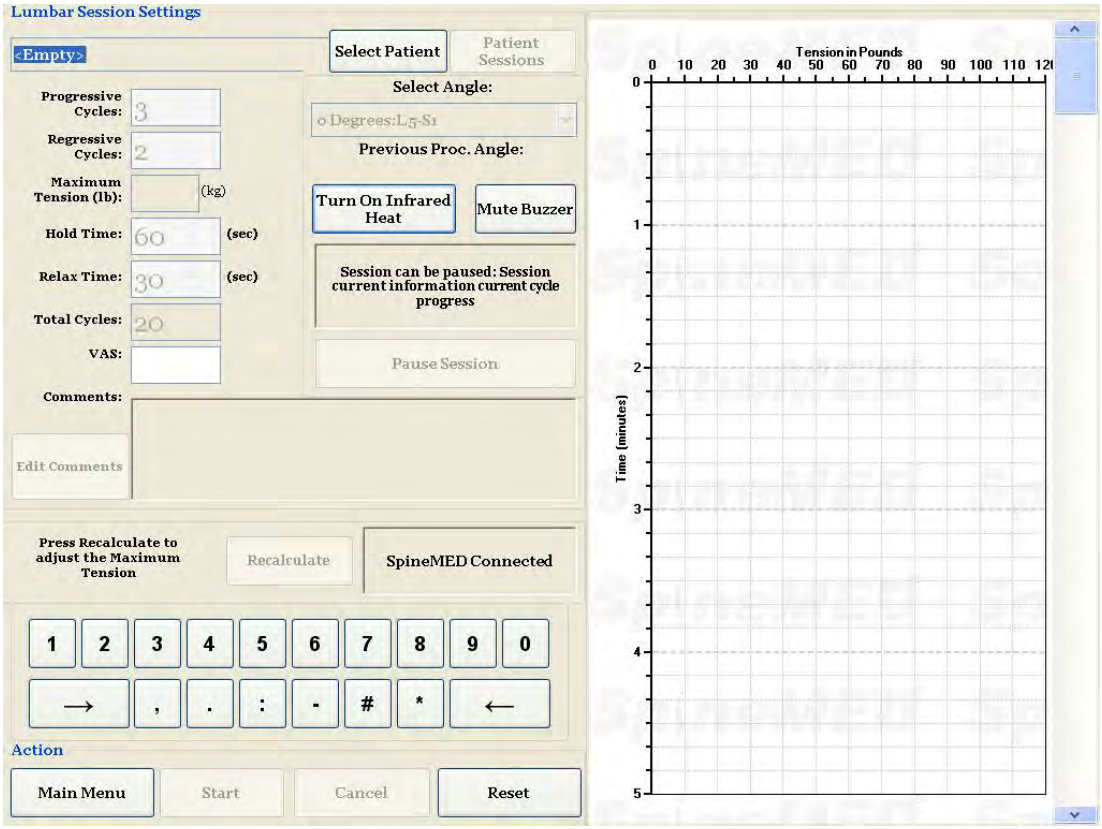
B) Turn Off: Pressing the “Turn Off” button will turn the SpineMED® off.

4. Lumbar & Cervical Procedure Screens

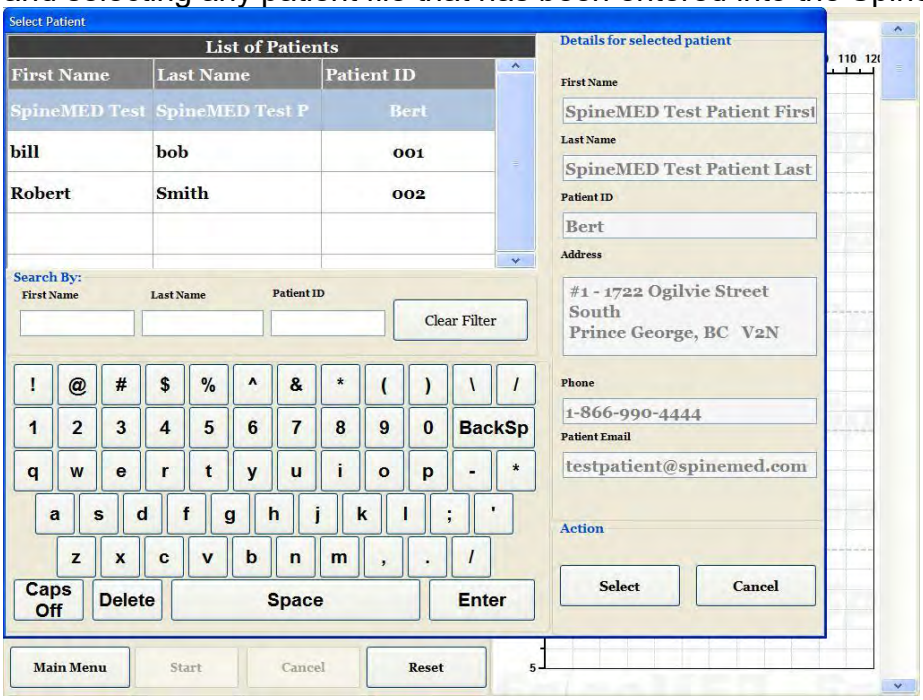
4.1 Lumbar Procedure Screen

The Lumbar Procedure Screen is used to enter the procedure parameters for a current session and to initiate the session.

⚠ *<u>Warning:</u>*
The Clinician or Operator of the SpineMED® System must always make the patient aware, prior to a SpineMED® session, if the patient feels that he/she is about to sneeze or cough during a session, that he/she presses the Patient Hand Held Electrical Emergency Switch or instructs the Operator to discontinue the session.



A) Pressing the “Select Patient” button will bring up a new window to allow for searching and selecting any patient file that has been entered into the SpineMED® Database.



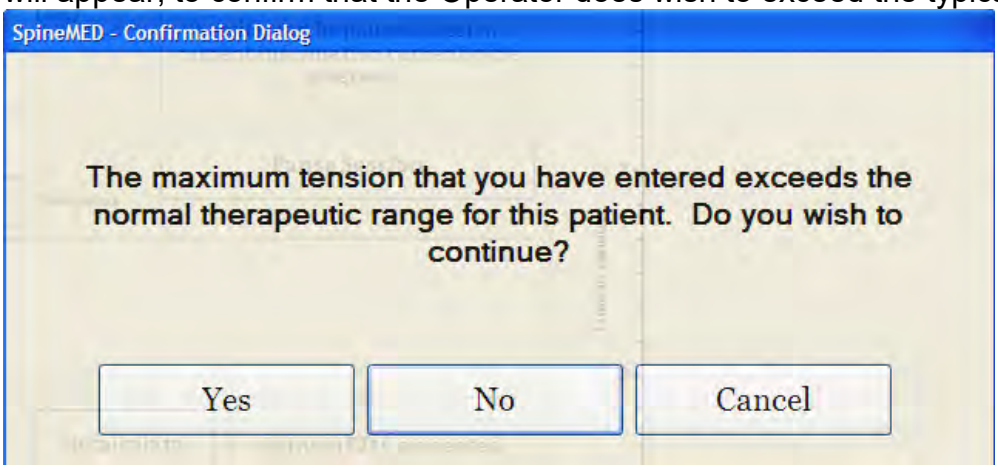
B) To select the appropriate patient from the database, you can either scroll down the list of patients, or search the database by the patient’s first and/or last name. To select the patient from the list, highlight the correct record and then press the “Select” button.

C) Progressive Cycles are the number of cycles the device will “ramp up” to the Maximum Tension at the beginning of the session. The default setting is 3 cycles and is not User modifiable.

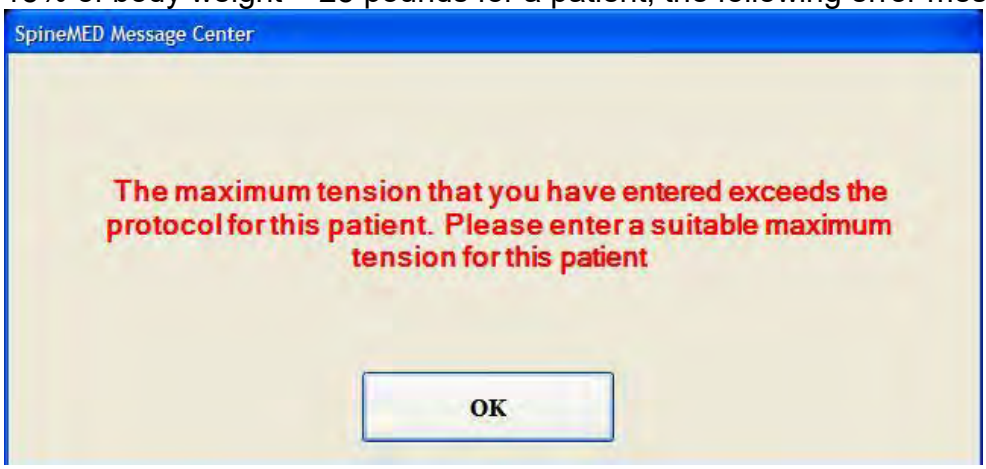
D) Regressive Cycles is the number of cycles the device will “ramp down” to zero tension at the end of the session. The default setting is 2 cycles and is not User modifiable.

E) Maximum Tension is calculated based on the patient’s body weight. Starting Tensions should be 15% of Body weight. (*i.e.160 lb. X 15% = 24 lb.) Gradual increase of distraction forces are based on patient response to the session plus the general guideline of 3-5 lbs. /session. Maximum distraction tensions of 15% of body weight + 25 lbs. is applicable to all patients. Most patients will find a comfortable plateau of tensions at approximately 15% of body weight + 15 to 20 pounds. It is very rare that tensions of 15% of body weight + 15 pounds is exceeded for any patient. The SpineMED® will enter the calculated Maximum Tension for the first session; however, the Operator can modify this value.

The SpineMED® software will alert the Operator in the event that they attempt to increase the Maximum Tension beyond 15% of body weight + 15 pounds. The following message will appear, to confirm that the Operator does wish to exceed the typical protocol:



The SpineMED® software will also prevent the Operator from exceeding the maximum recommended tensions for the patient being treated. If the Operator attempts to exceed 15% of body weight + 25 pounds for a patient, the following error message will appear:



**NOTE: The Maximum Tensions should never exceed the calculations for a 300 lb. (136 Kg.) patient. Therefore, patients over 300 lbs. (136 Kg.) can be safely distracted up to a maximum force of 100 lbs. (45 Kg.).

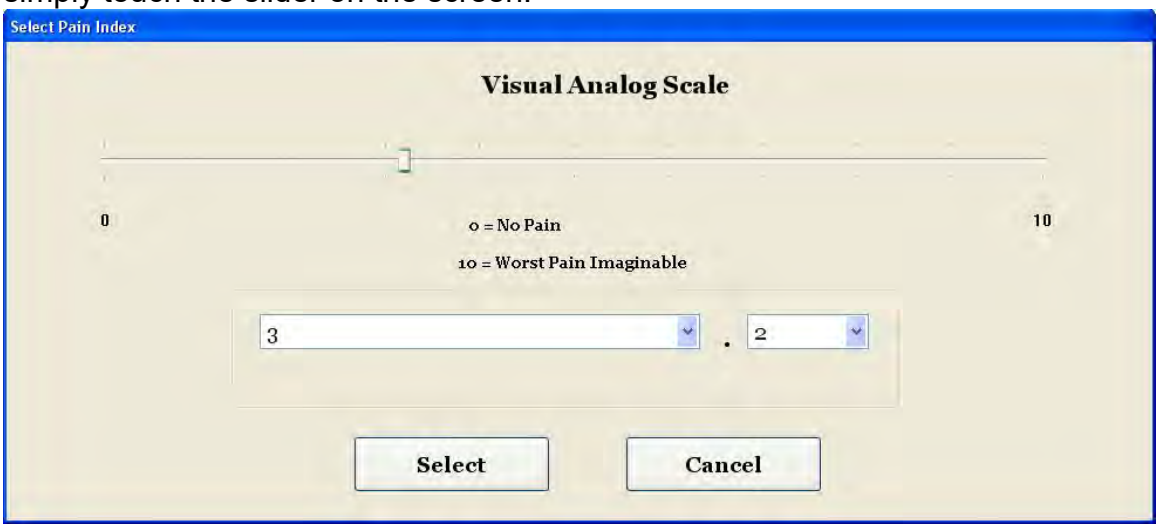
F) Recalculate: Pressing this button will calculate and reset the Maximum Tension entered to the recommended "Starting Tension" based on the patient's body weight.

G) Hold Time: The length of time in seconds that the Maximum Tension will be held during the distraction phase of the cycle. The default setting is 60 seconds and is not User modifiable.

H) Relax Time: The length of time in seconds that the Minimum Tension will be held during the relaxation phase of the cycle. The default setting is 30 seconds and is not User modifiable.

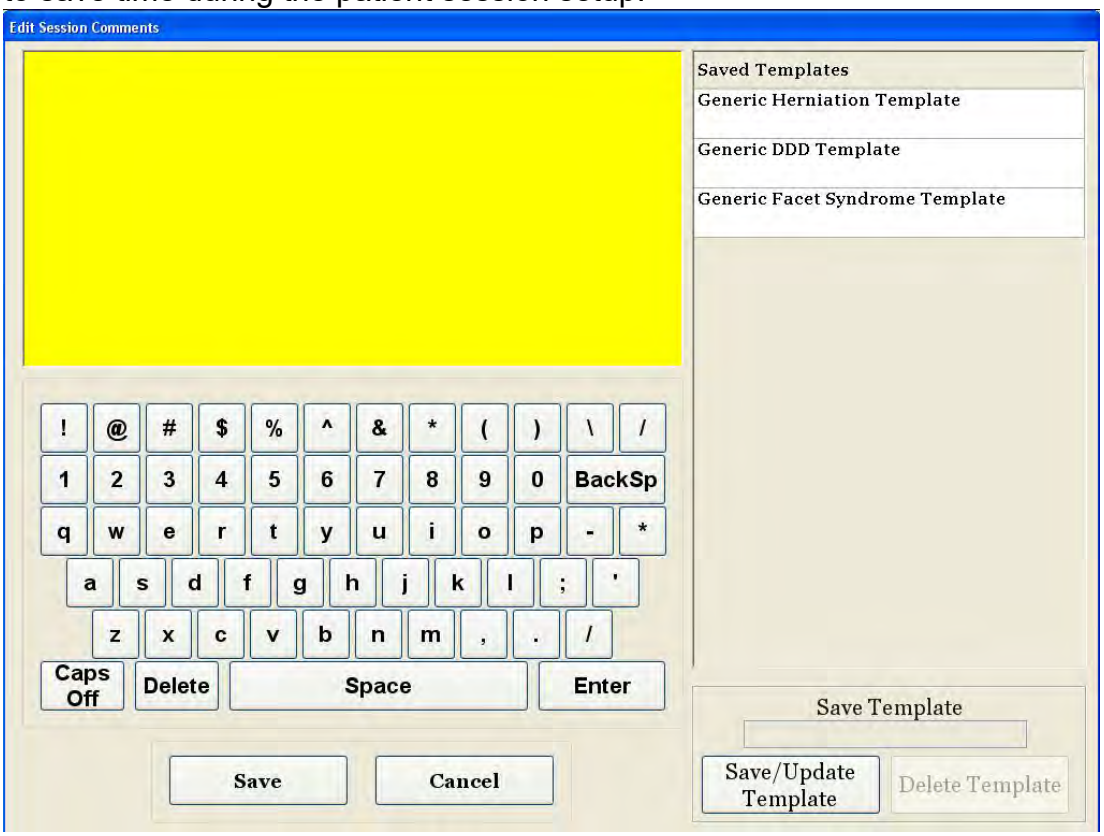
I) Cycles: This is the total number of cycles to be administered during the session. The default number is 20 cycles, for a total of 30 minutes (20 x 90 seconds = 30 minutes). In the event that a session has been interrupted, and must be restarted, this field can be modified to resume the session for the remaining period, rather than for an additional 30 minutes. The remaining period of the session will have to be restarted as a new session, and the number of cycles for the resumption period can be calculated by dividing the total number of minutes of a session remaining by 1.5 minutes (one complete cycle). For example, if a session were interrupted at 12 minutes, with 18 minutes remaining, you would divide the 18 minutes remaining in the session by 1.5 = 12 cycles for the resumption session.

J) Pain Index: This is the current Pain that the patient is experiencing before this session, rated between 0 and 10 (to one decimal point) as per the Visual Analogue Scale. You have the option to use the drop down menu to select the Patient's current VAS Index, or simply touch the slider on the screen.



K) Edit Comments: This field is for any observations, or comments regarding the patient's response to the session as of today. This should reflect the success of the procedure, patient's response or unusual occurrences. Clicking on the "Edit Comment" button will open a new window to enter in the comments text. You have the option to enter in comments for this particular session, or you can create common templates for various

session comments that will be available for any future sessions. There is no limit to the number of session comment templates you can create. These templates are designed to save time during the patient session setup.



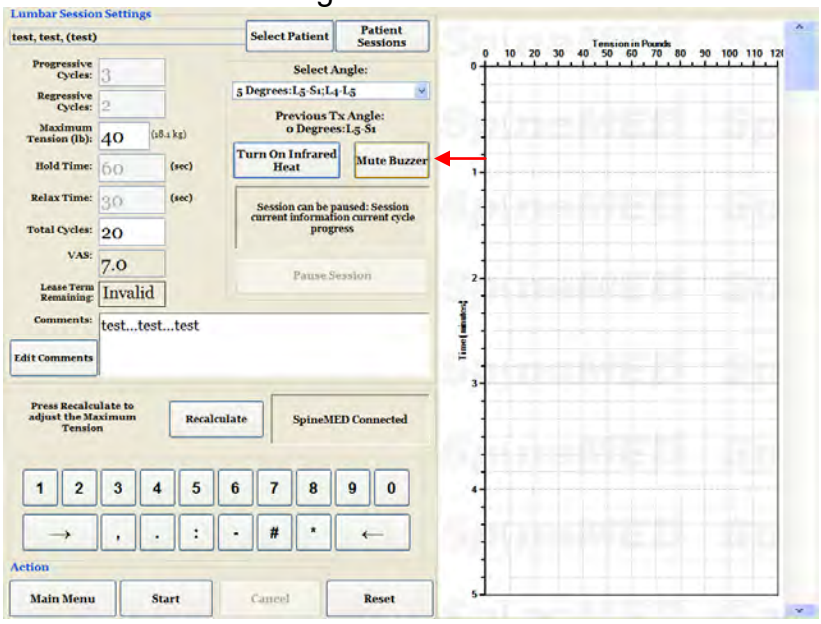
L) Select Angle: This function is to adjust the tilting section of the Table. The tilting section of the moveable lower Table section pivots from 0 to 25 degrees to tilt the Pelvis during distraction. The settings required for the angle of the Pelvis during the distraction, are entered into the Touchcomputer on the Lumbar Procedure Screen. See Section 5 for procedure details.

PROCEDURE ANGLES:

- L5-S1 ..... 0 degrees
- L5-S1, L4-L5 Multiple Level ..... 5 degrees
- L4-L5..... 10 degrees
- L4-L5, L3-L4 Multiple Level..... 15 degrees
- L3-L4..... 20 degrees
- L2-L3, L1-L2..... 25 degrees

M) Infrared Heat: Pressing this button will either turn off or turn on the Infrared Heating Pad in the Lumbar section of the Table. Touching the “Infrared Heat” button will toggle the Infrared Heating Pad from On and Off.

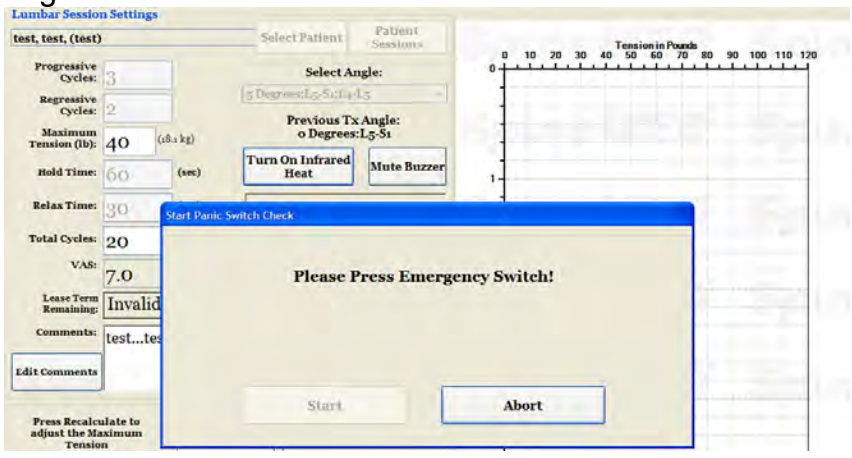
N) Mute Buzzer: Pressing this button will mute the buzzer in the Table.



O) Pause: The “Pause” button is used to pause or interrupt the session. Pressing this button will interrupt the session, and present you with another screen, allowing temporary interruption of the session to adjust the patient or to alter the Pelvic Tilt adjustment after the session has been initiated. The Pause feature can be used twice during a session.

P) Cancel: The “Cancel” button is used to discontinue or abort the current session. Once aborted, this particular session cannot be resumed.

Q) Start: Touch the “Start” button to begin the session. You will be prompted with a new screen requesting verification of the Emergency/Panic Switch before the session will begin.



R) Emergency/Panic Switch: Before the SpineMED® will begin the session; it will confirm the proper operation of the Emergency/Panic Switch. Immediately after touching the “Start” button, a message will come up in a small sub screen that reads, “*Please Press Emergency Switch!”.* If the Emergency/Panic Switch is working after patient depresses the button, message “*Click Start to Begin Session. Click Abort to Stop Session.*” will come on the screen.

S) SpineMED® Connected/Not Connected: This error message will notify the Operator if there is a communication error between the Touchcomputer and Control Board within the Table and the message will be circled in red as an alert.

T) Main Menu: Touch this button to return to the Main Menu Screen at the conclusion of the session to print reports, modify patient data, or shut down the SpineMED®.

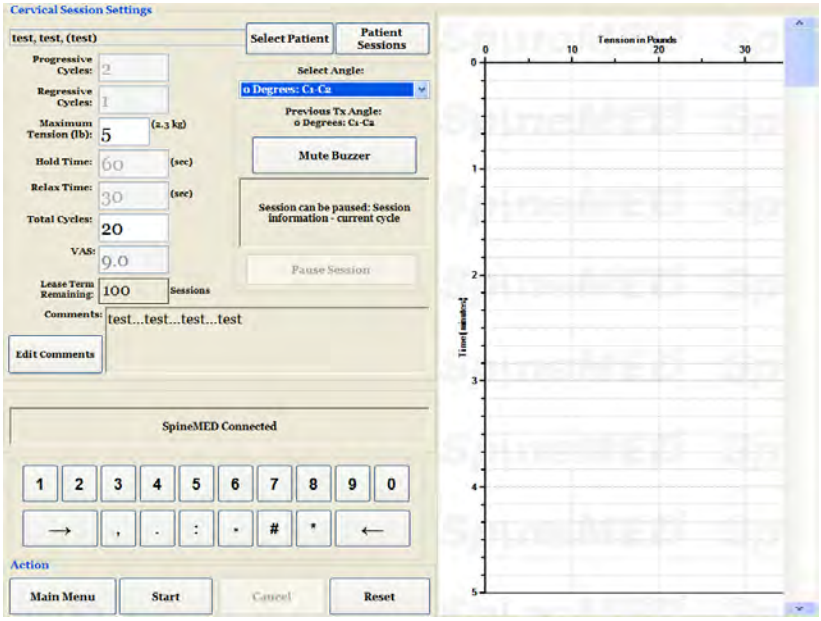
U) Trend Line Graph: The digital image of the Trend Line Graph illustrates the actual tensions being applied (in pounds) over the session (in minutes) and will be stored permanently in the Patient's Data File.

V) Reset: This button will reset firmware on Control Board. Use if communication between Control Board in Table and Touchcomputer is lost. Reset should re-establish communication.

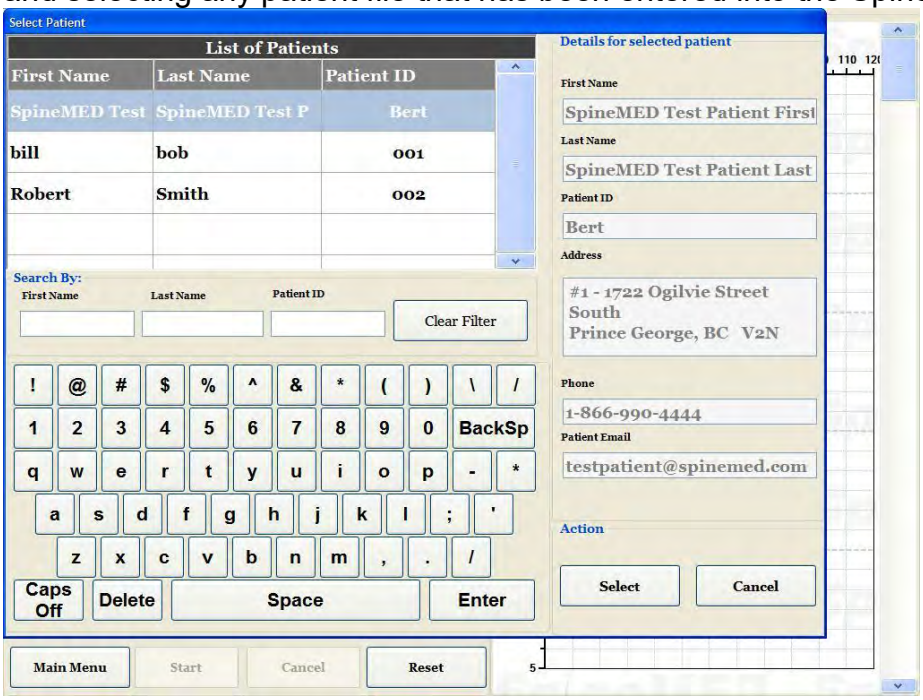
4.2 Cervical Procedure Screen

The Cervical Procedure Screen is used to enter the parameters for a current Cervical session and to initiate the session.

⚠ *<u>Warning:</u>*
The Clinician or Operator of the SpineMED® System must always make the patient aware, prior to a SpineMED® session, if the patient feels that he/she is about to sneeze or cough during a session, that he/she presses the Patient Hand Held Electrical Emergency Switch or instructs the Operator to discontinue the session.



A) Pressing the “Select Patient” button will bring up a new window to allow for searching and selecting any patient file that has been entered into the SpineMED® Database.



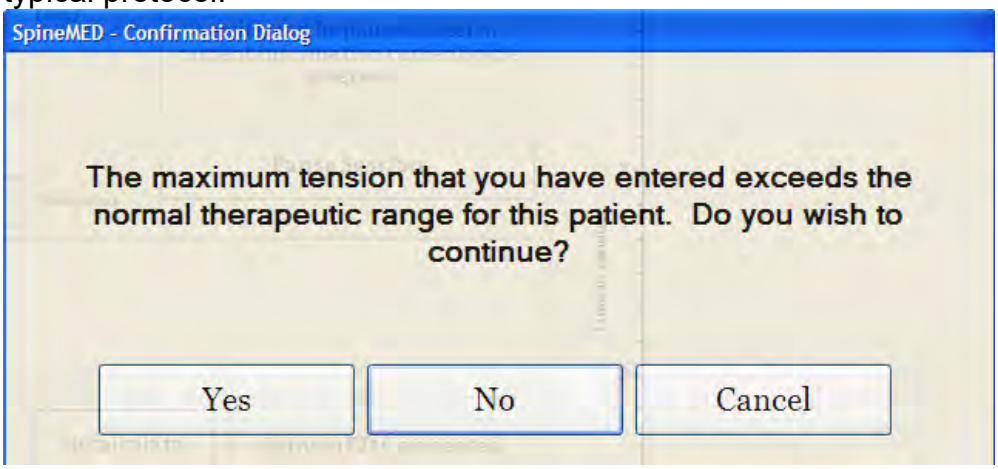
B) To select the appropriate patient from the database, you can either scroll down the list of patients, or search the database by the patient’s first and/or last name. To select the patient from the list, highlight the correct record and then press the “Select” button.

C) Progressive Cycles are the number of cycles that the device will “ramp up” to the Maximum Tension at the beginning of the session. The default setting is 2 cycles and is not User modifiable.

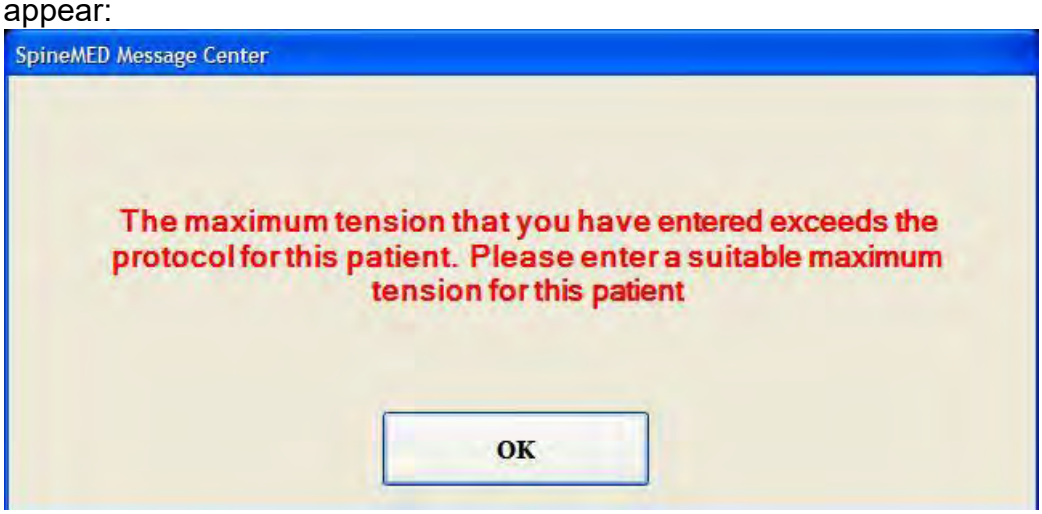
D) Regressive Cycles are the number of cycles that the device will “ramp down” to zero tension at the end of the session. The default setting is 1 cycle and is not User modifiable.

E) Maximum Tension for Cervical procedure is calculated based on the patient’s gender. Starting Tensions should be 4-5 lbs. for females and 5-6 lbs. for males. Tensions should be increased by 1-2 lbs. daily, until optimum tensions are reached. The Maximum Tension should never exceed 20 lbs. for females and 25 lbs. for males. Most male patients will reach a tension plateau of 15 lbs., while females will typically reach 12 lbs. The SpineMED® will enter the calculated Maximum Tension for the first session; however, the Operator can modify this value.

The SpineMED® software will alert the Operator in the event that they attempt to increase the Maximum Tension beyond 15 lbs. for females and 18 lbs. for males. The following message will appear, to confirm that the Operator does wish to exceed the typical protocol:



The SpineMED® software will also prevent the Operator from exceeding the maximum recommended tensions for the patient being treated. If the Operator attempts to exceed 20 lbs. for a female patient or 25 lbs. for a male patient, the following error message will appear:



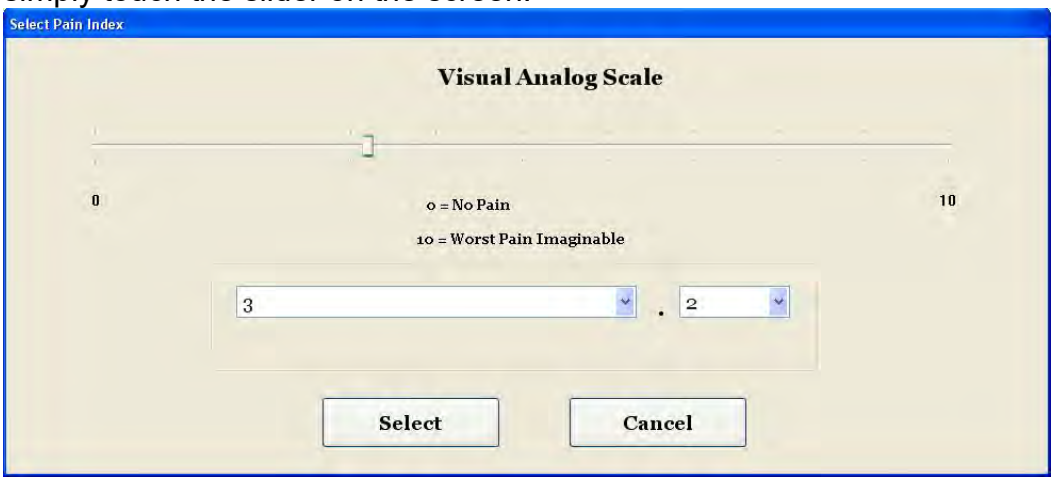
F) Recalculate: Pressing this button will calculate and reset the Maximum Tension entered to the recommended “Starting Tension” based on the patient’s gender.

G) Hold Time is the length of time in seconds that the Maximum Tension will be held during the distraction phase of the cycle. The default setting is 60 seconds and is not User modifiable.

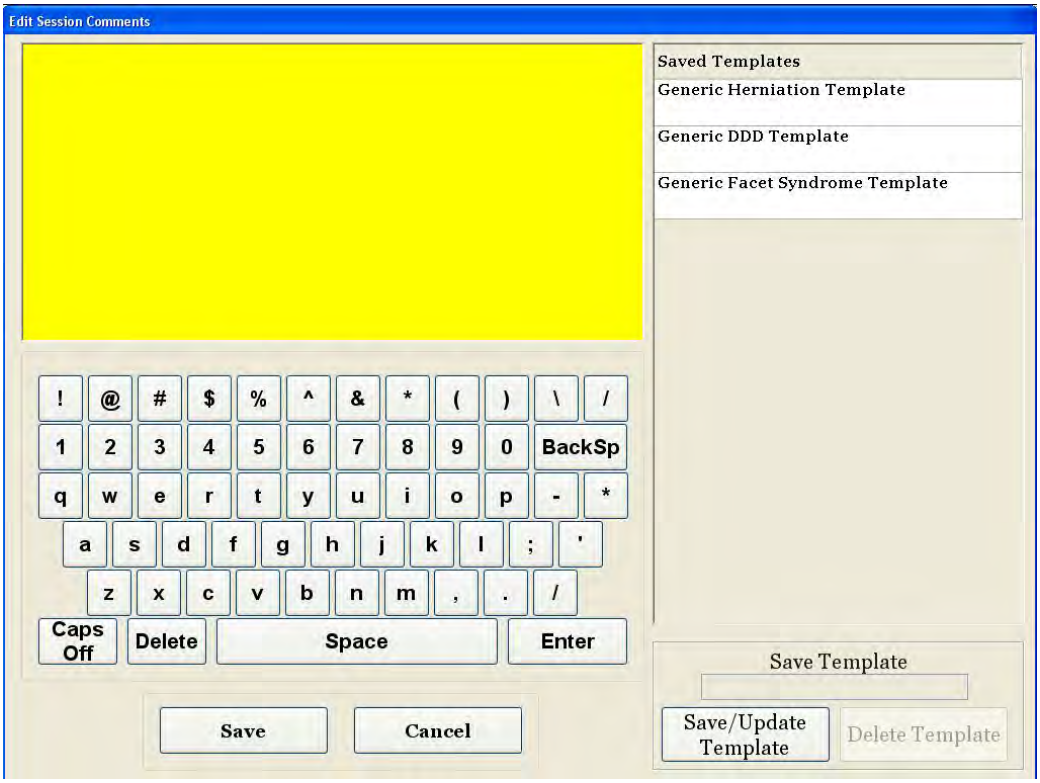
H) Relax Time is the length of time in seconds that the Minimum Tension will be held during the relaxation phase of the cycle. The default setting is 30 seconds and is not User modifiable.

I) Cycles: This is the total number of cycles to be administered during the session. The default number is 20 cycles, for a total of 30 minutes (20 x 90 seconds = 30 minutes). In the event that a session has been interrupted, and must be restarted, this field can be modified to resume the session for the remaining period, rather than for an additional 30 minutes. The remaining period of the session will have to be restarted as a new session, and the number of cycles for the resumption period can be calculated by dividing the total number of minutes of the session remaining by 1.5 minutes (one complete cycle). For example, if a session were interrupted at 12 minutes, with 18 minutes remaining, you would divide the 18 minutes remaining in the session by 1.5 = 12 cycles for the resumption session.

J) Pain Index: This is the current Pain that the patient is experiencing before this session, rated between 0 and 10 (to one decimal point) as per the Visual Analogue Scale. You have the option to use the drop down menu to select the Patient's current VAS Index, or simply touch the slider on the screen.



K) Edit Comments: This field is for any observations, or comments regarding the patient's response to the session as of today. This should reflect the success of the procedure, patient's response or unusual occurrences. Clicking on the "Edit Comment" button will open a new window to enter in the comments text. You have the option to enter in comments for this particular session, or you can create common templates for various session comments that will be available for any future sessions. There is no limit to the number of session comment templates you can create. These templates are designed to save time during the patient session setup.



L) Select Angle: This function is to adjust the tilting section of the Cervical Unit. The tilting section of the Cervical section pivots from 0 to 30 degrees to tilt the neck during distraction. The settings required for the angle of the Cervical Spine during the distraction, are entered into the Touchcomputer on the Cervical Procedure Screen. See Section 5 for procedure details.

PROCEDURE ANGLES:

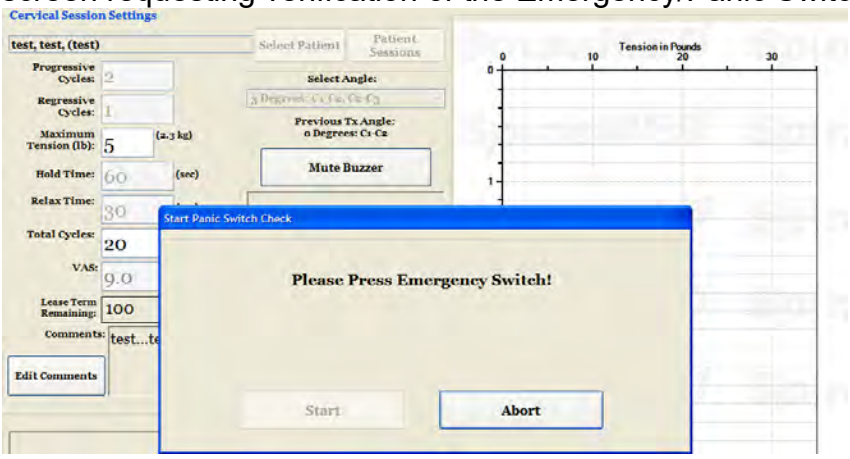
- C1-C2..... 0 degrees
- C1-C2, C2-C3 ..... 3 degrees
- C2-C3..... 7 degrees
- C2-C3, C3-C4 ..... 10 degrees
- C3-C4..... 14 degrees
- C3-C4, C4-C5 ..... 17 degrees
- C4-C5..... 21 degrees
- C4-C5, C5-C6 ..... 24 degrees
- C5-C6..... 28 degrees
- C5-C6, C6-C7 ..... 30 degrees
- C6-C7..... 30 degrees
- C7-T1 ..... 30 degrees

M) Mute Buzzer: Pressing this button will mute the buzzer in the Table.

N) Pause: The “Pause” button is used to pause or interrupt the session. Pressing this button will interrupt the session, and present you with another screen, allowing temporary interruption of the session to adjust the patient or to alter the Cervical Tilt adjustment after the session has been initiated. The Pause feature can be used twice during a session.

O) Cancel: The “Cancel” button is used to discontinue or abort the current session. Once aborted, this particular session cannot be resumed.

P) Start: Touch the “Start” button to begin the session. You will be prompted with a new screen requesting verification of the Emergency/Panic Switch before the will begin.



Q) Emergency/Panic Switch: Before the SpineMED® will begin the session; it will confirm the proper operation of the Emergency/Panic Switch. Immediately after touching the “Start” button, a message will come up in a small sub screen that reads, “*Please Press Emergency Switch!”.* If the Emergency/Panic Switch is working after the patient depresses the button, message “*Click Start to Begin Session. Click Abort to Stop Session.*” will come on the screen.

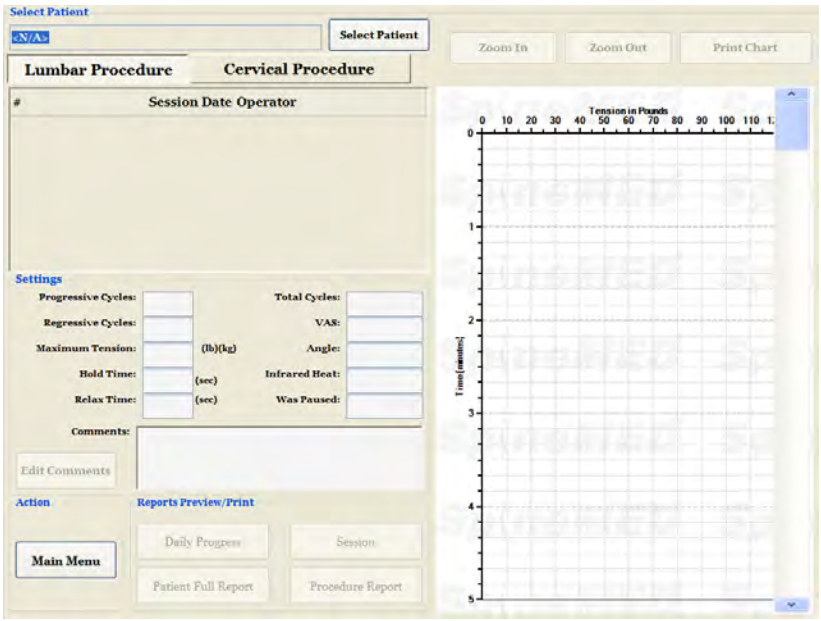
R) SpineMED® Connected/Not Connected: This error message will notify the Operator if there is a communication error between the Touchcomputer and Control Board within the Table and the message will be circled in red as an alert.

S) Main Menu: Touch this button to return to the Main Menu Screen at the conclusion of the session to print reports, modify patient data, or shut down the SpineMED®.

T) Trend Line Graph: The digital image of the Trend Line Graph illustrates the actual tensions being applied (in pounds) over the session (in minutes) and will be stored permanently in the Patient’s Data File.

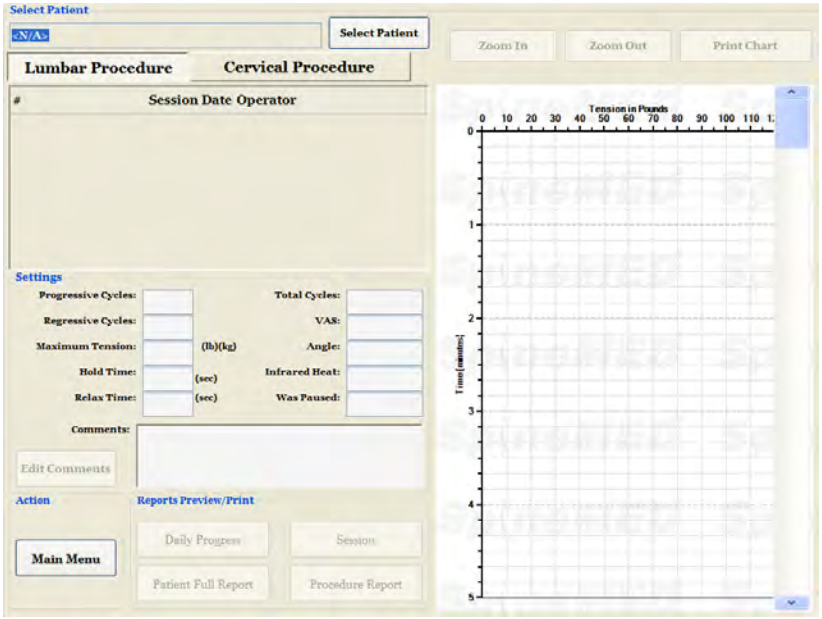
U) Reset: This button will reset firmware on Control Board. Use if communication between Control Board and Touchcomputer is lost. Reset should re-establish communication.

4.3 Reports Menu Screen

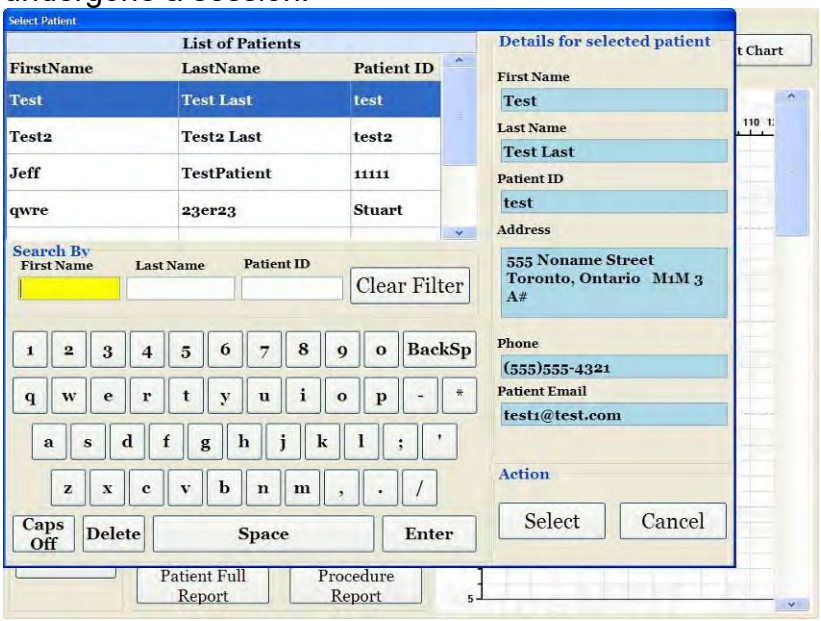


The Reports Menu is provided to search for, display and print every patient's individual session, or a summary report of all sessions administered to the patient on a particular SpineMED® device. The Reports Screen is divided into two sections. On the left side, every procedure in the database for the selected patient can be viewed and printed. On the right side, there is a digital image of the Trend Line Graph of the selected session.

4.4 Selecting Patient Data



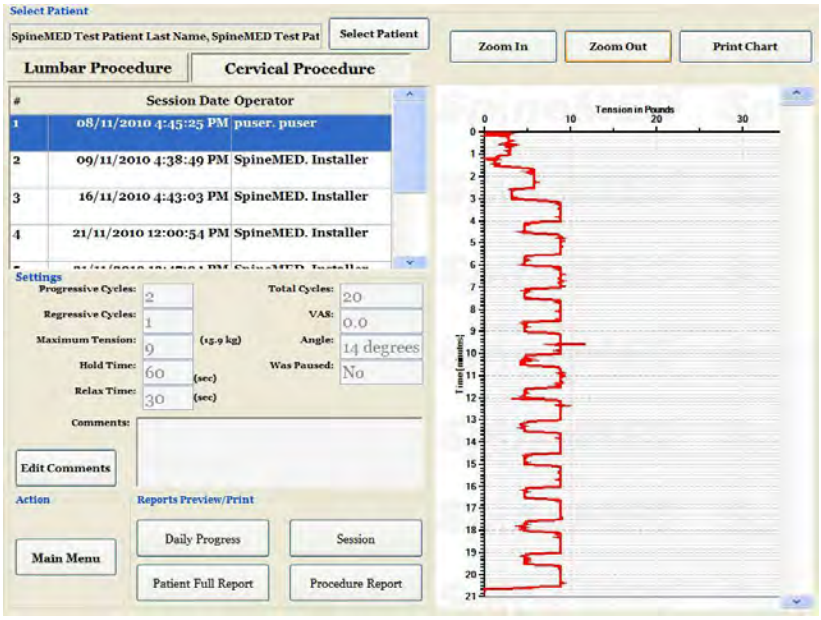
A) Select Patient: To select a current patient's records, press the "Select Patient" button. You will be presented with a new window to search for any patient record that has undergone a session.



B) There is a scrolling bar that is used to locate the patient's name. Scroll down and search for the patient's name or use the search fields; "First Name or Last Name or Patient ID" for the automated search. Then select the patient desired by touching on the name so that it becomes highlighted, and press the "Select" button. You will be returned to the Reports Screen.

C) All of the sessions completed with data for this patient record will be listed in chronological order. To select a particular session, scroll up and down the list of recorded sessions by touching the up and down arrows on the scroll bar image, then touch the desired record.

D) Once a particular session has been selected, all of the pertinent data regarding this selected session will be displayed; Progressive Cycles, Regressive Cycles, Maximum Tension, Minimum Tension, Hold Time, Relax Time, Visual Analogue Scale for Pain Index, Cycles administered, Angle of Distraction during session, Infrared Heat used during the session, and Comments for this session.

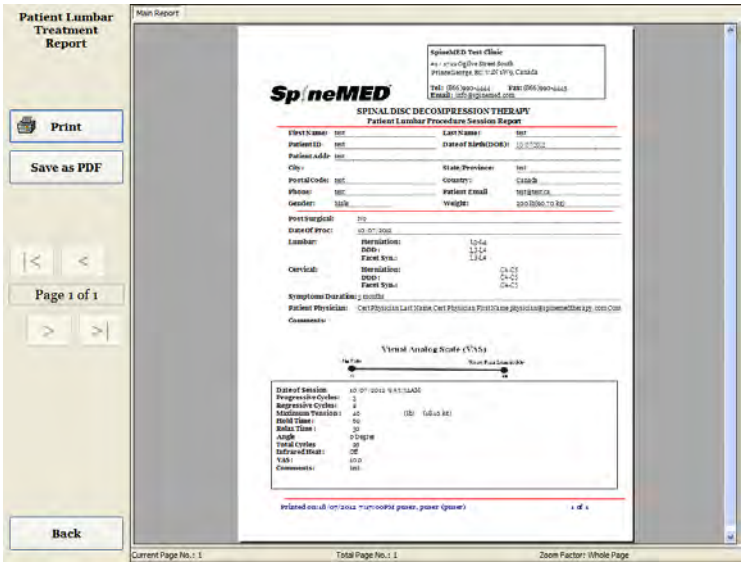


E) The digital Trend Line Graph of the selected session is displayed on the right of the screen and can be viewed at a different scale by touching the “Zoom In” or “Zoom Out” buttons. Using these buttons will change the number of pages required to display the entire procedure graph. For example, if the Zoom In feature has been used, you may only view 5 minutes of the total 30 minutes per page. The printed report will reflect the zoom factor current on the digital image. For example, if a printed report is selected while the graph has been zoomed in so that you can only view 5 minutes of the session, then the printed report will require six pages to print out the entire graph (5 minutes x 6 = 30 minutes). Therefore, it is important to Zoom Out so the entire session can be viewed on screen prior to printing the paper report.

4.5 Report Options

4.5.1 Session Report

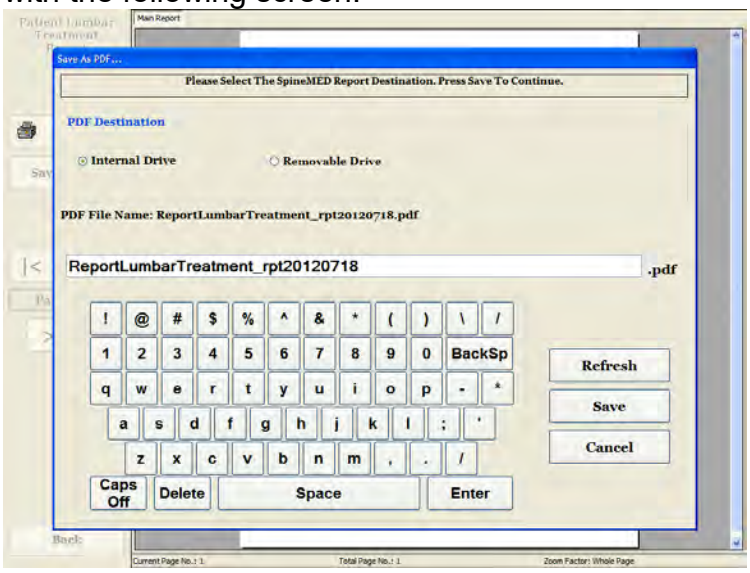
The Session Report will print a detailed report of the individual session currently selected.



A) Print: Pressing the “Print” button will output the displayed report to the SpineMED® Printer.

B) Back: Pressing the “Back” button will bring you back to the Report Selection Screen.

C) Save as PDF: Pressing the “Save as PDF” button, will output the displayed report to a PDF file, which can be saved internally or to an External Drive. You will be prompted with the following screen.



D) Refresh: Pressing the “Refresh” button will refresh the available Drives: for example, if you’ve inserted an External USB Drive into the USB Port of the Touchcomputer, pressing the “Refresh” button will add it to the menu of available drives. You can also modify the file name by selecting the text in the file name field and modifying the selected text.

E) Save: Pressing the “Save” button will save the file to the selected drive.

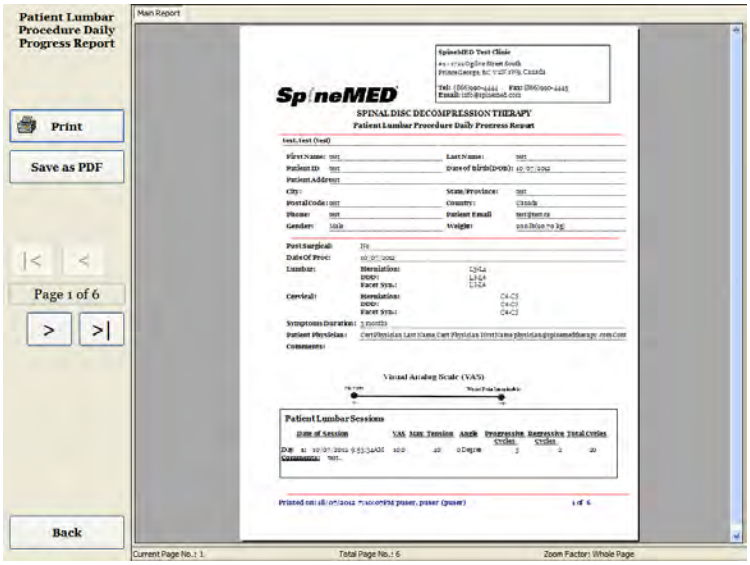
F) Cancel: Pressing “Cancel” button will return you to the Reports Menu Screen.

4.5.2 Daily Progress Report

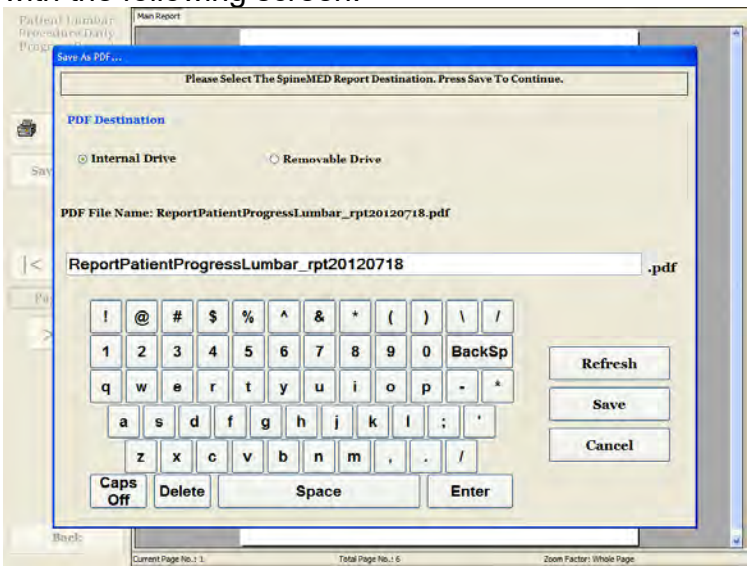
The Daily Progress Report will print a summary report of every session, either Lumbar or Cervical, administered to the selected patient.

A) Print: Pressing the “Print” button will output the displayed report to the SpineMED® Printer.

B) Back: Pressing the “Back” button will bring you back to the Report Selection Screen.



C) Save as PDF: Pressing the “Save as PDF” button, will output the displayed report to a PDF file, which can be saved internally or to an External Drive. You will be prompted with the following screen.



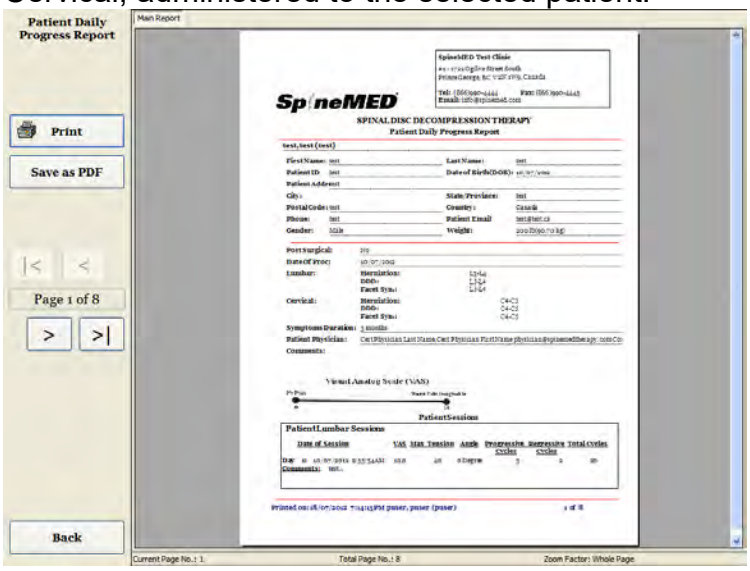
D) Refresh: Pressing “Refresh” button will refresh the available Drives: for example, if you’ve inserted an External USB Drive into the USB Port of the Touchcomputer, pressing the “Refresh” button will add it to the menu of available drives. You can also modify the file name by selecting the text in the file name field and modifying the selected text.

E) Save: Pressing the “Save” button will save the file to the selected drive.

F) Cancel: Pressing “Cancel” button will return you to the Reports Menu Screen.

4.5.3 Patient Full Report

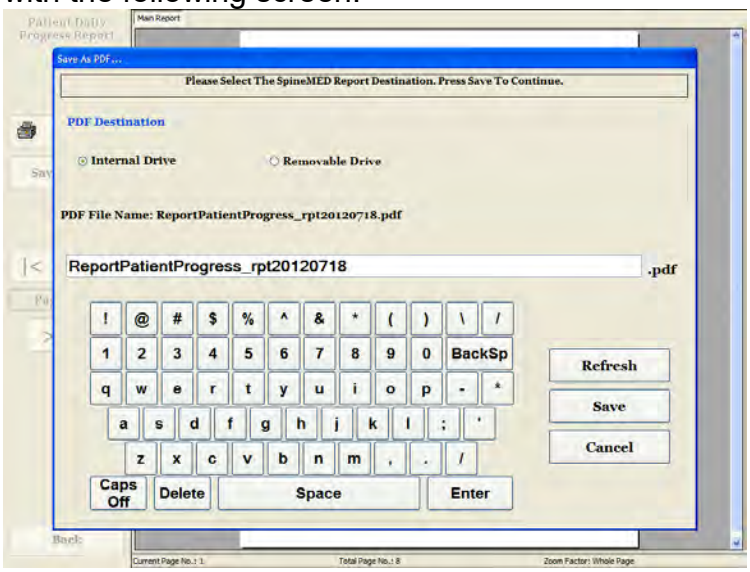
The Patient Full Report will print a summary report of every session, both Lumbar and Cervical, administered to the selected patient.



A) Print: Pressing the “Print” button will output the displayed report to the SpineMED® Printer.

B) Back: Pressing the “Back” button will bring you back to the Report Selection Screen.

C) Save as PDF: Pressing the “Save as PDF” button, will output the displayed report to a PDF file, which can be saved internally or to an External Drive. You will be prompted with the following screen.



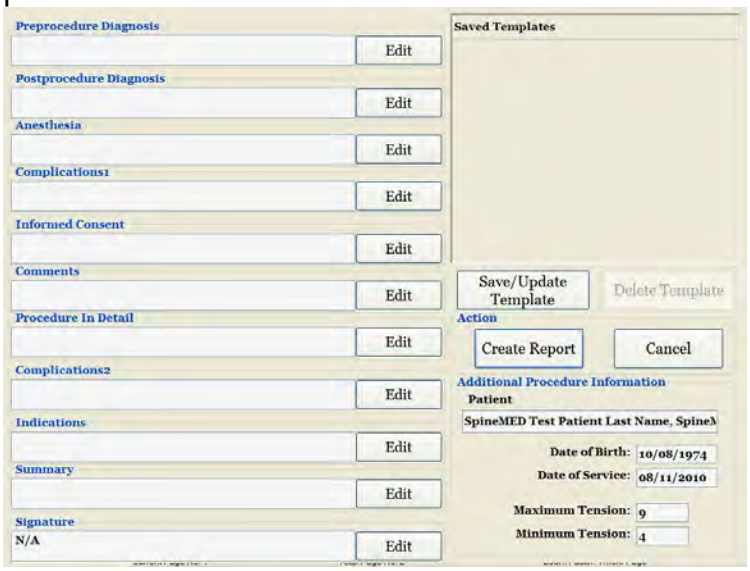
D) Refresh: Pressing the “Refresh” button will refresh the available Drives: for example, if you’ve inserted an External USB Drive into the USB Port of the Touchcomputer, pressing the “Refresh” button will add it to the menu of available drives. You can also modify the file name by selecting the text in the file name field and modifying the selected text.

E) Save: Pressing the “Save” button will save the file to the selected drive.

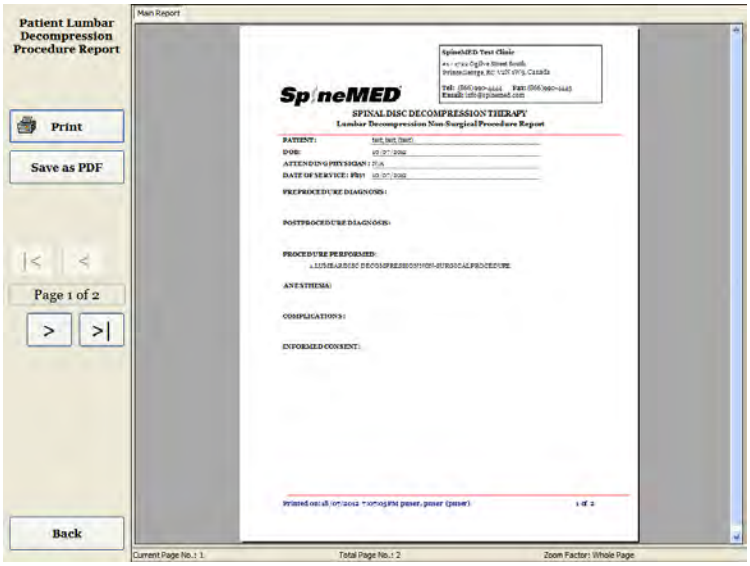
F) Cancel: Pressing “Cancel” button will return you to the Reports Menu Screen.

4.5.4 Procedure Report

The Procedure Report is a customizable procedure report that can be modified by the clinic for specific insurance requirements. You also have the option of creating an unlimited number of specific “templates” of various procedure reports for use with any patient in the future.



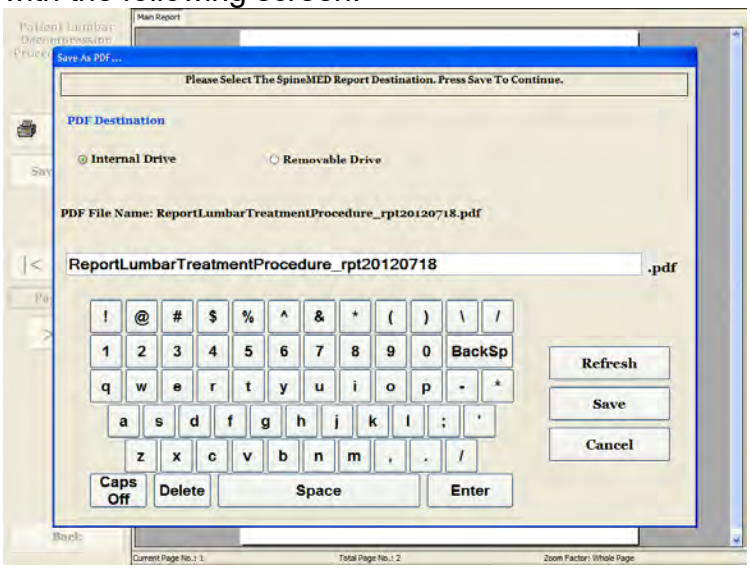
Each field can be edited to fit the description required for a particular session outcome. Once completed, click the save/update template to save this report as a unique template. You can also select one of the previously created templates for this report. Pressing the “Create Report” button will generate the current report for output to a Printer or as a PDF file.



A) Print: Pressing the “Print” button will output the displayed report to the SpineMED® Printer.

B) Back: Pressing the “Back” button will bring you back to the Report Selection Screen.

C) Save as PDF: Pressing the “Save as PDF” button, will output the displayed report to a PDF file, which can be saved internally or to an External Drive. You will be prompted with the following screen.



D) Refresh: Pressing the “Refresh” button will refresh the available Drives: for example, if you’ve inserted an External USB Drive into the USB Port of the Touchcomputer, pressing the “Refresh” button will add it to the menu of available drives. You can also modify the file name by selecting the text in the file name field and modifying the selected text.

E) Save: Pressing the “Save” button will save the file to the selected drive.

F) Cancel: Pressing “Cancel” button will return you to the Reports Menu Screen.

5. Procedure Session

5.1 Review of Individual Modalities of Each Session

There are four separate modalities administered during each session:

A) 20 – 30 Minutes of Infrared Heat or Dry Hydrotherapy pre decompression on the SpineMED® System.

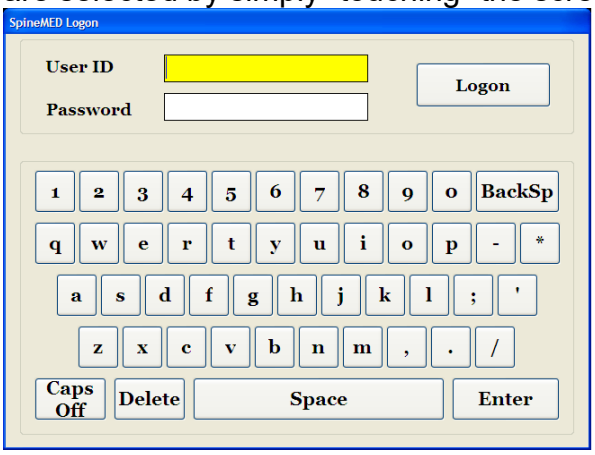
B) 30-minute decompression session on the SpineMED® System.

C) 15 minutes of interferential current immediately post decompression session.

D) 15 minutes cryotherapy or ice therapy post decompression session.

5.2 Data Entry for Lumbar Session

The SpineMED® System uses a touch screen interface with a digital keyboard to input data into the Touchcomputer. The appropriate letters or numbers imaged on the screen are selected by simply "touching" the screen with a finger over the desired selection.



A) Once the SpineMED® has been powered on and completed the boot sequence, the Operator will be presented with the Logon Screen.

B) Enter the User ID by touching the appropriate keys. If no data appears in the User ID field, ensure that there is a blinking cursor in this field by touching the white data area beside the User ID title.

C) After entering the User ID, the cursor should be blinking in the Password field. If it is not, touch the white data field beside the Password title. Enter the password by touching the appropriate keys.

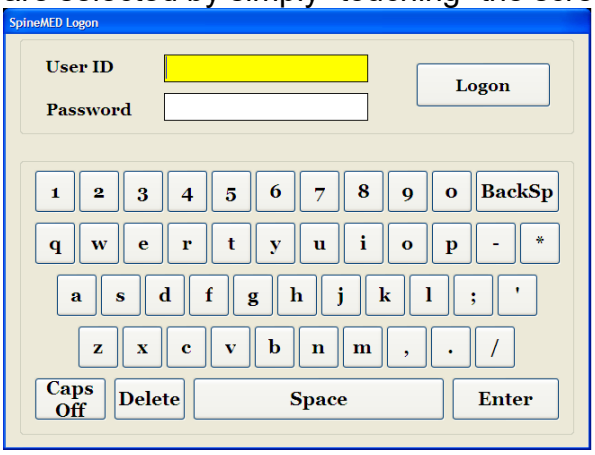
D) Press the "Logon" button to logon to the system and move to the Main Menu.

E) Go to the "Patients Menu" to enter a new Patient if necessary, and complete a new record as per Section 3.4 of this Operator Manual.

F) Once a Patient File has been created for the current patient, go to the "Lumbar Procedures Menu" to enter the procedure parameters for this particular session. Select the patient's file by touching the arrow on the right of the "Select Patient" field, and scroll to the desired patient and highlight the record. Enter the "Maximum Tension" (15% of body weight for the first session), the patient's V.A.S. Pain Index for today, Procedure Comments for today, the angle of distraction and activate the Infrared Heating Pad if required. For detailed instructions to program the SpineMED® for a procedure please refer to Section 4.1 of this Operator Manual.

5.3 Data Entry for Cervical Session

The SpineMED® System uses a touch screen interface with a digital keyboard to input data into the Touchcomputer. The appropriate letters or numbers imaged on the screen are selected by simply "touching" the screen with a finger over the desired selection.



A) Once the SpineMED® has been powered on and completed the boot sequence, the Operator will be presented with the Logon Screen.

B) Enter the User ID by touching the appropriate keys. If no data appears in the User ID field, ensure that there is a blinking cursor in this field by touching the white data area beside the User ID title.

C) After entering the User ID, the cursor should be blinking in the Password field. If it is not, touch the white data field beside the Password title. Enter the password by touching the appropriate keys.

D) Press the "Logon" button to logon to the system and move to the Main Menu.

E) Go to the "Patients Menu" to enter a new Patient if necessary, and complete a new record as per Section 3.4 of this Operator Manual.

F) Once a Patient File has been created for the current patient, go to the "Cervical Procedures Menu" to enter the parameters for this particular session. Select the patient's file by touching the arrow on the right of the "Select Patient" field, and scroll to the desired patient and highlight the record. Enter the "Maximum Tension", the patient's V.A.S. Pain Index for today, Procedure Comments for today and the angle of distraction. For detailed instructions to program the SpineMED® for a procedure please refer to Section 4.2 of this Operator Manual.

5.4 Instructions and Sequencing for Patient Set-up for Lumbar Session

⚠ *Warning:*
The Clinician or Operator of the SpineMED® System must always make the patient aware, prior to a session, if the patient feels that he/she is about to sneeze or cough during the session, that he/she presses the Patient Hand Held Electrical Emergency Switch or instructs the Operator to discontinue the session.

Following pre-session with infrared heat or dry hydrotherapy, steps taken by the Clinician for patient set-up:

A) If this is the first session for this patient, create a new patient record in the “Patients Menu” and store all of the pertinent patient data into the SpineMED® as described in Section 3.4 of this Operator Manual.

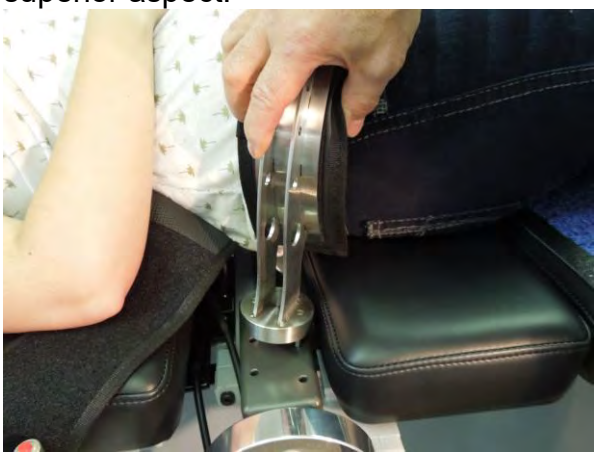
B) Be sure the “Slack Adjustment Indexing Lever” is positioned in the start position (fully counter clockwise).

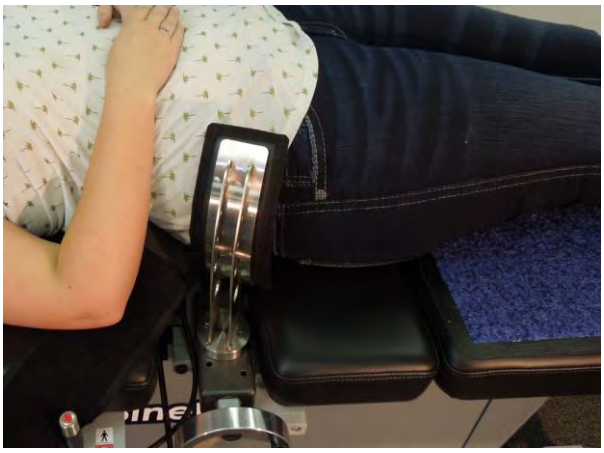
C) Walk the patient over to the Table and sit patient on the edge of the Table. The least amount of back flexion possible should be the guide. Once the patient is sitting on the edge of the Table, assist the patient to bring their legs up onto the Table, so that they are in a half-sitting position.

D) Once in the half sitting position, assist the patient to slowly recline to a lying position.

E) Slide the patient to the position on the Table so that their Iliac Crests are immediately below the position of the Pelvic Restraints.

F) Insert the Pelvic Restraints into each receptacle, so that they are positioned in the corresponding holes from one another. If necessary, reposition the patient so that the Pelvic Restraints are positioned immediately above the Iliac Crests, in the anterior superior aspect.





G) Turn the Crank Handle on the threaded assembly to move the Pelvic Restraints toward the patient’s Iliac Crests, and tighten to a comfortable, but firm tension.

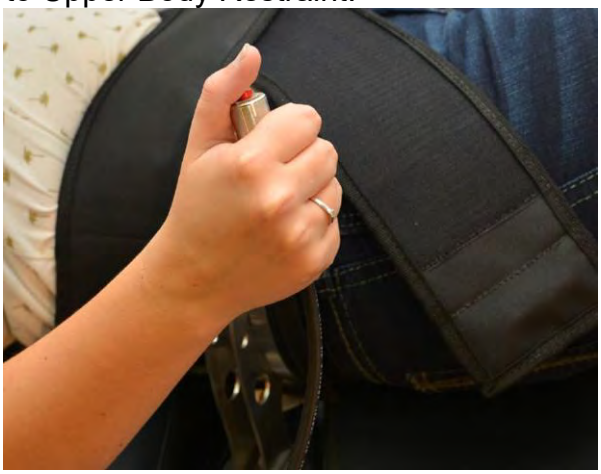
H) Position the Upper Body Restraint around the patient so that it is immediately below, and captures the lower margin of the ribcage, in an “X” pattern, so that it will not slide over the patient’s ribs.

I) Assist the patient to lift their head, and place the Head Pillow beneath their head.

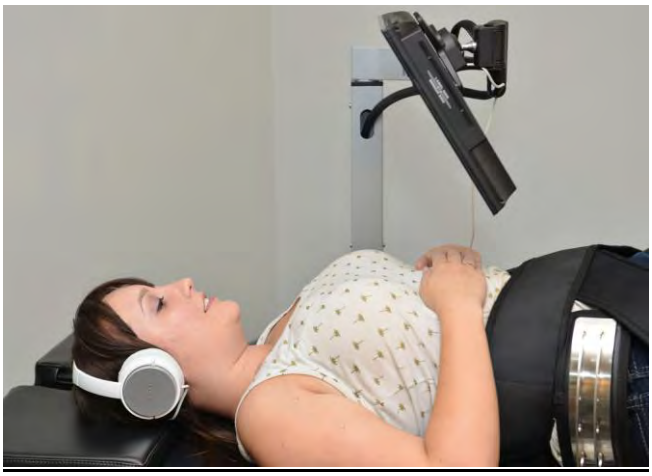
J) Assist the patient to bend their knees, and insert the Knee Bolster Support Cushion to the correct height for their leg length.

K) Inflate the Air Bladder beneath the patient’s Lumbar Spine to improve comfort during distraction. It should only be inflated enough to support the natural Lordosis.

L) If this is the patient's first session, position the Patient Emergency/Panic Switch in the patient's hand and instruct on its function, which is to immediately discontinue the session. For future sessions, the Emergency/Panic Switch may be located wherever it can easily be accessed by the patient, such as across the patient's abdomen or clipped to Upper Body Restraint.

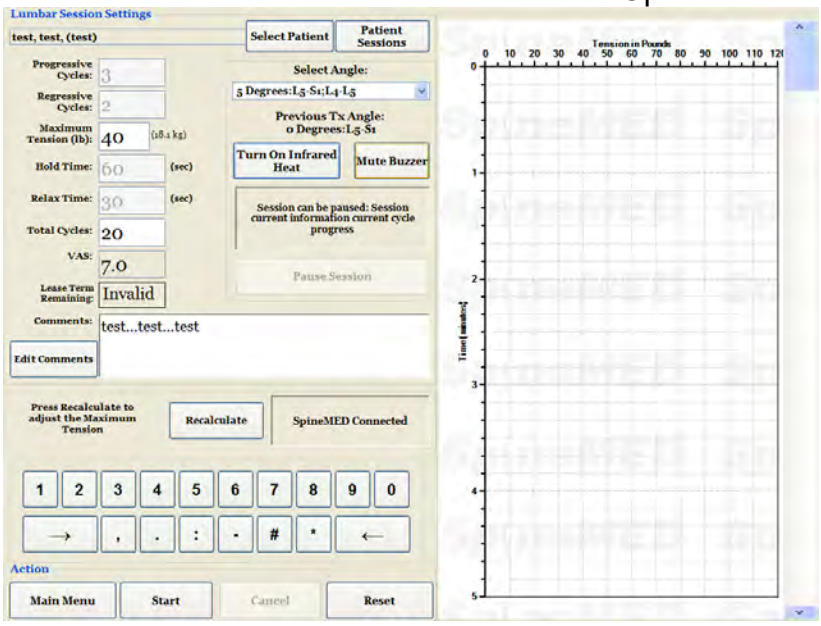


M) Position the Patient Monitor so the patient can view the screen while lying comfortably on the Table.



N) If desired, insert CD or DVD into the CD/DVD Drive integrated into the Patient Monitor. Place the Headphones comfortably on the patient's ears. Press the "Play" button and adjust the volume to patient comfort.

O) Once a new patient record has been created, or if this patient has already been created in the database, go to the “Lumbar Procedures Menu” to enter the procedure parameters for this session. Prepare the SpineMED® for this current session as per the instructions described in Section 4.1 of this Operator Manual.



P) Touch the “Start” button to begin the session.

Q) Retighten the Pelvic Restraints and readjust the Upper Body Restraint on the patient after the Pelvic Tilt has been activated.

R) Emergency/Panic Switch: Before the SpineMED® will begin the session; it will confirm the proper operation of the Emergency/Panic Switch. Immediately after touching the “Start” button, a message will come up in a small sub screen that reads, “*Please Press Emergency Switch!”.* If the Emergency/Panic Switch is working after the patient depresses the button, message “*Click Start to Begin Session. Click Abort to Stop Session.*” will come on the screen.

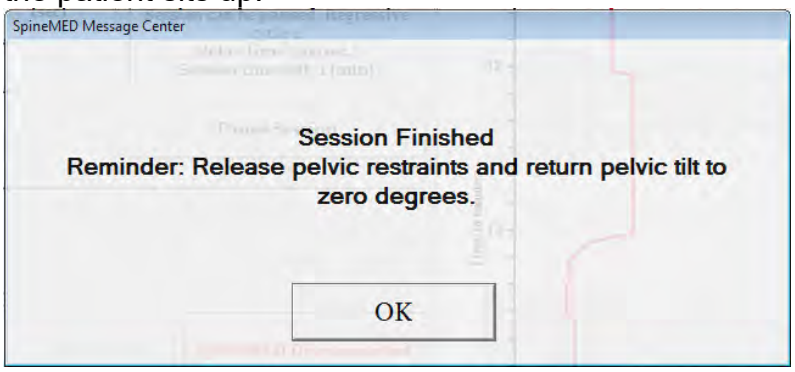
S) If the session does not begin, check that the patient has properly depressed the Emergency/Panic Switch, and if so, check to ensure the Emergency/Panic Switch is properly plugged into the Table.

T) The patient is instructed prior to the session that if they feel they are going to cough or sneeze, that they must press the Emergency/Panic Switch to stop the session, in order to prevent any muscle spasm from occurring while undergoing the session.

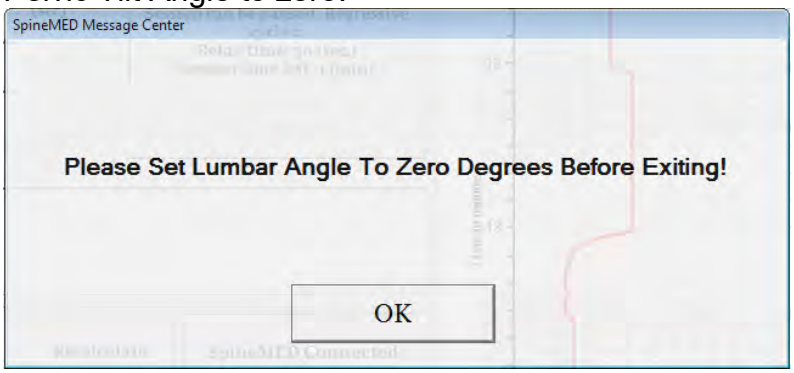
U) If the Lumbar Table section is opening excessively, and may abort the session due to reaching End Sensor, the Slack Adjustment Indexing Lever may be employed during the RELAX phase only, to reduce overall travel of the Table. Remove the slack in the Upper Body Restraint by pulling the Slack Adjustment Indexing Lever toward you, and then rotating the Slack Adjustment Indexing Lever clockwise to move the assembly, thereby removing slack in the Upper Body Restraint. The assembly can be moved in ½" increments, and care should be taken to ensure that the Upper Body Restraint is not over tightened, as this will create a preloaded tension on the patient.

V) During the session, if the patient is not comfortable, or for any reason the Procedure must be stopped, it can be paused, but if cancelled, the session will require re-programming and the remaining time left (i.e. 30 minutes - time) will be recorded as a second session.

W) After Lumbar session is finished, SpineMED® System will generate "Session Finished Reminder" message for the Operator to loosen the Pelvic Restraints, remove Upper Body Restraint and reset the Pelvic Tilt Angle back to zero. This should be done before the patient sits up.



X) If Pelvic Tilt Angle isn't reset to zero before attempting to return to Main Menu, a message "Set Lumbar Angle to Zero" will be generated to remind the Operator to set Pelvic Tilt Angle to zero.



Y) Return to the Main Menu Screen to go to the Reports Menu Screen if a printed report is desired for this session. Refer to Section 4.5 of this Operator Manual for report generation.

5.5 Instructions and Sequencing for Patient Set-up for Cervical Session

⚠ *Warning:*
The Clinician or Operator of the SpineMED® System must always make the patient aware, prior to the session, if the patient feels that he/she is about to sneeze or cough during the session, that he/she presses the Patient Hand Held Electrical Emergency Switch or instructs the Operator to discontinue the session.

**IMPORTANT NOTE: The Cervical patient setup is opposite to the Lumbar setup, in that the Cervical Tilt is administered BEFORE the patient is instructed to lie on the Table.

Following pre-session with infrared heat or dry hydrotherapy, steps taken by the Clinician for patient set-up:

A) If this is the first session for this patient, create a new patient record in the "Patients Menu" and store all of the pertinent patient data into the SpineMED® as described in Section 3.4 of this Operator Manual.

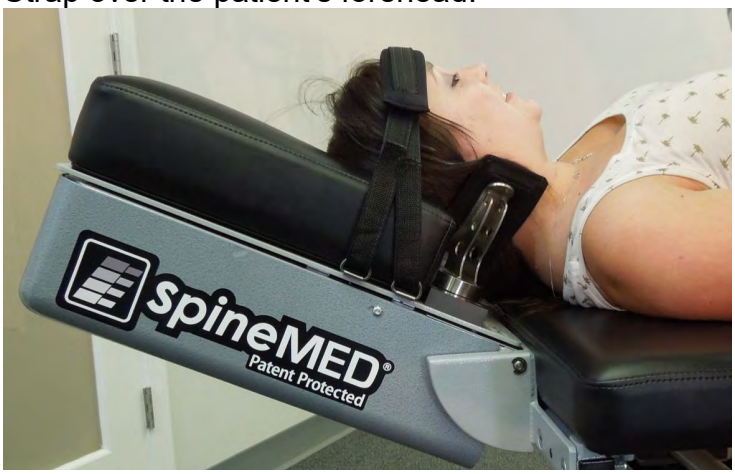
B) Once a new patient record has been created, or if this patient has already been created in the database, go to the "Cervical Procedures Menu" to enter the procedure parameters for this session. Prepare the SpineMED® for this current session as per the instructions described in Section 4.2 of this Operator Manual.

C) Adjust the Tilt Angle for the Cervical Unit for this session prior to placing patient on Table.

D) Walk the patient over to the Table and sit patient on the edge of the Table. The least amount of back flexion possible should be the guide. Once the patient is sitting on the edge of the Table, assist the patient to bring their legs up onto the Table, so that they are in a half-sitting position.

E) Once in the half sitting position, assist the patient to slowly recline to a lying position.

F) Slide the patient to the position on the Table so that their head is positioned comfortably in the Head Restraint Cushion and between Cervical Restraints. Tighten the Head Strap over the patient's forehead.

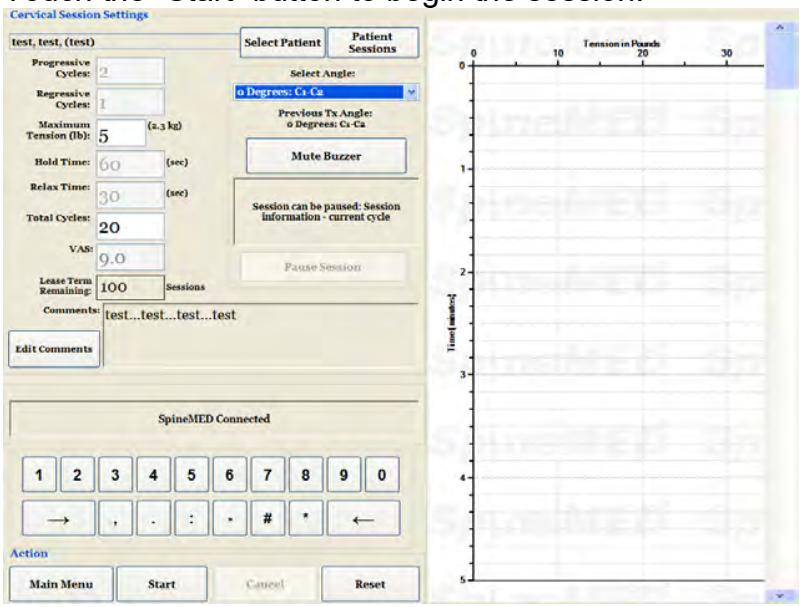


G) If desired, position the Knee Bolster Support Cushion under the patient's knees for added comfort.

H) If this is the patient's first session, position the Patient Emergency/Panic Switch in the patient's hand and instruct on its function, which is to immediately discontinue the session. For future sessions, the Emergency/Panic Switch may be located wherever it can easily be accessed by the patient, such as across the patient's abdomen or clipped to Upper Body Restraint.

I) If desired, insert CD or DVD into the CD/DVD Drive integrated into the Patient Monitor. Place the Headphones comfortably on the patient's ears. Press the "Play" button and adjust the volume to patient comfort.

J) Touch the "Start" button to begin the session.



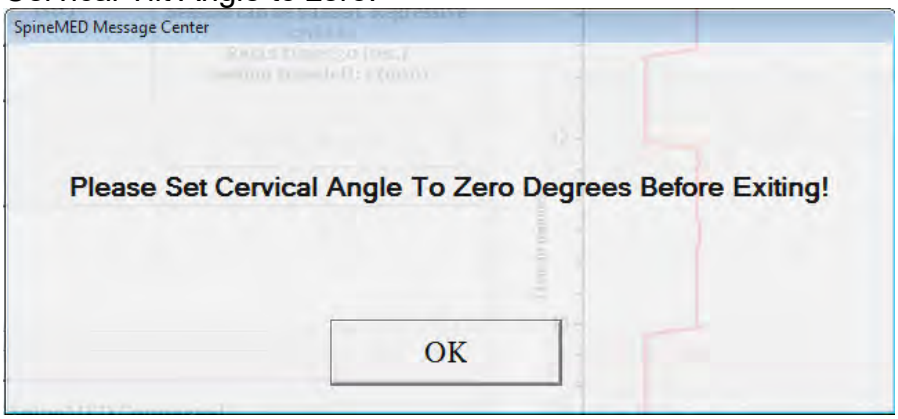
K) Emergency/Panic Switch: Before the SpineMED® will begin the session; it will confirm the proper operation of the Emergency/Panic Switch. Immediately after touching the "Start" button, a message will come up in a small sub screen that reads, "*Please Press Emergency Switch!".* If the Emergency/Panic Switch is working after the patient depresses the button, message "*Click Start to Begin Session. Click Abort to Stop Session.*" will come on the screen.

L) If the session does not begin, check that the patient has properly depressed the Emergency/Panic Switch, and if so, check to ensure the Emergency/Panic Switch is properly plugged into the Table.

M) The patient is instructed prior to the session that if they feel they are going to cough or sneeze, that they must press the Emergency/Panic Switch to stop the session, in order to prevent any muscle spasm from occurring while undergoing a session.

N) During the session, if the patient is not comfortable, or for any reason the session must be stopped, it can be paused, but if cancelled, the procedure will require re-programming and the remaining time left (i.e. 30 minutes - time) will be recorded as a second session.

O) If the Cervical Tilt Angle isn't reset to zero, before attempting to return to Main Menu, a message "Set Cervical Angle to Zero" will be generated to remind Operator to set Cervical Tilt Angle to zero.



P) Return to the Main Menu Screen to go to the Reports Menu Screen if a printed report is desired for this session. Refer to Section 4.5 of this Operator Manual for report generation.

6. Therapeutic Operational Guidelines

6.1 Outcome Measure Data Entry

Integrated into the software, is the Visual Analogue Scale for the objective measurement of the patient's Pain Index. The Patient is asked at the beginning of each session, what their current level of pain is, on a scale of 0.0 to 10.0, on a one level decimal point.

7. Precautions

7.1 Precautions for SpineMED® Procedure

⚠ CAUTION: FEDERAL LAW (CANADA/USA) RESTRICTS THIS DEVICE TO USE BY OR ON ORDER OF A PHYSICIAN, CHIROPRACTOR, PHYSICAL THERAPIST OR PRACTITIONER LICENSED TO USE THIS DEVICE. THIS EQUIPMENT MUST BE OPERATED/UTILIZED UNDER THE DIRECT SUPERVISION OF A LICENSED PRACTITIONER.

⚠ *Warning: The Clinician or Operator of the SpineMED® System must always make the patient aware, prior to a session, if the patient feels that he/she is about to sneeze or cough during the session, that he/she presses the Patient Hand Held Electrical Emergency Switch or instructs the Operator to discontinue the session.*

The Maximum Tensions for Lumbar sessions should never exceed the calculations for a 300 lb. (136 Kg.) patient. Therefore, patients over 300 lbs. (136 Kg.) can be safely distracted up to a maximum distraction force of 100 lbs. (45 Kg.).

The Maximum Tensions for Cervical sessions should never exceed 25 lbs. (11.3 Kg.) for males and 20 lbs. (9.1 Kg.) for females.

The maximum patient weight safe working load is 325 lbs. (147 Kg.).

⚠ *Warning: System contains UPS (Uninterruptible Power Supply) System: UPS (Uninterruptible Power Supply) System should be periodically checked.*

7.2 Precautions for Use of SpineMED® System

⚠ *Warning: To avoid risk of electric shock, this equipment must only be connected to Supply Mains with Protective Earth.*

⚠ *Warning: No modification of this Equipment is allowed.*

⚠ Caution: To prevent fire or shock hazard, do not expose SpineMED® System to rain or moisture. Use extension cords that maintain electrical safety and incorporate a power surge protector. To reduce the risk of electrical shock, do no remove covers. Refer servicing to qualified personnel approved in writing by Universal Pain Technology Canada Inc.

A) DO NOT expose SpineMED® System to rain or moisture.
B) DO NOT tamper with the SpineMED® System.
C) DO NOT disassemble, modify or remodel the SpineMED® System without prior written agreement with Universal Pain Technology Canada.

D) DO NOT connect the SpineMED® System to an electrical supply without first verifying that it is the correct voltage.
E) DO NOT use a damaged power supply cord.
F) DO NOT permit liquids or any foreign matter to enter the SpineMED® System.
G) DO NOT attempt to service SpineMED® System without qualified personnel approved in writing by Universal Pain Technology Canada.
H) DO NOT let a patient who weighs more than 325 lbs. (147 Kg.) undergo the procedure.

⚠ *Warning: The SpineMED® System is a stand-alone device and is NOT intended to be connected to any other systems, peripherals or office networks. If more than one SpineMED® System is being utilized within one clinical practice, and the SpineMED® database must be shared between devices, only a closed network system between the SpineMED® Systems alone may be used. This closed network system should only be installed and configured by a qualified SpineMED® Technician.*

⚠ *Warning: All I/O ports on the SpineMED® Touchcomputer and Patient Monitor must only be fitted with factory installed connections. No non-factory connections should be made with any port on the SpineMED® Touchcomputer or Patient Monitor.*

7.3 Degree of Protection Against Harmful Ingress of Liquids: IPX0 (ordinary equipment)

Degree of Safety in the Presence of Flammable Anesthetic Mixture with Air or with Oxygen or Nitrous Oxide: Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

7.4 Environmental Conditions for the Operation, Storage and Transport of the SpineMED®

Operating Environment		
Temperature		+10° C to +40° C (50° to 104° F)
Relative Humidity		30 to 85%
Air Pressure		500 to 1060 hPa
Maximum Operating Altitude		3000 meters
Storage Environment		
Temperature		-40° C to +70° C (-40° to 158° F)
Relative Humidity		10 to 95%
Air Pressure		500 to 1060 hPa

8. Maintenance

8.1 Disposal of SpineMED® System

At the conclusion of the useful life of the SpineMED® System (to be advised by Universal Pain Technology Canada), the device should be dismantled carefully, and disposed of by an appropriately approved disposal company, or returned to Universal Pain Technology Canada. There are no toxic or explosive substances within the SpineMED® System, the construction being primarily of extruded aluminum, steel and plastic.

8.2 Regular Maintenance

A) The SpineMED® System has been engineered to be relatively maintenance-free for several years of use and does not require regular maintenance other than cleaning. Qualified Universal Pain Technology Canada personnel must conduct any service or repairs required. The SpineMED® System should be recalibrated by Qualified Universal Pain Technology Canada personnel immediately following any relocation to another address and prior to the treatment of any patient.

B) The incorporated UPS (Uninterruptible Power Supply) System in the SpineMED® System has internal batteries that can be subject to wear and damage. The state of the batteries is indicated on the front panel of the UPS (Uninterruptible Power Supply) System, and defective batteries will cause an error LED to be lit on the front panel of the UPS (Uninterruptible Power Supply) System. See Section 8.5B for details of UPS (Uninterruptible Power Supply) System operation and indicators. The indicator panel on the front of the UPS (Uninterruptible Power Supply) System should be viewed for any error indicators on a daily basis prior to the treatment of any patient. The batteries in the UPS (Uninterruptible Power Supply) System have a life expectancy of 3 to 5 years, and therefore should be replaced every 5 years, or sooner, if any battery fault conditions occur.

8.3 Cleaning of Equipment

A) Clean the Touchcomputer occasionally as follows:

- Prepare a mixture of a gentle kitchen-use detergent (one that does not contain abrasive powder or strong chemicals such as acid or alkaline).
- Use water and detergent in ratio 5:1.
- Absorb the diluted detergent into a sponge.
- Squeeze excess liquid from the sponge.
- Wipe the surface with the sponge, using a circular motion and taking care not to let any excess liquid drip.
- Wipe the surface to remove detergent.
- Rinse the sponge with clean running water.
- Wipe the surface with the clean sponge.
- Wipe the surface again with a dry, soft lint-free cloth.
- Wait for the surface to dry completely and remove any cloth fibers from the Touchcomputer surface.

B) Following each session, the Table surface should be sprayed and wiped with a non-toxic, mild anti-bacterial agent.

C) The Head Pillow and Knee Bolster Support Cushion should also be sprayed and wiped with a non- toxic, mild anti-bacterial agent on a regular basis.

8.4 Service and Warranty

The SpineMED® System and its components are warranted to be free of defects of workmanship for one year from the date of delivery. Universal Pain Technology Canada will repair or replace defective components at no cost to the owner of the SpineMED® System once the part has been determined by UPTC, to be faulty. All warranty and maintenance services will be performed by UPTC authorized representatives during normal working hours. Any repairs or service to the SpineMED® by non-authorized UPTC service personnel will immediately terminate the manufacturer's warranty. SpineMED® Warranty Certificate can be found in the Appendix section of this Operator Manual. The SpineMED® System should be recalibrated by Qualified Universal Pain Technology Canada personnel immediately following any relocation of the SpineMED® System to another address and prior to the treatment of any patient.

FAILURE TO USE AND MAINTAIN THE SpineMED® SYSTEM AND ACCESSORIES IN ACCORDANCE WITH OPERATOR INSTRUCTIONS FOR MAINTENANCE, REGULAR CHECKS AND PRECAUTIONS FOR EQUIPMENT USE WILL INVALIDATE THE WARRANTY OF THE SpineMED® SYSTEM.

ITEMS NOT COVERED on SpineMED® Warranty

- Malfunction of any accessory /part resulting from misuse or other than intended use
- Improper installation or repair and/or use of Non-UPTC specified parts or products
- Improper application of components
- Damage caused by accident, fire, floods, acts of God, or mischief
- Replacement of building fuses or resetting of circuit breakers
- Service trips to your office to teach you how to use the SpineMED®
- Cushions, Gel Pads, Printer Cartridges, UPS (Uninterruptible Power Supply) System Batteries

8.5 Troubleshooting

A) The SpineMED® has error prompting, where error messages and correction instructions appear on the Touchcomputer screen to correct input and data errors.

B) Located on the front panel of the UPS (Uninterruptible Power Supply) System inside the front/head end of the Table, are system LED indicator lights and a digital display that will indicate System Status and System Errors to the Operator. System Status Indicator functions on the front panel of the UPS (Uninterruptible Power Supply) System are as follows:

1. ON/OFF: This button is used to turn the UPS (Uninterruptible Power Supply) System output ON or OFF. To turn ON, press the button until a ‘beep’ is heard. To turn OFF press and hold the “Power” button for approximately 5 seconds until a ‘beep’ is heard.

2. Online Indicator: If indicator (*Plug*) is on, the UPS (Uninterruptible Power Supply) System is receiving online voltage (power) from the wall outlet.

3. Battery Backup: If indicator (*Battery*) is on, the UPS (Uninterruptible Power Supply) System is in use as a result of Main Supply power failure or disconnection of device from wall outlet. An audible alarm will sound 4 beeps every 30 seconds during this condition.

4. Line Voltage: This indicator displays the wall outlet line voltage.

5. Battery Level: Indicator displays current charge level of battery.

6. Replace Battery : If indicator is displayed, the battery is defective and must be replaced. Contact Universal Pain Technology Canada.

C) Troubleshooting Table

	Problem	**Possible Causes**
No Power and “UPS (Uninterruptible Power Supply) System” LED light is on.	Power Failure but UPS (Uninterruptible Power Supply) System is on and still providing power.	• Defective cord to receptacle. • Non-functioning power receptacle.
No Power and “Check UPS (Uninterruptible Power Supply) System” LED light is on.	All components are not functioning Power Failure and UPS (Uninterruptible Power Supply) System is not working.	• Power failure due to external problem with power supply. • UPS (Uninterruptible Power Supply) System needs replacing.
The Procedure will not initiate when Emergency/Panic Switch is pressed.		• Patient did not push Emergency/Panic Switch. • Emergency/Panic Switch is broken. • Emergency/Panic Switch is disconnected from Table.
Table not functioning but Touchcomputer is functioning.		• Electrical wiring between Touchcomputer and Control Board within the Table is loose or defective.
Printer not functioning.	Printer will not print reports.	• Electrical wiring. • Data Cable loose. • Paper tray empty.
Unable to enter data for Procedure, display has Error Message on Screen.	Incorrectly attempting to set data outside of available parameters i.e. Unable to set tension at 170 lb. as maximum is 100 lb.	• Improper input of data outside protocol parameters.

8.6 Power Troubleshooting and Fuse Replacement

8.6.1 Power Troubleshooting

1. If the UPS (Uninterruptible Power Supply) System is emitting an alarm (beeping), it is indicating that power to the Table has been interrupted. As the batteries will power the device for a limited time, it is recommended that the Patient Monitor/CD/DVD Player be discontinued to allow completion of the session in progress. Once session is completed it is not recommended to perform any new sessions while on battery backup power.

2. If the UPS (Uninterruptible Power Supply) System is beeping, view the indicator panel on the UPS (Uninterruptible Power Supply) System at the front of the Table. If the "On Battery" indicator (#1 in Figure A) is lit, then the electrical power (wall outlet) to the SpineMED® has been interrupted (go to step #3). Remaining Time Indicator (#2 in Figure A) indicates the remaining battery life in minutes.

3. At this point the SpineMED® System should be powered down completely and unplugged from the wall outlet. Power down procedure is:
   i. On the Main Menu in the SpineMED® software, select LOGOUT/EXIT
   ii. On the LOGOUT/EXIT screen, select TURN OFF
   iii. It is imperative that you wait for the Touchcomputer to completely shut down before powering off the SpineMED® System. Once the Touchcomputer has shut down, the UPS (Uninterruptible Power Supply) System should be powered off. On the front of UPS (Uninterruptible Power Supply) System, press and hold the ON/OFF button (#3 in Figure A) for a few seconds until a beep is heard and display goes blank.
   iv. The Main Supply Power Switch should be turned off (O = Off) (Figure B) and then the Main Supply Power Cord can be unplugged from the wall outlet.

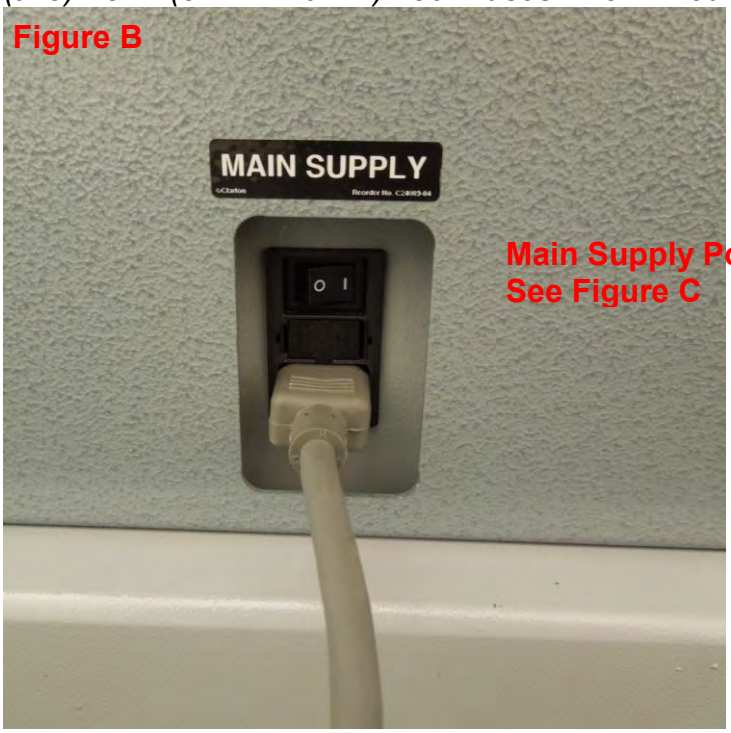
4. The wall outlet where the Main Supply Power Cord was plugged in should now be checked to confirm electrical power is present. An electrical appliance (such as a lamp) should be plugged into the outlet to verify power.

5. If the appliance does not work in the outlet, then it is likely that the circuit breaker in the building breaker panel has 'tripped'. Reset the breaker in the building power panel to restore power to the wall outlet. Confirm power supply was restored.

6. Once it is confirmed that power is present at the wall outlet, the fuses should be checked. This needs to be done before the Main Supply Power Cord is plugged back into the wall outlet.

7. Note: The fuses in the SpineMED® System will burn out if there is a power surge in the building or, in some cases, if the Main Supply Power Cord is removed from the wall without first turning off the Main Supply Power Switch. Always turn off the Main Supply Power Switch (#1 in Figure C) switch by pressing the "O" prior to unplugging the power cord from the wall outlet.
The system uses: 2 (two) T10AL (5mm x 20mm) 250V fuses when wired for 120V or 2 (two) T8AL (5mm x 20mm) 250V fuses when wired for 240V.

Figure B



Main Supply Power Switch location
See Figure C

Figure C

1. Main Supply Power Switch

2. Fuse Drawer

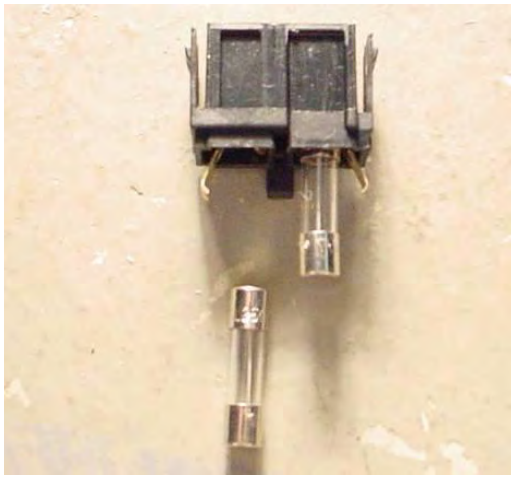
8.6.2 Fuse Inspection

1. The fuses are located in a Power Module on the side of the Table, which also houses the Main Supply Power Switch and the connector for the electrical Main Supply Power Cord. Figure C in Section 8.6.1 illustrates the location of the Fuse Drawer (#2 in Figure C), located in the center of the Power Module. *The system uses: 2 (two) T10AL (5mm x 20mm) 250V fuses when wired for 120V or 2 (two) T8AL (5mm x 20mm) 250V fuses when wired for 240V.*

2. **HAZARD** To avoid electrical shock while replacing fuses, the SpineMED® System should be turned off and unplugged from the wall outlet before the fuses are checked. The Fuse Drawer is removed by using a small screwdriver similar to the one illustrated below. To allow easier access to Fuse Drawer the Main Supply Power Cord may also be unplugged from the side of Table.

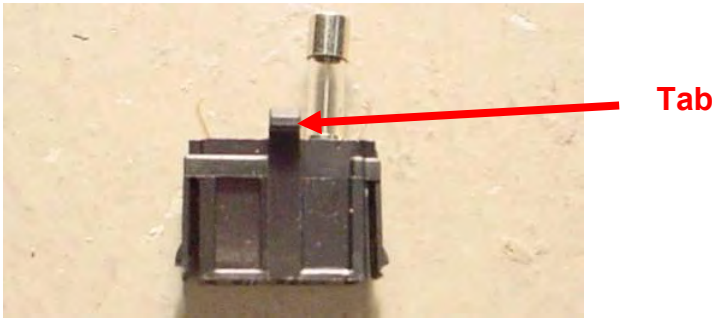
3. The Fuse Drawer is held in place by two small clips located on either side of the drawer face. To remove the Fuse Drawer, use the small screwdriver to release each clip, one side at a time.

4. Once you have released the second clip, the drawer will pop out of the Power Module as illustrated below.



5. Remove the Fuse Drawer. With the Fuse Drawer removed, you will be able to remove the glass fuses from the drawer for inspection. Check to see if the internal filament is burnt. If the fuses are damaged, replace the fuses with the appropriate fuses as described on the serial number label (located above Fuse Drawer and Main Supply Power Switch).

6. To replace the Fuse Drawer, it must be inserted in a specific position. You will notice that there is a small tab in the middle of the Fuse Drawer on one side of the assembly. This tab must face downward in order for the Fuse Drawer to be reinserted into the Power Module.



7. Insert the Fuse Drawer back into the Power Module, making sure that the tab is facing downward. Gently push the Fuse Drawer until a small audible click indicates that it has locked in place.

8. The SpineMED® System may now be powered on as follows:
   i. If required, re-attach the Main Supply Power Cord to the Table
   ii. Plug Main Supply Power Cord into wall outlet
   iii. Turn on the Main Supply Power Switch (I = On) (#1 in Figures B & C – Section 8.6.1)
   iv. Turn on the System by powering on the UPS (Uninterruptible Power Supply) System. This is done by pressing the ON/OFF button until beep is heard
   v. Turn on Touchcomputer (#1 in Figures 2.7C & 2.7D – Section 2.7)
   vi. Log into the SpineMED® software

9. Technical Specifications

9.1 Power Supply

Power to operate the device is supplied via the Main Supply Power Switch on the bottom rear side of the Table Unit. Press the Main Supply Power Switch to turn the system on. The system uses a 115 Volt, 60 Hz power supply (in North America), and is protected by an approved circuit breaker. For SpineMED® Systems supplied for use in Europe, the system is suitable for 230 Volt, 50 Hz power supply. Appropriate transformer taps are connected within the SpineMED® System for proper voltage requirements. The SpineMED® also has an Automatic Voltage Regulator incorporated into the Table, which corrects system input voltages to a consistent 115 VAC in the event of fluctuation in the wall supply.

Power Requirements:

A) Voltage: 110-120/220-240 Volts AC (Pre-wired for either voltage)
B) Frequency: 50/60 Hz
C) Amperage: 10 Amperes at 120VAC or 8 Amperes at 240VAC

9.2 Dimensions and Weight

1) Dimensions of SpineMED®
Table[1, 2]: 92” long x 48” wide x 49” high
(234 cm long x 122 cm wide x 125 cm high)
[1]Table height measurement is floor to top of Patient Monitor, length includes Cervical Unit.
[2]Total length required for proper Lumbar/Cervical operation is 106” (270cm).

2) Weight of SpineMED®
Table: 440 lbs. (199.5 Kg.)
Cervical Unit: 55 lbs. (25 Kg.)

9.3 Model Number Designation

1) SpineMED® S200U consists of Lumbar Only System.

2) SpineMED® S200UC consists of the Cervical System Only and is an add-on component to the base S200U Lumbar Only System. The S200UC Cervical Unit cannot operate as a free standing unit and can only function when connected to the S200U Lumbar Only System.

9.4 Type B Applied Parts

1) The SpineMED® S200U model uses Type B Applied parts consisting of:
   a. Vinyl Surfaced Table Cushions
   b. Lycra Covered Pelvic Gel Pads
   c. Emergency/Panic Switch
   d. Vinyl Covered Head Pillow/Cushion
   e. Vinyl Covered Knee Bolster Support Cushion
   f. Nylon Upper Body Restraint
   g. Patient Monitor with incorporated CD/DVD Player
   h. Wired Audio Headphones

2) The SpineMED® S200UC model uses Type B Applied parts consisting of:
   a. Vinyl Covered Head Cushion
   b. Nylon Cervical Head Strap
   c. Lycra Covered Cervical Gel Pads

9.5 Compliance Standards

The SpineMED® System is a Class II Type A Medical Equipment.

USERS IN USA: This device complies with Part 15 of the FCC rules. Operation is subject to the following conditions: (1) This device may not cause harmful interference; and (2) This device must accept any interference received, including interference that may cause undesired operation.
Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy, and if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case, the User would be required to correct interference at own expense. Shielded cables must be used with this SpineMED® System to ensure compliance with the Class A FCC limits.

USERS IN CANADA: This digital apparatus does not exceed the Class A limits for radio noise emissions from digital apparatus set out in the Radio Interference Regulations of the Canadian Department of Communications.
Le present appareil numerique n'emet pas de bruits radioelectriques depassant les limites applicables aux appareils numjberiques (de la class A) prescrites dans le Reglement sur le brouillage radioelectrique edicte par le ministere des Communications du Canada.

9.5.1 Electromagnetic Standards EN 60601-1-2 2015

The SpineMED® S200U/S200UC needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this Operational Instruction Manual.

The SpineMED® S200U/S200UC is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The Customer or User of the SpineMED® S200U/S200UC can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SpineMED® S200U/S200UC.

The SpineMED® S200U/S200UC is Class A Medical Electrical Equipment and is intended for use by healthcare professionals only. The SpineMED® S200U/S200UC may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the equipment or shielding the location.

Class A – The SpineMED® S200U/S200UC is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

9.5.2 Electromagnetic Environment Guidance

The SpineMED® S200U/S200UC is intended for use in the electromagnetic environment specified below. The Customer or the User of the SpineMED® S200U/S200UC should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 1	The SpineMED® S200U/S200UC uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The SpineMED® S200U/S200UC is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: ⚠ **Warning:** The SpineMED® S200U/S200UC is intended for use by healthcare professionals only. The SpineMED® S200U/S200UC may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the equipment or shielding the location.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

The SpineMED® S200U/S200UC is intended for use in the electromagnetic environment specified below. The Customer or the User of the SpineMED® S200U/S200UC should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line & ±0.5 kV, ±1 kV, ±2 kV line to ground	±0.5 kV, ±1 kV line to line & ±0.5 kV, ±1 kV, ±2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T (100% dip in U_T) for 0,5 cycle 0% U_T (100% dip in U_T) for 1 cycles 70% U_T (30% dip in U_T) for 30 cycles 0% U_T (100% dip in U_T) for 5 sec	0% U_T (100% dip in U_T) for 0,5 cycle 0% U_T (100% dip in U_T) for 1 cycles 70% U_T (30% dip in U_T) for 30 cycles 0% U_T (100% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the User of the SpineMED® S200U/S200UC requires continued operation during power mains interruptions, it is recommended that the SpineMED® S200U/S200UC be powered from an uninterruptible power supply or a battery.
Power Frequency Magnetic Field (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

The SpineMED® S200U/S200UC is intended for use in the electromagnetic environment specified below. The Customer or the User of the SpineMED® S200U/S200UC should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM Bands inside 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM Bands inside 150 kHZ to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the SpineMED® S200U/S200UC including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,7 GHz RF Communication equipment inside 80 MHz to 6 GHz	3 V/m 80 MHz to 2,7 GHz RF Communication equipment inside 80 MHz to 6 GHz	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]

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

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

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SpineMED® S200U/S200UC is used exceeds the applicable RF compliance level above, the SpineMED® S200U/S200UC should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the SpineMED® S200U/S200UC

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

Recommended separation distances between portable and mobile RF communications equipment and the SpineMED® S200U/S200UC			
The SpineMED® S200U/S200UC is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The Customer or the User of the SpineMED® S200U/S200UC can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SpineMED® S200U/S200UC as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.7 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.24
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

9.5.3 Compliance Standards Met

In compliance with:

A) IEC 60601-1:2005/A1:2012 (excluding Clauses 11.7 and 17)
B) IEC 60601-1-6:2010/A1:2013
C) IEC 62366:2007/A1:2014
D) CAN/CSA C22.2 No. 60601-1:2014-03 (excluding Clauses 11.7 and 17)
E) CAN/CSA C22.2 No. 60601-1-6:2011/A1:2015-10
F) CAN/CSA-IEC 62366:2014-01
G) ANSI/AAMI ES60601-1:2005/A1:2012 (excluding Clauses 11.7 and 17)
H) EN 60601-1:2006/A1:2013 (excluding Clauses 11.7 and 17)
I) EN 60601-1-6:2010/A1:2015
J) EN 62366:2008/A1:2015
K) IEC 60601-1-2:2007
L) IEC 60601-1-2:2014
M) EN 60601-1-2:2007
N) EN 60601-1-2:2015

10. Manufacturer

The SpineMED® is manufactured by: Universal Pain Technology Canada Inc.

10.1 Contact Information

Universal Pain Technology Canada Inc.
#1 – 1722 Ogilvie St. South
Prince George, BC V2N 1W9
Tel. (250) 564-5424
Fax. (250) 563-3177

10.2 European Union Authorized Representative

EC REP

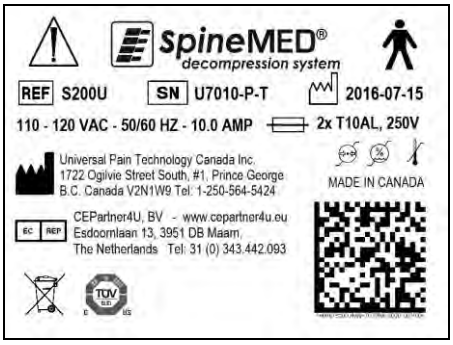
CEpartners4U BV
Esdoornlaan 13, 3951DB Maarn
The Netherlands
www.cepartner4u.eu

10.3 United States Authorized Representative

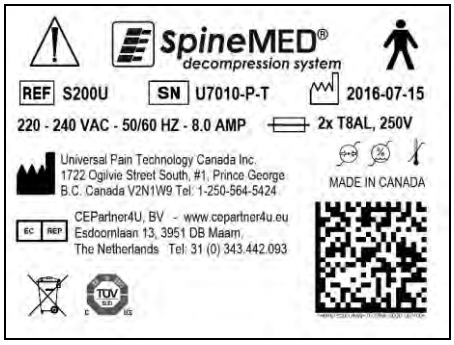
Emergo Group, Inc.
2500 Bee Cave Road
Building 1, Suite 300
Austin, TX 78746
Tel: 512-327-9997

10.4 Product Serial Label Examples

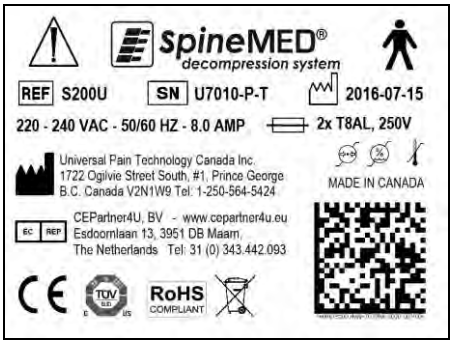
S200U – 110-120V – Non-RoHS



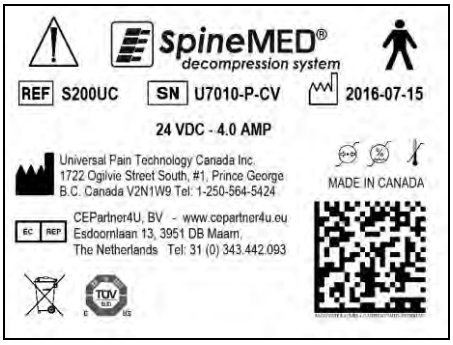
S200U – 220-240V – Non-RoHS



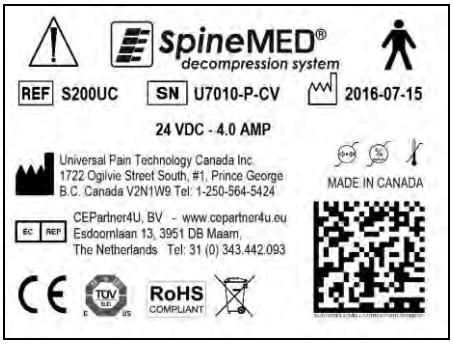
S200U – 220-240V – RoHS



S200UC – 24 VDC – Non-RoHS



S200UC – 24 VDC – RoHS



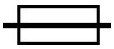
APPENDIX

Device Classification

The SpineMED® System is Class I Equipment, with Type B applied parts with Continuous Mode of Operation.

Definition of Symbols

Symbol	Description
	Alternating current
	Direct current
	Warning/Caution (See instructions for use)
	Follow Instructions for Use
	On/Off (UPS - Uninterruptible Power Supply)
	TYPE B Applied Parts
	Protective Earth (Ground)
	Off (Power: Connection to the Mains Supply)
	On (Power: connection to the Mains Supply)
	Pinch Point
	Not Hand Hold or Grab Bar
	Keep Hands Clear
	Emergency Stop (Patient Emergency/Panic Switch)
	No Sitting
	No Step

Symbol	Description
	Ethernet
	Manufacturer
	Date of Manufacture
	Authorized Representative in the European Community
	Temperature Limitation
	Atmospheric Pressure Limitation
	Humidity Limitation
	Catalogue/Model Number
	Serial Number
	Electrical and Electronic Equipment
	CE Marking of Conformity
	Fuse
	EU Directive 2011/65/EU (Restriction of the use of certain hazardous substances in electrical and electronic equipment)

Warranty Certificate

SpineMED® DECOMPRESSION SYSTEM
Standard Warranty

Universal Pain Technology Canada ("UPTC") warrants the SpineMED® Decompression Table and Cervical ("Equipment") is free of defects in materials and workmanship for a period of one (1) year, from the date of purchase by the original purchaser. If any part or component is found to be defective during the one (1) year warranty period, UPTC will repair or replace the defective part at UPTC's option and expense.

This warranty does not cover normal wear, cosmetic damage or damage due to acts of God, accident, misuse, abuse or negligence, improper usage, handling or care. This warranty covers parts and labor costs resulting from a mechanical or electrical failure of the SpineMED® Decompression System, caused by defects in workmanship and/or materials, excluding those experienced during normal wear and tear.

This warranty does not cover replacement of:

Pelvic Restraint Gel Pads, Pelvic Restraints, Cervical Restraint Gel Pads, Cervical Restraints, Upper Body Restraint, All Cushions, Printer, Printer Cartridges, Headphones and Patient Monitor with incorporated CD/DVD Player

CONDITIONS OF WARRANTY

The electrical power source for the operation of the Equipment must be a dedicated 15 amp. circuit. Operation of the Equipment connected to an electrical circuit other than a dedicated 15 amp. circuit will void this warranty. Any routine maintenance procedures set forth in this SpineMED® Manual must be performed by the Purchaser. Failure to perform any required routine maintenance shall void this warranty. A UPTC Service Technician or a qualified service technician, as designated by the Manufacturer, must make all repairs and modifications to the Equipment. Repair or modification by any other person shall void this warranty. This warranty is void if the factory-applied serial numbers on the Equipment have been altered or removed.

PURCHASER NAME:	
ADDRESS:	
SERIAL NUMBER TABLE:	
SERIAL NUMBER CERVICAL:	
INSTALLATION DATE:	
EXPIRY DATE:	

EXCEPT TO THE EXTENT PROHIBITED BY APPLICABLE LAW, ANY IMPLIED WARRANTY, INCLUDING THAT OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, IS HEREBY LIMITED IN DURATION TO THE WARRANTY PERIOD SET FORTH ABOVE. UPTC shall not be liable for any consequential or incidental damages in connection with the Equipment. The Purchaser may have specific rights which may vary from state to state and which may conflict or modify the foregoing. This warranty is valid in Canada and United States.

UPTC Commitment to Service

Recognizing the need to sustain UPTC services, on notice of defective operation by telephone or Fax transmission, UPTC will make its best effort to resolve the problem as expeditiously as possible. UPTC shall not be liable for default or delay in performance under its warranty caused by any circumstances beyond its control, including but not limited to Acts of God, fire, floods, strikes, material supply problems or government restrictions or restraints.

Services not covered by warranty will be rendered upon request at UPTC's regular rates for repairs and service.

To obtain Warranty service or information contact:

Universal Pain Technology Canada Inc.
#1 – 1722 Ogilvie St. South
Prince George, BC V2N 1W9
TELEPHONE 1-250-564-5424 or 1-866-990-4444
FAX 1-250-563-3177 or 1-866-990-4445