

Vertetrac and DBS

User Manual



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TABLE OF CONTENTS:

1.	Introduction	3
2.	Parts of the Vertetrac	5
3.	Instruction for Use of the Vertetrac	7
4.	Notes on the Vertetrac	10
5.	Additional Options	11
6.	Treatment Sessions	12
7.	Recommended Treatment Techniques	13
8.	Care and Maintenance of Your Vertetrac	14
9.	Parts of the D.B.S.	15
10.	Instruction for Use of the D.B.S.	16
11.	Notes about the D.B.S.	19
12.	Care and Maintenance of Your D.B.S.	21
13.	Labels	21
14.	Contact Information	22

1. INTRODUCTION

Congratulations on purchasing the latest concept in lumbar spine treatment – the Vertetrac. Offering safe, simple, compact, and effective treatment of lumbar spine disorders, the Vertetrac brings to both the patient and physician a means of powerful, dynamic traction with simultaneous, three-dimensional action without the need for traction beds or restrictive braces. Thus, the Vertetrac allows the patient maximum mobility with minimal restrictions or discomfort during treatment. Designed with the patient in mind, the Vertetrac facilitates the treatment of the patient by the health service professional while also allowing chronic sufferers to administer self-treatment under qualified medical supervision.

We wish you good luck and good health with your Vertetrac.

FOR YOUR OWN HEALTH AND SAFETY

Please read the following and familiarize yourself with all of the instructions before using your Vertetrac.

Indications for use of the Vertetrac:

- Lumbar disc disorders of primary origin
- Lumbar disc disorders of secondary origin
- Sciatica
- Spinal stenosis due to disc herniation
- Herniated disc

Indications for use of the Vertetrac with the D.B.S.:

- Idiopathic scoliosis (juvenile, adolescent, or adult)

Contra-indications for use of the Vertetrac:

- Do not allow contact between the device and open wounds.
- Cauda Equina Syndrome
- Pott's Disease and all infective or inflammatory diseases of the vertebrae
- Cardiac or circulatory disease and severe respiratory problems
- Pregnancy after the fourth month
- Contusions and stretching injuries of the lower back (damage of muscles, tendons, vessels, and nerves can be aggravated by traction)
- Post-operative patients within 3 months of back surgery
- Vertebral fracture within 6 months of initial injury
- Fusion with internal fixation.
- Neoplasms.

Adverse Reactions:

Although extremely uncommon, if any of the reactions listed below are experienced, immediately discontinue use of the Vertetrac and contact the administering medical professional.

- Dizziness
- Breathing difficulties
- Abnormal fatigue
- Aggravation of symptoms

WARNING: The sale of this device is restricted to individuals by or on the order of a physician. The instructions provided by your health care provider should be followed precisely. Do not exceed the recommendations of your health care provider. Exceeding these recommendations may aggravate an existing condition or cause additional injury. Traction should never cause pain. A stretching sensation or some slight discomfort may be felt during treatment. If pain is increased in the neck, back, arms or legs, or if you experience dizziness, nausea or any other type of pain or discomfort during or after treatment, discontinue use immediately and consult your health care provider before further use.

2. PARTS OF THE VERTETRAC



1. Upper frame
2. Lower frame
3. Traction release lever
4. Belt
5. Belt clips
6. Comfort pads

- 7. Horizontal pressure screw
- 8. Horizontal pressure pad
- 9. Horizontal pressure shaft
- 10. Horizontal screw release button
- 11. Ratchet
- 12. Ratchet handle
- 13. Traction rod
- 14. Traction lever



3. INSTRUCTION FOR USE OF THE VERTETRAC

Step 1: Begin with the Vertetrac in the “Zero Position” by inverting the Vertetrac unit on a horizontal surface and pressing the traction release levers and bringing the upper frame and lower frame to their closest possible position (**Fig. 1**). Return the Vertetrac to the upright position.



Fig. 1

Step 2: Open the two belt fasteners and retract the horizontal pressure pad fully by depressing the screw release button and pulling the horizontal force screw so that the Vertetrac may be placed on the patient’s body, **over a light shirt**. With the patient holding the lower frame, place it directly above the iliac crests (pelvis), with the horizontal force screw centered behind the spine.

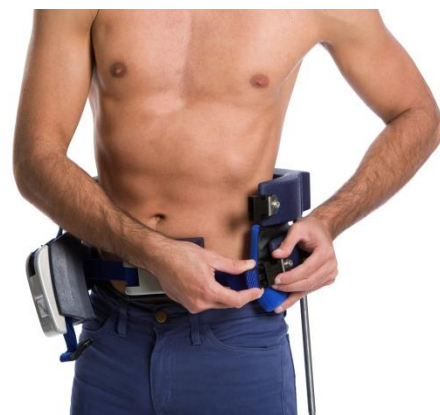


Fig. 2

Step 3: When the Vertetrac is properly positioned, fasten the lower belt fastener (**Fig. 2**) and begin tightening the lower ratchet so that the ratchet rests loosely in the middle of the patient’s body. Tighten the belt by moving the ratchet handle in a left-to-right motion, repeating until the appropriate amount of tension has been applied (**Fig. 3**). Do the same for the upper belt fastener. The upper frame should fit around the patient’s rib cage with no clothing, body parts, or other obstructions between the frame and the ribcage. Please note that when treating large-breasted patients, the patient’s breasts should be resting above the upper frame and not trapped between the frame and the body.



Fig. 3

Step 4: Begin adjusting the lower belt so that it fits tightly around the body. The lower belt should be sufficiently tight to prevent slipping of the apparatus during the treatment. It is recommended to center the ratchet horizontally on the belt, but this position may be changed as different patients may require a different position. Tightening of the upper belt should ensure that the upper frame is well pressed against the body, so that no space remains between the upper frame and the skin. Use the comfort pads if the patient feels excessive pressure beneath the sternum or on ribs or iliac crests (**Fig. 4**). For small-bodied patients, it may be necessary to use the comfort pads in order to allow the upper and lower frames to be tightened sufficiently.



Fig. 4

****If the belt is tightened excessively and the patient feels extreme discomfort, the tension may be released by opening the belt fasteners (on the left side).**



Fig. 5

Step 5: Apply lumbar traction by simultaneously jacking both traction levers at a consistent rate (**Fig. 5**) until the skin is tightly stretched between the upper and lower frames and there is considerable resistance to the movements of the handles (approximately 20 kg./45 lbs. of traction force on each side). The skin below the upper frame should be taut so that it cannot be caught between the fingers. The skin above the upper frame should be folded (**Fig. 6**).



Fig. 6

****When asymmetrical traction is recommended, apply simultaneous traction to the point where the patient feels a moderate traction force and then apply additional traction on the appropriate side (**Fig. 7**).**



Fig. 7

Step 6: When horizontal force is recommended, place the horizontal force pad at the desired level – L3, L4, or L5 (**Fig. 8**). Apply horizontal force by turning the horizontal pressure screw clockwise to the point where the patient feels relief from leg pain (**Fig. 9**).

Step 7: After treatment session has been completed, release the horizontal force by turning the horizontal force knob counter-clockwise. Release the vertical traction on the spine by lifting both release levers (**Fig. 10**), then open the upper and lower belt fasteners. To loosen the belt, pull the ratchet lever as far to the right as possible while lifting the U-shaped retaining clip. When the ratchet lever is locked in the open position (180 degrees) (**Fig. 11**) the ratchet can slide from side to side on the belt. Unlock the ratchet lever by pulling on the retaining clip in the ratchet handle and partially closing the handle.

Step 8: Remove the apparatus from the body of the patient. To prepare the Vertetrac for further use, lift the releasing levers and bring the upper frame to its lowest position (“Zero Position”). It is recommended to store the unit inverted and resting on the upper frame.



Fig. 8



Fig. 9



Fig. 10



Fig. 11

4. NOTES ON THE VERTETRAC

- Treatment session is 30 minutes, but may be varied slightly according to the tolerance of the patient. The patient should be examined every ten minutes and the traction increased when necessary. It is recommended for the patient to walk or participate in active exercises during the treatment session (i.e. on a treadmill or using elastic bands).
- If, at any time during the treatment, the patient feels excessive pressure and/or extreme discomfort, lower the upper frame immediately by pressing the release handles and open both the upper and lower belt fasteners.
- **Comfort Pads**
In general, each unit has four extra padding units – two soft pads for the iliac crest and two rigid pads to put under the ratchet. Use the comfort pads in accordance with patient needs to prevent discomfort during treatment. The extra padding should be installed before traction is commenced.
- **The use of padding is especially important for very thin patients, where there is a risk of rib fracture if a suitable amount of padding is not used.**



5. ADDITIONAL OPTIONS

- **Self Treatment**

The patient should be instructed in the proper and safe use of the Vertetrac. Once the patient is comfortable with the use and maintenance of the unit, the patient may begin performing self-treatment. The patient should follow a treatment schedule outlined by the physician. Long-term patients should be examined monthly by the physician in order to gauge the patient's condition and progress.

- **Active rehabilitation with treadmill or elastic bands**

- **Asymmetrical traction**

When asymmetrical traction is recommended, apply simultaneous traction to the point where the patient feels a moderate traction force and then apply additional traction on the appropriate side.



6. TREATMENT SESSIONS

- It is recommended to apply treatment with the Vertetrac as soon as possible after the onset of pain and diagnosis by the administering medical professional. All treatments should be performed as outlined by the administering medical professional.
- The amount of traction applied will always be dictated by the administering medical professional's diagnosis and the tolerances of the patient.
- Monitoring of the patient's response will help to determine the amount of traction force needed. The effectiveness of treatment should be evaluated according to relief of pain during treatment and not according to the magnitude of force applied.
- In certain cases, such as patients with sciatica, the use of the horizontal traction may be recommended. If applied and no change is experienced, stronger traction should be applied and the horizontal force readjusted. Occasionally (in less than 10% of patients), the patient may feel more pain with the use of horizontal force. In such cases, immediately discontinue the use of the horizontal force and continue with vertical traction.
- The procedure should be applied daily for 25-30 minutes. In severe cases, it may be applied twice daily.
- During the treatment, one or two adjustments in traction power are generally required to prevent slackening of traction and to maintain relief of pain.
- In chronic cases, the response to treatment may be less immediate and additional physiotherapy or other treatments may be required. Chronic patients will normally require more than 15 treatments.
- If, after three treatment sessions, the patient is not experiencing any improvement, discontinue treatment and re-evaluate the patient's condition. The patient may not be appropriate for this treatment.

7. RECOMMENDED TREATMENT TECHNIQUES

- **Malalignments of the apophyseal joints**

Only one or two treatments are needed.

- **Mild or moderate disc disorders, without sciatica**






Apply treatment immediately after onset of symptoms. A course of 12-15 daily treatment sessions is usually required. When the first treatment is applied two weeks or more after the onset of symptoms, or in cases with sciatica, 12 traction treatments are usually needed. In such cases, even if the patient is free of pain after the first few treatments, the treatment should be repeated at least 12 times in order to reduce the possibility of recurrence.

- **Long-standing cases with severe sciatica**

15 to 20 daily traction treatment sessions may be needed. If this treatment gives only partial relief, additional forms of treatment should be considered.

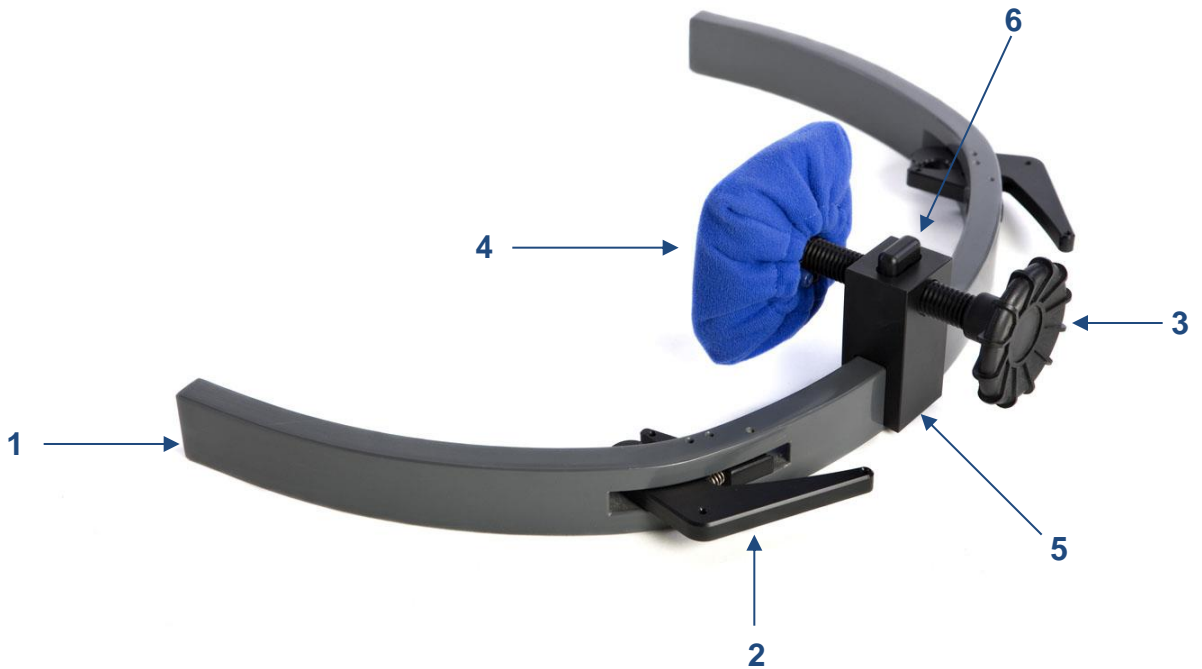
8. CARE AND MAINTENANCE OF YOUR VERTETRAC

While the Vertetrac applies powerful traction forces to the lumbar spine, it is a precision device that needs proper care. Make sure to follow these simple steps:

-  Be sure to handle the device gently.
-  Keep the device properly stored in the “zero position” in its original carrying bag when not in use.
-  Avoid exposing the device to water, excess humidity, or direct sunlight for extended periods of time.
-  Clean the device by wiping the plastic, polyurethane, and stainless steel parts with alcohol.
-  Don't tie the ratchet too close to the upper or lower frame of the device. it should be at the center of the patient's body.

In a clinical environment, it is recommended that spare sets of pads be kept on hand for convenience and comfort for the patient. You can order them from your D.B.S. and Vertetrac representative or directly from Meditrac.

9. PARTS OF THE D.B.S.



1. D.B.S. rail
2. Jaw clamps
3. Horizontal pressure screw
4. Horizontal pressure pad
5. Horizontal pressure bracket
6. Screw release button

10. INSTRUCTION FOR USE OF THE D.B.S.

Step 1: Remove the horizontal screw assembly of the Vertetrac by raising the upper frame and pulling the screw assembly upwards until it slides out of the lower frame. Place the horizontal screw assembly in the Vertetrac carrying case so that is readily available for the next use. Return the Vertetrac to the “Zero Position”.

Step 2: Attach the horizontal pressure bracket to the D.B.S. rail in the fully retracted “Zero Position”.

Step 3: Fasten the Vertetrac to the body according to the scoliosis level and begin applying vertical traction with the Vertetrac according to the Vertetrac instruction manual and the patient’s needs. Apply traction until the patient feels strong traction but little discomfort.

Step 4: Attach the D.B.S. rail to the Vertetrac by opening the two jaw clamps and placing the open jaws of the D.B.S. on the vertical traction rods of the Vertetrac in the position prescribed by the administering physician (**Fig. 12**). Allow the jaws to close firmly on the rods and apply a mild pulling force to check that it is securely positioned.



Fig. 12

Step 5: Adjust the vertical level of the D.B.S. rail and then make adjustments to the horizontal position of the horizontal pressure pad according to the patient's condition (**Fig. 13**), using the guidelines regarding treatment duration and frequency as previously outlined. Center the D.B.S. pad over the apex of the hump or over the convex side and use the horizontal pressure knob to apply force according to the tolerance of the patient (**Fig. 14**).



Fig. 13

- **C-Scolioses**

Apply asymmetrical traction force to ensure that the spine is straight during treatment. Place the horizontal pressure pad directly over the convex side (on the apical vertebra).

- **S-Scolioses/Double Compound**

Apply symmetrical traction force as firmly as possible.

- **Apical Vertebra at T-9 r Lower**

The upper frame of the Vertetrac should reach the angulus of the scapulae.

- **Apical Vertebra Above T-9**

The upper frame of the Vertetrac should reach the axillar fossa during traction (approximately Th-4). Supplementary cervical traction may be required in some cases.



Fig. 14

****** In complex cases or in cases where there is doubt that the D.B.S. treatment has been properly administered, it is recommended that the patient be X-rayed during the first treatment only. The spine should be at a level of 60-80% improvement.

Step 6: After treatment, carefully release the pressure of the pad by slowly turning the horizontal pressure screw counter-clockwise. After the pressure has been removed, release the traction forces of the Vertetrac according to the guidelines in the Vertetrac instructions. When the traction has been alleviated, open the jaw clamps and detach the D.B.S. rail from the vertical traction rods and remove the Vertetrac unit from the torso. Replace the Vertetrac horizontal screw assembly by inserting its vertical post into the slot in the bottom frame. Return the Vertetrac to the "Zero Position" so that it is ready for the next use.

11. NOTES ABOUT THE D.B.S.

It is imperative that the administering physician carefully read and become familiar with the preceding section of Vertetrac User's Guide before beginning treatment with the D.B.S.

The treatment of idiopathic scoliosis depends upon a number of factors, including the physiological age of the patient, the size and location of the curve, and the progress of the curve. Recommended treatment using the D.B.S. varies accordingly. Apply treatment based on the following criteria:








- Curves of less than 10° should not be considered idiopathic scoliosis.
- It is recommended to treat curves of less than 20° with the D.B.S. only when the patient suffers from continued lower back pain. In these cases, treatment is recommended once a day for 30 minutes, until the elimination of pain (about 15-20 treatments). An X-ray should be taken six months after the end of the treatment to ensure that the curve has not progressed.
- For curves of 20° - 30° in children who have no pain or other complaints, it is recommended to apply the D.B.S. treatment 2-3 times daily until maturity of the spine is reached. For these curves in children who do report pain, it is recommended to apply the D.B.S. treatment 3 times daily until the child reports no pain or until maturity of the spine is reached. For adults who report pain, it is recommended to apply the D.B.S. treatment once a day. Adults with curves of 20° - 30° who do not report pain should not receive the D.B.S. treatment. Patients should continue to receive treatments once a day for 2-3 years to prevent regression.

- Patients with curves of 30°-40° should begin D.B.S. treatment immediately, 3 times daily for 30 minutes until maturity of the spine is reached. Patients should continue to receive treatment 1-2 times daily for an additional 6 months, and once a day for 2-3 additional years.
- In all cases, X-rays should be taken every 3 months to monitor the progress of the treatment. If progression of the curve greater than 5° is discovered at any time, the patient should immediately begin to receive 3 daily treatments of 30 minutes each for 3 months. At the end of this time another X-ray should be taken, and if progression of the curve greater than 5° is discovered again, the administering medical professional should immediately re-evaluate the case.
- When applying traction with the Vertetrac and the D.B.S., apply as much traction as possible within the tolerances of the patient.

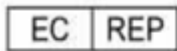
WARNING: The sale of this device is restricted to individuals by or on the order of a physician. The instructions provided by your health care provider should be followed precisely. Do not exceed the recommendations of your health care provider. Exceeding these recommendations may aggravate an existing condition or cause additional injury. Traction should never cause pain. A stretching sensation or some slight discomfort may be felt during treatment. If pain is increased in the neck, back, arms or legs, or if you experience dizziness, nausea or any other type of pain or discomfort during or after treatment, discontinue use immediately and consult your health care provider before further use.

12. CARE AND MAINTENANCE OF YOUR D.B.S.

While the D.B.S. applies powerful treatment forces to the spine, it is a precision device that needs proper care. In addition to the instructions for the care and maintenance of the Vertetrac, make sure to follow these simple steps:

-  Be sure to handle the device gently.
-  Remove the D.B.S. from the Vertetrac when not in use.
-  Keep the device properly stored in its original carrying bag.
-  Avoid exposing the device to water, excess humidity, or direct sunlight for extended periods of time.
-  Clean the device by wiping the plastic and polyurethane with a cloth dampened with alcohol.
-  Wipe the foam and polyurethane pads with alcohol after each use whether the unit is being used for one patient, two patients, or twenty patients.
-  In a clinical environment, it is recommended that spare sets of pads be kept on hand for the convenience and comfort of the patient. You can order them from your D.B.S. and Vertetrac representative or directly from Meditrac.

13. LABELS



Authorized Representative in the EU



CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician



Manufacturer



No Direct Sunlight



Keep Dry




Medical Device



Consult instructions for use

14. CONTACT INFORMATION

If you have any problems or questions regarding your Vertetrac or D.B.S., please contact us at:

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RPS/5269/2022

Meditrac's products carry the **FDA** and **ISO:13485**

and are registered with the United States Food and Drug Administration.

United States Federal Law permits the sale of these devices (within the US) by a doctor's prescription only



Vertetrac FDA: B-067323

Vertetrac UDI: 07290015711104

Vertetrac UDI-DI: 7290015711vertetracFS

D.B.S. FDA: B-067325

D.B.S. UDI: 07290015711302

D.B.S. UDI-DI: 7290015711D.B.S.H6

Model No. : VERT9

Model No.: DBS1

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