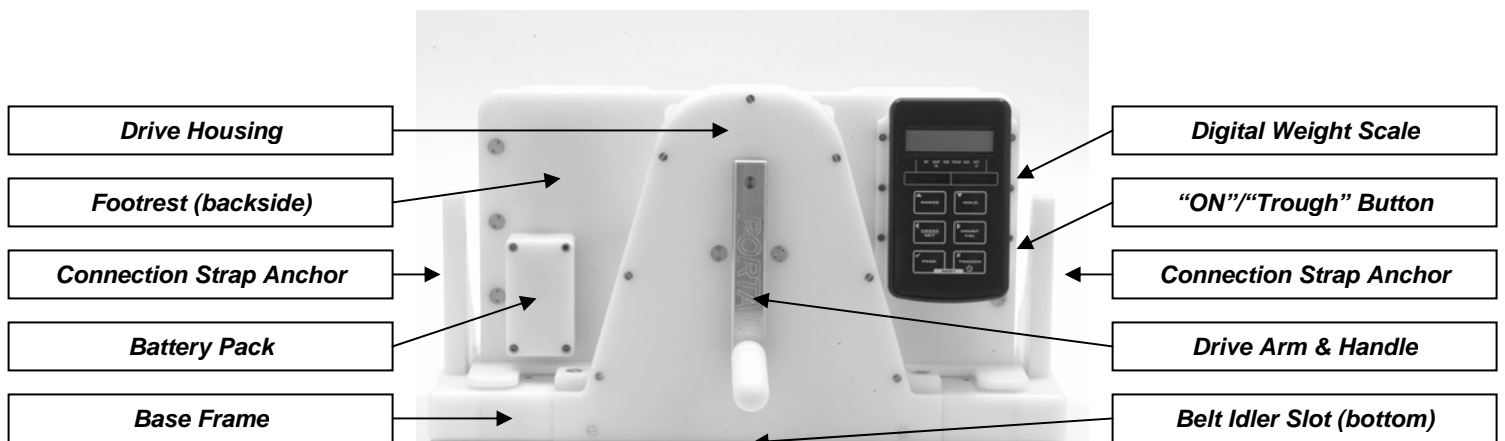
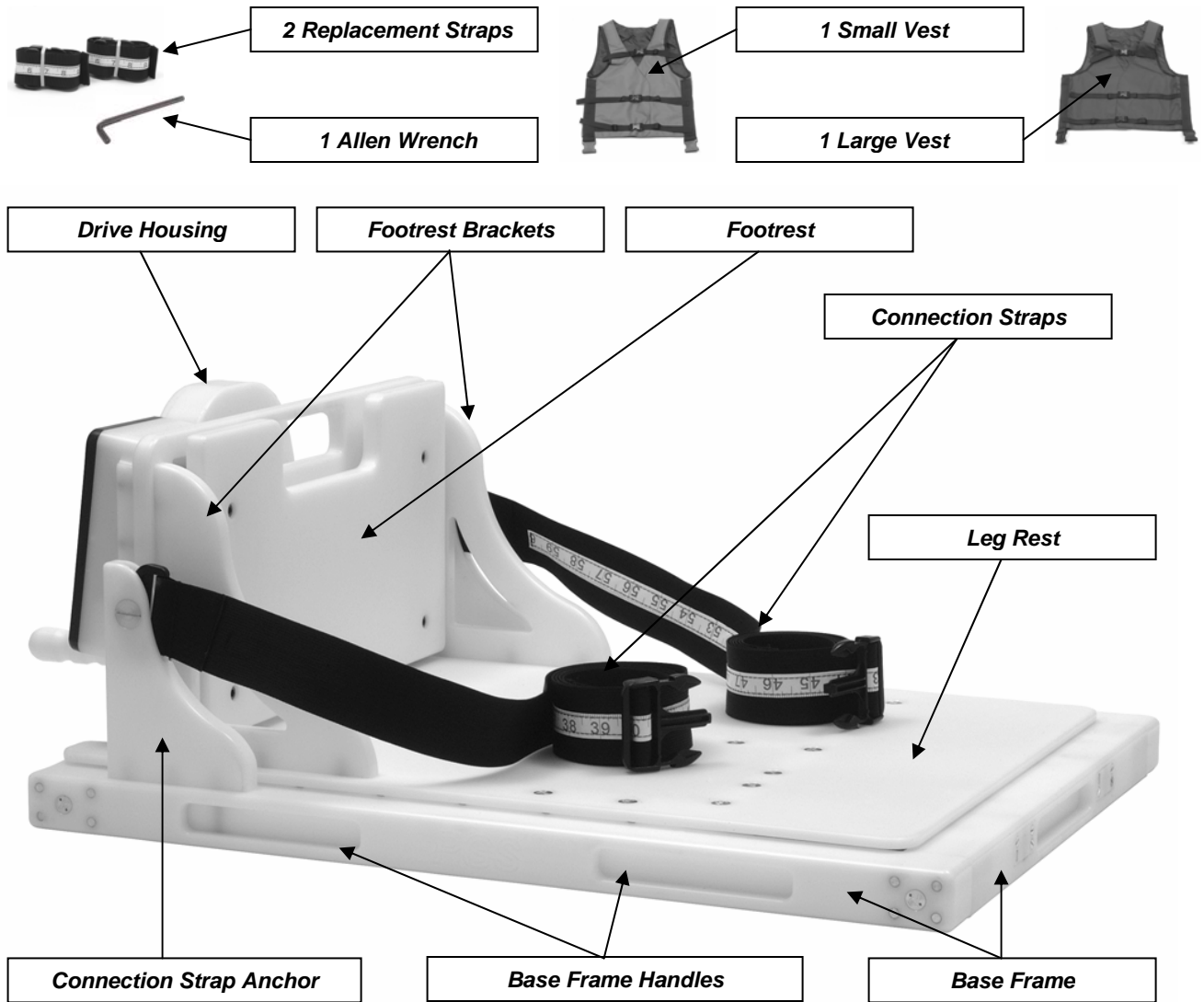


PGS SHIPPING CARTON CONTENTS

The PGS Shipping Carton contains the following:

A. The PGS axial compression accessory which is comprised of the components shown below:



DEVICE DESCRIPTION

The Portal Gravity System (PGS) is an accessory for diagnostic imaging equipment such as MRI and CT. The PGS has been developed to assist in diagnosing pathologies in the spinal column. The PGS places an axial load on a patient's spinal column during a diagnostic imaging procedure to provide an enhanced and more relevant diagnostic image of the spinal column. The PGS assists in identifying pathologies that may go undetected without axial compression.

INDICATIONS FOR USE

The Portal Gravity System is an accessory for axial compression of the spinal column in diagnostic imaging equipment for enhanced and more relevant diagnosis during research and clinical purposes.

A. CONTRAINDICATIONS/EXCLUSION CRITERIA

1. Severe osteoporosis;
2. Cancer;
3. Tumors of any kind;
4. Acute vertebral trauma;
5. Cardiopulmonary disease;
6. Trauma/abuse;
7. Psychiatric history;
8. Language illiterate individual;
9. Acute shoulder injuries;
10. Fractures;
11. Myofascia Syndrome;
12. Patient weighs over 350 lbs.

USING THE PGS

A. PRIOR TO THE AXIALLY LOADED EXAM

1. Preparing the patient for the axially loaded exam: An axially loaded diagnostic exam is something most patients have never experienced before. Consequently, it is important to adequately prepare patients for an axially loaded exam. When patients know what is happening and why, they are more relaxed and easier to work with during the exam. Prior to the axially loaded exam the technologist should explain the following to the patient:
 - A. The PGS will apply a load equal to 50% of the patient's body weight to the patient's spine to show pathologies that might otherwise go undetected;
 - B. The patient will feel pressure on the shoulder as if the patient is wearing a backpack;
 - C. The patient may feel some discomfort during the exam and may feel some tingling in the fingers and hands due to pressure on the brachial plexus;
 - D. The patient's symptoms may be recreated – particularly if the patient feels more pain while standing than while lying down;

- E. The axially loaded exam will last approximately 10 minutes;
 - F. At all times the patient has complete control over the load that is applied by the PGS and can release the load by simply bending her knees, however, if the patient can tolerate the discomfort or pain the additional information that is provided may be important to the treating physician.
2. Have the patient don the appropriate Patient Vest: Before the patient is placed on the exam table for the study, the patient must don a Patient Vest that will be connected to the PGS during the axially loaded exam.

Note: There are two sizes of Patient Vests provided with the PGS. The Small Vest is the light blue vest. See Figure 1. Its girth is adjustable from 36 inches to 56 inches and will accommodate most patients weighing below 230 lbs. The Large Vest is the navy blue vest. See Figure 2. Its girth is adjustable from 48 inches to 70 inches and will accommodate most patients weighing above 230 lbs., but below 350 lbs. Patients should wear the Patient Vest that provides the best fit during the exam. Patients with large chests may prefer to wear the Large Vest even if the Small Vest otherwise fits.

Figure 1



Figure 2



3. Place the PGS on the exam table: While the patient is putting on the appropriate Patient Vest the technologist should place the PGS on the end of the exam table. The PGS should be placed at approximately the location where the patient's feet will rest for the duration of the exam. See Figure 3. The Connection Straps should be moved to hang from the respective sides of the exam table to remain out the patient's way while becoming situated on the exam table.



Note: Depending on the patient's height, the type of coil used, and the surface of the exam table, it may be helpful to place a pad under the PGS.

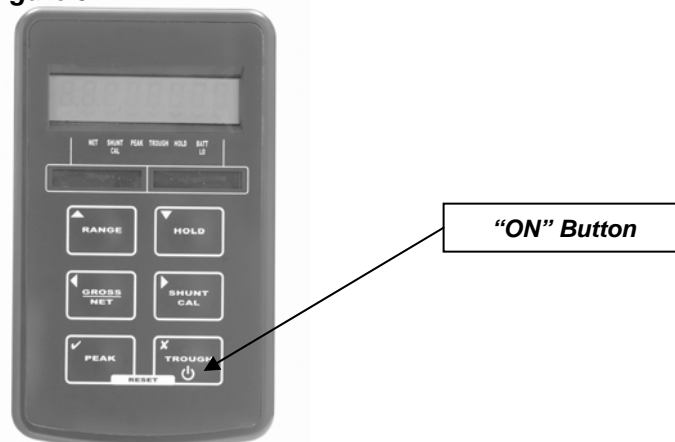
Precaution: The configuration of some MRI units requires that spinal exams conducted using the PGS be performed with the patient being introduced into the MRI head first.

4. Adjust the Patient Vest: Once the patient has donned the appropriate Patient Vest the technologist must ensure that the Patient Vest is properly adjusted. It is critical that the chest strap be securely fastened to position the shoulder harness pads of the vest as close to the patient's neck as possible without causing the patient discomfort. See Figure 4.



5. Place the patient on the exam table: While the patient is lying down on the exam table the technologist should ensure that the Patient Vest is not bunched or wrinkled behind the patient's back. Once the patient is lying on the exam table, the technologist should position the Patient Vest so the padded shoulder harness portion of the Patient Vest rests securely on the patient's shoulders. This may require the technologist to assist the patient in pulling the Patient Vest downward.
6. Activate the Digital Weight Scale: The technologist should locate the "ON" Button on the face of the Digital Weight Scale. See Figure 5. The technologist should press and hold the "ON" Button for 4 seconds until the LCD on the Digital Weight Scale is activated. Once the Digital Weight Scale has been activated the technologist should wait until the Digital Weight Scale displays an active weight reading (see Figure 7) before proceeding. For additional instruction on the operation of the Digital Weight Scale, see the section entitled Operation of Digital Weight Scale located below.

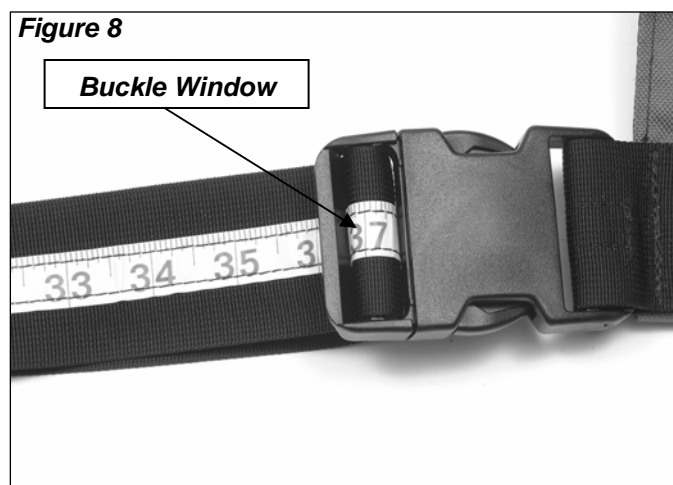
Figure 5



7. Remove pillows or other leg support. Any pillow or other support must be removed from beneath the patient's knees and the patient should straighten her legs until her knees are in the locked position prior to applying any axial load.
8. Move PGS to the patient's feet: Once the patient is comfortably situated on the table, the technologist should proceed to slide the PGS toward the patient until the soles of the patient's feet rest flat against the Footrest.
9. Attach Connection Straps to Patient Vest. Once the soles of the patient's feet are resting securely against the Footrest, the technologist should buckle the Connection Straps to the respective buckles located on each side of the Patient Vest. The technologist should proceed to pull the Connection Straps through the corresponding buckles until the Connection Straps are taut (see Figure 6) and the Digital Weight Scale reads between 25 and 30 lbs. See Figure 7.



10. Ensure the axial load is evenly distributed on the patient's shoulders. Once the technologist has pulled the Connection Straps taut, the technologist should ensure that the axial load will be evenly distributed on the patient's shoulders. The technologist should first refer to the numbers showing in the Buckle Windows (which indicate the adjusted length of the Connection Straps) on each of the Connection Straps to ensure that they are approximately same. See Figure 8. The technologist should then ask the patient if the load feels evenly distributed on her shoulders.



11. Position the patient for axially loaded exam: Once the patient is comfortably situated, she should be positioned for the axially loaded exam.
 - A. The technologist should instruct the patient to lie still while the full axial load is applied.

Note: To maximize patient comfort and minimize patient movement during the scan it is recommended that the patient lie with her hands folded across her chest or abdomen. Alternatively the patient may lie with her hands at her side.

12. Apply the axial load: Once the patient has been positioned for the axially loaded exam, the technologist should apply the full axial load using the PGS as follows:
 - A. The technologist should explain once again that he is going to apply a load to the patient's spine equal to 50% of the patient's body weight;

Precaution: The PGS Digital Weight Scale measures in lbs.

Precaution: Patients weighing above 350 lbs. should not be loaded on the PGS.

- B. The technologist should rotate the Drive Handle in a clockwise direction (See Figure 9) until the desired weight is indicated on the Digital Weight Scale (See Figure 10);



Figure 9

Figure 10



Precaution: The Footrest is able to travel toward the patient along the Base Frame for 4 ½ inches. Once the Footrest has traveled the full 4 ½ inches it reaches an internal hard-stop that prevents the application of any additional axial load to the patient. As the axial load is applied to the patient the technologist must pay attention to ensure that the internal hard-stop has not been reached. If the Digital Weight Scale shows no that no additional weight is being applied even though the technologist continues to rotate the Drive Handle, the internal hard stop has been reached. If this occurs before the desired weight has been reached, the technologist must reverse the rotation of the Drive Handle until the entire load is completely removed from the patient and the Footrest has returned to its resting position aligned with the brass screws

at the base of the Drive Housing. Once the Footrest is in its resting position the technologist must re-tighten the Connection Straps and re-apply the weight as indicated in Step 2.

- C. Once the desired weight is indicated on the Digital Weight Scale (Example: 110 lbs. for a 220 lbs. person), the technologist should instruct the patient to take a few deep breaths and relax for 10-15 seconds;
- D. After 10-15 seconds have passed the technologist should re-check the Digital Weight Scale and adjust the weight accordingly.

B. AFTER THE AXIALLY LOADED EXAM

- 1. After the axially loaded exam has been completed the technologist should release the axial load by rotating the Drive Handle in a counter-clockwise direction until the axial load has been completely removed from the patient.
- 2. Once the patient is out of the diagnostic imaging unit, and the entire axial load has been removed from the patient, the technologist should unbuckle the Connection Straps from the Patient Vest and allow the patient to stand up and remove the Patient Vest.
- 3. Before the PGS is used again the technologist must return the Footrest to its resting position by turning the Drive Handle counter-clockwise until the Footrest has returned to its resting position aligned with the brass screws at the base of the Drive Housing and Footrest

OPERATION OF DIGITAL WEIGHT SCALE



- A. To activate the Digital Weight Scale press and hold the “ON” or “Trough” Button located on the bottom of the right hand column of buttons. Hold the “ON” Button for 4 seconds or until the LCD is activated.
- B. Before proceeding wait approximately 5 seconds until the Digital Weight Scale displays an active weight reading. See Figure 7.
- C. Once an active weight reading is displayed proceed to apply a load according the instructions shown above.
- D. **DO NOT PRESS OTHER BUTTONS ON THE DIGITAL WEIGHT SCALE** – Pressing the other buttons on the Digital Weight Scale may cause it to display unfamiliar menus or results.
- F. If the Digital Weight Scale displays unfamiliar menus, results or does not respond to increased load, to reach the correct display simply press the “ON” or “Trough” Button slowly and repeatedly until the Digital Weight Scale displays an active weight reading (see Figure 7) or until the Digital Weight Scale deactivates.
- G. The Digital Weight Scale will automatically deactivate after 5 minutes.

PGS STORAGE & MAINTENANCE

- A. **STORING THE PGS:** The PGS should be stored in a dry environment at temperatures consistently between 50 and 90 degrees Fahrenheit.
- B. **TRANSPORTING THE PGS:** To adequately protect the PGS during transport place it in its original shipping carton and foam core and seal the carton with shipping tape.
- C. **MAINTENANCE & CLEANING:** The PGS is intended to be a maintenance-free device and if it is stored and transported properly, is extremely durable. However, the surface of the PGS may become soiled with use and may require occasional cleaning. To clean the PGS and the Large and Small Vests simply use a warm, damp cloth to wipe clean. Alternatively, ammonia based cleaners may be used to clean tougher stains.
- D. **REPLACING THE BATTERIES:** Prior to replacing the batteries, remove the PGS from the MRI suite and away from all magnetic fields. Only after the PGS has been fully moved out of the MRI suite and away from all magnetic fields is it safe to replace the batteries. Using the Allen Wrench provided with the PGS, remove the screws securing the Battery Pack Cover. Remove and appropriately discard the old batteries from the Battery Pack and replace with new AA batteries. Once new batteries have been installed in the Battery Pack securely re-fasten the Battery Pack Cover.

Warning: The batteries in the PGS are not MRI-safe. If the batteries are removed or are not properly secured in the Battery Pack while in or near a magnetic field, the batteries may be pulled into the magnetic field and may cause them to become potentially deadly projectiles.

Warning: The Allen Wrench provided with the PGS is not MRI-safe and should not be used in or in the proximity of MRI units. If the Allen Wrench is taken into or near a magnetic field, the Allen Wrench may be pulled into the magnetic field and may cause it to become a potentially deadly projectile.

PRODUCT WARRANTY

Portal, Inc. (Portal), warrants the Portal Gravity System (Product) to be free from defects in workmanship and material, under normal use and service conditions, for a period of one (1) year from the date of purchase.

This warranty extends only to the original purchaser of the Product at the original location to which the Product was delivered by Portal. Portal's obligation under this warranty is limited to replacing or repairing, at Portal's option, the Product by one of its authorized representatives. All repairs for which warranty claims are made must be pre-authorized by Portal. If the Product is shipped to a service center, freight charges to and from the service center will be the customer's responsibility. This warranty does not extend to any Product or damage to a Product caused by or attributable to transporting the Product; abuse, misuse, improper or abnormal usage or repairs not provided by an authorized Portal representative; Products used for rental purposes; or Products used as demonstration models. No other warranty beyond that specifically set forth herein is authorized by Portal.

Portal is not responsible or liable for indirect, special or consequential damages arising out of or in connection with the use or performance of the Product or damages with respect to any economic loss, loss or property, loss of revenues or profits, loss of enjoyment or use, costs of removal or installation or other consequential damages of whatsoever nature. Some states do not allow the exclusion or limitation of incidental or consequential damages. Accordingly, the above limitation may not apply to you.

The warranty extended hereunder is in lieu of any and all other warranties and any implied warranties of merchantability or fitness for a particular purpose is limited in its scope and duration to the terms set forth herein. Some states do not allow limitations on how long an implied warranty lasts. Accordingly, the above limitation may not apply to you.

This warranty gives you specific legal rights. You may also have other rights which may vary from state to state.

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