positioning
patients for life.®

PRODUCT GUIDE & USER MANUAL

RT-4558CB02

ZiFix™ Abdominal/Thoracic Motion Control System

Qfix | 440 Church Road | Avondale, Pennsylvania 19311 USA | +1 484-720-6053 | +1 610-268-0588 | www.Qfix.com

CE

EC REP	Advena Limited Tower Business Centre, 2nd Flr Tower Street, Swatar, BKR 4013 Malta	Made in the USA by Qfix 440 Church Rd, Avondale, Pennsylvania, USA +1 484-720-6053 www.Qfix.com

ZiFix is a trademark of Qfix.

Cidex is a registered trademark of Johnson & Johnson.

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GENERAL PRECAUTIONS

WARNING STATEMENTS

! WARNING ! NO MODIFICATION OF THIS EQUIPMENT IS ALLOWED. IF ANY PART OF THIS DEVICE EXPERIENCES A CATASTROPHIC LOAD, APPEARS DAMAGED OR FUNCTIONS IMPROPERLY, DISCONTINUE USE IMMEDIATELY AND CONTACT QFIX AT +1 484-720-6053 OR TECHSUPPORT@QFIX.COM.

! NOTE ! This device is to be used as reference only and should not be used in any other application.

! NOTE ! During normal operation, fluctuation of 10 mmHg, can be expected.

! NOTE ! It is recommended to re-inflate the bladder to its initial pressure after 2 minutes of initial inflation by opening the shutoff valve, squeezing the manometer bulb, and shutting the shutoff valve.

SERIOUS INCIDENTS

Please report any serious incidents (e.g. incidents which result in or have the potential to result in death or serious injury) to both Qfix and your country's Competent Authority.

SAFETY INFORMATION

In order to use the **ZiFix Abdominal/Thoracic Motion Control System** accurately and safely, the user must have the necessary expertise in a hospital setting.

To ensure safe use of the **ZiFix Abdominal/Thoracic Motion Control System**, it is recommended that the users are educated and trained on the safe operation of the product prior to use.

TREATMENT BEAM ATTENUATION

The Qfix ZiFix Abdominal/Thoracic Motion Control System will attenuate a radiotherapy beam. Actual attenuation based on setup should be verified with your particular equipment. Attenuation and increased skin dose should be taken into account during planning and treatment.

GENERAL PRECAUTIONS

MRI SAFETY INFORMATION

! NOTE ! Refer to page 9 for MR configurations.

⚠ Non-clinical testing has demonstrated the **Manometer Pump** is MR Conditional. This device may be used in an MR system under the following conditions:

- **Static magnetic field of 3T or less.**
- **You must disconnect the Manometer Pump from the device before scanning and remove the Manometer Pump from the patient table.**
- **Prior to scanning, you must move the manometer pump into gradient fields no greater than 200 mT (2000G), i.e. weaker gradient sections, of the magnetic field of the MRI scanner.**
- **If the magnetic field strength lines in your room configuration are not known, disconnect and remove the Manometer pump from the MR room prior to scanning. Consult the user manual for your MR system for information regarding magnetic field strength and spatial gradients for your system.**
- Once the above conditions are met, the **ZiFix Abdominal/Thoracic Motion Control System and associated components** may be used in an MR system meeting the following conditions outlined below.

⚠ Non-clinical testing has demonstrated the **Carrying Case** is MR Conditional. This device may be used in an MR system meeting the following conditions:

- **Static magnetic field of 3T or less.**
- **Prior to scanning, you must move the carrying case into gradient fields no greater than 200 mT (2000G), i.e. weaker gradient sections, of the magnetic field of the MRI scanner.**
- **If the magnetic field strength lines in your room configuration are not known, disconnect and remove the Carrying Case from the MR room prior to scanning. Consult the user manual for your MR system for information regarding magnetic field strength and spatial gradients for your system.**
- Once the above conditions are met, the **ZiFix Abdominal/Thoracic Motion Control System and associated components** may be used in an MR system meeting the following conditions outlined below.

GENERAL PRECAUTIONS

⚠ Non-clinical testing has demonstrated the **ZiFix Abdominal/Thoracic Motion Control System** is MR Conditional. Once the conditions for the **Manometer Pump** and the **Carrying Case** are met, the **ZiFix Abdominal/Thoracic Motion Control System** may be used in an MR system meeting the following conditions:

- **Static magnetic field of 3T or less.**

MR Non-clinical testing has demonstrated the **Compression Bladder Assemblies** are MR Safe. Once the conditions for the **Manometer Pump** and the **Carrying Case** are met, the **Compression Bladder Assemblies** may be used in an MR environment.

MR Non-clinical testing has demonstrated the **Compression Belt Straps** are MR Safe. Once the conditions for the **Manometer Pump** and the **Carrying Case** are met, the **Compression Belt Straps** may be used in an MR environment.

MR Non-clinical testing has demonstrated the **Compression Paddles** are MR Safe. Once the conditions for the **Manometer Pump** and the **Carrying Case** are met, the **Compression Paddles** may be used in an MR environment.

MR Non-clinical testing has demonstrated the **Compression Belt Buckles** are MR Safe. Once the conditions for the **Manometer Pump** and the **Carrying Case** are met, the **Compression Belt Buckles** may be used in an MR environment.

! WARNING ! THE USE OF QFIX REPLACEMENT PARTS IS RECOMMENDED TO ENSURE THE SAFETY, PERFORMANCE, AND MRI COMPATIBILITY OF THE PRODUCT(S), AS WELL AS TO MAINTAIN APPLICABLE WARRANTIES.

! WARNING ! USE OF UNAPPROVED MR ACCESSORIES MAY RESULT IN:

- **Injury to patient**
- **Damage to equipment**

GENERAL PRECAUTIONS

WARNING LABELS & DESCRIPTIONS

Refer to Qfix.com for a listing of symbols and their definitions.

MR CONDITIONAL

An item with demonstrated safety in the MR environment within defined conditions.

These conditions are defined on pages 5 & 6 in the MRI Safety Information section.

MR SAFE

An item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically non-conductive, nonmetallic and nonmagnetic.

125 mmHg MAX

PRESSURE RATING

The maximum recommended pressure for the Compression Bladder is 125 mmHg. Refer to the Operating Instructions section of this IFU for bladder inflation directions. DO NOT exceed the maximum pressure rating.

INTENDED USE

The **ZiFix Abdominal/Thoracic Motion Control System** is intended to apply abdominal compression for managing internal body motion during respiration while maintaining maximum comfort to the patient. The **ZiFix Abdominal/Thoracic Motion Control System** is also intended to promote shallow breathing, in radiation therapy or radiology.

! NOTE ! United States Federal law restricts this device to sale by or on the order of a physician.

PATIENT TARGET GROUPS

Patients undergoing radiation therapy or diagnostic imaging procedures.

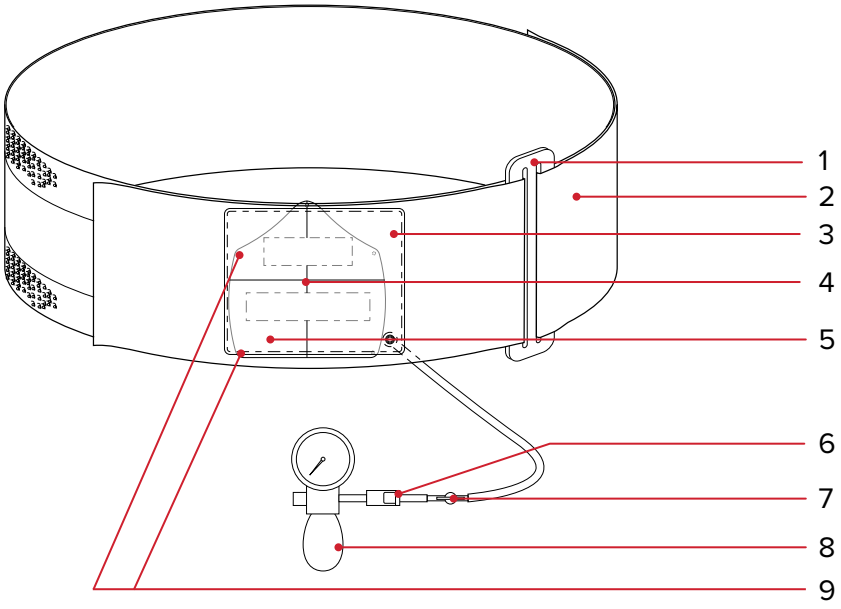
INTENDED USERS

The intended user for the products is a person qualified in accordance with the requirements of the regulatory region.

FEATURES

ZIFIX ABDOMINAL/THORACIC MOTION CONTROL SYSTEM

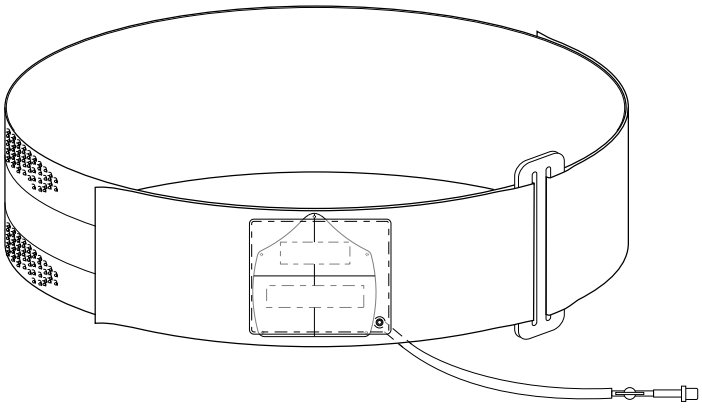
MR Conditional



1. **Compression Belt Buckles**
   - 13 cm
   - 20 cm
2. **Compression Belt Straps**
   - 130 cm x 13 cm
   - 170 cm x 13 cm
   - 170 cm x 20 cm
3. **Compression Bladder Assemblies**
   - 13 cm
   - 20 cm
4. **Alignment Lines**
5. **Compression Paddles**
   - 13 cm
   - 20 cm
6. **Quick Disconnect Fitting**
7. **Shutoff Valve**
8. **Manometer Pump**
9. **Virtual Indexing Marks**

ZIFIX ABDOMINAL/THORACIC MOTION CONTROL SYSTEM WITH MANOMETER REMOVED

MR Safe



OPERATING INSTRUCTIONS

SETUP

Initial Assembly

1. Determine the appropriate size belt, bladder and paddle for the patient (Fig. 1).

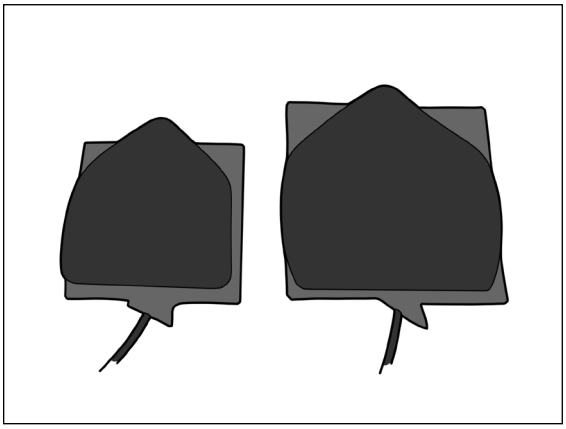


Fig. 1

2. Ensure paddle is appropriately aligned for attachment to the bladder (Fig. 2). Align hook-and-loop fastener.

! NOTE ! If using the white alignment lines on the paddle, complete alignment prior to attaching bladder. The alignment lines are for reference use only.

! NOTE ! The virtual indexing marks may be used to verify location in imaging. The virtual indexing marks are for reference use only.

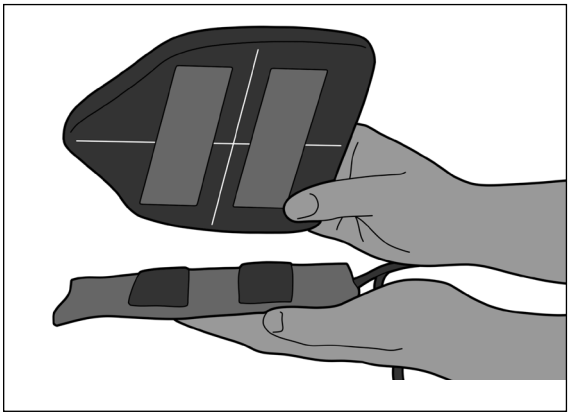


Fig. 2

OPERATING INSTRUCTIONS

POSITIONING ON PATIENT

1. Position belt behind patient with numbers facing up. Position belt with most of the length opposite the side of the planned treatment area (Fig. 3).

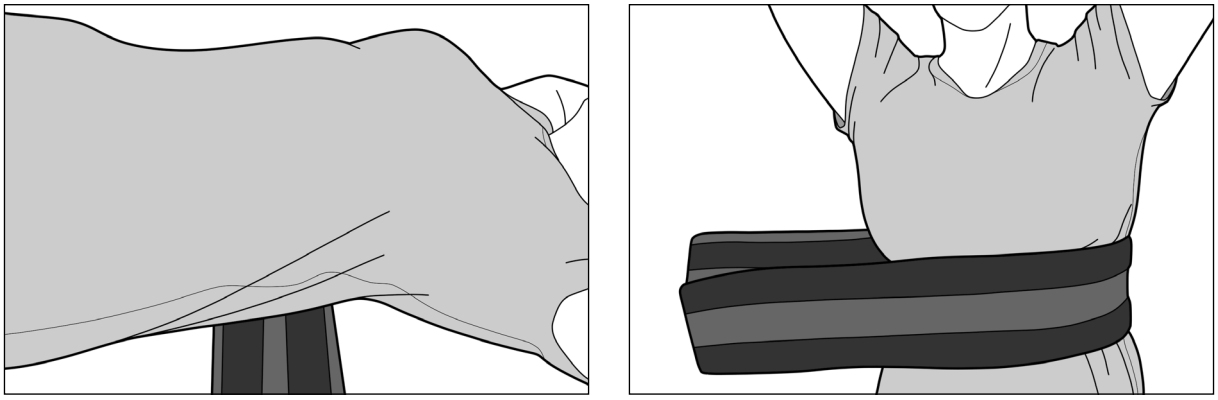


Fig. 3

2. Position paddle and bladder on patient with the tip of the paddle aligned with the patient's sternum and below xiphoid process (Fig. 4).

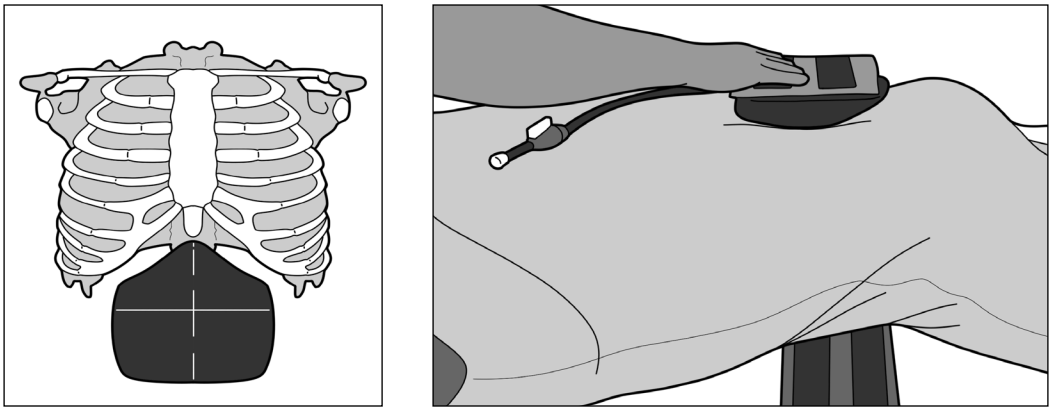
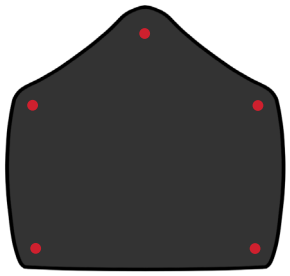


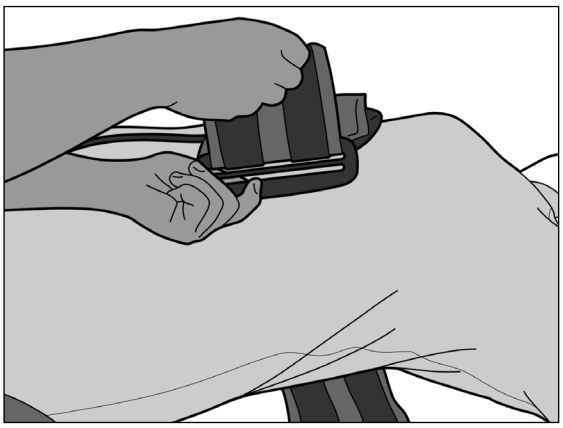
Fig. 4

! NOTE ! The five (5) fiducial markers located around the perimeter of the paddle may be used to aid in patient setup relative to patient anatomy under CT or X-ray imaging.



OPERATING INSTRUCTIONS

3. Feed the long end of belt through buckle. Return the belt on itself ensuring the full length of the hook is engaged on the loop (Fig. 5).



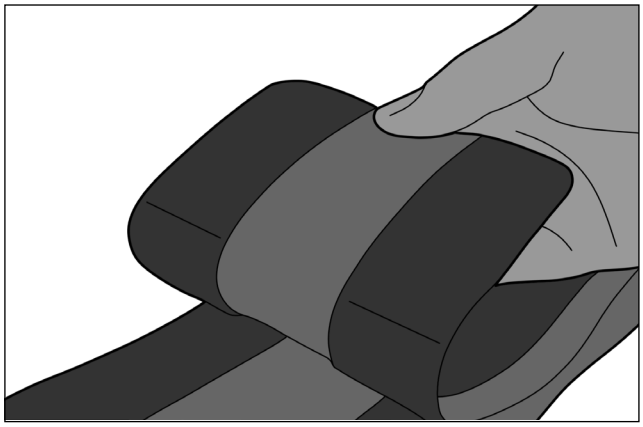
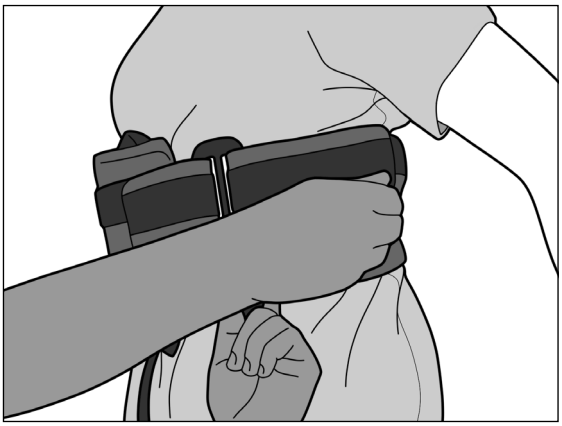


Fig. 5

4. Pull the shorter end of the belt over bladder & paddle assemblies. Ensure the loop on the belt aligns and engages with the hook on the bladder. Repositioning the belt under the patient may be necessary.

! NOTE ! Tighten belt as patient tolerance will allow (Fig. 6).



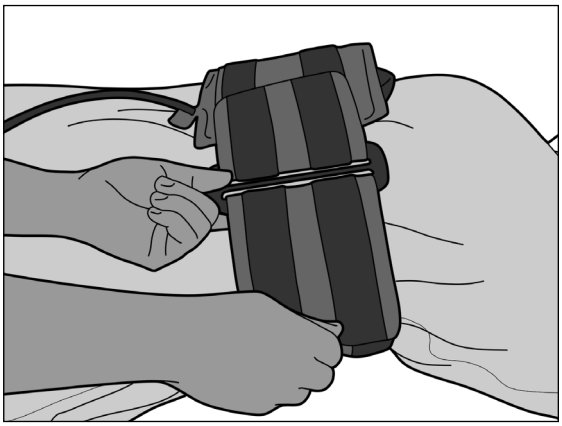


Fig. 6

5. Engage the “Quick Disconnect Fitting” of the pump to the “Quick Disconnect Fitting” of the bladder (Fig. 7).

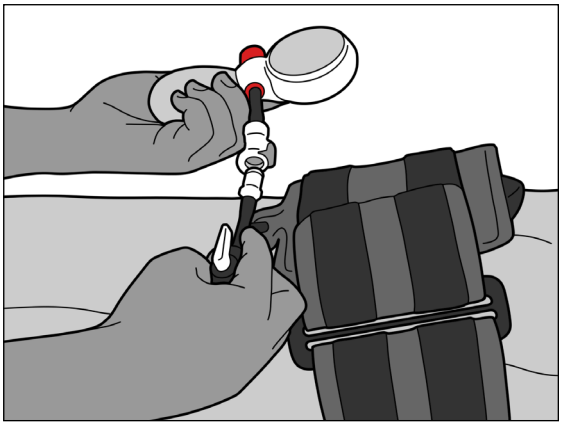


Fig. 7

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OPERATING INSTRUCTIONS

INFLATING/DEFLATING BLADDER

1. First close the valve by rotating the knob towards you (Fig. 8).

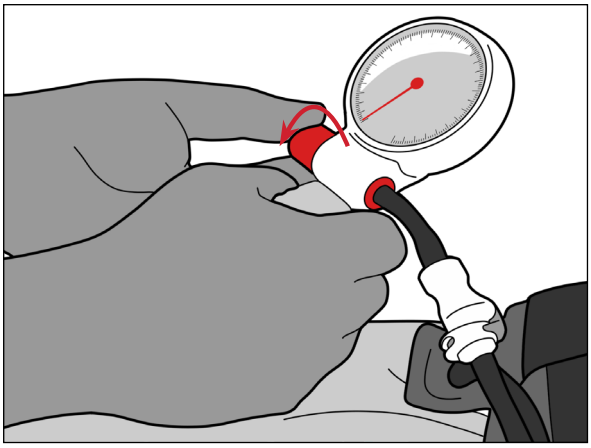

Fig. 8

2. Ensure that the shutoff valve is open. The valve handle should be in-line with tubing (Fig. 9).

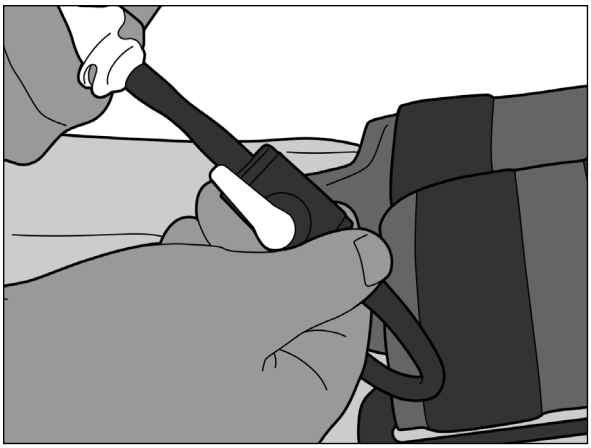

Fig. 9

OPERATING INSTRUCTIONS

3. Inflate the bladder to desired pressure by squeezing the bulb repeatedly (Fig. 10).

! WARNING ! DO NOT INFLATE BLADDER PRESSURE BEYOND 125 MMHG

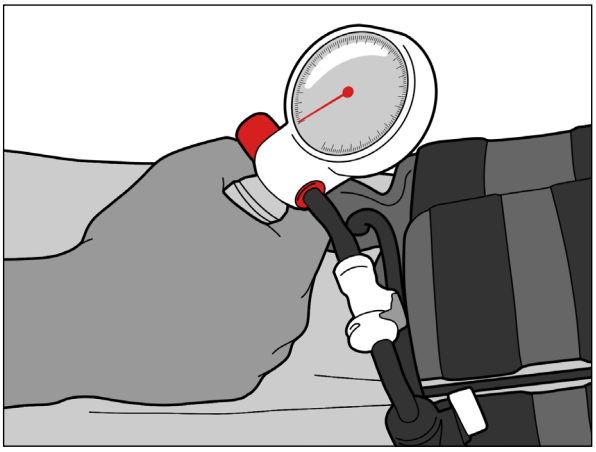

Fig. 10

4. Close the valve by turning the shutoff valve perpendicular to tubing. Wait 2 minutes (Fig. 11).

! NOTE ! It is recommended that the bladder is re-inflated to its initial pressure after 2 minutes of initial inflation.

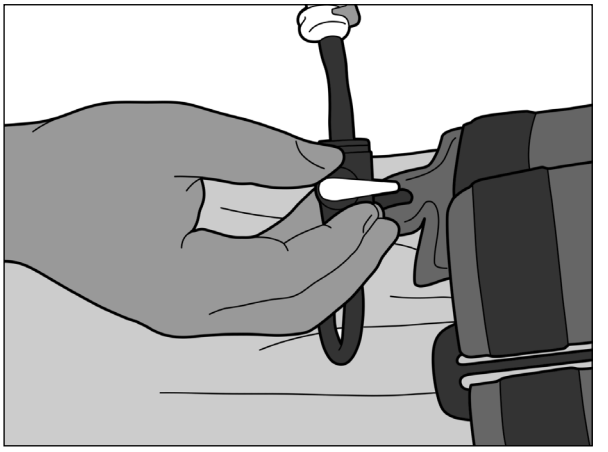

Fig. 11

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5. After 2 minutes, open the valve by turning valve in-line with tubing (Fig. 12).

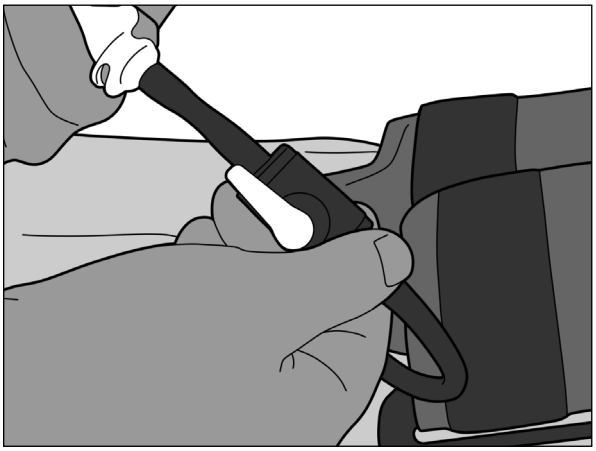

Fig. 12

6. Inflate the bladder to desired pressure by squeezing the bulb repeatedly (Fig. 13).

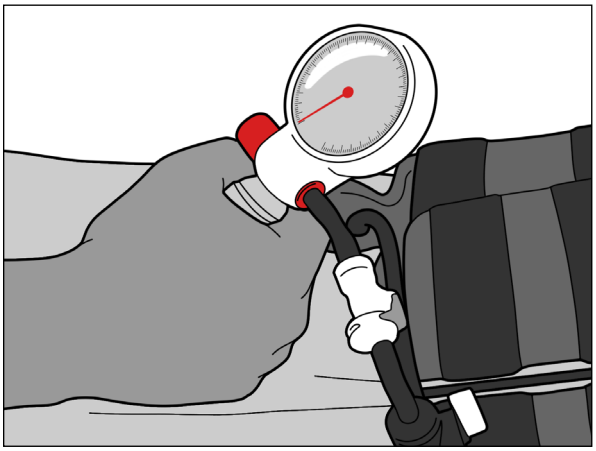

Fig. 13

7. Close the valve by turning the shutoff valve perpendicular to tubing (Fig. 11).

! NOTE ! Record manometer readout.

! WARNING ! MAX BLADDER PRESSURE 125 MMHG

! WARNING ! THE PUMP MUST BE DISENGAGED VIA THE "QUICK DISCONNECT FITTING" AND REMOVED FROM THE PATIENT TABLE BEFORE SCANNING OR TREATMENT.

OPERATING INSTRUCTIONS

REMOVE PUMP FROM BLADDER

1. Verify shutoff valve is perpendicular to tubing (Fig. 14).

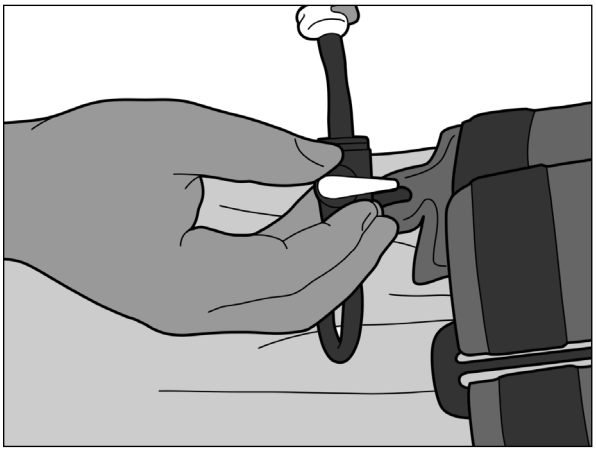

Fig. 14

2. Disconnect the Quick Disconnect Fitting by pressing the grey button on the Quick Disconnect Fitting (Fig. 15).

! NOTE ! Expect a small decrease in pressure if pump is reconnected and valve is reopened.

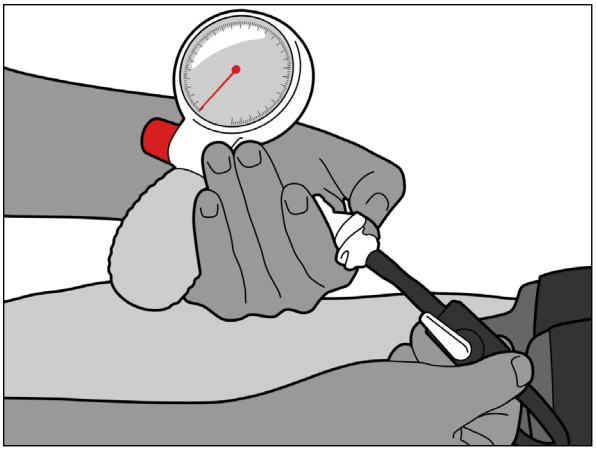

Fig. 15

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OPERATING INSTRUCTIONS

DEFLATING THE BLADDER

1. Disconnect Quick Disconnect Fitting. Open shutoff valve and release the air from the bladder (Fig. 16 & 17).

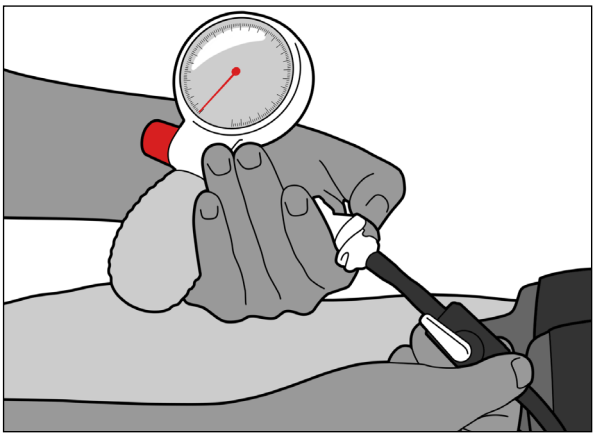


Fig. 16

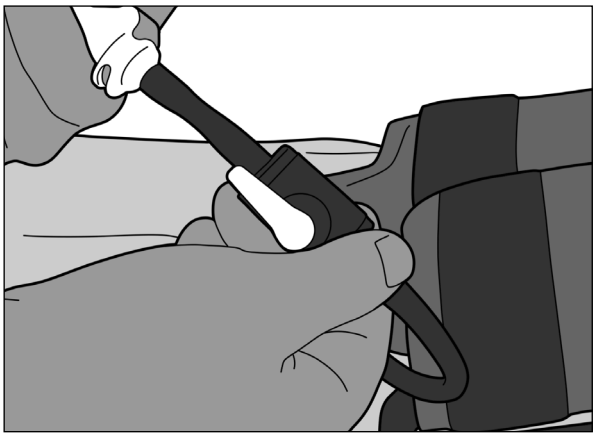


Fig. 17

—OR—

2. Rotate knob away from you (Fig. 18).

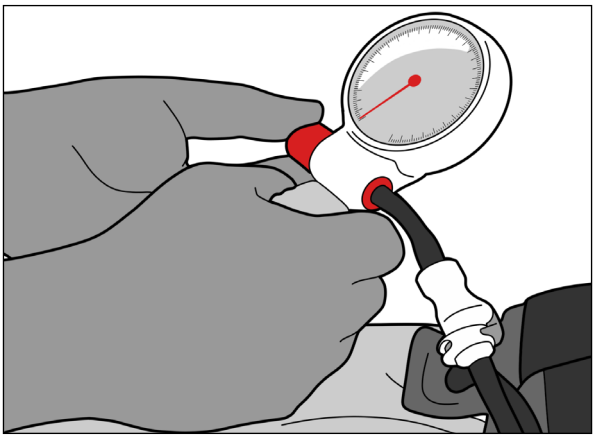


Fig. 18

! NOTE ! The instructions listed above are the exemplary method. Other setup workflows (i.e. lying down or standing) may be acceptable in achieving the desired immobilization. Ensure all warning and precautions are observed. Always ensure appropriate alignment of the device and verify setup is correct prior to initiation of treatment.

MAINTENANCE

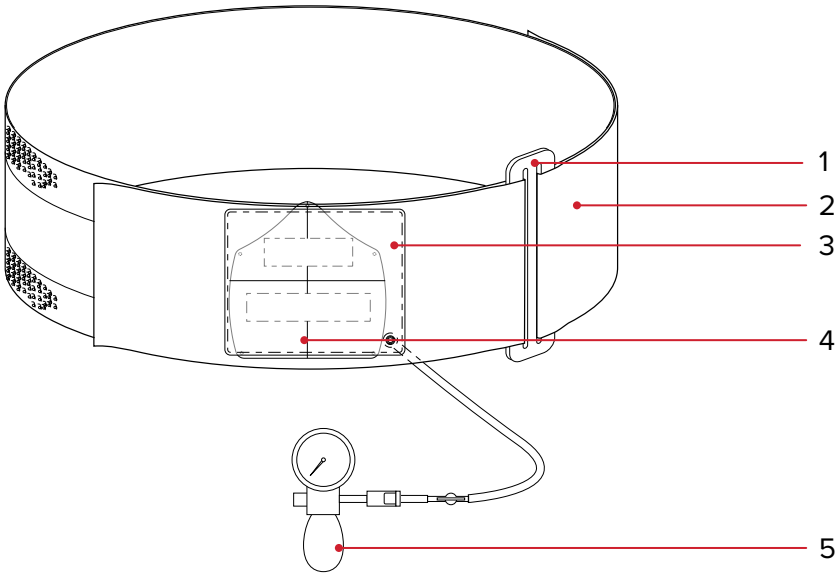
The **ZiFix Abdominal/Thoracic Motion Control System** can be cleaned using standard cleaning practices and common WATER-BASED hospital cleaning agents. The following cleaning materials have been tested and found to be appropriate:

- Cidex® 2.4% Activated Dialdehyde Disinfecting Solution
- Soap and Water
- Isopropyl Alcohol

DO NOT use other solvents to clean the device.

The gauge should be cleaned with a soft, dry cloth.

PARTS LIST



1. **Compression Belt Buckles**
   - 13 cm – 2007408
   - 20 cm – 2007407
2. **Compression Belt Straps**
   - 130 cm x 13 cm – 2007416
   - 170 cm x 13 cm – 2007263
   - 170 cm x 20 cm – 2007262
3. **Compression Bladder Assemblies**
   - 13 cm – 2007544
   - 20 cm – 2007545
4. **Compression Paddles**
   - 13 cm – 2007495
   - 20 cm – 2007496
5. **Manometer Pump**
   - 2007700

SETUP SHEET

ZIFIX ABDOMINAL/THORACIC MOTION CONTROL SYSTEM RT-4558CB02

Patient Name:

Patient ID #: Setup by:

Physician: Date:

Comments:

Belt used: ☐ 130 cm x 13 cm ☐ 170 cm x 13 cm ☐ 170 cm x 20 cm

Location for Left:

Location for Right:

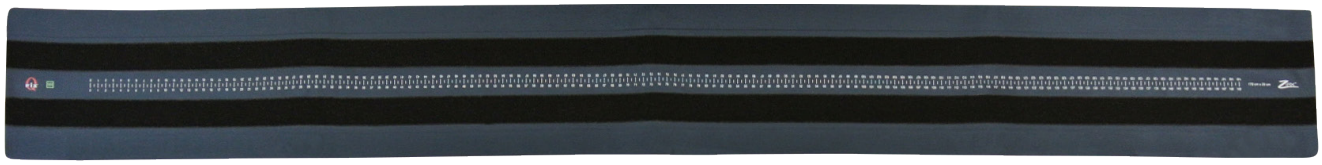
Manometer readout: mmHg (FOR REFERENCE ONLY) (Pressure fluctuation of about 10 mmHg is normal)

Notes:

CARRYING CASE SETUP

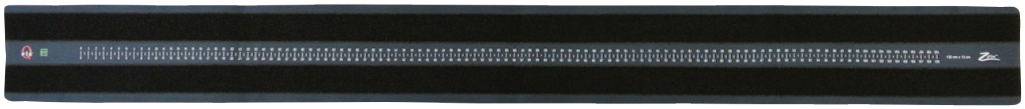
The following items may be stored in the ZiFix carrying case.

Compression Belt Straps 20 cm x 170 cm



Compression Belt Straps 13 cm x 170 cm

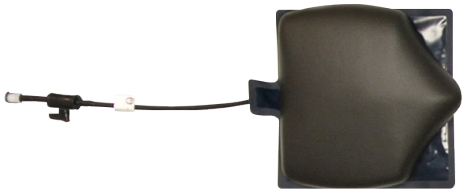
Compression Belt Straps 13 cm x 130 cm



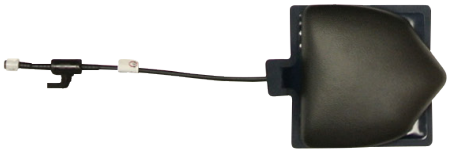
13 cm 20 cm

Compression Belt Buckles

Manometer Pump



20 cm Compression Paddles



13 cm Compression Paddles

CARRYING CASE SETUP

1

2

3

4

5

Buckles

6

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