B4000 Bed System Measurement Device

INSTRUCTIONS FOR USE

MADE IN THE USA

©2026 Bionix LLC | 1670 Indian Wood Circle
Maumee, Ohio 43537 | United States
Phone: 800.551.7096 (+1 419.727.8421)
Fax: 800.455.5678 (+1 419.727.8426)
Email: bionix@bionix.com (international@bionix.com)
www.bionix.com | RM95-4000 | Rev. 01

bionix®

Introduction

In 2006 the FDA, with the help of the Hospital Bed Safety Workgroup issued a guidance document entitled, “Hospital Bed System Dimensional Guidelines to Reduce Entrapment”. These guidelines aid in the design of new bed systems and assess entrapment risks associated with hospital bed systems. In response to these guidelines, Bionix offers the innovative Bed System Measurement Device.

Test Methods

Zone 1:
Potential head entrapment within the rail ..... **Page 4**
Zone 2:
Potential head entrapment between the bottom of the rail and the top of the compressed mattress, and between the rail supports or next to a single support ..... **Page 6**
Zone 3:
Potential head entrapment between the edge of the mattress and the inside of the rail ..... **Page 8**
Zone 4:
Potential neck entrapment between the top of the compressed mattress and the bottom of the rail at the end of the rail ..... **Page 10**

Assemble and Disassemble the Cone and Cylinder Tool

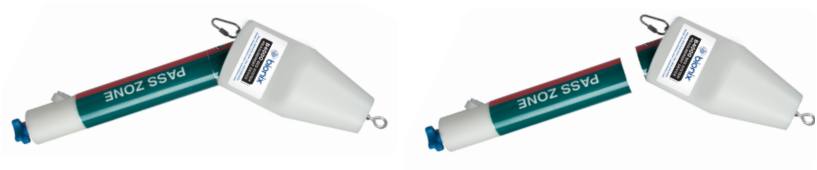

Figure 1: Assembly and disassembly of the cone and cylinder tool.

To assemble:

1. Align the red and green areas of the cone and cylinder.
2. Insert the connection shaft of the cone into the cylinder.
3. Turn the connection knob to tighten.

To disassemble:

1. Turn the knob to fully loosen and remove the connection shaft.
2. Pull the cylinder from the cone.

Digital Scale

Use the digital scale to apply 12 lbs (5.44 kg) of force to the cone in Tests 1 and 2. At the small end of the cone tool, insert the scale hook into the metal loop. Pull the scale slowly until the scale reads 12 lbs (5.44 kg).

Figure 2:
Use of digital scale.

Considerations for all Tests

- Bed Occupancy: For ease of mattress movement and measurement, the patient should not be in the bed during the measurement procedures.
- Bed Height: To avoid unnecessary bending or back strain, put the bed at a comfortable working height position.
- Bed Wheels: To prevent movement of the bed during testing, lock the wheels.
- Linens/Sheets: Assess the bed with sheets in place for typical patient care. Remove any pillows.
- Personal Safety: To avoid injury, use care when pulling the tool through openings in the bed rails. If the tool suddenly pulls through, you could lose your balance and fall. Always use the safety strap to keep the tool from injuring your feet if it falls.
- Borderline Decision: For some tests, it may not be clear whether the bed system passes or fails the test. Testers can get different results for the same bed system. This is because mattresses vary in softness and people handle tools slightly differently. If the result of pass/fail is in doubt, and you have trouble deciding whether the bed system passes or fails, make your best decision and mark the result with an asterisk (*) next to your answer to show that the result of pass/fail is in doubt.
- Order of Tests: Do the tests in any order you wish, as long as you do all of the tests on all of the rails.
- Intermediate Rail Position: Some rails have an intermediate stopping position or a high and low locking position. Follow the individual test instructions, which may require testing the rails at all positions.

Test Methods

Zone 1: Potential head entrapment within the rail

The tools needed to do this test include the cone with safety strap and spring scale.

Prepare for Test 1:

1. Lock the wheels.
2. Put the bed in the flat, horizontal position.
3. Fully raise all bed rails.
4. Put the bed at a comfortable working height position.

Do Test 1:

1. Attach the safety strap of the cone to the rail being tested. Make sure the strap is short enough to keep the tool from injuring your feet if it falls.
2. From inside the rail, insert the cone, small end first, into the largest opening in the rail. Try to pull the tool through the space (figure 3).
3. If the tool does not pull through freely, attach the spring scale to the end of the cone, and try to pull the tool through the rail by pulling on the attached spring scale using 12 lbs (5.44 kg) of force. Use care when pulling. If the tool suddenly pulls through the opening, you may lose your balance and fall, or the tool may fall on you.
4. Repeat steps 2 and 3 to check all other openings within the same rail. *Repeat test on all rails*
5. Interpret test result and record the results on the data sheet.

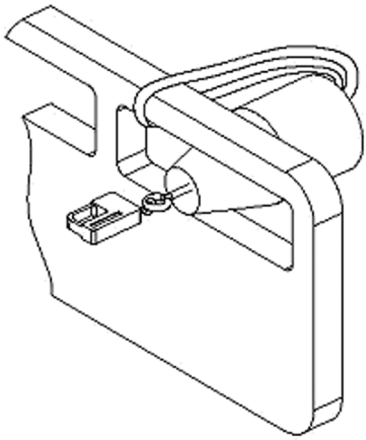

Figure 3: Test 1, within rail.

Interpret Test 1 Results:

- If the large end of the cone does not pass through any of the openings, this space passes the test (figure 4a).
- If the large end of the cone passes through any of the openings, this space fails the test (figure 4b).
- If the result of pass/fail is in doubt, and you have trouble deciding whether the bed system passes or fails, make your best decision and mark the result with an asterisk (*) next to your answer to show that the result of pass/fail is in doubt.

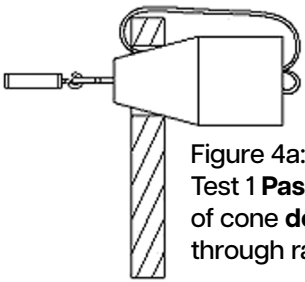

Figure 4a:
Test 1 **Pass**, large end of cone **does not** pass through rail opening.

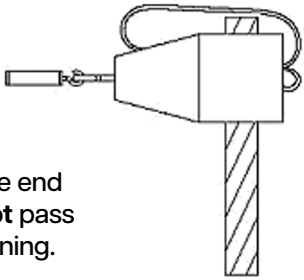

Figure 4b:
Test 1 **Fail**, large end of cone **passes** through rail opening.

Repeat Test 1 on the Other Rails:

Repeat the test for all other rails on the bed.

Zone 2: Potential head entrapment between the bottom of the rail and the top of the compressed mattress, and between the rail supports or next to a single support.

The tools needed to do this test include the cone with safety strap and spring scale.

Prepare for Test 2:

1. Lock the bed wheels.
2. Put the bed in the flat, horizontal position. Fully raise all bed rails.
3. Put the bed at a comfortable working height position.

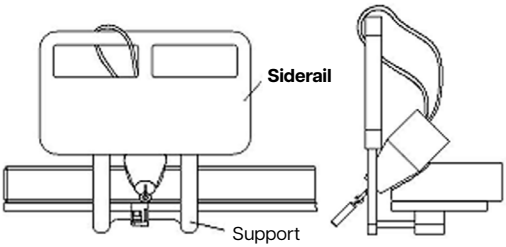

Figure 5a: Test 2, between rail and top of compressed mattress.

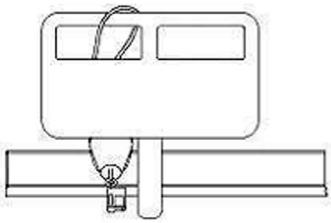

Figure 5b: Test 2, for single support.

Do Test 2:

1. Firmly push the mattress away from the rail being measured until it stops.
2. Identify the space where the test will be done (see Figure(s) 5a and 5b).
3. Raise and lower the head and foot sections of the bed. If the spaces where the test will be done don't change as the bed moves, the test will be done in the flat position.
   a. If the space changes when the head and foot sections are raised and lowered, the test will be done in the bed position where the space is the largest.
4. Attach the safety strap of the cone to the rail being tested. Make sure the strap is short enough to keep the tool from injuring your feet if it falls.
5. From the inside of the rail, insert the cone, small end first, into the gap between the mattress and the lower edge, between the rail supports. Let the cone compress the mattress. Do not force the cone into the area.

6. Attach the spring scale to the loop on the cone.
7. Pull on the spring scale with 12 lbs (5.44 kg) of force at any angle that increases the chances of the cone going through the space. Use care when pulling. If the tool suddenly pulls through the opening, you may lose your balance and fall, or the tool may fall on you. Observe whether the large end of the cone passes through the opening. *Repeat test on all rails*
8. Record the results on the data sheet.

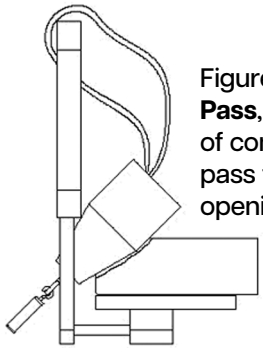

Figure 6a.
Pass, large end of cone **does not** pass through rail opening.

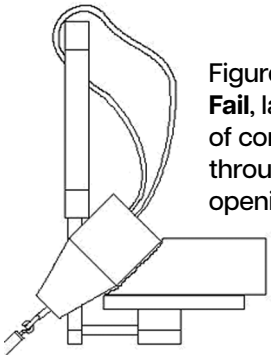

Figure 6b.
Fail, large end of cone **passes** through rail opening.

Interpret Test 2 Results:

- If the large end of the cone does not pass through the opening, this space passes the test (figure 6a).
- If the large end of the cone passes through the opening, this space fails the test (figure 6b).
- If the result of pass/fail is in doubt, and you have trouble deciding whether the bed system passes or fails, make your best decision and mark the result with an asterisk (*) next to your answer to show that the result of pass/fail is in doubt.

Repeat Test 2:

- On the same rail: If the rail has intermediate locking positions, do the test for every intermediate position.
- On the other rails: Do the test for all other rails on the bed, including intermediate and raised positions.

Zone 3: Potential head entrapment between the edge of the mattress and the inside of the rail.

The tools needed for this test include the cone with safety strap.

Prepare for Test 3:

1. Lock the bed wheels.
2. Put the bed in the flat, horizontal position.
3. Fully raise all bed rails.
4. Put the bed at a comfortable working height position.

Do Test 3:

1. Firmly push the mattress away from the rail being measured until it stops.
2. Put the cone near the rail being tested and attach the safety strap. Make sure the strap is short enough to prevent the tool from injuring your feet if it falls.
3. Put the cone horizontally in the gap. Do not push the tool down into the gap (figure 7a).
4. Turn the cone until the line on the end is horizontal (figure 7b).

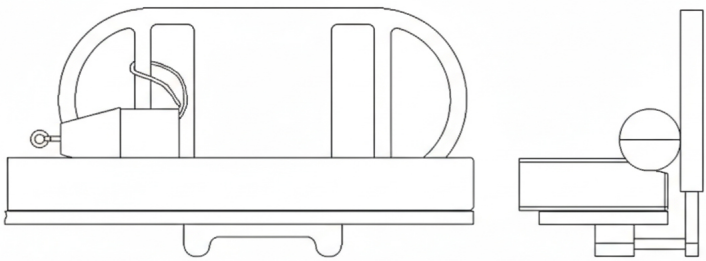

Figure 7a: Test 3, between mattress and inside of rail.

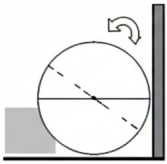

Figure 7b: Test 3, turning the cone.

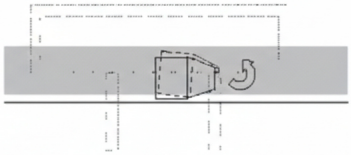

Figure 7c: Test 3, tilting cone.

5. Let the cone sink into the space by its own weight. If the cone is tilted, use one hand to gently level it (figure 7c). Do not push the tool down into the gap. Note: If a mattress stop, rail support or other structure keeps the cone from sinking in the gap, put the cone tool at a different location along the rail where there is no interference.
6. Determine whether the cone's center sinks completely below the surface of the mattress. *Repeat test on all rails*
7. Interpret test result and record the results on the data sheet.

Interpret Test 3 Results:

- If the line across the flat end of the cone is above or even with the surface of the mattress, the space passes the test (figure 8a and 8b). If the line across the flat end of the cone is below the top surface of the mattress, the space fails the test (figure 8c).
- If the result of pass/fail is in doubt, and you have trouble deciding whether the bed system passes or fails, make your best decision and mark the result with an asterisk (*) next to your answer to show that the result of pass/fail is in doubt.

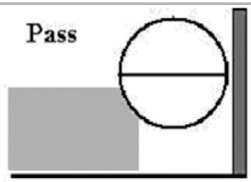

Figure 8a: Pass, line above mattress.

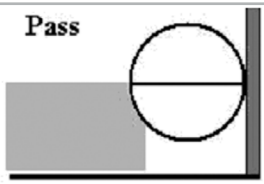

Figure 8b: Pass, line even with mattress.

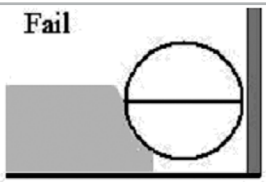

Figure 8c: Fail, line below mattress.

Repeat Test 3:

- On the same rail: If the rail has any intermediate positions, do the test at every intermediate position.
- On the other rails: Do the test for all other rails on the bed, including the intermediate positions.

Zone 4: Potential neck entrapment between the top of the compressed mattress and the bottom of the rail at the end of the rail.
The tools needed for this test include the assembled cone and cylinder with safety strap.

Prepare for Test 4:

1. Lock the bed wheels.
2. Put the bed in the flat, horizontal position.
3. Fully raise all bed rails.
4. Put the bed at a comfortable working height position.
5. Do the test on the end of the rail (figure 9). Test the rails in any order you choose. If the bed has split rails, you may need to lower the rail next to the one being measured to make room for the tools.

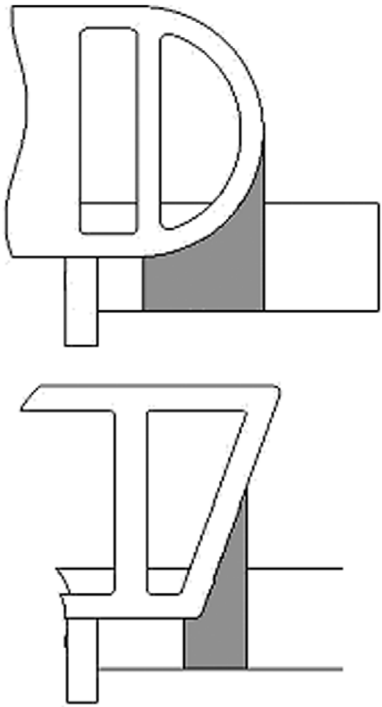

Figure 9: Test 4, between the rail and mattress, under the rail at the end of the rail.

Do Test 4:

1. Firmly push the mattress away from the rail being tested until it stops.
2. Attach the safety strap of the cone tool to the rail being tested.
3. Just beyond the end of the rail, rest the cone portion of the cone and cylinder tool on the mattress.
   Note: If the cylinder tool cannot fit into an area between the head or footboard and the end of a rail, the space passes.
4. Position the tool so that the base of the cone is flush or even with the edge of the mattress (figure 10a).
5. Slide the cone and cylinder toward the rail until it touches the rail or support and let the weight of the cone compress the mattress (figure 10b).
6. Hold the cylinder section and use the level on the end of the cylinder to keep the cone level.

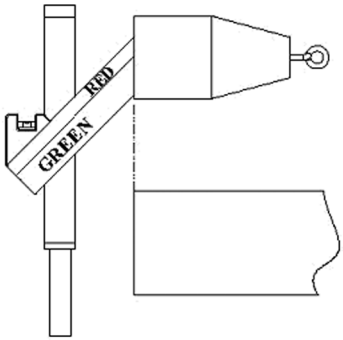

Figure 10a: Align cone with edge of mattress.

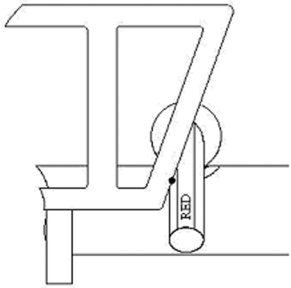

Figure 10b: Observe color of contact.

7. If the cylinder slides completely under the rail, this space fails. If the cylinder touches the rail, observe the color of contact: Red fails; Green passes (figure 11). *Repeat test on all rails*
8. Interpret test result and record the results on the data sheet.

Interpret Test 4 Results:

- If the cylinder touches the rail in the green area, the space passes (figure 11a).
- If the cylinder touches the rail in the red area, the space fails (figure 11b).
- If the cylinder passes completely under the rail without touching the rail, the space fails (figure 11c).
- If the cylinder tool cannot fit into an area between the head or footboard and the end of a rail, the space passes.

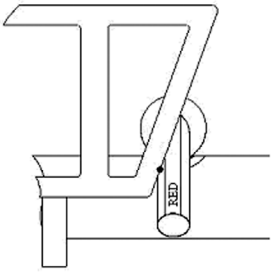

Figure 11a: Pass, contact in green.

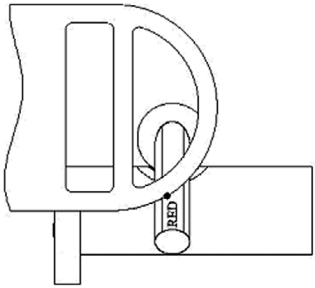

Figure 11b: Fail, contact in red.

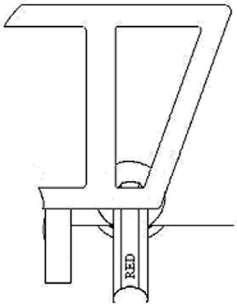

Figure 11c: Fail, passes under with no contact.

- If the result of pass/fail is in doubt, and you have trouble deciding whether the bed system passes or fails, make your best decision and mark the result with an asterisk (*) next to your answer to show that the result of pass/fail is in doubt.

Repeat Test 4:

- On the same rail: If the rail has any intermediate positions, do the test at every intermediate position.
- On the other rails: Do all steps of test 4 for both ends of all other rails on the bed, including the intermediate positions.

To Clean The B4000:

1. Prepare a solution of mild detergent and hot water (1 tsp (5ml) detergent per 1 gallon (3.8L) of water).
2. Wipe down all surfaces of the B4000 using the detergent solution and a soft cloth. ⚠**WARNING: DO NOT IMMERSE THE B4000 IN THE DETERGENT SOLUTION**
3. Thoroughly rinse the all surfaces of the B4000 using clean, detergent free water and a soft cloth.
4. Allow the B4000 to completely dry prior to use.

To Disinfect The B4000:

To avoid cross-contamination, the B4000 should be disinfected each time a different bed is measured.

1. Remove all surface contamination prior to disinfection.
2. Wipe down all B4000 surfaces with a disinfecting wipe/solution per the manufacturer's instructions for use. ⚠**WARNING: DO NOT IMMERSE THE B4000 IN THE DISINFECTING SOLUTION**
3. Allow the B4000 to completely dry prior to use.

Additional Information

- FDA Guidance Document: **https://www.fda.gov/regulatory-information/search-fda-guidance-documents/hospital-bed-system-dimensional-and-assessment-guidance-reduce-entrapment**
- Clinical guidance for the assessment and implementation of bed rails in hospitals, long-term care facilities and home care settings. - Developed by the Hospital Bed Safety Workgroup: **https://www.fda.gov/media/88765/download**
- Additional information is also available at www.bionix.com

Scan this QR Code to watch How to Use Videos for the B4000 Bed Measurement System

URL: qrco.de/b4000zones

Calibration

Annual calibrations are recommended. Register your B4000 device on the Bionix website (bionix.com/products/bed-system-measurement-device) to receive annual calibration reminders and other information related to your B4000.

Bionix Return Policy

Non-warranty related returns are accepted for thirty (30) days from the date of delivery, provided they are accompanied by a Return Materials Authorization (RMA) provided by the Bionix Customer Service Department. All returns are subject to a 20% restocking fee.
When returning products to Bionix, you must always contact the Customer Service Department prior to any and all returns/exchanges to our facility:

Bionix Customer Service Department

Monday – Friday, 8:00am – 5:00pm EST
Telephone: 1-800-551-7096 • Email: Bionix@Bionix.com

When contacting our Customer Service Department, please have the following information for faster processing of your return:

1. Your Bionix Account Number
2. Original Purchase Order Number that the order was placed on
3. The name of the item that will be returned
4. Reason(s) for return.

All returns require an RMA and the product must be returned in the same box(es) they were delivered in. Items returned without an enclosed RMA will be refused and returned to their sender. All RMAs are valid for a period of 30 days from the date of issue and items returned with an expired RMA will not be accepted.

Please send all returns to the below address:

Bionix LLC
Attn: Returns/ RA #
1670 Indian Wood Circle
Maumee, Ohio 43537

Bionix Manufactured One Year Limited Warranty

Bionix warrants that its Bed System Measurement Device, if properly used, is free from defects in materials and workmanship for a period of one (1) year from date of purchase.

Exclusive Limited Warranty

If the product that is the subject of this limited warranty fails during the warranty period for reasons covered by this Limited Warranty, Bionix, at its option, will:

- Repair the Device; or
- Replace the Device with another Device

The obligation of Bionix to repair or replace at its option is the sole and exclusive remedy for this limited warranty.

Extent of Limited Warranty

This limited warranty does not cover damages due to external causes, including accidents, usage not in accordance with product instruction, neglect and/or alteration. If the product is altered in any way, Bionix keeps the right to refuse any warranty on the product. The warranty excludes any products that are not manufactured by Bionix.

Limitations on Damage

Bionix shall not be liable for any special, consequential or incidental damages and buyer's damage are limited to the rights of repair or replacement under this limited warranty.

How to Obtain Warranty Service

To request warranty service, you should call Bionix at 800-678-7072 during normal business hours (eastern standard time), excluding holidays. Please be prepared to provide:

- The facility name, address and telephone
- Your name
- Proof of purchase
- Product description including lot and serial number

Note: The customer service representative may need additional information from you depending on the nature of the problem.

Warranty Exclusions

Bionix makes no expressed or implied warranties except for its limited warranty of repair and replacement provided above. Bionix makes no expressed or implied warranty of merchantability. Bionix makes no expressed or implied warranty of fitness for a particular purpose.

bionix®