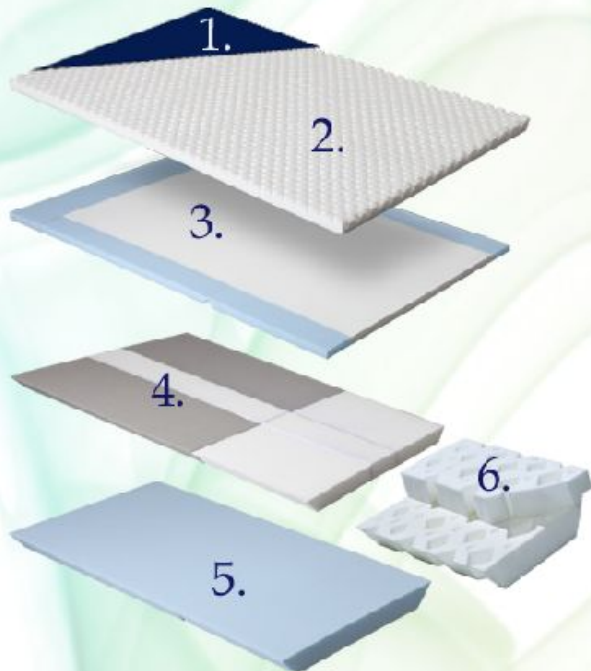


Rest-Q® GSV

by Comfortex®



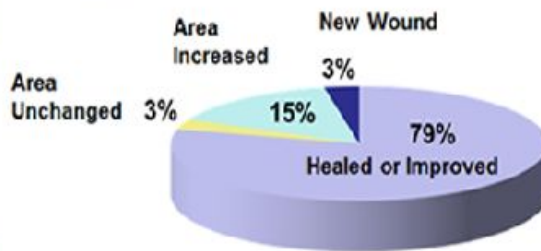
Shaped to fit...
...Engineered to perform.

Design Features and Benefits of the Rest-Q® GSV

1. Comfortex's Vapor Proof, Shear Reducing Top Cover is the Nation's most durable fabric in healthcare today. Other fabrics tend to fade, crack and can allow moisture vapor transmission.
2. This layer of soft, high specification (HS), high resiliency (HR) foam spans across the mattress to cushion boney prominences and ensure greater comfort, especially over the bed's exit points.

3. Additional soft (HR) material further enhances comfort and pressure redistribution. This layer also incorporates extra supportive perimeter foam that overlays the bed's raised metal edging at the center and exit points.
4. Embedded within the core are supportive sections that underlie the hips and shoulders. Between these support sections is a soft, pressure absorbing strip to help bridge the patient's pressure sensitive areas along the spinal column and sacrum.
5. A base layer of firm material helps ensure heavier patients will not bottom out. Both this firm base and the side-rail perimeters have relief cuts to allow the mattress to bend with the bed's position changes.
6. Rather than slope the lower legs downward, which could cause swelling, the heels rest into the dual-density top foam and our **Descending Diamond Heel Suspension System**. This heel suspension system absorbs the boney prominences of the heels while keeping the lower legs supported along the horizon of the mattress. The side-to-side chambers help accordion the foot end of the mattress if the bed frame is telescoped inward.

Prevention and Treatment



Full Studies Available

Treatment Capabilities (Independent Studies)

30 patients with pressure wounds (stages 2-4) were taken from more costly Group II surfaces and moved to the non-mechanical Rest-Q® mattress.

Nearly 80% of those wounds improved or healed.



Comfortex®

Innovating Healthcare Surfaces
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Hill-Rom recommends the use of the Hill-Rom® surfaces that have been designated and tested specifically for the VersaCare® Bed. The combination of the VersaCare® Bed and Hill-Rom® surface have been approved as a system including a full safety evaluation based on the level of risk associated with the product under medical device standards established by the FDA.

Some safety features of the VersaCare® Bed may not function or may not operate as intended with surfaces manufactured by other companies. Failure to do so could result in serious injury or damage to the equipment.

Below are some important factors to consider when purchasing a non Hill-Rom surface for the VersaCare® Bed:

Important Factors To Consider For A Surface On The VersaCare® Bed	Rest-Q® GSV Passed
1. Has the surface been tested and verified with the VersaCare Bed® that the bed's safety features (e.g. bed exit) operate properly?	✓
2. Has the surface been tested and verified with the VersaCare® Bed that the bed's patient controls (e.g. NaviCare® Nurse Call, head up/head down, speakers, knee function) operate properly?	✓
3. Does the surface have clinical/safety claims related to fall prevention or entrapment approved by the FDA?	✓
4. Does the surface meet applicable regulations (e.g. flammability), regulatory guidance (e.g. FDA, 510K), and technical standards (e.g. biocompatibility, IEC)?	✓
5. Does the surface meet federal, state and local fire codes?	✓
6. Does the surface have documentation to support its stated flammability testing and results?	✓
7. Does the surface utilize dimensions and construction to minimize gaps where entrapment could occur?	✓
8. Does the surface provide for sufficient height between the surface and the top of the siderail according to IEC 60601-2-38 to prevent accidental roll-over events?	✓
9. Does the surface provide appropriate firmness at the edges of the surface to facilitate safe transfer into and out of bed?	✓
10. Does the surface not interfere with the proper operation of the siderail?	✓
11. Does the surface have the appropriate slip properties in the ticking to prevent patients from migrating toward the foot section of the bed?	✓

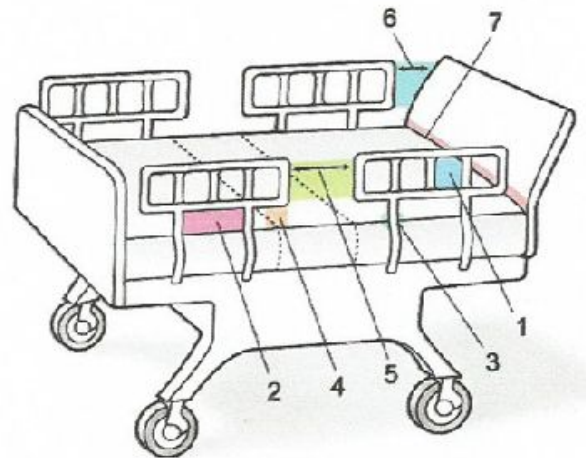
These recommended safety checks were completed on the Comfortex Rest-Q GSV mattress by a Minnesota based Health System prior to their GSV purchase.

Potential Zones of Entrapment

This guidance describes seven zones in the hospital bed system where there is a potential for patient entrapment. Entrapment may occur in flat or articulated bed positions, with the rails fully raised or in intermediate positions. Descriptions of the seven entrapment zones appear on pages 15-21 in this guidance. Summary drawings of entrapment for all of the zones appear in Appendix E.

The seven areas in the bed system where there is a potential for entrapment are identified in the drawing below.

- Zone 1:** Within the Rail
- Zone 2:** Under the Rail, Between the Rail Supports or Next to a Single Rail Support
- Zone 3:** Between the Rail and the Mattress
- Zone 4:** Under the Rail, at the Ends of the Rail
- Zone 5:** Between Split Bed Rails
- Zone 6:** Between the End of the Rail and the Side Edge of the Head or Foot Board
- Zone 7:** Between the Head or Foot Board and the Mattress End



Entrapment at the Bed Deck or Frame

Many of the entrapment event reports FDA received involved entrapment between the rail and the bed's "frame." It is unclear from the event descriptions whether this refers to the mattress deck, the bed frame, or even the hardware attaching the bedrail to the bed system. While this guidance does not recommend dimensional limits on the space at the deck or frame locations, FDA believes that meeting the other recommended dimensional limits would reduce the possibility of entrapment at the deck or frame locations.

Mattress Check Results:

Measured for the use of the Rest-Q® GSV atop the hospitals beds platform. Zones 2,3,4 & 7 are applicable. Zones 1, 5 & 6 relate to the bed frame and siderails.

Zone	Original equipment mattress	Rest-Q® GSV replacement mattress	FDA recommends
2	0 inches	0 inches	less than 4 ¾ inches
3	1 inch	½ inch	less than 4 ¾ inches
4	0 inches	0 inches	less than 4 ¾ inches
7	3 ¾ inches	3 inches	YTB Determined
Roll-Over Height	9 inches	8 ½ inches	8 ½ inches