

EVOLUTION

PATIENT POSITIONERS

Interface Pressure Mapping Report

Supine Positioners
Supine Torso Positioners
Supine Knee Positioner
Supine Foot Positioners
Supine Arm Positioner
Supine Arm Positioner Kit
Strap Retainer Kit



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1. Pressure Mapping Protocol

The protocol used to test the products is RD001IPMP issued by the Research & Development Department of VascoCare Medical Ltd.

2. Sensor System & Specification

The following system was used to measure Interface Pressure distribution during the trials.

| Component | Specification |
|--------------------------|---|
| System Software | Tekscan Pressure Measuring System: Conformat Clinical 7.02C |
| Sensor Mat | Model 5330 Serial Number: 5330/1079T1 |
| Number of Sensors in Mat | 32 x 32 |
| Dimensions of Sensor Mat | 480mm x 480mm |

| Component | Specification |
|--------------------------|---|
| System Software | Tekscan Economical Load And Force System (ELF) Version 3.4 112809 |
| Sensor Mat | Model 112809 Serial Number: 5330/1079T1 |
| Number of Sensors in Mat | 1 |
| Dimensions of Sensor Mat | 20mm x 20mm |

3. STP14 Supine Torso Positioner

| Description | Specification |
|----------------------------|--|
| Product Code | STP14 (STPL14 & STPR14) |
| Product Description | Evolution Supine Torso Positioner STPL14 Supine Torso Positioner Left Large STPR14 Supine Torso Positioner Right Large |
| Size | Large |
| Intended Use | Support Patient's Torso in a safe, secure and stable orientation that is anatomically correct and helps prevent the development of pressure sores on the bony prominence of the sacrum area while the patient is lying in the supine position. |

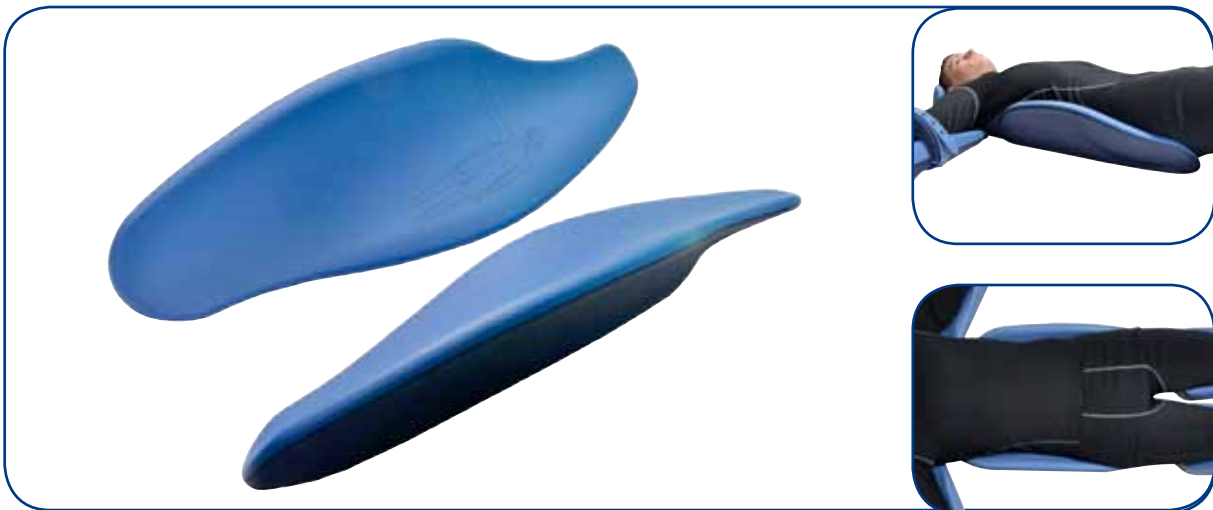


Figure. 1 STP14 Supine Torso Positioner (Pair)

Discussion

The trends for Peak Interface Pressure (mmHg) illustrate that the use of the Supine Torso Positioners redistribute the load over a wider area and away from the bone prominences of the Coccyx and sacrum area. The weight that is normally concentrated on the Coccyx is now redistributed around the outer hip area which can tolerate higher pressures. The Pressure Maps on Fig 2 & 3 illustrate that the Positioners redistribute the concentrated weight of the individual away from the Central Spinal area to the more fatty skin tissue. The Control Benchmark Surfaces Fig 4 and 5, illustrates the central loading of the weight of the individual along the spinal column and narrow area around it.

The graphs for Figure 6 & 7, Peak interface Pressure (mmHg) and Figure 8 & 9, Support Area (cm²) illustrate that the use of the Torso Positioners increase the support provided under the patient. After an hour, the trend is increasing for the area of support. This demonstrates that the products are still deforming to provide more support as time progresses. This trend would be expected to continue and level off over time. This is in keeping with the properties of the Visco Elastic Foam contained in the product. It is designed to soften with heat. So the heat conduction from the patient is aiding the foam softening process, hence providing more supporting surface area in contact with the individual lying on it.

Pressure Map Profiles

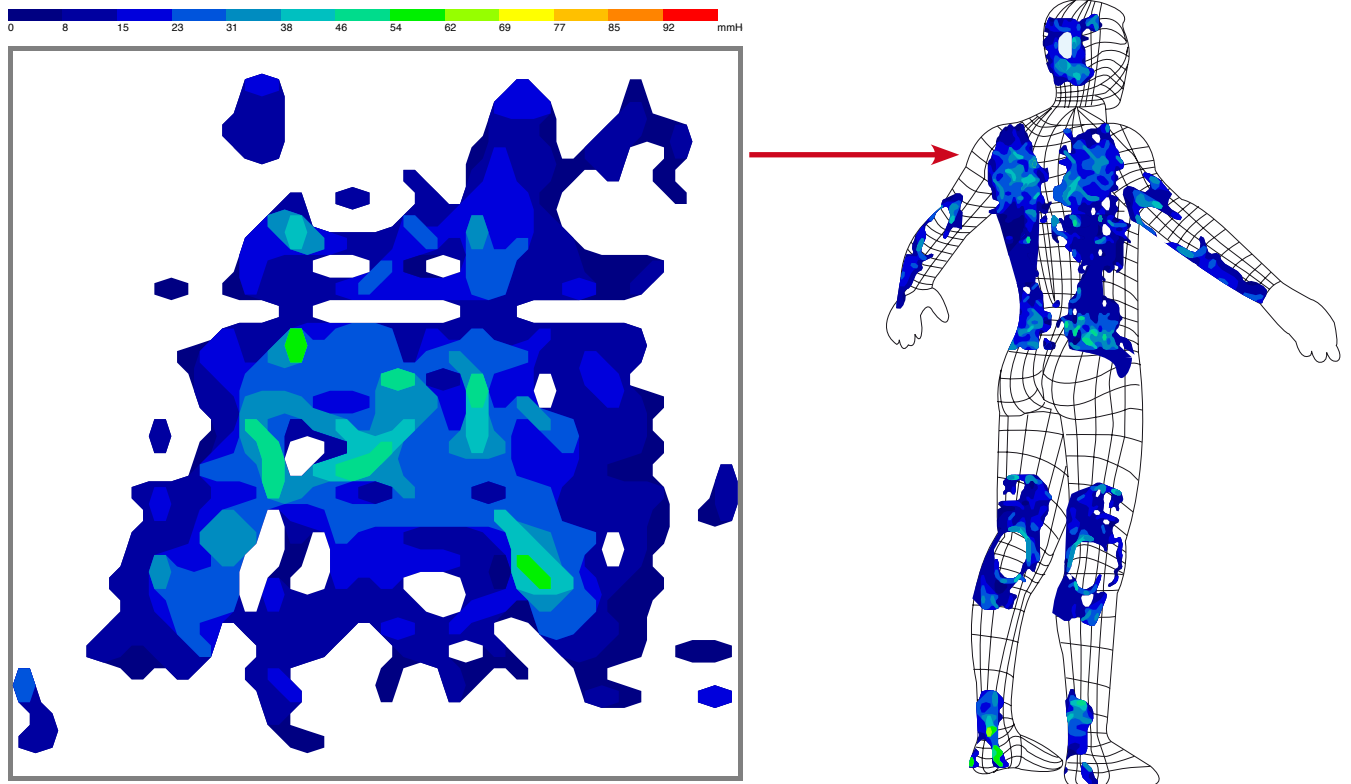


Figure 2 STP14 Upper Torso Positioner Profile

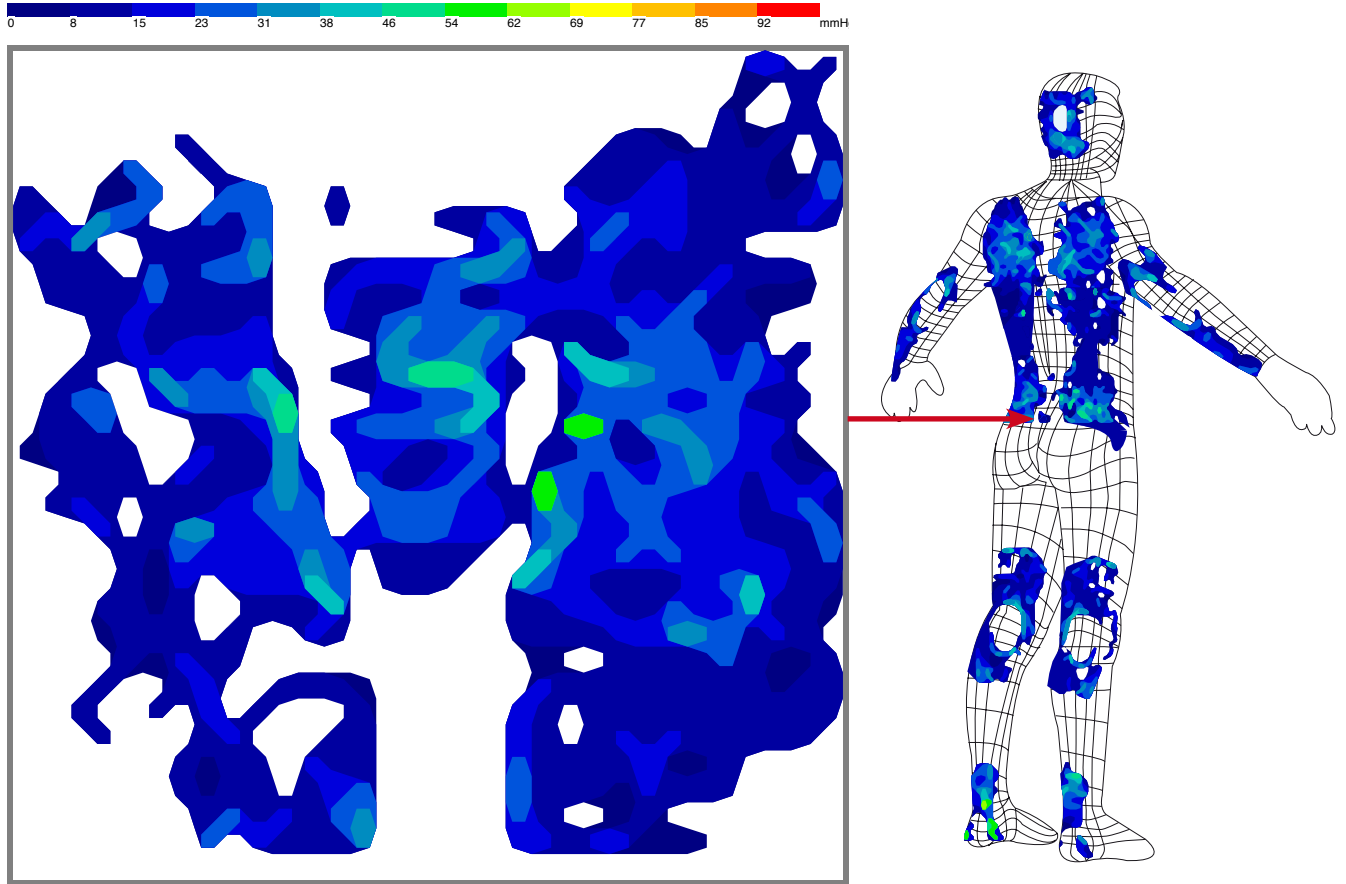


Figure 3 STP14 Lower Torso Positioner Profile

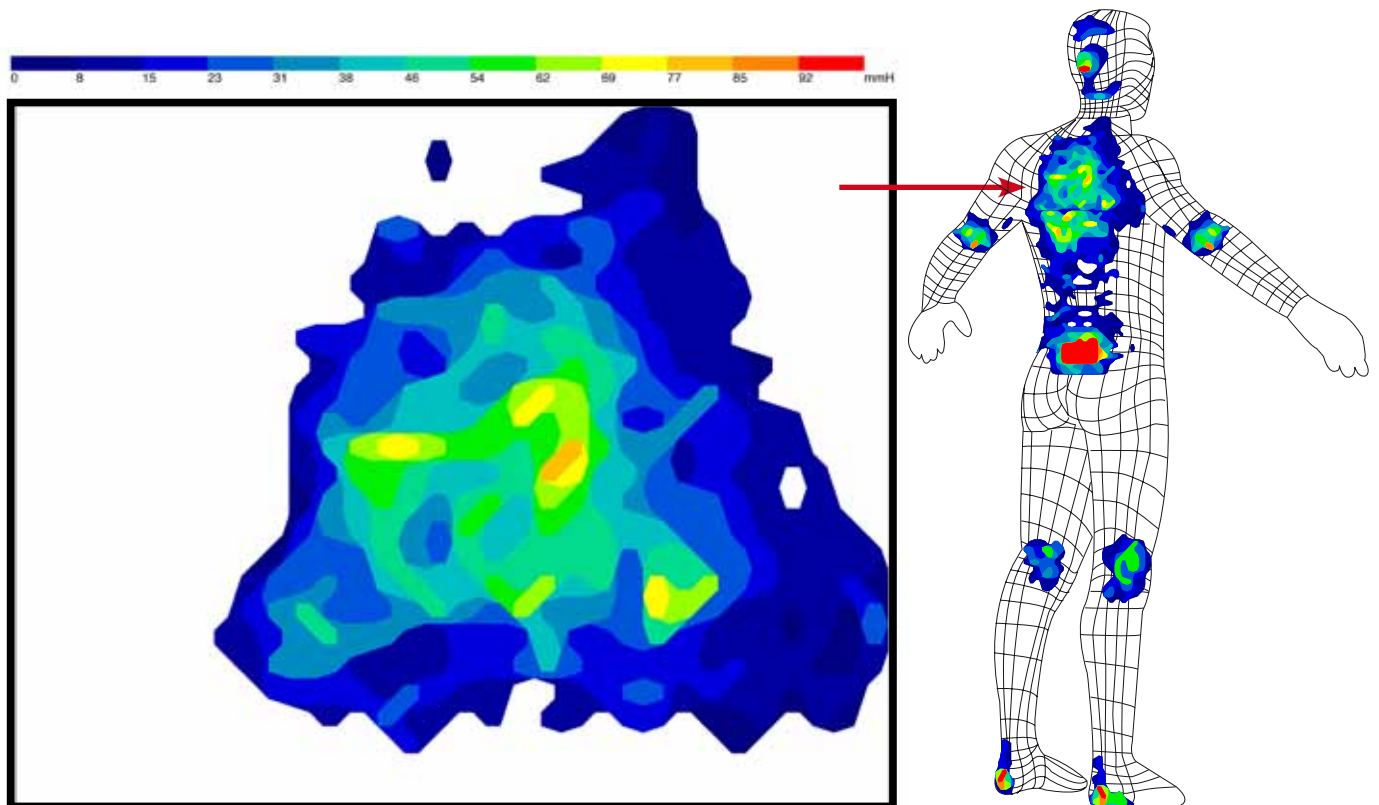


Figure 4 Control Surface Upper Torso Positioner Profile

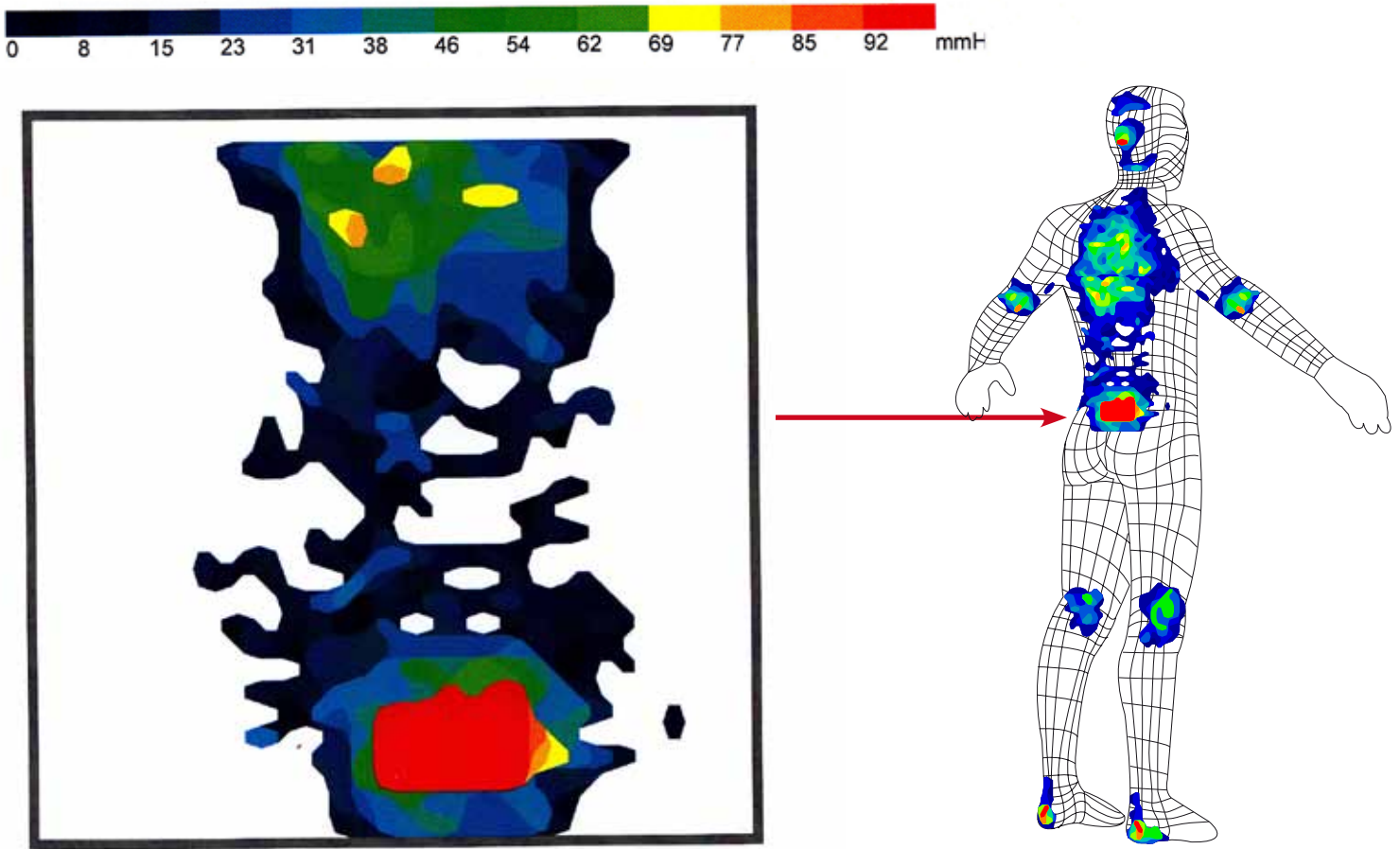


Figure 5 Control Surface Lower Torso Positioner Profile

STP14 Upper Torso Peak Pressure ML

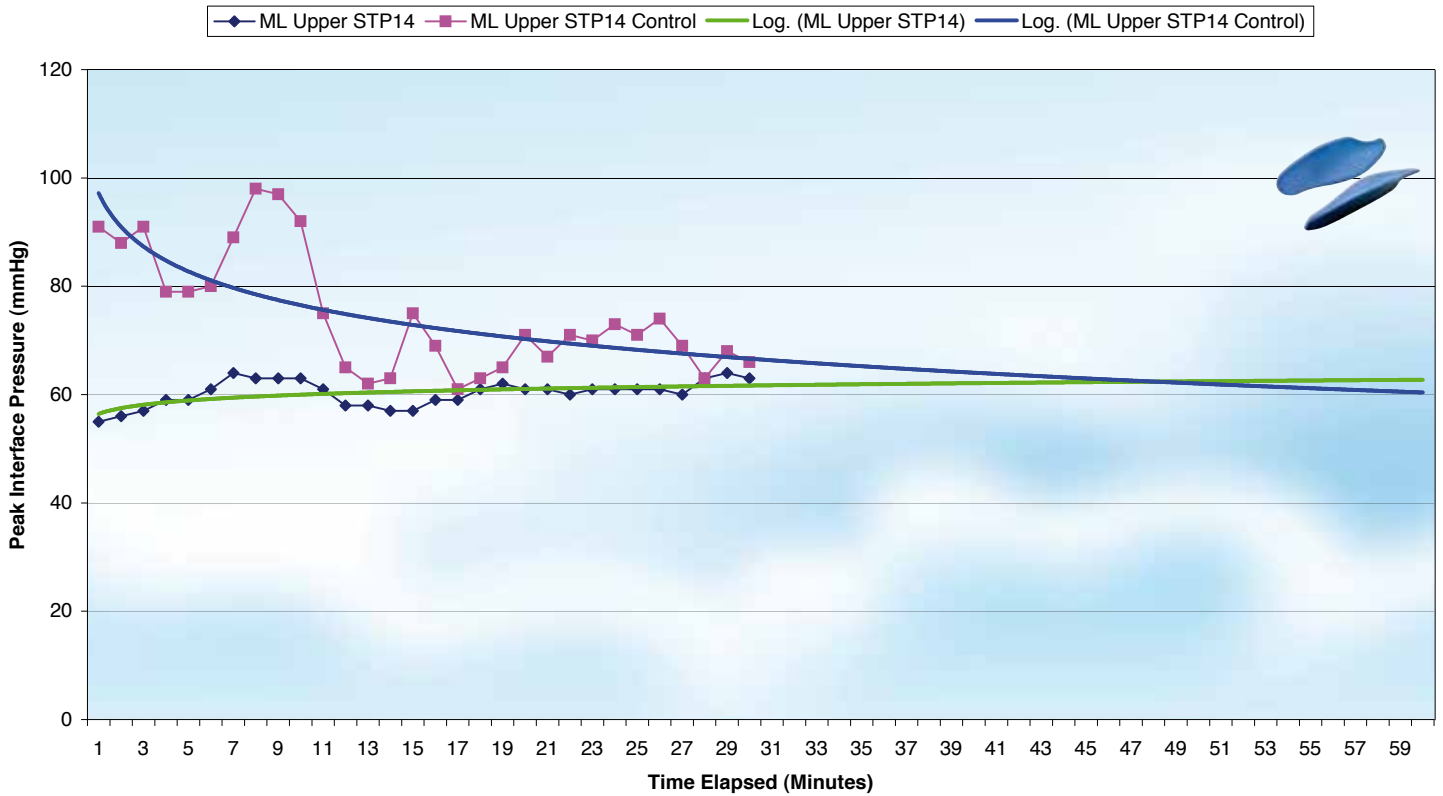


Figure 6 Upper Torso Peak Pressure

STP14 Lower Torso Peak Pressure ML

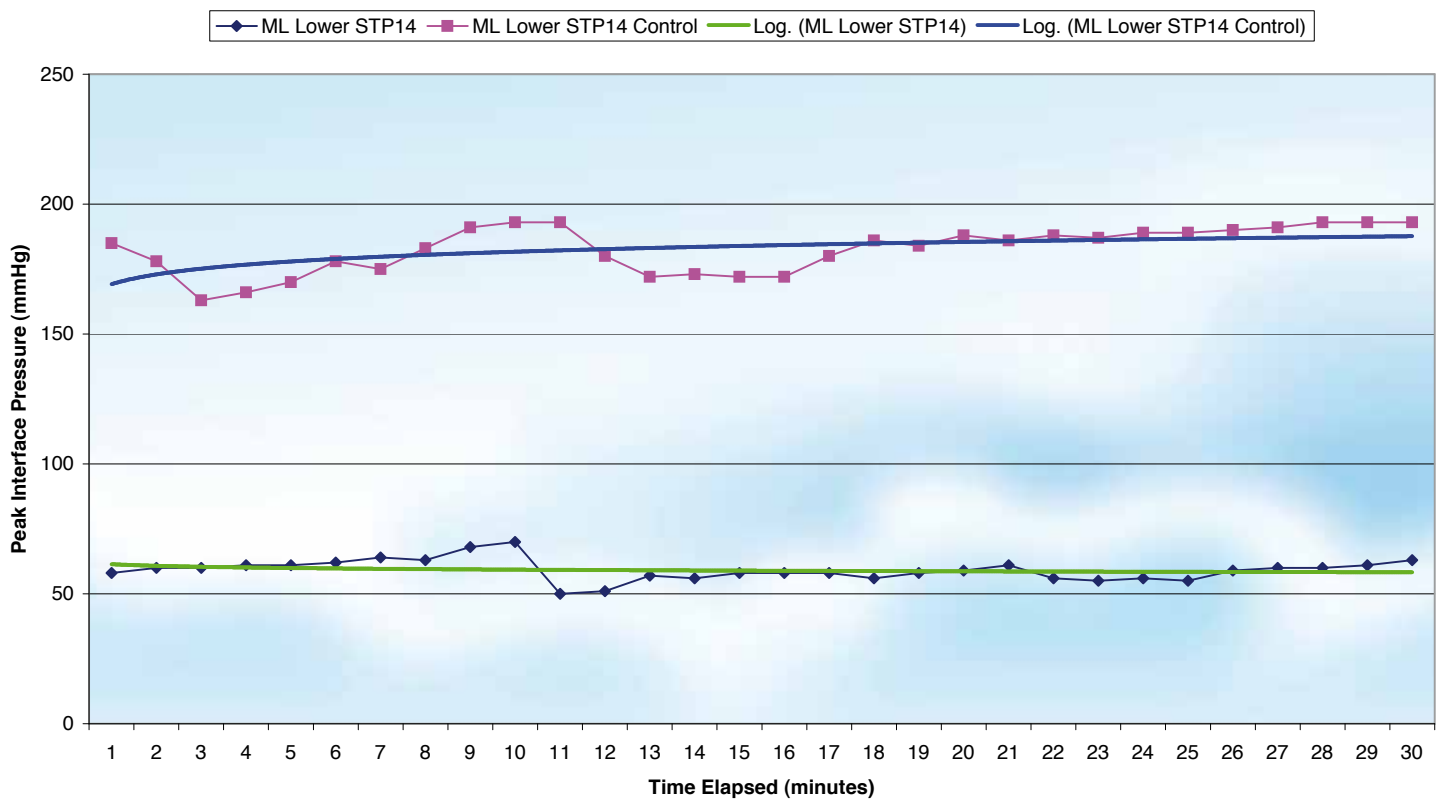


Figure 7 Lower Torso Peak Pressure

STP14 Upper Torso Surface Area ML



Figure 8 Upper Torso Surface Area

STP14 Lower Torso Support Area ML

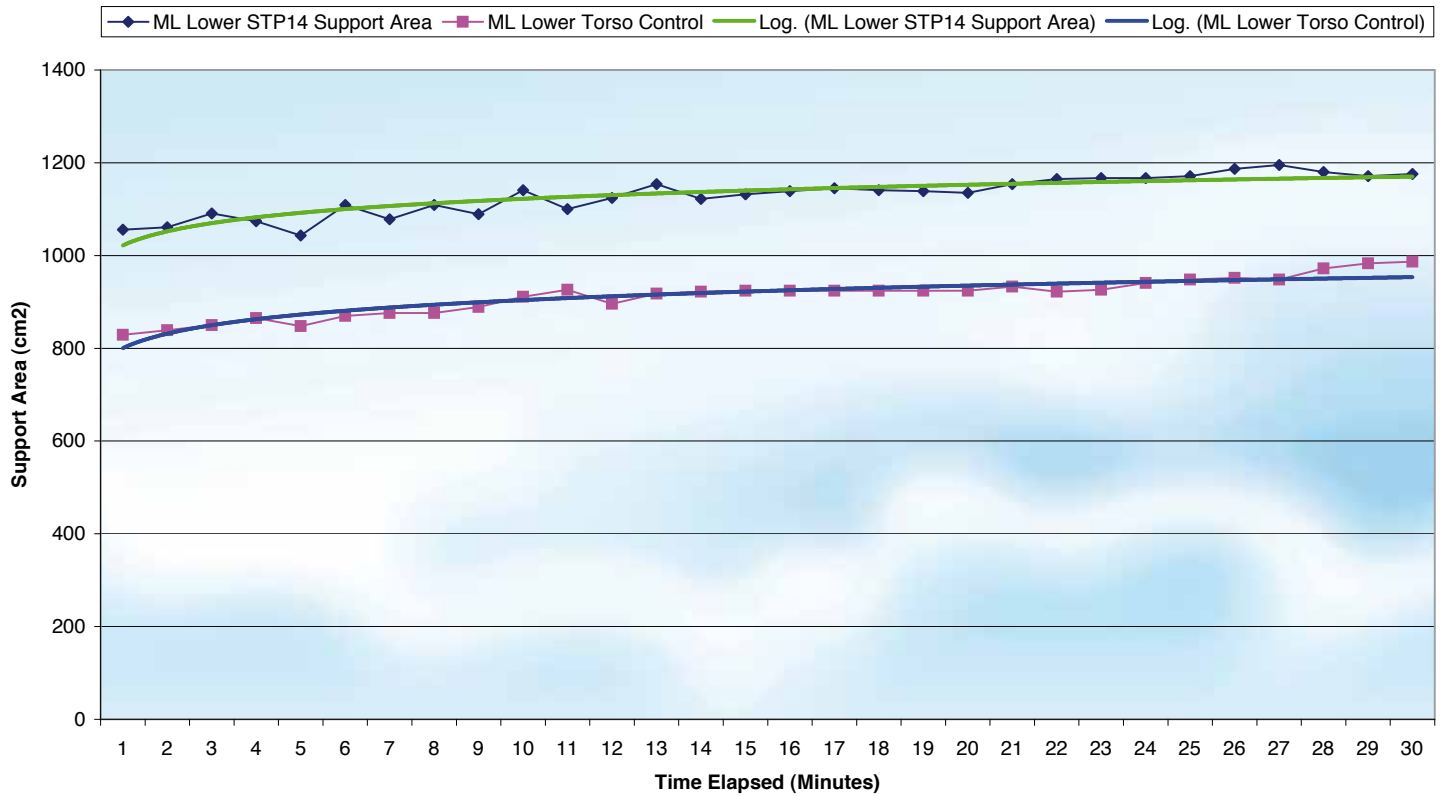


Figure 9 Lower Torso Support Area

Conclusion

Through the use of the pressure mapping system, the use of the products can be verified to function as intended. There is a significant benefit in using the set of Torso Positioners to relieve pressure on the sacrum area of an individual. The pair of products functions to redistribute pressure away from the area around the coccyx and to the non bony areas around the hips.

4. SKP14 Supine Knee Positioner

Product Specification

| Description | Specification |
|----------------------|--|
| Product Code | SKP14 |
| Product Description | Evolution Supine Knee Positioner Large |
| Size Intended Use | Large Support Patient's Knee in a safe, secure and stable orientation that is anatomically correct, reducing pressure on the back of the knee and helping prevent the development of Deep Vein Thrombosis in the legs area while the patient is lying in the supine position. |



Figure 10 SKP14 Knee Positioner

Discussion

The graph demonstrates trend lines of lower Peak Interface Pressure (Figure 13) and Higher Support Surface Area (Figure 14) by using the Knee Positioners over the control surface. The area supported under the leg was different for the Knee Positioner compared to the Dome Positioner (Substantive Market Equivalent). Refer to Pressure Mapping Profiles Figures 11 and 12 respectively. The Supine Knee Positioner distributed the load over a wider area along the leg. The Substantive Market Equivalent puts pressure under the knee resulting in discomfort for the individuals testing the products.

In some cases, the individuals were unable to complete 60 minutes of testing due to experiencing discomfort with the product. The Peak Interface Pressure trend of using the SKP14 tapered off over the hour and there is no evidence that it would not continue over an extended period of time.

On the other hand, the Substantive Market Equivalent trended upwards at a higher rate than the SKP14. There is a significant difference between the two products. The SKP14 deforms to accommodate the shape and weight of the leg and does not put a reactive force directly under the knee where it is sensitive to nerve damage and blood circulation complications.

The Support Surface Area was analysed to determine the functionality of the product. As illustrate on the Support Area Graphs attached, Figure 13 & 14, the SKP14 shows a gradual improvement in support area compared to the Substantive Market Equivalent. Again the redistributed weight of the leg is away from the area under the knee. There is a 50% extra area of support achieved using the SKP14.

Pressure Map Profiles

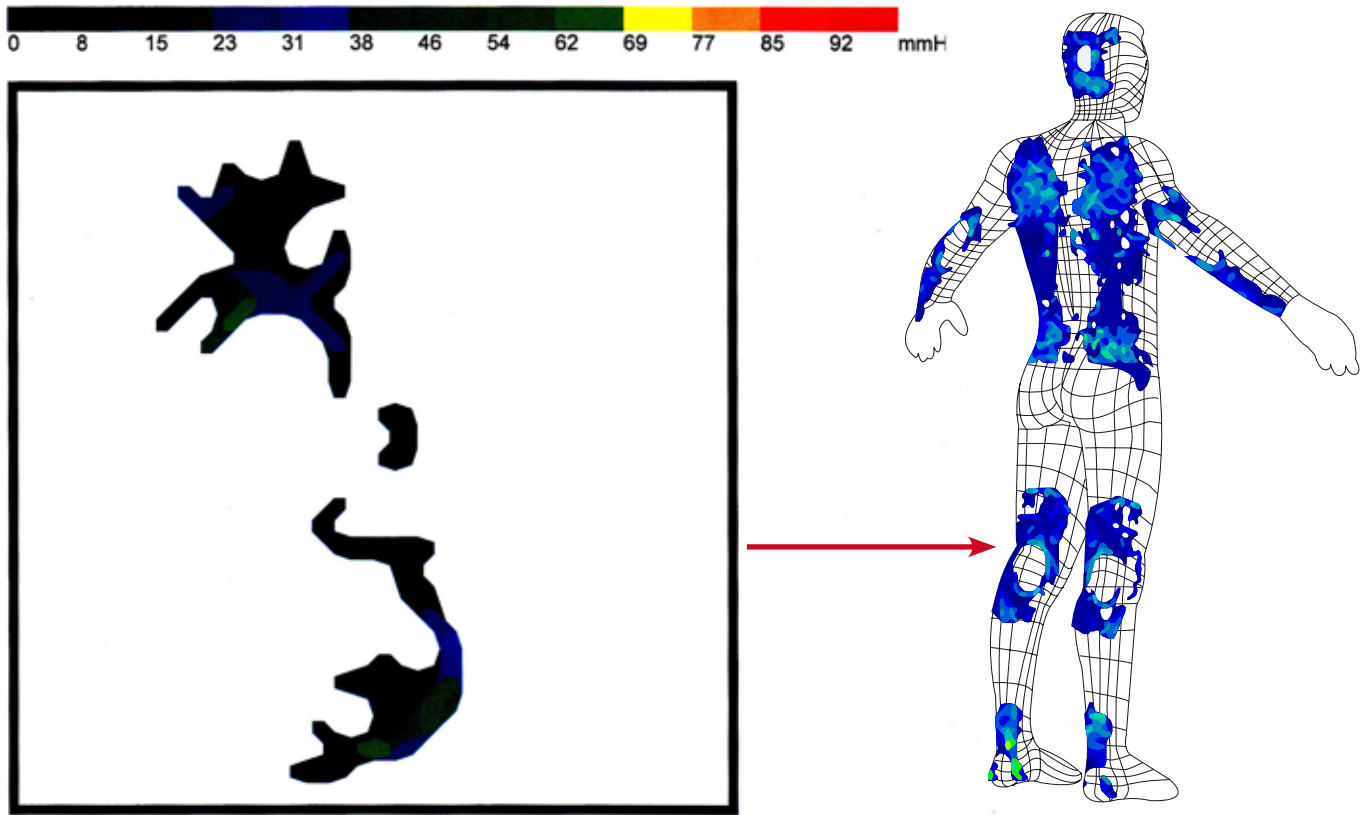


Figure 11 SKP14 Supine Knee Positioner Profile

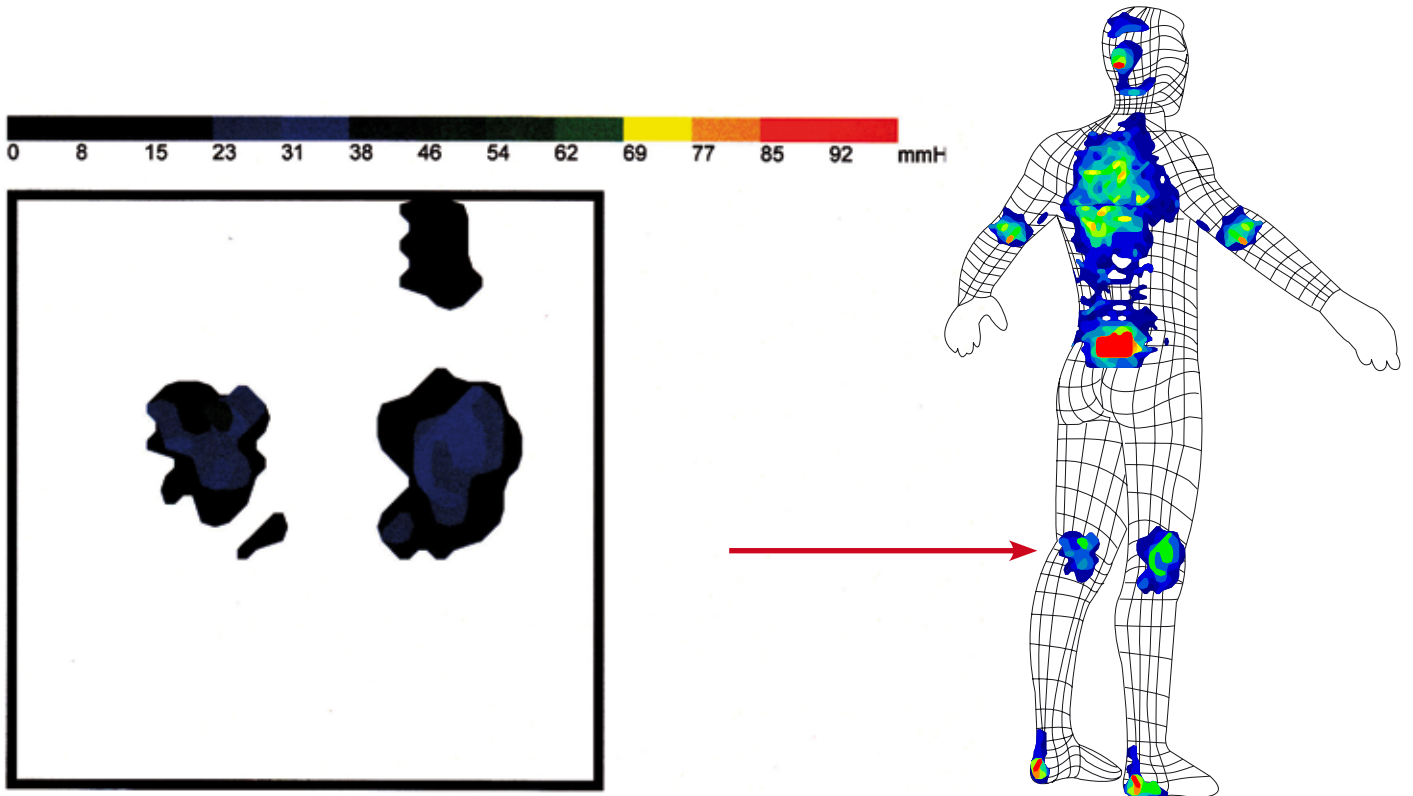


Figure 12 Gel Pad Positioner Profile

Pressure Mapping Graphs

SKP14 Peak Interface Pressure ML

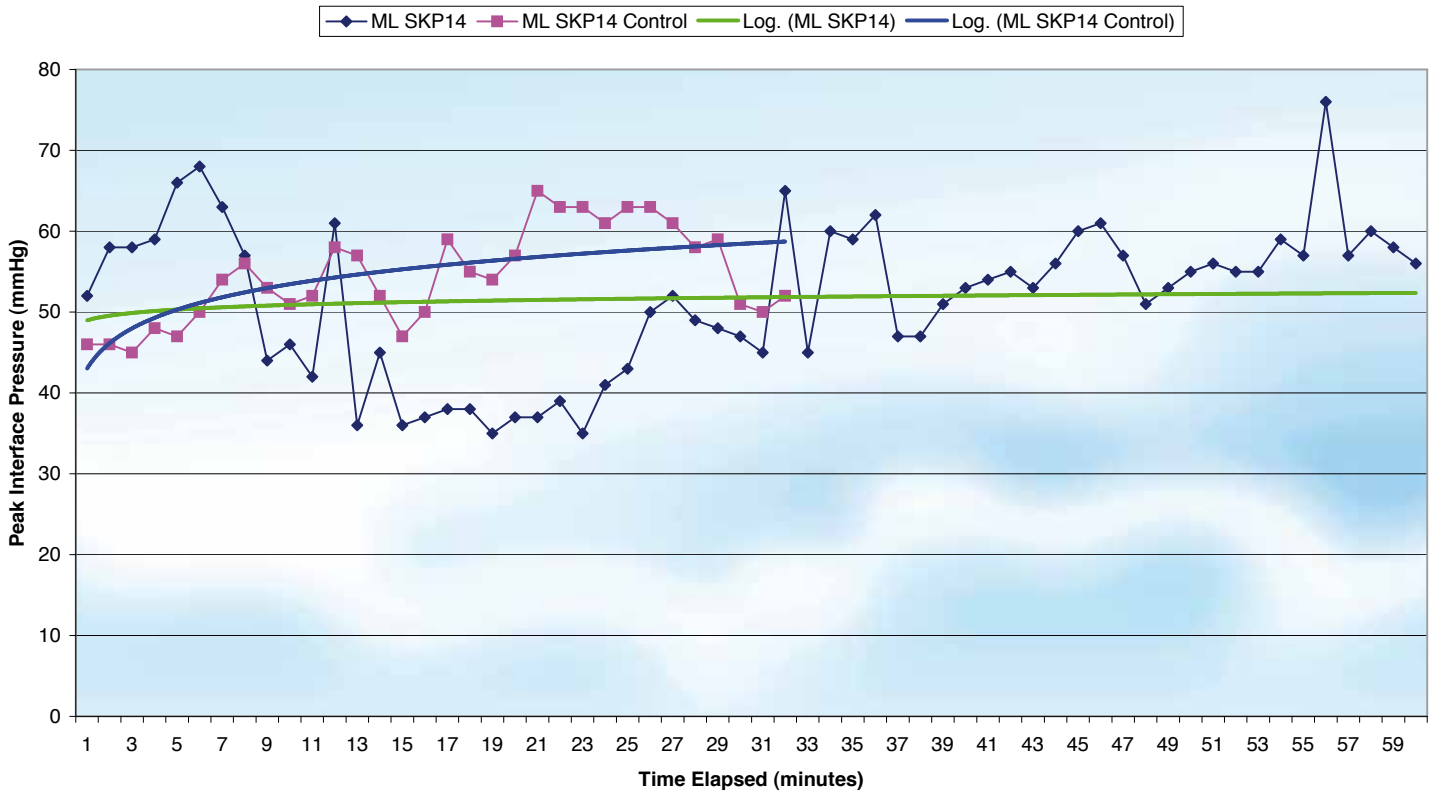


Figure 13 SKP14 Peak Interface Pressure

SKP14 Support Area ML

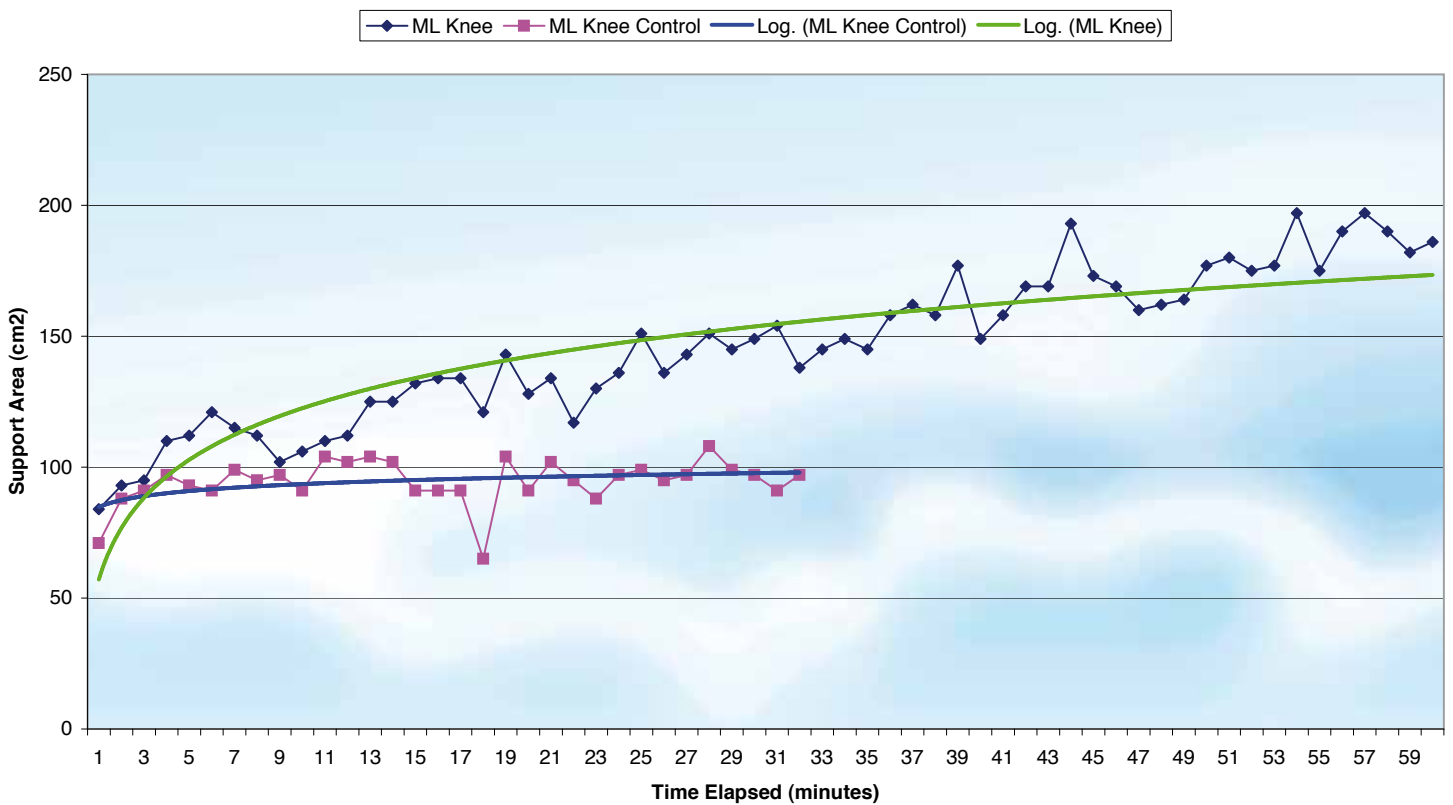


Figure 14 SKP14 Support Area

Conclusion

Through the use of the pressure mapping system, the use of the products can be verified to function as intended. There is a significant benefit in using the set of Knee Positioners to relieve pressure under the knees of an individual. The pair of product performs the intended task to redistribute pressure away from the area under the knee and to areas of the leg that are not prone to pressure.

5. SFP14 Supine Foot Positioner

Product Specification

| Description | Specification |
|---------------------|---|
| Product Code | SFP14 (SFPL14 & SFPR14) |
| Product Description | Evolution Supine Foot Positioner SFPL14 Supine Foot Positioner Left Large SFPR14 Supine Foot Positioner Right Large |
| Size | Large |
| Intended Use | Support Patient's Foot in a safe, secure and stable orientation that is anatomically correct and helps prevent the development of pressure sores on the bony prominence of the heel area while the patient is lying in the supine position. |



Figure 15 Foot Positioner

Discussion

The graphs demonstrate trend lines of lower Peak Interface Pressure (Figure 18) and Higher Support Surface Area (Figure 19) by using the Foot Positioners over the benchmark products. There is a significant difference in the trend lines between using the Supine Foot Positioner and the Substantive Market Equivalent. The pressure redistribution occurs under the lower leg where there is no bony prominence. This is illustrated on Figure 16 and 17. On the Market Equivalent, Figure 17, the peak pressure occurs directly under the heel of the individual being tested and along the Achilles tendon.

The trends for Peak Interface Pressure (mmHg) illustrate that the use of the Supine Foot Positioner redistributes the load over a wider area and away from the bone prominences of the Heel. See figure 16.

The weight that is normally concentrated on the heel is now redistributed around the out lower leg area and up along the foot which can tolerate higher pressures. The trend lines level off over the hour indicating that there is no increase in the intensity of peak pressure over time. On the other hand, the Substantive Market Equivalent illustrates a sharp rise in Peak Pressure over time which is not beneficial to the individual using them.

The Pressure Map on Fig 16 illustrates the Foot Positioner redistributing the concentrated weight of leg away to area to the more fatty skin tissue under the lower leg. The Pressure Mat picked up some hammocking of the mat over the aperture in the product. This is expected because the mat is contouring around the heel and foot area and the sensors in the mat are becoming strained. The Control Benchmark Surfaces Fig 17 illustrates the loading of the weight of the individual's leg directly on the lower leg.

The graphs for Support Area (cm²) illustrate that the use of the Foot Positioners increase the support provided around the lower leg and up along the foot. After an hour, the trend is increasing for the area of support. This demonstrates that the products are still deforming to provide more support as time progresses. This trend would be expected to continue and level off over time. This is in keeping with the properties of the Visco Elastic Foam within the product. It is designed to soften with heat. So the slight heat conduction from the patient is aiding the foam softening process, hence providing more supporting surface area in contact with the individual lying on it.

Pressure Map Profiles

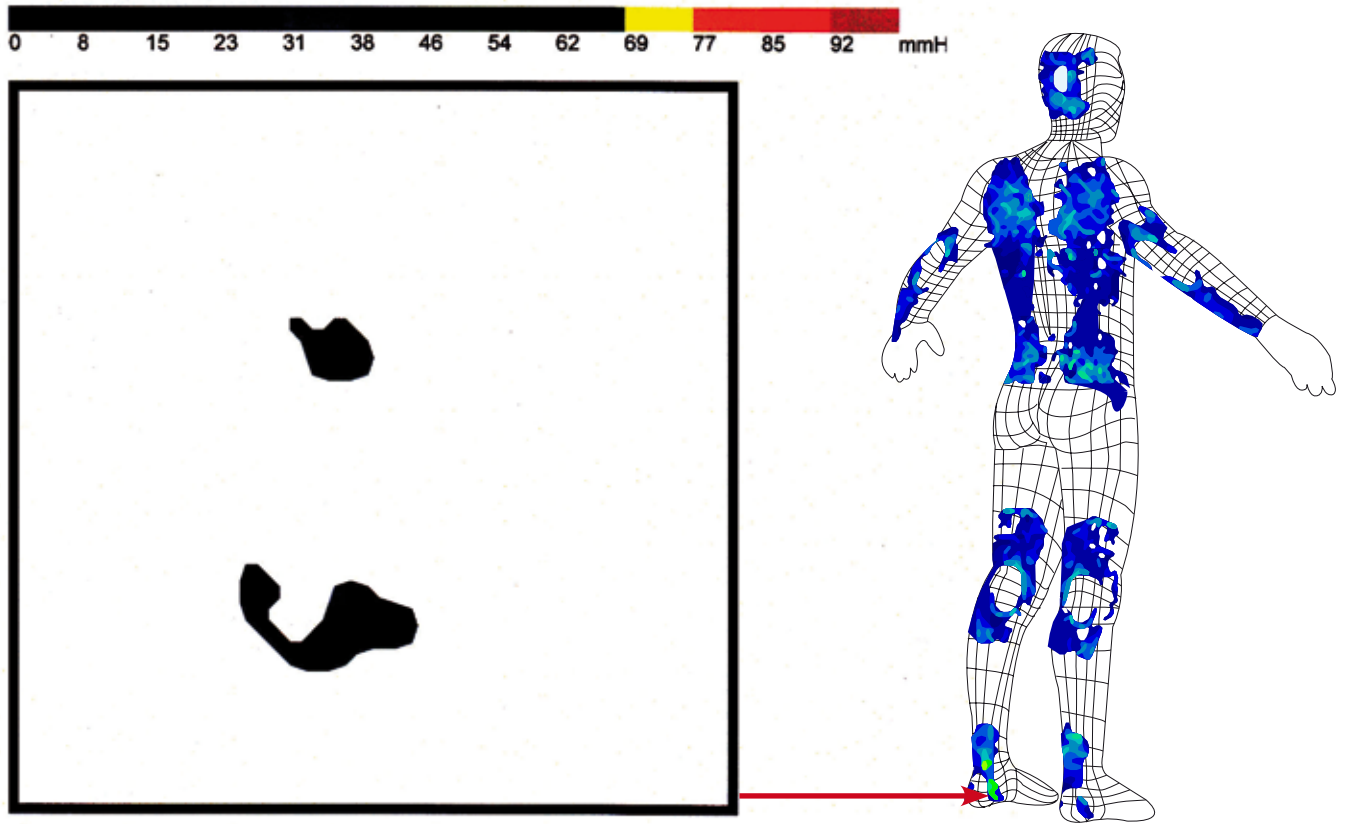


Figure 16 SFP14 Supine Foot Positioner Profile

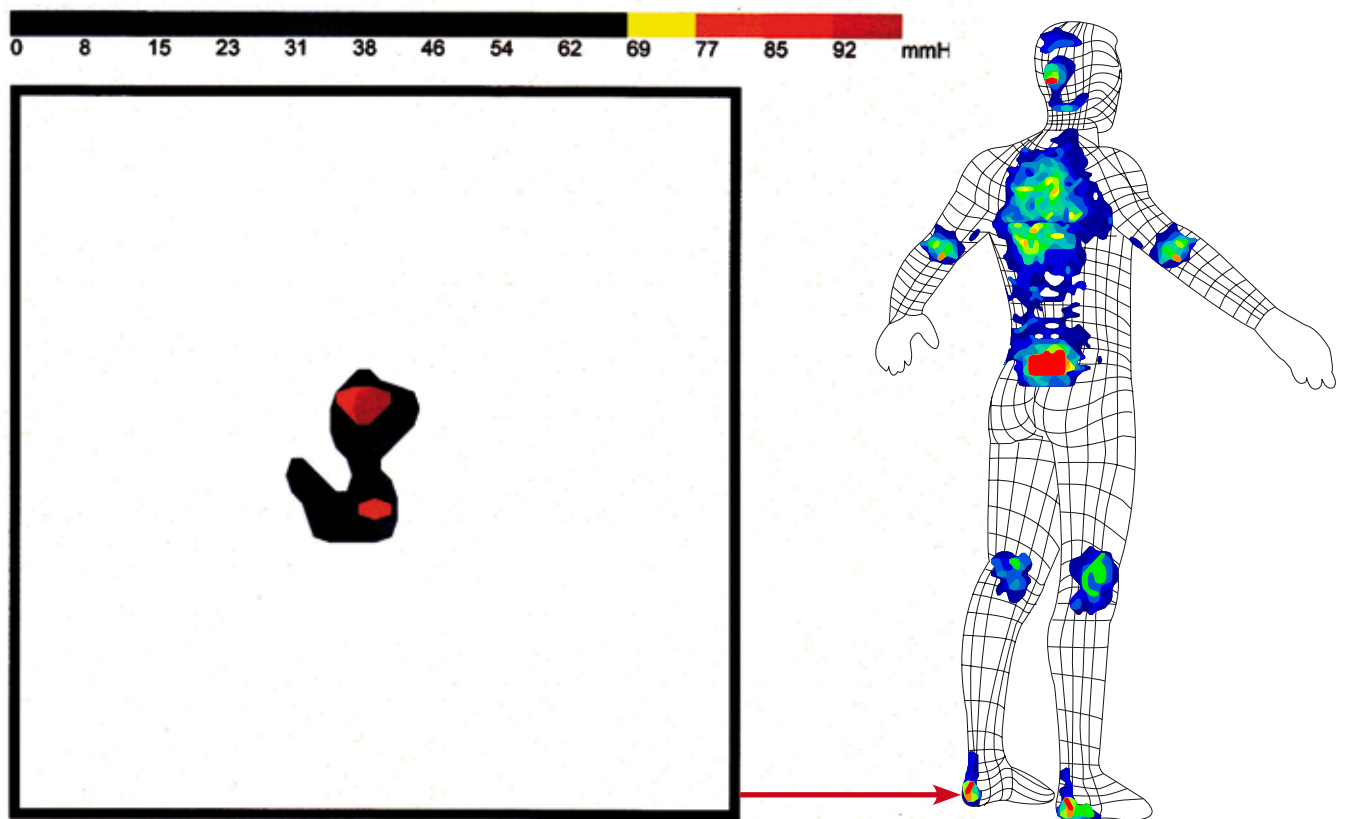


Figure 17 Heel Gel Pad Profile

Pressure Mapping Graphs

SFPL14 Foot Positioner Peak Interface Pressure ML

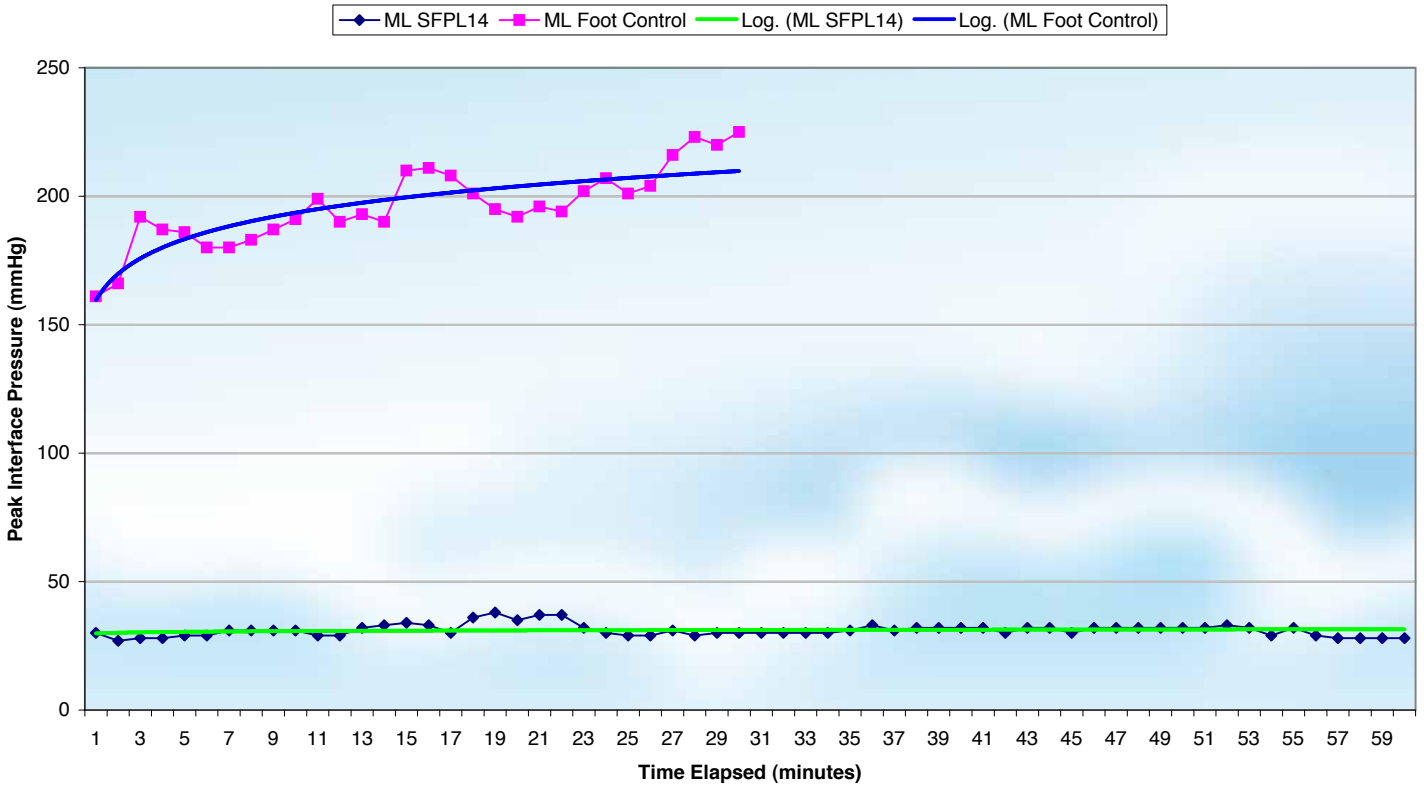


Figure 18 SFP14 Foot Positioner Peak Pressure

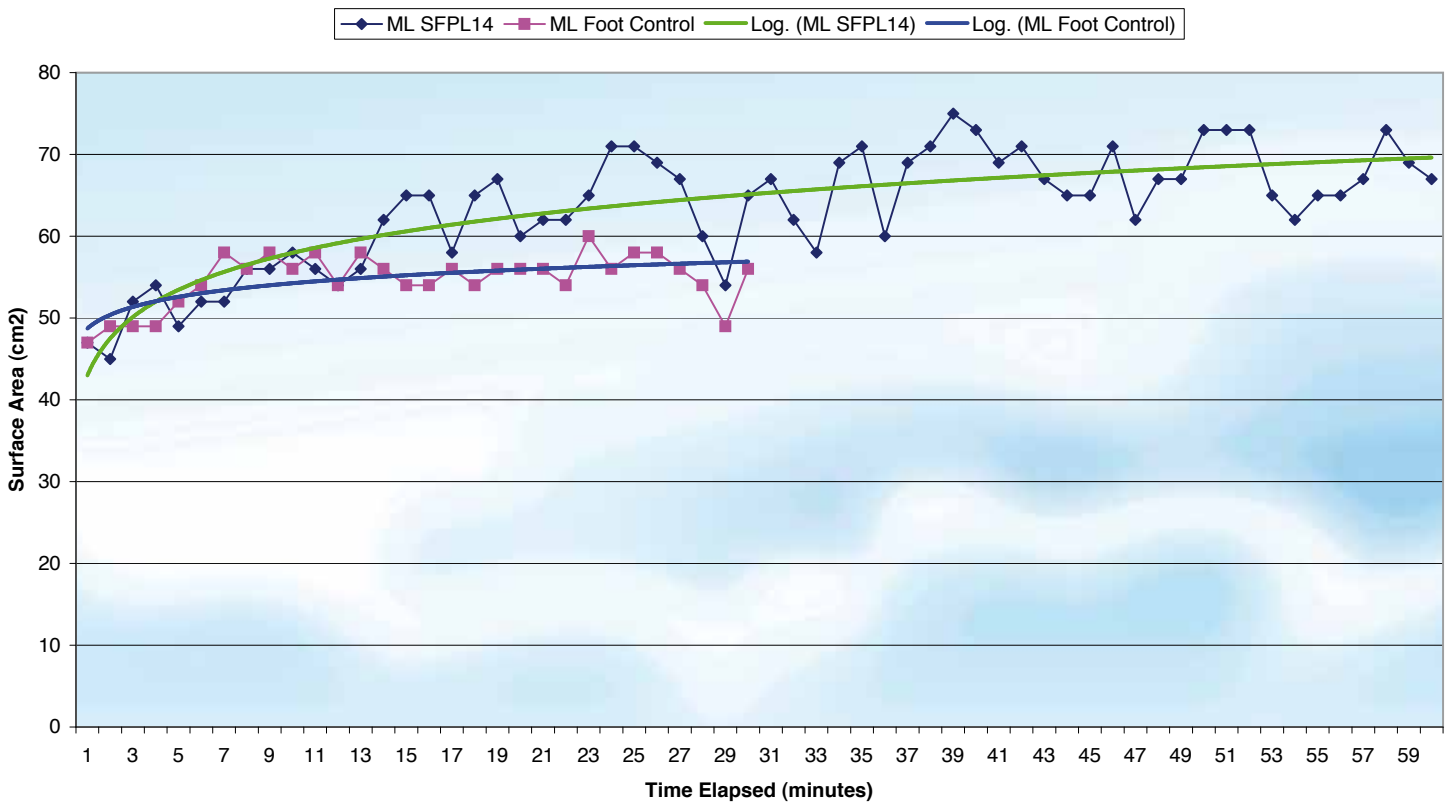


Figure 19 SFP14 Support Area

Conclusion

Through the use of the pressure mapping system, the use of the products can be verified to function as intended. There is a significant benefit in using the pair of Foot Positioners to relieve pressure on the heels of an individual. The pair of products functions to redistribute pressure away from the bony prominence of the heel and to the non bony areas around the lower leg and ball of the foot.

6. SAP14 Supine Arm Positioner

Product Specification

| Description | Specification |
|---------------------|--|
| Product Code | SAP14 |
| Product Description | Evolution Supine Arm Positioner |
| Size | Large |
| Intended Use | Support Patient's Arm in a safe, secure and stable orientation that is anatomically correct and helps prevent the development of pressure sores on the bony prominence of the elbow area and protects to Ulnar nerve and brachial nerve while the patient is lying in the supine position. |



Figure 20 Supine Arm Positioner

Discussion

The SAP14 Supine Arm Positioner was tested with and without the other Supine Positioners in place. The use of all the Supine Positioners aids in the correct alignment and positioning of the body but is not essential to have these. The arm positioning is a separate issue to the full Torso and Leg positioning.

The Graphs demonstrate trend lines of lower Peak Interface Pressure (Figure 23) and Higher Support Surface Area (Figure 24) compared to using the Gel Positioner as the Substantive Market Equivalent. The area supported under the arm was different for the Arm Positioner compared to the Gel Positioner (Substantive Market Equivalent). The Supine Arm Positioner distributes the load over a wider area along the arm. Refer to Figure 21. The Substantive Market Equivalent puts pressure under the elbow area and upper arm resulting in discomfort for the individuals testing the products. Individuals commented on the discomfort using the Gel Pad. Refer to Figure 22.

On the other hand, the Substantive Market Equivalent trended upwards at a higher rate than the SAP14. There is a significant difference between the two products. The SAP14 deforms to accommodate the shape and weight of the arm and does not put a reactive force directly under the elbow or upper arm where it is sensitive to nerve damage and blood flow complications.

Individuals testing the Gel Pad experienced that it was cold to the touch compared to the SAP14. They felt that their arms were more securely cupped in the SAP14 compared to the Gel Pad. The width and higher sides on the SAP14 provided great lateral support and protection along the arm. As the Retainer and Strap were used, the high contoured sides gave more protection than the shallow Gel Pad.

The contoured base allows the product to flex more making it accommodate more arm sizes. This aids the function of the product to provide more support area as the period of use is extended.

Pressure Map Profiles

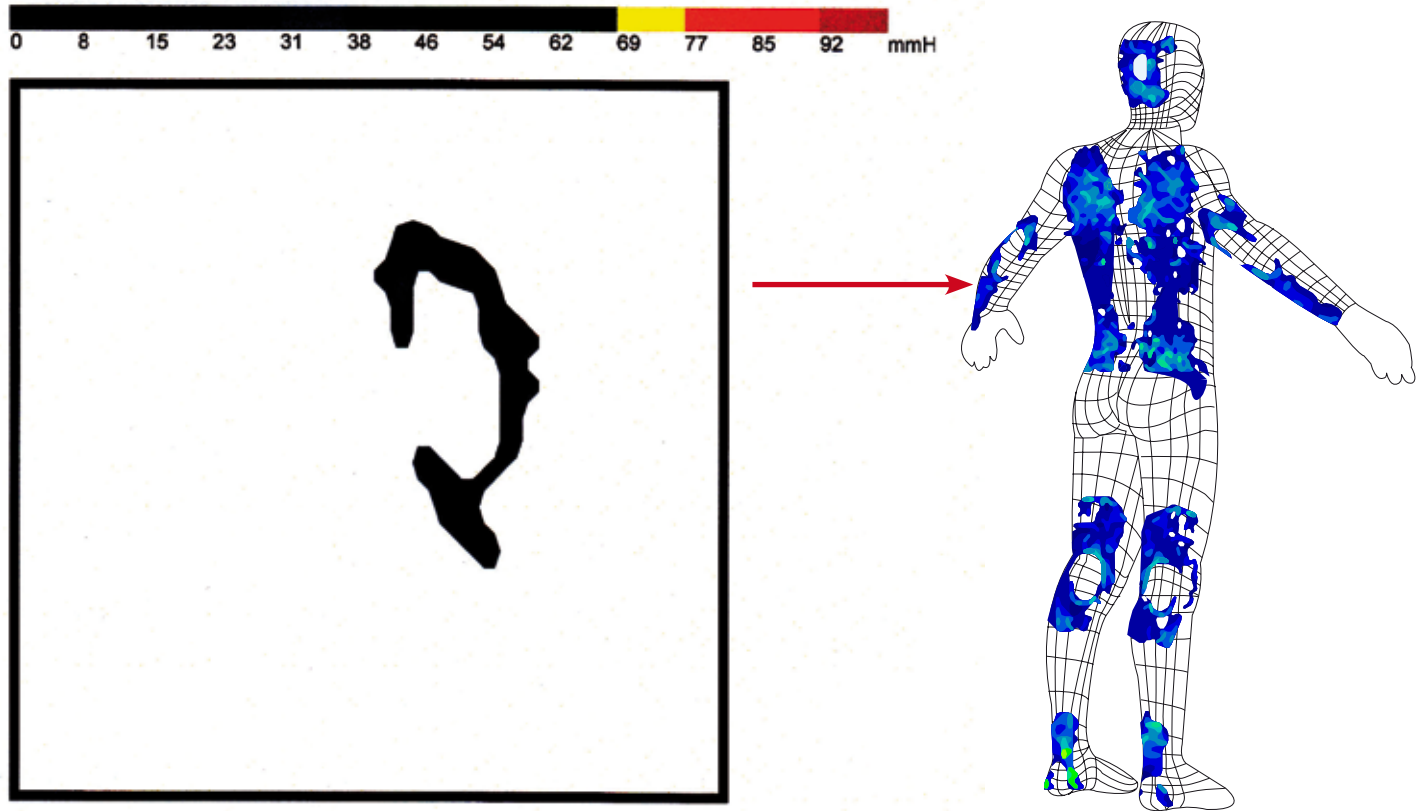


Figure 21 SAP14 Supine Arm Positioner Profile

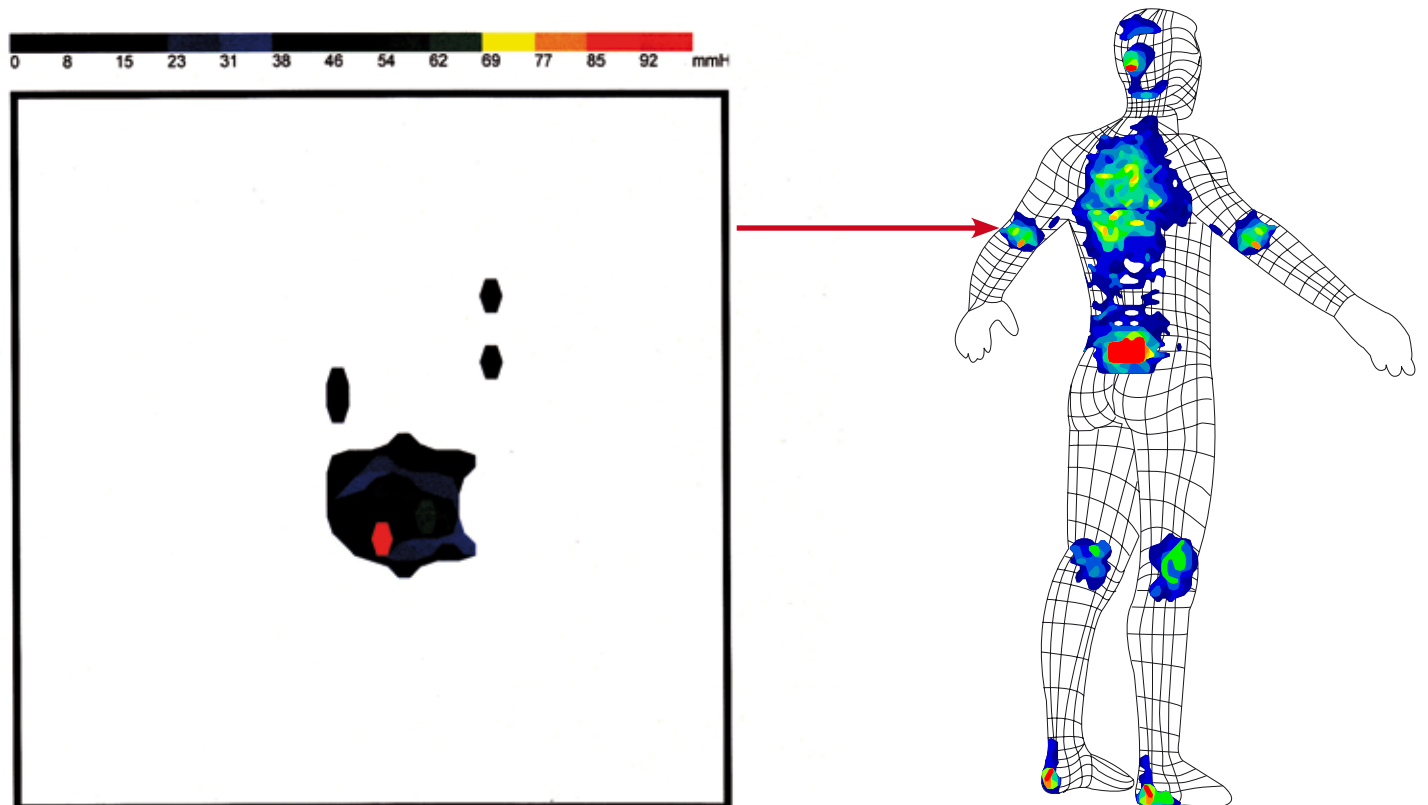


Figure 22 Gel Contoured Armboard Profile

Pressure Mapping Graphs SAP14 Vs. Gel Pad Peak Interface Pressure (JK)

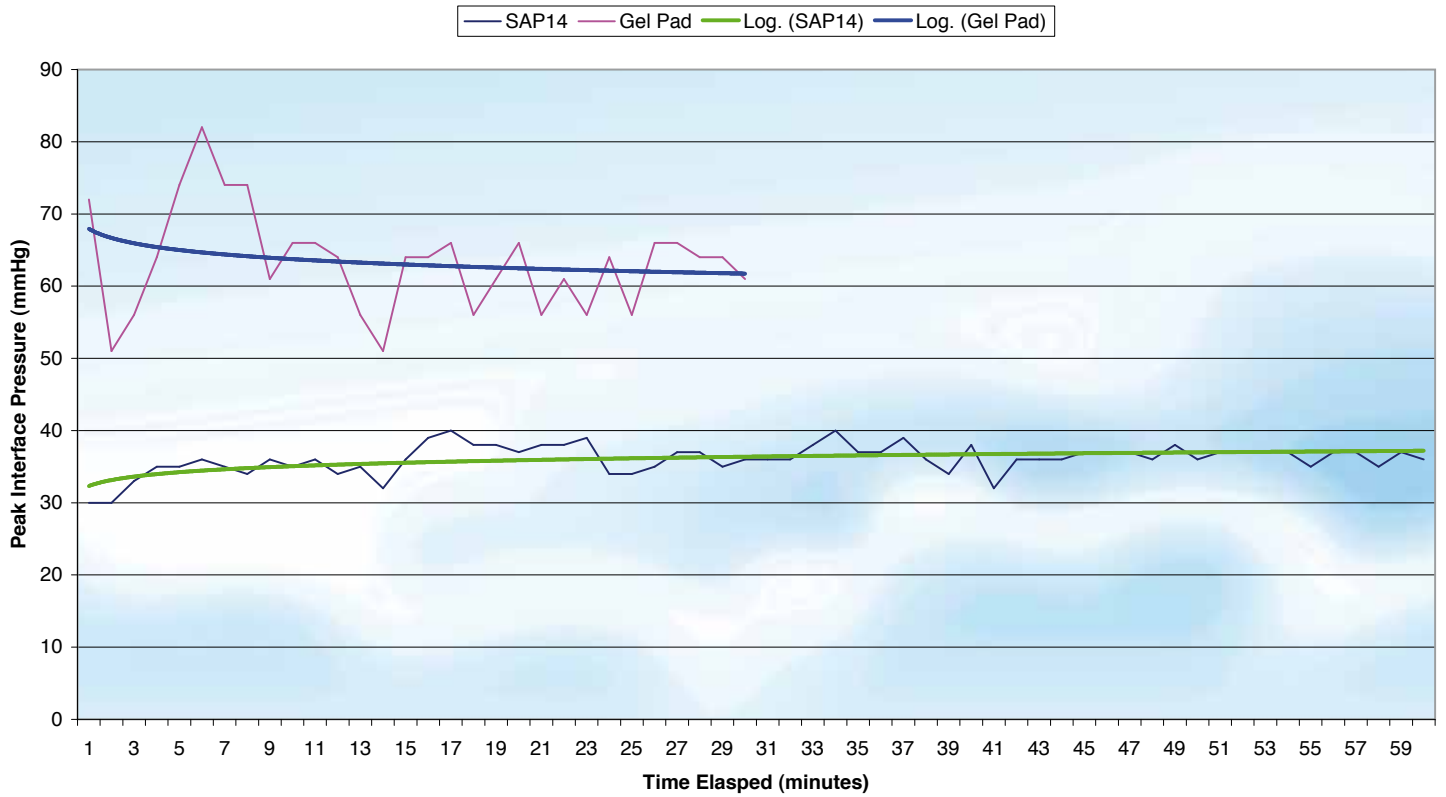


Figure 23 SAP14 Peak Pressure

SAP14 Vs. Gel Pad Support Surface (JK)

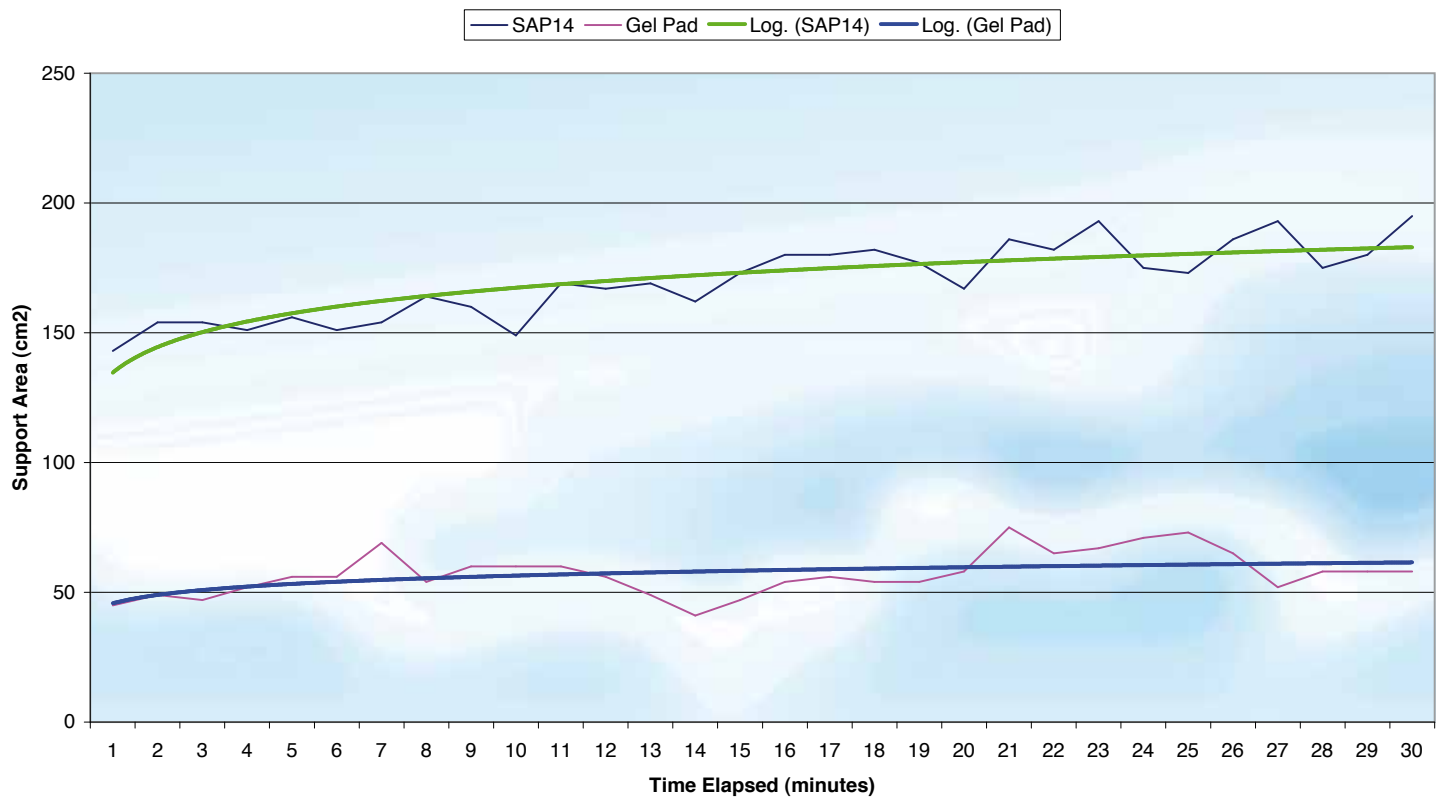


Figure 24 SAP14 Support Area

SAP14 Vs. Gel Pad Peak Interface Pressure (ML)

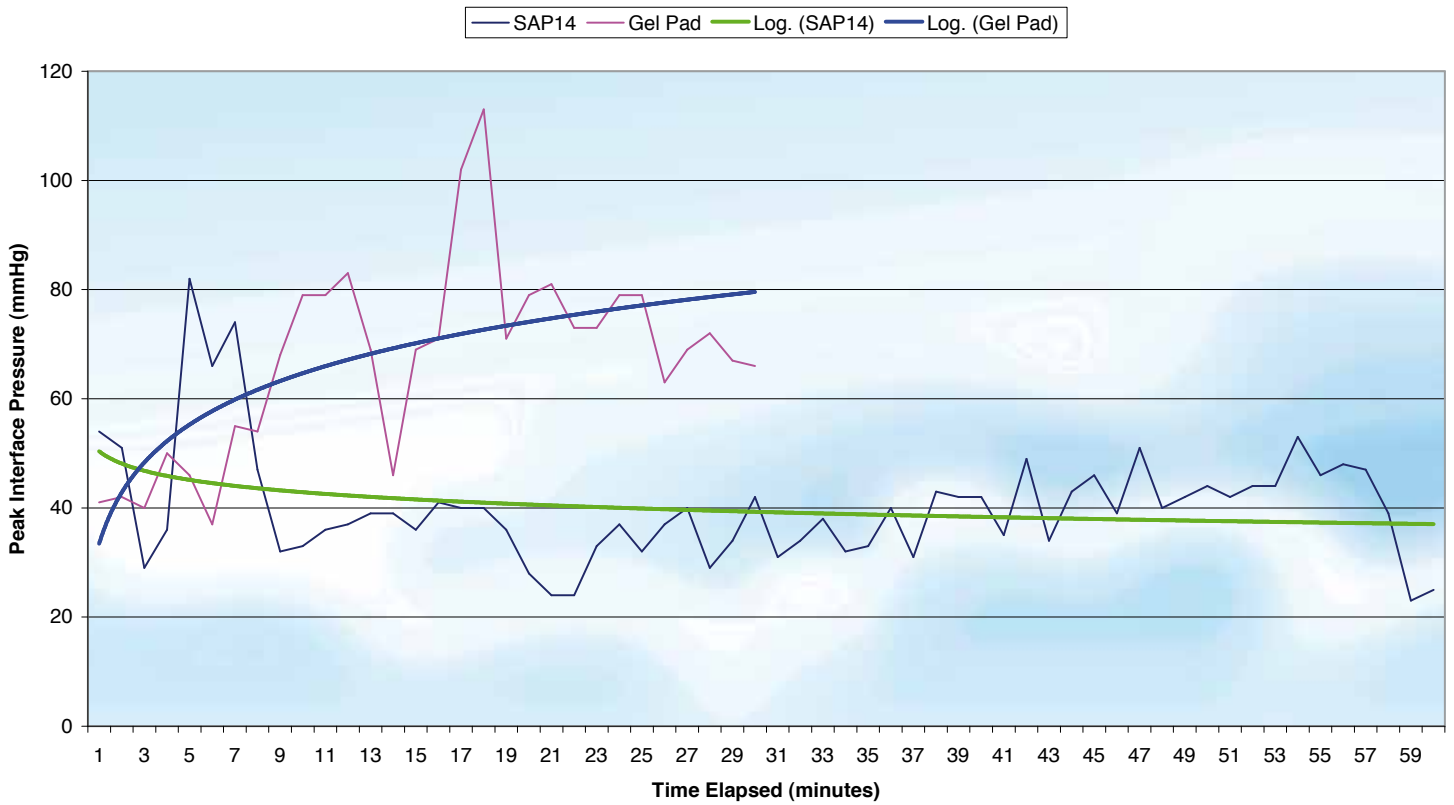


Figure 25 SAP14 Peak Pressure

SAP14 Vs. Gel Pad Support Surface (ML)

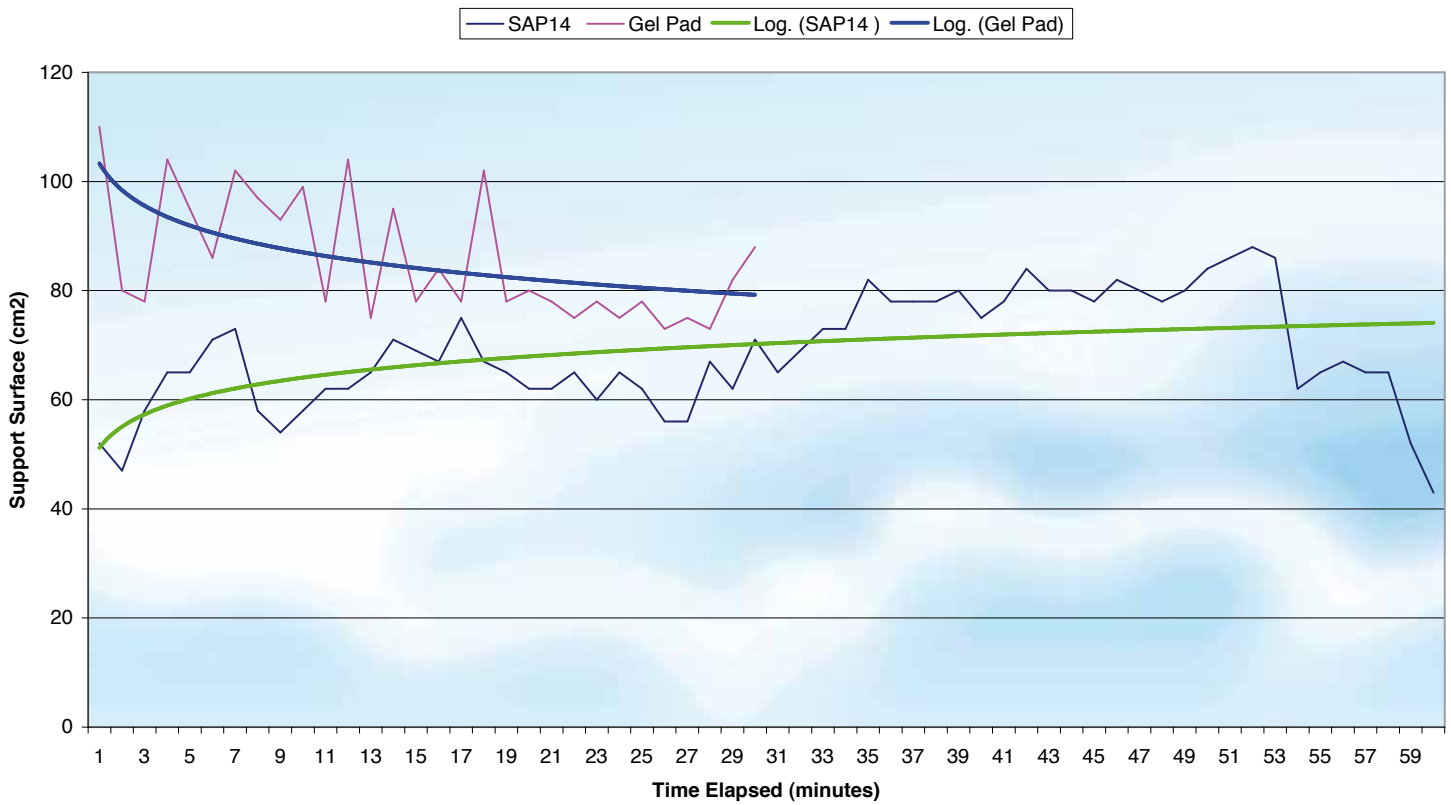


Figure 24 SAP14 Support Area

Conclusion

The Supine Arm Positioner SAP14 achieves its intended use by the evidence displayed in this report. It is suitable for its intended use as a Supine Arm Positioner only. All individuals testing it expressed an opinion that it was extremely comfortable. It can be used with or without the rest of the EVOLUTION Patient Positioner Range. Due to its concaved profile, it secures the arm even when the Armboard Attachment is tilted at vertical angles. The Gel Pad will not perform this function as well. The longitudinal rigidity of the SAP14 provides protection to the arm and prevents it falling off the Armboard.

7. SRK14 Strap Retainer kit

Product Specification

| Description | Specification |
|---------------------|---|
| Product Code | SRK14 (S14, R14 & P14) |
| Product Description | Evolution Strap Retainer Kit |
| Size | Large |
| Intended Use | Retain Patient's arm in a safe, secure and stable orientation in the Arm Positioner that is anatomically correct and helps prevent the development of pressure sores on the bony prominence of the elbow area and protects to Ulnar nerve and brachial nerve while the patient is lying in the supine position. |



Figure 27 SRK14 Strap Retainer Kit

Discussion

There is very little pressure mapping that could be performed on the Strap Retainer Kit. A Tekscan Single Sensor was used to measure the comparison between using the full Strap Retainer Kit compared to only using the strap. These are illustrated in Figures 28 to 31 below. In some cases where a thin arm is secured using the Kit, there was very little contact with the Retainer hence applying absolutely no load on the arm of the individual in the Arm Positioner.

The following are a summarized version of the comments on pressure applied and comfort experienced by individuals testing the product.

Patient Immersion into Product

Each individual found the product to be very comfortable and smooth fitting around the arm. The Retainer is designed in an extreme contoured shape with both the inner and outer surfaces profiled to suit the anatomical curvature of the arm without pinching it.

Assessment test for Shear Action generated by patient movement

All individuals experienced no shearing action on their arms. The product is designed to provide limited shearing force on the arm because it redistributes the area of load around a greater area of the arm.

Putting excess pressure on the patient's skin

Individuals commented that there was no pressure on the skin. Each found that the product was very comfortable from this point of view.

Assessment to establish that the Visco-elastic foam softness does not compromise the area around the bony prominence.

The foam was soft to the touch. It provides good cushioning effect because it has a good thickness to absorb the strain of the strap.

Conscious persons to determine patient discomfort.

The following factors were considered when assessing conscious individuals on with the combination of the SRK14 and SAP14 combining into the SAPK14.

- Cause hyper-extension of patient's anatomy.
- Cause Hyper-rotation of patient's limbs.
- Cause muscle stretch and strain to patients.
- Causes trauma of a bony prominence compressing vascular flow to the muscle.

For each of the above, all individuals experienced no discomfort. There was no hyper extension because the arm cupped well into the positioner with lots of room for movement. The SAP14 was designed to prevent muscle stretch and strain.

Assessment on products under various sizes of human bodies.

Various size individuals tested the products and found them to be very comfortable. Individuals with very slim arms, up to 290mm in girth, could move about in it when the SRK14 was tightened fully.

Assess conscious persons to see if it adversely affects patient's body.

There was no adverse affects on any individuals testing the products.

Pressure Map Graphs

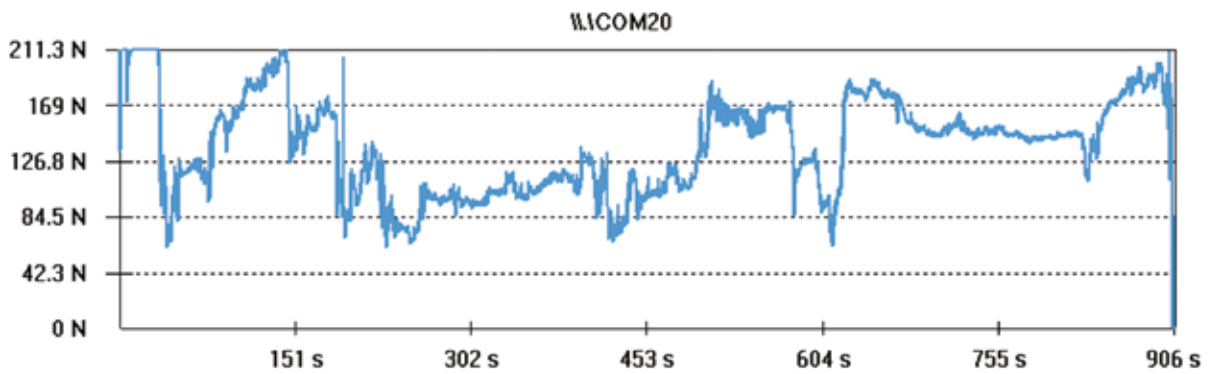


Figure 28 Michael Strap Only Filename: SRK14 None ML

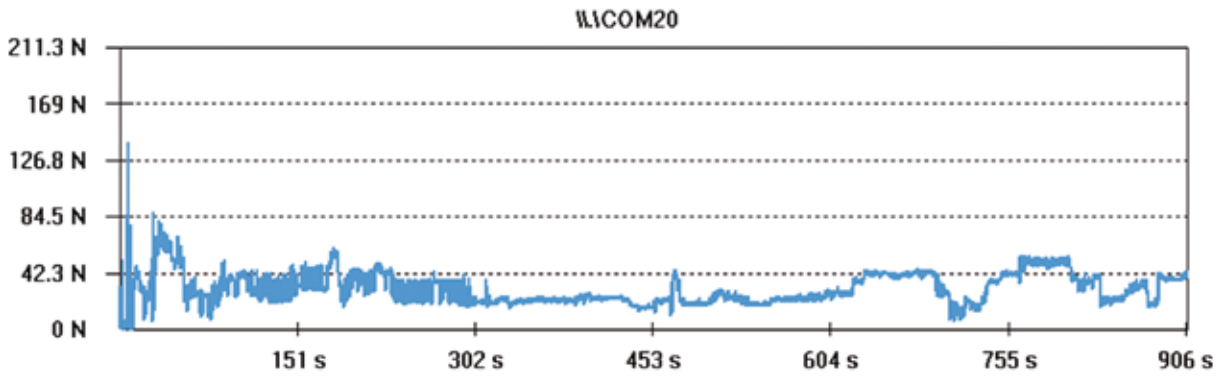


Figure 29 Michael SRK14 Filename: SRK14 ML

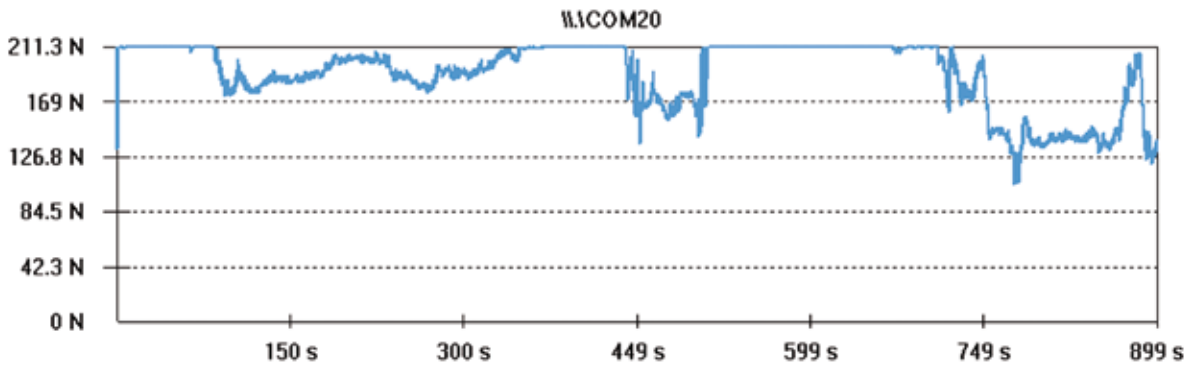


Figure 30 Roman Strap Only Filename: SRK14 None RM

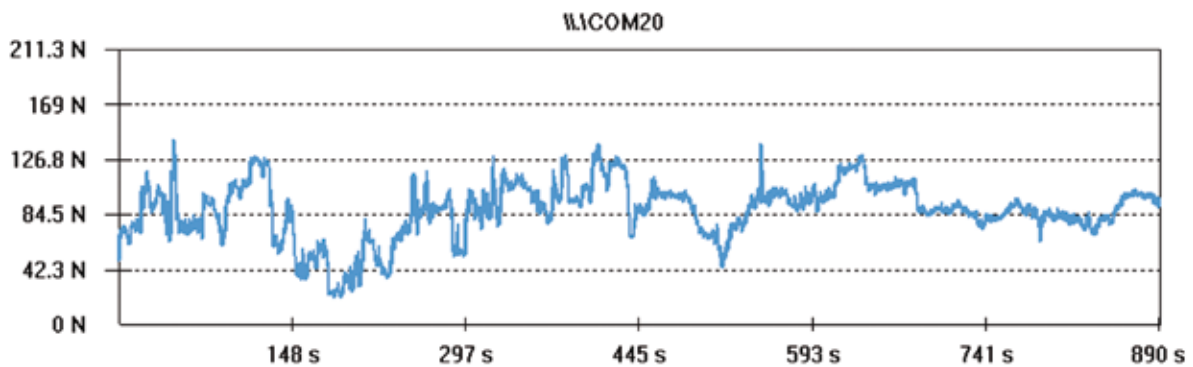


Figure 31 Roman SRK14 Filename: SRK14 RM

8. Supine Side Arm Positioner

Discussion

From analysis of the Peak Interface Pressure (Graph Figure 35), this illustrates that the new SSAP14 Supine Arm Positioner provides less concentrated peak interface pressure compared to the benchmark product. This pressure tends to occur on the bony prominences of the elbow.

The product is designed to cup the complete length off the arm and redistribute the pressure over the softer muscle of the arm. The end of the Positioner in contact with the arm is designed to flex slightly with the weight of the arm and not provide a strong reactive force against the bony prominences of the elbow.

The tests were preformed on conscious individuals that were aware of the pressure points of the arm and reported experiencing very good comfort from using the new product.

The benchmark product was cold to the touch and the hard polycarbonate component was uncomfortable. The cold feeling was experienced by individuals testing using their bare arms. This was due to the gel pad being a material with a high specific heat capacity so it took thermal energy away from the individual's skin through thermal conduction.

There are very little cushioning properties in the gel pad against the long plastic ski. This lead to higher peak interface pressure on the benchmark product as illustrated in Fig 34.

On analysis of the Surface Area Graph figure 36, it illustrated that the SSAP14 was better than the benchmark product. In most cases, the rate of increase of support area was greater for the new product compared to the other product. This was due to the flexibility of the positioner relative to the plastic ski.

In most cases, the new product provided a 50 per cent increase in support area. This support area is due to the ergonomic concave surface of the positioner. It is designed to wrap around the outer part of the arm providing maximum protection.

The new Supine Side Arm Positioner protects the arm from the elbow to the hand without exerting pressure on the patient's limb.



Figure 32 SSAP14 Supine Side Arm Positioner

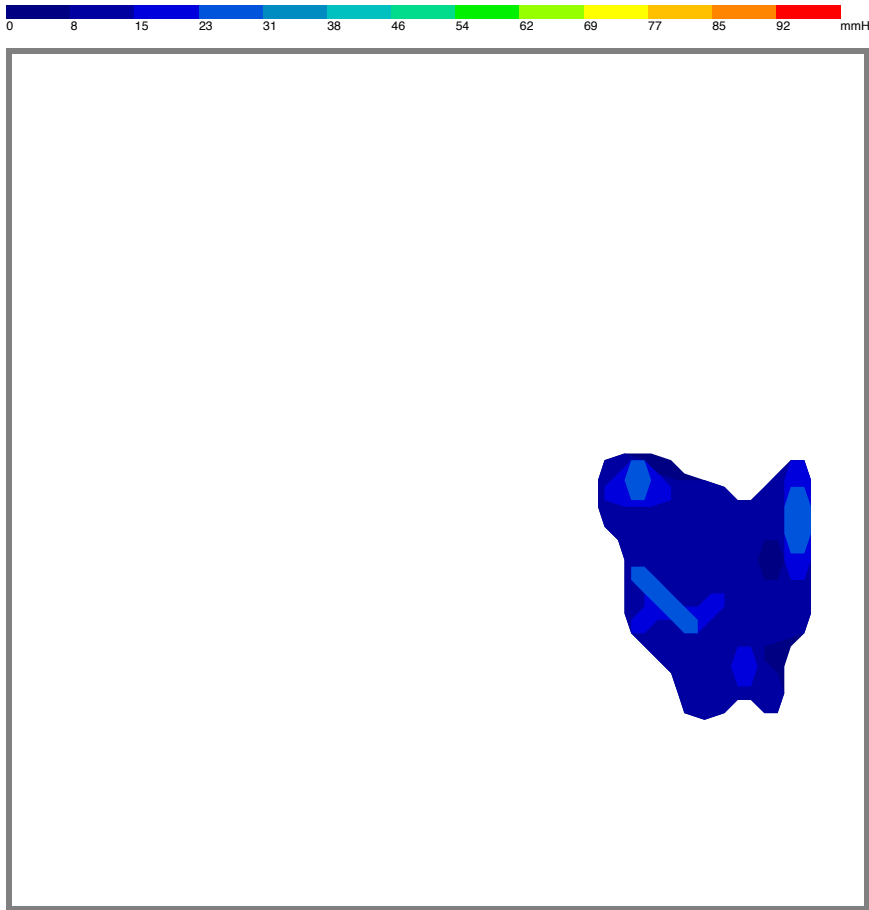


Figure 33 SSAP14 Supine Side Arm Positioner

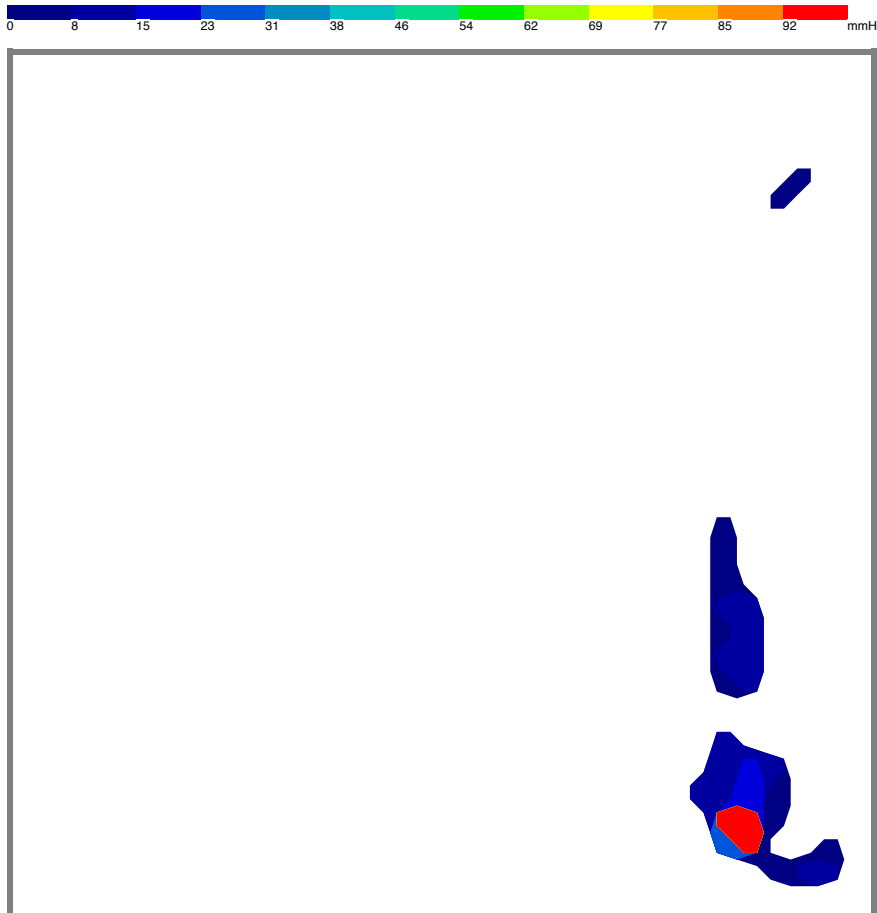


Figure 34 Benchmark Product

SSAP14 Vs. Benchmark Product Peak Interface Pressure (ML)

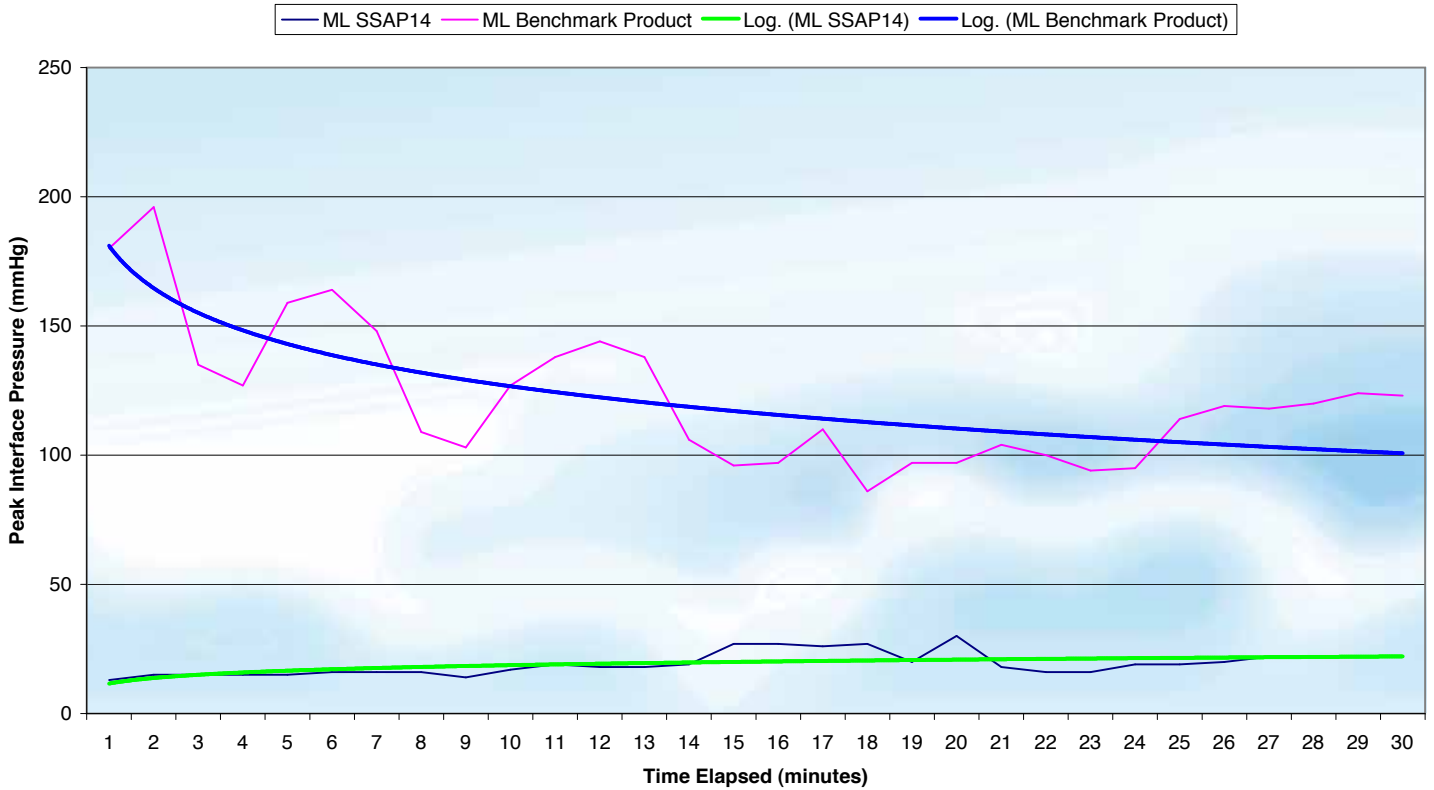


Figure 35 SSAP14 Supine Arm Positioner

SSAP14 Vs. Benchmark Product Surface Area (ML)

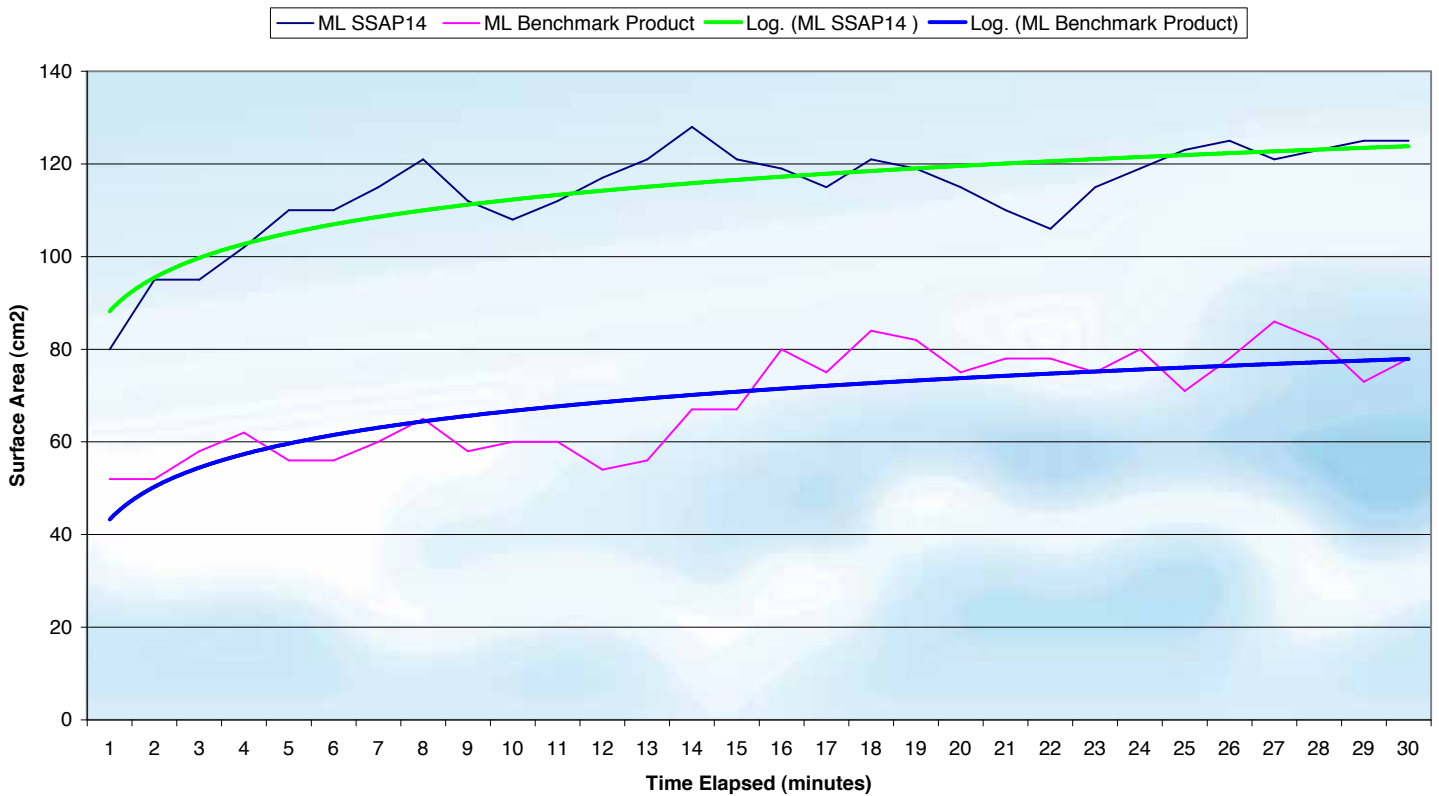


Figure 36 SAP14 Surface Area Graph

Conclusion

The SRK14 used in conjunction with the SAP14 to form the SAPK14 Supine Arm Positioner Kit functions to perform its intended use of retaining the arm in the Arm Positioner and holding the Arm Positioner on the Arm Board Attachment. This is the only validated use for the Strap Retainer Kit, i.e. used with the SAP14 Supine Arm Positioner.

It is easy to use and provides an excellent degree of comfort to the individual using it. The Retainer provides a good degree of cushioning from any tension on the Strap.

9. Appendices

Stats on Individuals testing products

| Individual's Name | Height (cm) | Weight (kg) | Foot Length (cm) |
|-------------------|--------------|-------------|------------------|
| Michael Lawler | 188cm 6'2" | 95 | 28.5 |
| Joe Kavanagh | 175cm 5'9" | 110 | n/a |
| Roman Molochko | 176 cm 5' 9" | 88.5 | n/a |

Competitor Products

The following tables contain the specification of the Substantive Market Equivalents.

Contoured Armboard Positioner

| Specification | Details |
|--|--|
| Product Code | 40306 |
| Product Description | Contoured Armboard Pad |
| Product Components | See Below |
| Product Component: Outer Liner | Polyurethane Film |
| Product Component: Inner Bulk Material | Polyurethane Gel |
| Product Weight | 3.7 kg |
| Manufacturer | Action Products Inc. |
| Size | 61cm 15cm 5cm (24in x 5 3/4 in x 2 1/4 in) |

Heel Support

| Specification | Details |
|--|---|
| Product Code | 40502 |
| Product Description | Heel Support |
| Product Components | See Below |
| Product Component: Outer Liner | Polyurethane Film |
| Product Component: Inner Bulk Material | Polyurethane Gel |
| Product Weight | 0.5 kg |
| Manufacturer | Action Products Inc. |
| Dimensions | 15cm x 8.3cm x 4.5cm (6in x 3 1/4 in x 1 3/4in) |

Dome Shaped Positioner

| Specification | Details |
|--|---|
| Product Code | 40603 |
| Product Description | Dome Shaped Positioner |
| Product Components | See Below |
| Product Component: Outer Liner | Polyurethane Film |
| Product Component: Inner Bulk Material | Polyurethane Gel |
| Product Weight | 3.7 kg |
| Manufacturer | Action Products Inc. |
| Dimensions | 36cm x 15cm x 7.6cm (14in x 6 in x 3in) |

Side Arm Positioner


| Specification | Details |
|--|---|
| Product Code | 5021A |
| Product Description | Arm Toboggan Pad & Shield |
| Product Components | See Below |
| Product Component: Outer Liner | Polyurethane Film |
| Product Component: Inner Bulk Material | Polyurethane Gel |
| Product Weight | 2 kg |
| Manufacturer | MHP Medical Inc. |
| Dimensions | 42cm x 19cm x 1cm (17in x 7 1/2 in x 3/8in) |

Report Completed By: _____ **Date:** _____

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