

The Clinical Evaluation for the **PressureCareReliefProducts®**

Conducted by:

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January 28th, 2015

Commissioned by:

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1) EXECUTIVE SUMMARY OF THE CLINICAL EVALUATION:

- The 2-layer Spacer Fabric **PressureCareReliefProducts®** Pad was evaluated on 6 subjects in a Care Home Environment over a 4-week period, in order to examine its effect on comfort and contribution to the prevention of pressure damage. The average age of the subjects was 86 years, with the oldest subject being 95 years and the youngest 70 years.
- The Water Score Range was 16-19, with the average Waterlow Score being 17. Therefore, all subjects were in the “High Risk” category. All of the subjects reported that the **PCRP®** Pad was comfortable and Care Home staff reported that **PCRP®** Pad was easy to use and move from bed to chair when needed. Staff also commented that the **PCRP®** Pad could be used as a very effective slide sheet when trying to move subjects across the bed. Comments were made that the **PCRP®** Pad was cooler than the previous mattress overlay (Repose) they were on and more comfortable generally and so were getting improved sleep.
- In terms of infection control, the staff commented on the ease of laundering the **PCRP®** Pad, as it could be machine washable. However, it was noticed that the bed parts began to lose form towards the end of the study period. The outer cover which was firmly attached to the under layer when first used became detached and was prone to wrinkling.
- Staff thought the bed pad would be better as a full bed length as it currently offers no protection to heel, which are prone to pressure damage. Also, if the bed pad could have some sort of bands at each corner to loop over underlying mattress it would help keep it in position better. Comments were also made about the benefits of producing the **PCRP®** Pads in a range of surface area sizes as some subjects had very narrow/small seats that they would sit on and it was sometimes awkward to fold the existing bed pad small enough to fit.
- Five of the subjects had no signs of existing pressure damage prior to the use of the **PCRP®** Pad on their scapulae, spine, sacrum, buttocks or hips. Use of the **PressureCareReliefProducts®** appeared to result in the continued good health of these areas. One subject has a grade-2 pressure ulcer in the left sacral area and this healed over the study period.

2) INTRODUCTION:

Preventing pressure damage is difficult, due to the large number of potential aetiological factors involved, although it is recognized that the largest single causative factor is unrelieved pressure. Concomitant to this are other predisposing factors, which may be intrinsic or extrinsic. These include, intrinsically malnutrition, incontinence, altered level of consciousness and altered level of sensation, and extrinsically, friction and shear forces. Many of these factors are often involved simultaneously, and for those patients who are confined to bed for prolonged periods, appropriate pressure redistributing equipment needs to be considered.

3) **PressureCareReliefProducts®**

The **PressureCareReliefProducts®** is a pressure-relieving pad marketed by the **Medi-Care Division of CASA C.S. Inc.**, which is designed to reduce the potential for development of pressure damage in people who are known to be at risk. The **PCRP®** Pad is marketed as an effective system, which offers 24-hour protection as it can be easily transferred between bed and chair.

4) AIM OF STUDY:

To evaluate the clinical efficiency of the 2-layer Spacer Fabric **PCRP®** Pad on a small group of Care Home subjects, when used in conjunction with their existing bed mattress and chair.

5) **METHODOLOGY:**

The six subjects for the study were residents in a Care Home. Five of the subjects had no existing pressure damage. One of the subjects has a grade-2 pressure ulcer in the left sacral area.

Prior to the evaluation, the subjects had been identified by Care Home staff as being at high risk of pressure damage.

Subject profile

- Initially, all subjects were on a standard static foam mattress with a Repose mattress overlay.
- Most subjects were independent in terms of repositioning in chair and bed, with some just needing minimal assistance.
- Four of the subjects were doubly incontinent and two subjects were incontinent of urine.
- The subjects were visited prior to the commencement of the evaluation, in order to collect baseline data.

Day 0

- The skin of each subject was examined for signs of pressure damage.
- Photographs were taken of the “at risk” areas – scapulae, spine, sacrum, buttocks and heels.
- A High Definition Ultrasound Scan was taken of each subject at risk areas.
- Subjects were asked to rate the comfort of their existing mattress overlay (Repose) on a scale of 1-10 (10 being most comfortable).
- The subjects then had their original mattress overlay removed from the bed and replaced by a 2-layer Spacer Fabric **PCRP**® Pad.

Day 7, 14, 21, 28

- The above methodology was repeated, with the exception that the bed pad remained on the bed and chair throughout the period of evaluation. Therefore, none of the subjects used their old mattress overlay during the period of the study. Also, the ultrasound scan was only repeated at day 28 (Ultrasound data and results in separate report).
- Staff was also asked for comments about the **PCRP**® Pad.

6) **RESULTS:**

The skin on all the subjects showed no visual signs of pressure damage or deterioration. The grade-2 pressure ulcer in the left sacral area of subject BG healed over the course of the study.

Using our comfort scale, the subjects reported their comfort level on their existing mattress overlay at the start of the study as being on average 4.5 (range 3-5). When transferred to the 2-layer Spacer Fabric **PCRP**® Pad, the subject average comfort score went up to 8.2 (range 8-9).

Staff made a range of comments which are mentioned on the report.

The individual case studies, with photographs, are presented from page 4 onwards of the report.

7) **CONCLUSION:**

The results of these case studies were positive. All of the subjects had exhibited no evidence of pressure damage during the initial assessment on Day 0 apart from on having a grade-2 pressure ulcer in the left sacral region. All of the subject's skin maintained this healthy profile throughout the study and the subject with the pressure ulcer healed. All patients' feedback showed a very positive assessment of **PCRP**® Pad as all found it comfortable and had improved their sleep. Staff also made very good constructive comments about further improvements, which could make this an even better product.

Subject 1: (BG)

Age: 77 years

Gender: Female

Waterlow Score: 18 (high risk)

MUST Nutritional Score: 0 (low risk)

Medical History: Angina, Alzheimer's

Continence: Doubly incontinent

Transfers: Standing transfers with the assistance of care staff

Mobility Status: Walks with assistance of care staff and a Zimmer

Repositioning Status: Independent

Length of time sitting: Approx. 8hrs during the day in a high seat armchair. Regime is 4hrs sitting the 4hrs bed, then 4hrs sitting, etc...

Existing Mattress: Standard divan bed and foam mattress. Repose mattress Overlay

Other relevant information: Subject had a grade-2 sacral pressure ulcer in the left sacral area
Approx. 2 months in duration.

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Day 0 Observations: 1. Apart from grade-2 PU in left sacral area no other damage present at initial assessment.
2. Current mattress overlay comfort score = 5

Day 0 Photographs:



Day 7 Observations: 1. Apart from PU in left sacral area no other damage present. PU has improved.
 2. **PressureCareReliefProducts®** comfort score = 8.
 3. Staff comments: Subject seems more settled on the bed pad than the previous overlay and sleep better.

Day 7 Photographs:



Day 14 Observations: 1. Apart from PU in left sacral area no other damage present. PU continuing to improve
 2. **PressureCareReliefProducts®** comfort score = 8
 3. Staff comments: Bed Pad easy to use and move from bed to chair.
 Full length bed pad would be good so heels get protected.

Day 14 Photographs:



Day 21 Observations:

1. Apart from PU in left sacral area no other damage present. PU continuing to improve
2. **PressureCareReliefProducts®** comfort score = 8
3. Staff comments: Same as Day 7 and 14 comments.

Day 21 Photographs:



Day 28 Observations:

1. Left sacral PU healed. No other signs of pressure damage.
2. **PressureCareReliefProducts®** comfort score = 8
3. Staff comments: Same as Day 7, 14, and 21 comments.

Day 28 Photographs:



Subject 2: (CB)

Age: 91 years

Gender: Female

Waterlow Score: 16 (high risk)

MUST Nutritional Score: 0 (low risk)

Medical History: Osteoporosis, Diabetes

Continence: Urinary Incontinence

Transfers: Standing transfers with the assistance of care staff

Mobility Status: Walking with assistance of care staff and a Zimmer

Repositioning Status: Independent

Length of time sitting: Approx. 8hrs during the day in a high seat armchair. Regime is 4hrs sitting then 4hrs bed, then 4hrs sitting, etc...

Existing mattress: Standard divan bed and foam mattress. Repose mattress overlay

Other Relevant Information: N/A

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Day 0 Observations:

1. No skin damage present at initial assessment
2. Substantial bruising in lower back due to previous fall
3. Current mattress overlay score = 4

Day 0 Photographs:



- Day 7 Observations:**
1. No sign of pressure injuries
 2. Bruising of lower back improving
 3. **PressureCareReliefProducts®** comfort score = 8
 4. Staff comments: Absorbance of sweat is good. Sleeping better.

Day 7 Photographs:



- Day 14 Observations:**
1. No sign of pressure injuries
 2. Bruising of lower back improving
 3. **PressureCareReliefProducts®** comfort score = 8
 4. Staff comments: Same as day 7.

Day 14 Photographs:



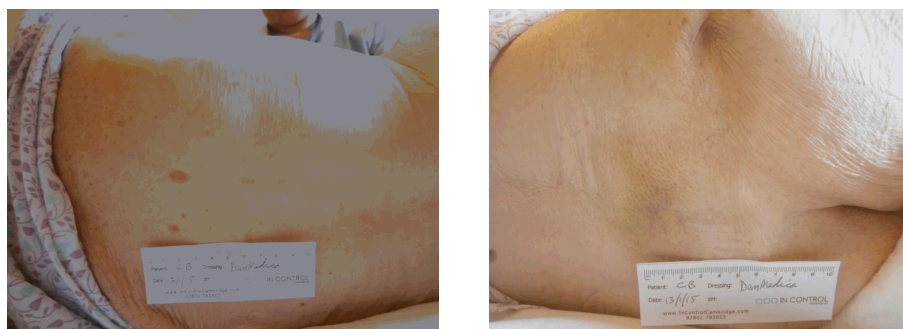
- Day 21 Observations:**
1. No sign of pressure injuries
 2. Bruising of lower back improving
 3. **PressureCareReliefProducts®** comfort score = 8
 4. Staff comments: Same as day 7 and 14.

Day 21 Photographs:



- Day 28 Observations:**
1. No sign of pressure injuries
 2. Bruising of lower back almost resolved
 3. **PressureCareReliefProducts®** comfort score = 8
 4. Staff comments: Same as day 7, 14 and 21.

Day 28 Photographs:



Subject 3: (DB)

Age: 87 years

Gender: Female

Waterlow Score: 16 (high risk)

MUST Nutritional Score: 0 (low risk)

Medical History: Hypertension

Continence: Urinary Incontinence

Transfers: Standing transfers with the assistance of care staff

Mobility Status: Walks with assistance of care staff and a Zimmer

Repositioning Status: Independent

Length of time sitting: Approx. 8hrs during the day in a high seat armchair. Regime is 4hrs sitting then 4hrs bed, the 4hrs sitting, etc...

Existing Mattress: Standard divan bed and foam mattress. Repose mattress overlay.

Other Relevant Information: N/A

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Day 0 Observations:

1. No skin damage present at initial assessment
2. Current mattress overlay score = 3

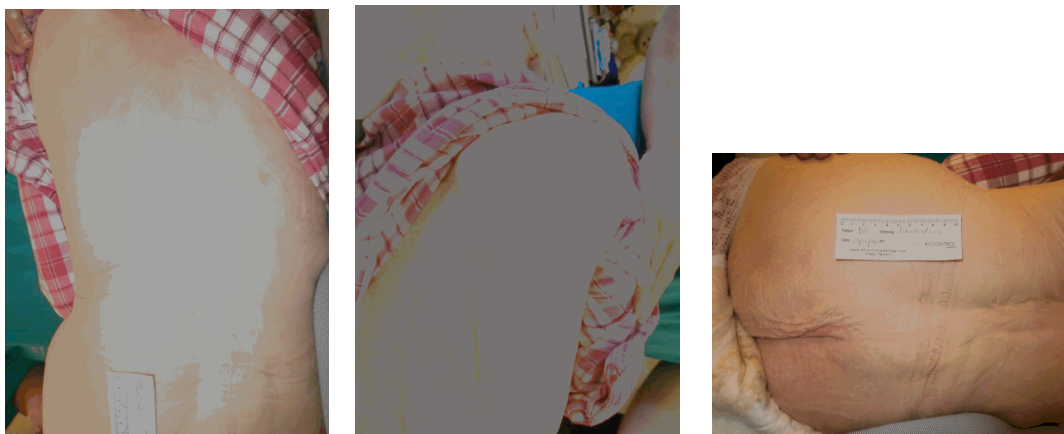
Day 0 Photographs:



Day 7 Observations:

1. No sign of pressure injuries
2. **PressureCareReliefProducts®** comfort score = 9
3. Staff comments: Subject finds bed pad cooler and more comfortable. Doesn't sweat so much.

Day 7 Photographs:



Day 14 Observations:

1. No sign of pressure injuries
2. **PressureCareReliefProducts®** comfort score = 9
3. Staff comments: Sleeping longer. Pad also acts as an effective slide sheet.

Day 14 Photographs:



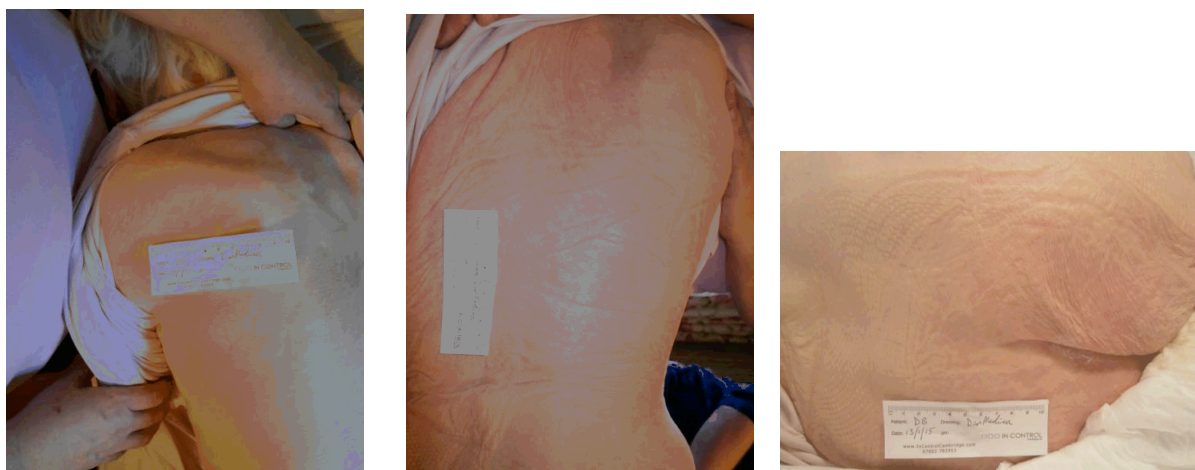
- Day 21 Observations:**
1. No sign of pressure injuries
 2. **PressureCareReliefProducts®** comfort score = 9
 3. Staff comments: Same as day 7 and 14.

Day 21 Photographs:



- Day 28 Observations:**
1. No sign of pressure injuries
 2. **PressureCareReliefProducts®** comfort score = 9
 3. Staff comments: Same as day 7, 14 and 21

Day 28 Photographs:



Subject 4: (HW)

Age: 70 years

Gender: Male

Waterlow Score: 19 (high risk)

MUST Nutritional Score: 0 (low risk)

Medical History: COPD, Parkinson

Continence: Doubly incontinent

Transfers: Assisted by carriers to do standing transfer

Mobility Status: Walks with assistance of care staff and a Zimmer

Repositioning Status: Independent

Length of time sitting: Approx. 8hrs during the day in a high seat armchair. Regime is 4hrs sitting then 4hrs bed, the 4hrs sitting, etc...

Existing Mattress: Standard divan bed and foam mattress. Repose mattress overlay.

Other Relevant Information: N/A

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Day 0 Observations:

1. No sign of pressure injuries present at initial assessment
2. Current mattress overlay score = 4

Day 0 Photographs:



- Day 7 Observations:**
1. No sign of pressure injuries
 2. **PressureCareReliefProducts®** comfort score = 8
 3. Staff comments: Subject finds bed pad comfortable and likes it on chair. Easy to keep clean.

Day 7 Photographs:



- Day 14 Observations:**
1. No sign of pressure injuries
 2. **PressureCareReliefProducts®** comfort score = 8
 3. Staff comments: As per day 7 comments.

Day 14 Photographs:



Day 21 Observations:

1. No sign of pressure injuries
2. **PressureCareReliefProducts®** comfort score = 8
3. Staff comments: As per day 7 and 14 comments.

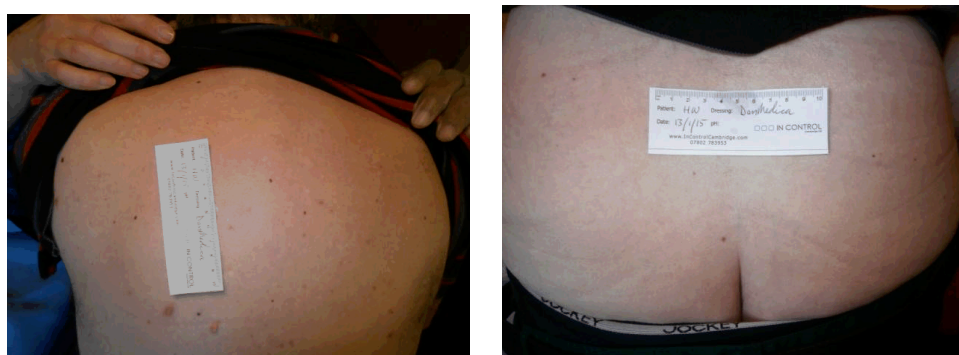
Day 21 Photographs:



Day 28 Observations:

1. No sign of pressure injuries
2. **PressureCareReliefProducts®** comfort score = 8
3. Staff comments: As per day 7, 14 and 21 comments.

Day 28 Photographs:



Subject 5: (JB)

Age: 94 years

Gender: Female

Waterlow Score: 17 (high risk)

MUST Nutritional Score: 0 (low risk)

Medical History: Ischaemic heart disease

Continence: Doubly incontinent

Transfers: Standing transfers with the assistance of care staff

Mobility Status: Walks with assistance of care staff and a Zimmer

Repositioning Status: Independent

Length of time sitting: Approx. 8hrs during the day in a high seat armchair. Regime is 4hrs sitting then 4hrs bed, the 4hrs sitting, etc...

Existing Mattress: Standard divan bed and foam mattress. Repose mattress overlay.

Other Relevant Information: N/A

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Day 0 Observations:

1. No sign of pressure injuries present at initial assessment
2. Current mattress overlay score = 5

Day 0 Photographs:



- Day 7 Observations:**
1. No sign of pressure injuries
 2. **PressureCareReliefProducts®** comfort score = 8
 3. Staff comments: Easy to use and move between bed and chair. Subject sleeps well.

Day 7 Photographs:



- Day 14 Observations:**
1. No sign of pressure injuries
 2. **PressureCareReliefProducts®** comfort score = 8
 3. Staff comments: As per day 7 comments.

Day 14 Photographs:



- Day 21 Observations:**
1. No sign of pressure injuries
 2. **PressureCareReliefProducts®** comfort score = 8
 3. Staff comments: As per day 7 and 14 comments.

Day 21 Photographs:



- Day 28 Observations:**
1. No sign of pressure injuries. Some bruising appears on back due to fall.
 2. **PressureCareReliefProducts®** comfort score = 8
 3. Staff comments: As per day 7, 14 and 21 comments.

Day 28 Photographs:



Subject 6: (JM)

Age: 95 years

Gender: Female

Waterlow Score: 16 (high risk)

MUST Nutritional Score: 0 (low risk)

Medical History: Ischaemic heart disease

Continence: Doubly incontinent

Transfers: Standing transfers with the assistance of care staff

Mobility Status: Walks with assistance of care staff and a Zimmer

Repositioning Status: Independent

Length of time sitting: Approx. 8hrs during the day in a high seat armchair. Regime is 4hrs sitting then 4hrs bed, the 4hrs sitting, etc...

Existing Mattress: Standard divan bed and foam mattress. Repose mattress overlay.

Other Relevant Information: N/A

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Day 0 Observations:

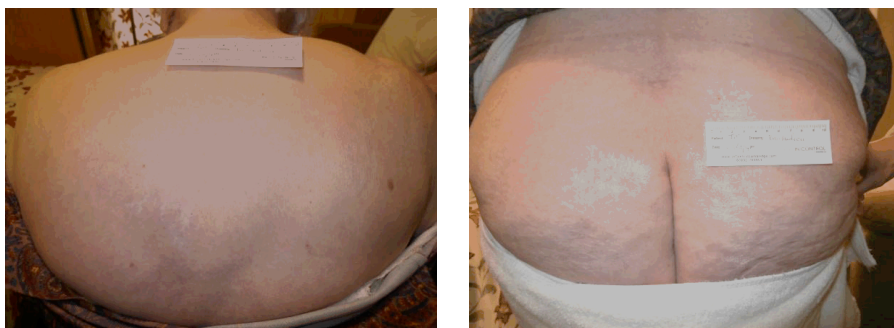
1. No sign of pressure injuries present at initial assessment
2. Current mattress overlay score = 5

Day 0 Photographs:



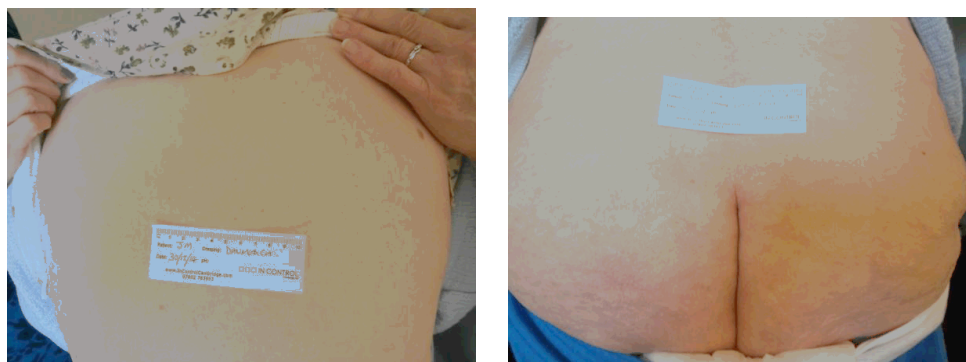
- Day 7 Observations:**
1. No sign of pressure injuries
 2. **PressureCareReliefProducts®** comfort score = 8
 3. Staff comments: Easy to use and move between bed and chair. Easy to clean when soiled. Subject sleeps well.

Day 7 Photographs:



- Day 14 Observations:**
1. No sign of pressure injuries
 2. **PressureCareReliefProducts®** comfort score = 8
 3. Staff comments: As per day 7 comments.

Day 14 Photographs:



Day 21 Observations:

1. No sign of pressure injuries
2. **PressureCareReliefProducts®** comfort score = 8
3. Staff comments: As per day 7 and 14 comments.

Day 21 Photographs:



Day 28 Observations:

1. No sign of pressure injuries. Some bruising appears on back due to fall.
2. **PressureCareReliefProducts®** comfort score = 8
3. Staff comments: As per day 7, 14 and 21 comments.

Day 28 Photographs:

