EPSUS MATTRESS CLINICAL STUDY – TABULATED SUMMARY

ITEM	DESCRIPTION
Product studied	EPSUS mattress
Type of study	Non-interventional prospective clinical study – observational type
Date of study	1995
Objective of the study	Assessing the performance of the EPSUS mattress when caring for person at risk of bedsores (PRBs) or persons suffering from bedsores (PSBs)
METHOD	
Criteria for inclusion	Persons admitted to hospital and presenting a risk of the appearance of bedsores or suffering from one or more bedsores rated from stages 1 to 3 on the Waterlow scale
Context and place of study	<u>Establishments</u> - Le Grau du Roi Functional Rehabilitation Centre (Gard Département), Functional Rehabilitation Department B head of the study: Dr. Romain (head of department) - Auch Hospital (Gers département), Neurology Department, head of the study: Ms. Garros (senior nurse) - Grasse Hospital (Alpes-Maritimes département), Gerontology Department, head of the study: Dr. J. Ribiere (head of department), Ms. Evenou (senior nurse) and Ms. Bremond (nurse) - Poitiers University Hospital (Vienne département), Medium-Stay Department B, head of the study: Dr. Lussier Bonneau (head of department) - Paul Coste Floret Hospital, Lamalou les Bains (Hérault département), Jeanne d'Arc Department head of the study: Dr. B. Garlenq (head physician) - Bédarieux local Hospital, (Hérault Département), Long-Stay Department head of the study: Dr. Torres (head of department) - Vallauris Retirement Home (Alpes-Maritimes département), Long-Stay centre, head of the study: Dr. Clauzon (head of department) - Tourcoing Hospital (Nord département), Department of Endocrinology and Pneumology heads of the study: Ms. Demaretz (senior nurse), Ms. Vandenmersch (senior nurse) - Font Pré Hospital, Toulon (Var département), Resuscitation Unit head of the study: Ms. Galvez (senior nurse) - La Tour Blanche Geriatric Hospital, Marseille (Bouches-du-Rhône département), Les Embiez Long-Stay Department, head of the study: Dr. Ollivier (head of department) - Princesse Grace Hospital, Monaco, Orthopædic Surgery Department heads of the study: Dr. Ballerio (head of department), Ms. Fabries (head supervisor) - Sainte Anne Army Teaching Hospital, Toulon (Var département), Anæsthesia and Resuscitation Unit head of the study: Dr. Palmier (head physician) - Roubaix Hospital (Nord département), Chronic Convalescent Patient Unit head of the study: Dr. Bonnière, Rose Romarin Department, head of the study: Ms. Simonowski (supervisor) - Senlis Hospital (Oise département), Long-Stay Medical Treatment Unit, head of the study: Ms. Leconte (supervisor) - Puteaux Hospital (Hauts de Seine département), Long-Stay Department, head of the study: Ms. Tessier (supervisor) - Rueil Malmaison Hospital (Hauts de Seine département), Medium- and Long-Stay Unit, head of the study: Mr. Houssard (senior nurse)
Main judgement criterion	Maintaining or improving the person's skin condition
Secondary judgement criteria	Healthcare staff to assess the effectiveness and ease of using the support Patient to assess the comfort provided by the support and the desire to keep it at the end of the study
Sample size	N = 93
Randomisation method	Not applicable
Method of analysing the results	Descriptive analysis

LA GRANDE ARCHE – PAROI NORD
– 92044 LA DEFENSE CEDEX – France
Tel.: +33 (0) 1 40 90 33 38 – Fax: +33 (0)1 40 90 31 01
Website: www.winncare.fr

RESULTS	
Number of subjects analysed	N = 93
Duration of monitoring	15 days
Patient characteristics (without group comparability)	W / M distribution: 1.35 Average age: 76 years Average weight: 62 kg Average height: 1.65 m 46 different pathologies *Neonatal encephalopathy, fracture of the neck of the femur, failure to thrive, right hemiplegia, high blood pressure, respiratory insufficiency, loss of independence, Alzheimer's disease, cardiopathy, arterial dementia, diabetes, left hemiplegia, hip prosthesis, fracture of the humerus, Malpighian carcinoma, change in general health, reactive depression, physical dependence, gastrectasis, disorientation, chronic insufficiency, senile dementia, pulmonary œdema, spinal-cord ischæmia, hip pain, digestive neopathy major eating disorders, Guillain-Barré syndrome, fracture of the ribs, amputation of the lower limbs, neuropathy, digestive hæmorrhage, Parkinson's disease, cerebro-vascular accident, brain hæmorrhage, knee prosthesis, functional disorder, cardio-respiratory insufficiency, neo-ovarian, tetraplegia, cranial trauma, left acetabular fracture, brain metastasis, fracture of the greater trochanter* PRB: N=60 (65%); PSB: N = 33 (35%) PRB: 16% at risk – Waterlow index]10-15], 44% at high risk index]15-20], 39% at very high risk off bedsores – index > 20 Seriousness of bedsores: 49% stage 1 (redness), 51% stage 2 or 3 PSB stage 1 – Redness observed: Pale 14.3%, Bright 57.1%, Very bright 28.6%
Characteristics relating to professional practices	<u>Carrying out massage</u> - PRB at risk: 55.5% - PRB at high risk: 91.7% - PRB at high risk: 85% - PSB, stage 1: 100% - PSB stage 2 or 3: 70.6% <u>Frequency of massage</u> - PRB at risk: 2 / day 0%, 3 / day 80%, more than 3 / day 20% - PRB at high risk: 2 / day 4.5%, 3 / day 45.5%, more than 3 / day 50% - PRB at high risk: 2 / day 5.9%, 3 / day 29.4%, more than 3 / day 64.7% - PSB, stage 1: data not reported - PSB stage 2 or 3: 2 / day 8.4%, 3 / day 41.6%, more than 3 / day 50% <u>Turning over</u> - PRB at risk: 22.2% - PRB at high risk: 66.7% - PRB at high risk: 46.1% - PSB, stage 1: by state of redness (pale: no, bright and very bright: yes) - PSB stage 2 or 3: 80% <u>Frequency of turning over</u> - PRB at risk: 2 / day 0%, 3 / day 100%, more than 3 / day 0% - PRB at high risk: 2 / day 7.2%, 3 / day 57.1%, more than 3 / day 35.7% - PRB at high risk: 2 / day 33.3%, 3 / day 16.7%, more than 3 / day 50% - PSB, stage 1: data not reported - PSB stage 2 or 3: 2 / day 9.1%, 3 / day 72.7%, more than 3 / day 18.2%
Results inherent in main judgement criteria	<u>Development of skin condition of PRBs</u>: PRB at risk: Favourable development 20%, Maintained 80%, Unfavourable development 0% PRB at high risk: Favourable development 25.9%, Maintenance 55.%%, Unfavourable development 18.6% PRB at high risk: Favourable development 0%, Maintenance 87.5%, Unfavourable development 12.5% <u>Development of PSBs stage 1</u>: Redness observed: Pale 77.8%, Bright 22.2%, Very bright 0: 0% Favourable development 87.5%, Maintenance 12.5%, Unfavourable development 0% <u>Development of PSBs stage 2 or 3</u>: Favourable development 35.3%, Maintenance 64.7%, Unfavourable development 0%
Results inherent in the	<u>Assessment of the support by staff</u>

LA GRANDE ARCHE – PAROI NORD
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secondary judgement criteria	Ease of use: yes 82.8%, No 17.2% Assessment of results: Excellent 43.7%, Good 42.5%, Average 6.9%, Poor 6.9% Assessment of the support by patients Comfort: Excellent 42.9%, Good 44.1%, Average 10.4%, Poor 2.6% The patient wishes to keep the mattress: yes 89.2%, No 10.8%
Secondary effects	None Bedsore prevention care was given at the same time.

SUMMARY

Development of stage 1 Bedsores in the PSB stage 1 population

	Initial assessment	Final assessment
Pale redness	14.3%	77.8%
Bright redness	57.1%	22.2%
Very bright redness	28.6%	0%

Development of the 5 populations

	Total population	PRB N = 60			PSB N = 33	
		Risk	High risk	Very high risk	Stage 1	Stage 2/3
Initial population	93	10	27	23	16	17
Efficacy	**93.78%**	**100%**	**81.4%**	**87.5%**	**100%**	**100%**
Favourable development	33.74%	20%	25.9%	0%	87.5%	35.3%
Stationary state	60.04%	80%	55.5%	87.5%	12.5%	64.7%
Unfavourable development	6.22%	0%	18.6%	12.5%	0%	0%

The preventive-care strategy combining massage, changes in position, and use of the EPSUS mattress proved effective across the 5 populations studied.

In the case of Persons Suffering from Bedsores (PSBs), prevention saw the lessening of redness or of constituted bedsores from stage "n" to stage "n-1".

The authors conclude that the EPSUS mattress is effective in helping prevent bedsores, since no patients at risk (as defined by Waterlow Scale criteria) developed bedsores on the mattress, whilst patients presenting redness on Day 0 showed either no change or lessened redness by Day 15.

Worthy of note is the large number of persons suffering from bedsores included in the EPSUS study: 35% of patients were part of PSB populations. The results showed that the EPSUS mattress was definitely effective for those populations.

Furthermore, it appears that the more integrating framework of the removable modules gives patients better stability and better access to care.

Removable elements of variable scope showed better effectiveness for the populations covered by the study, so they seem to better deal with the spread of load of the various parts of the body.

The EPSUS concept allows removable elements to be replaced with elements that use water, gel, or air, based on the development of the patient's general health, proved to be a more flexible support based on the development of the bedsore.

Abbreviations
PRB: Person(s) at Risk of Bedsores
PSB: Person(s) Suffering from Bedsores