The management of night-time incontinence:

An investigation into the effects of different pad changing routines on skin and sleep

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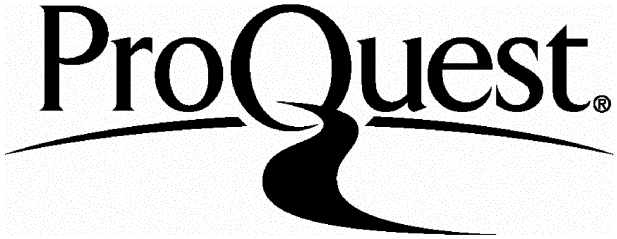

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ABSTRACT

AIMS OF STUDY: Absorbent pads are the main method of managing urinary incontinence in residential settings for elderly people. Improvements in technology have resulted in highly absorbent products which may be worn all night, but the effects of prolonged pad wearing on aged skin are unknown. Wet skin is known to be more susceptible to dermatitis, friction and abrasion. Night-time pad changing (and resident turning) have been found to be associated with sleep fragmentation. However it has not been demonstrated that changes in night-time continence management result in less sleep fragmentation. The following question was posed: What is the effect of different pad changing regimes on the skin health and sleep of elderly women living in residential settings? In addition, earlier findings were explored, which indicated that a substantial proportion of residents, who were turned by staff, also turned themselves

METHODS: A cross-over design was used. Following a two week baseline period subjects from residential settings were randomly allocated to one of two pad changing regimes: a *frequent* pad changing regime (whereby residents were changed at 22.00, 02.00 and 06.00) or a *less frequent* pad changing regime (with residents changed at 22.00 and 06.00 only). Each regime lasted four weeks and was followed by the alternative regime. Skin measurements were taken twice during each regime from selected skin sites using the following tools (i) the Diastron erythema meter (ii) visual grading scale (iii) the Servomed evaporimeter (to measure trans-epidermal water loss) (iv) a pH meter. The primary outcome variable was measurement of erythema using the Diastron erythema meter. Sleep measurements were made twice during each regime using the Stowood Scientific Instruments Visi-lab which comprises an infra-red camera and video with movement and audio detection.

RESULTS: Eighty one subjects from 18 nursing/residential homes for elderly people completed the skin component of the study and twenty-two subjects from 5 homes completed the sleep component. Statistical analysis for erythema meter, trans-epidermal water loss, pH and sleep fragmentation data (mean number of movements per hour) was carried out by fitting general linear models and visual grading data were analysed using the Mainland-Gart method. Video data (of self-turning) were analysed descriptively using a coding sheet. No significant differences were found in the severity of erythema, or skin pH, between regimes. However, measurements of trans-epidermal water loss were significantly higher in the *less frequent* pad changing regime indicating that skin was 'wetter' ($P = 0.01$; difference of means 12.14, 95% confidence interval 2.89 - 21.39). Five subjects developed grade 2 pressure ulcers (abrasions) during the *less frequent* pad changing regime, but none in the *frequent* pad changing regime; this result was not significant ($P = 0.1$; 95% confidence interval 0 - 1.09). No significant differences were found in the sleep measurements (mean number of movements per hour) between regimes. During both pad changing regimes staff seldom turned residents. Subjects who turned themselves were more likely to be turned by staff at the time of pad change, but overall redundant turning was not evident.

CONCLUSIONS: No evidence was found that a *less frequent* pad changing regime has an effect on skin erythema, pH or on sleep fragmentation. However, there is evidence that the skin is wetter, which may make it more vulnerable to friction and abrasion. The non-significant finding of greater incidence of grade 2 pressure ulcers is a cause for concern and merits further investigation.

MAIN RECOMMENDATIONS FOR PRACTICE:

- Residents may use one standard good quality night pad (without changing) throughout the night.
- Residents who have had (or develop) grade 2 pressure ulcers (including 'wet skin abrasions') should have their pads changed during the night to reduce skin wetness.

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CHAPTER 1

LITERATURE REVIEW AND RESEARCH QUESTIONS

1.1 Introduction

Three million people in the UK are incontinent of urine (Thomas et al. 1980; Cheater and Castleden, 2000) and the annual UK NHS bill for looking after their needs is estimated at £423m (Continence Foundation, 2000) . Furthermore, these figures are set to increase as the population ages. This project focuses on the 200,000 or so people (primarily women) who live in residential settings, who require products for heavy incontinence (MDA, 1998).

Forty to seventy percent of residents living in nursing homes and long-stay wards are incontinent of urine (Royal College of Physicians, 1995). Despite advances in continence management, many residents have intractable incontinence. The emphasis of their care is on management (usually involving absorbent pads) to minimise the impact of incontinence on their quality of life (Peet et al. 1996). These residents are often dependent with multiple disabilities including poor mobility and mental impairment, both of which are correlated with urinary incontinence (Sgadari et al. 1997; Jirovec and Wells, 1990; Ouslander et al. 1987; McGrother et al. 1990).

These individuals will be at risk of developing skin disorders, notably diaper dermatitis and pressure ulcers, which are associated with urinary incontinence (Panel for the prediction and prevention of pressure ulcers, 1992). The potential for skin deterioration is likely to be particularly important during the night-time when residents will not only spend prolonged periods of time in bed, but will also produce larger volumes of urine (per void and in total) (Ouslander et al. 1993; Colling et al. 1994) than during the day. Management with absorbent pads therefore needs to be devised with care.

Frequent pad changing is assumed to be good for skin health (because the skin is kept drier) but the effects of different pad wearing times on skin have not been studied. *Frequent turning* is recommended practice for pressure ulcer prevention but there is

evidence that turning regimes are sometimes applied to 'self-turners' who are unlikely to benefit (Schnelle et al. 1993b). Both are likely to be detrimental to the quality and quantity of sleep. Little work has been done to establish best practice yet many differing strategies are in use.

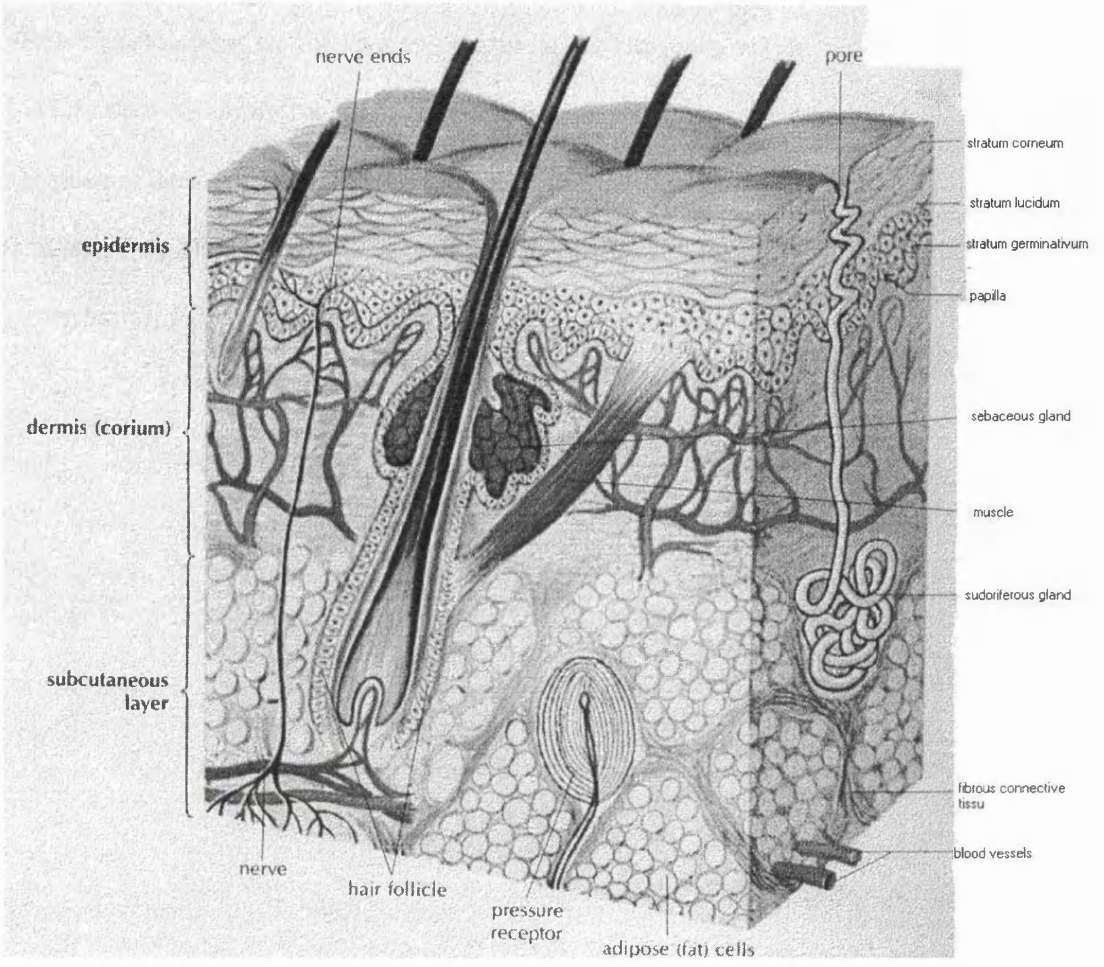
Whatever strategy they select, nurses have difficulty defending their practice with evidence. The central issue is finding a balance between maintaining skin health (which favours *frequent* pad changing and turning) and minimising sleep disturbance (which favours *less frequent* pad changing and turning). The issue is made more compelling by the considerable resource implications of patient turning and pad changing. Xakellis and colleagues calculated that patient turning was the most expensive method for preventing pressure ulcers (Xakellis et al. 1995). Managing incontinence using absorbent pads is also a costly business. We know from carrying out studies of pad performance (MDA, 1998) that it is common for an average of four pads to be used during the daytime and two or more at night in residential settings. Some pad manufacturers suggest that their night-time pads may be left on overnight and we know that this practice is carried out in some settings. The cost savings for using just one pad (instead of two), per resident per night would be very substantial. Proposing that 50% of residents with regular incontinence (around 110,000 people) currently use two pads per night, and this number was reduced to one pad per night, a saving of around 10 million pounds in pad costs per annum would be effected (based on a pad cost of 25p). However, we do not have evidence that this reduction in pad changing is safe practice for skin health.

1.2 Literature review: Skin health and incontinence

1.2.1 The skin as a barrier

The main functions of the skin are to protect the body from loss of fluids and from penetration by undesirable substances. The principal barrier mechanism of the skin is supplied almost entirely by the stratum corneum (Scheuplein and Blank, 1971). This semi-permeable membrane forms the final blockade between the body and the environment. The stratum corneum is the horny cell layer of the epidermis (Figure1:1) and is normally renewed every 13-14 days. The epidermis achieves this

Figure 1:1 Structure of skin (adapted from Brunner & Suddarth's textbook of medical-surgical nursing, Lippincott, 1996)



renewal by producing a pool of proliferative cells that migrate from the basal layer to the environment.

Evidence for the barrier being located in the stratum corneum comes from early work by Blank (1953) who showed that the water permeability of excised full-thickness skin did not change after successive stripping with adhesive tape until the lowest part of the stratum corneum was removed.

The properties of the skin barrier have a physiochemical basis and do not depend upon the activities of living cells. They are unaffected by reversal of the membrane and persist long after the skin is removed from the body (Swarbrick et al. 1982). Permeability of the stratum corneum is determined not by its thickness but by the lipid content of the intercellular material (Elias et al. 1981).

Hydration increases the permeability of the stratum corneum and water in itself is an effective penetration enhancer (Ebling, 1992) allowing for the greatly increased percutaneous absorption of some substances (Behl et al. 1980).

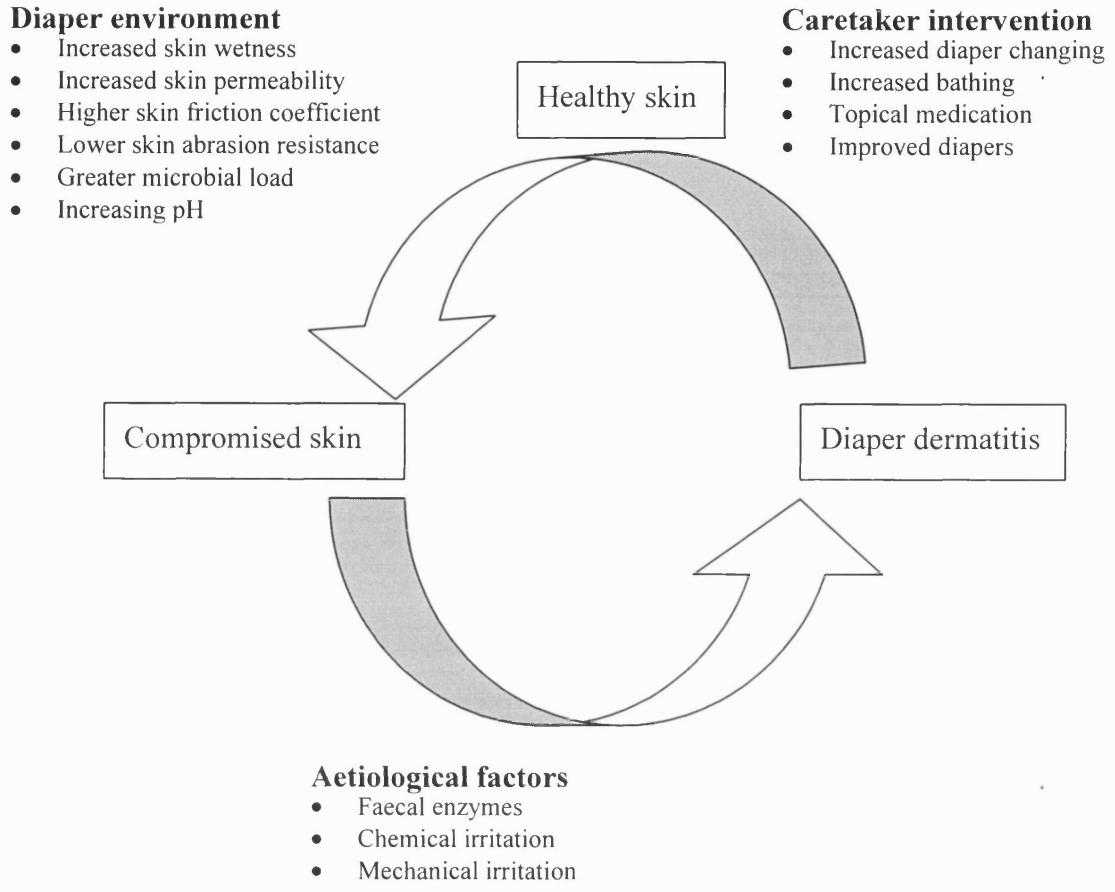
Skin that is exposed to prolonged contact with urine will therefore become over-hydrated which will increase permeability allowing for greater penetration of agents in urine and faeces. Most substances can act as skin irritants if applied for sufficient time and in sufficient concentration (du Vivier, 1992). The effects of such agents on the skin is known as *irritant contact dermatitis* and is characterised by skin inflammation. Immunological processes are not involved. Irritant contact dermatitis induced by the wearing of nappies or diapers is usually referred to as *diaper dermatitis* in the literature.

1.2.2 Diaper dermatitis: Mechanisms

Our knowledge of the effects of urine on skin health comes largely from studies of babies and baby diapers rather than elderly adults and incontinence pads. Even the prevalence of diaper dermatitis in elderly people has been sparsely examined. Brown (1994) studied 166 adults (mean age 74) from acute medical wards and reported that 35% of patients had mild to severe erythema (skin redness) on at least one location. Lyder and colleagues (1992) examined the introduction of a structured skin care regimen to prevent diaper dermatitis in a small sample (N= 15) of elderly patients on a geriatric psychiatry unit. The researchers found that 33% of the subjects in the unstructured skin care group and the same proportion of the subjects in the structured skin care group developed perineal dermatitis.

We know that wearing incontinence pads increases the hydration of the stratum corneum because urine is held next to the skin by the absorbent component of the pad (usually fluff pulp) and is contained within an outer plastic cover to prevent urine leakage. Berg (1988) hypothesised that this skin occlusion forms the basis for a chain of actions which result in diaper dermatitis. Berg's model of diaper dermatitis development and resolution (Berg, 1987) is shown in Figure 1:2.

Figure 1:2 Berg's model of the cycle of diaper dermatitis



The effects of prolonged occlusion on the skin of adults were studied by Faergemann and colleages (1983) on the backs of males. They found that the pH of the occluded skin rose from 5.6 to 6.7 over three days. In a similar experiment Aly and colleagues (1978) wrapped plastic film around the arms of 10 fellow researchers for a period of five days and removed portions every day. Microbial counts increased significantly, the mean pH rose from 4.38 to 7.05, and TEWL (trans-epidermal water loss) also increased, indicating damage to the barrier function of the stratum corneum.

TEWL constitutes the total amount of water lost through the skin and consists of both water loss by evaporation throught the epidermis and the secretion of sweat through the sweat glands. A boundary layer develops round the skin in which a vapour pressure gradient exists between the skin surface and ambient air. Measurement of TEWL is used for two purposes, firstly to determine damage to the barrier function of the stratum corneum (in which case TEWL is consistently raised above the normal baseline level). Secondly, measurement of TEWL is used to quantify the excess water

in over-hydrated skin (such as within a wet incontinence pad). Following removal of the source of over-hydration, skin exhibits a very high TEWL that rapidly drops as the excess water diffuses from the skin until baseline is reached. The measurement of TEWL is discussed in more detail in chapter 2, pages 37-41.

More recently Fluhr and colleagues (1999) studied the effects of different occlusion periods (24, 48, 72 and 96 hours) on stratum corneum barrier function of the forearm and found that TEWL increased and reached a plateau on day 2.

These studies indicate that simply by occluding the skin the barrier function of the stratum corneum is reduced and the pH of the skin rises.

Within an incontinence pad the pH of the skin rises not just as a result of skin occlusion, but also because of the activity of urea splitting micro-organisms in urine and faeces. Up until the 1970s there was a widely held belief that ammonia was the primary cause of diaper dermatitis. This theory was tested by Leyden and colleagues (1977) by measuring urinary ammonia concentrations in infants with and without diaper dermatitis, but no significant difference in the concentration of ammonia was found. In addition, application of ammonia solution to adult volar forearms did not illicit an irritative response except when the skin had been previously abraded. Quantitative microbiological studies also failed to demonstrate any difference in the types and number of bacteria capable of releasing ammonia from urinary urea in infants with and without diaper dermatitis (Leyden & Kligman, 1978).

The causal relationship between ammonia and diaper dermatitis was also questioned by Berg and colleagues (1986). These researchers used a hairless mouse to examine the role of urine and the role of faeces (Buckingham and Berg, 1986) in the aetiology of diaper dermatitis. They found that the irritant potential of urine by itself was minimal over short periods (48 hours) but after continuous exposure (10 days) skin damage became apparent. The researchers also measured skin permeability and found that continuous exposure to urine greatly increased skin permeability (more than 15 fold) compared to occluded skin or skin exposed only to water. However the addition of faeces greatly increased irritancy and this was accompanied by an increase in the pH of the urine/faeces mixture. A similar result was obtained by adding a solution of

urea rather than urine which suggested that the effect was caused by the production of ammonia from urea. The authors suggest that the presence of faecal urease results in the break down of urinary urea causing an increase in pH which increases the activities of faecal proteases and lipases leading to skin irritation. The authors concluded that the increase in irritancy was a function of the increase in pH rather than an effect of ammonia per se.

Zimmerer et al. (1986) examined the role of skin wetness in the development of diaper dermatitis by using the volar forearms of adult volunteers. They aimed to determine the effects of wet and dry diaper materials on skin health with respect to friction, abrasion damage, permeability and microbial growth. Pre-wetted patches of baby diapers were placed on the volar forearms of adults for two hours and then the skin was subjected to friction and abrasion. The coefficient of friction for the 'wet' skin was significantly higher than for 'dry' skin; although increased fluid loading of wet patches did not further increase skin friction. Similarly, skin over-hydrated with a wet patch showed a significant increase in skin abrasion damage relative to a dry patch. Again variations in the fluid loading of the patch did not produce significant changes in abrasion damage. Zimmerer (1986) also sampled the microflora of the skin after pre-loading with pre-wetted patches containing urine and found that the microbial counts were significantly higher for wet patches relative to the dry patch controls.

However it has not been demonstrated that volar forearms are a valid model for the skin exposed to an incontinence pad i.e. buttocks and groins. Schnetz and colleagues (1999) demonstrated that TEWL measurements from the volar forearm did not correlate with those taken from the face, although the left and right side of the face showed good correlation. The researchers concluded that TEWL measurements for the study of facial cosmetics should be taken from the face rather than the forearm. Similarly, studies using the volar forarm may not be valid for the buttocks and groin.

These studies indicate that the effects of prolonged contact of urine and faeces on skin are as follows:

- Skin occlusion leads to increased skin hydration which increases permeability.
- The over-hydrated skin has an increased friction co-efficient which lowers resistance to abrasion.
- The skin has a greater microbial load from the presence of urine and faeces.
- The combination of urine and faeces results in an increase in pH which leads to greater faecal enzyme activity.
- The skin is therefore compromised with impaired barrier function to chemical irritation from urine and faecal constituents.

1.2.3 Diaper dermatitis: Adult versus baby

There are difficulties extrapolating data from baby diaper studies to adult incontinence. The effects of ageing on the skin may mean that the skin of older people responds differently to hydration with urine. Age-related skin changes include thinning of the dermis, a reduction in collagens fibres and subcutaneous tissue (Richey et al. 1988), a reduction in skin elasticity (Doubal and Klemera, 1998), increased roughness (xerosis) and scaliness and decreased skin hydration (Manuskiatti et al. 1998). These changes may mean that aged skin is more susceptible to bacterial growth and more vulnerable to abrasion damage.

Wilhelm and others (Wilhelm et al. 1991), found no significant differences between young adults and aged volunteers in skin pH, sebum content and capacitance, however they did find significantly lower trans-epidermal water loss levels (TEWL) for aged skin across the anatomical sites measured (these included the volar forearm, but not the buttock). This finding of decreased TEWL in aged subjects is supported by Leveque et al. (1984) although Roskos and Guy (1989) found no dependence of TEWL on age. These findings taken together indicate that there may be no loss of the barrier functions of the stratum corneum because a higher TEWL (on non-wet skin) indicates lower skin barrier function (Freeman and Maibach, 1988).

Babies are always regularly incontinent of both urine and faeces, but double incontinence is much less common amongst adults in community settings (estimated to be about 0.4%) (Royal College of Physicians, 1995). However, 9 – 36% of residents in private or NHS residential and nursing homes are estimated to be incontinent of both urine and faeces (Peet et al. 1995) and this population may therefore be vulnerable to dermatitis.

1.2.4 Diaper dermatitis: Pad technology

Recent advances in 'absorbent' technology may mean that skin problems are less likely for both babies and adults. The inclusion of *superabsorbent polymers* (SAP) in baby diapers and adult incontinence pads has become widespread. When superabsorbent polymers (SAP) were first introduced to baby diapers, the manufacturers' researchers proposed that skin wetness would decrease and that the SAP would provide buffering capacity and thereby produce more normal skin pH. They anticipated that there would be less mixing of urine and faeces and that these factors would result in less diaper dermatitis (Berg, 1988).

This hypothesis was tested by comparing babies wearing disposable diapers *with* and *without* SAP and cloth diapers (Campbell, 1987). A significant reduction in skin wetness, as measured by evaporimetry, (a tool to measure trans-epidermal water loss) and in blinded diaper dermatitis scores was found. Davis and colleagues (1989) compared diapers *with* SAP, to diapers *without* SAP, in a cross-over study of 150 infants over 15 weeks. Skin wetness was measured using evaporimetry and clinicians graded the infants' skin for diaper dermatitis. Skin on which diapers *without* SAP were applied showed a rapid increase in evaporative water loss (TEWL) as the urine load increased, but the increase for diapers *with* SAP was significantly slower. This indicates that for the same urine loading, diapers *with* SAP result in less hydrated skin than diapers *without* SAP. Clinicians' grades showed that babies wearing diapers *with* SAP had lower severity ratings for dermatitis than those wearing diapers *without* SAP, but this result was significant only for the lower fluff pulp weight diaper.

In a similar study but involving only clinical grading of diaper dermatitis, Lane and colleagues (1990) randomised 149 newborn infants to diapers *with* or *without* SAP

for 14 weeks. At the end of the study period the infants wearing pads *with* SAP had significantly less diaper dermatitis than those wearing pads *without* SAP.

These clinical baby diaper studies showing differences in skin wetness between diapers with and without SAP are supported by a volar forearm study of wetted diaper patches carried out by Wilson and Dallas (1990). The researchers found that the patches *with* SAP kept the skin drier (when measured by evaporimeter) than the cloth diaper patches or those *without* SAP. However, in a later study the same authors (Dallas and Wilson, 1992) did not find significant differences in trans-epidermal water loss between *adult* incontinence pad patches *with* or *without* SAP, when used on adult volar forearms, although individual *brands* of pad with unusual designs or structures were significantly different from other brands. However, these findings cannot represent a valid contradiction because we do not know if adult volar forearms are a good model for baby (or adult) bottoms.

There have been few attempts to study diaper dermatitis in adults wearing incontinence pads and most researchers have used the term *perineal* dermatitis when referring to this condition in adults. Brown (1994) used visual scoring to compare perineal dermatitis in 166 patients who tested either diapers or underpads *with* and *without* SAP and cloth underpads. Using a visual grading scale she found that cloth underpads were associated with the most severely altered skin, followed by diapers and underpads *without* SAP respectively. Subjects using diapers and underpads *with* SAP had significantly better dermatitis scores than those using products *without* SAP and those using cloth underpads.

In summary, the literature indicates that a combination of urine and faeces in a pad is highly irritant to the skin and *less frequent* pad changing is likely to cause an increase in diaper dermatitis. Although urine alone has much lower irritant potential, over-hydrated skin is more permeable to irritants and more vulnerable to friction and abrasion and we cannot therefore be confident that *less frequent* pad changing (resulting in *prolonged* skin contact with urine) does not compromise skin health. Studies to date have focused on the effects of different pad materials and compositions on diaper dermatitis, but there are no studies examining the effects of

wearing diapers for different lengths of time on skin. Specifically, we do not know the effects of different pad wear times on the skin health of elderly people.

1.2.5 Pressure ulcers

The main extrinsic cause of pressure ulcers is compression of the tissues over bony prominences against the patient support surface (cushion or mattress) resulting in local ischaemia (Bain et al. 1999; Bader, 1990). Animal studies have shown that the main site of pressure damage occurs in deep subcutaneous structures, *not* at the skin and that the early skin signs of pressure sores are cutaneous responses to damage occurring in deeper structures. Shearing injuries occur when the skin remains stationary and the underlying tissues shift, causing diminished blood supply to the skin.

The role of urine in pressure ulcer development has not been well studied. There is little published literature examining the relationship between skin hydration and pressure. We do not know the effects of urine on ischaemic skin and whether prolonged hydration of the skin alone affects the skin's ability to recover from pressure or to resist pressure damage.

The primary risk factors for pressure ulcers are immobility and limited activity levels (Panel for the prediction and prevention of pressure ulcers, 1994). Incontinence is considered a secondary risk factor and is a component of several pressure ulcer risk assessment scores (Norton et al. 1962; Bergstrom et al. 1987); other secondary risk factors include impaired nutritional status and altered level of consciousness. In addition, nursing literature frequently includes reference to the role of skin care in the prevention of pressure ulcers (Jeter & Lutz , 1996). But it is not clear that wet skin, maceration or dermatitis have a major aetiological role in the development of pressure sores. Cooney (1997) comments that 'it is difficult to postulate that moisture of the skin would contribute to pressure-induced ischaemia of deep tissues'.

We have evidence that suggests that wet skin is more susceptible to friction and abrasion than dry skin (Zimmerer et al. 1986). It therefore seems likely that urine contributes to pressure-oriented skin damage from *without* (through friction and

abrasion), whereas pressure and shear forces damage the skin from *within* (through ischaemia). One would not therefore expect prolonged urine contact to affect the development of pressure ulcers except at the most superficial level i.e. abrasions.

However, an important factor that should not be overlooked is that a reduction in pad changing frequency may also lead to a reduction in patient repositioning (these actions are likely to occur simultaneously) with associated loss of pressure relief.

Turning or repositioning is an established method of preventing pressure ulcers. Indeed the US Clinical Practice Guidelines, *Pressure ulcers in adults: prediction and prevention,* state that any individual who is assessed as being at risk of pressure sores due to incontinence, immobility or other factors should be "repositioned every 2 hours, if this is consistent with overall care goals" (1992). Current European guidelines also stress the importance of repositioning for the prevention of pressure ulcers (European Pressure Ulcer Advisory Panel, 1998).

1.2.6 Turning strategies

Although many other pressure-relieving strategies exist, repositioning remains a standard practice for pressure ulcer prevention. But the need for turning some 'at risk' patients has been questioned by Schnelle et al (1993b). They found that, although two-thirds of residents in nursing homes turned *themselves* during the night, care staff managed them in the same way as the third who did not. They looked for simple predictors for self-turning and found the *Norton score* (Norton et al. 1962) to be best. There was a statistically significant difference in *Norton scores* between the two groups (non-turners: 10.8; self-turners: 12.5) but the two sets of scores were insufficiently distinct to enable individual self-turners to be identified with confidence.

Schnelle and colleagues (1993b) studied their subjects by monitoring their arm movements, using wrist actigraphy, and hip and shoulder movements, using pressure-sensitive film on the mattress. Arm movements were measured to calculate patients' wake / sleep patterns while substantial changes in the pressure distribution beneath hips and shoulders, in the absence of light and sound (indicating nursing intervention)

were assumed to be evidence of self-turning. Although the researchers demonstrated high levels of sensitivity and specificity when comparing direct observations with instrument recorded observations of movement, they point out that they were unable to determine if any movements resulted in a sustained change in position.

Examining patient turning behaviour using more direct observational methods than were available to Schnelle and colleagues should enable further assessment of self-turning, on the part of the patient, and also turning practice, on the part of the staff. However, mounting a clinical study powerful enough to draw any significant conclusions in terms of pressure ulcer development would require a patient sample in the region of 3000 and is therefore beyond the scope of this thesis (Bain et al. 1999).

1.3 Literature review: Sleep and incontinence

1.3.1 Structure and function of sleep

Sleep has been defined as the 'natural state of rest characterised by reduced body movement and decreased awareness of the surroundings' (Cooper, 1993). Although the nature and purpose of sleep is not fully understood, evidence suggests that the main function of sleep is restorative. Tissue synthesis is higher during sleep (Adam and Oswald, 1977); growth hormone (which promotes anabolic activity) is secreted (Takahashi et al. 1968) and oxygen consumption diminishes (Shapiro et al 1984).

Deprivation of sleep has been shown to affect cognition, memory and learning (Naitoh and Townsend,1970) as well as giving rise to anxiety, irritability and visual misperceptions (Horne, 1985). Animal studies have demonstrated the fundamental importance of sleep; complete sleep deprivation resulting in multiple pathology and death (Rechtschaffen et al. 1989).

The advent of electroencephalographic (EEG) techniques has enabled the nature and structure of sleep to be studied. In the adult, normal sleep consists of two different states which have distinctive physiological mechanisms and behavioural and neurophysiological markers. These two states are known as non-rapid eye movement (NREM) and rapid eye movement (REM) sleep. NREM sleep is divided into four stages (1-4). Sleep progresses in cycles of 90-120 minutes commencing with NREM

stages 1,2,3 and 4. After stage 4 is reached the sequence is reversed back through the stages, but stage 1 sleep is replaced by REM sleep. Throughout the night this sequence is repeated with each cycle becoming longer.

NREM sleep is sometimes referred to as 'quiet sleep'. During stage 1 there is deep drowsiness, from which a person can drift in and out and be awakened easily. Muscle activity is reduced and slow rolling eye movements occur.

As the cycle enters stage 2 sleep eye movements stop and brain waves become slower with occasional bursts of rapid waves (sleep spindles). During stage 3 the brain produces extremely low frequency (delta) waves, interspersed with smaller, high frequency waves and by stage 4 the brain exclusively produces these delta waves. During stages 3 and 4 there is minimal muscle activity and hence these stages are collectively known as 'deep sleep'.

The cycle then reverses and switches into REM sleep. This is characterised by the presence of rapid eye movements (REMs), although these may only be present at the onset and end of this stage. Complete muscle atonia occurs during this stage and this absence of muscle activity distinguishes REM sleep from stage 1, rather than the presence or absence of rapid eye movements which occurs only intermittently.

The architecture of sleep changes with age and the most striking characteristic is the decrease in stage 3 and 4 sleep activity, a corresponding increase in stage 2 sleep occurs and older people therefore spend less time in 'deep sleep'. There is also an increase in the specific sleep pathologies of sleep apnoea and periodic leg movements (Ancoli-Israel et al, 1985) both of which are likely to cause sleep fragmentation.

1.3.2 Quality of sleep in nursing and residential homes

Studies in residential settings have found disturbed sleep among residents. Allen et al (1987) made polygraphic recordings of 30 demented and 14 non-demented persons in a hospital geriatric unit and found all patients had fragmented sleep and took daytime naps, although demented patients had less total sleep time. Cohen et al (1983) interviewed 148 institutionalised, non-demented elderly residents about their sleep

and 45% met at least one of their criteria for sleep disturbance. Bliwise et al (1990) studied the sleep patterns of demented patients in residential settings using direct observation (every 15 minutes for 24 hours) and reported wide inter-subject differences with many residents awake for substantial portions of the night. Similar findings of a high degree of individuality in sleep/wake patterns were found by Regestein et al. (1987). Pat-Horenczyk et al. (1998) recorded the sleep of 67 demented nursing home residents using actigraphy (which uses an accelerometer to measure arm movement) and concluded that both the capacity to maintain sleep and the capacity to maintain wakefulness were impaired in dementia.

Ancoli-Israel and others (1989) recorded sleep using a portable system that combined actigraphy and respiration monitoring and found that residents averaged no more than around 40 minutes of sleep per hour and 50% woke at least two or three times per hour. The authors had difficulty accounting for the amount of sleep fragmentation experienced by residents; there were no significant differences in the amount of sleep between those with or without sleep apnoea, those receiving and not receiving sedative-hypnotics, or those who were ambulatory or non-ambulatory. The methods used to record sleep during this study did not enable the researchers to correlate nursing interventions (including continence management) during the night to sleep fragmentation, but the authors do suggest that nursing activities may have been partly responsible.

More recently Ancoli-Israel et al (1997) measured 24 hour circadian-rhythm patterns of sleep/wake activity in 77 nursing home patients using actigraphy and confirmed that sleep was extremely fragmented for both demented and non-demented patients.

The problem of sleep disturbance during the night extends into the daytime. Although residents spend longer in bed than any other population, the sleep fragmentation they experience affects their daytime performance. Daytime sleepiness has been found to correlate with multiple arousals during the night (Carskadon et al. 1982; Stepanski et al. 1984; Bennett et al. 1998).

Sleep fragmentation is multi-factorial with many possible causes. Recently Gentili et al (1997) interviewed 51 cognitively intact nursing home residents and found that

nocturia, environmental factors and pain were the most commonly perceived causes of sleep disturbance. Specific sleep pathologies, such as sleep apnea and periodic leg movement have been associated with poor sleep amongst elderly people (Ancoli-Israel et al. 1985; Bliwise et al. 1990), along with pain and toilet visits (Gentili, 1999; Clapin-French, 1986; Ersser et al. 1999a), physical disabilities (Foley et al. 1995) and nursing interventions (Schnelle et al. 1993a; Cruise et al. 1998; Gall et al. 1990). We cannot therefore assume that reducing nursing interventions *alone* during the night will result in less sleep fragmentation and improved sleep.

1.3.3 Continence management and sleep quality

There are no published studies of the impact of night-time incontinence management on sleep quality in the UK. In the United States there have been some systematic attempts to describe incontinence related nursing activity during the night and these studies form the basis of what we know about night-time care. American nursing homes are generally much larger than UK nursing homes, 400 bedded homes are common, compared to the average size of around 30 in the UK (Laing and Buisson, 1998) and the nursing care is reported to be more structured. The results of these studies may therefore be less valid for the UK.

Schnelle and colleagues (1993a) studied four long-stay facilities in the USA and found that nursing 'rounds' were made throughout the night with an average of 3.1 pad changing episodes recorded per resident during each 10 hour night period. Eighty seven percent of all incontinence care practices were associated with episodes of waking. In a later study by Cruise and colleagues (1998) of 10 nursing homes the same research group found that 76% of all incontinence care resulted in awakenings during the night. The authors concluded that the nursing home environment was not conducive to sleep and that nursing care practices, particularly those related to continence care, were responsible for a substantial amount of the sleep fragmentation that was common among nursing home residents.

1.3.4 Interaction between continence management, sleep quality and skin health

The effects of different continence interventions during the night have been published in two papers by the same research group (Schnelle et al. 1998; Schnelle et al. 1999). The earlier paper reports results from four nursing homes, the later paper from eight

homes. The researchers set out to examine whether individualised continence care and a noise abatement programme during the night reduced waking episodes and improved sleep. Participating nursing homes were randomised to control or intervention phases with residents in control homes receiving their usual continence management at night (usually 2-3 hourly) and then receiving the intervention later (delayed intervention).

Residents in the intervention phase of the study were assigned to a 2 or 4 hour continence care schedule based on the resident's skin problems and body movements. Researchers provided continence care only if the residents were found to be awake on their hourly checks. If the resident had not woken (and been changed) during the preceding 2 or 4 hour period the resident was woken for pad changing on the next hourly check (i.e. they were woken on the 3rd or 5th hour respectively). Around a third of residents were assigned to the 2 hour continence care regime and two thirds to the 4 hour regime. Thus the majority of residents received less continence care than they would normally and this was accompanied by staff efforts to reduce the noise and light associated with the care.

The researchers reported that there was a significant differential improvement in the intervention group on only two sleep measures: awakening associated with a combination of noise plus light and awakening associated with light (but not noise alone). Both these outcomes were manipulated by the researchers (i.e. they were a product of the intervention regimes) and therefore significant differences would be expected. Other measures of sleep, including percentage of time spent asleep, did not show significant differences.

In the earlier paper (Schnelle et al. 1998) skin health was also examined. Interestingly, the researchers found that not only were there no adverse changes in skin health for the intervention group, but skin health improved significantly. The authors discussed this surprising finding and several explanations were offered. The most plausible explanation was that the amount of intervention offered by the researchers, although thought to be less than was offered by regular care staff, may have amounted to more or more consistent continence care than the study residents usually received.

Although these studies indicate that less incontinence care at night results in less waking associated with incontinence care, most sleep measures were not found to be significantly different between the intervention and control groups. To date it has not been demonstrated convincingly that residents who are *not* disturbed by carers at night sleep better that those who *are* disturbed.

In conclusion, little work has been done to establish best methods for the night-time management of incontinence. There is therefore a need to provide evidenced-based guidelines to inform practice.

1.4 Research questions and hypothesis

The following questions were posed.

In patients with night-time urinary incontinence, living in residential settings:

I. Does *less frequent* pad changing (8 hourly) result in deterioration in skin health compared to *frequent* pad changing (4 hourly)?

II. Does *less frequent* pad changing (8 hourly) result in improved sleep compared to *frequent* pad changing (4 hourly)?

In addition two secondary research questions were posed which would be of clinical value if (i) it were demonstrated that a *less frequent* pad changing regime resulted in damage to skin health, and (ii) if it were demonstrated that there was evidence of redundant turning of residents by staff.

i. What are the subject characteristics (predictors) of deterioration in skin health during a *less frequent* pad changing regime?

ii. What are the characteristics of those incontinent adults, who turn themselves at night and are also turned by staff?

The hypothesis was that there were no differences between subjects who have *less frequent* (8 hourly) pad changing during the night compared to those who have *frequent* (4 hourly) pad changing in terms of skin health and sleep.

In order to answer these questions measurement and assessment tools were selected which focused on (i) skin health; (ii) sleep duration and self-turning; and (iii) subject characterisation.

CHAPTER 2

METHODS: SKIN HEALTH AND SLEEP MEASUREMENT

2.1 Non-invasive methods of measuring skin health

A plethora of non-invasive methods of measuring skin health exist. Dermometrology is used in biological, medical, and skin care research and by the drug and cosmetic industries. However, there is little published work aimed at validating techniques and standardizing measurements and there has been much lament regarding the lack of quality control procedures for assessing uniformity of data collection and interpretation (Pierard, 1995). Instruments therefore need to be selected with care.

Selecting the most appropriate instruments for measuring skin health requires consideration of their reliability and reproducibility; their validity (i.e. the extent to which the instruments measure the process or pathology of interest), their sensitivity to change and the relative costs and pragmatics of their use.

A further consideration is whether to use a mono-instrumental or multi-instrumental design. (Serup, 1995), makes a persuasive case for the use of multi-instrumental designs for skin measurements on the grounds that skin disorders often exhibit more than one skin change and the mono-instrumentalist not only runs the risk of missing the right variable, but also cannot corroborate his or her findings with the support of other (secondary) measures.

Changing an incontinence pad *more* or *less* frequently is likely to affect the skin in three main measurable ways.

- Less frequent pad changing may lead to greater hydration of the skin due to the increased volume of urine within the pad and the prolonged period of time in contact with the skin.

- Less frequent pad changing may lead to an increase in pH of the surface of the skin due to the action and interaction of urine and faeces.

- The greater permeability (due to increased hydration) of the skin may lead to an increase in chemical irritation from urine and faecal constituents resulting in *diaper dermatitis*

Methods to measure dermatitis, skin hydration, and pH are therefore most appropriate and have been most commonly employed in diaper research (Davis et al. 1989; Zimmerer et al. 1986; Dallas and Wilson, 1992; Campbell, 1987).

2.1.1 Measurement of dermatitis and erythema

Erythema is the main clinical sign of inflammatory skin conditions such as diaper dermatitis (Serup and Agner, 1990) and can be observed visually by the clinician or researcher. Measurement of change in erythema is therefore needed to determine changes in dermatitis.

2.1.1.1 Visual grading

Although the eye is a very sensitive tool and able to distinguish subtle differences between two colours, we cannot memorize colour with precision and may fail to tell the difference between two colours if shown them at separate times. The eye is therefore most reliable when the areas being compared are presented simultaneously (Takiwaki and Serup, 1995). This is not possible when comparing changes that occur over time; we cannot simultaneously compare the skin colour of the buttocks from last week, with those of today. Additionally we cannot accurately quantify differences in colour but can only express them roughly on an *ordinal* scale by visual grading. Scores may also differ from observer to observer (inter-rater reliability) and may be affected by a number of factors, such as ambient light, oedema, tanning of skin and the experience and visual acuity of the observer (Lahti et al. 1993).

Visual grading is not therefore an ideal method for measurement of changes in erythema, but is of value as a secondary measure, to validate findings from instruments designed to measure colour quantitatively. It would be important to know that instrument recorded changes in erythema were accompanied by clinically observable changes.

2.1.1.2 Instrumental methods of colour and erythema measurement

A variety of instruments have been devised with the objective of obtaining reproducible results of colour estimation. The definitive method of measuring skin colour uses reflectance spectrophotometry. This method has been developed and refined for more than a century, has been widely used for the study of skin colour and has been demonstrated to produce reproducible results in different laboratories (Bjerring, 1995). Reflectance spectrophotometers are constructed based on one of two principles: (i) broad band irradiation of the skin with filtering of the reflected light before detection, or (ii) irradiation of the skin with filtered light and detection of light with a broad band detector (Bjerring, 1995; Bjerring and Andersen, 1987). The principle output of these instruments is a percentage reflectance curve relative to a calibration surface (usually a white reference sample). Absorption peaks can be found for important molecules such as melananins, bilirubin and haemaglobin (Kollias & Baqer, 1985; Hannemann, Dewitt, et al. 1979). The measured spectral curves also provide data for the computation of CIE (Commission Internationale de l'Eclairage) colour values (see below).

The emission from the light source is fed through a fibre-optic probe to the test site at an angle of 45 degrees and the probe collects the reflected light at the same angle. This reflected light is fed into the optical spectrum analyser.

Reflectance spectrometry provides *all* spectral data on skin reflection, gives detailed information about physical skin properties and offers reproducible results. However reflectance spectrometers are expensive, heavy laboratory instruments and are not designed for routine clinical use.

Colour measurement tools (colorimeters) have since been developed which quantify surface colour using the CIE (Commission Internationale de l'Eclairage) system (Westerhof, 1995). This system uses a different principle to reflectance spectrophotometry and is based on the non-linear colour perception of the human eye. A colour is expressed as a three-dimensional co-ordinate with an a^*axis (green-red), a b^*-axis (yellow-blue) and an L-axis (brightness) (Figure 2:1), referred to as tristimulus colour values. The numerical values of colours are available as published tables and are known collectively as the CIE standard observer.

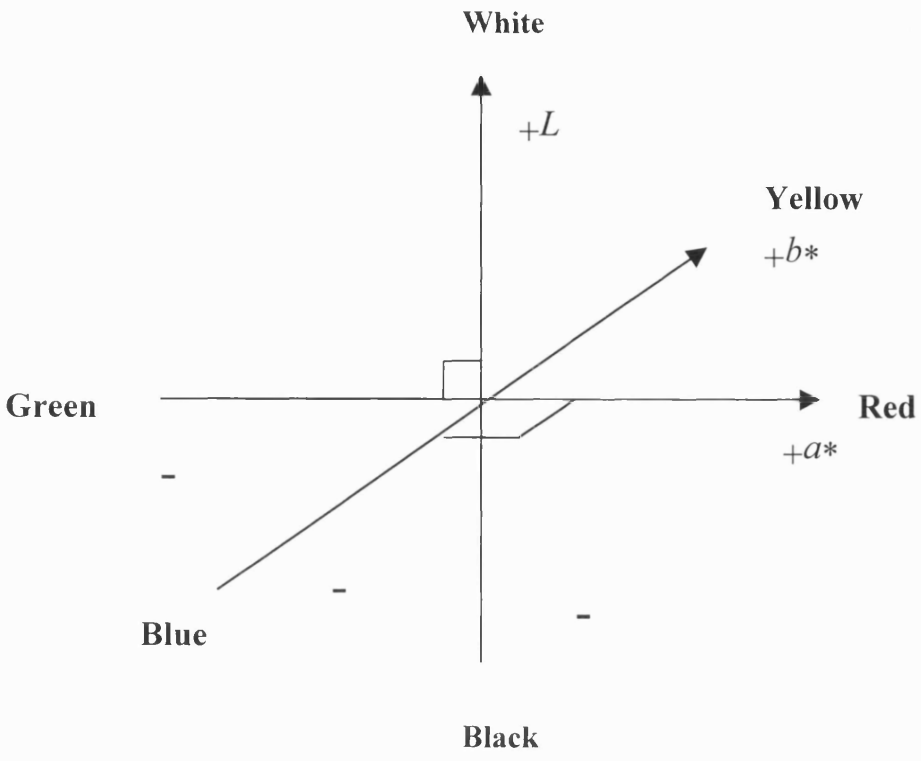


Figure 2:1 Colour co-ordinates of the CIE tristimulus colour observer

There are several commercially available colorimeters and most are based on illumination with a xenon flash light, although there are differences in the way the illumination chambers are constructed (Serup and Agner, 1990). Optical fibres lead the signal to the photoreceiver and the tristimulus optical analysis unit with silicon photocells is located either in the probe or the main body of the instrument.

Colorimeters have been compared with clinical grading by a number of researchers and have shown good correlation with observable degrees of erythema (Serup and Agner, 1990; Lahti et al. 1993).

A further refinement of colour measurement has been the development of erythema meters which uses the same principle as reflectance spectrophotometry. The chief need in dermatology is to quantify *selected* colours which are mainly determined by the two chromophores, haemoglobin and melanin (Takiwaki and Serup, 1995). Although simple photoelectric reflectance meters for the quantification of erythema have been available for years these prototypes were not suitable for routine use and it is only comparatively recently that commercial erythema meters, designed for clinical use, have become available (Takiwaki and Serup, 1995).

Erythema meters are based on the principle that the quantity of haemoglobin in the skin corresponds directly to the extent of erythema and this is expressed as the 'erythema index'. Similarly the quantity of melanin is expressed as the 'melanin index'.

Oxyhaemoglobin shows high absorption of light in the spectral range 520-580 nm (green light). Absorbence falls rapidly with increasing wavelength and absorption in the red part of the visible spectrum is minimal. In erythema the skin is red due to an increase in the blood content of the subpapillarly plexus; a greater amount of green light is therefore absorbed (and less is reflected). However the amount of red light absorbed or reflected shows little change with this vasodilation and remains low. Therefore the greater the blood content of the superficial dermis, the less green light is reflected whilst the amount of red light reflected remains constant. By dividing the red component of reflected light by the green the erythema index is obtained which corresponds to the blood content of the superficial epidermis (Diffey et al. 1984).

The erythema index is expressed as follows:

$$\text{Erythema index} = \log_{10}\left[\frac{\text{Intensity of red component of reflected light}}{\text{Intensity of green component of reflected light}}\right]$$

There are two main types of erythema meter available. One type has a halogen or tungsten lamp as the light source that emits white light to the object and the reflected light is selected within the two narrow bands centred at 546 and 672 nm using two interference filters (Diffey et al. 1984). The other type has two (Pearse et al. 1990) or three (Feather et al. 1988) light emitting diodes (LEDs). As these LEDs emit narrow-band radiation no wavelength-selective filters are needed in the optical system. All these instruments measure the reflectance of the skin within the narrow bands of the spectra corresponding to green and red light. After photoelectric conversion of reflected light by photodiodes the reflectance signals are processed by analogue electronics or microcomputers and the erythema index is displayed.

A strong linear correlation ($r=0.92$, $p<0.001$) was shown between the erythema index and the a* representing the red-green axis in the CIE standard observer (Takiwaki et

al. 1994). Lahti and colleagues (1993) found good correlation between erythema index and visual grading (although aged skin was not used).

Erythema meters have been used clinically in a number of studies. Farr and Diffey (1984) in their study of UV irradiated skin showed that the erythema index is linearly related to the logarithm of the radiation dose from the minimal erythema dose up to about 15 times this value. Diffey and Oakley (1987) also reported that vasodilation occurs in the 'latent period' before the erythema becomes visible. The erythema index was also used for the objective evaluation of the efficacy of some drugs on UVB induced erythema and on sun-damaged skin (Trevithick et al. 1992) , and the assessment of antihistamines against histamine flare reaction (Hoch et al. 1997). The erythema index is influenced by the melanin index (Feather et al. 1988) and caution is therefore needed to avoid comparing sites with different levels of pigmentation (Takiwaki and Serup, 1995).

In comparison with the conventional methods of colour measurements using reflectance spectrophotometry or tristimulus colorimetry the use of the erythema meter appears to offer notable advantages:

- The intensity of erythema can be separately and conveniently quantified as an index.
- The erythema index is expected to have a roughly linear relationship with the content of the red blood cells in the upper dermis.
- The instruments are portable and suitable for clinical use.

The available evidence would therefore suggest that selection of the erythema meter would be the most appropriate colour measurement tool for quantifying erythema.

An alternative method of quantifying erythema is to measure cutaneous blood flow using laser Doppler flowmetry (LDF). This technique has been used for more than a decade to study the microcirculation of the skin and currently more than 10 different LDF instruments are available. LDF is an optical technique whereby light from an He-Ne laser is directed by an optical fibre to the skin and the Doppler shift of emitted

light versus back-scattered light is measured and displayed in arbitary units. The blood flow under an area of about 1mm^2 and down to a depth of less than 1mm is measured. The equipment measures total blood flow i.e. the combination of capillary flow and arteriolar regulatory tone (Gigli et al. 1996). Colorimeters and LDF therefore measure somewhat different features of cutaneous circulation; colorimeters measure mainly capillary accumulation of blood and the LDF measures total blood flow, mainly determined by arteriolar tone (Gigli et al. 1996).

Good correlations have been found between visually observed erythema and LDF values (Blanken et al. 1986; Nilsson et al. 1982; Willis et al. 1988; Andersen and Staberg, 1985; Stelling and Hale, 1996). Although a clear dose-response relationship has been reported between a standard skin irritant (sodium lauryl sulphate) and recorded blood flow values (Serup and Agner, 1990; Agner and Serup, 1990; Agner and Serup, 1989; Nilsson et al. 1982), sometimes this has not been clear (Blanken et al. 1986).

There have been controversial results on the repeatability of LDF measures and intra-subject co-efficient of variation has been reported to be as high as 25% (Bircher et al. 1994). Serup and Agner (1990) compared colorimetry with LDF using repeated measures under laboratory condition on the same sites and reported much lower intra-subject co-efficients of variation for the two colorimeters than for the laser Doppler flowmeter. In particular they noted that colorimetry was relatively unaffected by factors such as noise and talking, whereas the laser Doppler flowmetry, which records a dynamic situation, was sensitive to such factors and may therefore be less suitable for routine clinical work. Similarly Lahti and colleagues (1993) when comparing an erythema meter, a colorimeter and laser Doppler flowmetry found that although all instruments produced a good correlation with visual grading the LDF gave the least repeatable results.

A further factor for consideration when selecting an appropriate tool for erythema measurement is the issue of pragmatics and measurement *in the field.* Virtually all studies of skin measurement use patch testing under laboratory controlled conditions on adult volunteers rather than testing in clinical situations. Only one study could be found that had used any of these instruments to measure erythema in a clinical setting.

Byers and colleagues (1995) compared four types of skin cleansing regimes used for incontinence care in a residential setting. They used the Diastron erythema meter and found statistically significant differences in the erythema index (the value produced by the erythema meter) between regimes despite having a relatively small number of subjects (N = 10). An expert commentator (Kemp, 1995) questioned the *clinical* significance of the Byers study and suggested that inclusion of a visual grading scale would have been advantageous. The researchers did not report any difficulties with the clinical use of this instrument.

- From this analysis of methods it was concluded that for the measurement of erythema the most appropriate instrument for this study was the erythema meter. In addition the use of a visual grading scale would validate and corroborate instrumental measures

2.1.2 Measurement of skin hydration

Measuring skin hydration is of primary concern to the cosmetic industry, who have a commercial need for quantitative assessment of the efficiency of various moisturising products. But it also has clinical value for the assessments of pathological skin conditions which affect skin hydration such as atopic xerosis (Tagami, 1995).

In vivo there exists a concentration gradient of water within the stratum corneum, highest in the lowermost layer and lowest in the uppermost portion. The stratum corneum is the rate limiting barrier for transfer of water from the saturated tissues of the epidermis to the dry outer environment. Water diffuses through the stratum corneum as a passive process.

In vitro isolated samples of stratum corneum become hard and brittle when dehydrated and hydration with water (rather than the application of oil based products such as petrolatum) has been found to restore softness and flexibility (Blank, 1952). Thus the goal of maintaining adequate hydration of the skin has become particularly important to the cosmetic industry and this has spurred the development of quick and easy methods of measuring skin hydration (Berardesca, 1997). A small number of commercially available instruments are now available such as the Corneometer, the Nova DPM and the Skicon, which are designed to do so using electrical methods.

2.1.2.1 Electrical methods

The most commonly used electrical method involves the measurement of skin impedance. Impedance (Z), is the total electrical opposition to the flow of alternating current and depends on resistance (R) and capacitance (C). These parameter are related as follows:

$$Z = [R^2 + (1/2\pi fC)^2]^{1/2}$$

where f stands for a frequency of an applied alternating current. As the frequency of the alternating current increases the capacitance of a circuit becomes increasingly important in determining its impedance. For a given voltage, the higher the impedance and resistance of a circuit the less current flows. The higher the capacitance and the higher the frequency of the alternating current the lower the impedance.

Tregear (1965) suggests that the reciprocal of impedance (i.e. conductance) should be a measure of the hydration of the skin surface and Leveque and de Rigal (1983) and Tagami and colleagues (1980) have reported good sensitivity to the water content of the skin surface using impedance measurement.

The measurement of capacitance is based on the assumption that the electrode, stratum corneum and upper parts of the epidermis work as a variable capacitor (Barel and Clarys, 1995) and that the total capacitance is only influenced by changes in the dielectric constant of the skin in contact with the electrodes. The dry horny layer (the stratum corneum) acts as a dielectric medium and when hydrated a significant change in the dielectric properties of this medium has been observed (Leveque and de Rigal, 1983). Skin conductance and capacitance have been found to correlate strongly ($r = 0.95$) (Tagami, 1995), except in the palmoplantar skin surface, where capacitance has been shown to be disproportionately low compared with conductance. Thus some researchers choose to measure conductance alone, whilst others believe that capacitance is a more valid measure (Barel and Clarys, 1995).

Fairly recently, the physics behind electrical measurements of skin hydration were examined by the European Group for Efficacy Measurements on Cosmetics and Other Topical Products (Berardesca, 1997) and the reliability and validity of such methods questioned. These authors suggest that the relationship between electrical conductance

and water content is not linear, but depends on the binding state of water molecules to keratin chains. As a result of this variability in water binding strengths electrical conductance is not directly proportional to total water content. Alterations to the keratin-water network are therefore likely to change conductance without affecting the water content of the skin.

The group goes on to challenge the use of the term 'capacitance' on the grounds that, unlike true electrical capacitance, the 'capacitance' measured by these skin instruments is frequency dependent. They propose that as the standard physical parameters of resistance, reactance and capacitance are *not* frequency dependent, to derive such parameters from impedance and conductance (which are frequency dependent) is fallacious.

Furthermore, there is a need to take into account intrinsic and extrinsic factors that affect measurement. In particular, measurements are strongly affected by skin temperature such that it is possible for skin that is moist and cool to give exactly the same electrical response at a single frequency as skin that is warm and dry (Berardesca, 1997). Commercial instruments operate at different frequencies and using different pressures to apply the electrode to the skin. It is not possible to accurately calibrate the instruments (Barel and Clarys, 1995) and results can give only relative indications and not absolute measures. In addition there has been a lack of standardisation of operating procedures leading to problems of reproducibility and difficulties comparing data from different laboratories and experiments. Despite these problems, the simplicity, relative cheapness and ease of use of these instruments is attractive and they have been used in clinical studies. Schnelle and colleagues (Schnelle et al. 1997) elected to use an impedence method in their study of skin disorders in nursing home residents.

However, it seems that although electrical measurements appear promising and can differ by four orders of magnitude between dry and wet skin (Campbell et al. 1977), there are fundamental difficulties in determining the relationship between impedence, capacitance and skin hydration and no standardised method of electrical measurement currently exists.

2.1.2.2 Evaporimetry

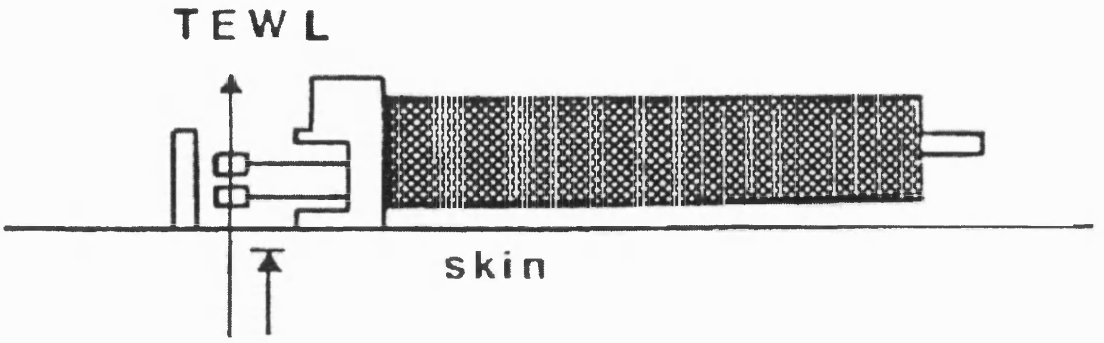
An alternative to electrical methods of measuring skin hydration is the measurement of trans-epidermal water loss (TEWL). The evaporimeter is a non-invasive device that measures the vapour pressure gradient (due to evaporative water loss) immediately above the skin surface. It is most commonly used in dermatological research and in the cosmetics industry on 'dry' skin (i.e. skin that is not wet) to measure the barrier function of the stratum corneum. A wide variety of irritants such as detergents and solvents exert their damage on the skin by impairing the barrier function of the stratum corneum. A raised TEWL is an early sign of skin irritance (Freeman and Maibach, 1988; Tupker et al. 1990).

This method has also been used to measure skin water-loading in baby diaper research (Davis et al. 1989; Zimmerer et al. 1986; Campbell, 1987) in patch testing of disposable and reusable adult incontinence pads (Dallas and Wilson, 1992) and in the textile industry (Hatch et al. 1997).

Water loss by evaporation from the human body consists of two different processes: a continuous diffusion of water vapour through the epidermis and secretion of sweat through the sweat glands. The summation of the two is termed 'trans-epidermal water loss' (TEWL) and constitutes the total amount of water lost through the skin. In the absence of forced or natural air convection a boundary layer develops around the skin (approximately 10 mm high) in which a water vapour gradient exists between the skin surface and ambient air. If the vapour pressure of the boundary distribution layer is known the evaporative water loss can be expressed in terms of this gradient (Nilsson, 1977; Pinnagoda et al. 1990).

The Evaporimeter utilizes a probe with a pair of sensor units (hygrosensors coupled with thermistors) for the determination of relative humidity and temperature at two levels above the skin (3mm and 9mm), (Figure 2:2).

Figure 2:2 Evaporimeter probe showing detail of sensors

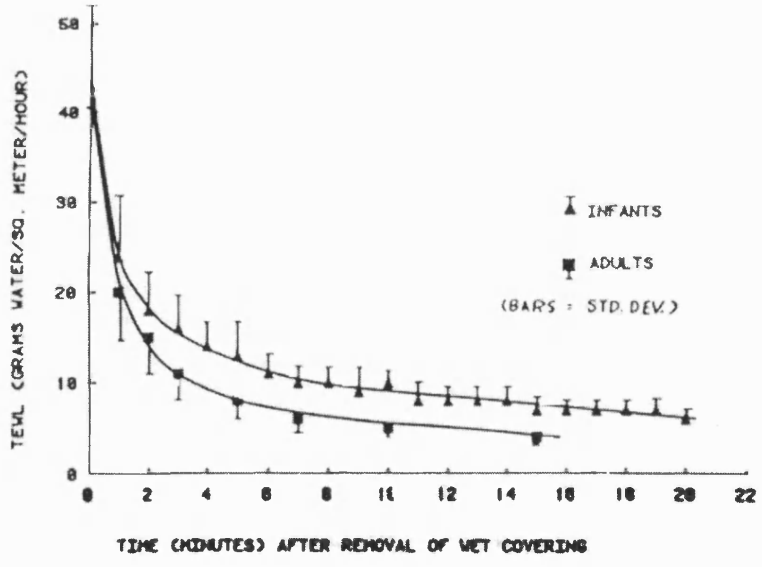


A European standardisation group have provided guidelines for the measurement of TEWL using the Servomed evaporimeter (Pinnagoda et al. 1990) which has until recently been the only commercially available instrument for TEWL measurement. This group identified three main sources of variables that affect TEWL measurements: those related to the *individual* (the subject being measured); the *environment*; and the *instrument*. Individual variables that affect TEWL include age and anatomical sites (but not sex or race), thermal and emotional sweating and skin surface temperature (but not simple vasoconstriction or vasodilation). Environment variables that affect TEWL include air convection, ambient air temperature, ambient air humidity, and direct light. Instrument variables include zero drift, probe contact pressure, the use of probe protection covers and probe temperature changes (from the operator's hand and subject's skin), and deviation of the probe from a horizontal orientation. Practical guidance is provided to enable evaporimeter operators to minimise sources of variation in order to produce repeatable results. However these guidelines are aimed at laboratory based researchers using evaporimetry to measure 'dry' skin states and no similar guidelines have been produced for 'wet' skin states, or for use in non-laboratory settings. Further work on standardisation has demonstrated that subjects need to be rested for 15 minutes before TEWL measurements are taken (Van Sam et al. 1994), that TEWL measurements vary between different areas of the volar forearm (with measurements towards the wrist being significantly higher than other forearm sites) (Panisset et al. 1992), and that there are significant differences between the dominant and non-dominant arm (Treffel et al. 1994).

The reproducability and variability of TEWL in 'dry' skin states has been assessed by Blichmann (1987) on the forearm and hand palms with a single researcher taking measurements. Inter-subject variability was found to be high with a co-efficient of variation ranging from (48-53%) on the forearm. In contrast the repeated measures on the same individual showed considerably smaller variation and more acceptable reproducibility (11–19%).

Most of the researchers who have used TEWL in 'wet' skin states have based their work on that of Zimmerer and colleagues (Zimmerer et al. 1986). These researchers measured the TEWL of babies who had worn specially prepared diapers that had been pre-wetted with different loads of dyne solution (a urine analogue). These were left on for an hour and TEWL measurements were taken at 2 minute intervals until baseline TEWL was achieved. In addition adult subjects wore patches of diapers pre-loaded with urine, for two hours before continuous TEWL measurements were taken until baseline was achieved. The decay curves showing the inter-subject variability are shown in (Figure 2:3).

Figure 2:3 Decay curves for TEWL (as reported by Zimmerer et al, 1986)



Zimmerer recommended that measurements are taken 2 minutes after the diaper or patch have been removed to allow for greater precision due to the rapid initial drop in

values. Subsequent researchers have not always agreed with Zimmerer's exclusion of the first 2 minutes of recording. Davis et al (1989) chose to record TEWL *only* during the first two minutes on the grounds that this measures the skin when it is at its 'wettest'. Others have taken repeated measurements after exposing the skin for two minutes (Dallas and Wilson, 1992; Cameron et al. 1997). Although TEWL from 'dry' skin reaches a stable state within a couple of minutes, wet skin that is 'drying out' is more difficult to characterise, because a stable state is not reached until the skin has become 'dry' (i.e. returned to baseline). This takes twenty minutes or more depending on the level of hydration. Selecting a valid time period over which to take measurements has therefore been a challenging task for researchers.

It is evident from this analysis of the literature that there is currently no *gold standard* method of measuring skin hydration in 'wet' skin states. Electrical methods are simple, cheap and easy and have mainly been employed to measure the effects of cosmetics (particularly moisturisers) and other topical treatments. However, these methods have been strongly and fundamentally criticised (Berardesca, 1997) and are only *proxy* methods of measuring skin hydration. Measurement of TEWL using evaporimetry is a more difficult technique and there is some disagreement in the literature about the length of time and timing of measurement that should be adopted. However TEWL is a *direct* measurement of skin hydration (because it measures water diffusing through the stratum corneum) and therefore has greater validity. In addition it is the method most commonly cited in the literature for measurement of skin hydration in 'wet' skin states including baby diaper research and occlusive textile research. It was therefore concluded that evaporimetry was the most appropriate method for measuring skin hydration.

2.1.3 Measurement of skin pH

Berg proposes that diaper dermatitis occurs because the interaction of faeces with urine produces an alkaline environment which increases the activity of faecal enzymes thereby causing irritation to the skin (Buckingham and Berg, 1986) and most studies of baby diapers have included the measurement of pH (Davis et al. 1989; Berg, 1988; Berg et al. 1994). Davis and colleagues found that skin pH of babies wearing diapers with super-absorbent polymers did not rise with increasing urine loads, but the pH levels of skin under fluff-pulp only diapers did so. There is

therefore some indication from clinical studies that pads with higher urine loads (as is likely to be the case for pads changed less frequently) may have an effect on skin pH.

Although the choice of instruments for measuring skin pH is relatively uncontentious and any commercial portable pH meter can be used (Zlotogorski, 1995), the measurement of skin pH has been much criticised by Rieger (Rieger, 1989). He questions both the way that measurements are typically carried out and what it is that the methods are measuring. The definition of pH is the negative logarithm to the base 10 of the concentration of hydrogen ions in an aqueous solution and it is expressed on a scale of 1 – 14, with 1 being very acidic and 14 very alkaline. Rieger protests that the definition of pH is in itself problematic as applied to skin, which is not an aqueous solution. Although pH can be measured by wetting the skin he claims that what is measured is not the pH of the skin but the 'pH of the (extractable) water-soluble constituents of the skin'. In this way he argues that it is the pH 'on' the skin that is being measured rather than the commonly described pH 'of' the skin.

Rieger also questions the assumption that pH is independent of the concentration or activity of the extracted constituents and suggests that any measured pH will be dependent on concentrations of the components of the aqueous skin eluate and therefore the quantity of water applied is of importance.

Rieger (1989) calls for more specific published information regarding the measurement of pH and in particular the amount of water used, in order to permit precise replication in other studies. Analysis of the literature showed that most published studies are indeed scanty in their description of the method of measuring pH and often do not describe the amount of water used. Standard recommendations are for 'one or two drops' of water to be applied to the skin or electrode as a contact medium (Zlotogorski, 1995).

Rieger's criticisms of both the reliability and validity of measuring skin pH are mainly related to its use in the cosmetic industry where much has been made of the possible advantages of applying creams and soaps with a similar pH to the skin. There is a much stronger case for measuring pH in diaper studies where it is the skin

environment that is of interest. It is the pH of this environment (i.e. *on* the skin) that has been demonstrated to be associated with diaper dermatitis.

A variety of different pH meters are commercially available and following discussions with manufacturers a medium priced pH meter from Russell was considered appropriate.

In conclusion, the following instruments were selected for the measurement of skin health:

- The Diastron erythema meter for the measurement of *erythema*
- A visual grading scale for the measurement of *erythema*
- The Servomed evaporimeter for the measurement of *skin hydration*
- The Russell pH meter for the measurement of *skin pH*

These three skin instrument measurements have been successfully piloted by Byers and colleagues (Byers et al. 1995) who carried out a small study to examine the effects of different incontinence cleansing regimes on skin integrity. This study demonstrated the *feasibility* of using these measurement techniques in a similar population to that of this study.

2.2 Methods of measuring sleep and self-turning

Although it is possible to make a general observation as to whether a person is asleep or awake, these observations are only approximate and subjective and it was not until the advent of electroencephalography (EEG) techniques that the nature and structure of sleep could be described and measured (Cooper, 1993).

The use of EEG to characterise sleep is commonly supplemented with other methods, in particular electromyography (EMG) to record muscle activity during sleep, and electro-oculography (EOG) to measure eye movement. Sometimes infra-red video is used to record movement and methods to assess respiratory function (such as oximetry and plethysmography) may be incorporated. Computer analysis then enables different aspects of sleep to be quantified. This multi-method of recording

sleep is known as polysomnography and is regarded as the *gold standard* in terms of objective measurement of sleep (Cooper, 1993; Closs J, 1999).

Such a complex system can only be delivered in a sleep laboratory with staff in attendance and is unsuitable for studying elderly people in residential settings. Simpler instrumental methods for studying sleep which are recommended for home use (Cooper and Bradbury, 1993) include EEG and oximetry, but electrode placement and/or leads to face or limbs are again inappropriate for elderly populations who may have mental impairment, may have difficulty in tolerating equipment and difficulty in understanding and consenting to the procedure. In addition any invasive method may in itself interfere with sleep.

Three simple non-invasive methods of studying sleep in natural situations (rather than sleep laboratories), have been reported in the literature: direct observation, patient questionnaire and limb actigraphy.

Direct observation has been used by several researchers (Meguro et al. 1990; Bliwise et al. 1990; Carroll et al. 1989; Regestein and Morris, 1987; Cohen-Mansfield et al. 1990), but has the major limitation of being labour intensive, requiring staff to regularly visit patients and record their wake/sleep status. Also it is only an approximation of sleep status (an unmoving, person with closed eyes may be defined erroneously as asleep) and only an intermittent record can be made. Although this method has been shown to have good inter-rater reliability (Carroll et al. 1989; Cohen-Mansfield et al. 1990) highly motivated regular staff or paid researchers are a pre-requisite to the collection of reliable data.

Patient questionnaire has been used to record subject perceptions of sleep quality, but has been found to have a poor correlation with staff perceptions of the same patient's night of sleep (Cohen et al. 1983). The reliability of patients' self-report of sleep is also doubtful because of difficulties with memory and missing data (Ersser, 1999b). This method is restricted to patients without cognitive impairment and is therefore unsuitable for settings where patients are likely to be mentally impaired.

Limb actigraphy measures movements using an accelerometer on a simple wristband (similar to a watch) and has been the most common method used to measure sleep in residential settings (Cruise et al. 1998a; Schnelle et al. 1993a; Ouslander et al. 1998a; Pat-Horenczyk et al. 1998; Ancoli-Israel et al. 1989; Ancoli-Israel et al. 1997). This method has been shown to have a good correlation with EEG for total sleep time ($r = 0.81$) and high sensitivity and specificity (87% and 90% respectively) when compared to direct observations (Ancoli-Israel et al. 1997). Actigraphy has advantages over direct observation and questionnaire, because it provides a *continuous* record of wake /sleep status, does not require additional staff effort and is not dependent on unimpaired mental status.

However, although actigraphy provides movement data, it does not include any information about the type of sleep movements that occur during the night (in particular self-turning or nursing interventions). Schnelle and colleagues (Schnelle et al. 1993a) used actigraphy to study sleep and patient turning activities (including turning and self-turning) and attempted to enhance the information supplied by actigraphy by using pressure sensitive film on the subject's bed to monitor shoulder and hip movements. But the authors acknowledge that with this method they were unable to detect whether the patient had actually *repositioned* themselves (or been repositioned) or simply shifted body weight only to return to the same position in bed that they had previously occupied (i.e. no self-turning or staff-turning occurred). Monitoring patients using audio/video recordings (using an infra-red light source) is an established method of assessing sleep disturbance due to respiratory problems (Stradling, 1993). A commercial instrument is available known as the Visi-lab. This method is non-invasive and requires no patient leads (unless an oximeter is used). The subject is monitored visually, and movements can therefore be classified unamibiguously. This method therefore offers greater validity than can be achieved by the surrogate measures used by Schnelle and colleagues (Schnelle et al. 1993b). Bennett et al. (1998) compared the Visi-lab with other methods of measuring sleep (polysomnography, EEG and autonomic arousal) and found that measurement of body movements per hour as an index of sleep fragmentation (using the Visi-lab) during the night was the best predictor of subsequent daytime sleepiness.

The use of a measurement of sleep fragmentation as an outcome measure is also supported by Carskadon et al. (1982). These researchers demonstrated that daytime sleepiness (as measured by the Multiple Sleep Latency Test) is sensitive to change with nocturnal sleep. Different methods of measuring sleep were used to measure the sleep of nursing home residents and and there was a high correlation between sleep fragmentation and daytime sleepiness. However the correlation between other measures of sleep (total sleep time and sleep stages measured by EEG) was poor. Selecting a method of measuring sleep fragmentation would therefore seem to offer greater validity than other available methods.

The Visi-lab was unique in providing enabling measurement of sleep fragmentation (by movement detection) and self-turning (by direct visualisation) whilst avoiding any contacts with the patient (which might disturb the patient and disrupt their sleep).

Although there appear to be no published studies where this method has been used in residential settings with elderly people the equipment is semi-portable and the method feasible.

For the measurement of self-turning and sleep fragmentation this instrument was therefore selected:

- The Visi-lab (Stowood Scientific Instruments)

2.3 Measurement of subject characteristics

It would be desirable to determine if certain subject characteristics were associated with self-turning and erythema (providing it was demonstrated that there was a regime effect). However if these characteristics were to be clinically helpful, they needed to be recorded quickly and easily and preferably already in use in residential settings. Self-turning is a self-generated movement and it therefore seems likely that scales that contain components of movement assessment should be of greatest value. In their study of night-time incontinence management Schnelle and colleagues (Schnelle et al. 1993b) found that there were significant differences in the Norton score (Norton et al. 1962) between *self-turning* patients and those who did not turn themselves (although

both groups of patients were turned by staff). The Norton score was developed as a predictor of pressure ulcer development and contains two components (of five) that relate to movement and mobility. Several other pressure ulcer predictor scales have been developed, all of which contain items relating to movement and mobility. The Braden score (Bergstrom et al. 1987) has received the most testing for reliability and validity and is recommended for use by the USA pressure ulcer panel. Both these scores have been tested in elderly populations and are in use on both sides of the Atlantic, although both tend to over predict the risk of pressure ulcers (Hamilton, 1992). Both the Braden and Norton scores were therefore chosen to characterise study subjects with the aim of seeking associations between scores and self-turning.

Similarly, scores of independence in activities of daily living also contain elements of movement and mobility and are therefore likely to be markers of self-turning. Many scores exist and have been reviewed and evaluated by Wade (1992). He recommends that the Barthel score (Wade and Collin, 1988) is used for most research purposes because of its simplicity and extensiveness of testing in different patient groups. In the USA the Katz score (Katz et al. 1963) is more commonly used and therefore both scores were selected for use in this study.

No measurement tools exist that are specifically designed to predict the development of diaper dermatitis. Brown (Brown, 1995) considered that scores of pressure ulcer development were likely to be of most value in doing so, but did not find significant differences between scores of subjects who did and did not develop diaper dermatitis.

For subject characterisation the following were selected:

- The Norton score
- The Braden score
- The Barthel score
- The Katz score

Use of these scores should enable the results of this research to be relevant to those working in residential settings in both the USA and the UK.

2.4 Summary of selected measurement methods

For the measurement of skin health;

- The Diastron erythema meter for the measurement of *erythema*
- Visual grading for the measurement of *erythema*
- The Servomed evaporimeter for the measurement of *skin hydration*
- The Russell pH meter for the measurement of *skin pH*

For the measurement of self-turning and sleep fragmentation:

- The Visi-lab (Stowood Scientific Instruments)

For subject characterisation:

- The Norton score
- The Braden score
- The Barthel score
- The Katz score

2.5 Piloting and development of selected measurement tools

2.5.1 Diastron erythema meter

This instrument was obtained from the manufacturer and a demonstration given by a company representative. The meter consists of a fibre optic cable attached to a probe that illuminates the skin with light from a tungsten halogen bulb (Figure 2:4). The principle of operation has been described in section 2.1.

The probe is placed on the skin using a probe support which is designed to protect the end of the probe and ensure that the probe tip lies flush against the skin (Figure 2:5). Measurements can be taken in one of two modes: in the 'free mode' the readings are continuously updated to display instantanous readings, in 'mean mode' when a measurement is taken the instrument will average 100 fast samples over a three second period and display a mean erythema index. The erythema index is calculated

Figure 2:4 Diastron erythema meter

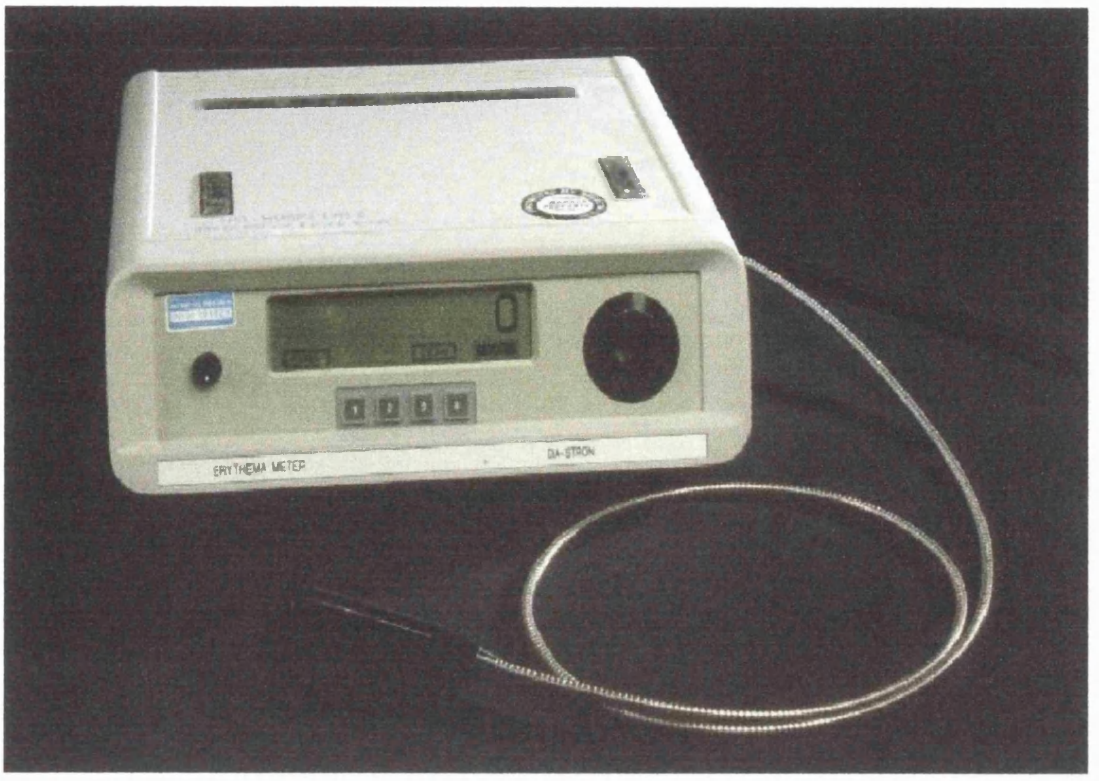
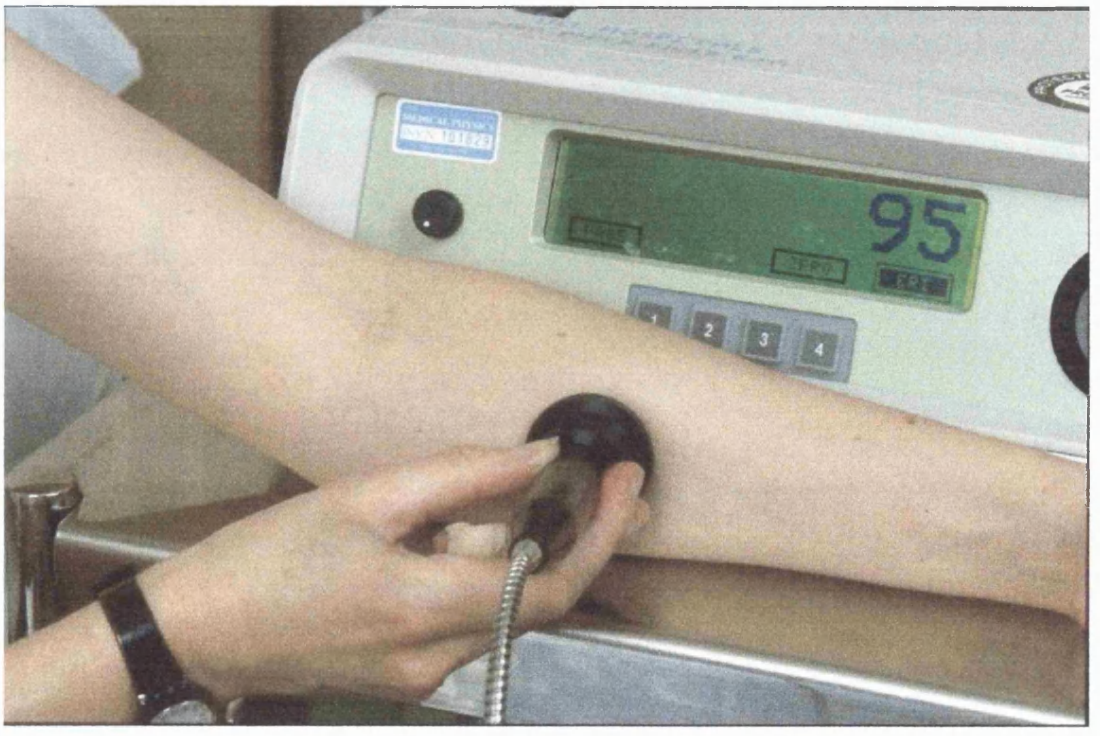


Figure 2:5 Diastron erythema meter shown with probe support



and displayed on the meter as a digit from 0-999, zero being white and progressively higher numbers indicating deeper shades of red.

The meter is zeroed as follows. Firstly the probe is placed in a probe holder within the meter box which has a pure white reference material, the zero button may then be pressed to zero the meter. It is recommended that the autozero is performed every fifteen minutes to prevent drift and after it has been switched off for any period. Secondly, a standard red sample card which has a known erythema index of 323, is placed under the probe daily to check that the reading is accurate (consultation with the manufacturer is necessary if it is not).

2.5.1.1 Piloting of Diastron erythema meter

Preliminary testing was carried out on healthy volunteers, on various anatomical sites to compare different skin shades and tones and different levels of erythema induced by mild irritation and trauma. The manufacturer's recommended technique was utilised i.e. to take three measurements on one site using 'mean mode' and average the three measurements. Particularly attention was paid to practising probe application with minimal pressure in order to avoid blanching and to obtain repeatable results. Fullerton and colleagues' (Fullerton et al. 1996) guidelines for colorimetry were implemented which recommend measurement taking on the same subject sites, in the same position, and at the same time of day to reduce intra-individual and environmental related variability.

Once confident with using the erythema meter a small number of elderly people on long-stay wards were recruited to participate in reliability and validity testing. Seven subjects agreed to participate and informed consent was obtained (if they were unable to fully give consent for themselves, assent was also obtained from their next of kin).

Erythema index measurements were made from various anatomical sites within the buttock and groin areas typically covered by a bodyworn incontinence pad. These sites were also graded visually on a scale 0 – 4 (see *visual grading* below). However, few erythematous areas were identified during the piloting, and a comparison between the erythema index and visual grading was difficult at this stage.

Erythema measurements and visual grading results from subjects in the first test location were therefore compared. Sites graded as 0 (on the visual grading scale) had a mean score of 26.5 (SD 35.9) and those graded as 3 had a mean score of 181.5 (SD 53.1). No skin was measured as grade 4 (which indicates broken skin).

In addition the reproducibility of the erythema index was established by taking three sets of repeated measurements at the same site at two-minute intervals. A co-efficient of variation of 11% was obtained which I considered adequate. This compared to about 3% obtained by Diffey and colleagues (1984). Co-efficient of variation is influenced by the size of the values recorded and for any given dispersion it will be inversely related to the size of the mean. The recordings were made during this piloting work were mainly on non-erythematous or mildly erythematous skin. Although Diffey does not state the nature of the skin used for his reproducibility studies it is likely that experimentally irritated skin (such as with sodium lauryl sulphate) was used which would produce much higher values, and a commensurately lower co-efficient of variation.

2.5.2 Visual grading scale

A five point scale was devised for the visual grading of erythema which was based on the 'international contact dermatis score' (Quinn et al. 1993).

0 = no erythema
1 = very mild erythema (barely perceptible)
2 = moderate erythema (skin pink)
3 = more intense erythema (skin deep pink/red
4 = broken, abraded skin

2.5.2.1 Piloting of visual grading scale

The skin of the seven subjects was examined together with colleagues who would be participating in the project, to establish agreement regarding the rating of erythema. It became clear that light conditions were an important variable and light standardisation was necessary. A magnifying light with a colour matching bulb designed for dermatological work (Figure 2:10) was therefore obtained in order to illuminate the skin sites.

Test-retest reliability was assessed by asking the researcher to verbally rate multiple skin sites of subjects (which were recorded) and then re-rate the sites again about 30 minutes later. A weighted Kappa score was then calculated to be 0.7. (see Table 2:1), which indicates good (but not very good) agreement. The main source of disagreements occurred between grades 0 and 1 (no erythema and barely perceptible erythema). It was considered that these discrepancies could be real (i.e. the skin colour changed slightly during the lapsed time period) or as a result of error (because the degree of difference between the two grades was very slight and therefore difficult to accurately grade). Reassessment did not improve the Kappa score and it was therefore decided to group grade 0 and grade 1 erythema together for analysis. Grouping grade 0 and 1 together gave a Kappa score of 0.94 (see Table 2:2) which indicates very good agreement.

Table 2:1. Test-retest reliability of visual grading (0 - 3)
Weighted Kappa 0.7

	0	1	2	3	4	Total
0	29	7	0	0	0	36
1	5	14	0	0	0	19
2	0	1	7	0	0	8
3	0	0	0	5	0	5
4	0	0	0	0	0	0
Total	34	21	7	5	0	

Table 2:2 Test-retest reliability of visual grading (0/1 – 3)
Weighted Kappa 0.94

	0/1	2	3	4	Total
0/1	55	0	0	0	55
2	1	7	0	0	8
3	0	0	5	0	5
4	0	0	0	0	0
Total	56	7	5	0	

2.5.3 Servomed evaporimeter

An evaporimeter (Figure 2:6) was purchased from Servomed in Sweden and was demonstrated in England by the company representative. The evaporimeter consists of a probe comprising a teflon capsule containing two hygrosensors and two thermistors positioned in an open-ended cylindrical chamber to take measurements at 3 and 9 mm above the skin (Figure 2:7). A gold-plated cover is placed over the surface of the probe that is in contact with the skin to facilitate cleaning.

The evaporimeter is connected to a laptop computer and runs a windows-based programme for collection and storage of data. Based on information from the sensors trans-epidermal water loss (TEWL) in $g/m^2/h$ is calculated and displayed on a digital readout and on the computer. An instrumental checking programme is recommended for daily use to ensure that the instrument parts are functioning correctly. It is necessary for the evaporimeter to be switched on for 15 minutes to equilibrate to ambient room temperature before calibration can take place. The evaporimeter is calibrated by turning the probe so that the axis of the cylindrical chamber is horizontal, enabling the TEWL reading to settle to zero. If this does not occur the offset button may be used to zero the instrument. Pinnagoda et al (1990) advise that between measurements the evaporimeter should be allowed to settle to zero, rather than adjusting the offset button in case water vapour is trapped in the probe and a false zero is obtained.

2.5.3.1 Piloting of Servomed evaporimeter

Preliminary testing was carried out using the skin of the researchers' volar forearms. Patches of incontinence pads (10cm x 10cm) were preloaded with 100 ml water (this represents a heavy fluid loading) and taped to the central portion of the volar forearm. These patches were then left in place for a pre-determined period before measuring TEWL. However, the software programmes provided by the manufacturer (which are used primarily for measuring 'dry' skin states) record the mean TEWL and standard deviation after a variable length of time (up to a maximum of two minutes). In 'wet' skin states a rapidly falling decay curve is produced and therefore the measurement of a mean over a short period of time is inappropriate.

Figure 2:6 Servomed evaporimeter

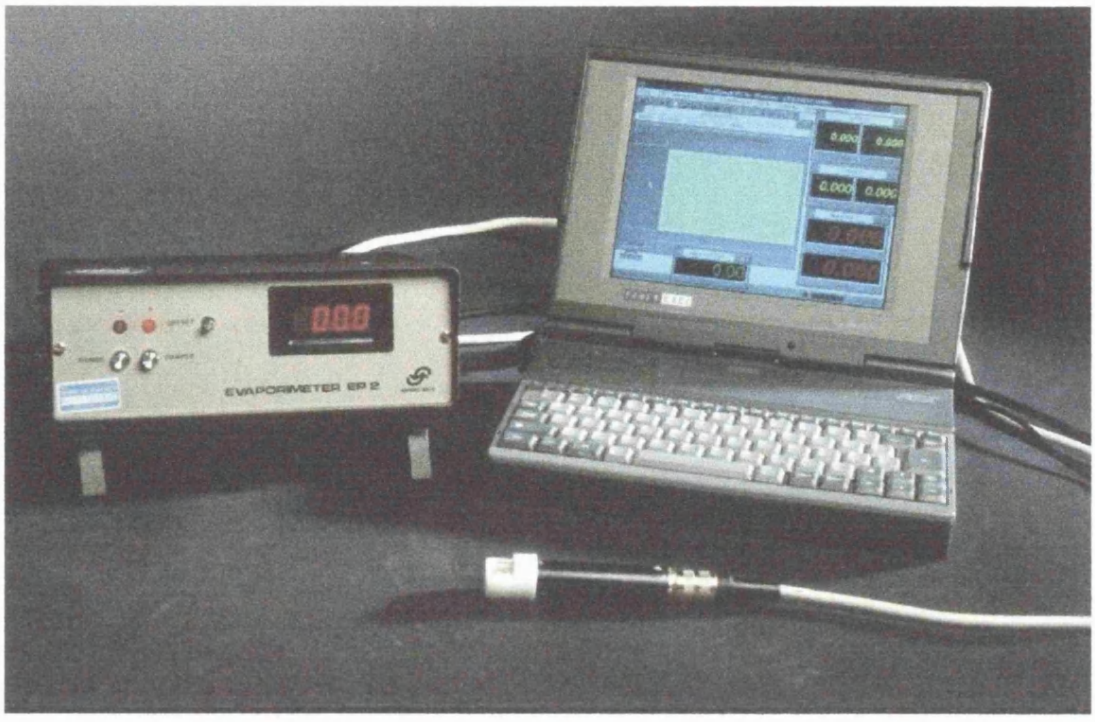
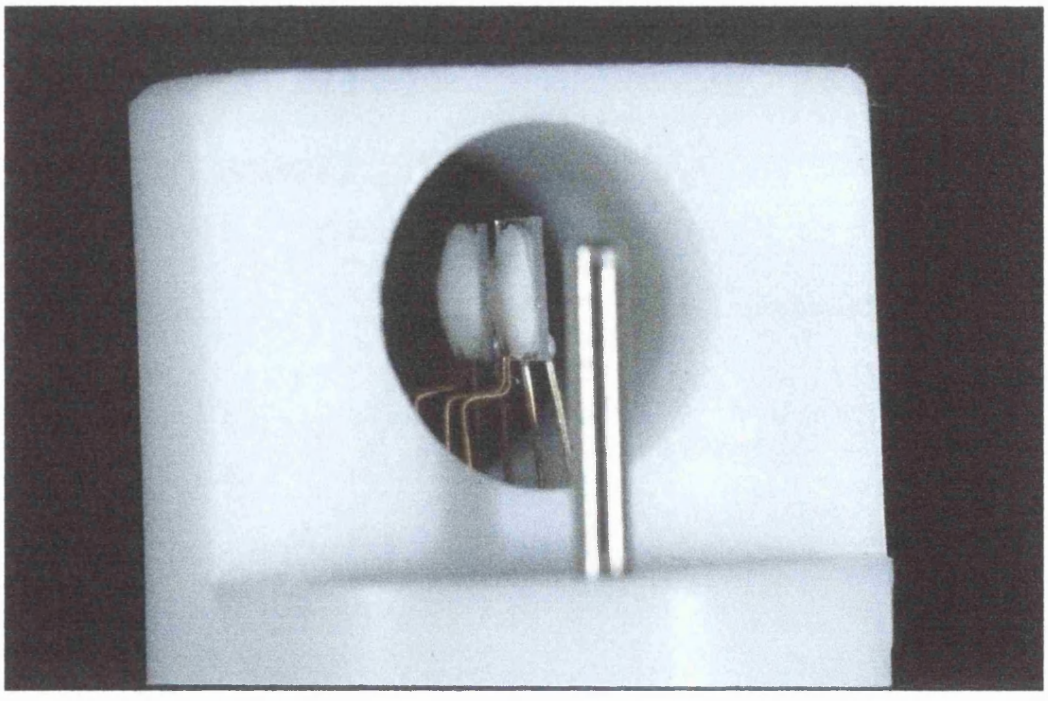


Figure 2:7 Evaporimeter probe showing detail of sensors



This method also requires the probe to be taken off and placed back on the skin intermittently. To obtain a full decay curve a simple programme was needed, which measured TEWL *continuously*. In consultation with the manufacturers, Servomed, a software programme that would enable measurements to be taken over a continuous period was devised. This provided data that could then be imported into a spreadsheet (Microsoft Excel) for display and analysis.

The preliminary patch testing (described above) was then repeated decay curves plotted. Although an environmentally controlled room was not available basic attempts were made to reduce air convection and recorded temperature and humidity conditions were recorded. Preliminary findings indicated that although TEWL curves did follow a similar pattern to those published by Zimmerer (1986) the 2 minute measure (which he suggests) was not a reliable indicator of the remainder of the curve. It was not therefore adequate to take a single measure to indicate the fluid loading of the skin.

Ideally, measurement of the *area under the curve* should be made, which would give the excess water (g/m^2) in the skin over and above what would have been there in the absence of the wet pad. But this would entail taking measurements continuously until baseline was reached. This was found to take at least 20 minutes (a similar time to Zimmerer's findings) and often much more (depending on the level of skin hydration). This was considered to be impractical, both in terms of the subject's tolerance and comfort and the impact this would have on the overall time taken for subject measurements. By measuring TEWL continuously for 10 minutes a single measurement could be taken at 2 minutes, and it would also be possible to measure the main drop in TEWL values, which occurs during the first 5-10 minutes. This would give a reasonable indication of what the whole area would be. Sample decay curves are shown in (Figure 2:8). The decision was made to use 10 minutes of continuous measurement of TEWL for the study.

Due to time contstraints this preliminary testing of evaporimetry did not include further testing of the reproducibility of TEWL and its sensitivity to changes in different skin loading quantities (of water/urine). Although the reproducibility of TEWL has been examined by Zimmerer (see figure 2.3) this was determined using

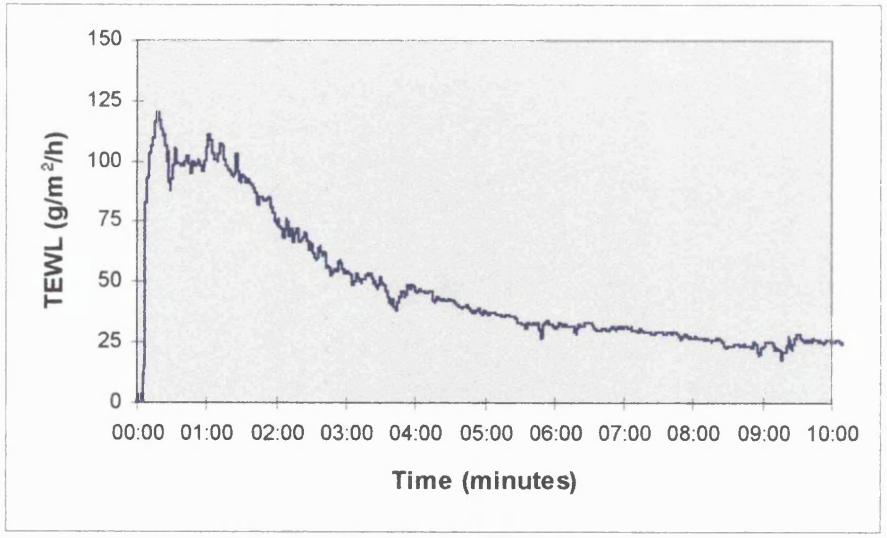


Figure 2:8a 'Normal' TEWL trace for wet skin

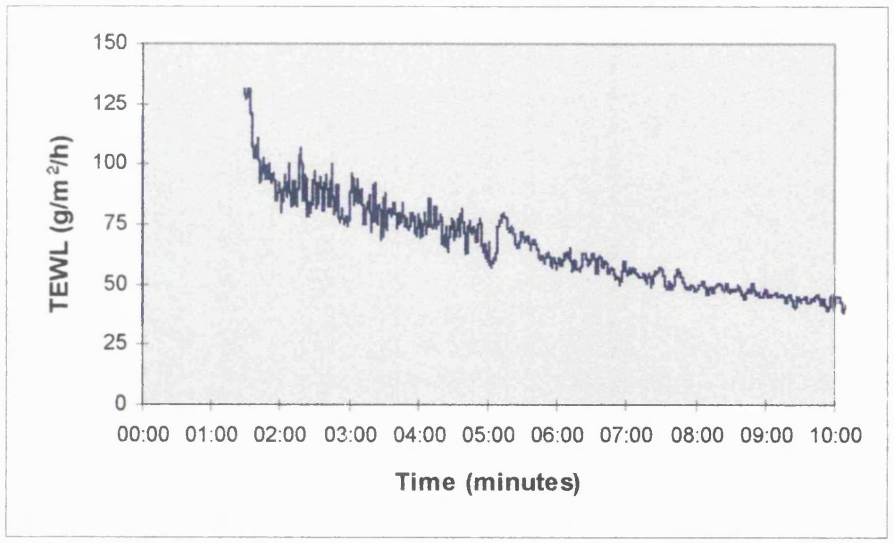


Figure 2:8b TEWL trace showing high values for the first two minutes

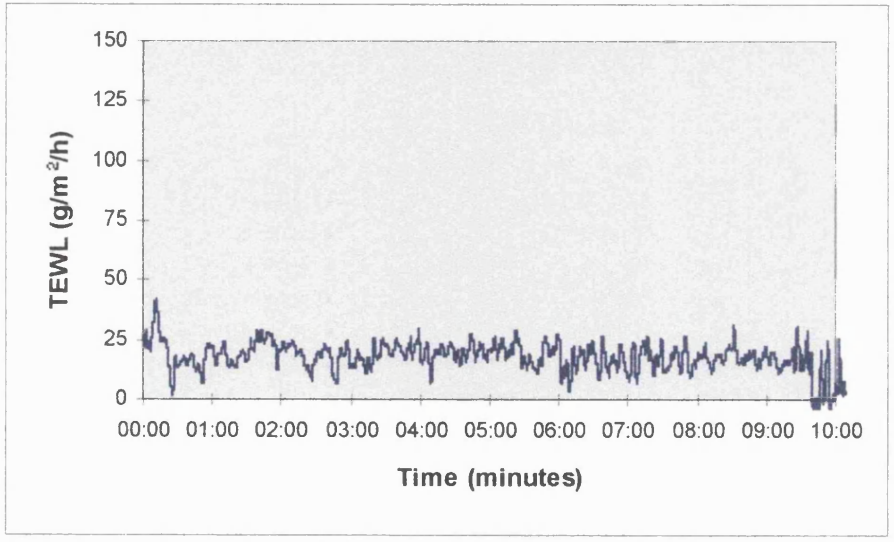


Figure 2:8c TEWL trace for 'non-wet' skin

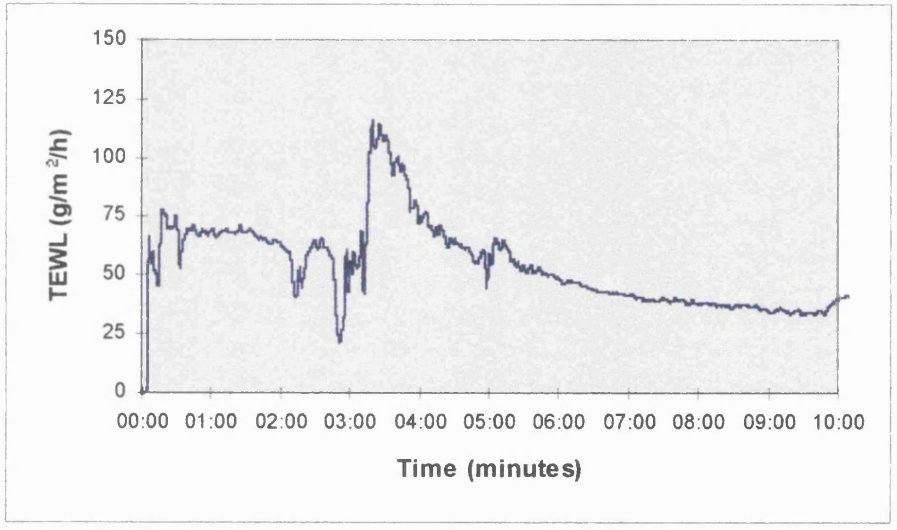


Figure 2:8d TEWL trace showing displacement of the sensor

Figure 2:8 Sample TEWL traces

Figure 2:9 Russell pH meter

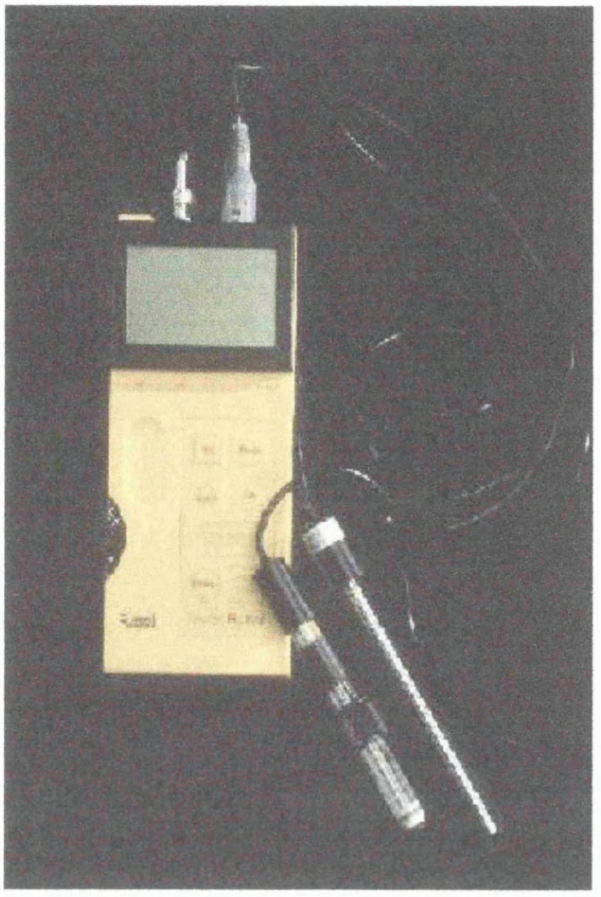
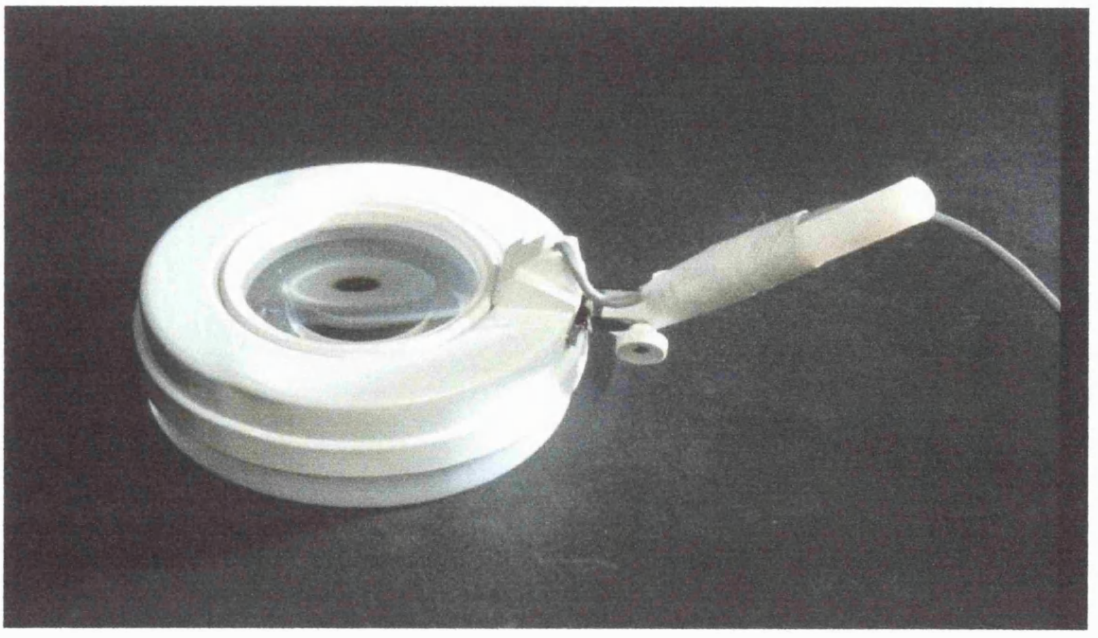


Figure 2:10 Carlton Professional Skinscope magnifying lamp (adapted)



only one level of fluid loading. It would be valuable for further research on this tool to determine the reproducibility of TEWL under different fluid loading conditions. The results of the piloting work carried out for this study indicate that measurement of TEWL can discriminate between *high, medium, low* and *no* fluid loading levels but further systematic study is needed.

2.5.4 Russell pH meter

This consists of a digital meter, a temperature probe and a flat combination glass electrode and is recommended by the manufacturer for use on the skin (Figure 2:9) The measuring end of the electrode is made of very thin glass and acts as a semi-permeable membrane. This creates a small flow of electrical current which sets up a voltage across the internal connections to the electrode, this voltage is converted to pH units and displayed on a meter. The voltage is not only dependent on the pH, but it also varies with temperature. An additional temperature probe is needed tocompensate for variations in temperature and the meter then displays the corrected pH value. Due to changes in the resistance of the glass the meter needs to be calibrated on a regular basis. This corrects for the change and is achieved by placing the probe in a buffer solution with a known pH of 7.0. It is also essential that the electrode tip is kept moist and the manufacturers advise that the electrode is stored in a pH storage solution. In addition, to prevent the build up of protein on the probe membrane the electrode requires regular treatment with a membrane cleaning solution.

2.5.4.1 Piloting of Russell pH meter

Experimentation was made with different anatomical sites for the measurement of pH and the groin was selected, because it provides a natural channel and a relatively horizontal plane on which to place the drop of water and the electrode.

2.6 Selection of skin sites, measurement times and infection control

2.6.1 Selection of sites for skin measurement

There has been no consistency amongst researchers over the labeling and demarcation of different sites for observing skin health. For example Schnelle et al (1997) refers to front and back 'central and peripheral' areas and used a grid of 40 components to rate

all areas covered by an incontinence pads. Byers et al (1995) confined themselves to one 'representative' area only (the inner thigh) whilst others have broadly categorised the skin into 5 main areas (Davis et al. 1989).

There are difficulties involved with the analysis of measurements taken from multiple areas, because if analysed separately, there is an increasing risk of finding a spuriously significant result. There is also likely to be difficulty with the accurate (and therefore reliable) identification of very large numbers of areas.

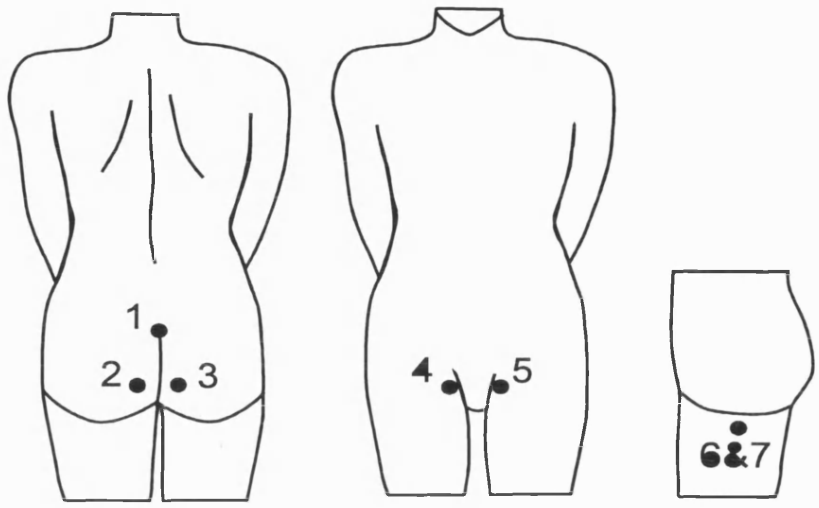
There is little published data to indicate where skin is most likely to be affected by dermatitis. Schnelle found that the areas of skin most affected by erythema were the front central and back central areas that were closest to the urethra and anus, although it is unclear from their description where exactly this area of skin lies. Paediatric studies of dermatitis indicate that the crotch, followed by the buttock areas are the most commonly affected (Davis et al. 1989).

The decision was therefore made to make observations for erythema from the main sites identified in the literature i.e. the crotch and buttocks (using the erythema meter and visual rating scale) on the following six sites (Figure 2:11):

- Groins – Left and Right
- Upper inner thighs – Left and Right
- Lower buttock – Left and Right

These sites do not lie over bony prominences (in the supine or lateral/supine positions) and are therefore measurements are not likely to be confounded by localised erythema (reactive hyperaemia) caused by pressure. However, the sacrum was included as a measurement site although it was recognised that at this site it would not be possible to discriminate between erythema caused by dermatitis and that caused by pressure.

Figure 2:11 Skin measurement sites



Site number	Site location
1	Sacrum
2	Buttock (L)
3	Buttock (R)
4	Groin (R)
5	Groin (L)
6	Thigh (R)
7	Thigh (L)

For the measurement of TEWL it was necessary to use a site that would:

- Be accessible for at least 10 minutes without the subject moving
- Present a smooth, hairless surface
- Provide a reasonably horizontal surface
- Reliably become wet after any incontinence episode

The inner thigh site was excluded because this was the most difficult site to access. The groin site was affected by hair and was also found to be poorly tolerated by pilot subjects. The lower buttock site met all the above conditions, but care needed to be

taken to ensure that the subject was turned over as far as possible to provide a reasonably horizontal surface. The buttock site was therefore selected.

The groin site was selected for the measurement of pH because it provided a natural 'groove' for placing the drop of water and the probe.

2.6.2 Cleaning skin instruments

All the tools that came into contact with skin were cleaned between subjects. The probes and the probe protectors from both the erythema and TEWL meters were cleaned with a detergent solution and alcohol wipes after every use. The pH probe was cleaned with alcohol following each use.

2.6.3 Timing and time of day of skin instrument measures

During the piloting phase each measurement was timed in order to estimate the number of subjects that could be included in each data collection period. The *order* in which item would be measured was also carefully considered to make best use of time and to ensure that each measurement item did not affect the others. TEWL, for example needed to be measured first because it had to occur immediately after pad removal.

In order to measure TEWL the researcher needed to be present at the time that the night pad was removed. This meant that measurements had to be taken during the early morning around the time of the early morning pad change. It became evident that this would also be the optimum time for taking the remaining measurements for the following reasons:

- Subjects would all be horizontal and there would therefore be consistency in terms of pressure (and therefore reactive hyperaemia) on pressure points.
- Subjects would be wearing only nightclothes, which would make for easier access to the buttocks and perineum.
- There would be less demands made on Home staff to help position the subject (if the subject was up in a chair it would be necessary to move them to bed to take measurements)
- Subjects were very likely to be present for measurements (during the daytime they may be engaging in social or other activities)

- Taking measurements at different times of the day is a source of measurement variation for erythema and TEWL. Guidelines for both these measurements recommend that each time a measurement is taken the same time of day is used for repeats(Pinnagoda et al. 1990; Fullerton et al. 1996).
- There would be less disruption to the subject if measurements were taken together at one time of day than if the measurements were spread over more than one visit.

The disadvantage of taking all measurements together at this time of day was that there was a relatively small time window within which measurements could be taken. Nursing home staff usually started changing pads at around 06.00 in preparation for patients getting up (or sitting up) for breakfast. It was therefore necessary to accomplish all measurements by around 08.30. In practice each subject's instrument measurements took around 20-30 minutes and therefore a maximum of 5 subjects could be completed in one morning.

2.7 Piloting and development of sleep and self-turning measurement tools

2.7.1 Stowood Scientific Visi-lab

The Visi-lab consists of a computer, television, video-player and camera that is used in conjunction with an infra-red light to monitor movement during the night (Figure 2:12). The equipment was purchased from Stowood Scientific Instruments together with a large trolley to enable transport between subjects.

The Visi-lab is not a simple piece of equipment, it is made up of many independent parts connected with leads and much time was required to become familiar with it. For the purpose of this study it was important that the equipment could be dismantled and reassembled successfully in order that it could be moved between nursing homes. All the leads therefore needed to be carefully labelled and considerable time and practise was necessary to ensure that it was possible to take the equipment apart and put it back together reliably and efficiently.

The Visi-lab was piloted on two subjects on the long-stay wards, and some practical problems were identified in the early stages.

Figure 2:12 Stowood Scientific Instruments Visi-lab

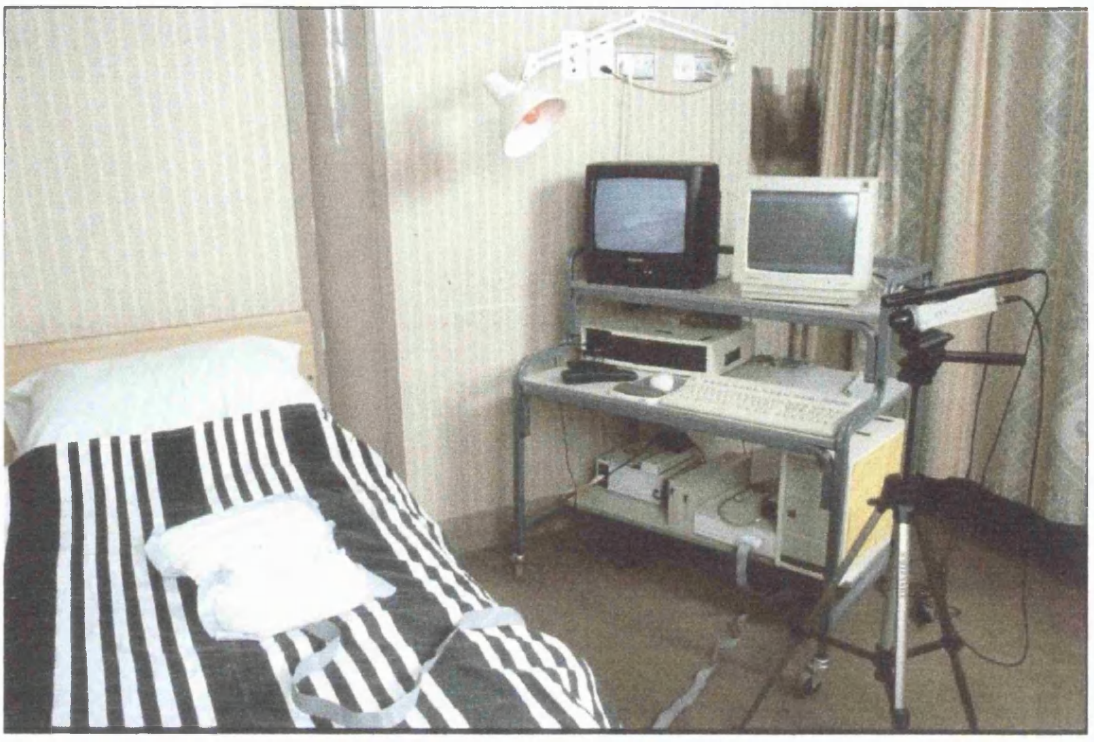
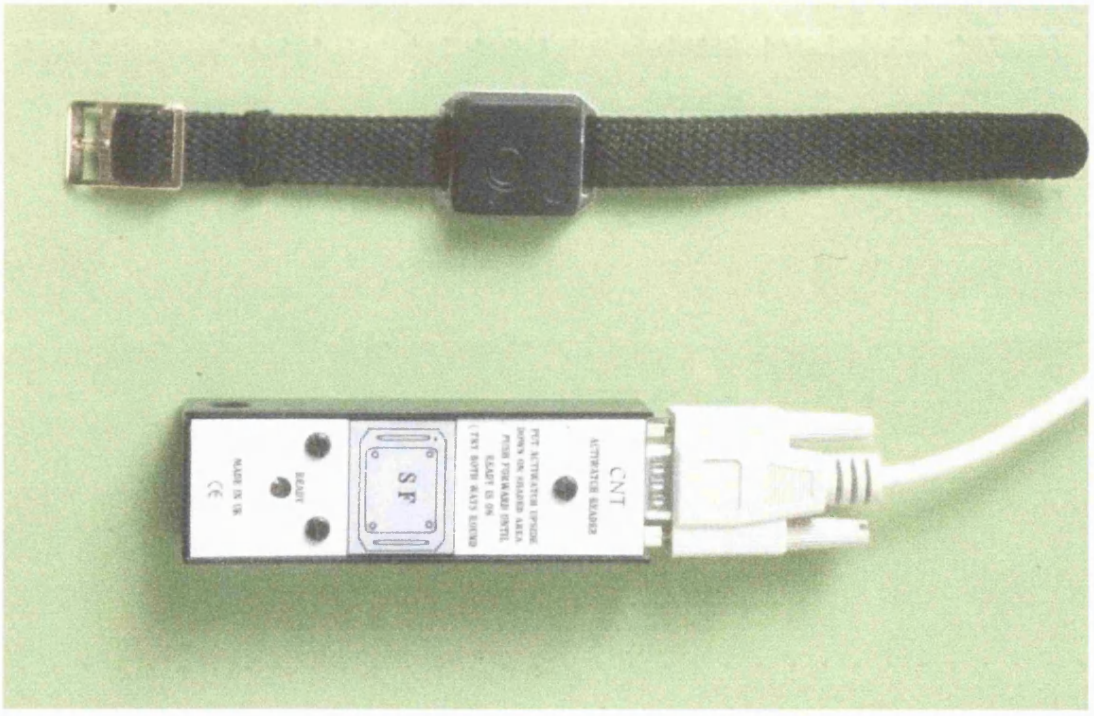


Figure 2:13 Cambridge Neurotechnology Actiwatch and Actiwatch reader



minute threshold set at 10 and 15. The total proportion of sleep / wake minutes was calculated and compared to the proportion of sleep / wake minutes recorded by the Actiwatch for the same period. The threshold 10 movements per minute was found to give the closest match (in terms of proportion of sleep / wake minutes) to the Actiwatch.

The measurements of sleep / wake produced by the Actiwatch and the Visi-lab were compared in two ways. Firstly the proportion of 'wake' obtained from the Actiwatch was plotted against the proportion of 'wake' obtained from the Visilab (Figure 2:14).

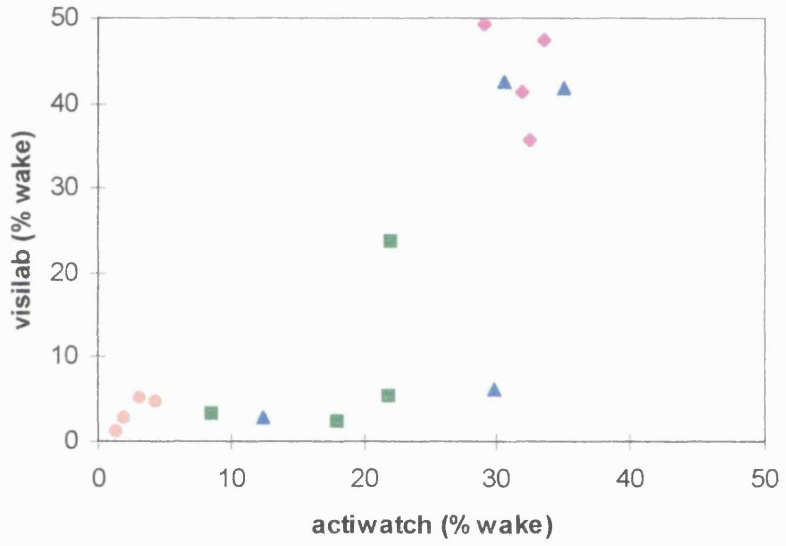


Figure 2:14 Scatterplot showing the relationship between the percentage 'wake' as measured by the Actiwatch and the Visi-lab. Each coloured symbol represents a subject (4 recordings per subject).

Secondly comparisons were made between the results of each minute of Actiwatch and Visilab recording to measure agreement. Overall there was good agreement between the methods (84% agreement between the Actiwatch and the Visi-lab sleep/wake minutes) although there were considerable differences between subjects (range 76.7% - 95.9%). Because this method of assessment does not take account of chance agreement, we also calculated agreement using Kappa (chance corrected proportional agreement) by comparing every minute of wake / sleep recorded by each

method. Overall a Kappa score of 0.53 was obtained which is moderate agreement (see Table 2:3 below).

Table 2:3. Method agreement between Actigraphy and Visilab - minutes sleep (0) and wake (1)

Kappa 0.53

		Visilab	
Actigraphy	0	1	Total
0	5465	516	5981
1	643	925	1568
Total	6108	1441	

This Kappa score does not reflect as high a level of agreement as might be expected for two methods that purport to measure the same thing (movement). However, the way that movement is measured may partly explain this. The Visi-lab measures *all* detectable movement within the field of the camera lens and therefore some artefact movement (such as curtains flapping or staff walking past) will be picked up as movement, which is not caused by the subject. In contrast the Actiwatch is only applied to one arm and it is therefore possible that neurological and musculo-skeletal disorders affecting the subject uni-laterally will under-detect the amount of movement the subject makes. Further work to measure the agreement of these methods undermore controlled conditions would be of value

CHAPTER 3

STUDY DESIGN, SUBJECTS, ETHICS, PRAGMATICS AND PROCEDURES

3.1 Study design

To answer the research questions posed at the end of chapter 1 (1.4), a randomised cross-over study comparing two pad changing regimes was planned.

Regime A (the *frequent* pad changing regime) involved changing pads at 10.00pm, 02.00am and 06.00am. (i.e. the subject would have their pads changed *during* the night).

Regime B (the *less frequent* pad changing regime) involved changing pads at 10.00pm and 06.00am (i.e. the subjects would wear the *same* pad *all* night).

The primary outcome measure selected was the erythema index and this was used to define the power of the study (see below 3.1.2). The hypothesis was that there would be **no** difference in erythema index between the two groups.

The advantage of a randomised cross-over design is that each patient acts as his or her own control and fewer patients are needed to assess outcome (than using a randomised controlled trial) because within-patient variability is less than between-patient variability (Bowling, 1997). It is known from the work of other researchers (Ouslander et al. 1993) that there are considerable challenges in meeting sample sizes for studies in residential settings. This is due mainly to the frailty of the subjects which leads to drop-outs resulting from illness, death and hospitalization and also difficulties with consent.

A cross-over design is suitable for patients with stable or chronic conditions that are unlikely to fluctuate spontaneously during the course of the study and in whom neither intervention is, a priori, likely to result in irreversible effects. The patient group in this study (elderly women with night-time incontinence) was therefore appropriate for such a design. However, other difficulties needed to be taken into consideration concerning order and time. Randomisation of the order of the regimes is important to reduce *primacy* effects. There may be also be treatment order effects,

whereby the first treatment has residual long-term effects which may affect the response to the second treatment. To minimise this problem measurements from the first two weeks of the second regime were not included. This would allow sufficient time for any dermatitis experienced at the end of the first treatment to subside before measurements were taken in the second regime.

The second issue concerns the duration that subjects would be involved in the study. By and large, subjects participating in a randomised cross-over design will take part for twice as long as would be the case in a randomised control trial. Although this constitutes more demands on an individual patient I did not believe that this was excessive. The interventions (*frequent* or *less frequent* pad changing regimes) would already be applied to the patient whether they were participating in the study or not. Piloting of the instrument measures indicated that they were not onerous for the patient and could be undertaken with the patient comfortably lying down.

By using a randomised cross-over design, not only were we able to reduce the number of *individual* subjects for the study, but also, as a result the total number of residential settings needed would be substantially reduced. Previous studies of patients in nursing and residential homes have stressed the high work-load and difficulties involved in setting up and co-ordinating projects in such Homes.

3.1.1 Statistical methods and power of the study

Erythema is the main clinical sign of inflammatory skin conditions such as dermatitis (Serup and Agner, 1990). The *primary outcome measure* for assessing the effect on skin health of the different pad changing regimes therefore came from the erythema meter and calculation of the necessary sample size was based on this measurement. The sample size (n) was estimated using the method described by Senn (1993). This method depends on the choice of significance level (α), the power to detect a difference of size δ, and the ratio d (δ/σ). δ is the difference in the primary outcome measure made by the erythema meter (i.e. the amount of skin redness) that is taken to be a clinically relevant difference between the two interventions, and σ is the standard deviation of the 'basic estimator' of the treatment difference i.e. the standard deviation of erythema measurements on our population.

The eye can detect a change in colour of 20-30 points as measured by the erythema meter (Diffey et al. 1984). Twenty-five points were taken to be a visually observable change in skin redness (and one which may be lead to action, such as the application of topical creams) and therefore a clinically significant difference. σ was estimated to be about 50 (Gawkrodger et al. 1991), although as with many dermatology studies these measurements were taken from adult volunteer forearms, rather than elderly people.

Taking $d = 0.5$, $\alpha = 0.05$ (i.e. allowing for the probability of finding the outcome by chance to be 5%), and power = 0.8 (i.e. allowing for the probability of detecting a statistically significant difference should one exist to be 80%) gives n to be about 32. But allowing for other choices of power and uncertainty in the estimate of d, n would need to be between 22 and 82 for d between 0.4 and 0.6 and power between 0.8 and 0.95.

This power calculation is based on finding a difference between the two interventions, when the hypothesis is that there will be no difference. To account for this it was decided to set a very *high* level of power. A relatively *low* level of power (say 80%) would increase the probability of a Type II error which is a false negative finding. As the hypothesis is that no difference exists it is particularly important to minimise the probability of Type II error. The sample size selected was therefore at the upper estimated level i.e. 80 subjects.

3.2 Subjects

3.2.1 Ethics

The study protocol was reviewed and approved by the Camden and Islington community NHS trust local research ethics committee.

3.2.2 Sampling and recruitment

Ideally, to recruit patients to this study a sampling frame of incontinent women in UK residential settings for elderly people would be compiled and subjects selected by simple random sampling methods. This would mean that each member of the target population would have an equal, non-zero and calculable chance of inclusion in the final sample. This would yield data of high external validity and allow

generalisability to the target population i.e. elderly women with incontinence in residential settings.

Unfortunately, such a sampling frame does not exist and if it did, this method would demand that the researcher co-ordinate the study and collect data in residential settings (Homes) around the country and it would be likely that there would only be one (or perhaps two) subjects in each Home. This would clearly be impractical. A defined geographical area for sampling and recruitment is therefore necessary, although the main disadvantage of recruiting subjects from a specific geographical area is that subjects from other areas may differ in some way and therefore external validity is reduced.

A further factor is that it would be impractical to sample subjects such that *each* subject could come from *any* residential setting. This would mean that up to 80 Homes could be involved in the study. Given that a very considerable amount of preparation and training was essential for each Home it was necessary to sample in such a way as to reduce the number of participating residential settings to a number that could be managed within the set time frame of 18 months.

Two levels of sampling were therefore applied. Firstly, the sampling of Homes within a defined geographical area, and secondly the sampling of subjects from within the Homes.

The inclusion of *all* Homes within a defined geographical area obviates the need for sampling. However, staff in some Homes may not *agree* to take part and this may create an ascertainment bias because those who wish to take part are likely to be different from those who do. Given that it is essential to the success of the project that staff agree to be involved and are willing to cooperate and apply the protocol, selection bias is difficult to avoid.

Subjects were recruited to the study as follows:

- A list of all nursing, residential settings and long-stay wards, with a minimum of 25 beds (see below), and within a 5 mile area of the north London based researchers, was made using a directory of nursing and residential homes (Laing & Buisson, 1998).
- Heads of homes/ward managers were contacted by post. The study was described and they were invited to take part.
- Positive responses were followed up with a visit to discuss the project with staff and Head of home.
- Those Homes indicating a willingness to take part were visited during the night to ask night staff to identify patients who fulfilled the inclusion/exclusion criteria.
- Consent was sought from all identified patients (or assent from relatives where necessary).
- All consented and assented patients began the first phase of the study to test whether measurement methods would be tolerated and to quantify level of faecal incontinence (if any).
- Subjects who tolerated measurement methods and had faecal incontinence two times per week or less were recruited into the intervention study.
- Homes were recruited into the study, with those closest to the researchers being approached first, until sufficient subjects were recruited.

The number of subjects that could be managed in one morning of data collection at one Home was 5-6. It was therefore necessary to include Homes that were large enough to potentially recruit this number of subjects. This was estimated as follows:

A Home with 25 residents is likely to have around 5 men. Of the remaining women about half will be incontinent of urine. Of these one or two will be frequently incontinent of faeces. Consent or assent will not be possible for about a third of the 8-9 women who are incontinent of urine (but not frequently of faeces) leaving a total of around 6. One resident is likely to be withdrawn or drop out for various reasons.

Although this method yielded sufficient Homes and subjects for the skin component of the study, few Homes were suitable for the sleep component (i.e. large rooms, corridors and lifts to enable transportation and setting up of equipment). Additional large Homes were therefore approached to be included in the sleep component of the study.

3.2.3 *Inclusion / exclusion criteria*

It was important to minimise the exclusion criteria in order to represent the target population i.e. residents for whom decisions about pad wear times are made. Women dominate this population. Not only is the proportion of women in residential settings much greater than men, but also there are more incontinence management options available to men (such as sheath drainage systems) and incontinent men are therefore less likely to wear an incontinence pad than women. Including men in the study is likely to produce a small subset which may in some way be different to the predominant female group and will therefore undermine the power of the study.

- The inclusion criteria was therefore restricted to women.

The majority of people in residential settings are elderly, although a minority are younger people with physical or mental disabilities. Given that there are demonstrable differences in 'young' skin, compared to 'aged' skin, the skin of younger people may respond differently to changes in pad changing protocols. As with including men, including younger people would be likely to produce a small subset, possibly different to the main sample.

- It was therefore decided to include only women over the age of 65 in residential settings for elderly people.

The target population for this study was women in residential settings who use pads for night-time incontinence. Experience of carrying out previous studies in nursing homes and other residential settings (MDA, 1998) indicated that generally two types of incontinence pads are in use: medium sized pads for day-time incontinence and larger pads for night-time incontinence. Larger urine volumes (per pad) are known to occur at night (MDA, 1998). Exceptionally, some residents may use different (usually

smaller) pads if they are deemed to have lighter incontinence, or may not use pads every night because their incontinence is intermittent. It would be expected that these residents would not receive the same skin challenge as those requiring night-time incontinence pads every night.

- It was therefore decided to include women using incontinence pads for night-time incontinence every night.

It would be difficult to reliably apply the different pad changing protocols to women who had regular faecal incontinence. Discussions with staff revealed that pads are changed as soon as practically possible after faecal incontinence and adhering to a standard regime would therefore be problematic. Piloting also showed that faecal incontinence made measurement taking very difficult or impossible.

- It was therefore decided to exclude women with regular faecal incontinence.

It was expected that quite a high proportion of subjects would have mental impairment and therefore would not readily understand the nature of the study or consent for themselves. Although assent would be obtained from relatives (see later), subjects who had difficulty tolerating or complying with measurement taking would clearly be indicating their *dissent* and therefore should not be included in the study.

- It was therefore decided to exclude residents who were unable to tolerate or comply with measurement taking.

Subjects who were acutely ill or in the terminal phase would not be in the medically stable state needed for a cross-over study, and would have more immediate concerns than the participation in a research study.

- It was therefore decided to exclude residents who were acutely ill or in the terminal phase of an illness.

It would also be difficult to justify the inclusion of subjects who had pre-existing skin conditions in the groins, upper thighs or buttocks, including grade 2 pressure ulcers. The application of a pad changing regime that was less favourable to the treatment or improvement of their condition would be ethically problematic. In addition

standardisation of subject's skin care regimes precluded the use of creams which may be required for treatment of a specific skin condition.

- It was therefore decided to exclude residents who had a pre-existing skin condition affecting the skin covered by the incontinence pad.

Subjects were eligible for inclusion if they were:

- Female, aged over 65.
- Resident in a nursing or residential home for elderly people with physical or mental disabilities.
- Using incontinence pads suitable for night-time incontinence every night.

Subjects were excluded if they were:

- Frequently (three or more times per week) incontinent of faeces during the night.
- Unable to tolerate or comply with measurement taking.
- In the terminal phase of an illness.
- Acutely ill.
- Affected by an existing skin condition of the groins, upper thighs or buttocks requiring topical treatment or grade 2 pressure ulcer.

3.2.4 Consent / assent

A patient information sheet and relative information sheet were devised to explain the study in non-technical terms. Potential subjects were identified by the nursing staff and were visited. The study was discussed with them and they were given the information sheet to read. Comprehension was assessed by asking the potential subject questions about the study to see if they could understand its purpose and what would be required of them. Each subject was informed that they were free to withdraw from the study at any time without affecting their care and without giving a reason.

Subjects who were unable to give their consent (and those whose comprehension of the explanation of the study was doubtful) were included conditional on the agreement of a relative or named individual (Medical Research Council, 1991).

It was therefore necessary to contact the relatives to discuss the study with them. Occasionally it was possible to arrange to meet with relatives to ask for their assent, but more often this proved impossible because of unpredictable visiting times. Initially relatives who could not be met were telephoned, but this method was soon found to be unsatisfactory, because relatives were unprepared and sometimes unnerved by the call. In addition it was felt that it was inappropriate to contact relatives without providing them with preparatory information.

The Homes were therefore asked to send a letter (which were provided; see Appendix 1) on their own headed notepaper to the relative. This informed relatives that the Home was taking part in the study, that their relative had been identified for possible inclusion and that a researcher would be contacting them to discuss the study in more detail.

After a week or so the relative was contacted by telephone and the project discussed with them. Considerable sensitivity had to be shown during these conversations because relatives were not always aware that the subject was incontinent. Relatives who gave their assent were then sent a letter, together with a relative information sheet and an assent form. A stamped addressed envelope was enclosed for return of the assent form. On receipt of the form a photocopy was made and sent back to the relative.

During the course of the study subject's relatives sometimes made contact regarding the progress of the subject on the study; this was often well after the subject had finished. It was felt that there was a need to keep subjects' relatives more systematically informed about when their relative had finished the study and letters were therefore sent to subject's relatives to inform them that they had finished (or been withdrawn from) the study.

Consent or assent was obtained *before* randomisation of the order of the pad changing regimes to avoid bias.

3.3 Staff and residential settings

3.3.1 Preparation of Homes

Taking part in research can be very demanding on Homes (Ouslander et al. 1993) particularly in terms of resources, time and effort. A number of elements were therefore put in place both for the Home and for the individuals who took part in the study to minimise the resource impact that the study had and to acknowledge the effort made by the individuals. The aim was to encourage the staff to feel that the study was a collaborative effort rather than a study with 'us' doing it to 'them' or worse, 'us' making 'them' do it. However, it was also necessary to avoid any sense that inducements were being offered to obtain their co-operation.
The Homes were provided with:

- The pads and pants for the study subjects (for a Home with 5 subjects this would amount to a saving of about £350).
- A framed certificate acknowledging the Home's contribution to the study.
- Book tokens worth £30.

Individual nursing and care staff were provided with:

- £5 Boot's vouchers for attending information meetings.
- Chocolates and magazines throughout the data collection period.
- Named certificates acknowledging their contribution to the study.
- £5 Boot's vouchers at the end of the study.

These arrangements were all reviewed by the ethics committee.

The researchers aimed to 'fit in' as well as possible with Home routines and organised the staff information meetings (see below) to suit the times of the Homes (and in particular, the night staff). Staff were also encouraged to make contact if they had

any queries or concerns about the study and contact information was provided on all literature related to the study.

During the data collection period it was clear that interventions with the subjects could be disruptive for the night staff during the busy early morning period. Subjects' pads and bedclothes were therefore changed and the subject was left comfortable and in need of no further attention from the night staff.

3.3.2 Home Information meetings

The Homes were visited and the nature of the study was discussed with the Head of Home and other nursing staff. A member of the clinical staff was nominated to be the main contact person. But it was the information meetings held with the night staff to discuss the study which were key to the success of the project. These staff would carry out the protocol and it was imperative that they were committed to the project if this was to be done properly. The meetings were carried out during the preceding two to three weeks before the study commenced in each Home and were carried out in the early part of the night at times that were most convenient for the night staff. The meetings were informal and aimed to establish a good rapport with the staff. The chocolates and tokens were provided and the study discussed with emphasis on the night staff's role. They were provided with leaflets about the study (Appendix 2) During this meeting it was also emphasised that it was important that they did not reveal which regime the subjects' were on to the research nurse responsible for the measurements. A list was made of all regular night staff to ensure that all staff attended a meeting or (if not) that they were spoken to personally about the study at some other time.

Although the day staff were not so closely involved with the study, two aspects of the study affected them: (i) the application of the skin care regime (see below) and (ii) the use of the study pads. Day staff meetings were therefore arranged and leaflets provided. In addition small colourful posters (Appendix 3 & 4) describing the study and the roles of the day and night staff were produced and placed in prominent places around the nurses station.

3.3.3 Skin care regimes

Skin care regimes varied widely between Homes and often involved the use of various topical applications, cleansing agents and talcum powder. This variety of products could potentially present a confounding variable by causing skin irritation for some residents. Some skin products also purport to provide a 'barrier' to penetration of the skin by water and this may affect TEWL measurements, although the effects of different skin products on skin wetness has not been studied.

The staff in all Homes were therefore asked to apply the same, consistent, skin care regime to the subjects for the period that they took part in the study, as follows:

- Wash the area enclosed by the pad with an unperfumed, uncoloured soap ('Simple' soap) and water twice a day.
- Wash with water only at pad changes (if urinary incontinence only).
- Applying no creams or powders .

Small posters were put up in all subjects' bathrooms to remind staff of the study cleansing regime (Appendix 5)

3.3.4 Pad provision and pad design

At the start of the study numerous different pads were being used by the different Homes for the study participants. It was therefore necessary to rationalise their variability. Standard pads were provided for use by subjects during both the day and the night. Although the day pads were not manipulated these were supplied as a benefit for the homes. The night pad selected was the 'Moliform Extra' pad made by Paul Hartmann who are one of the three main pad suppliers in the UK. Typically, most pad companies produce two levels of high absorbency pads for night use. However, of these two, the *most* absorbent pad type is not commonly purchased for cost reasons. No Homes involved in this study used this type of very highly absorbent pad. The more 'standard' night pad was therefore more representative of the type of pad that would normally be used at night. A standard high absorbency night pad (the Moliform Extra) was therefore selected for use in this study.

Paul Hartmann also supplied net pants in medium, large and extra large sizes to fit study subjects.

Considerable work has been carried out (mostly unpublished) by baby diaper manufacturers with the aim of reducing skin wetness and diaper dermatitis. Current pad designs (for both babies and adults) involve layering of different materials with the intention of providing fast absorbency of fluid into the deeper layers of the pad structure to minimise skin wetness. Different pad designs and levels of absorbency may therefore have a measurable impact on skin. For the purposes of this study the pad used needed to be broadly representative of those in current use. However, further work examining the effect of different pad designs and materials on skin health would be valuable.

3.4 Study procedures

3.4.1. Randomisation of regimes

It was considered that randomisation of regime order *by* subject would be prohibitively difficult for staff. This would entail the application of different changing regimes to different subjects at different times and would be likely to cause confusion and unreliable application of the protocol. Randomisation of the order of the regimes was therefore done by Home (rather than by subject) and was determined by the toss of a coin. All subjects within each Home were then allocated to the regimes in the same order.

3.4.2 Overview of data collection

Baseline period (2 weeks)

During the first week of the study the test location was given the study pads to use and began to follow the 'general' skin regime (see 3.3.3). During this first week the subjects had their first measurement of visual grading, in the second week the first instrument measurements were taken. If the subjects were found not to meet the inclusion criteria (particularly regarding faecal incontinence and compliance) they were excluded from the study at this point.

Regimes (4 weeks + 4 weeks)

The cross-over design employed during the study involved the application of the two pad changing regimes in random order. During the 8 week intervention period staff applied the designated pad changing regimes for four weeks each (either *frequent* 10.00, 02.00 and 06.00; or *less frequent* 10.00 and 06.00).

Table 3:1 Summary of data collection timetable

Measurement	**Week number**									
			Randomised pad changing regimes							
	Baseline		First regime				Second regime			
	1	2	3	4	5	6	7	8	9	10
Visual grading	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Erythema meter	×	✓	×	×	✓	✓	×	×	✓	✓
TEWL	×	✓	×	×	✓	✓	×	×	✓	✓
PH	×	✓	×	×	✓	✓	×	×	✓	✓

Measurements were taken weekly. Homes were studied in blocks of four, with each block lasting 10 weeks (see Appendix 6). The starting dates for each block of four Homes were staggered such that two Homes started together and two other Homes started two weeks later. This was done to optimise the use of the instruments. Only one set of instruments was available and instrument recordings could only be taken early in the morning from one Home. By staggering the starting times of the Homes instrument recordings were not all required at the same time.

3.4.3 Blinding

The research nurse who took the measurements from the patient was blind to the regimes they were currently undertaking. This was achieved in the following ways:

- The order of regimes for each Home was kept in a locked filing cabinet.
- The research nurse *only* collected data and did not participate in any other activities (which might involve mentioning the regimes) in the Homes .
- The staff of each Home were instructed verbally and on all the written documentation, not to discuss the regime with the research nurse.

- The research nurse preceded her conversations with Home staff with the words "please don't tell me which pad changing regime patient X is on, but ....", to ensure that the staff did not accidentally include discussion of the regime in the conversation.

3.4.4 Pad changing protocol

A *pad changing record* was devised (Appendices 7 & 8) to indicate clearly to staff *when* the pads should be changed for the subject. Staff were asked to sign for each pad change in order to keep a record of protocol adherence. Pad changes for other reasons (e.g. faecal incontinence) were also recorded.

3.4.5 Intensive skin care regime

If the subject was found to have erythema rated as '3' the subject's skin care was changed to an 'intensive' skin regime, consisting of Sudocrem applied to the affected area at each pad change and after washing. The regime reverted to the 'general' skin care regime one the affected area was rated as being less than '3'. A small poster describing the 'intensive' skin regime was put up in the subject's bathroom when the intensive regime was in progress (Appendix 9). The rationale for use of an intensive skin care regime was that it was of clinical (and ethical) importance that patients who developed severe erythema received appropriate treatment. Data on application of the intensive regime was not analysed because these subjects would already be coded for erythema grade 3 on the visual grading scale (and therefore included in the analysis of visual grading).

3.5 Procedures for data collection

3.5.1 Standard operating procedures for skin measurements

Instruments used:

- Visual grading scale (using Carlton Professional adapted hand-held light)
- Diastron erythema meter
- Servomed evaporimeter
- Russell pH meter

- A standard temperature and humidity meter (purchased from RS Components on the basis of moderate price and ease of use)

The research nurse, who was blinded to the regimes, arrived at the designated Home at around 5.30 am to prepare the equipment for data collection. The Home staff were greeted and consulted regarding the measurement taking for the morning, to ensure that this fitted in with their routines. If the subjects had individual rooms a sign was placed on the outside of each room to remind Home staff that the research nurse was visiting and requesting that the resident's pad was not changed until the sign was removed.

3.5.1.1 Preparation of equipment

The equipment was assembled on a trolley (Figure 3:1) and calibrated as follows:

- The evaporimeter was switched on to allow it to warm up for around 15 minutes.

- The evaporimeter software check programme was run on the laptop computer.

- The evaporimeter probe was turned through 90 degrees such that the sensors were in a horizontal position (to allow the hygrosensors and thermistors to sample the same ambient air). This results in a zero vapour pressure gradient, and the digital read-out settles to zero; the 'off-set' (calibration) button was turned to zero only if this did not occur.

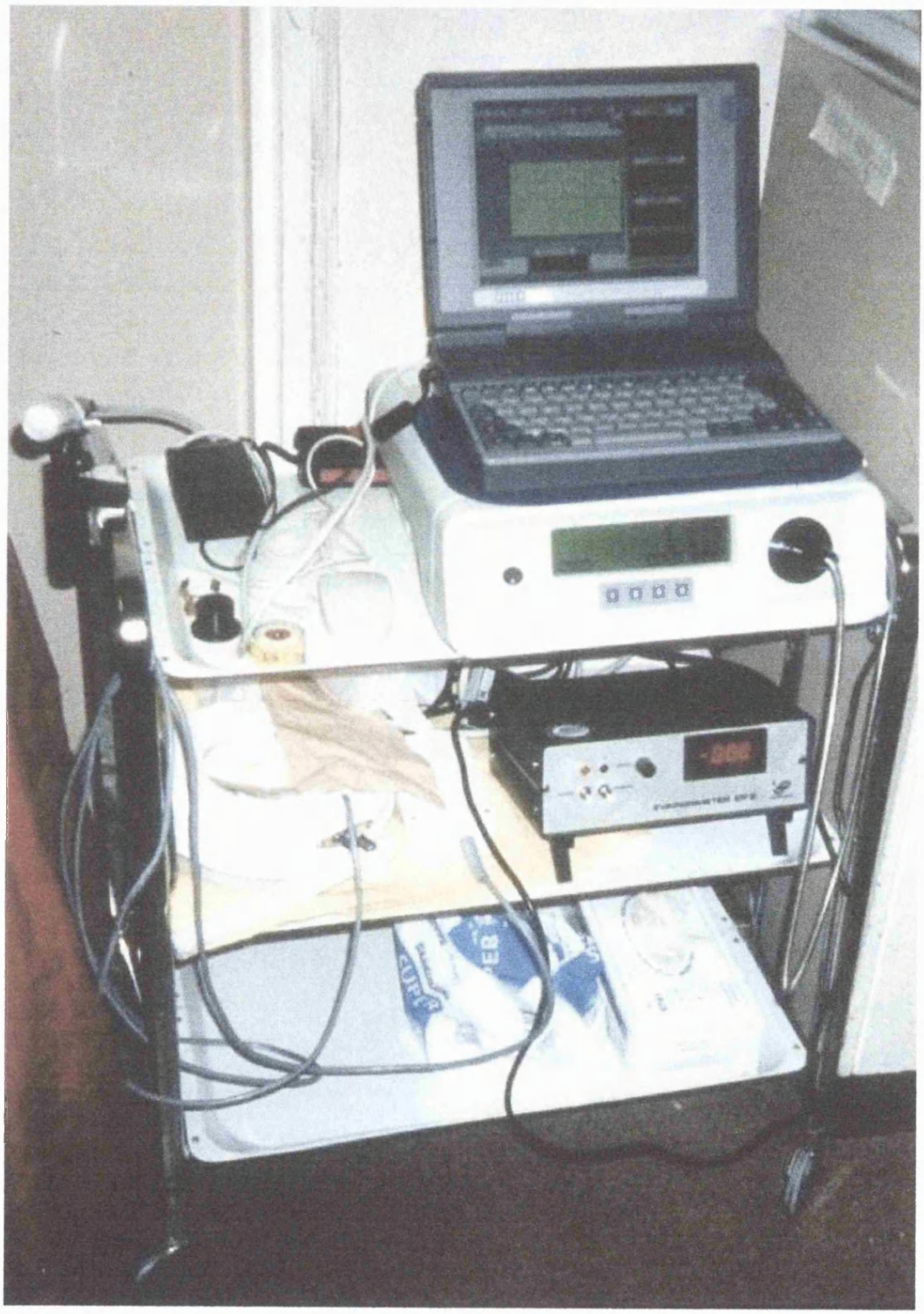
- The erythema meter was calibrated by placing the probe in the port and running autozero (see piloting).

- The pH meter was calibrated using standard buffer solutions.

3.5.1.2 Preparation of subjects

Each subject was visited in turn and gently woken (if asleep). The subject was greeted and a brief explanation of the purpose of the visit given. If the subject had her own room the door was shut to minimise air convection. Open windows were shut.

Figure 3:1 Equipment assembled on trolley ready for measurement taking



3.5.1.3 Temperature and humidity

These were recorded using a digital thermohygrometer.

3.5.1.4 Evaporimeter procedure

- The subject was turned on her side (as far over as possible so that the measurement site was horizontal) and made comfortable.

- The subject's pants were pulled down whilst holding the pad in position.

- The researcher put a thermal insulating glove on the hand holding the probe.

- Just before the subject and researcher were ready to start measurement taking the software programme was started (this was because there was a time delay of a few seconds to initiate the programme).

- The subject's pad was pulled away from the buttock and the probe immediately placed on the buttock site.

- The researcher used her free hand to fold the end of the pad within its plastic backing (to prevent water evaporation from the pad interfering with the TEWL measurement).

- Measurements were taken for 10 minutes (timed using a digital time read out on the laptop computer).

- The programme was terminated and the probe placed in the probe holder.

- The subject's used pad was then placed in a plastic bag and weighed to determine the amount of urine in the pad.

3.5.1.5 Erythema meter procedure

Table 3:2 Measurements of erythema were made using the erythema meter at the sites shown in this table (see also Figure 2: 11):

Site	Subject position	Location of site
Sacrum	Lateral	At the distal point of the buttock fold
Buttock (L)	Lateral	At the level of the anus, 3cm laterally from buttock fold
Buttock (R)	Lateral	At the level of the anus, 3cm laterally from buttock fold
Thigh (L)	Lateral	3cm distal to thigh/perineal junction
Thigh (R)	Lateral	3cm distal to thigh/perineal junction
Groin (L)	Supine	3cm distal to adductor longus
Groin (R)	Supine	3cm distal to adductor longus

- The probe support was positioned over each site, using minimal pressure.
- Three measurements were taken in quick succession.
- Measurements were recorded verbally onto a dictaphone (using the subject code for identification purposes).

3.5.1.6 Visual grading procedure

Four sites were rated *in addition* to those above. These were the groin and thigh *creases* (both L and R). These areas are considered susceptible to dermatitis because they lie within skin folds, but they could not be readily accessed using the erythema meter because of the size of the probe cuff.

- The skin at each site was illuminated with the hand-held light.
- Visual rating was recorded onto a dictaphone.

3.5.1.7 pH meter procedure

This measurement was taken at one groin crease site with the subject supine.

- The probe was removed from its storage solution and rinsed with distilled water.
- 0.1ml of distilled water was placed on the skin.
- The probe was placed on the skin with the temperature probe adjacent.

- Measurement was taken when the pH meter readings were stable.
- Measurement was recorded onto a dictaphone.

TEWL and pH measurements were taken from only one lateral site and the same side was used for each subject for all repeats.

The subject's pad was then changed and she was made comfortable in her bed and thanked. Each set of measurements took about 20-30 minutes per subject, thus five subjects could be completed between 05.30 and 08.00.

3.5.1.8 Instrument cleaning

Between subjects the erythema probe support and evaporimeter protection cover were cleaned with detergent and water followed by an alcohol wipe. The pH probe was cleaned with an alcohol wipe and at the end of each week it was treated with a membrane cleaning solution to prevent a protein build-up.

3.5.1.9 End of data collection session

At the end of each data collection session the equipment was dismantled, packed up and taken to the Home that was next scheduled for data collection on the following morning. On return to the office dictaphone measurements were played back and recorded in the subjects' case record forms. The TEWL file was copied to disc and a further copy was stored as a backup on the office computer.

3.6 Preparation of Homes for sleep study

In addition to skin measurements a sub-set of subjects from the larger Homes who agreed to participate in the sleep component of the study (see Sampling and recruitment 3.2.2) gave their consent (or relatives/carers assented on their behalf) to take part in the *sleep* component of the study. The same inclusion / exclusion criteria were used. Subjects continued with their usual medication (including hypnotics, if

used regularly). For two nights during each regime, these subjects were recorded on the Visi-lab.

3.6.1 Preparation of staff

The night staff were shown the Visi-lab equipment and their role explained . The staff's role was limited to changing the pad when the subject was undergoing the *frequent* pad changing regime.

It soon became clear that some staff were reluctant to take part in this component of the study primarily because they were concerned about appearing on the video themselves (albeit for a very short period of time). We therefore approached all staff members for consent to take part in the study and assurance regarding confidentiality of the videos was given.

3.6.2 Visi-lab procedure

- The Visi-lab equipment trolley (Figure 2:12) was positioned near the subject's bed during the afternoon before the recording was due to take place.

- The camera was positioned next to the equipment. The same position was used for each subject for all recordings.

- The infra-red light was turned on.

- All loose cables were taped down or moved to minimise any tripping hazards.

- The equipment was switched on to ensure that the camera angle was appropriate (i.e. the subject was in full view) and that the sound, movement and incontinence sensors were functioning.

- The Visi-lab was set to record from 22.00 until 08.00 the next morning.

- The equipment (apart from the infra-red light and camera) was covered with a sheet to minimise its obtrusive and technical appearance.

- If staff members were unfamiliar with the Visi-lab i.e. had not been on duty when it had been used before, they were visited shortly before the recording was due to start to explain the procedures.

- During the night the removed pads were saved in separate plastic bags.

- The Visi-lab automatically finished recording at 08.00.

- Later that morning the equipment was removed and either moved to the next subject or stored it in a pre-arranged location.

- The subject's pads were weighed and the weight recorded on the video label and in a pad weight record book. The recording was copied to disc and stored together with the video in a locked data storage cupboard.

3.7 Timescale of study

The total timescale for all study components are shown in table 3.3 below:

Study activity	Time taken
Literature review, protocol writing and ethics committee application	9 months
Preparation of instruments, preparation of Homes and subject recruitment	12 months
Data collection (skin and sleep data)	18 months
Further data collection (sleep data)	6 months
Data entry and analysis	3 months
Report writing	6 months

CHAPTER 4

SKIN HEALTH DATA: ANALYSIS AND RESULTS

4.1 Subjects

4.1.1 Subjects entered and withdrawn

186 subjects were identified who were eligible to enter the study from 18 residential settings. Consent or assent (from their relative) was gained from 131 subjects.

Forty-six subjects were withdrawn during the early stages of the study. Twenty-six subjects were withdrawn during the baseline period for the following reasons: four did not meet the inclusion criteria (three were not incontinent of urine and one had a grade two pressure ulcer); fourteen could not comply with the measurement taking; six requested to withdraw; one relative withdrew assent; one subject had highly pigmented skin (from which reliable measurements could not be taken).

Twenty subjects were withdrawn early during their first regime for the following reasons: five did not meet the inclusion criteria (three due to incontinence of faeces and two due to a pre-existing skin condition identified during the baseline period); thirteen could not comply with the measurement taking; one became acutely ill; one subject's relative withdrew assent. Eleven subjects were withdrawn whilst in the *frequent* pad changing regime and nine whilst in the *less frequent* pad changing regime.

Four subjects were withdrawn from the study with complete data for the first regime (two from the *frequent* pad changing regime and two from the *less frequent* pad changing regime): three subjects died and one was admitted to hospital. An 'intention to treat' analysis using these data was not carried out. This would have entailed copying the data obtained in the first regime into the second for the subjects who withdrew after entering the intervention phase of the study. This would have biased the results in favour of the hypothesis (that there is no difference in skin health between the two regimes).

Table 4:1 Subject withdrawals by regime and reason

Reason for withdrawal	Baseline	*Frequent* pad changing regime	*Less frequent* pad changing regime	Total
Did not meet the inclusion criteria	4	3	2	9
Unable to comply with measurements	14	7	6	27
Other reason	8	3	3	14
Total	26	13	11	50

4.1.2 Intention to treat

Two subjects were withdrawn from their first regime (from the *less frequent* pad changing regime) because they developed grade 2 pressure ulcers. A further subject was withdrawn from the *less frequent* pad changing regime because she could not comply with the measurements and she had also developed a skin problem affecting her labia.

The removal of these three subjects' data from the analysis could bias the study in favour of the hypothesis (that there would be no difference in skin measurements between the two regimes). Had they continued in the study, the subjects with skin problems in the *less frequent* pad changing regime may not have had problems in the *frequent* pad changing regime. Their visual rating score data was therefore included in the analysis as 'intention to treat' by entering visual measurement data for the *frequent* pad changing regime that would have been found had they showed no skin problems in this phase of the study. This has the effect of modelling outcomes for these subjects that is unfavourable to the hypothesis.

4.1.3 Completed subjects

Data from eighty-one subjects were included in the analysis. Seventy-eight subjects had completed the study (although not *all* measurements were possible in *all* subjects) and three subjects were included as 'intention to treat' (see above). The subject characteristics are shown in Table 4:2 below:

Table 4:2 Characteristics of subjects

Subject characteristics (N = 81)	Median (IQ range)
Norton score	11 (10-13)
Braden score	13 (12-15)
Barthel score	2 (1-5)
Katz score	2 (1-3)
Age (mean)	85.2 (SD 8.7)
Number using a dynamic mattress	20

The subjects were a very elderly group of women with a high level of dependence in activities of daily living and considered 'at risk' or borderline risk of developing pressure ulcers.

4.1.4 Adherence to pad changing regimes

Staff maintained records of pad changing times (Appendices 7 & 8) in the Pad Change Record books. The staff were asked to sign for every pad change in order that their compliance to the different pad changing regimes could be monitored. In addition, the staff were telephoned and visited frequently to encourage compliance to the regimes and to check in the Pad Change Record books that the regimes were being complied with. For the *frequent* pad changing regime 5% of pad changes were not recorded and for the *less frequent* pad changing regime 4% were not recorded. Staff compliance to pad changing regimes appeared therefore to be very good. This was further supported by the measured differences in urine volumes obtained from pads collected during the two regimes; with higher volumes being obtained from the pads in the *less frequent* regime (see section 4.3.2 below).

4.2 Data preparation and analysis

4.2.1 Preparation of TEWL data

The evaporimeter logs five TEWL measurements per second which were recorded onto the laptop computer whilst recordings were taken. Measurements were downloaded into Excel and plotted. These graphs were examined and anomalous data coded. Several typical variations from the characteristic TEWL trace for the drying out of wet skin were identified: dry skin (i.e. when the subject had not been incontinent) resulted in a flat trace. If the probe became displaced there was a sudden

fall in TEWL values, followed by a sharp rise (if the probe was inadvertently replaced on a previously occluded area). Agitated or restless subjects produced rapid fluctuations in values. TEWL sample traces are shown in Figure 2:8.

Most problems of probe displacement and subject restlessness occurred after five minutes, because it was difficult for some subjects to keep completely still for a prolonged period of time. It was therefore decided to use the first five minutes of each trace and omit only traces which were aberrant *throughout* the recording. Measurements that were taken from dry skin, and had flat traces, were taken for a two minute period and this data was then extrapolated to five minutes. The evaporimeter was unable to log measurements above 135g/m^2/h. When TEWL exceeded this level error codes were logged until the TEWL dropped below 135g/m^2/h. To correct for this data loss the error codes were replaced with 135g/m^2/h to represent this TEWL value although the actual value was unknown.

The TEWL data were then analysed in MathWorks MATLAB version 5.3.0 (which is a mathematical computer software package) to calculate both the sum of the TEWL values for 5 minutes (representing the area under the curve up to 5 minutes) and the mean. The mean TEWL value was then used to examine differences between regimes. These were entered onto Microsoft Excel and prepared as described below.

4.2.2 Data entry and statistical analysis for erythema meter, TEWL and pH

Erythema meter, TEWL and pH readings were prepared in Microsoft Excel. Statistical analysis was carried out in Minitab by fitting general linear models with the following factors:

- *Order* (representing the order that each of the two pad changing regimes were applied).
- *Subjects* (nested within order).
- *Period* (representing the weeks during which each of the two pad changing regimes were applied, i.e. weeks 3 and 4; and weeks 7 and 8 of the intervention phase).
- *Regimes* (*frequent* or *less frequent* pad changing regime).

Residuals were checked for consistency with normally distributed errors. General linear modeling (GLM) is a complex statistical process that represents a broadening of the paired *t* test (which compares the mean of the selected outcome variable between groups). The rationale for using general linear modeling is that it enables other factors, that may influence the outcome, to be added to the analysis. In the case of a cross-over design it is important that the effect of the *order* of the regimes is taken into account and also the time period *(period)* of the repeated measures.

4.2.3 Preparation of pad weight data

The mean weight of five dry pads was calculated and deducted from the wet pad weights of the saved pads. This difference (the urine weight) was then entered into Excel.

4.2.4 Preparation of visual grading data

These data were entered into Microsoft Excel. The visual grading score for the two readings taken during the last two weeks of each regime were used to form an overall code for each regime. Where a visual grading score was missing (usually due to subject related problems such as faecal incontinence) the measurement from the preceding week of the regime (week 2 or week 5, depending if this occurred in the first or second regime) was used. The various possible combinations of visual grading scores for the two measurements were reduced into 6 codes for ease of analysis (see below). The coding was designed to take account of both severity and persistence of dermatitis. Measurements were not included from the first week of each regime to avoid contamination due to 'carry-over' effects.

Table 4:3 The overall **visual codes** are shown in this table

Visual grading score combinations	Visual code	Skin condition
0/0, 0/1, 1/0	0	No erythema or barely perceptible (on one occasion only)
1/1	1	Barely perceptible erythema, but persistent
0/2, 2/0, 1/2, 2/1	2	Moderate erythema (one occasion)
2/2, 0/3, 3/0, 1/3, 3/1	3	Persistent moderate erythema or intense erythema on one occasion
2/3, 3/2	4	Moderate/intense persistent erythema
3/3	5	Persistent intense erythema
0/4, 4/0, 4/1, 1/4, 2/4, 4/2, 3/4, 4/3	6	Broken skin (on one occasion)

4.2.5 Data entry and statistical analysis for visual grading scale data

The visual codes for the two regimes were then analysed by the following comparisons:

0-1 versus 2-6

0-2 versus 3-6

0-3 versus 4-6

This was done by the Mainland-Gart (Mainland, 1963) method based on the numbers of each type of discordant pair (i.e. subjects who developed erythema in one regime but not the other) for each *order* in which the regimes were applied. The Mainland – Gart method (ref) is similar to the more commonly used McNemar's test, but has the advantage of enabling other factors (in this case *order)* to be taken into account.

4.3 Results

4.3.1 Results of erythema meter, TEWL and pH

The results of the erythema meter, TEWL and pH skin measurements are shown in Table 4:4 below. Fewer subjects provided erythema data than other measurements because of difficulties caused by breakdown of the instrument. This caused data loss from a considerable number of subjects from one regime only but these subjects could not be included in the analysis because data was not obtained from both regimes.

Table 4:4 Summary of results for erythema meter, TEWL and pH data

No. of subjects	Measure-ment	Site	*Frequent* pad changing regime Mean (SD)	*Less* frequent pad changing regime Mean (SD)	Difference Of means	95% confidence intervals
58	Erythema index	R groin	89.6 (36.5)	93.3 (29.1)	4.33	-4.23 – 12.89
58		L groin	92.9 (33.7)	93.8 (35.1)	-2.02	-10.69 – 6.65
39		R thigh	142.5 (37.3)	145.0 (43.5)	3.76	-10.73 – 18.26
39		L thigh	140.5 (45.3)	139.9 (39.0)	1.64	-13.85 – 17.13
64		R buttock	125.4 (41.2)	132.8 (44.2)	4.83	-3.21 – 12.87
64		L buttock	133.0 (41.6)	133.0 (42.6)	3.58	-5.71 – 12.87
58		Sacrum	144.1 (51.6)	142.6 (52.9)	1.50	-11.40 – 14.40
69	TEWL		55.8 (31.7)	67.7 (33.6)	12.14	2.89 – 21.39
63	pH		6.7 (0.4)	6.7 (0.5)	-0.08	-0.19 – 0.02

Table 4:4 summarises results for the pad changing regimes for erythema meter, TEWL and pH. 95% confidence intervals for the difference in means are shown (this difference is for *less frequent – frequent* regimes). Therefore a negative sign shows less erythema in the *less frequent* regime. P values for the regime effect were obtained by fitting the general linear model described earlier. For the erythema meter indices these P values are all greater than 0.2, for TEWL it is 0.01 and for pH it is 0.13. Therefore, from this model only TEWL showed a significant difference between pad changing regimes.

There was no significant dependence on order for any of the measurements in this table.

4.3.2 *Pad weight analysis*

Urine loading of pads was higher in the *less frequent* pad changing regime (Figure 4:1).

Mean urine weight in *less frequent* pad changing regime = 316g (SD 185.g)
Mean urine weight in *frequent* pad changing regime = 170g (SD 131.g).

Pad weight was therefore added to the general linear model as a co-variate for the analysis of TEWL. TEWL was strongly dependent on pad weight ($p<0.00005$) and with the adjustment for pad weight, there was no significant difference in TEWL between the two pad changing regimes ($P= 0.44$). This implies that it is the greater wetness of the pads (albeit caused by the *less frequent* pad changing regime) that is the main determinant of wetter skin as measured by TEWL

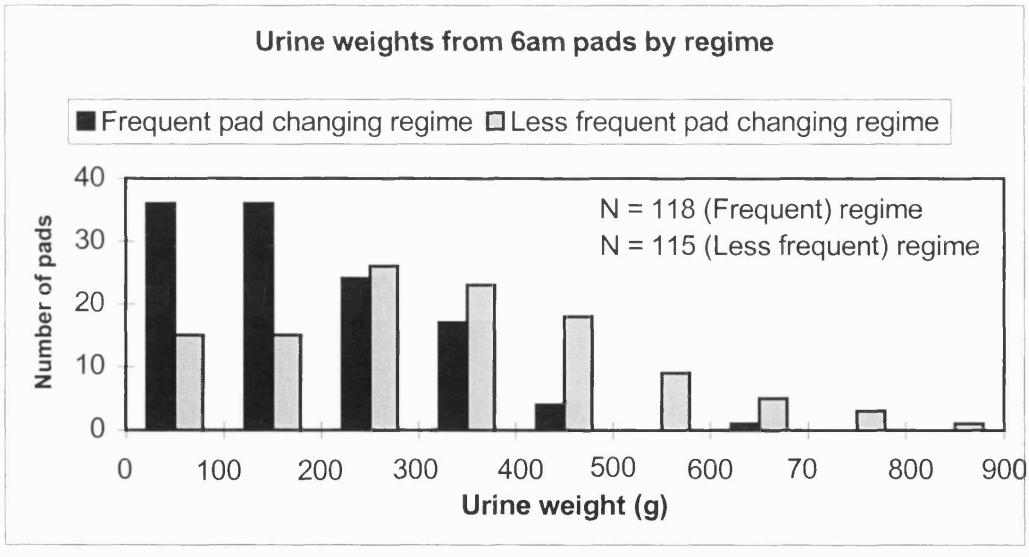


Figure 4:1 Histogram of urine weights by regime

4.3.3 *Analysis of visual grading scale*

The table below shows the results of the comparison of the visual codes 0-1 versus otherwise (i.e. no/barely perceptible erythema versus moderate/intense erythema, see 4.2.4) between pad changing regimes. Use of the Mainland-Gart method showed that there was no significant order effect or regime effect at any of the 11 sites ($P>0.05$ for

all tests). The table gives estimates of the ratio of the odds on a 0-1 code for the less *frequent* pad changing regime against a 0-1 for the *frequent* pad changing regime and corresponding 95% confidence intervals for this odds ratio. Odds ratio is a simple method of expressing the *risk* of developing erythema. An odds ratio of 1.00 means that the risk of developing erythema in each regime is the same. An odds ratio of more than 1.00 means that the risk of developing erythema in the *frequent* pad changing regime is more than that of the *less frequent* regime.

Table 4:5 Summary of results for visual codes 0-1 versus 2-6 (i.e. no/barely perceptible erythema versus moderate/intense erythema)

Site	No. of subjects	Odds ratio	95% confidence interval
R groin	80	1.00	0.29 – 3.45
R groin crease	80	1.20	0.37 – 3.93
L groin	80	2.00	0.60 – 6.64
L groin crease	80	1.75	0.51 – 5.98
R thigh	72	0.89	0.34 – 2.30
R thigh crease	73	0.86	0.29 – 2.55
L thigh	72	0.89	0.34 – 2.30
L thigh crease	73	1.00	0.32 – 3.10
R buttock	80	0.71	0.32 – 1.61
L buttock	81	0.92	0.40 – 2.08
Sacrum	75	1.09	0.48 – 2.47

This analysis was repeated making the comparisons of the visual codes 0-2 versus 3-6 and 0-3 versus 4-6 and no significant differences were found. These results concur with the results from the erythema meter indicating that there were no significant differences in erythema/dermatitis between the different pad changing regimes.

4.3.4 The prevalence of erythema/dermatitis

The proportion of subjects with moderate/intense erythema/dermatitis (i.e. visual codes 2-6) within each regime was determined by site and is shown in the table below. There were no between-group differences. The buttock sites were the most commonly affected.

Table 4:6 Proportion of subjects with moderate/intense erythema (i.e. visual codes 2-6) within each pad changing regime by site, based on visual grading

Measurement sites	*Frequent* pad changing regime (%)	*Less frequent* pad changing regime (%)
R Groin	6.0	6.0
R groin crease	8.3	7.1
L groin	9.5	4.8
L groin crease	9.5	6.0
R thigh	15.8	17.1
R thigh crease	16.9	18.2
L thigh	17.3	18.7
L thigh crease	18.2	18.2
R buttock	28.9	33.7
L buttock	30.9	32.1
Mean % for all sites	16.1	16.2

The overall prevalence of moderate/intense erythema/dermatitis (i.e the proportion of subjects who were coded as having moderate/intense erythema on any site during each regime) were as follows:

Less frequent pad changing regime 60%
Frequent pad changing regime 55%

4.3.5 Pressure ulcers

Five subjects developed grade 2 pressure ulcers (i.e. a visual code of 6), all of which occurred in the *less frequent* pad changing regime. These subjects were withdrawn following pressure ulcer development Three of the five subjects had already undergone the *frequent* pad changing regime. In two of the five subjects the *less frequent* regime was first. For the purposes of this analysis it was assumed that these subjects would *not* have developed a pressure ulcer in the *frequent* pad changing regime.

Despite only observing pressure ulcers in the *less frequent* the 95% confidence interval for the odds ratio was 0 – 1.09. This indicates that the range of possibilities went from pressure ulcers only occurring in the *less frequent* pad changing regime, to

the possibility that pressure ulcers were in fact slightly *more* common in the *frequent* pad changing regime (although none were observed in this regime). The P value was 0.1.

4.3.6 Summary of results

Overall the results show that no differences were found between regimes in terms of severity of erythema or pH, but the TEWL measures were significantly higher in the *less frequent* pad changing regime (the skin was therefore significantly 'wetter'). Subjects developed pressure ulcers in the *less frequent* pad changing regime only, but this fell short of statistical significance.

CHAPTER 5

SLEEP AND SELF-TURNING DATA: ANALYSIS AND RESULTS

5.1 Subjects

5.1.1 Subjects entered and withdrawn

Seven of the eighteen Homes who participated in the skin study were eligible to take part in the sleep study i.e. they had rooms and corridors large enough for the equipment and had suitable lifts. However only three Homes agreed to take part and two additional residential settings were therefore recruited to provide sufficient subject numbers. Subjects from these two residential settings did not undergo skin measurements.

Twenty-six subjects consented to be in the study and twenty-two subjects completed data collection. Four subjects did not complete data collection due to death (1), discharge from the Home (1) or their own request (2).

Table 5:1 Characteristics of the subjects

Subject characteristics (n = 22)	Median (IQ range)
Norton score	12 (8-14)
Braden score	14 (13-17
Barthel score	3 (0-5)
Katz score	2 (1-3)
Age (mean)	84 (SD 8.9)
Number using dynamic mattress	7

The characteristics of these subjects were very similar to those of the skin study (4.1.3).

5.2 Data preparation and analysis

5.2.1 Visi-lab data preparation and analysis

Each night of sleep recording was produced as a print-out, using the custom-built software (see example Figures 5:1 & 5:2). Some variation in the

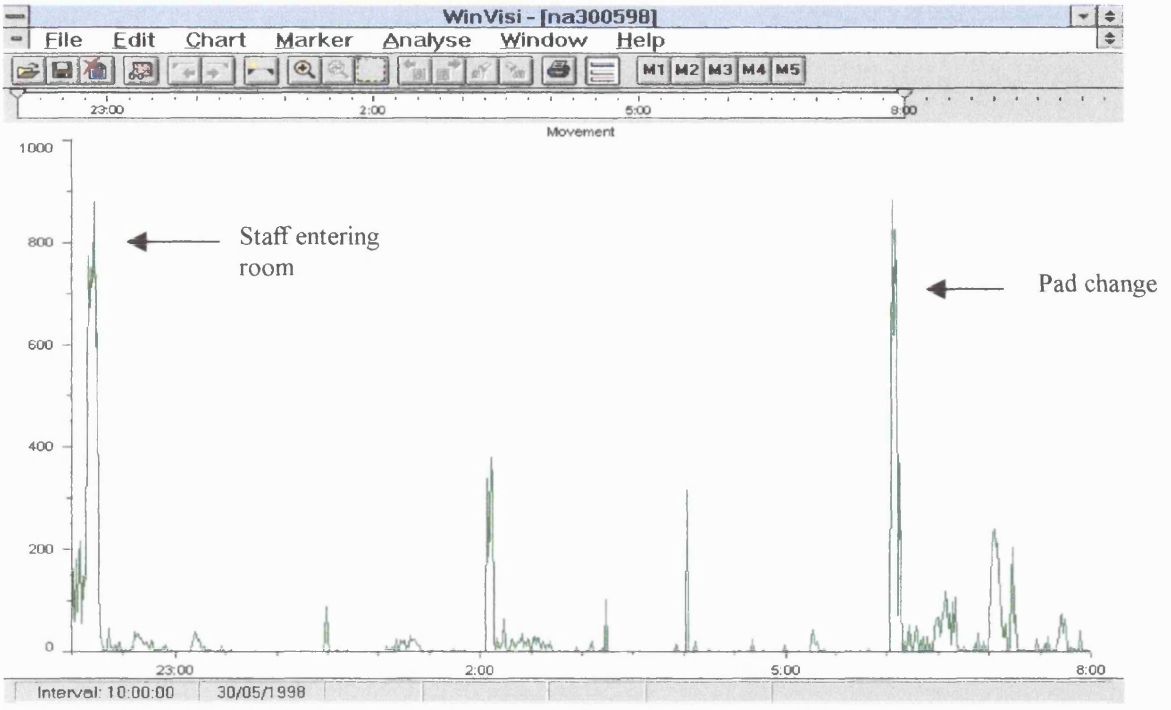


Figure 5:1 Visi-Lab print out from customized software showing relatively high movement (high sleep fragmentation)

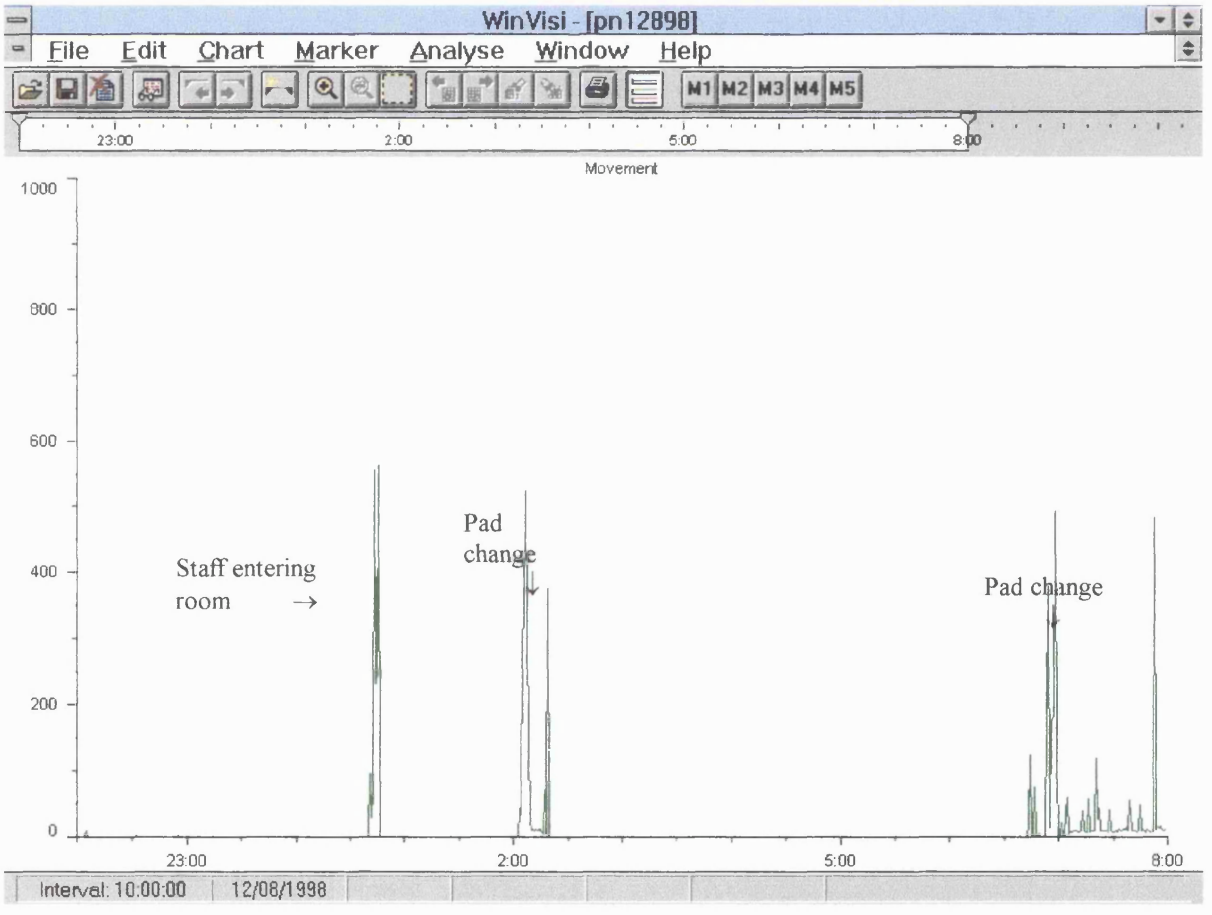


Figure 5:2 Visi-Lab print out from customised software showing relatively low movement (low sleep fragmentation)

exact time that subjects had their pads changed was found and analysis of data was therefore made from the termination of the first pad change (at around 22.00) to the commencement of the 06.00 pad change. This represented the total time during which the subject *could* be asleep and avoided particularly early or late pad changes confounding the data. For each sleep recording the time period was selected and analysed using the visi-lab software. This gives the mean number of movements detected per hour during the selected period. These values were entered into Excel.

Visi-lab data were analysed in the same way as the erythema meter data using general linear modeling (4.2.2)

5.2.2 Video-tape preparation and analysis

The purpose of the video-tapes was to allow for accurate identification of subject turning events (either staff or self-oriented). Sample video-tapes were screened on fast-forward and examined in conjunction with the Visi-lab print-out in order to observe the sensitivity of the Visi-lab to the detection of movement events. Overall a high degree of sensitivity was observed with even very small movements (such as a slight hand movement) being detected as a rise in movement values. Zero movement values (or a flat trace) reliably indicated no observable movement on the videotape. Gross movements, such as the subject turning over or a member of staff entering the field of view, were shown as steep rises in movement values.

This enabled analysis of the video-tapes to be made without viewing the whole tape. A print-out summarising the data from each night was made and the video-tape directly observed during all time periods where movement was detected on the print-out. When no movement was indicated for a period of time, visual checks were made to ensure that this concurred with no movement on the videotape, but continuous observation was not made. This made the viewing of the (nearly 100) tapes, each showing 8 hours of 'sleep' a less time-consuming and taxing task.

Each video-tape was analysed using a coding sheet (Appendix 10) to record pad changing and turning events (either staff or self turning). An Excel spreadsheet was created to record the number of staff and self-turning episodes for each night.

5.3 Results

5.3.1 Results of Visi-lab data

The sleep measurements (movements per hour) are shown in Table 5:2 below. The confidence interval indicates that there was no significant difference between pad changing regimes (P = 0.34). Data from one subject was excluded from this part of the analysis because they did not have recordings from both regimes.

Table 5:2 Summary of results for Visi-lab data (movements per hour).

No. of subjects	*Frequent* pad changing regime: mean movements per hour (SD)	*Less frequent* pad changing Regime: mean movements per hour (SD)	Difference of means	95% confidence interval
21	57.0 (38.6)	71.4 (48.3)	8.6	-9.38-26.60

5.3.2 Results of video-tape analysis

Subjects were classified into four groups based on turning: (i) self turners only, (ii) self and staff turners, (iii) non turners and (iv) staff turners only (Table 5:3). Five subjects turned themselves *fully* (side to side, back to side or side to back) on at least one of the four recorded nights and two additional subjects turned themselves *partially* (i.e shifted position) on one of their recorded nights. Of these subjects that turned themselves, five were also turned by staff; three of these five were turned at the pad change and two were turned at other times.

The subjects who did *not* turn themselves (n=15) were *not* turned by staff (either at the pad change or at other times) during *either* pad changing regime.

Turning at a pad change therefore seldom occurred and then only for subjects who turned themselves.

Table 5:3 Characteristics of turning and non-turning subjects showing median scores and interquartile ranges

Subject characteristics	Self turners only (N = 2)	Self and staff turners (N = 5)	Non turners (N = 15)	Staff turners only (N = 0)
Norton	10.5 (2.1)	12.4 (2.3)	10.9 (2.7)	-
Braden	15.5 (2.1)	15.2 (2.2)	13.7 (2.3)	-
Barthel	3 (2.8)	4.2 (2.6)	2.7 (2.7)	-
Katz	1.5 (0.7)	3 (1.2)	1.9 (1.4)	-
Age (mean, SD)	93.5 (0.7)	79.4 (12.8)	84.3 (7.2)	-
Number using dynamic mattress	0	0	7	-

The numbers of subjects in each group are very small and were not therefore analysed statistically. However, as no redundant staff turning was identified (see discussion) it was not necessary to attempt to characterise subjects who were self-turners but were turned unnecessarily by staff.

CHAPTER 6

DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

6.1 Skin

No evidence was found that the severity of erythema/dermatitis within the groin, inner thigh or lower buttock areas of elderly female subjects in residential settings was greater if their night time incontinence pads were changed every 8 hours rather than every 4 hours. The hypothesis that there would be no difference in erythema/dermatitis between regimes was therefore not refuted.

A higher proportion of subjects were found to have moderate/intense erythema/dermatitis in the thigh and buttock areas than reported by Brown (1994) (thigh 18% versus 6%, buttock 30% versus 8%), but a slightly lower for the groin area (7% versus 13%). There are several possible explanations for this finding. The subjects in Brown's study were younger (mean age 74.5 versus 85.2) and were recruited from acute medical wards. Around half her subjects were *not* previously incontinent before admission. Although the Brown study was carried out over a 12 week period subjects were included in the study for the length of their hospital stay which could be much shorter (the mean length of stay was not stated). In addition erythema was rated by a mixture of nursing staff and researchers and inter-rater reliability was not reported. It is possible that the subjects in this study who were older and had long-standing incontinence were more vulnerable to the development of dermatitis in the thigh and buttock areas. It is also possible that there were systematic differences between the ratings made in both studies, with the rater in this study tending to score erythema as being more severe than the rater(s) in Brown's study.

Of the secondary outcome variables it was found that the *less frequent* pad changing regime was not associated with significantly higher skin pH. But, the skin of subjects during the *less frequent* pad regime was significantly wetter (as measured by TEWL) than during the *frequent* pad changing regime. However, this additional skin wetness did not result in increased severity of dermatitis.

Why was the increase in skin wetness not associated with greater levels of dermatitis? One possible explanation is that study subjects did not experience frequent night-time faecal incontinence and that the action of faecal enzymes is key to the development of dermatitis. This is supported by the finding that there were no significant differences in the pH on the skin between both regimes. Other researchers have postulated that it is the interaction of urine and faeces (which produces ammonia and faecal enzyme activity) which is crucial to the development of dermatitis and it is therefore not surprising that no association between wetter skin (alone) and dermatitis was found.

However, relatively high mean pH readings for both regimes (6.7) was found; the 'normal' pH *on* the skin is in the range of 5.0 – 6.0 (Rieger, 1989). One possible explanation is that the skin within an incontinence pad is exposed to urine and the constituents of urine contribute to the measured pH. Although fresh urine has a mean pH of around 6.0 (range 4.5 – 8.5) the presence of urease producing micro-organisms creates more alkaline urine (in the range of 7.5-9.5) (Getliffe and Dolman, 1997) and bacteriuria is very common among female nursing home residents (Ouslander et al. 1995). Occlusion of the skin is also known to have an effect on pH. Aly and colleagues (1978) found that skin that had been occluded for prolonged periods showed high pH readings (up to 7.5). In addition Rieger (1989) points out that the water that is necessary (as a contact) to take the pH measurements may also dilute the results. The results from this study do not indicate a difference in pH between pad changing regimes. However, they do indicate that the pH of skin exposed to urine under an incontinence pad is higher than that reported for skin in 'normal' dry and unoccluded environments.

The finding that five subjects in the *less frequent* pad changing regime developed a grade 2 pressure ulcer (in the upper buttock areas) compared to *none* in the *frequent* pad changing regime is a cause for concern. Grade 2 pressure ulcers are defined by the European Pressure Ulcer Advisory Panel as 'partial thickness skin loss involving epidermis, dermis or both. The ulcer is superficial and presents clinically as an abrasion or blister'(European Pressure Ulcer Advisory Panel, 1999). One possible explanation for the occurrence of these ulcers is that the subjects were *turned* less frequently during the *less frequent* pad changing regime and that the ulcers arose from ischaemic pressure damage. However, during the sleep study it was observed that

subjects were seldom turned or repositioned at the time of pad changing. Pad changing therefore did not appear to contribute substantially to pressure relief. In addition, in all cases these pressure ulcers appeared as abrasions and healed within 1-3 weeks. The failure to progress to grade 3 suggests that the pressure ulcers were not due to underlying ischaemic tissue damage.

The TEWL results indicate that the five subjects who developed these ulcers during the *less frequent* pad changing regime would have had wetter skin than during the *frequent* pad changing regime. Wet skin has been demonstrated to be more easily damaged by abrasion than dry skin (Zimmerer et al. 1986). It seems far more likely that these 'pressure' ulcers resulted from the friction and abrasion of macerated skin and this may have been caused by the *less frequent* pad changing regime. In this case the term 'wet skin abrasion' may be more appropriate than grade 2 pressure ulcer. As the study was not powered using the development of grade 2 pressure ulcers as the primary outcome variable, it is possible that larger subject numbers would have yielded a significant result.

This study was conducted using a good quality standard pad, which is typically used for night time incontinence. Most pad manufacturers produce a pad with a higher level of absorbency (often using greater quantities of superabsorbent polymers) and it may be that use of such a product would not result in the significant difference in TEWL that we found in this study. The cost of a single highly absorbent night pad is around 4-7p more than for a standard night pad and is therefore substantially less than the cost of two standard night products.

It was observed during visits to the Homes, that although some Homes followed a specific pad changing regime (such as *always* changing pads during the night; or *always* not doing so), some Homes attempted to individualize pad changing depending on the perceived needs of the resident. However, in no Home was there a method for systematically recording *when* pad changing should be carried out or a method for accounting for it being done.

In addition, although some Homes used a pressure ulcer risk assessment tool (such as the Norton score) to determine resident repositioning requirements, this information

was not usually available in a readily accessible form to all night staff, nor was there a method for accounting for repositioning being carried out.

Some form of documentation to record residents' individual requirements (for pad changing and repositioning) is therefore needed to provide continuity between different night shifts and account for the care given. This would also provide a method of monitoring pad consumption to account for pad costs. Changes in skin health could therefore be matched to the current frequency of pad changing and repositioning applied for the individual and alterations to the resident's regime made. Appendix 11 shows a suggested form.

How should staff determine which residents are likely to need a *frequent* pad changing regime? Currently there is no method of doing so with confidence. Although the evidence from this study suggests that dermatitis is not associated with a *less frequent* pad changing regime, there is uncertainty about the relationship between skin abrasions and wetter skin. Subjects who developed wet skin abrasions during the *less frequent* pad changing regime generally had lower scores (and therefore higher risk) for the pressure ulcer prevention and levels of independence scales. But there were too few subjects to determine which subjects are more at risk of developing abrasions when wearing pads for prolonged periods i.e. during a *less frequent* pad changing regime. Given the importance of preventing such skin problems it would be unwise to claim that a *less frequent* pad changing regime is safe for skin health.

6.2 Sleep

No significant differences in measured sleep fragmentation (movements per hour) between the two regimes were found. Although the sample was small and therefore possibly lacking power to detect significant differences, the trend was directed towards *less* sleep fragmentation in the *frequent* pad changing regime. This would indicate that changing pads somehow promotes sleep. This could be explained by subjects's being more comfortable after their pads are changed at 02.00 (and therefore sleeping better during the latter half of the night). Data for the last 2.5 hours of the night (03.00 – 05.30) were therefore analysed to examine the strength of difference between the two regimes at that time. However the difference was less, not greater.

Why might there in fact be no difference in measured sleep between the two regimes? One explanation is that during pad changing subjects are disturbed for a comparatively short period of time (usually only a few minutes) and this may simply have little effect on overall sleep fragmentation. Alternatively, the method used to measure sleep may not be sufficiently sensitive.

Schnelle and colleagues(Schnelle et al. 1999) in a recent study of an intervention on sleep in nursing homes suggested that the method they used (actigraphy) did not measure sleep with sufficient precision to detect intervention effects. Both the actigraphy and the Visi-lab equipment measure movement (which has been shown to have a good correlation with EEG), but do not measure sleep stages or transient arousals, which may possibly show change as a result of night-time interventions. However, such EEG methods are invasive and unsuitable for elderly subjects with mental impairment. In addition, the relationship between changes in sleep stages or transient arousals and other perhaps more important sleep outcomes, such as daytime sleepiness have not been established.

6.3 Turning

It was surprising to find that subjects were rarely turned or repositioned when they had their pads changed although this would appear to be an ideal opportunity to do so. Interestingly, subjects most likely to be repositioned were those that repositioned themselves. Schnelle (Schnelle et al. 1993b) and colleagues had also found this to be the case, but were unable to explain this finding, because their methods did not enable direct visualisation of subjects and carers.

The findings from the video recordings in this study did suggest an explanation. Two of the subjects who were self-turners, turned themselves into somewhat unusual and precarious positions (for example with limbs hanging over the bedside). When staff looked in at the subjects they would see the unusual positions and therefore take steps to reposition them. Unfortunately, this was usually in the same position from which the subjects had turned themselves, sometimes only minutes before, and after a good deal of effort. Three other self-turners were also turned by staff at the time of the pad change, although video analysis did not disclose the reason why this happened.

Seven of the fifteen subjects who were *non-turners* had a dynamic mattress on their bed. Although manufacturers recommend that patients are repositioned regularly on these mattresses, on questioning we found that staff generally perceived no need to do so. Of the eight remaining non-turning subjects, six had Norton or Braden scores that indicated that they were at risk of developing pressure ulcers. These subjects did not therefore receive the frequency of repositioning that their risk assessments would indicate. Although they did have other forms of less intensive pressure relief e.g use of Spenco and Propad.

6.4 Problems and limitations of the study

There are several limitations in this study related to the measurement methods used. These concern primarily the measurement of TEWL and the measurement of sleep.

In the piloting phase of the study considerable efforts were made to develop the software and techniques used with the evaporimeter to enable valid measurement of skin water loading. It was established at that stage that simple 'one-off' measurements at a certain time would not predict the remainder of the decay curve accurately and continuous measurement was needed. However, analysis of the hundreds of TEWL curves produced during the main body of the study indicated that although the majority of curves are reasonably typical of those found by Zimmerer, there are common aberrations which are difficult to explain. For example, the rate of the decay curve may be unusually slow and very high TEWL values may persist during the first few minutes followed by very slow decay. Although this was associated with high fluid loading, similarly high levels of fluid loading would more frequently produce a typical more rapidly decaying curve. These findings may be related to the timing and quantity of urine voided. For example, it is likely that a large volume of freshly voided urine at the end of the night will produce different results to smaller volumes produced frequently throughout the night. Further experimentation to establish the reproducibility of TEWL using different fluid loadings and under different controlled conditions would be important, before undertaking further clinical studies involving use of this equipment in the field.

The limitations of the Visi-lab method of measuring sleep relate mainly to its size and complexity. Space limitations make this equipment difficult to use and maneuver and its complexity make for problems with reliability in the field. For the purposes of this study the Visi-lab provided direct visualisation of subjects which was important for analysis of turning. But for simple measurement of sleep in nursing home subjects, the Visi-lab is not recommended . The Actiwatch provides a much simpler, neater alternative which requires much less staff input and provides more reliable recordings. During the piloting phase of the Visi-lab comparisons were made between the Actiwatch and Visi-lab data to examine method agreement. The results were fair but not as good as expected; this may partly be explained by recordings being taken in nursing homes where it was difficult to control conditions. Repeating the method agreement study under more controlled circumstances would be helpful. Since the study was completed a new model of the Actiwatch has been produced which stores vastly more data (sampling every 2 seconds) which should enable easier comparison with the Visi-lab output (which samples every second).

Overall many problems experienced during the study related to the equipment. The tools used were primarily designed for use in a laboratory and not constructed for fieldwork. There were problems with moving the equipment, both between subjects and between Homes. Great care had to be taken in packing and unpacking the equipment and testing the instruments to ensure that they were working as intended.

In addition, many of the subjects who took part in the study had dementing illnesses which made measurement taking difficult and sometimes impossible. The erythema meter was damaged on two occasions; once by over-bending the cable to access difficult sites and on another by pulling on the fibre optic cable. On the first occasion the problem was not recognised for some time, because the calibration method did not reveal the problem initially. This unreliable data then had to be discarded. As data from both regimes was required this resulted in considerable loss of subject numbers.

For many subjects it was not possible to take all measurements or take them from all sites. The inner thigh site proved particularly inaccessible (due to inability to abduct hips) and was very difficult for taking erythema meter measurements, consequently fewer data were achieved from this site than from all others.

On the whole, measurements taken from the rear of the subject (with the subject in the lateral position) were found to be more acceptable for subjects. Measurements from the front (the groin or inner thigh) seemed to be the most unacceptable (and were therefore sometimes impossible to take) for some subjects. Damage to equipment was also more likely to occur when taking measurements from the front of the subjects, through grabbing or pulling cables.

Some Homes had more difficulty complying with the pad changing regimes than others. The Homes were visited at least weekly to monitor adherence to the current pad changing regime (by checking the pad changing records) and to discuss the study with staff. Some Homes had difficulty applying the pad changing regime that they did not *usually* apply. This happened for several reasons, either because staff 'forgot' which regime they were applying; because they did not seem to 'approve' of a particular pad changing regime; or because they did not like the pads supplied and therefore felt they should be changed more often. On two occasions Homes had to be asked to repeat the regimes because they had not been able to adhere to the protocol.

Some staff also had problems adhering to the skin cleansing regimes. Many Homes used creams or talcs liberally and some staff objected to not using them. Creams and talcs were occasionally applied when they should not have been and this sometimes interfered with measurement taking. To minimise this problem (with permission) each subject's collection of creams and talcs were temporarily removed.

There were difficulties ensuring that the research nurse responsible for measurement taking remained blinded to the current regime that the Home was following, as the staff tended to tell the research nurse which regime they were following in conversation. Adherence to the regime was encouraged by vigourous verbal and written reinforcement of the importance of the protocol.

There was considerable difficulty recruiting sufficient subjects (and Homes) to the sleep component of the study. Many subjects, relatives and staff found the idea of being filmed unacceptable. Staff were particularly concerned about the implications of their practice being recorded on film, whereas subjects and relatives objected to the intrusiveness of the method. As a consequence it was not possible to achieve the

target sleep subject numbers and therefore it is possible that this part of the study lacked power to find significant differences in sleep measures between regimes.

6.5 Conclusions

No evidence was found that a *less frequent* pad changing regime has an effect on erythema/dermatitis, but there is evidence that skin is wetter, which may make it more vulnerable to friction and abrasion. The non-significant finding of greater incidence of grade 2 pressure ulcers (wet skin abrasions) during the less frequent pad changing regime merits further investigation. It is not possible to be confident that a less frequent pad changing regime has no effect on skin health.

No evidence was found that a *less frequent* pad changing regime results in less sleep fragmentation. Sleep disturbance in institutional settings is multi-factorial and it is therefore likely that a single additional pad change does not have a measurable effect on sleep. Staff seldom turned residents even at the time of pad changing, although the few residents who did turn themselves were more likely to be turned by staff.

6.6 Implications for nursing

Can the practice of *not* changing the pads of incontinent residents during the night be defended? The results of this study indicate that residents are *not* more likely to experience more severe dermatits if they wear their pads throughout the night (i.e. without changing). However, it is possible that a small minority of residents will experience a 'wet skin abrasion' (grade 2 pressure ulcer), but these are likely to be superficial and not involve deeper skin structures. If pads *are* changed during the night, the results of this study would suggest that this is unlikely to affect sleep.

The results from this study indicate that the following is defendable practice for elderly women with night-time incontinence who are resident in long stay residential settings:

- Residents may use one standard good quality night pad (without changing) throughout the night.

- Residents who have had (or develop) grade 2 pressure ulcers (including 'wet skin abrasions') should have their pads changed during the night to keep their skin less wet.

- Changing residents during the night may take place as this is unlikely to affect sleep.

Additionally the following are recommended:

- An account is kept of the pad changing and turning regimes selected and delivered to residents (see Appendix 11).

- If possible night pads with the highest possible absorbency are used (a single highly absorbent night pad is much cheaper than two standard night pads).

6.7 Recommendations for further research

Further study of different pad changing regimes:

- An important finding of this study was that grade 2 pressure ulcers occurred in the *less frequent* pad changing regime, but not in the *frequent* pad changing regime (see 4.3.5). A similar study comparing the same two interventions using the development of grade 2 pressure ulcers as the primary outcome variable is therefore necessary before *less frequent* pad changing practices can be accepted unequivocally.
- Following further work on the measurement of TEWL (see below) clinical studies comparing different pad designs and materials (using the same pad changing frequency) and the effect this has on skin wetness (as measured by TEWL), other skin measurements and on grade 2 pressure ulcers are needed. This should provide evidence, based on skin health, to guide both pad design and pad purchase (see 3.3.4)

Further study of TEWL measurement:

- The volar forearm is much more convenient for skin measurements than the buttock. A comparison of volar forearm and buttock skin using TEWL is therefore necessary to establish the validity of using the volar forearm as a model for the buttock (see 1.2)
- There is a need for studies examining the reproducibility of TEWL using different fluid loadings on the skin, different time periods and different measurement conditions. This important work needs to be carried out to further establish the reliability of TEWL as a method of measuring skin wetness (see 2.5.3.1). Preliminarily this work could be carried out on volar forearms (if found to be valid).

Study of the effects of friction, abrasion and pressure:

- The vulnerability of wet skin to friction and abrasion damage has been demonstrated on adult volar forearm skin, but not on aged skin (see 1.2). Studying the effects of friction and abrasion on aged skin (with different levels of fluid loading) is therefore necessary to establish the vulnerability of aged skin (see

1.2.3) and then to establish the extent to which different pad designs, materials and wear-times can mitigate such damage.

- Although the evidence suggests that incontinence is unlikely to have an effect on the development of ischaemic pressure ulcers (see 1.2.5), the effects of different *pad designs* on interface pressures has not been investigated. It is unknown whether pads reduce or increase interface pressures and whether it is possible to manipulate pad designs to minimise pressures. Equipment for measuring interface pressures and for carrying out pressure mapping already exists for this work.
- Skin products that purport to protect the skin from diaper dermatitis or protect the skin from 'over-hydration' from urine are commonly used for nursing homes subjects (see 3.3.3). There is currently very little evidence to support their use and their widespread use has cost implications. Their efficacy in protecting the skin from over-hydration could be examined using TEWL measurements on the volar forearms (in the first instance), followed by clinical studies incorporating other methods of skin measurement.

Further study of sleep and incontinence:

- It would be valuable to repeat the method agreement study (comparing the Visi-lab to the Actiwatch) under more controlled conditions than were possible in the nursing home environment (see 2.7.2). This would help to validate the Visi-lab which has undergone considerably less study than the Actiwatch.
- There is a need to investigate further the relationship between sleep and incontinence. It is possible that frequent pad changing reduces sleep fragmentation because patients sleep better (see 6.2). This would require a much larger sample than was possible in this study but could be accomplished considerably more easily (and with less resources) using the Actiwatch method rather than the Visi-lab.

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Nursing Home headed notepaper

5th November 1998

Dear

********* Nursing Home is taking part in a research project which is being undertaken by a team of nurses and other academic and health care professionals from University College London. The project is being funded by the NHS Executive Research and Development Programme.

At ****** Home we are happy to be involved with research that aims to improve the care that the residents receive. This project is looking at the optimum duration of wearing incontinence pads during the night and the effects on skin health and sleep.

The nursing staff have suggested that your relative may be suitable to take part in the project. Mandy Fader or Sinead Clarke-O'Neill, who are research nurses from University College London, will be contacting you by telephone to tell you about the study in more detail and to give you an opportunity to discuss it and ask any questions. They will also send you some additional written information about the study.

If having spoken to the research nurse and read the information you are happy for your relative to take part in the study you will be asked to complete an 'assent form' and return it in the freepost envelope provided.

If, however, you do not want your relative to be involved in the study you can either tell the research nurse when you speak to her or you can indicate this on the assent form and return it in the *freepost* envelope provided. There is no obligation whatsoever to take part in the project.

If you have any queries about the project before the research nurses phone please feel free to contact me.

Yours sincerely

Mr A N Other
Home Manager

The 'morning' research nurse may need your help when she visits the home to take the skin measurements, however in return she will help you with some of your work.

We will occasionally ask you to save and weigh some of the night pads from each subject. We will provide you with some scales and plastic bags.

WHERE CAN I GET MORE INFORMATION?

The home has a file called a *Test location file* which can be found in the office this contains more detailed information about the study. The 'evening' research nurse will also be able to discuss any other queries you may have.

WILL THERE BE ANY BENEFITS FROM TAKING PART?

- We will bring *chocolates,* as a thank you for changing the pads at the specified time periods.

- The results of the project will enable research-based guidelines to be made to improve patients night-time continence care.

THE RESEARCH TEAM

PROJECT RESEARCHERS:	Ms Sinead Clarke-O'Neill Ms Dawn Cook
PROJECT LEADER:	Ms. Mandy Fader
DEPARTMENT HEAD:	Dr. Alan Cottenden
CONTACT ADDRESS:	5th Floor South Wing St Pancras Hospital St Pancras Way London NW1 0PE
TELEPHONE:	0171 530 3402/3981

SKIN & SLEEP STUDY

INFORMATION FOR CARERS

Appendix 2

WHAT IS THE SKIN AND SLEEP STUDY?

The skin and sleep project is funded by the NHS Executive Research and Development programme. It is being undertaken by University College London.

The aim of the project is to find out:

i) how the skin on a person's bottom is affected by wearing pads for different lengths of time
ii) whether changing pads at night affects a person's sleep.

WHO IS INVOLVED?

- The home that you are working in has agreed to participate in the 'skin' part of the study.
- The night staff are primarily involved with the study as it involves night-time pad changing.
- Some of the residents have consented to take part in the study or their relatives have assented on their behalf and they have become subjects in the study.
- One research nurse will visit the home once a week early in the morning.
- Another research nurse will visit once a week in the evening.

WHAT WILL HAPPEN DURING THE STUDY?

The study will last for ten weeks, for the first two weeks there will be no change to the subjects' routine. However, they will wear the standard incontinence pads that we provide and follow a standardised skin care regime. The 'morning' research nurse will visit them and take the skin measurements in the pad area.

During the next four weeks the subjects will follow one of two regimes:

A) Pads changed three times a night
B) Pads changed twice time a night

For the following four weeks they will swap over and follow the other regime.

Throughout this period the 'morning' research nurse will visit the home early in the morning and will take some measurements from the subjects' skin. She will also visit later on one or two morningss a week to look at the subjects' skin in the pad area.

*For the research to work it is important that you do not tell the **'morning'** nurse how many times during the night the subject is having their pad changed.*

The 'evening' research nurse will visit/phone the home twice a week to talk to you about the study and to check if you have any problems.

Each subject will have their own booklet called a *Pad change record.* This contains forms showing which pad change regime is being followed, for the night staff to sign to say that they have changed the pads at the given times.

Some of the subjects may also be observed whilst they sleep using a video camera, this is so we can see how many times they wake up during the night. The research nurses will be responsible for setting up the camera and the video.

WHAT WILL I HAVE TO DO?

The most important thing is to make sure that the pads are changed at the correct times. You will be asked to record that you have done this on the coloured sheets provided in the *Pad change record.*

SKIN & SLEEP STUDY

INFORMATION FOR DAY STAFF

- The residents that are taking part in this study will be using different pads and pants for the ten week period of the trial. The day pads are ***yellow***. Please ensure that these pads and pants are used at all times.

- Residents will also be using special 'Simple' soap and it is important that they only use this soap.

- There will be a cleansing regime in each person's bathroom please follow this regime.

- Wash with soap and water morning and night (and if incontinent of faeces)

- Wash with water *only* at all other pad changes.

- **Please do not put any creams, lotions or talcum powder** on the skin in the pad area.

- Do not use any bubble baths or shower gels.

- If you notice any areas of soreness or red skin please tell the nurse in charge who will notify one of the research nurses. Please do not apply any cream until you have spoken to one of the research nurses.

- If a red area does develop one of the research nurses will visit and advise you of another skin cleansing regime which will be displayed in the resident's bathroom.

- If you have any questions or problems please ring Sinead or Mandy on: 0171 530 3402

Thank you

SKIN & SLEEP STUDY

INFORMATION FOR NIGHT STAFF

- The residents that are taking part in this study will be using different pads and pants for the ten week period of the trial. The night pads are ***blue***. Please ensure that these pads and pants are used at all times.

- Residents will also be using special 'Simple' soap and it is important that they only use this soap.

- There will be a cleansing regime in each person's bathroom please follow this regime.

- Each resident will have a 'pad change record' booklet kept with their nursing notes. For the first two weeks of the study please record the times you change their pads during the night on the white sheet titled 'baseline period'. This will be used as a record of their 'normal routine'

- For the next four weeks you will be allocated a regime to follow with a set time to change the resident's pads, this will be either 'Regime A or Regime B'. It is important that you change the pads at these set times.

- 'The pad change record' contains the forms (Regime A or Regime B) that tell you what time to change the pads and gives room for you to sign to say that you have done so.

- If you are early or late changing a pad or you have had to change one for another reason, please record this in the space provided.

- After you have completed four weeks of one regime you will swap over and follow the other regime. Please continue to sign the 'pad change record' in the same way as before.

- If you notice any areas of soreness or red skin please tell the nurse in charge who will notify one of the research nurses. We will then visit and advise you of another skin cleansing regime which will then be displayed in the resident's bathroom.

If you have any questions or problems please ring Sinead or Mandy on:
0171 530 3402

Thank you

SKIN & SLEEP STUDY

GENERAL SKIN CLEANSING REGIME

It is important that all the residents who are taking part in this study have their bottoms and groins cleaned in the same way when their incontinence pads are changed. Please carry out the following skin cleansing regimes for all the residents:

Soap and water wash *(Using the 'Simple' soap provided)*

This method should be used twice a day:

- in the morning when preparing the resident to get up

and

- in the evening for the final wash before going to bed/sleep

This method should also be used if the resident has been faecally incontinent

- ***Cleaning with water only***

This method should be carried out at all other pad changes.

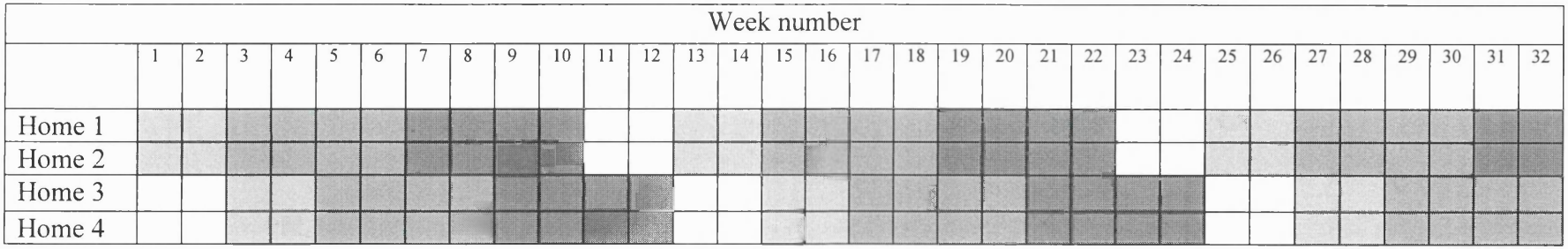
PLEASE DO NOT USE ANY CREAMS ON THE RESIDENT'S BOTTOM.

PLEASE DO NOT USE ANY OTHER SOAPS OR BATH GELS.

IF YOU NOTICE ANY RED AREAS ON THE SKIN PLEASE NOTIFY THE 'EVENING' RESEARCH NURSE OR YOUR UNIT MANAGER.

~Thank you~

Timing of data collection periods for Homes on study



	Baseline period
	Regime 1
	Regime 2

Faecal incont Key:
0 = None
S = Smear
M = Moderate
L = Large

Regime A

WEEK 1

MONDAY ***(mon pm - tues am)*** **DATE:**

Pad change time	Actual time pad changed	Faecal incontinence (See key)	Signature	It is *very* important for the success of this research that you do change the pads at the given times. Please make a note in the space provided if any problems have occurred.
10-11pm				
2-3 am				
6-7 am				

TUESDAY ***(tues pm- wed am)*** **DATE:**

Pad change time	Actual time pad changed	Faecal incontinence (See key)	Signature	It is *very* important for the success of this research that you do change the pads at the given times. Please make a note in the space provided if any problems have occurred.
10-11pm				
2-3 am				
6-7 am				

WEDNESDAY ***(wed pm - thurs am)*** **DATE:**

Pad change time	Actual time pad changed	Faecal incontinence (See key)	Signature	It is *very* important for the success of this research that you do change the pads at the given times. Please make a note in the space provided if any problems have occurred.
10-11pm				
2-3 am				
6-7 am				

THURSDAY ***(thurs pm - fri am)*** **DATE:**

Pad change time	Actual time pad changed	Faecal incontinence (See key)	Signature	It is *very* important for the success of this research that you do change the pads at the given times. Please make a note in the space provided if any problems have occurred.
10-11pm				
2-3 am				
6-7 am				

Faecal incont Key:
0 = None
S = Smear
M = Moderate
L = Large

Regime B WEEK 1

MONDAY ***(mon pm - tues am)*** **DATE:**

Pad change time	Actual time pad changed	Faecal incontinence (See key)	Signature	It is *very* important for the success of this research that you do change the pads at the given times. Please make a note in the space provided if any problems have occurred.
10-11 pm				
6-7 am				

TUESDAY ***(tues pm - wed am)*** **DATE:**

Pad change time	Actual time pad changed	Faecal incontinence (See key)	Signature	It is *very* important for the success of this research that you do change the pads at the given times. Please make a note in the space provided if any problems have occurred.
10-11 pm				
6-7 am				

WEDNESDAY ***(wed pm - thurs am)*** **DATE:**

Pad change time	Actual time pad changed	Faecal incontinence (See key)	Signature	It is *very* important for the success of this research that you do change the pads at the given times. Please make a note in the space provided if any problems have occurred.
10-11 pm				
6-7 am				

THURSDAY*(thurs pm - fri am)* **DATE:**

Pad change time	Actual time pad changed	Faecal incontinence (See key)	Signature	It is *very* important for the success of this research that you do change the pads at the given times. Please make a note in the space provided if any problems have occurred.
10-11 pm				
6-7 am				

SKIN & SLEEP STUDY

'INTENSIVE' SKIN REGIME

Name of resident: _____

Date: _____

Please apply a thin layer of ***Sudocrem*** to the affected area(s) for 7 days beginning on the date above, at the following times:

- after every *soap and water wash* in the morning and evening
- after every *water only wash*, at every pad change.

The resident will continue on the pad changing regime that they are currently following.

After 7 days the skin will be inspected again. If it is improved the resident will resume the general skin regime.

Subject code :
Date of recording:

Activity	Time(*s*)			Any other comments
Pad change (start time)				
Staff causing artefact movement				
Artefact movement e.g curtain moving				
Self-turning				
Staff-turning subject				
Perodic leg movement				
Snoring				
Anything of note:				

Signed: _____ Date: _____

Pad changing and resident repositioning form: Night of dd.mm.yy

Initials	Night pad used	Minimum frequency of pad change	Minimum frequency of re-positioning	Norton Score	Stage of pressure ulcer if present	Actions	Actions	Actions
A.A.	Extra	4 hourly	4 hourly			Time: Pad changed yes / no Repositioned yes / no Signature:	Time: Pad changed yes / no Repositioned yes / no Signature:	Time: Pad changed yes / no Repositioned yes / no Signature:
B.B.	Extra	4 hourly	4 hourly			Time: Pad changed yes / no Repositioned yes / no Signature:	Time: Pad changed yes / no Repositioned yes / no Signature:	Time: Pad changed yes / no Repositioned yes / no Signature:
C.C.	Extra	8 hourly	4 hourly			Time: Pad changed yes / no Repositioned yes / no Signature:	Time: Pad changed yes / no Repositioned yes / no Signature:	Time: Pad changed yes / no Repositioned yes / no Signature:
D.D.	Extra Plus	8 hourly	8 hourly			Time: Pad changed yes / no Repositioned yes / no Signature:	Time: Pad changed yes / no Repositioned yes / no Signature:	Time: Pad changed yes / no Repositioned yes / no Signature:
E.E.	Extra Plus	8 hourly	8 hourly			Time: Pad changed yes / no Repositioned yes / no Signature:	Time: Pad changed yes / no Repositioned yes / no Signature:	Time: Pad changed yes / no Repositioned yes / no Signature: