AMBULATORY SUB-BANDAGE PRESSURE ASSESSMENT – BACKGROUND AND IMPLEMENTATION

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Declaration

I declare that the thesis has not been, nor is currently being, submitted for award of any other degree of similar qualification

Signed.....

Date.....

Ambulatory sub-bandage pressure assessment – background and implementation

Abstract

Venous leg ulcers are recognised as a major health care problem that has significant cost implications for health services as a well as quality of life issues for sufferers. This thesis presents work undertaken towards the assessment and monitoring of ambulatory sub-bandage interface pressures, on healthy volunteers and patients, as the basis for more in-depth future studies.

The projected study required a literature review concerning the socio-economic aspects, aetiology and healing methods (focusing on compression therapy) of venous leg ulcers, interface and stiffness measurement studies, and contemporary pressure measurement technologies. Gaps in knowledge relating to the effects of walking speed on sub-bandage pressures and the variation of dynamic stiffness indices during movement were identified. The planned outcome was the specification and development of an electronic measurement instrument capable of monitoring sub-bandage pressure during ambulation. This is described as the *Wound Assessment Laboratory* in this thesis.

Such a system was designed and developed and provided an array of 10 pressure sensors and 4 gait indicators. This system was battery powered and allowed wireless transmission of pressure transducer data to a portable computer for analysis and display. The system performed well when tested for linearity, hysteresis, repeatability, noise, drift and crosstalk effects. Due to time constraints and practical issues that are discussed in the thesis, however, it was not possible to completely validate the system in a clinical laboratory context. Consequently, further future investigations are recommended that should include studies involving human volunteers and patients, with the aim of monitoring and characterising sub-bandage force distributions and dynamic stiffness indices at various walking speeds.

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1 Introduction

This thesis describes the specification and development of a device to allow measurement of pressure under a bandage, applied to a human subject, during ambulation.

This objective originally formed part of a much wider proposed PhD study that also included measurements of the pressure and forces applied on people lying on pressure-relieving hospital beds. The plan of work became focused on the measurement of pressure under bandages at the MPhil to PhD transfer stage. The external reviewer considered that the original plan of work was too broad and ambitious. These helpful comments shaped the refinement of the proposed plan of work to that reflected in the body of this thesis.

The original PhD plan called for the application of the pressure measurement system in small scale human volunteer studies to assess the practicality and usability of the developed system. However due to time constraints, this final part of the originally proposed work plan has not been completed. Accordingly this thesis restricts itself to the specification, development and laboratory validation of the pressure measuring system, its software and hardware.

1.1 Skin and soft tissue ulcers

Skin and soft tissue ulcers are recognised as a significant health care problem and have both cost and quality implications for health services. Such ulcers form where predisposing condition impairs the tissue's ability to maintain its integrity or heal damage (Davies, 1993). In addition an ulcer could be considered as an abnormal break in the skin, as the result of cell death or damage (Rainey, 2002).

Various types of such ulcers exist including pressure ulcers, venous leg ulcers, diabetic foot ulcers, arterial ulcers and rheumatoid ulcers (Morison, 1999). Although the causes for each of the above ulcers differ there is a common characteristic, the long period of time they require to heal. For example McGuckin et al. (2000) have illustrated that the healing time for patients with venous leg ulcers can take more than 12 weeks depending on the size.

1.2 Implications of skin and soft tissue ulcers

Skin and soft tissue ulcers are a common, serious and costly medical problem. Venous leg ulcers in particular have high occurrence rates and the costs for management, nursing time spent and treatment are very high, mentioned with more detail in chapter 2. Preventing such ulcers can be proven beneficial for health care systems. The total cost of providing ulcer care to the NHS (National Health Service) is unclear but estimations are in the range of £1 billion, including prevention management, equipment dressings, drugs, litigations, nursing care time and education (Bennet, 1995). A different estimation suggested that the direct costs of treating various ulcers in the United Kingdom are about £450 million annually (Cole-King and Harding, 2001).

The aim of this MPhil study is to identify and develop measures for parameters believed to affect the occurrence of skin and soft tissue ulcers and more particular venous leg ulcers. The programme's literature review (including library and on line search) has shown that physiological measurements could play a crucial role in the improvement of skin and soft tissue ulcer prevention. Such measurements include temperature, humidity, interface pressure, microcirculation readings and others. The outcomes could help the future preventive tools for such ulcers, for example better and more efficient compression bandage design.

1.3 Venous leg ulcers

A leg ulcer can be defined as an area of discontinuity of the epidermis and dermis on the lower leg persisting for 4 weeks or more, excluding ulcers confined to the foot with the major cause of leg ulcer being venous disease accounting for about 70% of all leg ulcers (Rainey, 2002; Hollinworth, 1998). According to Briggs and Closs (2003) the prevalence of patients with open leg ulcers receiving treatment from health authorities is in the region of 0.11% to 0.18% and the percentage of people who suffer from recurrent leg ulceration is likely to be 1% to 2% of the population.

Furthermore the treatment costs are high. Morrell et al. (1998) estimated that in a 12 weeks treatment period for a patient with venous leg ulceration the mean costs are £878 (clinic care)

and £859 (home care). Franks et al. (1995a) estimated that the treatment of 200 ulcer patients over a period of 24 weeks cost £193,000 i.e. about £1,641 for each patient.

Venous leg ulceration can be treated with a number of methods including dressing materials, limb elevation, skin crafting and use of growth factors, drug treatment, venous surgery and compression therapy (Simon et al., 2004). The principal treatment method however is compression therapy which aims to improve the abnormal venous return (Phillips, 2001; Moffatt, 2003).

1.4 Initial aim of the MPhil/PhD study

The initial MPhil/PhD proposal focused on a broad range of chronic ulcers, including pressure and venous ulcers. The prime aim of the investigation was to identify the key parameters such as interface pressure, temperature and humidity and the way in which they influence pressure ulcer formation. A measuring system was to be specified and developed with a view to characterising the interface between a mattress and human subjects. The initial objectives included a critical review of studies related to mattress design, pressure ulcer formation and available measurement technologies. Further requirements included the development and validation of an instrumentation system capable of characterising the interface between a patient and a support surface. The initial study also required the design and execution of a set of trials in the laboratory and the development and initiation of studies in order to attempt to characterise the patient support surface interface. The requirements of the initial aims and objectives led to the design and development of the Wound Assessment Laboratory which is discussed in the next paragraph.

1.5 The Wound Assessment Laboratory

One of the key elements of this project is the identification of measurements that would enable better understanding of the local physical and physiological causes and healing of common chronic wounds.

Such measurements (based on the literature reviews of chapters 2 and 3) include the pressure or force applied to the skin and soft tissues, measurements of skin temperature and humidity. These important measurements may be considered to form the heart of any assessment which allows judgments to be made on the origin, prevention and treatment of chronic wounds. In this thesis this group of key measurements will be described as the Wound Assessment Laboratory (***WAL***) given that with future development and refinement it may be possible to conceive of a single measurement device that captures all of the key variables required to characterize wounds and their progression.

For the present project the Wound Assessment Laboratory includes the electronic measurement system that aims to record and monitor sub-bandage interface pressure during locomotion and the set of measurements that were planned to be taken during future studies. Further discussion on the selection and justification of the key aspects that constitute the WAL is included in chapter 4.

Other possible applications of the WAL could include the following:

i) Sub-bandage pressure measurements while the subject is not mobile.
ii) Comparison of sub-bandage pressures for different kind of bandages.
iii) Comparison of sub-bandage pressures with other measurements related to static and dynamic stiffness.

1.6 Change of direction of the research programme

As stated in 1.4 the initial aims and objectives concerned measurements regarding pressure ulcers. However during the execution of the research and instrumentation development it became evident that some change in direction would be beneficial.

The reasons for this were:

i) The developing wound assessment laboratory was displaying a good capability in assessing sub-bandage force distribution in ambulatory subjects. This clearly displayed potential to underpin a deeper understanding of the mode of action of compression

therapy in the treatment of venous leg ulcers as previously indicated. In particular very significant clinical interest was expressed by clinicians in the Cardiff wound clinics.

ii) The new focus of attention aligned closely with an associated study which also required the evaluation of the performance characteristics of a range of existing and new bandage system types. This linkage provides a very strong base for the ongoing research.

iii) During the application for transfer from MPhil to PhD it was suggested by the external assessor that the research should focus only on venous leg ulcers since the linkage between the two fields would be to difficult to handle and overambitious.

The change of direction suggested by clinicians included the clinical advisor of the supervision team. The focus of the knowledge contribution became:

To develop a greater understanding of the nature of sub-bandage compression in ambulatory patients – in particular to question whether pressure and overall pressure distribution correlate with healing of leg ulcers. The revised aims and objectives are shown in the following section.

1.7 Statement of aims and objectives

Following the suggestions of the external reviewer (during the transfer from the MPhil to the PhD), the aims and objectives of the research project had to be changed. The revised aim is shown below:

The prime aim of the current investigation is to identify and monitor the sub-bandage interface pressure during leg movement. A measuring system was to be specified and developed with a view to record sub-bandage pressures while a person is mobile.

The revised objectives are shown below:

i) To conduct a critical review of studies concerning compression therapy application in relation to venous leg ulcer formation. Particular aspects to be examined include the amount of compression that various bandage systems and stocking apply to the limbs

during leg movement. Compression intends to include the sub-bandage interface pressure measurements in locomotion. The outcome was intended to be a formal review detailing the current status of knowledge of how bandage systems and stockings influence venous leg ulcer formation.

ii) To identify and justify key parameters and develop an initial specification for the required measurements of sub-bandage interface pressure in the laboratory and on human subjects. This is to include the initial development of ethics protocols where necessary. The outcome was to be a definition of the required measurements and proposed protocols.

iii) To undertake a critical review of available measurement technologies and commercial systems. This is to involve a number of feasibility and proving studies. The intended outcome was a specification for the measurement system and measurement modes.

iv) To develop and validate the instrumentation system and application protocols using laboratory and human volunteer testing. This would include the operation protocols of the system. The outcome from this stage was the initial prime measurement system.

v) To design and execute a set of trials in the laboratory and on human volunteers for a defined set of compression systems and materials in common use. The required outcome from this was a definitive report indicating comparability of action against product design criteria, versatility in use, and more detailed knowledge of the sub-bandage interface pressure while a human subject moves.

vi) To develop and initiate studies to attempt to correlate the understanding developed in (v) with the effect of compression therapy. Note that ethical approval is identified and required in advance of this phase of work. By necessity this aspect of work was to involve a degree of statistical processing.

Access to patients and volunteers was to be obtained through an established collaboration between the School of Electronics and the Wound Healing Research Unit, Cardiff University.

1.8 Description of thesis

This dissertation comprises a literature review that focuses on the cause, development, healing methods and the socioeconomics aspects of venous leg ulcers. Significant focus is given on compression therapy and the available interface pressure technologies and measuring devices. Finally there is a detailed description of the design and development of the electronic device for the measurement of ambulatory sub-bandage interface pressure.

Chapter 1 includes a brief description of chronic ulcers, focalising on venous leg ulcers. The Wound Assessment Laboratory is briefly described. Furthermore, there is a statement of the aims and objectives, providing details of the evolution of the research programme and the shift of interest.

Chapter 2 details a literature review commenting on the aetiology, socioeconomics and healing methods of venous leg ulcers. The focus lies upon compression therapy, support stockings, pneumatic compression, Unna's boot and compression bandage systems. Section 2.6 provides a discussion on compression therapy analyzing various aspects arising from a number of studies.

Chapter 3 shows an investigation of the key parameters concerning physiological and physical measurements. The chapter focuses on interface pressure and stiffness measurements combined with lower limb compression. Section 3.5 demonstrates various gaps in research in relation to ambulatory measurement studies and provides recommendations for further research based on a number of research questions.

Chapter 4 discusses the available sensor technologies and various sensor issues (for example the characteristics of an "ideal sensor"). Furthermore, there is a description of available pressure measuring devices. Finally the specification and justification for the required measurements and the Wound Assessment Laboratory is illustrated in section 4.4

Chapter 5 describes the design and construction of the Wound Assessment Laboratory, providing information about the technical side of the device and the various phases of

prototype development. Characterisation measurements are included, while there is a description of the problems faced towards the completion of the device.

Chapter 6 constitutes the conclusion of the present MPhil project, providing an overview and giving recommendations for further development and research studies.
Appendix A shows a publication by this author concerning interface pressure measurement technologies and their performance characteristics. In this there is a discussion about the challenges faced during the execution of interface pressure measurements, for example sensor positioning or the effect of clothing on the measurements. There follows a list of project relevant publications to which this author contributed.

Appendix B shows the complete instrumentation system detail including circuit diagrams and images of the testing configuration and each part of the system.

Appendix C shows a detailed discussion relating to the following aspects of venous leg ulceration: aetiology, assessment, prevalence, economic implications, management and healing methods. This research was conducted early on in the project before its redefinition but is nonetheless valuable in the overall context. A summary of these aspects is given in chapter 2 (literature review), however due to thesis size constraints the main volume of the material has been located in appendix C.

2 Venous leg ulcers, critical issues

Venous leg ulcers present a major problem to health systems and may seriously affect patients' life quality. This chapter aims to describe some of the major aspects of venous ulceration and relate the commonest type of treatment (compression therapy) with the current research.

The literature base supporting the work has evolved over a six year period. Searching commenced using the online database MEDLINE, later combined with CINAHL. Relevant citations, such as books and articles were obtained following review of the initial articles acquired. The literature was updated and further increased with manual search at the University of Glamorgan library, by using the Wound Healing Research Unit sources and journal collections and by searching the Cardiff University, College of Medicine Library. Further publications were obtained from the British Library and other internet electronic journals. MEDLINE was searched for relevant papers from 1966 to 2007 using the terms venous leg ulcers, interface pressure, bandage, multilayer, single layer, short and long stretch, economics, management, healing methods, treatment, epidemiology, measurement equipment and other related terms in combinations. Initial searches produced more than 3 thousand publications which however were narrowed down to suit the aim of this thesis. The choice of the studies, used for the current research, was based on the following criteria:

- Original key studies that presented either definitions or theories (for example papers related to the aetiology of venous ulceration).
- Choice of key studies and reviews (mainly published by recognized authors) based on the following key words: interface pressure measurements, physiological measurements, compression therapy, bandages, economic implications, prevalence, interface pressure and movement.
- The focus centred on studies published after 2000. In total around 250 papers were reviewed.

The following paragraphs provide a brief description of the aetiology, assessment, management, healing methods (except compression therapy) and socioeconomic factors of venous ulceration. A much more detailed analysis of wound aspects underlying the work in

this thesis, conducted by this author as part of the research is provided as a reference source in Appendix C.

2.1 Aetiology and assessment

The aetiology of venous ulceration is not completely understood. There are 3 theories that attempt to determine the aetiologic factors. These are:

- The **Fibrin Cuff** theory, suggested by Browse and Burnand (1982), involves the high ambulatory venous pressure and the accumulation of large molecules in the capillaries resulting in occlusion and tissue death.
- The **White Blood Cell Trapping** theory suggests that the occlusion of capillaries is created by white cells, which realise toxic metabolites and eventually lead to ulceration (Coleridge Smith, 1988; Saharay et al., 1997).
- The **Trap Hypothesis** suggests that macromolecules trap growth factors and render them unavailable for the maintenance of tissue integrity and the repair process (Falanga and Eaglstein, 1993).

Successful treatment of leg ulcers requires throughout assessment to allow the diagnosis of the underlying pathology. This detailed assessment in turn provides the foundation for further diagnostic evaluation, determination of the origin of the ulcer, and development of an appropriate treatment method. The initial assessment of a patient should include parameters that characterize patient's general condition. Furthermore the following assessment methods are commonly used:

- Doppler Ultrasound (Rajendran et al., 2007a)
- Tourniquet Testing (Bryant, 2000)
- Plethysmography (Rudolph, 1998; Bryant, 2000; Fernandes Abbade and Lastoria, 2005)
- Colour Doppler Ultrasound (Bryant, 2000)
- Magnetic Resonance Imaging (Nelzen, 2007)
- Phlebography (Vowden and Vowden, 2001a)
- Ambulatory venous pressure (Nelzen, 2007)

2.2 Prevalence of venous leg ulcers

Venous ulceration is a common problem that affects the general population in western countries. The reviewed studies indicate that ulcer prevalence ranges from 0.062% (Baker et al., 1991) to 8.5% (Marklund et al., 2000) (this difference in rates can be explained by looking at the population sizes, i.e. 238,000 for the first compared to 4000 for the second). However, a broader literature review indicates that the average prevalence value is around 1.5% of the population involved in the studies. The populations studied varied from 4000 (Brålanda, Sweden Marklund et al., 2000) to 1 million (Lothian and Health Valley, Scotland Callam et al., 1985). In addition the elderly are affected more from leg ulcers. For example Margolis et al., found that the prevalence in the elderly population was 1.69% compared to 1.2% for younger people (Callam et al., 1985; Cornwall et al., 1986; Baker et al., 1991; O'Brien et al., 2000; Marklund et al., 2000; Wipke-Tevis et al., 2000; Margolis et al., 2002; Graham et al., 2003; Briggs and Josè Closs, 2003; Moffat et al., 2004).

Women develop leg ulcers more frequently than men. The following four studies demonstrate the higher prevalence rates for women:

- Ratio of men to women 1 / 2.8 (Callam et al., 1985)
- Ratio of men to women 1 / 1.8 (Baker et al., 1991)
- The study by O'Brien et al., (2000) reported ratio of men to women 1 / 1.77
- Moffatt et al., (2004) found ratio of men to women 1 / 1.77

Finally venous ulcers significantly affect lifestyle because of chronic pain sometimes combined with discomfort, inability to work and frequent clinic or hospital visits. The studies by Walshe (1995), Hofman et al. (1997), Persoon et al. (2003), Hareendran et al. (2005), Stevens (2006) and Bentley (2006) investigated the impact of ulcers on patients' daily life. A number of significant problems were reported. These are: pain, itching, altered appearance, loss of sleep, leakage and smell, functional limitations and disappointments with treatment.

2.3 Economic implications

The management and treatment of venous leg ulceration consumes considerable recourses from health care services. Costs related to venous ulcers could be divided into "direct" and "indirect" ones. The first category involves the treatments related to the patient (for example NHS or nursing home). The second category includes costs related to society (i.e. lost production by patient or family members, poor life quality that could affect mobility) (Franks and Bosanquet, 2007).

There have been studies that investigated the economic implications of venous ulcer in large scale. For example Wilson (1989) found that the treatment costs range from £150 to £650 million per annum. A more recent estimation by Laing (1992) has shown that treatment costs were from £294 to £650 million per year in the UK. Bosanquet (1992) found that the cost for ulcer care to be between £230 and £400 million for 1990-1991 prices. Table 2.1 summarizes the findings of other studies.

Franks et al., 1995a	Calculated treatment costs for 200 patients with venous ulcers for 24 week period. The cost per healed ulcer was £1964 (£193,000 in total)
Farejsö et al., 1997	Calculated direct and indirect costs of treating leg ulcers in Sweden. For 1 year £197 millions are spent
Morrell et al., 1998	Calculated treatment costs in clinics and at home by nurses. The cost per patient was £878 (in clinics) and £859 (treated home by nurses), in 1995 prices
Marston et al., 1999	Calculated the average cost for 10 weeks of outpatient treatment to be $2198± $445
Tenvall and Hielmgren, 2005	Estimated the cost of treating patients with venous ulcers in Sweden and in the UK for 1 year. The average costs were from €1332 to €2582 in Sweden and from €814 to €1994 in the UK

Table 2.1 Cost implications of venous ulceration

2.4 Management and healing methods

Correct management and treatment of patients with a venous leg ulcer can lead to faster healing, save important resources of health services and significantly improve patient's quality of life. Management and healing of venous ulcer is achieved by addressing the underlying aetiology (i.e. venous and capillary hypertension) and consequently improve venous return, which reduces oedema formation and increases the velocity of blood flow (Bryant, 2000).

Dowsett (2005) has suggested 3 points that relate to ulcer management:

- Reduce blood pressure in the superficial venous system
- Aid venous return of blood to the heart by increasing the velocity of flow in the deep veins
- Reduce oedema by reducing the pressure differences between the capillaries and the tissue

The main treatment technique which effectively manages the underlying factors of leg ulcers is compression therapy and is extensively detailed in the next paragraph. The following list illustrates other healing methods:

- Dressings (Bradley et al., 1999)
- Low Intensity Laser Therapy (Miller, 1996)
- Electrical Stimulation (Moore, 2007)
- Topical Negative Pressure Therapy (Jones et al., 2005; Sibbald et al., 2003)
- Surgical and other types of Debridement (Brem et al., 2004; Fernandes Abbade and Lastoria, 2005)
- Plastic Surgery (Araujo et al., 2003)
- Limb Elevation (Simon et al., 2004)
- Ultrasound Therapy (Peschen et al., 1997)
- Radio Frequency ablation (Bradbury, 2003)
- Endovenous Laser Therapy (Bradbury, 2003)
- Powered phlebectomy (Bradbury, 2003)
- Foam sclerotherapy (Bradbury, 2003)

2.5 Compression therapy

Compression therapy could be defined as the application of external pressure to the lower extremity in an effort to promote the return of blood from the peripheral veins to the central circulation (Reichardt, 1999). While compression has been used for many centuries for the treatment of oedema and other leg disorders, the exact mechanisms of action remain poorly understood (Moffatt, 2007). There are many ways of applying external compression. These are: elasticated bandages, multilayer compression bandages, short and long stretch bandages, elastomeric hosiery (stockings), orthotic devices and Unna's boot (non compliant, plaster type bandage) (Cullum et al., 2001).

The pathophysiological effects of compression are closely related to the abnormal function of the venous system of the legs. Partsch (2003) described the action of bandage treatment stating that the application of adequate levels of compression reduces the diameter of the major leg veins (can be identified by both phlebography and ultrasound). This reduction of diameter results in increased and faster blood flow to the other parts of the body.

Oedema, a condition that develops when the capillary filtration rate exceeds the lymphatic drainage rate for a sufficient period of time, is reduced with the application of compression. The reduction of oedema is the result of the decrease of lymphatic fluid due to compression. It has been reported that increased capillary permeability causes oedema (Moffatt, 2007). There is evidence that diabetics with peripheral neuropathy, that reduced sympathetic tone, had increased capillary permeability (Lefrandt, 2003). However there have not been any studies affiliating the sympathetic nervous system tone with capillary permeability for patients with venous ulcers and therefore this issue was not taken under consideration in the development of this project.

Partsch (2003) stated that compression therapy can be very effective reducing pain and oedema while promoting healing, provided that the level of compression does not affect arterial flow. It should be noted that the sub bandage pressures are influenced by the control of oedema. As the bandage begins to reduce limb swelling sub bandage pressure falls since there is no longer the same squeeze on the now smaller leg.

Moreover it is thought that compression could play a major role in preventing transient ischaemic reperfusion injury to the endothelium and consequently to the development of venous leg ulcers (Moffatt, 2003).Compression bandaging is a very important part of treatment regimen since it counteracts the harmful effects of ambulatory venous hypertension while avoiding the need for bed rest (Bauer, 1998).

The action of compression therapy is also closely related to the internal pressures of the leg. For example in a standing individual the venous pressure is about 80-100 mmHg. During walking however the veins are squeezed by the mechanism of the calf muscle and foot pump which results in reduced pressure (i.e. about 20 mmHg). If the valves are damaged, blood will oscillate up and down in the veins producing backward flow and therefore ambulatory venous hypertension. Compression manages to increase retrograde flow and to reduce venous reflux. The external pressure needed to achieve this effect in a supine individual is about 10 mmHg, while more than 30 mmHg does not increase the beneficial effects of compression. In the upright position the pressure in the lower leg ranges from 20 to 100 mmHg meaning that there is a need for higher external pressures (i.e. 40-50 mmHg) (Moffatt, 2007).

2.5.1 Support stockings

Support stockings (also known as compression hosiery) are used to control oedema, manage varicose veins and aid in the prevention and treatment of venous lymphatic disorders (A colour guide to the nursing management of chronic wounds, 1997). Coull et al. (2005) have provided a table that summarizes the reasons for which compression hosiery are worn (Table 2.2).

- Prevention of venous leg ulcer recurrence following the initial healing of the wound
- Healing of venous leg ulcers
- Primary prevention of leg ulcers where varicose veins are present
- Prevention of deep vein thrombosis (DVT)
- Prevention of complications following DVT
- Maintenance of reduction of lymphoedema in the lower leg

Table 2.2 Benefits from using compression hosiery [Adapted from Coull et al., 2005]

Hosiery exert a resting pressure instead of the high working pressure produced by compression bandages, while their therapeutic characteristics are significantly decreased over the course of 3 to 6 months because of loss of elasticity (Johnson, 2002). Hosiery classification is based on the amount of compression (measured in mmHg) applied to the lower leg. For example there is the German standard (German Standard RAL – GZ 387; 1987), the European Standard (Draft ENV 12718; 2001) and the US standard (Coull et al., 2005). Table 2.3 describes the British standard (BS 6612:1985 Specification for graduated compression hosiery).

Class	Support	Pressure	Condition
I	Light	14-17 mmHg	• Mild varicose veins • Venous hypertension in pregnancy
II	Medium	18-24 mmHg	• Moderate varicose veins • Mild oedema • Prevention of ulcer occurrence
II	Strong	25-35 mmHg	• Severe varicose veins • Prevention of venous ulcers

Table 2.3 British Standard 6612:1985
Specification for graduated compression hosiery (BS 6612, 1985)

2.5.2 Intermittent pneumatic compression

Intermittent pneumatic compression (IPC) could be defined as:" a technique that uses an air pump able to inflate and deflate (periodically) bladders contained into sleeves which envelop legs or arms". IPC implementation can vary. For example compression can be applied either using single of multiple chambers/bladders or by using different types or pumps and compression cycles. IPC has been used to prevent the development of blood clots during long periods of rest and treat limb swelling, lymphoedema and venous leg ulcers (Mani et al., 2001). The device is usually worn for about 1-2 hours at a time and can be used on top of bandages (Anderson, 2006).

There have been studies that investigated the efficiency of IPC. For example in a study in the early 90s Coleridge Smith et al. produced a randomized trial involving patients that had an ulcer for a minimum of 12 weeks. Forty five patients were randomly allocated into 2 groups,

the first one comprising of 24 patients (control group – mean age 58 years) and the second group including 21 patients (Sequential Compression Device (SCD) – mean age 53 years). Both groups received graduated compression stockings that exerted 30 to 40 mmHg. The 2nd group (SCD) however was also treated with pneumatic compression (used on daily basis in their homes – 4 hours per day). Patients were treated until their ulcers were healed or for 3 months maximum. The authors reported that 11% of the total ulcers in the control group were found to have healed by week 12, whereas 48% in the SCD group were found to have healed over the same period. Moreover it was found that the median healing rate for the control group was 2.1% area per week, compared to 19.8% for the SCD group. These results have shown that sequential gradient pneumatic compression may be used as part of treatment of venous ulceration. However as the authors commented the control group had a clinical history of ulcers that had been particularly resistant to healing with standard treatment regimens. Furthermore it is noted that the healing rates of the SCD group may have been due to the patients elevating limbs for longer (Coleridge Smith et al., 1990).

A more recent study by Rowland (2000) attempted to compare the effect of high stretch bandaging versus an intermittent pneumatic compression pump on healing of venous leg ulcers. Sixteen patients were randomized to receive compression therapy using high stretch bandaging (Setopress) or intermittent pneumatic compression pump (Flowtron; HNE Healthcare, Lidcomb, NSW, Australia) for a period of 2 or 3 months depending on the rate of healing. Only 11 patients were assessed and there was not any significant difference either for healing rates or oedema. The author noted the fact that the sample size was too small (only 11 patients). Moreover it was concluded that IPC and bandages have the same effect on ulcer healing rates but a lesser effect at controlling oedema. The IPC treatment appeared to have better compliance by patients.

From these 2 studies it can be seen that IPC can be an effective treatment for venous ulceration. Coleridge Smith et al. (1990) publication demonstrated higher healing rates for the combination IPC and hosiery instead of just compression hosiery. It was noted however that other factors could affect these results, for example more persistent ulcers for the IPC group and longer limb elevation. In the contrary the study by Rowland (2000) did not show any

significant difference between the 2 treatments (Setopress and IPC). Furthermore the sample size was relatively small (only 16 cases).

2.5.3 Unna's boot

Unna's boot is a special gauze bandage that can be used for the treatment of venous ulcers. Named after the physician who originated the concept (Dr. Paul Gerson Unna), Unna's boot is a zinc based paste wrap able to create a conformable inelastic "boot" around the lower extremity. The application procedure is illustrated in Table 2.4.

Unna's boot is recommended for ambulatory patients because it works primarily by providing static support of the calf muscle pump. The decrease of oedema and limb circumference reduces the therapeutic effect of the boot which means that there is usually a need of boot change every week or 2 weeks in some case (Bryant, 2000).

In a recent study Polignano et al. (2004) compared healing rates, handling properties and patient comfort of a four layer bandage system (Profore) and Unna's boot in the treatment of venous ulcers. The study took place in Italy and included 68 patients with venous ulcers. The healing time was recorded for a maximum of 24 weeks. It was reported that after 24 weeks complete healing was observed in 66% of the Unna's group compared to 74% of the Profore group. In addition more Profore than Unna's boot applications were rated as excellent. The authors concluded that Profore 4 layer bandage system can be as effective as Unna's boot when treating venous ulcers.

1.Apply gloves
2. Gently wash extremity and dry
3. Place patient in supine position with affected leg elevated. Foot and leg should be at least a 90 degree angle
4. Open all paste bandage wrappers and cover wrap. Estimate at least two layers of paste bandaging on the leg
5. Holding paste bandage, roll in non dominant hand. Begin to apply bandage at base of toes
6. Wrap twice around toes without using tension
7.Continue wrapping bandage around foot, ankle, and heel using a circular technique, with each strip overlapping the previous strip approximately 50% to 80%
8. Smooth paste bandage is applying and remove any wrinkles and folds
9. Wrap up to knee and finish smoothing
10. Remove gloves
11. Apply cover wrap using the same technique
12. Remove twice weekly, or every other week if indicated by leakage, hygiene or anticipated decrease in oedema.

Table 2.4 Procedure for paste bandage application [Adapted from Bryant, 2000].

2.5.4 Compression bandages

Bandage is a strip of material such as gauze used to protect, immobilize, compress or support an ulcer or injured body parts. Initially bandages were made from woven cotton, a material similar to the paste bandages. Later however rubber was incorporated into bandages and hosiery (Nelson, 1996). Nelson (1996) stated that:"The ideal compression bandage can be defined in terms of its pressure profile – that is, the magnitude, distribution and duration of the pressure achieved – as well as its performance on the limb". Bandage performance is characterized by a number of attributes described by Clark (2003). These are:

Tension: this property is determined initially by the amount of force applied to the fabric during application. However the ability of a bandage to sustain a certain amount of force and therefore tension is designated by its elastomeric properties, which are a combination of the manufacture procedure and the yarns.

Extensibility: This is the ability of a bandage to increase in length in response to an applied force. The terms short-stretch (minimally extensible, inelastic, passive) and long-stretch (highly extensible, elastic, active) originated from this aspect of bandage's performance.

Power: Is the amount of force required to cause a certain increase in the length of an elastic bandage. Therefore for a prearranged extension an elastic bandage produces the corresponding amount of pressure.

Elasticity: Designates the ability of a bandage to return to its original (unstretched) length as the tension is reduced.

Bandages are also classified by the British Standard technical committee. Their scope is to specify requirements for flat, non-adhesive, extensible bandages manufactured from woven or knitted fabrics and to classify them according to their function and performance. Compression bandages can be applied in combinations. Table 2.5 demonstrates those combinations. Table 2.6 illustrates bandage classification into types according to their function.

Combination compression systems
Short-stretch/ inelastic: orthopaedic wool plus 1-3 rolls of short-stretch bandage (e.g. Comprilan by Beiersdorf)
Inelastic paste system: past bandage plus support bandage (e.g. Elastocrepe by Smith & Nephew)
Unna's Boot: Non compliant paste bandage covered with a cohesive compression bandage
Three-layer elastic multilayer: orthopaedic wool plus class 3c bandage (e.g. Tensopress by Smith & Nephew) plus a shaped tubular bandage (e.g. Shaped Tubigrip by SSL)
Four-layer elastic multilayer: orthopaedic wool plus support bandage (crêpe) plus a class 3a bandage (e.g. Elset by SSL) and a cohesive bandage (e.g. Coban by 3M)

Table 2.5 Combination compression systems
[Adapted from Cullum et al., 2001]

Bandage Type	Description	Characteristics and function
1	Conforming stretch bandage	Conforms well to body contours and permits free movement without applying significant sub-bandage pressure. Designed to hold dressings in place and should not be used to apply compression
2	Light support bandage	Used to restrict movement and to provide intermittent sub-bandage pressures
3	Compression bandage	Applied to reduce oedema and facilitate venous return in limbs with varying degrees of venous incompetence. The pressure developed beneath compression bandage is directly proportional to the number of layers used but it is inversely proportional to the diameter of the limb and bandage width. The following are sub-categories of compression bandages.
3A	Light compression bandage	Able to achieve and maintain low levels of sub-bandage pressure. For example up to 20 mmHg on an ankle 23 cm in circumference, when applied with a 50% overlap
3B	Moderate compression bandage	Able to achieve and maintain low to moderate levels of compression i.e. up to 30 mmHg on an ankle 23 cm in circumference, when applied with 50% overlap
3C	High compression bandage	Able to achieve and maintain moderate levels of compression i.e. up to 40 mmHg on an ankle 23 cm in circumference, when applied with a 50% overlap
3D	Extra high-compression bandage	Able to achieve and maintain high levels of pressure i.e. up to 60 mmHg on an ankle 23 cm in circumference, when applied with a 50% overlap

Table 2.6 Bandage classification into types according to function [BS 7505, 1995]

The extensibility of a bandage determines if it's of the short or long stretch type. More specifically:

Short stretch bandages have the ability to maintain a semi rigid cylinder. The inelastic/short stretch materials do not extend when the calf muscle expands, meaning that there is a major increase of pressure as a result of walking or movement. The sub-bandage pressures are raised resulting in greater venous return to the heart due to the actions of calf and foot muscle pumps. Periods of inactivity produce lower pressures however. In brevity, effective short stretch bandaging is achieved through low resting sub-bandage pressures and high working sub-bandage pressures. The majority of short stretch bandages are made of cotton, while the material's weave pattern limits their extensibility. Moreover short stretch bandages are always applied at full stretch which means that less formal training is needed and that they can be applied or re-applied by wound care specialists, patients or carers. This type of bandage can be beneficial when primary and secondary dressings need to be changed more frequently. Moreover the majority of people have an ankle circumference of less than 25 cm therefore needing only 2 layers and avoiding problems like the ankle being hot, sweaty and bulky (Williams, 2002). In addition short stretch bandages have durable construction and contain minimal elastic fibres meaning that they can be washed or used many times without loosing their function and be worn by patients sensitive to rubber materials. However, the ease at which re-bandaging can be undertaken using short stretch bandages provides a greater opportunity for the patients to be non-compliant. Another disadvantage is the need for re-bandaging 12-48 hours after the initial bandage application. Finally short stretch bandages are generally applied in simple spiral technique and double spiral technique (Krishnamoorthy and Melhuish, 2000). The spiral technique is implemented by applying the bandage with a 50% extension (elastic bandage) and 50% overlap ensuring evenness if two layers of bandage are all the way up the limb. The figure-of-eight technique has the same overlap and extension but because of the multiple layers, higher pressures exist (Thomas, 1990).

Long stretch bandages are characterized by their ability to stretch as the calf muscle pump expands. They are made up of elastomeric fibres and can be washed. This type of bandage has the ability to sustain sub-bandage pressure, while their fabrics return to their original length after stretching, resulting in more effective compression, both during exercise and at rest. The

degree of long stretch bandage extension is dependent on the ankle circumference and can be sought from the manufacturer's instructions (Eagle, 2001; Edwards, 1998).

Effectiveness of compression therapy greatly depends on the application of the bandage on the limb which can be proven difficult. Nelson (1995) assessed the bandaging technique of 18 nurses using a pressure monitor. She noted that the pressures achieved were unsatisfactory but were significantly improved after training.

Bandages can be applied on the leg either multilayered or single layered. While single layer application is carried out with the figure-of-eight or spiral technique, multilayer bandage application is more complicated since it involves more types of bandages. Multilayer bandage systems could be divided into two categories (Moffatt, 2007):

Multilayer elastic systems consist of a wool padding combined with a three or four elastic bandages that provide sustained compression. The outer layers may be cohesive in order to provide rigidity and prevent slippage.
Multilayer inelastic systems consist of a first wool padding layer combined with a number of cotton bandage layers applied at full stretch to the limb. The development of the multilayer system (four layer) helped to (Moffatt, 2005; Rajendran et al., 2007b):

- Manage exudate and protect bony prominences
- Sustain sub-bandage pressure
- Provide 40 mmHg of pressures at the ankle
- Overcome disproportionate limb size and shape
- Remain in position on the leg
- Prevention of ulcer recurrence if hosiery is not tolerated
- Symptomatic relief of superficial thrombophlebitis
- Traumatic wounds with local oedema, for example pretibial lacerations
- Venous/lymphatic disorders
- Ulceration of mixed aetiology with an oedematous component

Table 2.7 summarizes the advantages and disadvantages of multilayer and short stretch/cohesive short stretch bandaging.

Nelson described 3 types of multilayer application (Nelson, 1996):

- Two layer: this consists of a base layer of absorbent padding either over vulnerable areas only or for the whole limb with an additional compression layer (Class 3c bandage applied with the spiral technique).
- Three layer: this consists of a first layer of absorbent padding, the second layer being a 3c class bandage applied in spiral and finally a 3rd layer of shaped tubular bandage of a tubular retaining bandage.
- Four layer: it includes a first layer padding, a second layer of crêpe bandage to smooth the 1st layer, a 3rd layer of 3c bandage (applied in a figure-of-eight) and a 4th layer consisting of a cohesive bandage applied with the spiral technique.

Table 2.8 shows the possible 4 layer bandage combinations in relation with the ankle circumference.

	Advantages	Disadvantages
Four-layer bandaging	• There is an abundance of literature and several RCT's to support its use and safety • It is possible to gradually increase bandage pressures so that patients can adjust to the system • Pressures are adjustable by the use of combination of layers so the system is usable for mixed aetiology as well as for venous ulcers • Most community nurses and all leg ulcer specialist nurses know how to apply the system, so training is not an issue and supervision of new practitioners is readily accessible	• The system is bulky, meaning patients are restricted with their footwear and clothing • It can be an expensive option when compared to other systems available • Sub-bandage pressures can be too high or too low and achieving the correct tension is not an exact science, margins for error are potentially high risk • The time spent on application of 4LB can put a lot of strain on the nurses' backs, particularly in a community setting
Short stretch/ cohesive short stretch bandaging	• Only two layers, so less bulky than four • Can be more comfortable to wear at rest for the patient • Quicker than 4LB to apply, so less risk of back injury or strain to nurse • Same bandage is usable for all limb sizes • In the case of CSSB, slippage is less of a problem • Reduced risk of over compression, as the bandage is applied at full stretch. Potential margins for error are lower than 4LB • Has similar healing rates as 4LB • Can be used on mixed aetiology ulcers • Can be used on patients with limited mobility • More chance of patient concordance, as easier and more comfortable to wear • Short stretch bandages can be washed and reused (CSSB cannot) • Is a cheaper system than 4LB even when bandages are not reused	• May need a new training programme to be put in place, as can be an unknown system to many nurses. However the manufacturing companies will often assist • Further RTC studies would be advantageous • Totally immobile patients are usually not suitable for this system

Table 2.7 Advantages and disadvantages of four layer and short stretch bandages [Adapted from Puffett et al., 2006]

Ankle Circumference	Bandage regimen
Up to 18 cm	2 or more wool padding 1 light stretch bandage 1 light elastic bandage 1 cohesive bandage
18 cm to 25 cm	1 wool padding 1 light stretch bandage 1 light elastic bandage 1 cohesive bandage
25 cm to 30 cm	1 wool padding 1 high elastic bandage 1 cohesive bandage
Greater than 30 cm	1 wool padding 1 light elastic bandage 1 high elastic bandage 1 cohesive bandage

Table 2.8 Four layer bandages to accommodate ankle size [Adapted from Eagle, 2001]

Thomas stated: "the degree of compression produced by any bandage system is determined by complex interactions between four principle factors, the physical structure and elastomeric properties of the bandage, the size and shape of the limb to which it is applied, the skill and technique of the bandager, and the nature of any physical activity undertaken by the patient" (Thomas, 2003a). Laplace's law can be used to calculate or predict sub-bandage pressure and hence the level of compression applied to the limb. In brevity factors affecting the pressure that can be achieved under a bandage are given in the equation (Stephen-Haynes, 2006; Thomas, 2003b):

$$P = \frac{N * T}{C * W} \qquad (1)$$

Where

P is pressure exerted by the bandage

T is the bandage tension

C is the circumference of the limb

W is the bandage width and

N is the number of bandage layers

However, the implementation of this equation is questionable. Melhuish et al (2000a) published a study which aimed to investigate the physical forces under long stretch bandages applied at their manufacture's extension/tension and at constant tensions to 3 defined radii ("model limbs"). The writers measured the sub-bandage pressures using temperature compensated strain gauge force transducers. The force was measured under one, two and three layers of 8 long stretch bandages. They stated that the outcomes of this equation may be just an approximation of the actual forces since it can only be correctly applied on hard surfaces. Moreover they observed changes in sub-bandage pressure related to changes in radius, tension, foam hardness and number of layers. Finally it was noted that simple leg movements actually change the sub-bandage pressures.

Numerous articles have been published over the years that attempted to estimate the efficiency or even compare the healing rates and pressures achieved from bandage systems. Phillips (2001) in a publication reviewed venous leg ulcer treatment options and more specifically compression therapy. Her research was undertaken using medical databases like Cochrane and Medline. She concluded that the majority of small venous ulcers of short duration could be treated successfully with compression therapy, while more persistent case could be treated with other methods like surgery or skin grafting. Table 2.9 describes the findings of various studies before 2000. Other studies after 2000 are given in Table 2.10.

More recent publications investigated various aspects of compression therapy. For example Scriven et al. (2000) conducted a study which aimed to develop an alternative graduated multilayer bandage system for the treatment of venous leg ulcers. This alternative system was assessed for graduated compression and was compared with the Charing Cross bandage system. The authors found that the alternative system sustained pressure well and the healing rate over one year was 88%. Brown (2001) concluded that: "It is evident from the literature reviewed that graduated compression is the most effective form of treatment for healing venous leg ulcers. The four layer system appears to be easier to apply and produces more consistent, accurate sub-bandage pressures than single layer bandages and therefore might be safer `choice` of bandage". Table 2.10 demonstrates the results of 3 studies that compared various bandaging systems and techniques.

Aim	Method	Results	Conclusion
Comparison of 4LB system with traditional adhesive plaster bandaging in terms of a) compression achieved and b) healing of venous ulcers (Blair et al., 1988).	One hundred and twenty six patients with venous leg ulcers were randomly assigned with one of 5 dressings. In addition pressure measurements with both types of bandage sequentially, were made on 20 consecutive patients.	4LB produced higher initial pressures at the ankle of 42.5 mmHg instead of 29.8 mmHg for plaster. One hundred and ten out of 148 venous ulcers completely healed within 12 weeks (treated with 4LB).	The 4LB seems to be unique in producing the necessary compression to prevent capillary transudation and able to accelerate ulcer healing.
Estimation of the clinical and cost effectiveness of compression systems for treating venous leg ulcers (Fletcher et al., 1997).	Conducted a systematic review using structured guidelines. The search comprised 19 specialist databases including MEDLINE, CINAHL and EMBASE.	Identified 24 relevant controlled studies. Healing of venous ulcers is improved with compression therapy, while multilayer high compression performs better than low compression systems.	The cost effectiveness of bandages needs further investigation.
Comparison of 2 multilayer bandage systems with 2 single layer compression bandages in terms of consistency of sub-bandage pressures achieved by experienced and inexperienced practitioners (Stockport et al., 1997).	Four bandage systems were used, 2 single layer (Tensopress and Setopress), 2 multilayer systems (Charing Cross and Profore). The bandages were applied by 37 health professionals (25 nurses, 12 doctors). Pressures were measured using an Oxford Pressure Monitor II (Talley).	Considerable variations in pressures achieved by practitioners (10-20%). Multilayer bandaging is not likely to achieve dangerously high pressures.	Demonstrated that multilayer bandage systems are easier to apply. Moreover, more consistent pressures are obtained than single layer compression bandaging. 4LB should be the bandage of choice when using high compression treatment.
Comparison of the efficacy of compression bandages of varying pressure and material (elastic, long-stretch Vs inelastic, short-stretch bandages, 4LB) (Partsch et al., 1999).	Twenty one patients with venous leg ulcers were recruited, while venous volume and venous filling index was measured using an air plethysmograph. Pressure measurements were undertaken from patients while wearing elastic, inelastic and multilayer bandages.	The initial median value of venous filling index without compression was 8.45 ml/sec. For 25 mmHg of external pressure this value decreased to 3.25 ml/sec, while for elastic material and 40 mmHg pressure the venous filling index was 4.25 ml/sec.	For same sub-bandage pressure it was shown that inelastic materials and 4LB are more effective at reducing deep venous refluxes.

Table 2.9 Bandage studies before 2000

Aim	Methods	Results	Conclusion
Comparison of the performance of 2 compression systems (multilayer elastic – Profore and short-stretch – Comprilan) in the treatment of venous leg ulcers in a randomized controlled trial (Ukat et al., 2003).	Eighty nine patients with venous leg ulcers were divided into 2 groups. Forty four received Profore while 45 were bandaged with short-stretch bandage.	There was significant evidence that patients treated with Profore healed faster (2.9 times faster over a 12 week period). Furthermore costs were lower for the Profore group. Analytically €1345 for the short stretch and €587 for Profore, while for healed ulcer €5502 and €1845 respectively.	Profore multilayer compression system healed ulcers faster than short-stretch for less spent funds.
Comparison of 2 systems of high compression elastic bandaging, the 4 layer bandage system and the 2 layer bandage system, for venous leg ulcers. Furthermore record secondary factors like withdrawals from the treatment, adverse events and cost of care (Moffatt et al., 2003).	Fifty seven patients were randomized to 4LB (Profore™) and 52 to 2LB (Surepress™). The duration of the trial was 24 weeks or until closure of all areas of ulceration.	Eighty eight percent of the patients randomized with 4LB had ulcer closure compared with 77% of the 2LB group over the 24 week period. While unit cost for the 4LB was higher, the cost per week was higher for patients in the 2LB group because of the higher frequency of dressing changers i.e. $119.87 (£79.91) on 4LB and $125.34(£83.56) on 2LB.	Patients tolerated the 4LB better than the 2LB, with fewer withdrawals from treatment. Furthermore better healing rates are achieved with 4LB. costs are higher with 2LB due to increased number of bandage changes.
Comparison of the differences in compression produced on a limb using a spiral and a figure-of-eight bandaging technique (Coull et al., 2006).	A sample of 26 experienced nurses and trained in bandaging were selected. Bandage stretch and overlap were measured. Pressure measurements were recorded on both techniques. This procedure took place in 1999.	Pressures were statistically significantly higher with the figure-of-eight than the spiral technique. Differences in pressure in mmHg were 20.3, 22.2, 9.4 and 0.9 for ankle, gaiter, calf and knee respectively.	Both techniques provided graduated compression. However the figure-of-eight method produced higher pressures at ankle, gaiter and calf. Replications of the study should be made but using padding layer as well.

Table 2.10 Studies comparing bandage systems and techniques

2.6 Further discussion on compression therapy

While compression therapy (either applied as intermittent pneumatic compression, Unna's boot, hosiery or bandages) remains the basic and commonest treatment for venous ulceration the exact mechanisms of action remain poorly understood. The intention of the present thesis is to explore the sub-bandage interface pressure that develops when a person walks at a controlled speed. Therefore this analysis will focus only on bandage research and outcomes.

Over the years many research and clinician groups attempted to assess the characteristics of bandages and bandage systems by conducting various measurements. Most of the published studies dealt with comparisons concerning long and short stretch bandages or multilayer and single layer bandage systems, or even different limb bandaging techniques (for instance figure-of-eight and spiral).

For example studies by Thomas (1990), Williams (2002) and Krishnamoorthy and Melhuish (2000) explored characteristics of short stretch bandages stating that their effectiveness is achieved through low resting sub-bandage pressures and high working sub-bandages pressures. Furthermore it is noted that short stretch materials have durable construction and can be beneficial when primary or secondary dressings need to be changed more frequently. However there is a need for re-bandaging after 12-48 hours of the initial application since there can be a decrease of sub-bandage pressures. In the contrary Eagle (2001) has suggested that long stretch bandages can be more effective since they are able to sustain sub-bandages pressure while their fabrics return to their original length after stretching.

Nelson (1995) stated that the effectiveness of compression greatly depends on the application of bandage on the limb. Modes of application include single layer (figure-of-eight, spiral technique), multilayer which can be divided into another 2 sub-categories, elastic and inelastic. The two last techniques differ in the outer bandages. Rajendran et al. (2007b) and Moffatt (2005) noted some of the advantages of the development of the multilayer technique

.

The compression produced by a bandage or a bandage system is a complex interaction and according to Thomas (2003a) it is the outcome of 4 principle factors (as mentioned in page 26).

One way to calculate or predict the amount of compression is by the use of Laplace's law. Melhuish et al. (2000) however questioned its use, saying that the outcomes of this equation are only an approximation of the actual forces. This statement is also supported by Partsch (2005a) who measured interface pressure and stiffness of short-stretch and long stretch bandages applied with variable strength on 12 volunteers. The measurements took place while the individuals stranded or lied in the supine position. For some bandages the measurements differed up to 10 or more mmHg, showing that interface pressures change dynamically depending on other factors, in this case position. In addition, difficulties appear from the transducers used and the measuring equipment (will be discussed in detail in the next chapter). For example Harries and Pegg (1989) stated that interface pressures between bandage and leg are notoriously difficult to measure and depend upon the underlying tissues and the calibration of accuracy of the instrumentation used.

The recommended standard pressure that should be obtained under compression bandaging has to be in the range of 30 to 40 mmHg (Casey, 2004). However Moore (2002) stated that there has been little research to support this figure and pressures may need to be much higher to reverse venous hypertension. In addition he noted that there is also little research to demonstrate whether optimal pressures are achieved under bandages and if these are sustained.

Another area of debate concerns the effectiveness and healing rates achieved by various bandages and bandage systems. For example Fletcher et al. (1997) produced a review paper that concerned studies conducted in the 90's regarding the clinical and cost effectiveness of compression systems. The authors concluded that high compression performs better when applied as multilayer system rather than low compression and single layer, mentioning however the quality of research in the area was poor mainly due to small sample sizes and other deficiencies (for example lack of bandage application description). Stockport et al.

(1997) also favoured the multilayer compression. They stated that bandage systems are easier to apply and achieve more consistent pressures when compared to single layer compression.

A similar category of comparisons, conducted by 3 scientific groups (Moffatt et al. 2003, Ukat et al. 2003, Iglesias et al. 2004), focused on the cost and clinical effectiveness of 4 layer bandage systems and short stretch bandages (both normal and cohesive). All groups stated that both the 4 layer and short stretch bandages achieve similar healing rates. All however declare that there is a slight superiority of the 4 layer system, either because it seemed to achieve higher healing in the early stages of treatment or because this system can sustain better compression and can be tolerated better than the short stretch type. Ukat et al. were more specific noting that the 4 layer system achieved 2.9 times better healing than short stretch (more information about these studies can be found in Appendix C). In the same research area Coull et al. (2006) favoured the spiral bandage application technique (for high compression bandages) instead of the figure-of-eight method. The main difference, according to Coull et al. (2006), is that the latter technique produces high pressures at certain areas, like the Achilles tendon.

A major area in the research is associated with the ambulatory sub-bandage pressure. As described in this section all measurements in bandages' studies were carried out while the subject sat or stood still (apart from those that did not include volunteers). The present chapter has focused on most of the aspects associated with venous ulceration, for example aetiology, epidemiology, and economic implications. It has also described various healing methods illustrating the importance of compression therapy. There is however the field of physiological measurements research which is centred on sub-bandage interface pressure measurements (either standing still or moving) and their difficulties. This area of research, also related to the current project, is extensively reviewed in the next chapter, demonstrating and reviewing previous work and the issues arising from such measurements.

2.7 Summary

Chapter 2 has provided a brief description of the aetiology, management, socioeconomic aspects and healing methods of venous leg ulceration. The analysis focused on compression therapy and more specifically compression bandages (sections 2.5 and 2.7).

A review of the related studies suggested the following:

- Although compression bandages are extensively used, their mode of action is not completely understood.
- While 30 to 40 mmHg of compression is generally considered to be the most appropriate for healing, there has not been adequate research to support this figure.
- There are not enough studies to prove the effectiveness of long stretch over short stretch bandages.
- Effective bandage application can significantly improve applied pressure and consequently healing rates.
- The use of Laplace's equation, when characterizing sub-bandage pressure, is questionable and it can only produce approximations of the amount of compression.
- Multilayer compression is more effective than single layer bandages and can sustain pressure for longer periods.

These outcomes and in general the discussion in this chapter form the basis of the analysis in the following chapter, regarding sub-bandage interface and stiffness measurements, and provide useful information towards the specification of the Wound Assessment Laboratory and the required measurements.

3 Key assessment parameters

In the literature concerning the prevention and treatment of venous ulcers, assessment is commonly associated with physical and physiological measurements. There has been a focus towards the measurement of microcirculation; temperature; body plethysmography, interface pressure and stiffness of the lower limbs (Grant, 1985; Hirai, 1999; Steins et al., 2001; Maskell et al., 2002; Yukata et al., 2002; Partsch, 2005b; Sayre et al., 2007).

In literature the baseline and commonest parameter measured is interface pressure and there have been articles that focused on the difficulties and accuracy of such measurements (Clark, 1994; Finnie, 2000; Bethaves, 2002).

The following sections outline physical and physiological measurements that dominate literature, describe interface pressure and stiffness and finally discuss the gaps in research associated with ambulatory sub-bandage measurements.

3.1 Physiological and physical measurements

Physiological measurements (related to wound healing) belong to a group of measurements that help to determine the aetiology and the progress of healing over time (Flanagan, 2003). Physiological measurements are sometimes confused with physical measurements. The 1st category includes measurements that relate to body's physiology (for example blood flow and skin temperature) while the 2nd type concerns the measurement of physical forces applied to the body (for example external pressure). Physiological measurements have been used extensively in venous ulcer research. Table 3.1 illustrates the type of measurement and the corresponding study.

However for the purposes of this thesis the focus will be on physical measurements and more specifically interface pressure and stiffness.

Microcirculation	Pascarella et al., 2005 Wollina et al.,2005 Steins et al., 2001 Gschwandtner et al., 2001 Melhuish et al., 2004
Temperature	Kelechi et al., 2003 Cherry and Wilson, 1999 Sayre et al., 2007 Santilli et al., 1999 Robinson and Santilli, 1998
Plethysmography	Gobbard et al., 2001 Warwick et al., 1994 Haenen et al., 2001 Maskell et al., 2002 Bauer et al., 2002
Venous pressure	Ibegbuna et al., 2003 Yukata et al., 2002 Fukuoka et al., 1998 Oduncu et al., 2004 Schneewind, 1954 Fronek et al., 2000

Table 3.1 Physiological measurement studies

3.2 Interface pressure

Interface pressure can be defined as external pressure (usually measured in mmHg) transmitted from the body surface to the underlying skeleton (Kosiak, 1959). This term is mainly used in pressure ulcer research for the measurement of pressure between the patient and the support surface (Clark, 1994; Fletcher, 2001). Interface pressure measurements are undertaken in health care as useful tool to assist in understanding the pressures that exist between the skin surface and another surface, for example a bandage (Finnie, 2000).

The measurement of interface pressure has been used extensively in pressure ulcer research field in order to assess the damage risk (i.e. pressure needed to cause capillary blood occlusion, ischaemia and consequently pressure ulcer) for patients lying in various support surfaces. The outcomes have been used to characterise new bed technologies. For example Hardin et al. (2000) examined the relative effectiveness of a dynamic low air loss (LAL) mattress and a static fluid mattress in reducing the risk of pressure ulcer development. This investigation consisted of two parts:

i) A comparative laboratory study
ii) A retrospective clinical study

The laboratory study compared the relative effectiveness of the two products in reducing tissue interface pressures at 3 interface sites (sacrum, trochanter and heel). Six healthy volunteers took part with mean age of 35 years. The subjects lied in supine and side lying positions, while the interface pressures were measured using the Xsensor Pressure Mapping System (Xsensor Technology, Corporation, Calgary, Alberta, Canada). This device comprises of a high resolution sensing pad which contains 1024 capacitive sensors. The authors reported an accuracy of 10% of the device. Table 3.2 demonstrates the results.

Site	Low Air Loss	Fluid Mattress
Sacrum	24.8	31.47
Trochanter	54.75	53.02
Heel	47.82	39.10

Table 3.2 Study results (mean pressures in mmHg)

For the second part of this study, the sample consisted of 73 patients that undergone a heart or liver transplantation (mean age of 50). The study was undertaken over a 2 year period. During the 1st year of the study, patients were placed on the LAL surface, while in the 2nd year the support surface was changed to the static fluid product. It was noted that the length of hospital stay of the static fluid group (16.9 days) was significantly lower than that of the LAL group (22.8 days). Five patients of the LAL group developed a pressure ulcer (13.8%) while only one patient (2.7%) from the static fluid group developed a pressure ulcer. Despite the laboratory pressure measurements which illustrated low magnitudes at sacrum, 4 out of 6 pressure ulcers were developed at the sacral area (for the LAL group). The authors, however, stated that there are parameters that could explain these ulcers. These are (Hardin et al., 2000):

i) The magnitude of the shear forces developed at the interface between patient and support surface.
ii) The laboratory study consisted of healthy volunteers.
iii) The volunteers were dressed in normal clothes.
iv) Interface pressure measurement sites could not be standardised across subjects or across products because of the nature of the measuring device.
v) The body build was not taken under consideration.
vi) The static fluid mattress seemed to distribute pressure better than of the LAL surface.

Other studies concerning interface pressure measurements and comparisons of effectiveness of support surface are illustrated in Table 3.3. In venous ulcer research however the outcomes from interface pressure measurements have been used to characterise and compare products (bandages and stockings) and to help practitioners improve bandage application and to avoid pressure damage. For example Melhuish et al. (2000b) investigated the physical forces under long stretch bandages applied at their manufacturers' extension/tension and at constant tensions to 3 defined radii ("model limbs"). The bandages were applied to 3 rigid plastic tubes and were covered with a layer of foam (Allevyn, Smith & Nephew). Furthermore the pressures were assessed under one, two and three layers of one of the long stretch bandages, with the transducer mounted under the 1st layer on the foam. The pressures were measured using a resistive transducer. It was concluded that the sub-bandage pressure results form a complex relationship between the bandage type, tension, radius, number of layers and surface hardness.

Table 3.4 demonstrates some example studies that used interface pressure measurements as a tool for the evaluation of compression systems.

Description	Equipment
Comparison of the sacral interface pressures obtained in 4 mattresses, in two positions adopted for surgical procedures in order to determine the differences and similarities between them (Scott et al., 1999)	Force Sensing Array (Vista Medical) comprising of an array (15x15) of sensors each 2.5 cm x 2.5 cm
Comparison of 8 foam mattresses with a standard 130 mm hospital mattress in order to define their ability to reduce the incidence of pressure ulcer formation and to provide comfort. The mattresses used were: Clinifloat, Cyclone, NHS standard contract 120mm, Omnifoam, Softform, STM5, Therarest, Transfoam, Vapourlux (Collier, 1996)	Talley Pressure Monitor 3 (96 sensor interface pressure monitor), Talley Medical
Comparison of interface pressures between 3 different mattresses (Nimbus II, Pegasus Airwave, Quattro DC2000) (Pring, 1998)	Oxford MKII
Interface pressure measurements were taken at the ischial tuberosities, sacrum and heels, while the subject sat upright and lied supine in an ambulance. The study identified any shifts in pressure from one side of the subject to the other during changes in moving speed. The interface pressure measured between a standard ambulance stretcher and a spinal board was compared (Parnham, 1999)	Oxford Pressure Monitor (Talley Medical)
Evaluation of the efficiency of 2 anti decubitus cushions comparing the interface pressure and transcutaneous oxygen pressure measurements. The cushions under test were Soft Care and Reston TM. (Colin et al., 1995)	The interface pressures were recorded using an electro pneumatic device which consisted of a 20 cm^2 sensor.

Table 3.3 Example studies employing interface pressure measurements

Description	Equipment
Fourteen nurses bandaged the same limb with 2 different 4 layer bandage systems: i) the "Charing Cross" system ii) a modified 4 layer system. The efficacy of the bandaging was quantified using a sub-bandage pressure monitor (Taylor and Taylor, 1999)	Three channel bandage pressure monitor, constructed from a range of commercially available components. The reported accuracy was ± 0.5 mmHg
Forty three patients were randomized to be treated with either long or short stretch bandages. Pressure measurements were measured regularly for up to 1 year (Danielsen et al., 1998)	Oxford Pressure Monitor (Talley Medical)
Twenty five healthy volunteers were bandaged with a 4 layer bandage system in order to test the use of low-cost sub-bandage system and a pulse oximeter, as a part of quality control measure for graduated compression bandaging (Satpathy et al., 2006a)	Three low cost interface pressure monitors (Kikuhime Sub-Bandage pressure monitor) manufactured by Harada Corporation (Japan) were used for the measurements
Comparison of the performance of 4 commercial 4 layer bandage systems when applied to the leg. The systems used were the Profore Regular [Smith and Nephew], Ultra-four [Robinson], System 4 [Seton], K-Four [Parema](Dale et al., 2004)	Borgnis Medical Stocking Tester (MST) placed at 3 anatomical points (ankle, gaiter and mid-calf)

Table 3.4 Example studies that use interface pressure as a tool in the evaluation of compression bandages

Undoubtedly, the measurement of interface pressure is a difficult task. Harries and Pegg stated that: "Interface pressures between bandage and leg are notoriously difficult to measure and depend upon the underlying tissues and the calibration and accuracy of the instrumentation used" (Harries and Pegg, 1989). The reliability and accuracy of interface pressure measurements depend upon:

i) The electrical and physical characteristics of the sensors and the recording devices.

ii) The measurement procedure, for example the sensor positioning.

Grant (1985) produced a list of characteristics of the ideal sensor. These are:

i) It should be small, for example 1mm thick and 10mm diameter; highly flexible without distorting the readings.

ii) It should have continuous electrical output, impervious to all body secretions, and be able to withstand severe mechanical abuse.

iii) It should be able to measure shear as well as normal perpendicular pressure.

iv) Should be of low cost.

Ferguson-Pell (1980) stated that the perturbing effect of the sensor during an interface pressure measurement is a matter of considerable concern. Using mathematical analysis and based on results from previous studies, regarding pressure measurements between support surfaces and subjects, he suggested that the maximum sensor diameter should not exceed 1.4mm. The author, assuming that a 5% difference between mean and peak pressures is acceptable, produced the following formula:

$$r' = 3P_o / 40k \quad (2)$$

Where

k is a constant

P_o is the peak pressure at the centre

r' is the radius of the sensor

In the same study Ferguson-Pell attempted to estimate maximum sensor thickness, noting however that thickness depends upon the amount of flesh at the point of measurement and the thickness of the support surface. When the pressure beneath a compression bandage is measured, errors may be significant if the thickness of the pressure transducer is excessive. Ferguson-Pell produced the formula shown in the next page:

$$d = \frac{l}{2}\sqrt{\left(\frac{lP}{2Et}\right)} \qquad (3)$$

Where

l is the diameter of the sensor

P is the perturbation pressure

E is the stiffness of the bandage

t is the thickness of the bandage

It was suggested that the behaviour of a pressure sensor is a function of both of the sensor's thickness and diameter. An aspect ratio (thickness: diameter) between 1/30 and 1/10 is indicated.

Grant (1985) stated that the thinner and more flexible the sensor, the more reliable the reading, while Melhuish et al. (1997) declared that a large sensor may change the profile of the limb such as to disguise the true nature of the readings. In addition Wertheim et al. (1999a) wrote that the interference of a thick pressure sensor could alter the results, thus a low profile sensor could minimize these side effects.

Another source of error can be the inability of the sensor to measure accurately pressure on curved surfaces. Since the human body is not flat, a rigid and large sensor might not show the actual pressure. Grant (1985) said that when pressure measurements are taken with curved surfaces, the sensor should be able to comply with the surface contour. Therefore sensor testing should include known loads on surfaces of varying radii of curvature. Ferguson-Pell (1980) however mentioned the possibility of the introduction of spurious signals when the planar sensor surface becomes spherical. These spurious signals are the side effects from the production of stresses or local distortion of the sensing materials. Reger et al. (1988) undertook calibration and clinical measurements using human volunteers, in order to establish the boundaries of agreement among the common pressure evaluating systems using a practical measurement protocol.

The author compared 4 electro pneumatic systems which were:

i) PSP-1 from Gaymar Industries.
ii) Scimedics sensor from Scimedics Inc.
iii) Pressure Evaluating Pad (PEP) from Texas Institute of Rehabilitation Research.
iv) Oxford Pressure Monitor from Talley Medical.

The method for the curved surface testing involved the placement of a bowling ball (7.3 kg) on the sensor, which rested on a 3 inch thick polyurethane foam cushion. It was concluded that the shape of the load was found to be critical for the accuracy and reproducibility of the sensors.

The environment in which measurements are taken could produce unwanted effects changing the behaviour of the sensor. A change in temperature could affect the electrical characteristics of a sensor, while environmental humidity and moisture might produce errors or permanent damage to some sensor (Ferguson-Pell, 1980). Gyi et al. (1998) suggested that suitable sensor protection should be applied when measurements are affected by temperature or humidity.

Other considerations regarding the reliability of interface pressure measurements relate to the manner that the measurements are carried out. Finnie (2000) listed some of these issues. These are:

- Leg shape.
- Effect of posture.
- Effect of time.
- Sensor placement.

The human limb is not a symmetrical cylinder. There are big differences between each individual with variations in underlying bone, fat and subcutaneous tissue. Taking under consideration the analysis by Ferguson-Pell (1980) it could be said that a measurement at a curved anatomical point combined with a large sensor could seriously affect the outcomes. In

addition Dawson et al. (1988) noted that tissue differences make the standardization of pressure measurement very difficult.

Furthermore the change of posture can have significant effect when undertaking measurements. A change in the muscle tone of the leg could increase or decrease the reading shown by the pressure recording device. For example Mosti and Mattaliano (2007) assessed the validity of measuring changes of sub-bandage pressure and leg circumference in different body positions for an in vivo characterization of the elastic properties of bandage system. Fifty patients (mean age 54 years) were included in the study. The strain gauge (used to measure stiffness) and the pressure probe were placed at the point B1 of the leg (i.e. on the medial aspect of the calf behind the tibia). Six different compression bandages were applied on the leg. The variations of interface pressure and leg circumference were measured simultaneously by a pressure monitor (Kikuhime, TT Medi Trade) and a strain gauge plethysmograph (Angioflow2, Microlab, Padua, Italy) during the following manoeuvres:

- Supine position with 3 dorsiflexions.
- Standing up from the supine position.
- Tip-toeing for 10 times.

The authors found that the sub-bandage pressure varied between 40 and 70 mmHg depending on bandage type and strength of application. It was noted that the pressure increased during dorsiflexion, standing and tip toeing. Partsch (2005a) measured interface pressure and stiffness of short stretch and long stretch bandages applied with variable strength. Twelve healthy individuals (aged between 26 and 65 years) participated in the study. Pressure measurements were taken using the Kikuhime pressure sensor (TT Medi Trade) at the B1 point of the leg. The subjects were asked to lay in the supine position and stand in order to complete the measurements. The interface pressure between supine and standing varied between 2 to 33 mmHg.

Another variable that affects sub-bandage pressure measurements is the effect of time. For example Hafner et al. (2000) studied the interface pressure between the leg and 8 different multilayer bandage systems during postural changes (sitting, standing, and supine), exercise

(walking on a treadmill – 200 m at 3.2 m/s) and over 2 days of wear time, using the Oxford Pressure Monitor (Talley Medical). The study included 10 healthy volunteers (aged between 26 and 65 years). Twelve sensors were distributed as follows:

- 3 points at medial aspect of the leg
- 2 points at the lateral aspect
- 1 point at the medial lateral space
- 1 point at the retromalleolar space
- 1 point at the distal dorsum of the foot
- 1 point over the wrist
- 1 point at the pretibial area
- 1 point at the Achilles tendon
- 1 point at the calf

For the 2 days of wear time, readings were taken after the bandaging and after 6, 24 and 48 hours. The measurements illustrated a pressure loss depending on the wear time and the 4 layer bandage system worn. Initially (after six hours) the pressure loss was more intense, slowing down until the last measurement (after 2 days). The pressure decrease ranged between 6 to 18 mmHg (depending on the compression system) (Hafner et al., 2000). Placing the sensor, before the commencement of the measurements, is a challenging task. For example the lateral or medial aspects of the leg are mostly fleshy and tend not to have prominent bone above the malleolus, while the anterior aspect tends to be bony (Finnie, 2000). Each of these anatomical points could show a different pressure reading. Melhuish et al. (2006b) investigated the physical parameters of an elasticated tubular bandage (Tubigrip) on the leg and in durability studies. The study involved 6 healthy volunteers and 16 patients. Pressures were measured while subject stood and in the supine position. It was concluded that: "the location of the force transducer on the lower leg can greatly influence the recorded pressure. Transducers should not be placed on hard bony areas as they can give high point loading errors". From literature research it is unclear where the optimal points for sensor placement are. Table 3.5 demonstrates a number of studies and the positions at which the sensors were located. Finally Gyi et al. (1998) noted a technical difficulty. They stated that if a sensor is

fixed with tape, the tension of the sensor could create errors. Other measurement issues, closely related to the electronics and the sensor characteristics, include type of technology, creep, hysteresis, accuracy, precision and resolution (extensively analyzed in chapter 4).

Description	Equipment	Sensor location
Assessment of the validity of measuring changes of sub-bandage pressure and leg circumference in different body positions for an in vivo characterization of the elastic properties of bandage systems (Mosti and Mattaliano, 2007)	Kikuhime (TT Medi Trade)	Point B1 of the leg (Medial aspect of the calf behind the tibia)
Investigation of the effect of creep, friction and angle of bandaging on the pressure profile of the compression bandages (Ghosh et al., 2007)	Prototype system consisting of 3 strain gauge sensors	Ankle, calf and knee. No specific points were mentioned (in cm)
Measurement of the interface pressure and stiffness of elastic short stretch and inelastic long stretch bandages, applied with different compression strengths (Partsch, 2005a)	Kikuhime (TT Medi Trade)	On the leg behind the edge of tibia at the height of B1 (between 10 and 15 cm above the medial malleolus)
Definition of the pressures and gradients achieved by different bandages when applied by alternative bandaging techniques (Lee et al., 2006)	Borgnis Medical Stockings Tester (MST), which comprises of 4 pressure sensors	Ankle (5 cm above the lateral malleolus), gaiter point (8 cm ankle point), calf (11 cm above gaiter point), upper calf (11 cm above the calf point)

Table 3.5 Anatomical points used for sub-bandage interface pressure measurements

3.3 Pressure measurement and limb compression

The effectiveness of compression bandages depends on the amount of compression (or sub-bandage) pressure that is applied to the limb. If the pressure is low the bandage is ineffective, while if the pressure is too high, pressure induced damage may take place (Partsch et al., 2008). Section 3.3 attempts to answer the following questions:

- How much pressure does a bandage apply (based on classification systems)?
- Is graduated compression achieved?
- How long does a bandage apply pressure for?

Pressure measurements are closely associated to the various types of compression systems. For instance the classification of bandages is based on the amount of pressure they exert on the limb. Table 2.5 (chapter 2) demonstrates the British Standard (7505:1995) classification for the elastic properties of flat, non adhesive, extensible fabric bandages. In addition bandages are also categorized according to their elastic properties (Table 3.7).

Partsch et al., (2008) provided a table with the "practical stretch" of a bandage (%) on the human leg to achieve a sub-bandage pressure of 40 mmHg in the gaiter area (23cm circumference) (Table 3.6).

	Inelastic		**Elastic**
	Rigid Non stretch	**Short stretch**	**Long stretch**
Practical Stretch (%) 1N/cm width*	0-10	20-50	40-120

*For a bandage with 50% overlap exerting 40 mmHg at the gaiter area (B1)

Table 3.6 "Practical stretch" of bandage [Adapted from Partsch et al., 2008]

While the classification of compression bandages provides useful information about the amount of pressure they exert on the limb, in literature Stemmer (1969) set the gold standard stating that the recommended sub-bandage pressure of 40 mmHg at the ankle gradually reducing to 20 mmHg just below the knee is needed in order to achieve graduated compression. Effective compression bandaging is critical for leg ulcer care. There have been numerous studies that attempted to achieve graduated compression. For example Blair et al.

(1988) achieved graduated compression in a study that concerned the comparison of 4 layer bandage system with a traditional adhesive bandaging in terms of compression achieved and healing of venous ulcers. The 4 layer bandage system produced higher pressures at the ankle (42.5 mmHg) which was kept for 1 week while the adhesive plaster produced much lower initial pressure at the ankle (29.8 mmHg) which however fell to 10.4 mmHg after a day. Furthermore it was reported that the healing of venous ulcers was much faster with the 4 layer bandage system.

Inelastic (Non extensible because the fibres used in their construction are crimped and do not recover their original length).	**Short Stretch Rigid**	These bandages have the ability to maintain a semi rigid cylinder. The inelastic/ short stretch materials do not extend when the calf muscle expands, meaning that there is a major increase of pressure as a result of walking or movement (Williams, 2002; Krishnamoorthy and Melhuish, 2000; Partsch et al., 2008; Lee et al., 2006).
Elastic (Contain elastomers, latex or elastane, which return to their original length after stretching).	**Long Stretch**	These bandages are characterized by their ability to stretch as the calf muscle pump expands. They are made up of elastomeric fibres and can be washed. This type of bandage has the ability to sustain sub-bandage pressure, while the fabrics return to their original length after stretching, resulting in more effective compression, both during exercise and at rest. The degree of long stretch bandage extension is dependent on the ankle circumference and can be sought from the manufacturer's instructions (Eagle, 2001; Edwards, 1998; Partsch et al., 2008; Lee et al., 2006).

Table 3.7 Elastic properties of bandages

Danielsen et al., (1998) compared the sub-bandage pressures of 43 patients that received treatment with long stretch and short stretch compression bandages. The bandagers tried to obtain pressure of 40 mmHg 4 cm above the medial malleolus. The authors reported the following figures after a day of wear time:

Long Stretch Bandage		**Short Stretch Bandage**	
≥ 35mmHg ≤ 45mmHg	35.7%	≥ 35mmHg ≤ 45mmHg	16.7%
> 45mmHg	35.7%	> 45mmHg	2.8%
< 35mmHg	28.6%	< 35mmHg	80.6%

Table 3.8 Compression after a day of wear time

Satpathy et al., (2006) produced a study that tested a portable, battery powered pressure monitor as part of quality control process for graduated compression. The study included 22 healthy volunteers and 16 patients. Measurements were taken using the Kukihime sub-bandage pressure monitor (Harada Corp. Japan) at 3 points of the leg (2 cm above the medial malleolus, on the widest part of the calf and on a point midway between them). Initially, pressure was monitored in the supine position with the leg resting on the couch. After the application of the 3rd and 4th layer, the subjects were asked to stand on both feet, while another measurement was taken. Finally 15 out of 25 healthy volunteers participated in a further measurement, which included a gently lift of the leg. Target pressures for 3 and 4 layer bandages were:

Target pressure (mmHg)			
Bandage	**Ankle**	**Gaiter**	**Calf**
3-layer	17 - 24	10 - 15	8 - 10
4-layer	35 - 45	25 - 30	20 - 25

Table 3.9 Target pressures

The results of Satpathy et al. study are illustrated in Table 3.10.

Bandage	Ankle (mmHg)	Gaiter (mmHg)	Calf (mmHg)
3-layer (supine)	22.5 (21.0 - 24.0)	32.2 (30.0 - 34.5)	25.1 (23.0 - 27.3)
3-layer (standing)	28.2 (26.5 - 30.0)	33.7 (27.9 - 39.5)	23.6 (21.5 - 25.7)
4-layer (supine)	32.3 (30.8 - 33.9)	41.5 (39.1 - 43.9)	33.5 (31.2 - 35.9)
4-layer (standing)	38.4 (36.0 - 40.8)	43.5 (40.4 - 45.7)	32.4 (30.0 - 34.8)

Table 3.10 Pressures beneath bandages

The authors stated that the 35 to 40 mmHg pressure at the ankle was achieved only in 36% of the legs by experienced practitioners (healthy volunteers). For the patients however the percentage of successful graduated compression was higher (48%). After reapplication of the bandages the percentage was increased (78%). The authors concluded that training of care providers and nurses is necessary for successful application of compression bandages.

Nelson et al. (1995) produced a study which was designed to answer the following questions:

- What are the bandaging skills of nurses caring for leg ulcer patients?
- What effect does a bandage tension indicator have on bandaging skill?
- Does feedback from a pressure monitor enhance bandaging skill?
- To what extend are improvements in bandaging technique sustained?

Eighteen nurses were asked to use the Granuflex adhesive bandage and undertake the following tasks:

- Baseline: Application of the bandage to a volunteer's leg using his or hers normal bandaging technique.
- Marked Bandage: Each nurse was asked to apply a marked bandage and was informed when the recommended extension had been reached.
- Feedback: Nurses were given feedback on the actual pressures achieved during application of bandages and received guidance from experienced bandagers. The same nurses were invited back for reassessment of their bandaging technique after two weeks.

For the purposes of this study the sub-bandage pressures were monitored with Strathclyde Pressure Monitor at the following anatomical points of the leg:

- Ankle: 4 cm above the malleolus.
- Calf: at the widest circumference.
- Gaiter: at a point midway between the calf and ankle.

The following results were produced:

Mean (95% Confidence Interval)	Baseline	Marked Bandage	After Training	Two weeks later
Ankle Pressure (mmHg)	26.7 (19.3 - 34.1)	26.3 (19.2 - 28)	29.1 (24.5 - 33.7)	36.5 (30.4 - 42.6)
Pressure Ratio $\left(\frac{Calf\ \text{Pressure}}{Ankle\ \text{Pressure}}\right)$	1.05 (0.88 - 1.22)	1.15 (0.9 - 1.4)	0.75 (0.61 - 0.89)	0.7 (0.5 - 0.9)

Table 3.11 Mean values of ankle pressure and pressure ratio [Adapted from Nelson et al., 1995]

Nelson et al. (1995) concluded that although the initial pressure profiles were unsatisfactory, after training and feedback there was a measurable improvement in bandage proficiency (that can be seen from the results – Table 3.11). Lee et al. (2006) investigated the pressures and gradients achieved by different bandages when applied by alternative bandaging techniques. More specifically, the issues under investigation were:

- Do similar bandages give similar pressure gradients?
- How does cohesion affect pressures/gradients?
- Which bandages/application techniques provide the most consistent pressures?
- How does posture affect different bandages/application techniques?

An expert bandager applied 6 different bandages (Actiban-Non cohesive, Comprilan-Non cohesive, Secure Forte-Cohesive, Coban-Cohesive, Tensopress-High compression non cohesive) on the left leg of a 30 year old female subject. Measurements were taken using the Borgnis Medical Stocking Tester at 4 fixed points on the leg (ankle 5cm above the lateral

Malleolus, gaiter 8 cm above the previous point, calf 11 cm above and the upper calf 11 cm above). The bandages were applied using the simple spiral method, the figure-of-eight and the Pütter method (only with non cohesive elastic bandages). It was observed that the mean pressure for all bandages was 30 mmHg ranging from 37.8 mmHg (at the ankle) to 20.9 mmHg (at the upper calf). The authors reported successful graduated compression for 71% of all cases.

Finally Dale et al. (1983) undertook a study which aimed:

- To measure pressures exerted by on commonly used compression bandage on the leg below the knee.
- To measure the pressures exerted by the same type of compression bandage before and after washing.
- To measure the pressures exerted by the same type of bandage combined with a paste bandage.

Only healthy volunteers were included in the project. Sub-bandage interface pressures were measured using the Borgnis Medical Stockings Tester, while two kinds of bandages were used: the Elastocrêpe and Viscopaste PB. Pressure measurements were recorded at the foot, ankle and knee while the subject was standing still. Measurement recordings were taken on application and after 15 and 30 minutes. The authors reported satisfactory initial pressure gradient ranging from 44 mmHg at the ankle to 24 mmHg at mid calf. They noticed however a rapid fall of pressure after 30 minutes (17% at the ankle and gaiter areas and 26% at the calf). The combination of the paste and elastic bandage produced an additive effect which was sufficient to maintain a higher pressure. It was concluded that a combination of Viscopaste PB and Elastocrêpe bandages produces a higher initial pressure which is maintained at a higher level than by the compression bandage alone. Furthermore the evaluation of performance with a pressure measuring device results in a more consistent bandaging technique.

Sub-bandage interface pressure measurements have been used to investigate the effect of time on compression. As mentioned in the previous section (3.2) there is a loss of pressure after

certain periods of time. In an old study Raj et al. (1980) investigated the effect of time on sub-bandage pressures.

The project included 40 healthy volunteers divided into 4 groups of 10, each group receiving a different bandaging, illustrated below:

- Group I: Bandages applied to the whole leg from the toe to the groin.
- Group II: Bandages applied to over STD (compression pad made of polyester foam).
- Group III: Bandages applied between the ankle and the knee joints.
- Group IV: Similar to Group III but compression pads were used.

The bandages used were: Crevic crêpe and fibrospun rayon. The system used for the measurements consisted of a 20 ml syringe, a manifold tap, a pressure transducer, a digital voltmeter and 4 pressure sensors. As the authors stated, the sensors were placed at 3 arbitrary points which were 5 cm above the medial malleolus, 5 cm below the joint line of the knee, 5 cm above the joint line of the knee and mid thigh along the course of the saphenous vein. Recordings of pressure were taken after the application of the bandage and in intervals of 2 hours up to 8 hours. Table 3.12 demonstrates all the sub-bandage pressures. It was concluded that although the initial pressures achieved are at satisfactory level, there is a significant fall in the effective pressure after 6 to 8 hours; therefore there is a need for reapplications of the bandage after 8 hours in order to maintain sufficient pressure.

Table 3.13 (a and b) demonstrates a number of studies and the amount of pressure loss. Although these studies are not completely comparable, since they use different bandages, the positions of the sensors are not at the same points and the periods of time under investigation are not the same; it can be concluded that there is a pressure loss with time. The pressure depends on bandage application, type and most importantly the wear conditions (for example walking while bandaged).

Group I: Whole leg bandage without foam					
	0h	**2h**	**4h**	**6h**	
Ankle	30.5 ± 7.0	18.4 ± 6.0	12.4 ± 6.9	7.62 ± 4.3	
Below-knee	28.1 ± 8.0	18.4 ± 6.0	11.7 ± 4.1	7.9 ± 4.3	
Above-knee	26.7 ± 7.9	16.4 ± 6.9	8.1 ± 7.0	4.7 ± 6.7	
Mid-thigh	23.7 ± 6.2	11.6 ± 5.0	5.3 ± 5.7	1.5 ± 3.1	
Group II: Whole leg bandage with foam					
Ankle	47.0 ± 9.9	30.0 ± 9.6	23.2 ± 8.0	13.3 ± 5.4	
Below-knee	50.0 ± 7.9	33.8 ± 9.6	28.9 ± 8.0	20.9 ± 9.7	
Above-knee	38.4 ± 6.0	20.6 ± 6.5	15.1 ± 9.0	12.4 ± 4.0	
Mid-thigh	30.1 ± 7.1	18.4 ± 4.0	10.6 ± 7.0	2.1 ± 2.0	
Group III: Below-knee bandage excluding the joints without foam					
	0h	**2h**	**4h**	**6h**	**8h**
	66.7 ± 17.2	55.4 ± 14.0	38.0 ± 6.0	30.61 ± 3.3	25.9 ± 4.0
Group IV: Below-knee bandage excluding the joints with foam					
	0h	**2h**	**4h**	**6h**	**8h**
	70.1 ± 14.8	66.2 ± 10.0	44.4 ± 7.0	39.1 ± 5.6	17.8 ± 3.2

Table 3.12 Sub-bandage pressures and time [Adapted from Raj et al., 1980]

Aim	Measurement Points	Pressure Loss and Time
i) To measure the pressures exerted by one commonly used compression bandage on the leg below the knee ii) To measure pressures exerted by the same type of compression bandage before and after washing iii) To measure pressures exerted by the same type of bandage combined with a paste bandage (Dale et al., 1983).	Recording points were spaced at ankle, upper gaiter area, calf and below knee.	For paste bandages the pressure fell by 17% after 30 min (ankle, gaiter area) and 26% (calf). Much slower decline of pressure for the combination of elastocrêpe and PB7. The declines for every part of the limb were as follows: Ankle: From 60 mmHg to 38 mmHg after 2 h Gaiter area: From 55 mmHg to 39 mmHg after 2 h Calf: From 35 mmHg to 31 mmHg after 2 h.
Comparison of 4 layer bandage system with traditional adhesive plaster bandaging in terms of (a) compression achieved and (b) healing of venous ulcers (Blair et al., 1988).	2 cm above the medial malleolus, in the gaiter area, at mid calf and below the knee.	Only with adhesive plaster bandage pressure fell from 35 mmHg to 15.5 after 4 h and to 10.4 after 24 h. For the 4LB from 40 mmHg increased to 44.5 mmHg after 8 h and fell to 36.3 after 24 h.
To compare the sub-bandage pressures of a long stretch and short stretch bandage (Danielsen et al., 1998).	3 sensors at 4 and 8cm above the medial malleolus and the widest circumference of the lower leg.	Long Stretch / Short Stretch Supine: 0.3mmHg ↓ (after 24h), 3.2 ↓ (after 7d) / 9.8mmHg ↓ (24h) Dependent: 1.4 ↑ (24h), 1.1 ↓ (7d) / 9.9 ↓ (24h) Upright: 1.3 ↑ (24h), 0.4 ↑ (7d) / 9.9 ↓ (24h) Walking: 0.7 ↑ (24h), 0.5 ↓ (7d) / 10 ↓ (24h) *

*These measurements are taken from the same number of subjects. It was reported that for various reasons the intended sub-bandage pressure measurements could not be carried out at regular intervals in all cases.

Table 3.13a The effect of time on sub-bandage pressures

Aim	Measurement points	Pressure loss and time
To study the interface pressure between the leg and 8 different multilayer bandage systems during postural changes, exercise (walking and over 2 days of wear time (Hafner et al., 2000).	3 points at medial aspect of the leg, 2 points at the lateral aspect, 1 point at the medial lateral space, 1 point at the retromalleolar space, 1 point at the distal dorsum of the foot, 1 point over the wrist, 1 point at the pretibial area, 1 point at the Achilles tendon, 1 point at the calf.	Interface pressures at the distal medial calf. Bandage Type — Pressure Decrease (after 48 h) 1 — 6.0 mmHg 2 — 8.0 mmHg 3 — 9.0 mmHg 4 — 12.0 mmHg 5 — 10.5 mmHg 6 — 16.5 mmHg 7 — 18.0 mmHg 8 — 11.0 mmHg
To investigate the commercially available compression bandages as regards with their performance with time (Ghosh et al., 2007).	Ankle, calf and knee on a mannequin leg.	For 7 different bandages, the pressure drop after 1000 min Ankle / Calf / Knee 1: 1.01 / 0.31 / 0.31 2: 1.14 / 1.54 / 0.31 3: 0.26 / 0.31 / 0.52 4: 1.27 / 0.85 / 0.48 5: 4.1 / 0.44 / 0.35 6: 1.19 / 0.44 / 0.44 7: 1.36 / 0.39 / 9.12

Table 3.13b The effect of time on sub-bandage pressures

3.4 Stiffness

The European pre-standard for compression hosiery (CEN) defined stiffness as the increase of compression per centimetre increase in the circumference of the leg expressed in hectopascals per centimetre and/or millimetre of mercury per centimetre (CEN European Prestandard, 2001). Partsch et al. (2006) noted that:" This parameter characterises the distensibility of a textile, which plays an important role concerning the performance of a compression device during standing and walking".

Stiffness is divided into 2 categories, static and dynamic. The static stiffness index is defined by the difference between the interface pressure in the standing and lying positions, expressed in mmHg/cm (Partsch, 2005b). Partsch (2005b) stated that static stiffness ideally would be measured at a lower leg level whose circumference will be enlarged by 1 cm by the position change between the relaxed supine position and the active standing position. In the contrary the dynamic stiffness is measured while walking and indicates the pressure increase of the medical compression hosiery when the circumference of the leg increases by 1 cm, expressed in mmHg/cm (Stolk et al., 2004). Both dynamic and static stiffness indices are expressed in mmHg.

Partsch (2005a) produced a study in which the interface pressure and stiffness of short stretch and long stretch bandages, each applied with 3 different compression strengths, were measured. An experienced bandager applied 5 bandages (3 long stretch and 2 short stretch) to 6 healthy volunteers (aged between 26 and 65 years). The bandages were applied initially with low pressure, then with moderate (corresponding to routine pressure) and high pressure in an ascending spiral technique. Sub-bandage pressures were recorded using the Kikuhime sub-bandage pressure monitor (TT Medi Trade) with a single sensor placed between 10 and 15 cm above the medial malleolus. The following Table (3.15) demonstrates the difference of supine and standing pressures for all bandages, for all 3 ways of application (low, moderate and high).

	Low	Moderate	High
(A) Perfekta®super	2.0	7.0	14.5
(B)Perfekta®strong	2.0	5.5	9.5
(C)Velpeau®Vein Plus Forte	8.5	6.0	8.5
(D)Rosidal®	6.0	14.0	23.0
(E)Rosidal®Sys	10.5	21.0	33.0

Table 3.14 Difference between supine and standing position (in mmHg) [Adapted from Partsch, 2005a]

Partsch (2005a) stated that these pressure values (i.e. difference between supine and standing position) can be used to characterize the stiffness of a bandage.

Partsch et al. (2006) compared pressure and stiffness of ready made compression stockings (Venosan) of different classes measured on the leg and by laboratory testing. The stockings under test were: Venosan (Class I, Class I+I, Class II and Class III). In vivo measurements involved 6 healthy volunteers (mean age 42.3years); while in vitro measurements were taken on a wooden leg. For both setups, interface pressure was measured using a medical stockings tester (MST, Salzmann Medico, Switzerland) at the following anatomical points:

- Ankle behind the inner malleolus (ankle).
- 8cm above (where the tendinous part changes into the calf muscle) (gaiter area).
- 19cm above the ankle at mid-calf (largest calf circumference).
- 30cm above the ankle (below knee).

Stiffness was calculated by finding the difference of the interface pressure values between active standing and relaxed supine position. The differences in pressure at the anatomical points were:

- Ankle (-2.96 ± 8.19).
- Gaiter (3.78 ± 3.84).
- Calf (3.06 ± 4.44).
- Below knee (1.96 ± 7.82).

The authors recommended that in vivo stiffness measurements should be carried out at the B1 point of the leg (i.e. 8 cm above the ankle), while the difference of pressure between standing and being in the supine position should be used to calculate stiffness.

3.5 Gaps in research

Sub-bandage pressure measurement studies could be divided into 2 categories:

i) Studies involving static measurements (for instance while standing or being in the supine position). These studies assessed bandages, investigated graduated compression, stiffness and observed the effect of time on bandages (such studies are described in the previous sections).

ii) Studies involving dynamic measurements (i.e. measurement of pressure during exercise, for example walking on a treadmill).

There have been relatively few attempts to characterize the dynamic behaviour of bandages and stockings. Initially Sockalingham et al. (1990) produced a portable sub-bandage pressure measurement system for continuous monitoring of pressures. Their system consisted of 3 parts: the pressure sensing device, a goniometer to determine the posture of the leg and the data logger for recording the output of the measuring devices. The equipment was used to evaluate 3 compression bandages: i) Granuflex adhesive bandage (ConvaTec), ii) Lesterflex bandage (Seton) with Viscopaste (Smith & Nephew) and iii) Elastocrêpe (Smith & Nephew) with Viscopaste.

The single pressure sensor was placed at the midpoint on the line connecting the tibial condyle and the lateral malleolus using surgical tape. All bandages were applied by a professional trained bandager. The data logger was set to record samples at a frequency of 0.3 Hz and was attached to the waist of the subject. Measurements were taken for 7 days for each bandage, while the subject was asked to repeat standard moves every 3 hours (stand, still and lie). Figure 3.1 illustrates a graph relating knee angles and corresponding interface pressures, while Figure 3.2 demonstrates interface pressures at mid-gaiter during standing for 3 bandages. It was found that all 3 bandages generated highest pressure in the standing posture. Furthermore

considerable pressure variations were observed during daily activities and walking. These variations depended on the bandages used. It was concluded that the data provided by only one sensor is limited and that further research is needed to assess other parameters like functional pressure variations and the assessment of their physiological significance.

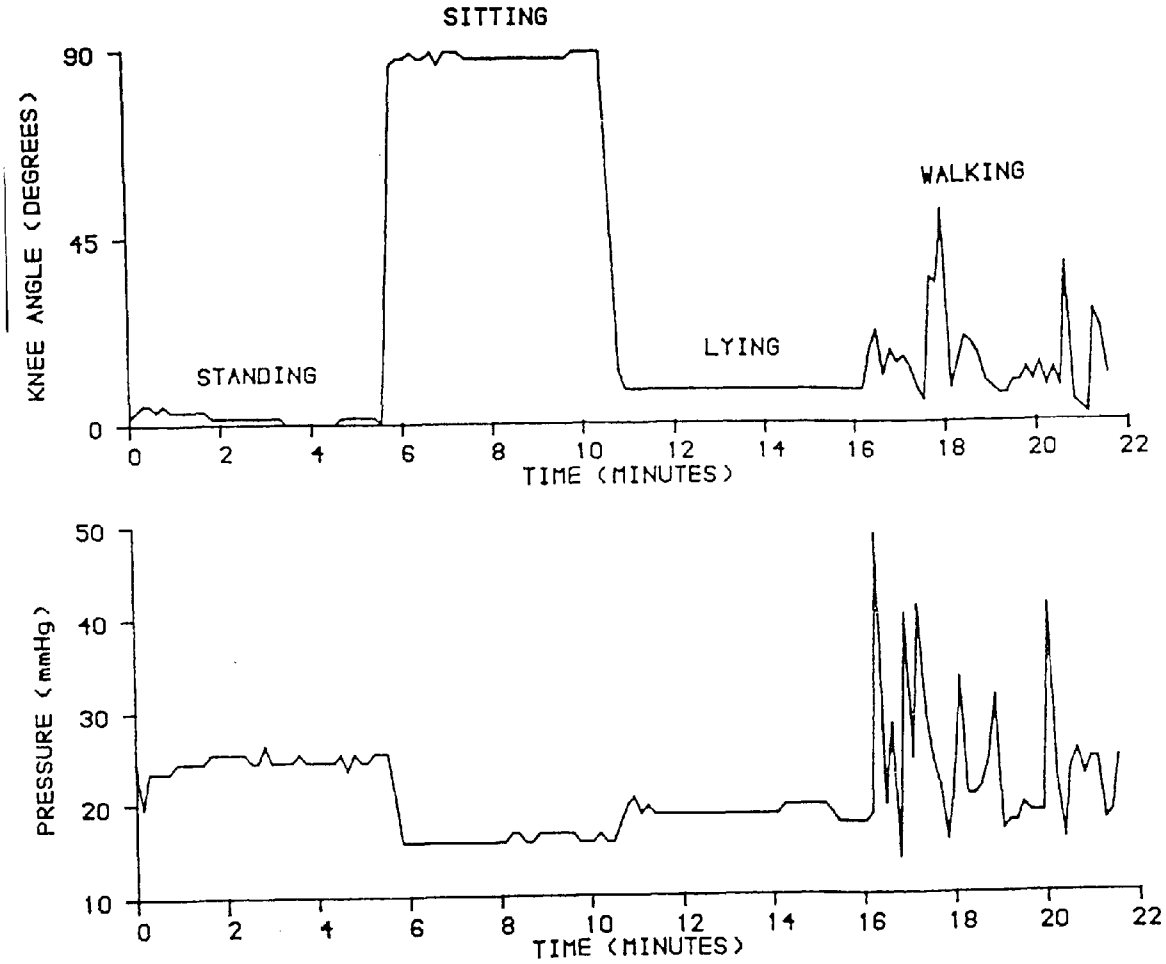

Figure 3.1 Knee angle changes and interface pressures [Adapted from Sockalingham et al., 1990]

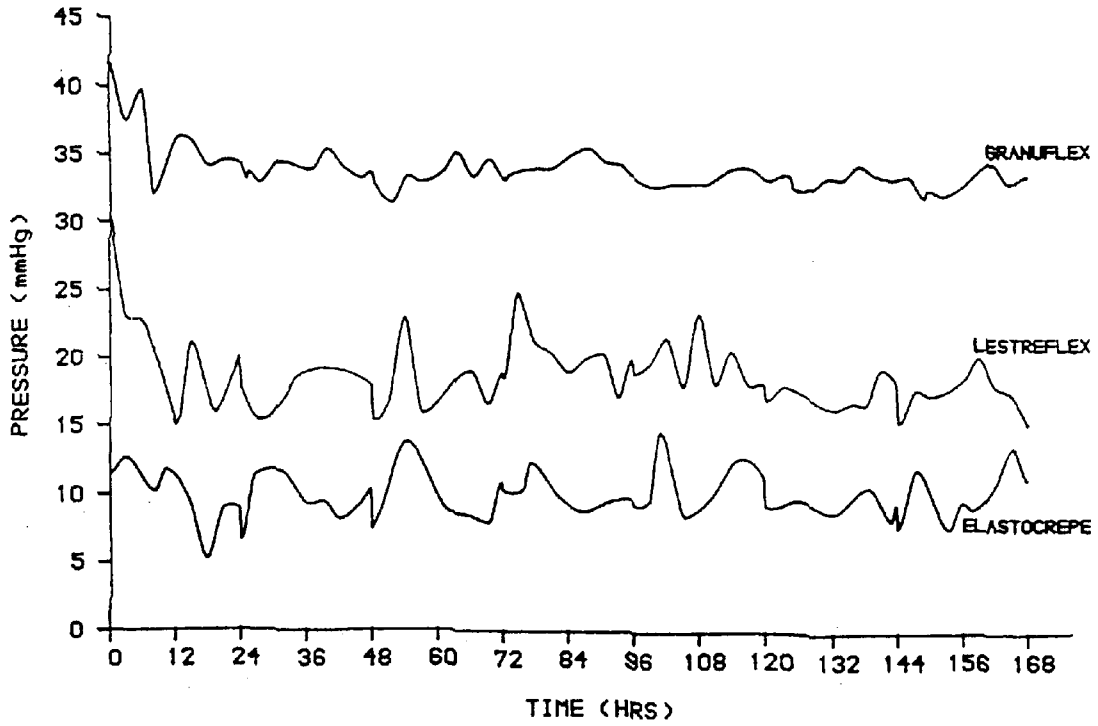

Figure 3.2 Interface pressures at mid-gaiter during standing for 3 bandages [Adapted from Sockalingham et al., 1990]

Danielsen et al. (1998) measured the sub-bandage pressures of 43 patients (randomized to wear long and short stretch bandages) during rest and walking for up to 1 year. This study mentioned walking without however providing any further details (for example where, what speed, under what circumstances, what distance and where were the sensors placed). The measurements were taken using the Talley Oxford Pressure Monitor (Talley Medical), which does not produce continuous output, and are illustrated in Table 3.15

Hirai (1998) compared the pressure profiles obtained under elastic and short stretch bandages and quantified the effect of posture and exercise on compression (observed in relation to the initial pressures at the time of application). Twenty healthy volunteers (mean age 20 years) were included in the study. The compression was measured using an Air Pack Type Analyser (Ami Co. Japan) able to record pressure continuously at intervals of 100 mS (accuracy ±1%).

Walking pressures				
Time	**n**	**Long stretch mean (mmHg)**	**n**	**Short stretch mean (mmHg)**
0h	49	39.1	38	37.8
2h	44	39.1	35	31.3
24h	42	39.8	33	26.8
2-6 days	28	41.6		
7 days	10	38.6		

Table 3.15 Sub-bandage pressures exerted during walking [Danielsen et al., 1998]

The sensors were placed on the posteromedial area of the mid calf on each leg. Two types of bandages were applied on each leg (Elodur – long stretch bandage with a maximal tension of 170% and Compridur – short stretch bandage with a maximal tension of 45%). The bandages were applied in such way, so they could produce a different initial pressure of approximately 10, 20, 30, 40, 50, 60 and 70 mmHg (determined with the pressure measuring device). Hirai stated that walking took place at a speed of 2 steps per second. The following results were obtained (Table 3.16):

Elodur (Long stretch)	**Walking – Mean (SD)**	**Compridur (Short stretch)**	**Walking – Mean (SD)**
10 mmHg	12.4 (3.4)	10 mmHg	13.8 (4.3)
20 mmHg	19.7 (3.6)	20 mmHg	27.2 (7.1)
30 mmHg	31.8 (5.2)	30 mmHg	37.1 (10.0)
40 mmHg	40.1 (4.3)	40 mmHg	51.3 (8.4)
50 mmHg	52.1 (4.0)	50 mmHg	62.5 (8.0)
60 mmHg	62.4 (4.5)	60 mmHg	76.8 (7.2)
70 mmHg	79.6 (10.5)	70 mmHg	99.7 (14.7)

Table 3.16 Walking pressures [Adapted from Hirai, 1998]

The author stated that from the pressure waveform (which however is not included in the study), during tip toe and walking there was a larger pressure variation in short stretch bandages than with long stretch bandages. Furthermore it was observed that when a bandage is applied with forces of 40 mmHg and greater, the sub-bandage pressures during walking do not differ significantly, meaning that there may not be any benefit from such high bandaging

pressures. Hirai (1999) quantified the influence of posture and exercise on the interface pressure obtained under elastic stockings with compression pads. Pressure measurements were undertaken with the method described before (Hirai, 1998). Twenty four healthy volunteers (mean age 20 years) were included in the study. Three compression systems were investigated (Comprinet – Stocking class II, Elodur – long stretch bandage, Comprilan – short stretch bandage). Pressures were recorded 5-10 s during supine resting, standing, tip-toe exercise at 1 s rhythm and walking at a speed of 2 steps per second. Figures 3.3 and 3.4 illustrate the results.

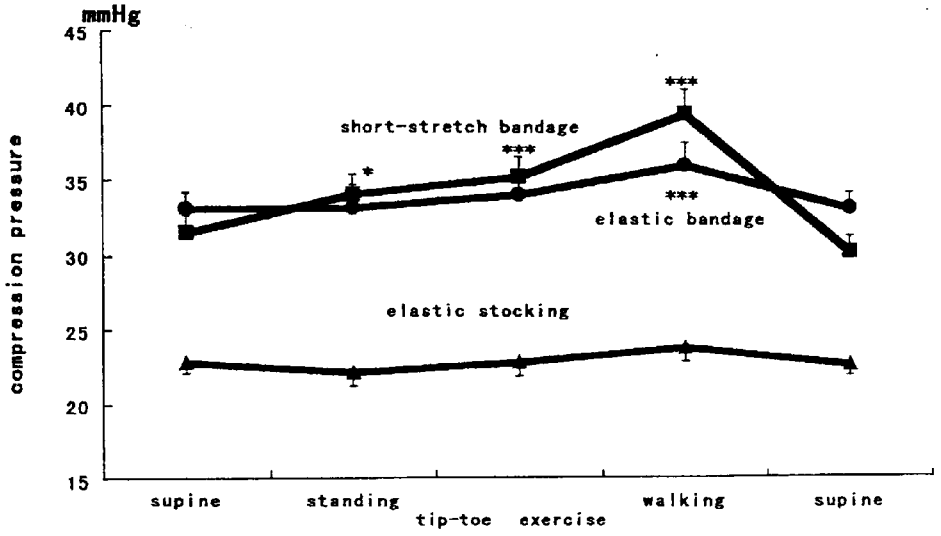

Figure 3.3 Sub-bandage pressures without compression pads at different postures [Adapted from Hirai, 1999]

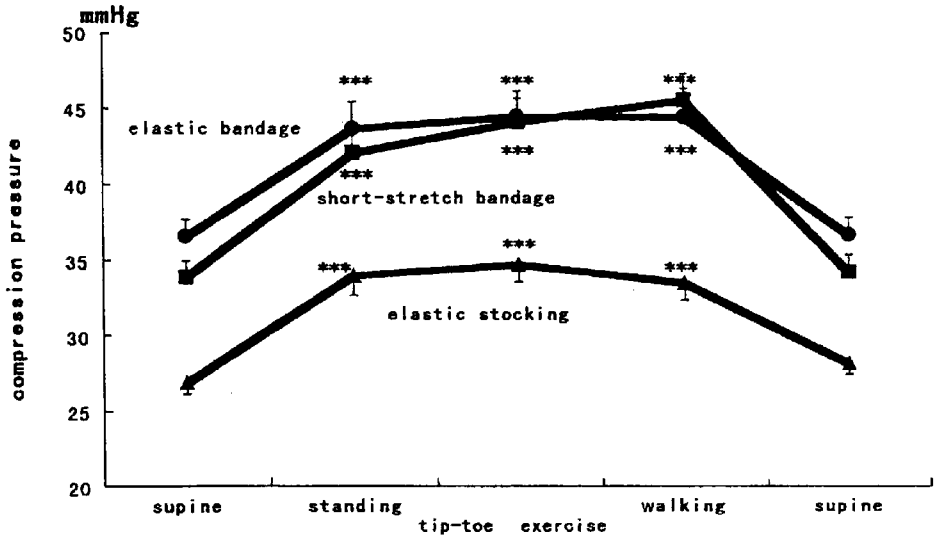

Figure 3.4 Sub-bandage pressures with compression pads at different postures [Adapted from Hirai, 1999]

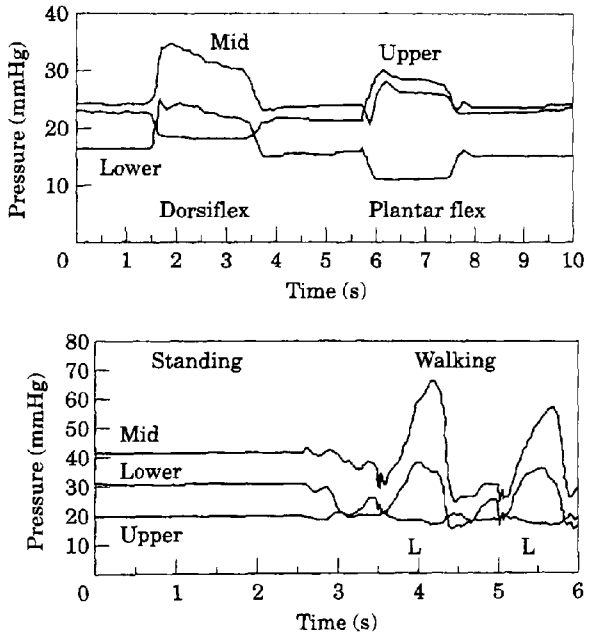

Figure 3.5 Changes in pressure under compression stockings associated with dorsiflexion and plantar flexion of left foot (upper), changes in pressure under compression stockings associated with short period of walking [Adapted from Wertheim et al., 1999c]

Wertheim et al. (1999b, 1999c) developed a system for monitoring sub bandage pressures in order to investigate compression under graduated compression stockings. The study included six healthy volunteers (mean age 42 years). Three Fontanometer sensors (Gaeltec Ltd. Scotland) were placed 9 cm above the medial malleolas, at the largest calf circumference and the 3rd sensor was placed on the upper border of the calf muscle. In addition the researchers placed two Force Sensing Resistors (FSR) on the sole of each foot in order to monitor the walking pattern. After the application of the stocking, pressures were recorded during short periods of standing, including dorsiflexion and plantar flexion, followed by walking 2 or 3 steps. Figure 3.5 shows the continuous output signal that represents the pressures during movement. It was suggested that these variations in pressure may contribute to the calf muscle pump and thus influence ambulatory venous pressure.

Hafner et al. (2000) studied the interface pressure between the leg and 8 different multilayer bandage systems during postural changes, exercise (walking) and over 2 days of wear time. For the measurement of sub-bandage pressures during walking a pressure sensor (from an Oxford Pressure Monitor, Talley Medical – non continuous reading) was placed at the distal medial calf (gaiter area) of the left leg of 10 healthy volunteers. The measurements were carried out while the subject walked on a treadmill during 1 minute at 3.2 m/s and 0^{o} incline. Figure 3.6 illustrates the pressures exerted by the bandage systems. Hafner et al. mentioned that most multilayer bandages generate effective pressure waves during exercise as long as they contain a short stretch or a medium stretch bandage in their composition.

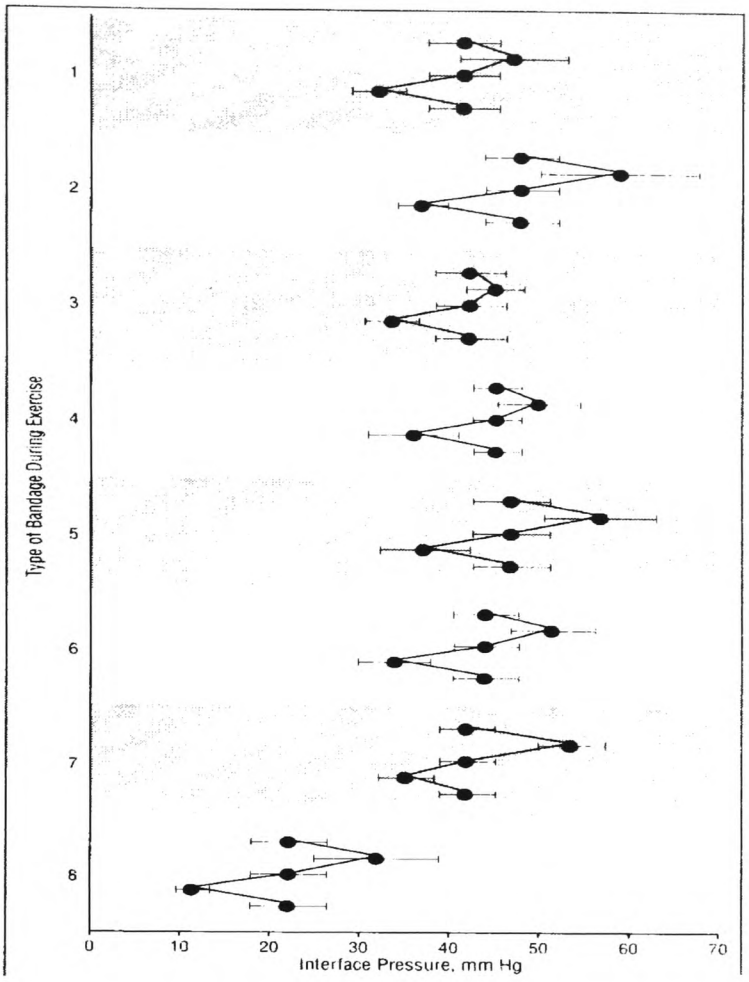

Figure 3.6 Interface pressures during exercise (walking) [Adapted from Hafner et al., 2000]

Finally Stolk et al. (2004) developed a method for investigating the dynamic behaviour of medical compression stockings during walking. Five healthy volunteers (mean age 49 years) participated in this study. Initially the static measurement of the circumference of the lower leg of the volunteers was recorded. This was accomplished by using a flexible metal measuring tape (placed horizontally at 2 cm intervals from the foot to the knee of the standing volunteer). The measurements were performed at 3 positions: i) with the ankle 90° flexion with the foot, ii) with the foot in maximal dorsi flexion and iii) with the foot in maximal plantar flexion.

During these 3 measurements the tape remained on the volunteer's leg. In order to dynamically measure the changes of circumference during walking, the researchers registered the largest differences in the circumference between the maximal dorsi flexion and maximal plantar flexion of the foot that occurred at the level of transition from the gastrocnemious muscle into its aponeurosis (cB1 point according to the European Committee for standardization). At the same time the subject walked on a treadmill (at 5 km/h). The leg was measured both with and without the stocking. The information gathered from the previous 2 stages was used for simulations on an artificial leg segment model (consisted of an air filled drum covered with a rubber skin). An air generator produced a dynamic pressure signal to the drum that could be adjusted for all its parameters (gait cycle, amplitude and form of signal). The same medical stocking worn by the volunteer was placed on the air drum, while the pressure delivered by the air generator produced the same dynamic curve. The signals obtained by the simulated model were recorded using a TruWare pressure transducer. Finally the authors introduced a new term: the dynamic stiffness index which indicates the pressure increase of the stocking when the circumference of the leg increases by 1 cm. This term helped to quantify the dynamic behaviour of the stocking and was calculated by the hysteresis curve produced by the pressure and circumference recordings over time. Using the changes in circumference at point cB1 gathered from the volunteers walking on the treadmill, the authors produced a simulation result shown in Figure 3.7. Furthermore Figure 3.8 illustrates the pressure pattern simulation with the air filled drum. The pressure of the stocking varied between 10.8 and 51.2 mmHg. The hysteresis curve used for the calculation of the dynamic stiff index is shown in Figure 3.9. The index value was found to be 58 mmHg/cm. The researchers concluded that there was a large difference between the pressure of the stocking with the patient at rest and in the ambulant situation and stated that the therapeutic effect of the stocking will depend on the difference between minimum pressure and maximum pressure during walking.

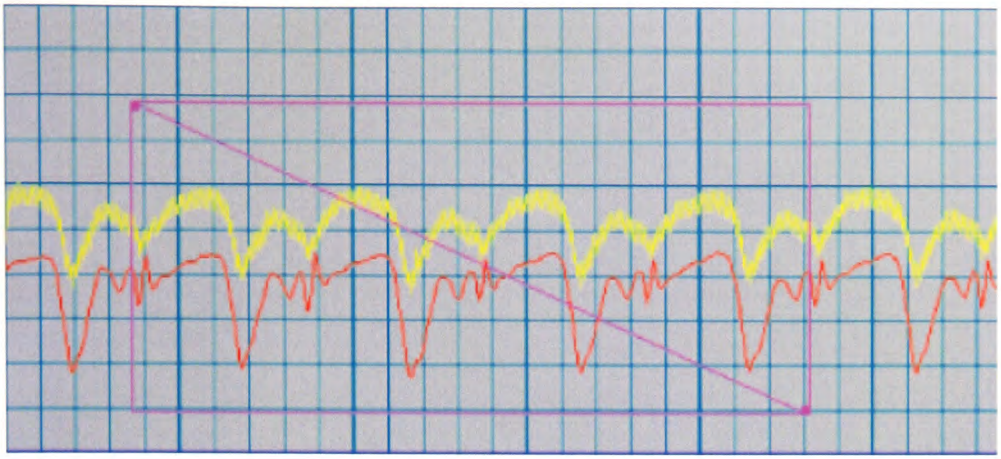

Figure 3.7 Simulation results representing angle and circumference changes on the leg (Yellow line is the ankle angle, ranging from +7° to -23°, while the red line represents the circumference)
[Adapted from Stolk et al., 2004]

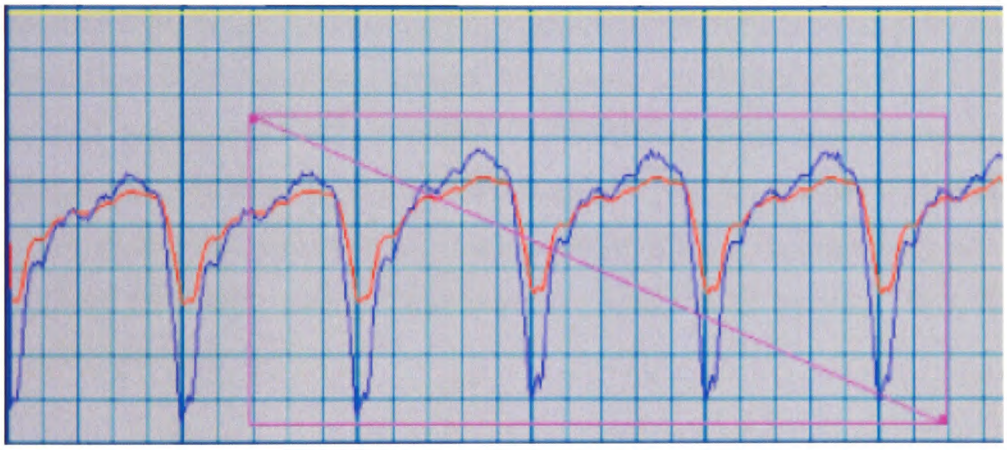

Figure 3.8 Simulation illustrating pressure changes beneath stocking (Blue line is the pressure pattern applied to the leg model in order to simulate the circumference signal from the treadmill – every horizontal block represents 1 s)
[Adapted from Stolk et al., 2004]

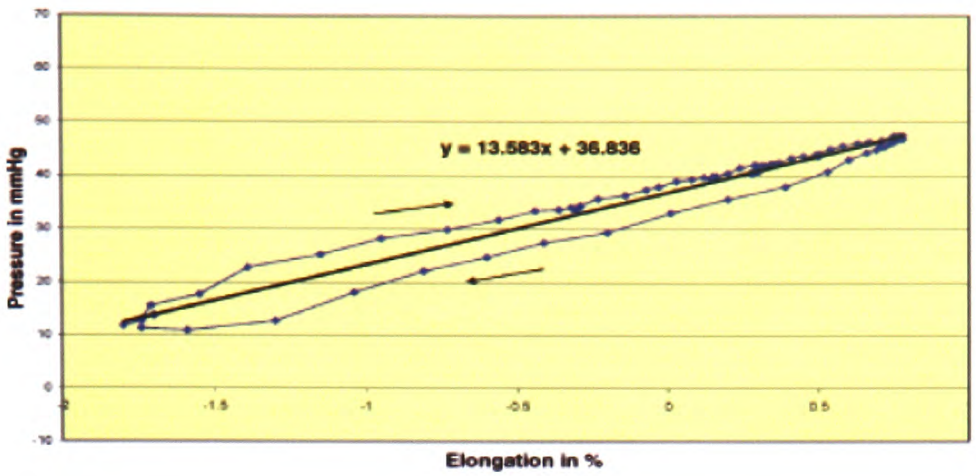

Figure 3.9 Hysteresis curve used to calculate dynamic stiffness index [Adapted from Stolk et al., 2004]

The assessment of the dynamic behaviour of compression systems provides useful information about the variation of sub-bandage pressures during exercise. Wertheim et al. (1999b, 1999c) stated that their system could help to further understanding of the mechanisms of action of compression therapy, while Stolk et al. (2004) suggested that the changes in pressure during walking could explain the effectiveness of compression therapy in ambulatory patients. The studies described show diversities in the pressure produced during walking. These differences can be explained by Table 3.17.

Compression System	Walking Speed	Duration of walking	Measuring Device	Sensor location
3 compression bandages, 2 of them were applied with cohesive layer (Sockalingham et al., 1990).	N/A	Not specified (over a period of 7 days)	Prototype consisting of 1 pressure sensor, goniometer and data logger	Midpoint on the line connecting the tibial condyle and the lateral malleolus.
Long and short stretch bandages (Danielsen et al., 1998).	N/A	N/A	Oxford Pressure Monitor	4 and 8 cm above the medial malleolus and the widest circumference of the lower leg.
Long and short stretch bandages (Hirai, 1998).	2 steps per second	5 to 10 seconds	Air pack Type Analyser*	Posteromedial area of the mid calf.
Long and short stretch bandage, stocking (Hirai, 1999).	2 steps per second	5 to 10 seconds	Air pack Type Analyser*	Distal calf.
Stocking (Wertheim et al., 1999b and 1999c).	N/A	2 to 3 steps	Fontanometer Sensor*	9 cm above medial malleolus, level of greatest prominence of the calf muscle, upper body of the calf muscle.
Multilayer compression bandage systems and Unna's boot (Hafner et al., 2000).	3.2 m/s	1 minute (or 200m)	Oxford Pressure Monitor	Distal medial calf (gaiter area).
Stockings (Stolk et al., 2004).	5 km/h	N/A	Flexible metal measuring tape for measurement of circumference	For circumference measurements (later used in simulation): the measuring tape was placed at 2cm intervals from the foot to the knee.

* Continuous output

Table 3.17 Differences in ambulation measurement studies

From Table 3.17 the following comments could be made:

- **Compression systems**: The studies described included almost all the available compression systems (long stretch, short stretch, multilayer bandages, stockings, Unna's boot). Hafner et al. (2000), Hirai (1999, 1998), Danielsen et al. (1998) and Sockalingham et al. (1990) made comparisons between the systems. However there is not any study that compares the dynamic behaviour of stockings and bandage systems.
- **Walking speed**: Only Hafner et al. (2000) and Stolk et al. (2004) mentioned actual walking speeds. This information however is not correlated with any of the results and there is no explanation of how walking speeds affect sub-bandage pressures
- **Duration of walking**: Hafner et al. (2000) provided details about the duration (1 minute or 200m as distance). Sockalingham et al. (1990) stated that measurements were carried out for 7 days for every bandage, but there is no information of how much time was spent walking. From the data given by Stolk et al. (2004) it could be calculated that the walking time was 6 seconds, which however is not stated by the authors. Again sub-bandage pressures are not correlated with time.
- **Measuring device**: The exact variation of forces beneath compression systems can be monitored with a system that outputs continuous signal or provides a sampling rate that is much faster than the variation of pressures during exercise (for example normal walking at about 5 km/h corresponds to about 4 steps per second). Oxford Pressure Monitor (electro-pneumatic) used by Danielsen et al. (1998) and Hafner et al. (2000) can produce 6 samples per second. Clark (1988) stated that electro-pneumatic sensors prevent the measurement of variations in interface pressure over a period of time. In the contrary Sockalingham et al. (1990), Hirai (1998, 1999) and Wertheim et al. (1999b, 1999c) used a system able of producing a continuous signal and therefore more detailed picture of the pressures.
- **Sensor location**: Almost all studies used one sensor placed at the widest circumference of the calf. Wertheim et al. (1999b, 1999c) used 3 sensors obtaining a better picture of the pressures introducing though more cables and possible measurement errors. Partsch et al. (2000) recommended the following anatomical points under a compression system: B (ankle at point of minimum girth), B1 (area at which the Achilles tendon changes into the calf muscles (~10-15 cm proximal to medial malleolus), C (calf at its maximum girth), D (just below the

tibial tuberosity), E (centre of the patella and over the back of the knee), F (between K and E – mid thigh between patella and groin), G (5 cm below the centre point of the crotch), H (greatest lateral trochanteric projections of the buttock), K (centre point of the crotch).

Adding to these comments the fact that stiffness (both static and dynamic) is simulated in only one study (Stolk et al., 2004) it could be concluded that further research is needed to answer the following research questions:

- How do various compression systems behave at different walking speeds?
- How would the sub-bandage pressures change after certain periods of walking?
- Would detailed monitoring of variation of sub-bandage pressures (with appropriate devices and number of sensors) provide useful information to clinicians?
- How would the sub-bandage pressures of stockings and bandages compare during exercise?
- What would the dynamic stiffness indices for compression bandages and bandage systems be?

3.6 Summary

Interface pressure and stiffness measurements are widely used in clinical studies in order to characterize applied pressure. For example bandage classification or even the effectiveness of graduated compression is specified with the use of pressure measurements. However, from a research perspective there is a difficulty in validating such measurements since there are a number of issues (for example sensor geometry) that could affect the outcome.

Section 3.5 addressed the topic of sub-bandage pressure measurements during activity and provided a number of research questions that form the basis for future studies. The issues raised create the framework for the required measurements and combined with the discussion in chapter 4 lead to the specification and development of the Wound Assessment Laboratory.

Other key findings of chapter 3 include:

- Graduated compression is difficult to achieve.
- The compression is reduced with wear time.
- Interface pressure measurements can be affected by a number of factors i.e. sensor geometry, limb movement and body position.
- Further research is needed to address the variation of sub-bandage forces under various conditions (for example different walking speed).

4 Sensor technologies

The measurement of interface pressure beneath a compression system or between a patient and a support surface may be accomplished by the use of commercial or original measurement systems. This chapter focuses on the available sensor technologies and provides an overview of the pressure monitors that are/may be used in venous ulcer research. At the end of the chapter, the specification for the required measurements system is outlined.

4.1 Physical measurement technologies

A sensor is a device which measures a physical quantity and converts it into a signal which can be read by an observer or by an instrument. The term sensor should be distinguished from transducer. The latter is a converter of one type of energy into another, while the former converts any type of energy into electrical. A sensor is always a part of a larger system which may incorporate many other detectors, signal conditioners, signal processors, memory devices, data recorders and actuators. Sensors can be divided into two categories, passive and active. Passive sensors directly generate an electric signal in response to an external stimulus. In the contrary active sensors require external power for their operation, which is called excitation signal (Fraden, 1997).

Sensor use is widespread in venous ulcer research. They are used for the measurement of microcirculation, temperature, interface pressure etc. The measurement of the latter (interface pressure) is achieved with the use of electronic instruments that comprise sensors that implement different technologies.

4.2 Sensor issues

An ideal sensor is designed and fabricated with ideal materials and it is used in such way that always represents the true value of the stimulus. This however is not possible since the materials, the application and the nature of measurements introduce variables that affect the output.

Undoubtedly the measurement of interface pressure is a difficult task. Sensor dimensions in combination with the characteristics of the human body, usually affect measurements corrupting their reliability. Ferguson-Pell (1980) provided some important design criteria which could be used for the evaluation of a pressure measuring system. Although this list is produced for pressure monitors concerning pressure ulcer measurements; it can also be applied for sub-bandage pressure monitoring. These criteria are shown below:

i) The diameter of the individual sensors should be small relative to the interface curvature to ensure good contact with the skin and for the pressure acting on the sensor to be homogeneous.
ii) Maximum sensor thickness should be at about 0.5 mm. However this is a rough estimation since there can be individual differences in the mechanical properties of the tissues.
iii) Sensors should be flexible to conform the curved surfaces.
iv) There should be good repeatability of the measurements.
v) The sensors should be durable and the recordings not significantly affected by environmental temperature and humidity.
vi) The calibration technique should stimulate conditions at the interfaces being measured
vii) Consideration should be given to the effects of hysteresis.
viii) The sensors should not deform the interface, have optimum sensitivity and range. Moreover be linear at the range of interest.

Diane et al. (1998) added the following to the previous list:

i) Detailed consideration should be given to the actual experimental situation.
ii) Consideration of the output, for example, the measurement of static or dynamic pressure; real time or recorded.
iii) Consideration of any published literature regarding the experiences of other users.
iv) Experimental investigations should be performed on any pressure measuring equipment prior to purchase or use in experiments.

Partsch et al. (2006) summarised the characteristics of an "ideal pressure sensor", illustrated in Table 4.1.

• Size-insensitive to force concentrations
• Flexibility-insensitive to bending, but not distensible
• Durability
• Reliability
• Overload tolerance
• Electronic Simplicity
• Low cost
• Low hysteresis
• Little creep
• Insensitive to temperature and humidity changes
• Continuous output
• Linear response to applied pressure
• High sampling rate – locomotion studies
• Operating range consistent with biological parameters
• Accuracy
• Resolution (time<0.1 sec, amplitude <0.1 mmHg)
• Thin
• Variable sensor sizes

Table 4.1 Characteristics of an "ideal pressure sensor" [Adapted from Partsch et al., 2006]

Other technical characteristics that describe the behaviour of a sensor are given below:

Accuracy: Accuracy refers to how closely the measured value agrees with the true value of the parameter being measured (Kularatna, 1996)

Resolution: Resolution of an instrument is the smallest change in the measured value to which the instrument will respond (Kularatna, 1996).

Precision: Refers to the exactness of successive measurements; it is also sometimes considered as the degree of refinement of the measurement (Carr, 1996).

Hysteresis: For pressure sensors or monitors, hysteresis is the difference in the sensor output response during increased loading and decreased loading at the same force. Figure 4.1 shows a graph with the effect of hysteresis (Fraden, 1997).

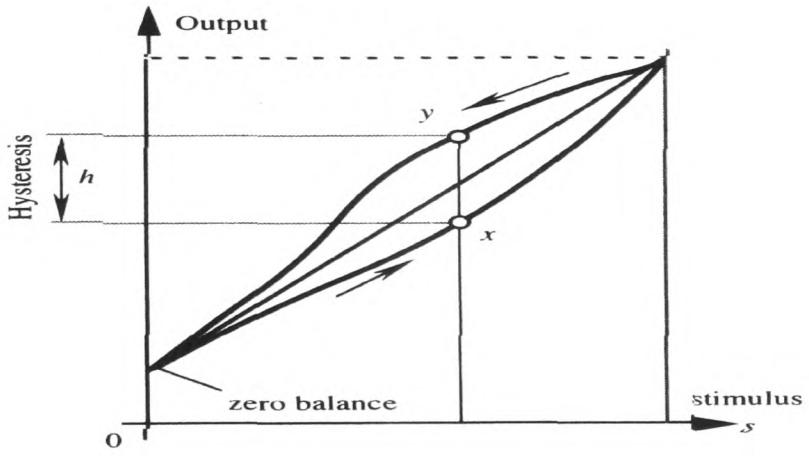

Figure 4.1 Hysteresis while loading or unloading a sensor [Adapted from Fraden, 1997]

Linearity: "Linearity is a measure of the proportionality of the sensor's response to the applied load over the range of loading" (Ferguson-Pell et al., 2000).

Repeatability: Refers to the ability of an instrument to return the same value when repeatedly exposed to the exact same stimulant (Carr, 1996).

Drift: Drift could be defined as the behaviour of the sensor when a constant force is applied over a period of time. The drift of a sensor is usually measured after 1 or 2 hours of constant load. However in some applications the drift may not be so important if the measurements are taken in short time periods (Van Putten, 1988).

Reliability: Reliability is the ability of a sensor to perform a required function under stated conditions or a stated period (Fraden, 1997).

Environmental Conditions: The term environmental conditions usually refers to the room temperature that the measurements are taken. Different temperatures could alter the behaviour of the sensor and therefore change the measurements. A powerful way to improve long term stability is to pre-age the component at extreme conditions, for instance decrease or increase the operating temperatures and record the outcomes for a certain load (Van Putten, 1988).

4.3 Pressure measurement devices

Pressure mapping devices have become commercially available over the last decades. These devices could be divided into two categories:

- The first category includes devices that comprise of a large number of sensors, usually fit into a mat, designed to monitor interface pressure over a large area (for example between a mattress and a patient).
- The second category includes devices that consist of a number of single sensors, designed to measure interface pressure at certain anatomical points (for example at the widest circumference of the leg beneath a bandage).

Pressure measuring devices can also be classified as producing either a continuous output or only intermittent readings:

- **Continuous output devices** give both the pressure and its variation with time (for example devices that are connected to strain gauge sensors).
- **Static pressure devices** give a measure of the pressure at a single instant (for example systems that use electro-pneumatic sensors) (Barbenel, 1983).

Bethaves (2002) has produced a table that presents a selection of commercially available interface pressure measuring systems (Table 4.2). This paper (Bethaves, 2002) is included in Appendix A of this thesis. Moreover Partsch et al. (2006) produced a table that included some of the commercial systems with the type of sensor they use (Table 4.3).

Measuring Device	Pliance (Novel Germany)	Xsensor (Crown Therapeutics)	Oxford Pressure Monitor MKII (Talley Medical)	S7b (Gaeltec)	FSA (Vista Medical)	Clinseat (Tekscan)
Sensor Type	Capacitive Transducer	Capacitive Sensor	Pneumatic	Resistive, Strain gauge	Piezoresistive sensors	Resistive Technology
Pressure Range (mmHg)	NS	0-220	0-300	0-300	0-100* or 0-200**	0-200 0-1000
Sample rate (samples per second)	10,000	Up to 5000	2.7 at 300 mmHg 6 at 0 mmHg***	Continuous reading	3072	NS
Resolution (mmHg)	NS	1	1	2	1	1
Accuracy	NS	Approximately 10 mmHg	±4 mmHg	2 mmHg	Variation Coefficient**** less than 10% at manufacture	NS

NS= not specified in manufacturer's technical literature
*Bed system
**Seat and back system
***Single-cell sampling rate
****Variation coefficient is the standard deviation expressed as percentage

Table 4.2 A selection of commercially available interface pressure measuring systems]Adapted from Bethaves, 2002]

Pneumatic, pneumatic-electric or pneumatic-piezoelectric	✓ **Oxford Pressure Monitor** (Talley Ltd, Ramsey, Hampshire, UK) ✓ **Talley Pressure Evaluator** (Talley Ltd) ✓ **MST MKIII Salzmann** (Salzmann Medico, St Gallen, Switzerland) ✓ **Digital Interface Pressure Evaluator Pad** (Vista Medical, Winnipeg, MB, Canada) ✓ **Kikuhime** (Meditrade, Soro, Denmark) ✓ **Juzo Tester** (Elcat, Wolfratshausen, Germany) ✓ **Sigat Tester** (Ganzoni-Sigvaris, St Gallen, Switzerland)
Piezoelectric Fluid Filled, fluid-filled resistive	✓ **Strathclyde Pressure Monitor** (University of Strathclyde, Scotland) ✓ **FlexiForce** (Tekscan, South Boston, MA, USA) ✓ **Skip Air Pack Analyzer** (AMI Co., Japan)
Resistive and strain gauge	✓ **FSR, FSA** (Vista Medical, Winnipeg, MB, Canada) ✓ **Fscan, Iscan** (Tekscan, South Boston, MA, USA) ✓ **Rincoe SFS** (Rincoe and associates, Golden, CO, USA) ✓ **MCDM** (Mammendorfer Inst. Physic, Munich, Germany) ✓ **Fontanometer** (Gaeltec Ltd, Dunvegan, Isle of Skye, Scotland) ✓ **Diastron** (Diastron Ltd, Andover, Hampshire, UK)
Capacitive	✓ **Kulite XTM190** (Kulite Semiconductor Products, Leonia, NJ, USA) ✓ **Precision** (Precision Measurement CO., USA) ✓ **Xsensor** (Crown Therapeutics, Belleville, IL, USA) ✓ **Pliance** (Novel, Munich, Germany)

Table 4.3 Types of commercial interface pressure sensors [Adapted from Partsch et al., 2006].

There have been numerous studies that either evaluated or compared pressure measuring systems. For example Reger et al. (1988) compared 4 pressure measuring devices using both calibration experiments and clinical trials. In the laboratory calibration experiments the systems (Scimedics pressure gauge, TIRR-PEP system and Oxford Pressure Monitor) underwent 3 tests. Initially a load (bowling ball – 7.3 kg) was applied in a localized spot on the sensors located on a hard surface. Then the ball was applied by a curved surface and finally the sensors were placed between two parallel, interconnected, flat rubber envelopes which could be inflated by increasing pressure simultaneously. The clinical trials were carried out using the Scimedics pressure gauge, the TIRR-PEP system and the Gaymar PSP-1 pressure sensor. For the trials the subjects were tested in the sitting, side lying and supine positions using 3 support systems successively. The 1st calibration test illustrated that all transducers exhibited position sensitivity, meaning that the readings were higher in relation to the centre of the sensor. For the second test, the Hertz contact stress was calculated for comparison with the actual values. The percentage difference between the derived value and the reading was 15%, 38% and 50% for TIRR-PEP, Scimedics and Oxford Pressure Monitor respectively. The authors stated that this percentage difference represents the material and structural differences between vinyl sensor bags. For the clinical tests, regression equations of sensor outputs were produced in order to compare their behaviour. It was shown that there was moderate to strong correlation between the systems. It was concluded that many factors affect the results of interface pressure measurements with the most important being sensor size and shape, the load shape and its interaction with the support material, the method of equilibrium detection and the uniformity of the measurement technique.

Barbenel and Sockalingham (1990) produced a paper that described the construction and performance of a pressure sensing device with a continuous electrical output. The device consisted of the sensor cell and tubing, the transducer and the conditioning unit. The sensor cell and tubing (acquired by Talley Medical) was connected to a transducer consisting of a Wheatstone bridge, responsible of transforming the pressure into electrical signal. The sensor cell, tubing and transducer were filled with vegetable cooking oil which was used as the means of pressure propagation from the cell to the transducer. The signal conditioning circuit was connected to the output of the transducer and consisted of a differential amplifier in series with

a gain amplifier and an LCD display that illustrated the pressures. Accuracy measurements were carried out for the values between 0 and 37.5 mmHg (the authors described this pressure range as working values) showing an excellent linear relationship between the applied pressure and output voltage. Hysteresis test was completed by gradually increasing and decreasing the hydrostatic pressure applied to the sensor. It was found that the maximum difference in the output reading was 1 mV (equivalent of 0.5 mmHg). In addition the accuracy was calculated to be ±2%. Finally long term stability was investigated by measuring the output voltage continuously for 5 h. The maximum deviation was found to be 1 mV with no significant drift. Barbenel and Sockalingham recommended the system for use beneath compression bandages and stockings.

Steinberg and Cooke (1993) designed and developed a pressure measuring device able to record pressure beneath compression bandages. The system comprised of 8 electro-pneumatic sensors (product of Talley Medical) connected to piezoelectric pressure transducers. These transducers consisted of a Wheatstone bridge and 2 ports, one connected to the electro-pneumatic sensor and the other open to atmospheric pressure to which all readings were referenced. The output of the transducer was a DC signal, proportional to the pressure produced by the sensors. The signal conditioning part consisted of an instrumentation amplifier and a sample and hold circuit. Finally the interface pressure was displayed by a liquid crystal display. The operation of the device was controlled by a digital circuit. The authors stated that the device had an accuracy of about 10% at 40 mmHg or better under 30 mmHg. Furthermore the hysteresis of the system was higher for 200 mmHg declining at lower pressures. Table 4.4 illustrates sensor hysteresis and measurement tolerance. The sample rate of the system was reported to be 2.9 (~3) samples per second.

Pressure (mmHg)				
Supply	**Opening**	**Closing**	**Hysteresis**	**Tolerance (%)**
200	78	14	64	53
100	58	19	39	37
40	38	27	11	10

Table 4.4 Sensor hysteresis and measurement tolerance [Adapted from Steinberg and Cooke, 1993]

Taylor and Taylor (1998) produced a study which described the construction and calibration of a 3 channel bandage pressure monitor. This electronic instrument consisted of 2 parts, the pressure sensors (ARB-1, Synectics Medical – latex anorectal catheter balloons, prolate ellipsoid with dimensions of 50 mm/35 mm, 3 mm thickness), tubing section (flexible silicone rubber – Altsil HS Silicone Tube, Altec Products Ltd) and the recording unit that facilitates the measurement. The recording unit consisted of three transducers (SDX05D4), each connected to two differential amplifiers each in series with a gain amplifier transferring the signal to a liquid crystal display. The sensors were calibrated by measuring the interface pressure between a circular nylon rod and the cuff of a sphygmomanometer. The system had the ability to measure pressures in the range of 0-199 mmHg. The authors stated that the system have been found to be reliable, accurate (typically $\leq \pm 0.5$ mmHg) and reproducible during operation over a year. A major advantage of this system is its cost (less than £500).

Ferguson-Pell et al. (2000) evaluated a sensor designed for the measurement of interface pressure beneath bandages, compression stockings and pressure garments. The sensor was made of 2 layers of a polyester film. On each layer, a conductive material (silver) was applied followed by a layer of pressure sensitive ink, the electrical resistance of which varied with applied force. The full measurement system consisted of data logger, a computer and a piece of software responsible of processing and displaying the data.

The system was evaluated by undergoing the following characterisation measurements:

- Drift test (for 50 and 30 g the drift was 1.7% and 2.5% logarithmic time respectively)
- Repeatability (coefficient of variation for 50, 30 and 10 g was 2.3%, 3.2% and 6.6% respectively)
- Linearity (for 50, 40, 30, 20 and 10 g the coefficients of variation were 1.9%, 3.8%, 4.0%, 6.0% and 9.9% respectively)
- Hysteresis (the mean ± SD of the maximum difference in the output for increasing and decreasing load, was 5.4 ± 2.5%)
- Curvature test (when pressures were applied to the curved surface, the outputs of the sensor changed the offset and sensitivity of the sensor)

Ferguson-Pell et al. concluded that the sensor has acceptable characteristics and is suitable for measurements on flat and curved surfaces with the radii greater than approximately 32mm under static conditions.

Satpathy et al. (2006b) tested the use of low-cost, portable battery powered sub-bandage pressure monitor as part of a quality control process for graduated compression bandaging. The pressure monitors tested were three low cost (£150 each) pressure monitors (Kikuhime, Harada Corporation Japan), which consisted of a 3 x 4 cm pressure sensor balloon, tubing and recording unit. The system was calibrated in 3 steps: initially only a sphygmomanometer was used, then the sphygmomanometer and a simulated leg (plastic drain pipe of 9.5 cm diameter covered with bubble wrap) and finally a water tank in which the sensors were placed at certain depths. The authors reported that the system had a linear response for pressures between 0-160 mmHg (with agreement of 95% coefficient interval) and was accurate to ±1 mmHg. It was noted that the pressures usually varied with the change of position and movement. Furthermore it was concluded that "devices like Oxford Pressure Monitor and other medical stocking testers are expensive and complex for routine use. Our result suggests that it is important to have a tool that is easy to operate".

There have been minimal attempts to compare different systems. For example Ruckley et al. (2002) compared the consistency of 3 pressure measurement systems. These were the Salzman MST, the Oxford Pressure Monitor and the Diastron. Sub-bandage pressure measurements were undertaken using 5 bandages (tubular elastic straight, tubular elastic graduated, short stretch non elastic, long stretch elastic and cohesive elastic). The bandages were applied to standard models (plastic tubes). The sensors were placed at 3 points corresponding to the ankle, gaiter and mid calf. A total of 135 readings (for each machine) plus 81 (for each bandage) were carried out. It was reported that the mean pressures among the 5 bandages ranged from 12.2 to 35 mmHg. The lowest variances were observed for the Salzman MST, while the other 2 systems illustrated similar variances. The authors concluded that the MST is better system than the other two.

From the studies described above, the following conclusions can be drawn:

- All systems compared or developed have illustrated good electrical characteristics. The tests were focused on accuracy, linearity, hysteresis and curvature effects since these are the parameters that are responsible for a precise and accurate measurement beneath a compression bandage. However drift, noise and repeatability are rarely mentioned.
- Continuous output (i.e. very high sampling rate) is preferable to non continuous output (for example 1 reading per second). As mentioned in the previous chapter, a device able to produce a continuous signal can monitor sub-bandage forces in more detail under dynamic conditions (for example walking), capturing the increase and decrease of pressure. The only two devices that had non continuous output were the one developed by Steinberg and Cooke (1993) and Oxford Pressure Monitor (Ruckley et al., 2002).
- Measuring systems tend to become smaller, lighter and portable. For example the system by Barbenel and Sockalingham (1990) was bulky while the system evaluated by Satpathy et al. (2006) was small and portable. This second category of devices appears to be more appropriate for dynamic pressure measurements since they can be easily carried by subjects without affecting movement.
- Device power source is very important since it introduces more cables (when connected to the mains) and might need isolation from high voltages. The systems described by Taylor and Taylor (1998), Ferguson-Pell et al. (2000) and Satpathy et al. (2006) were battery powered.
- Finally the systems were developed with different number of sensors. Barbenel and Sockalingham (1990) had 3 sensors, Steinberg and Cooke (1993) system was developed with 8 sensors, Taylor and Taylor (1998) had 3 sensors, Ferguson-Pell et al. (2000) system included only one sensor and finally Satpathy et al. (2006) system had one sensor per transducer but they used 3 transducers for recording the forces. However more sensors means more electronic circuits, difficult multiplexing, more power consumption, more cables, higher cost but better monitoring of the forces and better picture of the force interactions beneath compression systems. It should be mentioned that the action of the leg muscles may influence pressure measurements dependent upon where the sensors are placed above or around the muscles, however consensus in recent years regarding sensor

positioning suggests that by placing sensors at the same points on the leg could reduce this source of error (Partsch et al., 2006).

A comparison of the studies described before is demonstrated in Tables 4.5a and 4.5b. It could be concluded that a good system able to monitor sub-bandage forces should be small, lightweight, portable, battery powered, with continuous output, good electrical characteristics, low cost and developed with at least 3 sensors.

Other studies that described comparisons or developments of pressure measuring devices for area pressure monitoring are demonstrated in Table 4.6.

Device	Type of Sensor	Characterization/Calibration	Comments
Scimedics Pressure Gauge TIRR-PEP system Oxford Pressure Monitor (Reger et al., 1988)	Electro-pneumatic sensors for all systems	Curved surface and plane loading calibration	For curved loading the transducers demonstrated position sensitivity. The plane load calibration resulted in best agreement between the externally applied load and the measured values. There are no other calibration measurements. The examined systems were commercially available.
Prototype pressure sensing device (Barbenel and Sockalingham, 1990)	Electro-pneumatic	Linearity, hysteresis, noise, drift using sphygmomanometer	The system illustrated well performance for all measurements. The device could produce a continuous electrical output. However it was bulky and had to be connected to the mains limiting its transportability. Three sensor system.
Prototype interface pressure measuring device (Steinberg and Cooke, 1993)	Electro-pneumatic	Hysteresis, accuracy and the maximum available sample rate	Hysteresis was significant at high pressures (at 200 mmHg), declining at lower values (40 mmHg). The system could produce 2.9 samples of pressure per second. The accuracy was acceptable for only 1 of the 4 tested channels. The system was bulky and needed to be connected to a power source. Comprises of 8 sensors.
Prototype low cost bandage pressure monitor (Taylor and Taylor, 1998)	Pneumatic sensor connected to piezoresistive transducer	Accuracy, linearity and hysteresis using a sphygmomanometer	The device performed well during the measurements illustrating good hysteresis, accuracy and linearity. Three channels device with low cost (less than £500). Mains powered system.

Table 4.5a Comparison of studies concerning development and testing of pressure measuring devices

Device	Type of Sensor	Characterization/Calibration	Comments
Evaluation of a single sensor connected to a sensor-handler and a computer (Ferguson-Pell et al., 2000)	The sensor employed an ink capable of varying its electrical resistance with applied force	Drift, repeatability, linearity, hysteresis and curvature measurements using a loading rig	Single sensor that performed well at the characterization measurements. Could be used for single site measurements beneath bandages.
Testing of low cost, portable, battery powered sub-bandage pressure monitor (Satpathy et al., 2006)	Electro-pneumatic	Accuracy and linearity measurements using a sphygmomanometer, a simulated leg and a water tank	The systems illustrated very satisfactory electrical characteristics. The system is battery powered and low cost. However it comprises of only one sensor. It can be used for sub-bandage pressure measurements.
Comparison of 3 sub-bandage pressure measurement systems Salzman MST Oxford Talley Diastron (Ruckley et al., 2002)	Electro-pneumatic Resistive	Comparison of the consistency of pressure measurements acquired below 5 kinds of bandages applied to standard models	Statistically significant differences were observed, with the lowest variances for the Salzman and similar variances for the Oxford Talley and Diastron.

Table 4.5b Comparison of studies concerning development and testing of pressure measuring devices

Description	Conclusion
Development of a pressure measuring device for the assessment of subject cushion interface pressures. The system consisted of 10 fluid filled vinyl sensors connected to a 10 way valve used as a switching network. The valve was connected to a transducer and to an amplifier that displayed the value.	The system proved useful for comparative measurements of different cushions (Holley et al., 1979).
Evaluation of the relative performance of various interface pressure measurement transducers when used on different sitting surfaces. The transducers under investigation were LQS-125-200, Model 156, Scimedics Pressure Evaluator Pad, miniature single cell (experimental design). After calibration, each sensor was placed between two square slabs of soft material while the pressure was changed.	It was concluded that the performance of a given transducer is highly dependent on the properties of interface materials and on the ratio of transducer surface area to the contact are of the interfacing materials (Reddy et al., 1984).
Description of the development of a system for measuring pressure distribution at the patient support interface. The system consisted of a mat of pneumatic sensors, signal conditioning circuit and on analogue display. The system had an accuracy of 3% of full scale (250 mmHg).	The system (Oxford Pressure Monitor) is suitable for clinical use as long as its limitations are taken under consideration (errors due to the finite size of the individual cells) (Bader and Hawken, 1986).
Assessment of Talley SA500 pressure evaluator, Digital Interface Pressure Evaluator (DIPE-Next Generation Co Inc, USA) and 19 mm diameter water bladder system. The systems were tested for accuracy linearity and repeatability using 2 layers of foam with the sensors placed in the middle.	Talley system was the most accurate, while all systems had a problem measuring the pressure beneath 20 mmHg. It was also concluded that the interface itself affects accuracy (Allen et al., 1993).
The aim of the study was the establishment of the ideal specifications for clinically useful pressure mapping systems and use of this specification for the design of an innovative wheelchair pressure mapping system. Furthermore 3 pressure mapping systems were compared (Tekscan, TPM3 and FSA). Comparison tests included repeatability, hysteresis and creep. Tests were carried out in laboratory and clinical setting involving spinal cord injured subjects.	TPM3 system was found to be most accurate, stable and reproducible. Tekscan and FSA shown hysteresis and creep errors. Furthermore TPM3 produced the least hammocking effects while Tekscan and FSA demonstrated the most potential influence (Ferguson-Pell and Cardi, 1993).

Table 4.6 Comparisons and developments of area pressure mapping systems

4.4 Development, justification of the specification and sensor selection for the required measurements

A key objective of this MPhil study was to specify for and execute a set of sub-bandage interface pressure measurements during walking. The specification for the required measurements should include the following:

i) Designation of the type of bandage system that should be used
ii) The number of anatomical points that the pressure sensors should be located
iii) Type of pressure sensor
iv) If monitoring of walking pattern is needed
v) Minimum sub-bandage pressure sampling rate
vi) Required accuracy, linearity, hysteresis, repeatability and drift of the developed system
vii) Safety and portability (based on current legislation)
viii) Data handling and other software requirements

The choice and justification is as follows:

i) Designation of the type of bandage system

The literature review in chapter 3 (3.5 Gaps in research) has demonstrated that there has been minimal research work that investigated the dynamic properties of multilayer compression bandages under various walking speeds or the dynamic stiffness indices. Furthermore, the literature review in chapter 2 has shown that the 4-layer bandage systems achieved the best healing rates when compared with other compression systems and can sustain sub-bandage pressure successfully longer (Blair et al., 1988; Carr et al., 1999; O'Brien et al., 2003; Moffatt et al., 2003a; Iglesias et al., 2004; Fletcher et al., 1997; Ukat et al., 2003). Therefore the use of the well known Profore (Smith and Nephew) 4-layer bandage system would be ideal for the execution of the pressure measurements.

ii) Number of anatomical points for the sensors

Section 3.5 (Gaps in research) has demonstrated that studies involving sub-bandage measurements during ambulation used the most 3 sensors (Wertheim et al., 1999b and 1999c). Higher number of sensors could help to better monitor the interactions beneath compression bandages. In addition Partsch et al. (2006) suggested that measurements of pressures beneath bandages should be taken at 9 anatomical points. The initial prototype system (described in chapter 5) consisted of 6 sensors. It was therefore decided to design a device capable of making measurements with 10 sensors in order to provide a better picture of the interaction of forces beneath bandages.

iii) Type of pressure sensor

For the Wound Assessment Laboratory, it was decided to use the Fontanometer strain gauge sensors (also discussed in 5.2), product of Gaeltec Ltd (Gaeltec Ltd, Dunvegan, Isle of Skye, Scotland). This sensor features a robust sensing diaphragm within small stainless steel disc shaped housing (shown in Figure 4.1). The diameter of the sensor is 12 mm while the thickness is 3 mm. Its characteristics are shown in Table 4.7

Sensor	Metal diaphragm with directly deposited resistive strain gauges
Excitation	5V AC rms or 1V DC maximum
Bridge Resistance	1.5 kΩ nominal
Sensitivity	5 μV/V/mmHg or as appropriate to range
Linear Pressure Range	0-150 mmHg or as specified (up to 5 atmospheres nominally)
Compensated Temperature Range	15-40 °C
Temperature Coefficient of Zero	<0.05% FS/°C
Temperature Coefficient of Sensitivity	<0.2%/ °C
Linearity and Hysteresis Error	<±1% FS BSL
Leakage Current	<10 μA at 240 V AC 50 Hz
Cable	Reinforced flexible silicone rubber
Connector	6 pin Lemo series as on the appropriate extension lead type EL-1

Table 4.7 Fontanometer sensor characteristics

Previous work by Wertheim et al. (1999a, 1999b, 1999c) has shown that it is possible to monitor sub-bandage pressures with the Fontanometer sensor. Also, the use of the Fontanometer sensor was tested in two small studies, which also involved the author of the present thesis.

Firstly Melhuish et al. (2001a) assessed sub-bandage pressure and shear components under long stretch bandages, applied using standard bandaging techniques. Pressure measurements were undertaken using the Fontanometer sensor. In a similar study Melhuish et al. (2001b) examined the changes in sub-bandage pressures when applied to six model legs. Eight long stretch compression bandages were applied at constant tensions of 2, 4, 6, 8, 10 Newton's to six model legs constructed from plastic tubes. The sub-bandage interface pressures were again measured with the Gaeltec Fontanometer sensors.

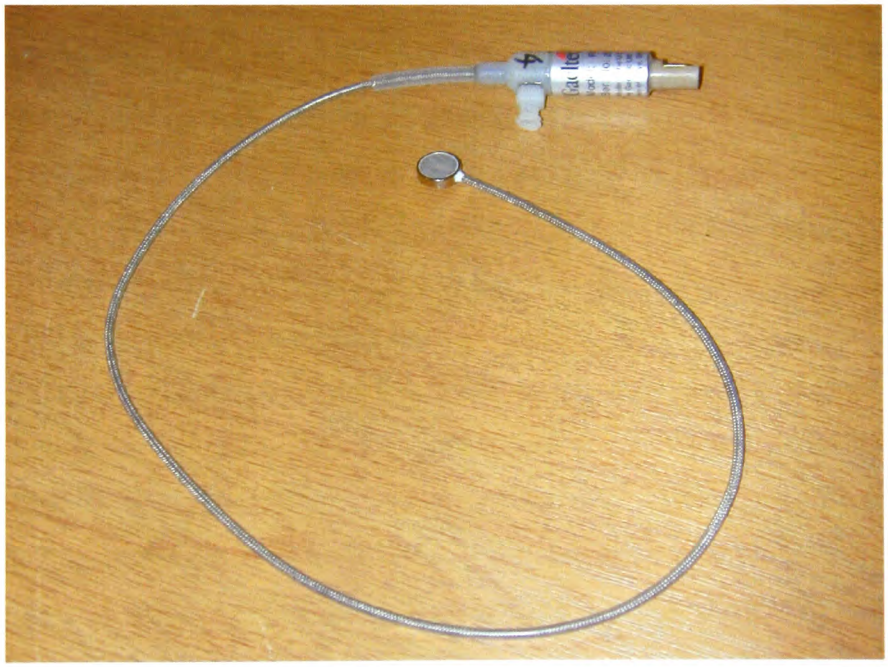

Figure 4.2 Fontanometer sensor

The use of such sensor requires a source of excitation signal and a signal conditioning section for amplification, zeroing and filtering. Furthermore, multiplexing is needed in order to minimise the use of components, power consumption and space requirements on the circuit board (discussed in chapter 5).

iv) Need for monitoring of the walking pattern

The majority of studies that involved monitoring of forces during postural changes and exercise (for example walking) gathered data during dorsiflexion and plantar flexion (Wertheim et al., 1999b and 1999c; Mosti and Mattaliano, 2007; Hirai, 1999 and 1998; Hafner et al., 2000). The application of an indicator able to show the walking pattern could correlate force variation with movement of the leg. It was decided to design the system including the gait indicators (that would be placed at the big toe and heel of each leg). These indicators are simple force sensing resistors that change their resistance with the variation of pressure.

v) Minimum sub-bandage pressure sampling rate

The required minimum sampling rate can be specified by considering two factors:

- Heartbeat rate: The resting heartbeat rate of a normal adult ranges from 60 to 100 beats per minute. During relaxed exercise (i.e. slow walking) the heartbeat rate is expected to increase about 20 beats per minute. Every beat produces an increase of blood pressure, which is translated into a slight increase of sub-bandage pressure. Considering approximately a heartbeat of 2 Hz it can be concluded that 4 Hz should be minimum sampling rate.
- Walking speed: Previous studies have shown that there is a peak sub-bandage pressure during every step (Sockalingham et al., 1990; Hirai 1998 and 1999; Wertheim et al., 1999b and 1999c; Hafner et al., 2000; Stolk et al., 2004). The anticipated measurements will involve walking at 5 km/h (maximum) which results in about 4 steps per second. Since measurements will be taken from only one leg, minimum 4 samples per second will be sufficient to produce a picture of sub-bandage pressures.

Considering these 2 factors it can be concluded that 4 Hz should be the minimum sampling rate.

vi) Required accuracy, linearity and hysteresis performance of the system

Linearity: Ferguson-Pell et al. (2000) stated that linearity is the proportionality of the sensor's response to the applied load over the range of loading. The intention is to produce a system that has a linear response over the pressures produced beneath bandages during walking. Sockalingham et al. (1990) illustrated a pressure range of 45 mmHg (from 5 mmHg to 45 mmHg). Danielsen et al. (1998) illustrated pressures at about 40 mmHg while Hirai (1998) observed forces ranging from about 10 mmHg to 90 mmHg. Wertheim et al. (1999b and 1999c) observed pressures between 17 mmHg to 70 mmHg. Finally Hafner et al. (2000), for various bandages, obtained pressures between 10 mmHg to about 70 mmHg, while Stolk et al. (2004) stated that the pressure of the stockings varied between 10.8 mmHg and 51.2 mmHg. To sum up the pressure range beneath compression systems varies between 10 and 90 mmHg. Therefore the system is required to be linear for pressures varying from 0 to 100 mmHg. Accuracy: accuracy could be defined as a figure of merit which describes the probability that the measurand is correct (Van Putten, 1988). An ideal system should be 100% accurate. However as illustrated in Table 4.2, commercial systems have accuracies ranging from ±10 mmHg to ±2 mmHg. Furthermore the systems described in section 4.4 have accuracies ranging from ±2% (Barbenel and Sockalingham, 1990), ±3 mmHg (Steinberg and Cooke, 1993), ±0.5 mmHg (Taylor and Taylor, 1998) and ±1 mmHg (Satpathy et al., 2006b). For this system the target was to develop a device with accuracy ±2 mmHg over the linear range of 100 mmHg. Hysteresis: Hysteresis is the difference in the sensor (or system) output response during increased loading and decreased loading at the same force (Fraden, 1997). Barbenel and Sockalingham (1990) stated that hysteresis was not a problem with their system since the maximum difference in pressure between increasing and decreasing loading was 0.5 mmHg. Steinberg and Cooke (1993) system illustrated high hysteresis error for high supply pressure to the pneumatic sensor (200 mmHg) but much lower for lower supply range (40 mmHg) at a fixed outside pressure (30 mmHg). It was calculated that when the pneumatic sensor was supplied with a 40 mmHg the maximum deviation of the measured interface pressure from the true value was 10% exhibiting a more accurate reading. Ferguson-Pell et al. (2000) found that the mean ± SD of the maximum difference in output for increasing and decreasing load was 5.4 ± 2.5%. Finally Taylor and Taylor (1998) found that for inflation and deflation the values

for the 95% coefficient intervals ranged from 0.3 to 0.7 mmHg. These results show that most of the systems developed produce a hysteresis within the limits of their accuracy. The intention of system design is to produce a hysteresis during loading and unloading, lower than ±2 mmHg. Drift and repeatability: Ideally a measuring device should produce drift free signals and be able to replicate the same reading when a measurement is executed under the same conditions. The majority of the studies reviewed did not provide information concerning the drift and repeatability characteristics of the systems they used for the pressure measurements (Sockalingham et al., 1990; Hafner et al., 2000; Wertheim et al., 1999b and c; Hirai, 1998; Danielsen et al., 1998; Satpathy, 2006, Taylor and Taylor, 1998). In the contrary Ferguson-Pell et al. (2000) stated that the sensor they evaluated (using small weights of 10, 30 and 50 g) reached outputs 98.05% of the stable values after 10 min while the sensor produced similar readings for the same stimulus to within ±1.03 g. The authors stated that the sensor performance was acceptable. Barbenel and Sockalignham (1990) reported that their system drift (after being measured for 5 h) did not exceed the 1 mV (translated into 0.5 mmHg). For the developed system it was interned to produce repeatable measurements to within the accepted error (±2 mmHg) while the system drift should not exceed the ± 2 mmHg barrier (for at least 30 min to 1 h, which is the likely time for one complete ambulatory measurement).

Finally the system will be checked for noise and crosstalk effects.

vii) Safety and portability

Successful completion of the measurements involves a safe and portable electronic instrument. Medical devices directive (93/42/EEC) states that:"Devices must be designed and manufactured in such way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed correctly" (Annex I, paragraph 12.6 – Protection against electrical risks) (European Parliament and the council of, 1993). Safety with medical devices is usually achieved with the use of transformers that isolate the mains supply from the instrument and the patient. A device connected to the mains gives the freedom to the designer to choose parts that consume a lot of power but could limit the movement of the subjects since the system needs to be plugged. A battery powered device however requires components that use less power but gives freedom of movement to

the subject. The analysis in section 4.3 demonstrated that the sub-bandage pressure monitors are shifted towards battery power. Data processing of the prototype and commercial systems described is realised either on the device (data usually displayed using an LCD display) or transferred via cables to a portable computer for illustration. This could limit the freedom of movement of the subject since there is a need for being in a certain range from the data processing computer. However any wireless system should comply with the Directive 2004/108/EC relating to electromagnetic compatibility (Annex I, paragraph 1, a and b) (European Parliament and the Council of, 2004). Taking under consideration the factors analysed it was decided to design a battery powered, wireless system. However the use of a single channel FM transmitter poses 2 significant challenges: i) the multiplexing of the inputs and, ii) the digitization of the multiplexed signals in order to be ready for transmission.

viii) Data handling and other software requirements

Data handling may be achieved with the use of the FM receiver and a portable computer with a data acquisition card (DAQ700 – National Instruments), connected to the receiver using a manually developed electronic board acting as interface. The programming language selected for the development of the data handling software is LabView 6.1 from National Instruments. It's a graphical programming language specialized on data acquisition cards and hardware control. The programme should be able to handle the incoming data, demultiplex them, be able to display them and finally save them in spreadsheet format. Further programming especially regarding microcontrollers (used for the excitation signal and multiplexing) is undertaken using C language and assembly.

Table 4.8 summarizes the characteristics of the specified system and introduces additional design issues

Bandage System	Profore (Smith & Nephew) 4 layer bandage system
Pressure Measurement	
Type of sensors	Gaeltec Fontanometer type sensor (Titanium 2.3 mm thick, 6 mm wide) and Force Sensing Resistors (Interlink Electronics) as gait indicators
Number of sensors	10 Fontanotmeter and 4 FSRs
Connector Type	6 pin Lemo series with EL-1 lead type
Sensor excitation signal	2 kHz TTL
Input Signal Stage	Differential input (from Fontanometer sensors) fed to 10 instrumentation amplifiers (INA121) set to 107 gain
Performance Characteristics	
Minimum sub-bandage pressure sampling rate	4 samples per second
Required Linearity, Hysteresis error, repeatability, drift and accuracy	Linear response over 0-100 mmHg range, hysteresis error of ±2 mmHg within pressure range of 0-100 mmHg, accuracy of ±2 mmHg. Drift and repeatability within the ±2 mmHg. The system will be checked for noise, and crosstalk error.
Signal Gain	Adjustable over the ±5 V range. Adjustable signal zero level
Safety and Portability	
Applied Legislation	Directive 93/42/EEC relating to medical devices Directive 2004/108/EC relating to electromagnetic compatibility
Power Source	2 x 9 Volt batteries
Operating Power	±5 V
Data Transmission	FM transmitter and receiver at 433MHz capable of transmitting 50 kbps, interface using a multiplexer and the 16F74 PIC microcontroller
Data Handling and Software Requirements	
Data Recording	Data will be displayed and store in a portable computer
Data Handling Programme	LabView 6.1 from National Instruments (Graphical programming language)
Data Acquisition Card	DAQ700 from National Instruments
Microcontroller software	C and Assembly language

Table 4.8 Wound Assessment Laboratory specification

4.5 Summary

This chapter has looked at commercial and prototype systems aimed to measure interface pressure (either at single points or over an area), discussed design and sensor performance sensor issues, reviewed studies that concerned the development of measuring devices and finally provided a specification concerning the Wound Assessment Laboratory and the required sub-bandage measurements.

The measurement of interface pressure involves the use of measuring devices connected to various types of sensors such as resistive, capacitive, piezoelectric, pneumatic and electro-pneumatic. At a practical level difficulties are encountered in the design of pressure measuring devices since a number of factors have to be addressed like system accuracy, hysteresis, linearity etc. In addition sensor design can be very challenging since the geometric characteristics of the sensor could affect, alter or even give a false measurement.

There have been many attempts to develop systems that can measure interface pressure. A literature review has shown that the majority of the systems have shown good electrical characteristics and in many cases were constructed with low cost and commercially available components. However many disadvantages were observed including the number of sensors, portability issues as well as device size.

Analysis of these studies has led to the development of the specification of the Wound Assessment Laboratory, which is essential for the completion of the required measurements. The construction and characterisation measurements are discussed extensively in the next chapter.

5 Design and development of the Wound Assessment Laboratory

Chapter 5 describes the design and development of the electronic instrumentation required for the sub-bandage ambulatory pressure measurements. The following account consists of 4 development phases corresponding to:

i) Benchmark performance of sensor technology.
ii) Evaluation and confirmation of the suitability of existing technology.
iii) Development of a prototype original measurement system.
iv) Execution of a final design and its validation.

5.1 Test regimes

Throughout the 4 phases it was evident that there would be a need for common development performance evaluation regimes. These would include:

- Practical application issues.
- Performance evaluation (i.e. accuracy, linearity, hysteresis, repeatability, crosstalk).
- Noise and drift issues.

The apparatus (illustrated in Figure 5.1) chosen and used for the performance and characterisation measurements consisted of a sphygmomanometer (able to measure pressures from 0 to 300 mmHg), a plastic case suitable for the Fontanometer sensor and a LabView characterisation program (written by the author) able to handle the pressure readings produced by Gaeltec Amplifiers (discussed in 5.1) and the author's designed systems. Known amounts of pressure are applied to the sensors utilizing the following procedure: Initially the Fontanometer sensor is placed into the plastic case. Using the metal latch, the case is firmly sealed in order to prohibit any air leakage. The inflation bulb is used to increase the air pressure inside the plastic case while the pressure reading is shown on the manometer. The one way screw valve can be used to adjust the amount of pressure inside the plastic case. This apparatus has been used for the measurement of linearity, hysteresis, repeatability and crosstalk. All measurements were completed in a temperature controlled room.

On the contrary, drift and noise was measured using the configuration shown in Figure 5.2. The Fontanometer sensor was positioned on a hard surface and held using medical tape (checking that no pressure reading was produced by the tape), while small weights ranging from 1 g to 50 g were placed on the sensor. This measurement method was preferred instead of the sphygmomanometer method in order to avoid any air leakage and consequently pressure decrease during the long periods of noise and drift performance tests (whereas constant applied pressure is needed).

The following sections provide the methodology of the performance tests carried out during the 4 development phases. It has to be noted that each of these tests was executed separately for every channel for every system.

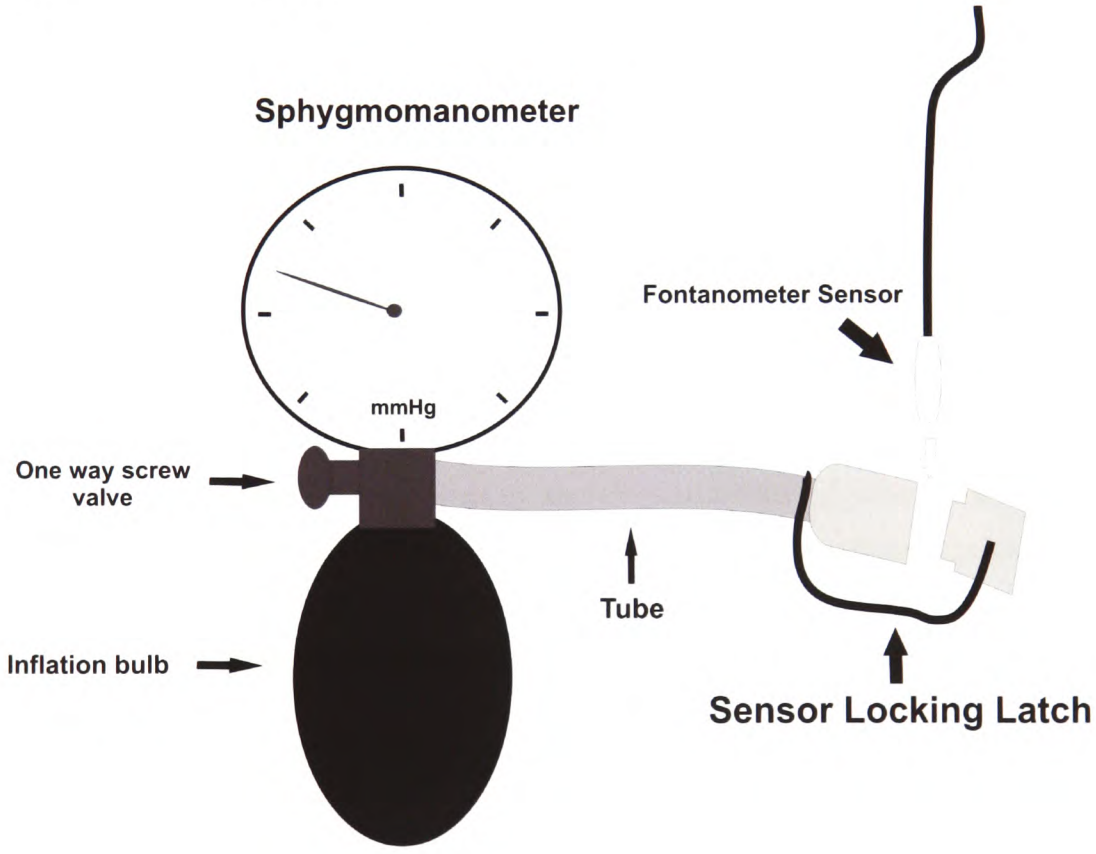

Figure 5.1 Calibration apparatus

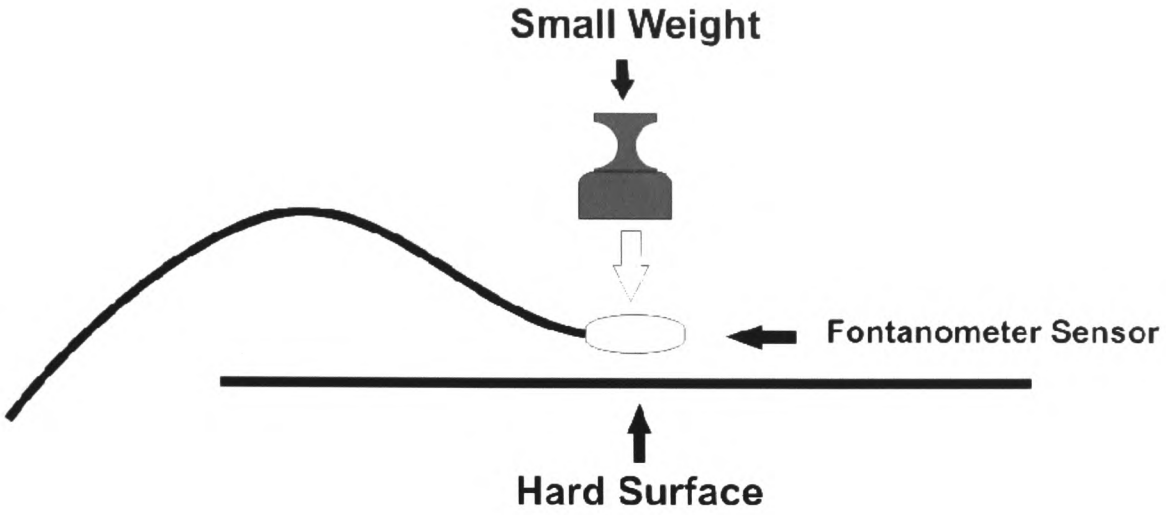

Figure 5.2 Characterisation method using weights

5.1.1 Resolution

Resolution was measured by applying very small pressures, between 0.01 to 5 mmHg, to each sensor using both the sphygmomanometer and small weights. The output was observed using an oscilloscope and recorded by the LabView program. The smallest detectable incremental change that could be observed indicated systems' resolution.

5.1.2 Accuracy

Accuracy measurement was accomplished by applying the following pressures to each sensor in turn: 20, 40, 60 and 80 mmHg. The pressures were applied using the sphygmomanometer. This test was repeated 5 times for every channel, during the 4 development phases. The maximum positive and negative deviations of pressure are used as indicators of accuracy of each channel.

5.1.3 Linearity

Linearity tests were completed by applying gradually increasing pressure to each sensor, in turn, using the sphygmomanometer (as shown in Figure 5.1). The pressure was applied in 10 mmHg increments starting from 0 to 100 mmHg. The results are illustrated as applied pressure

versus pressure reading. It has to be noted that all linearity trend lines are included in an envelope created by the two trend lines representing the following equations:

$$y = x + c_1 \qquad (4)$$

$$y = x - c_2 \qquad (5)$$

Where

c_1 and c_2 are the maximum positive and negative (respectively) differences from the applied pressure. This test was repeated 5 times per channel.

5.1.4 Hysteresis

The pressure on each sensor was incremented and decremented in 10 mmHg steps, increasing from 0 to 100 mmHg and then decreasing it back to 0 mmHg in steps of 10 mmHg. The difference between increasing and decreasing pressure (for the same applied pressure) is used as the hysteresis error indicator. The test was repeated 3 times for every channel.

5.1.5 Drift

System drift was measured by loading each sensor, in turn, with a constant mass, corresponding to 40 mmHg (as shown in Figure 5.2). The output was recorded by the test program. Considering the duration of the anticipated ambulatory measurements (i.e. no more than 40 minutes), the drift tests were designed to last for 1 hour, while pressure samples were recorded every 20 seconds. A 10 point moving average filter was applied to every complete measurement in order to isolate the signal from noise. The drift is expressed as the difference between the initial and the final pressure value. The maximum positive and negative difference from the initial pressure value (40 mmHg) was also measured. This measurement showed the maximum fluctuations of the output pressure signals in relation to the initial applied pressure during the measurement period. The test was executed once for every channel. The results are presented graphically as applied pressure versus time.

5.1.6 Noise

System noise measurements aimed to answer the following questions:

i) What is the nature of noise and its origin?
ii) What is the noise size and its relation to signal size?
iii) Does the noise depend on signal size?
iv) What is the signal to noise ratio?
v) Can the noise be filtered?

The nature and origin of noise was defined with the use of a spectrum analyser. For the purposes of questions (ii), (iii) and (v) the following method was used: pressure and voltage values were recorded every 100 ms for 1 hour, with static zero input (0 mmHg), mid pressure input (40 mmHg) and high pressure input (80 mmHg). This procedure was completed for every channel in turn, for each system. After the completion of a measurement, the recordings were processed using a 100 point moving average filter, in order to isolate the signal from the noise. By subtracting the signal from the initial noisy reading, the pure noise can be acquired. The standard deviation of noise provides the noise scatter (in voltage value) and can be used to translate this voltage value into pressure equivalent. The signal to noise ratio can be found by dividing the pure signal mean by the standard deviation of noise. The answer of (v) depends on the system of each development phase. In the graphs, the original noisy signal is represented with blue colour, while the averaged signal is shown in pink. In some cases the quantisation effect of the measurement program is apparent. However, after the application of the moving average filter the signal can be clearly observed (as in Figure 5.9/p 112).

5.1.7 Repeatability

Repeatability tests were carried out as follows:

i) The system was switched on and left to settle.
ii) Two constant pressures (40 mmHg and 80 mmHg) were applied to each sensor (in turn), while the output was recorded.

iii) The system was switched off and the procedure was repeated every 15 minutes for 2 hours.

iv) Steps (i) to (iii) were repeated for 2 days.

Pressure was applied using the sphygmomanometer, while room temperature was recorded in every occasion using a digital room thermometer. Device settling time was either provided by the manufacturer (i.e. Gaeltec amplifiers) or calculated taking under consideration the system drift tests, depending on the development phase. In the tables representing the results, the pressures of each experiment are illustrated as mean pressures. The numbers inside the brackets are the standard deviations for each experiment. The last line of each table shows the coefficients of variation which are calculated by taking the mean of the standard deviations (from all channels) divided by the average pressure (from all channels) for every experiment. The mean, standard deviations and coefficients of variation of the recorded pressures were used as indicators of each system's repeatability

5.1.8 Crosstalk

Crosstalk was measured according to the following method:

i) All pressure sensors were disconnected from the system, under test.

ii) A 100 Hz sine wave signal was connected to channel 1 while all other channels were connected to ground. The maximum amplitude of the signal was chosen to correspond to 40 mmHg, for example in the final system the signal amplitude was 0.4 volts.

iii) The output voltage of all grounded channels was measured using an oscilloscope. The output signal was also viewed with the test program.

iv) The steps (i) to (iii) were repeated for all channels in turn.

The noise measured without and with the sine wave test signal was expressed in dBs. The 100 Hz signal was chosen since all systems are designed with a 200 Hz low pass filter aimed to remove the 2 kHz excitation signal connected to the pressure sensors.

5.1.9 Simulations

It has to be mentioned that the circuits (during the last 2 development phases) were simulated before the commencement of actual construction. National Instruments Multisim 9.0 was utilised in order to predict and assure the performance of the circuits. The simulation was completed in two phases:

i) Initially the circuits were simulated using "ideal" components in order to acquire a general picture of the circuit behaviour.

ii) In the second stage, components with real characteristics and tolerances (at least the ones that existed in Multisim 9.0) were used. A more realistic behaviour of the circuits was provided which used as a guide for the following development.

5.2 Justification for the choice of the sensor

The Gaeltec Fontanometer sensor was selected because:

i) Previous studies had successfully utilised this type of sensor. For example Melhuish et al. (1997, 2000a, 2000b) used the Fontanometer sensor for static measurements both on leg models and subjects while Wertheim et al. (1999a, 1999b, 1999c) actually executed ambulatory sub-bandage measurements with the Gaeltec sensors.

ii) The author took part in two small studies that assessed the sub-bandage pressures produced by different bandage techniques and 8 long-stretch bandages using the Fontanometer sensors in combination with the S7b Gaeltec amplifiers. Both studies were completed using leg models while the findings were presented at the 11th ETRS annual conference (Melhuish et al., 2001a and 2000b).

iii) The sensors had been assessed by the author before the assembly of the system by applying a bandage to a subject and check if the amplifiers produced a satisfactory reading (i.e. around 40 mmHg). This procedure was followed while the subject stood, seated on a chair and under ambulation (1 to 2 steps).

5.3 Phase 1 - Preliminary tests, benchmark performance of sensor technology

Before the commencement of system development it was evident that the benchmark performance of sensor technology would:

i) Provide useful information about the electrical characteristics of the sensor (and Gaeltec amplifier) and confirm that its performance lies within the required specification.

ii) Create the basis of performance results that can be compared with the performance outcomes of the oncoming development phases.

The tests were carried out using the configuration shown in Figure 5.3 that consisted of the following components:

- A Fontanometer sensor (Gaeltec Ltd. - Figure 4.2/p92).

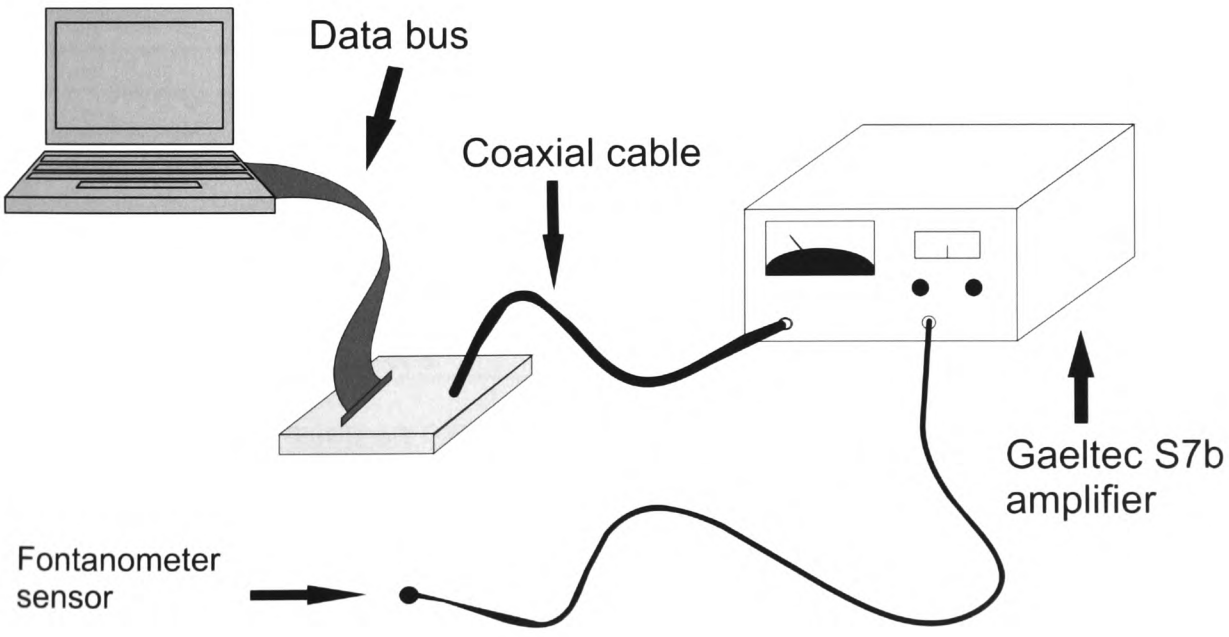

Figure 5.3 Benchmark tests configuration

- An S7b Gaeltec amplifier (Figure 5.4). This portable device amplifies and conditions outputs from the Fontanometer sensors and is powered by rechargeable 9 V Ni/Cd batteries. Sensor zero is set by means of a 10 turn potentiometer (ZERO) while a second potentiometer (SPAN) provides for gain adjustment. The conditioned sensor output is provided for further processing via the BNC output on the front panel. The S7b amplifier specification is shown in Table 5.1.

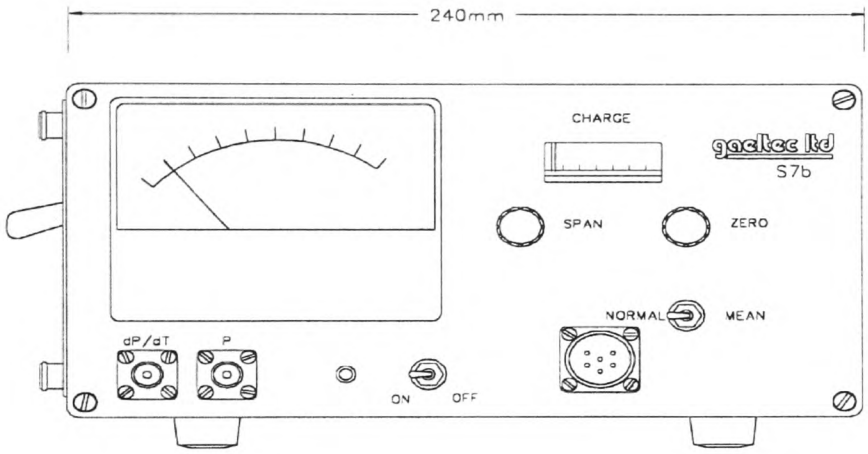

Figure 5.4 Gaeltec S7b Amplifier

Dimensions	240x120x100 mm grey A.B.S. housing
Weight	1.5 kg (approx.)
Transducer drive	2.5 V rms, 2 kHz square wave
Gain	Fully adjustable
Noise level	0.25 mmHg equivalent
Frequency response	DC to 100 Hz
Transducer input connector	Cannon WK6
Battery size	9 V rechargeable PP9 supplied
Output connector	BNC

Table 5.1 Gaeltec S7b amplifier specifications

- A portable computer connected to a data acquisition card (DAQ700, PMCIA type – National Instruments). The card is connected to the computer as shown in Figure 5.5 and via a data bus it can be connected to a standard 50 pin connector for data input. The DAQ700 specifications are shown in Table 5.2.

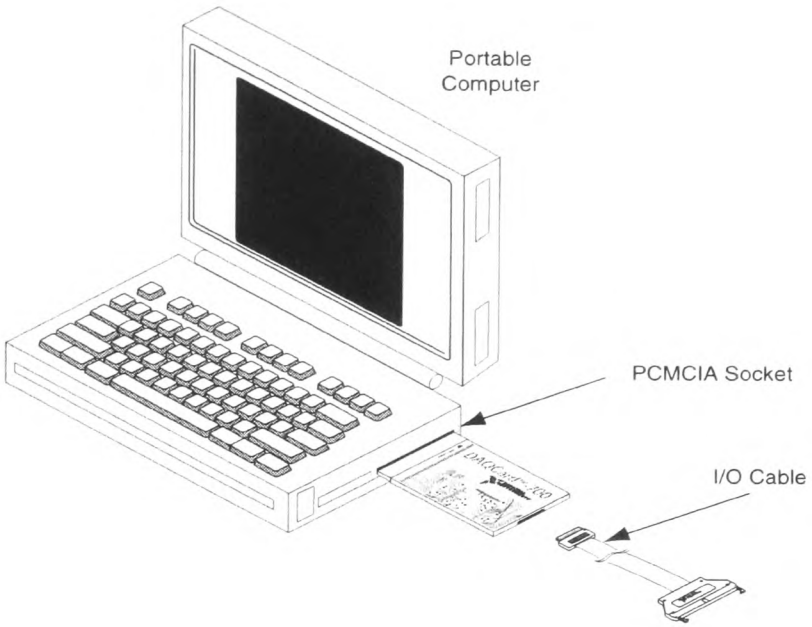

Figure 5.5 DAQ700 configuration
(Adapted from National Instruments)

Number of channels	16 single ended or 8 differential
Resolution	12 bits
Max sampling rate	100 kS/s
Input signal ranges	±10 V, ±5 V, ±2.5 V
Operating temperature range	0° to 70° C
Provides	5 V, 1 A

Table 5.2 DAQ700 specifications

- A simple circuit board acting as interface, connecting the BNC output (amplifier) to the 50 pin data bus of the data acquisition card (DAQ700).

The components were assembled as shown in Figure 5.3. The application of pressure to the Fontanometer sensor caused the S7b amplifier to produce a signal that was sent via the BNC cable and data bus to the portable computer, where it was displayed as a pressure value.

The apparatus used for the benchmark tests included the sphygmomanometer and the small weights (discussed in 5.1). Before the commencement of all measurements a fully charged

battery was placed in the S7b amplifier in order to avoid power reduction issues during the measurement process. Furthermore, according to S7b manufacturers' recommendations the amplifier was allowed to settle for 5 minutes before any measurements were executed.

The benchmark performance measurements executed included resolution, accuracy, linearity, hysteresis, drift, noise and repeatability (methods described in section 5.1.1 to 5.1.7). All tests were carried out in a temperature controlled room. The results are given below:

- Resolution: With the aid of the oscilloscope it was found that the smallest detectable pressure was 0.01 mmHg.
- Accuracy: The results are shown in Table 5.3. The outcomes are within the specified ±2 mmHg value.

Channel	Maximum Positive Difference (mmHg)	Maximum Negative Difference (mmHg)
1	1.14	1.06

Table 5.3 Maximum positive and negative differences from the fixed initial applied pressures (in mmHg) – Benchmark performance tests

- Linearity: Figure 5.6 illustrates the envelope which includes all linearity measurements. The error does not exceed the ±2 mmHg (positive maximum error 1.35 mmHg/ maximum negative error 1.04 mmHg). The envelope includes the results of a typical measurement (3rd measurement).

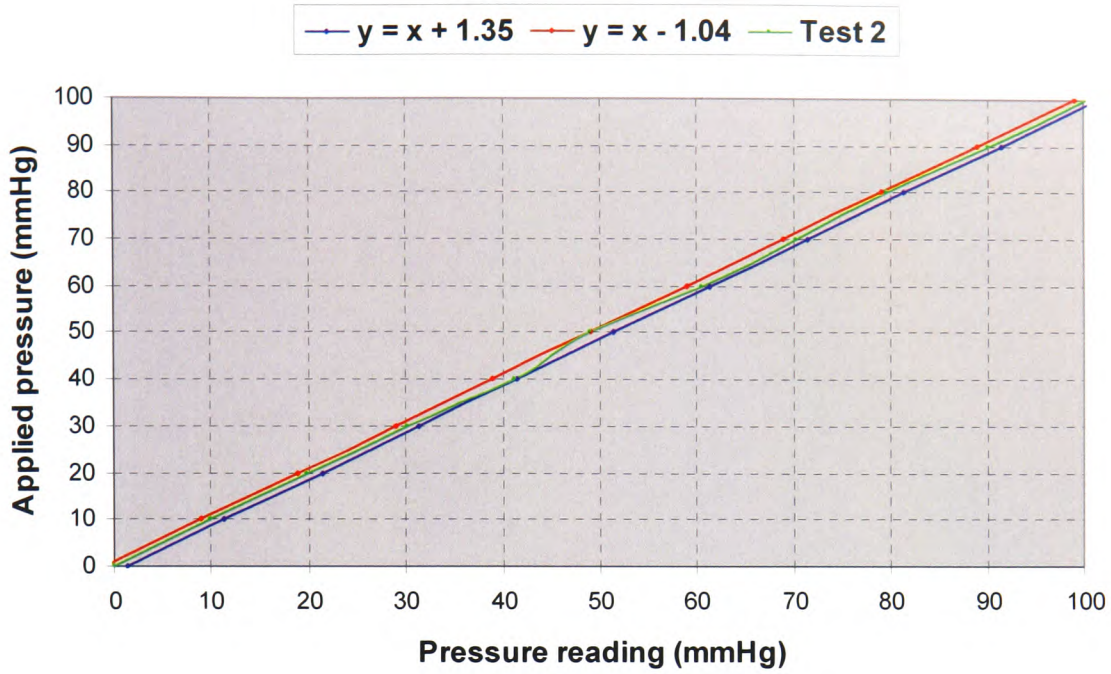

Figure 5.6 Linearity measurements – Benchmark performance tests

- Hysteresis: The maximum hysteresis error found was 1.88 mmHg. Figure 5.7 illustrates a typical measurement.

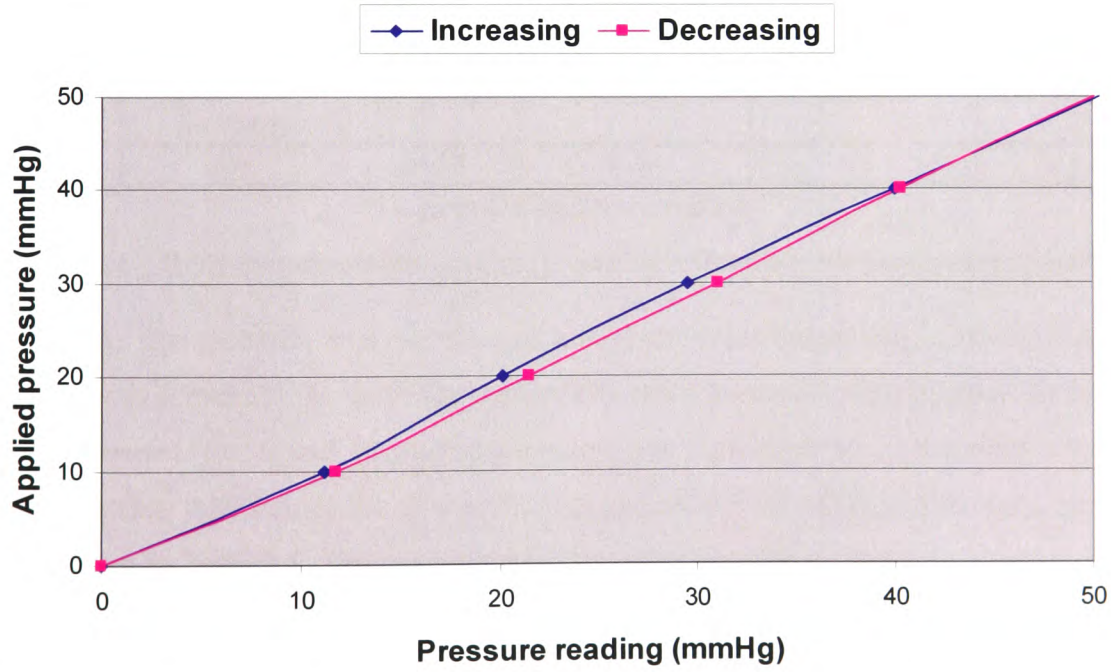

Figure 5.7 Typical hysteresis effect measurement – Benchmark performance tests

- Drift: Figure 5.8 illustrates the drift results during the benchmark performance measurements. Table 5.4 provides the detailed results.

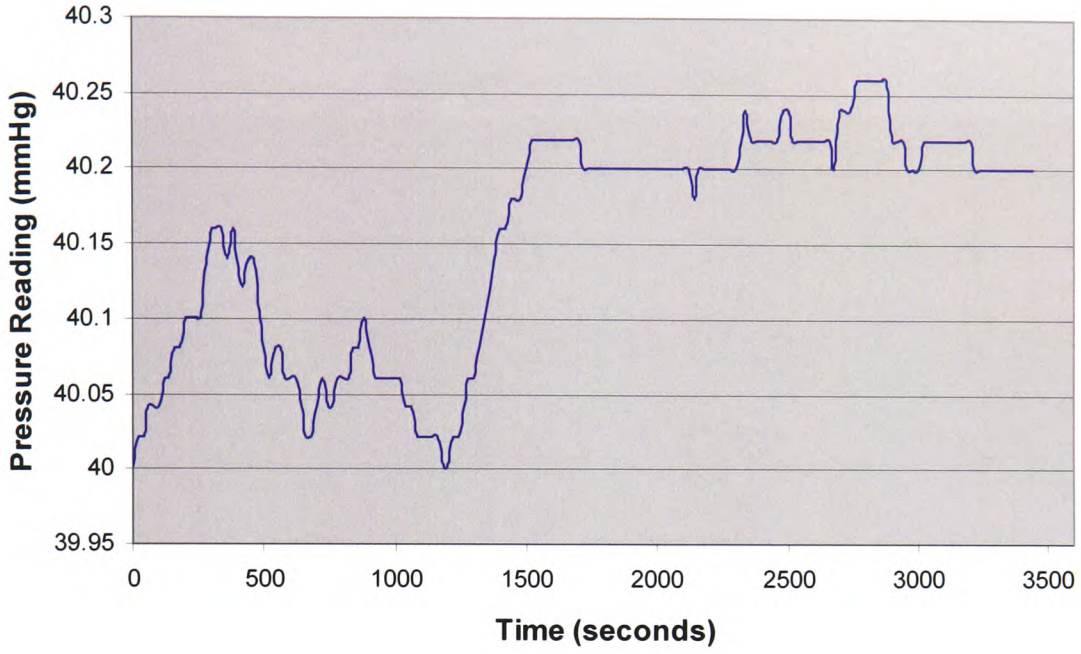

Figure 5.8 Drift measurement – Benchmark performance tests

Channel	Initial applied pressure (mmHg)	Average pressure (mmHg)	Maximum positive drift (mmHg)*	Maximum negative drift (mmHg)*	Final drift (mmHg)
1	40	40.15	0.26	0	0.2

*From initial pressure reading

Table 5.4 Drift measurement results in mmHg – Benchmark performance tests

- Noise: The spectrum analyser showed a uniform noise bandwidth, meaning that only white noise was present in the amplifier output. The noise increased slightly when the applied pressure increased. For 0 and 40 mmHg the noise was equivalent to 0.18 mmHg while the noise increased to 0.26 mmHg for 80 mmHg (average noise 0.22 mmHg). The signal-to-noise ratios are given in Table 5.5. The quantisation effect is strong in this case.

Channel	40 mmHg	80 mmHg
1	47	49

Table 5.5 Signal to noise ratio in dBs – Benchmark performance tests

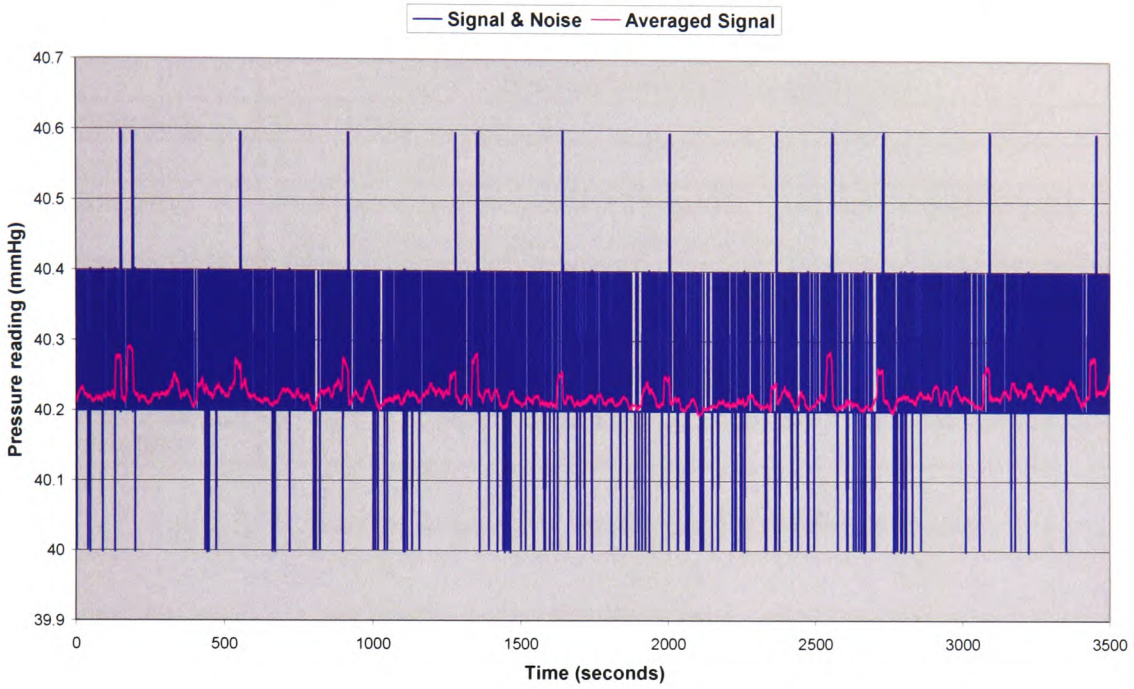

Figure 5.9 Noise measurement (40 mmHg applied pressure), the pink line in this figure corresponds to the averaged signal after the application of the moving average filter – Benchmark performance tests

- Repeatability: The summary of results is given in Table 5.6. The pressures are expressed as average values while the numbers in brackets are the standard deviations. The tests revealed a very repeatable system with very small differences between the applied pressure and the readings.

	Day 1 (20°C)		Day 2 (20°C)		Day 3 (21°C)	
Pressure (mmHg)	**40**	**80**	**40**	**80**	**40**	**80**
Channel 1	40.26 (0.51)	80.15 (0.21)	40.14 (0.44)	80.08 (0.43)	40.14 (0.37)	80.13 (0.46)
Coefficient of variation	0.012	0.002	0.01	0.005	0.009	0.005

Table 5.6 Summary of repeatability measurements (average values in mmHg) – Benchmark performance tests

- Crosstalk: There were no crosstalk effects since the measurements were carried out with only one amplifier.

The summary of results is given in Table 5.7.

	Benchmark performance tests
Resolution	0.1 mmHg
Accuracy	±1.14 mmHg
Linearity	Maximum positive error 1.35 mmHg/ maximum negative error 1.04 mmHg over the 0 - 100 mmHg range
Hysteresis	Maximum error 1.88 mmHg over the 0 - 100 mmHg range
Drift	Maximum positive 0.26 mmHg / negative 0 mmHg
Noise	Equivalent to 0.22 mmHg (average)
Repeatability	Maximum standard deviation 0.51 mmHg over 3 days
Crosstalk	N/A

Table 5.7 Results summary – Benchmark performance tests

By observing the results, it can be concluded that the sensor performance (in conjunction with the S7b amplifier) was within the required specification. Furthermore the acquired results formed the basis for comparisons between the performance of the benchmark configuration and the later developed systems.

5.4 Phase 2 - Application and evaluation of existing technology

The first step towards the development of the final instrumentation was the assembly of a system that utilized known technology. The aim of this system was to illustrate the feasibility of ambulatory sub-bandage measurements of the type required and to test different software approaches. The system is shown in Figure 5.10 and consisted of the following components:

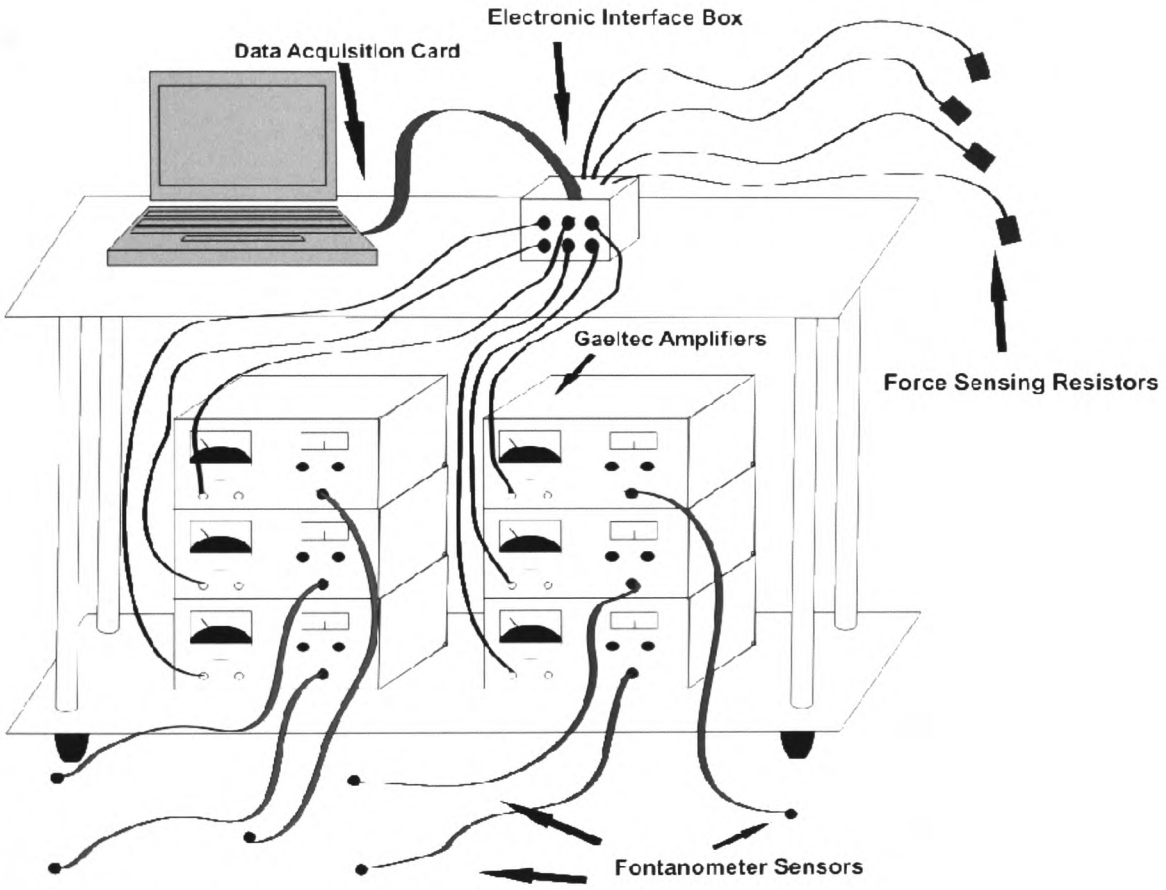

Figure 5.10 Initial system

- Six Gaeltec S7b amplifiers (Figure 5.4).
- Six Fontanometer sensors (Gaeltec Ltd) for pressure measurements (discussed in 4.4)
- Four Force Sensing Resistors (Interlink Electronics) as gait pattern indicators. Table 5.8 illustrates their specifications. The device is shown in Figure 5.11.

Dimensions	2.5 x 2.5 cm
Thickness	0.20 to 1.25 mm
Force sensitivity range	<100 g to >10 kg
Stand off resistance	>1 M
Device rise time	1-2 ms (mechanical)
Temperature range	-30° C to +70° C

Table 5.8 Force Sensing Resistor specifications

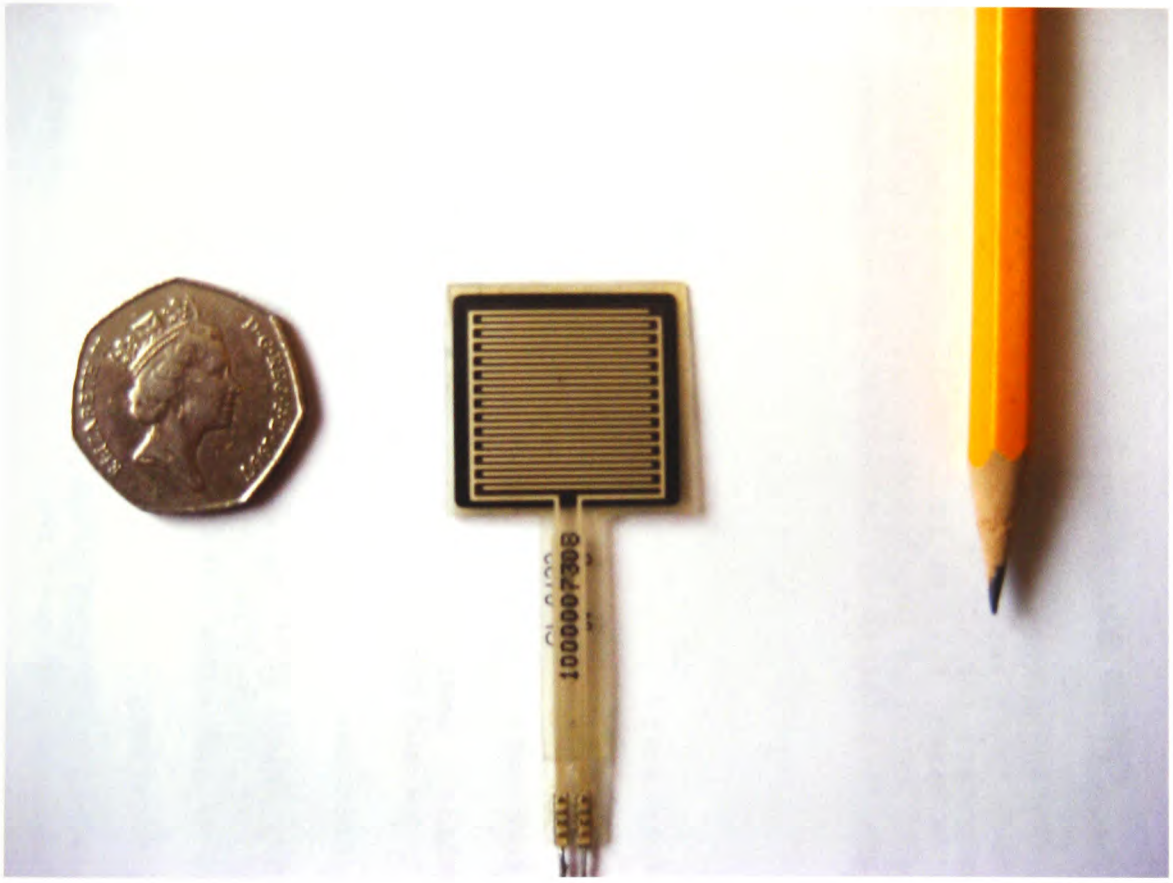

Figure 5.11 Force Sensing Resistor

- A portable computer connected to a data acquisition card (DAQ700, PMCIA type – National Instruments – discussed in 5.3).
- An interface circuit, responsible for connecting the amplifiers and the Force Sensing Resistors to the data acquisition card. The interface circuit was built in a small die cast box and provided connections for the FSR cables, six BNC inputs for the Gaeltec amplifier

buffered signal output cables, location for the 50 pin connector of the data acquisition card and a set of resistive voltage dividers that adjusted the gain of the signals from the FSRs.

- A LabView (LabView 6.1 – National Instruments) program for displaying and processing data (Figure 5.12). This program was used for both performance tests and ambulatory measurements.
- An equipment trolley for portability and stability.

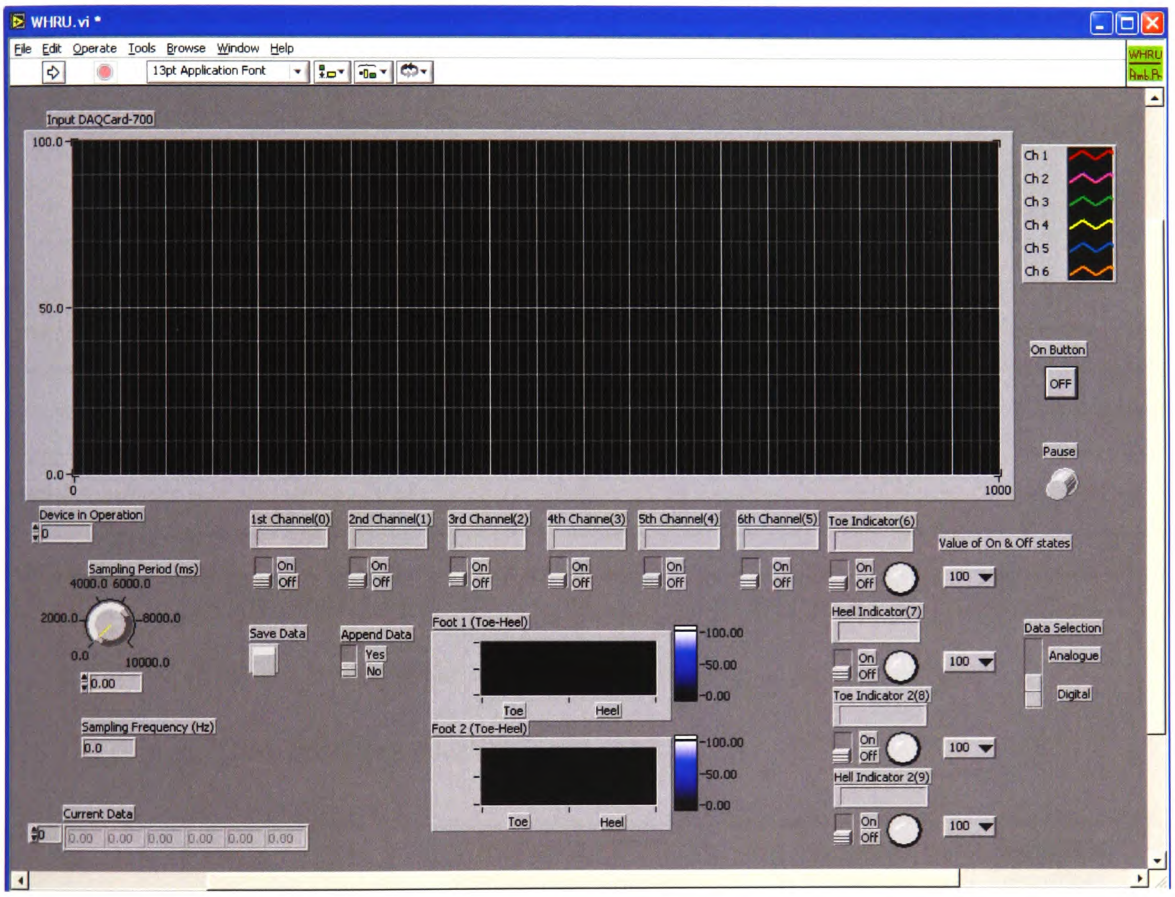

Figure 5.12 LabView programme used for characterisation and ambulatory measurements

The system was connected as apparent from Figure 5.10. When pressure is applied to any sensor, the corresponding amplifier produces a signal that is sent (via the interface circuit) to the data acquisition card and is displayed by the portable computer (using the LabView program). The signal from the gait indicators was produced by connecting each FSR to a voltage divider followed by an inverting amplifier whose gain could be set by a variable

resistance. These circuits were powered by the data acquisition card and provided 4 signals that could be processed simultaneously with the other pressure readings. Fully charged batteries were placed in each amplifier while a 5 minute settling period was allowed before the beginning of the each test. Each amplifier was calibrated using the sphygmomanometer method discussed in 5.1.

5.4.1 Performance tests and discussion

The description of performance measurement methods can be found in sections 5.1.1 to 5.1.8. The results are shown below:

- Resolution: Resolution measured for each channel is illustrated in Table 5.9.

Channel	Resolution (mmHg)
1	0.1
2	0.12
3	0.1
4	0.11
5	0.1
6	0.12
Average	0.108

Table 5.9 Resolution results (in mmHg) – Initial system

- Accuracy: The results are given in Table 5.10.

Channel	Maximum Positive difference (mmHg)	Maximum Negative difference (mmHg)
1	1.56	1.45
2	1.65	1.89
3	1.84	1.86
4	1.69	1.46
5	1.85	1.53
6	1.94	1.91
Average	1.75	1.68

Table 5.10 Maximum positive and negative differences from the fixed initial applied pressures (in mmHg) – Initial system

No channel exceeded the ±2 mmHg limit. The accuracy therefore could be expressed ±1.94 mmHg (being the maximum difference measurement).

- Linearity: Linearity results are shown in Figure 5.13. Typical trend line (from channel 3) is illustrated in green colour. The linearity error does not exceed the ±2 mmHg specified limit. The maximum positive error is 1.69 mmHg while the maximum negative error is 0.63 mmHg.

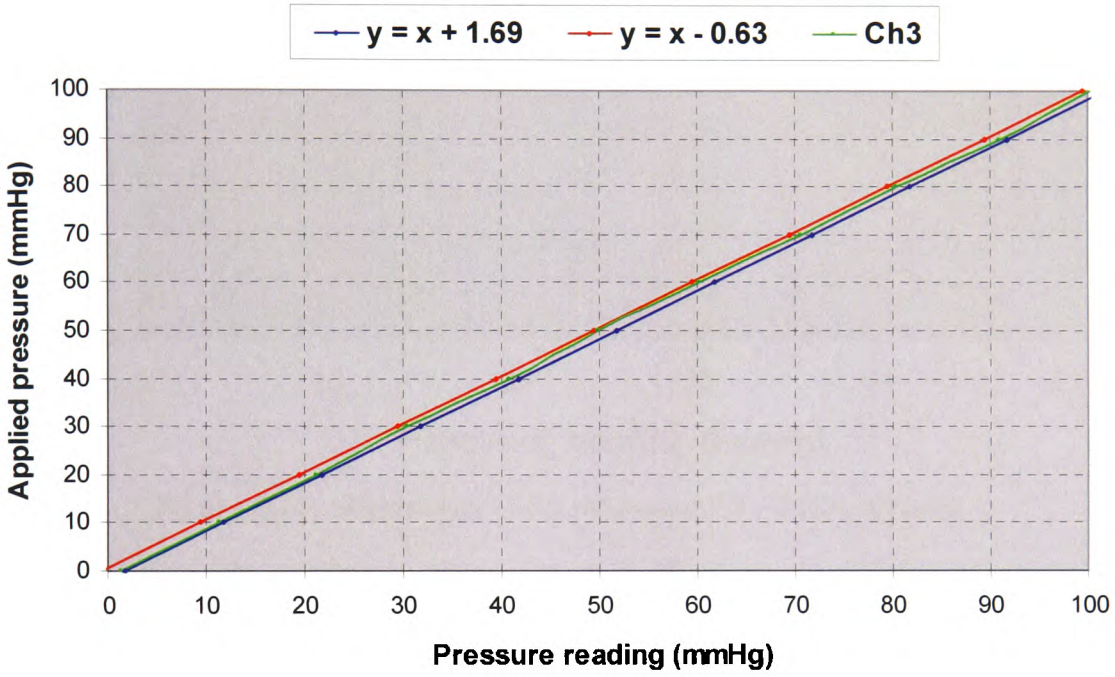

Figure 5.13 Linearity measurements – Initial system

- Hysteresis: Table 5.11 shows the results.

Channel	Maximum difference (mmHg)
1	1.23
2	1.7
3	1.75
4	1.77
5	1.58
6	1.74
Average	1.63

Table 5.11 Hysteresis effect results in mmHg – Initial system

Figure 5.14 illustrates the typical hysteresis error on channel 3 (for pressures that are expected during the anticipated measurements). As it can be seen from Table 5.10, the hysteresis effect did not exceed 2 mmHg limit.

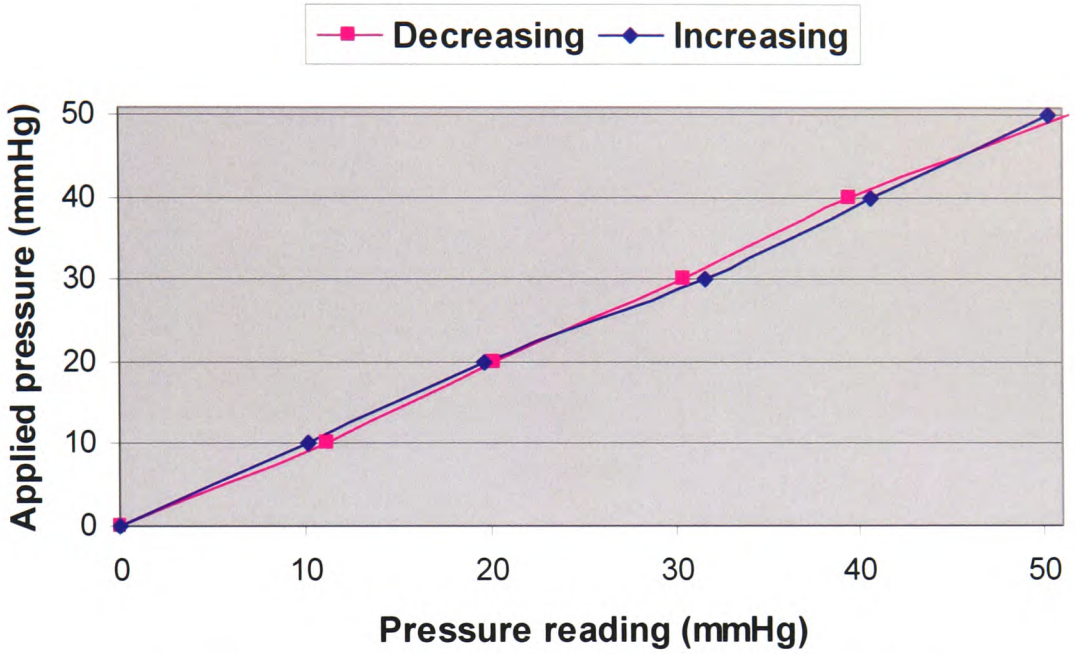

Figure 5.14 Hysteresis effect on channel 3 – Initial system

- Drift: The summary of the results is given in Table 5.12, while Figure 5.15 shows a typical drift measurement (Channel 5).

Channel	Initial applied pressure (mmHg)	Average pressure (mmHg)	Maximum positive drift (mmHg)*	Maximum negative drift (mmHg)*	Final drift (mmHg)
1	40.49	40.53	0.1	0.2	0.1
2	41	41.02	0.12	0.04	-0.02
3	40.15	39.67	0	0.93	-0.75
4	40.21	40.15	0.06	0.21	-0.1
5	40.81	40.63	0.02	0.42	-0.42
6	40.4	40.52	0.06	0.12	0.02
Average	40.51	40.42	0.06	0.32	0.23

*From initial pressure reading

Table 5.12 Summary of drift measurements in mmHg – Initial system

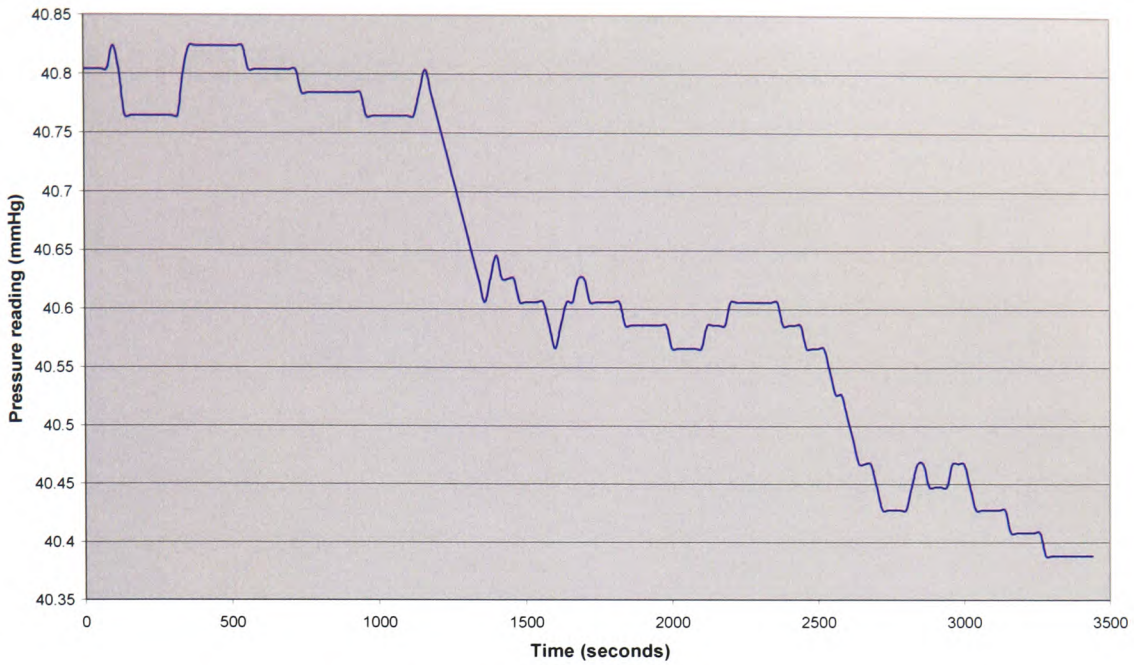

Figure 5.15 Drift measurement (Channel 5) – Initial system

- Noise: The observation of the outputs with the spectrum analyser showed that the system noise was uniformly spread and therefore it can be said that it was of thermal origin. The noise increased slightly with the increase of applied pressure. Table 5.13 summarises the average equivalents (in mmHg) of the noise levels measured on each channel. Figure 5.16 illustrates a typical measurement while Table 5.14 shows the signal to noise ratios acquired from the noise measurements.

Average noise (mmHg)	Ch 1	Ch 2	Ch 3	Ch 4	Ch 5	Ch 6
	0.24	0.23	0.23	0.2	0.26	0.25

Table 5.13 Average noise levels in mmHg – Initial system

Channel	40 mmHg	80 mmHg
1	44.08	51
2	44.94	48
3	45.7	50.6
4	46.16	49.6
5	43.23	40.98
6	45.01	40.99

Table 5.14 Signal to noise ratios in dBs – Initial system

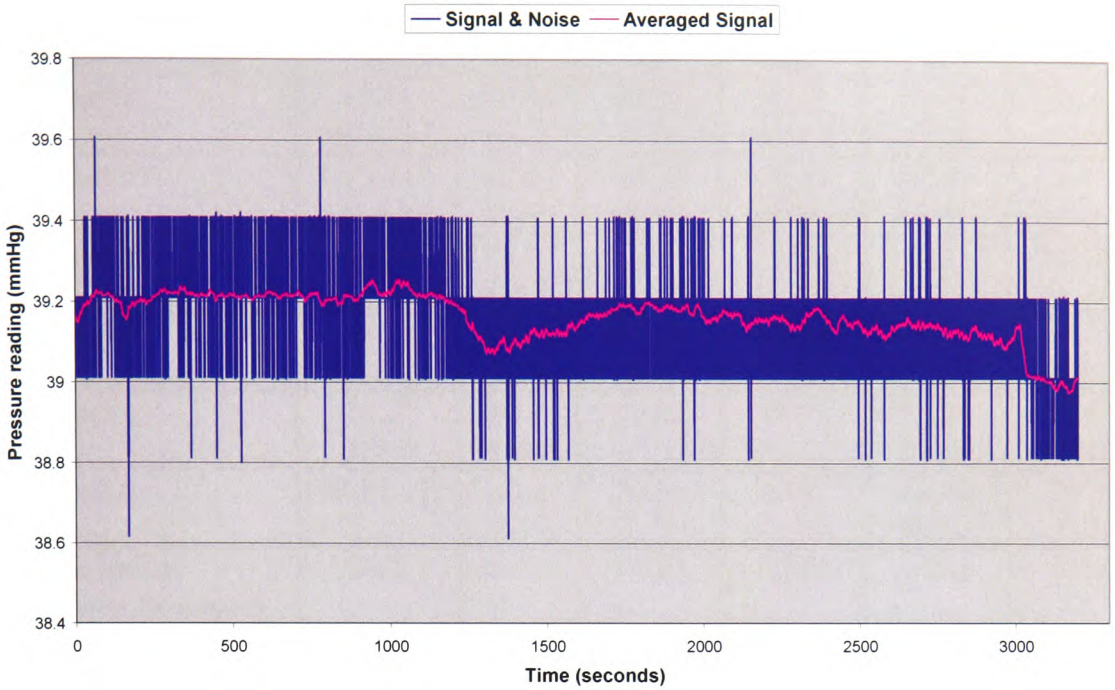

Figure 5.16 Signal and noise translated to pressure reading for channel 4 – Initial system

The application of a simple RC filter (100 Hz cut off) at the output of the system did not improve the signal to noise ratio (measured with the 40 mmHg applied pressure).

- Repeatability: Table 5.15 summarizes the repeatability measurements. The results reveal a repeatable system.

- Crosstalk: The crosstalk effect was checked following the method described in 5.1.8. As expected the effect was negligible since the amplifiers were not connected to each other and the interface box did not produce any interference. For example channel 5 had the same level of noise when a 100 Hz signal was connected to channel 4 and corresponded to 0.26 mmHg.

	Day 1 (20.1°C)		Day 2 (19.8°C)		Day 3 (20.2°C)	
Pressure (mmHg)	**40**	**80**	**40**	**80**	**40**	**80**
Channel 1	40.41 (0.64)	80.14 (0.2)	40.27 (0.73)	80.52 (0.91)	40.56 (0.38)	79.6 (0.77)
Channel 2	40.01 (0.42)	80.09 (0.42)	40.22 (0.98)	79.31 (0.78)	40.57 (0.28)	80.21 (0.79)
Channel 3	40.39 (0.33)	80.59 (0.45)	40 (0.48)	79.6 (1.27)	40.21 (0.92)	80.14 (1.09)
Channel 4	40.32 (0.57)	80.05 (0.5)	40.14 (1.01)	80.34 (0.72)	40.2 (0.53)	79.75 (0.74)
Channel 5	40.27 (0.38)	80.1 (0.65)	40.06 (1.13)	80.55 (1.1)	40.28 (0.23)	79.81 (1.07)
Channel 6	40.3 (0.3)	80.4 (0.59)	40.36 (1.16)	80.26 (1.18)	40.42 (0.54)	79.78 (0.8)
Coefficient of Variation (average)	0.01	0.005	0.022	0.012	0.011	0.01

Table 5.15 Summary of repeatability measurements – Initial system

The summary of results is shown in Table 5.16.

	Initial system
Resolution	Average 1.08 mmHg
Accuracy	±1.94 mmHg
Linearity	Maximum positive error 1.69 mmHg/ maximum negative error 0.63 mmHg over the 0 – 100 mmHg range
Hysteresis	Maximum error 1.77 mmHg over the 0 – 100 mmHg range
Drift	Maximum positive 0.12 mmHg / negative 0.93 mmHg
Noise	Equivalent to 0.235 mmHg (average – all channels)
Repeatability	Maximum standard deviation 1.27 mmHg
Crosstalk	Negligible

Table 5.16 Results summary – Initial system

The assembled system that utilized existing technology performed within the required specification. It can be seen that the results were similar to the ones (see Table 5.7) acquired during the benchmark tests. This was expected since this system was assembled using S7b amplifiers while the interface box did not decrease the overall system performance. In summary, the accuracy was close to the specified ±2 mmHg value (worse than benchmark tests), while the maximum channel drift was almost 4 times that of the benchmark

measurements but still well within the specification. The noise level could not seriously affect the pressure measurements and it was almost the same as measured in the initial tests. The measured pressures were repeatable (standard deviation 1.27 mmHg) with no significant crosstalk effects present in the system.

This system was assembled in order to gain experience with software development and to establish the practicality of ambulatory sub-bandage pressure measurements. The performance measurements illustrated a system that could reliably execute ambulatory sub-bandage measurements.

However, the system had 3 major disadvantages:

a) The volume of the amplifiers that had to be placed on the trolley.
b) The amount of cables connecting the sensors to amplifiers limiting comfortable movement.
c) The number of pressure sensors (6 compared to the 10 sensors required). More sensors could provide a better picture of both sides of the leg.

5.4.2 Ambulatory measurements

Initial ambulatory measurements were taken as follows: The subject had to stand next to the apparatus while the pressure sensors were placed on the left leg at the anatomical points shown in Figure 5.17. These anatomical points were:

- 1st on medial malleolus (Channel 1)
- 2nd 4 cm above medial malleolus (Channel 2)
- 3rd 8cm above medial malleolus (Channel 3)
- 4th ½ way between 4th and 2nd sensor (Channel 4)
- 5th Great circumference of calf muscle (Channel 5)
- 6th Top of the calf muscle (Channel 6)

The subject was attached to the system as shown in Figure 5.18. The FSRs were placed at the big toe and heel of each foot. All sensors (both Fontanometer and FSRs) were positioned on the leg using a non cohesive medical tape (Micropore™). The cables connecting the sensors to

the amplifiers were tied together and then tied to the subject at waist height using a string. An experienced bandager was asked to apply a 4 layer bandage system to the left leg, aiming to achieve graduated compression.

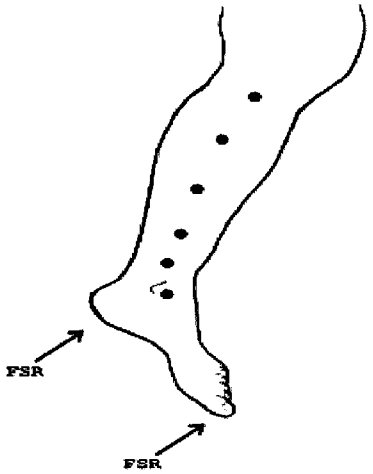

Figure 5.17 Pressure points

Initially the subject was asked to stand still in order to record the pressures and then was asked to walk for about 15 metres. The program was set to record samples every 10 ms. The trolley was pushed in parallel with the subject while the pressures were recorded. Figure 5.18 demonstrates the measurement configuration with a compression stocking.

Figure 5.19 illustrates some typical results. The results show the effect of ambulation on sub-bandage pressure over 12 to 13 steps on level ground over a total period of approximately 7 to 8 seconds. Figure 5.20 shows a combination of the ambulatory pressures with the signal produced by the gait indicator placed on the big toe of the left leg (only on and off status, the 100 mmHg readings does not represent a true pressure value). It represents the period of time for which the big toe of the left leg touches the ground. This signal can be combined with the 3 other signals (left heel, right big toe and heel) from the gait indicators (also recorded by the program) in order to illustrate the walking pattern of the subject.

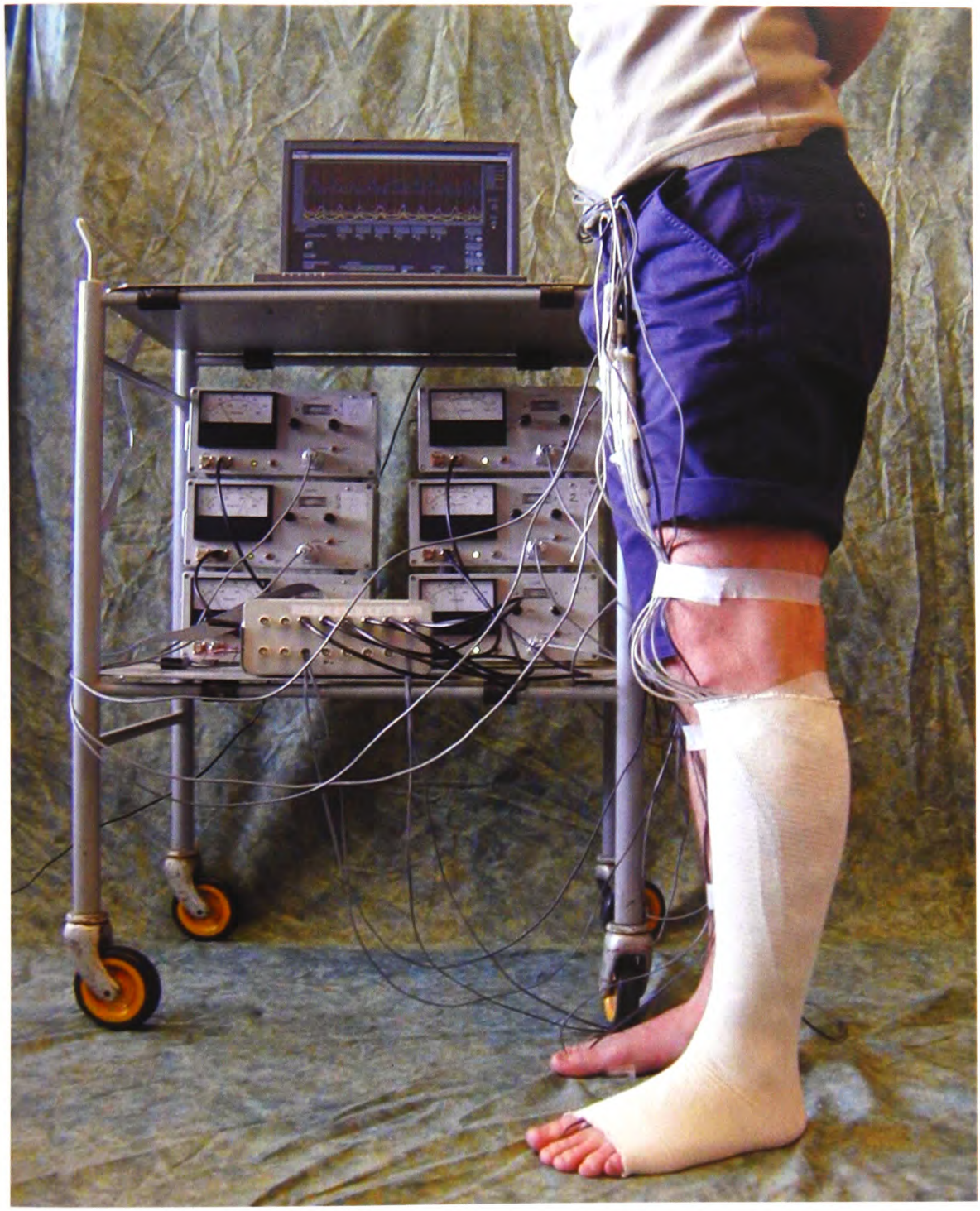

Figure 5.18 System and leg with compression stocking

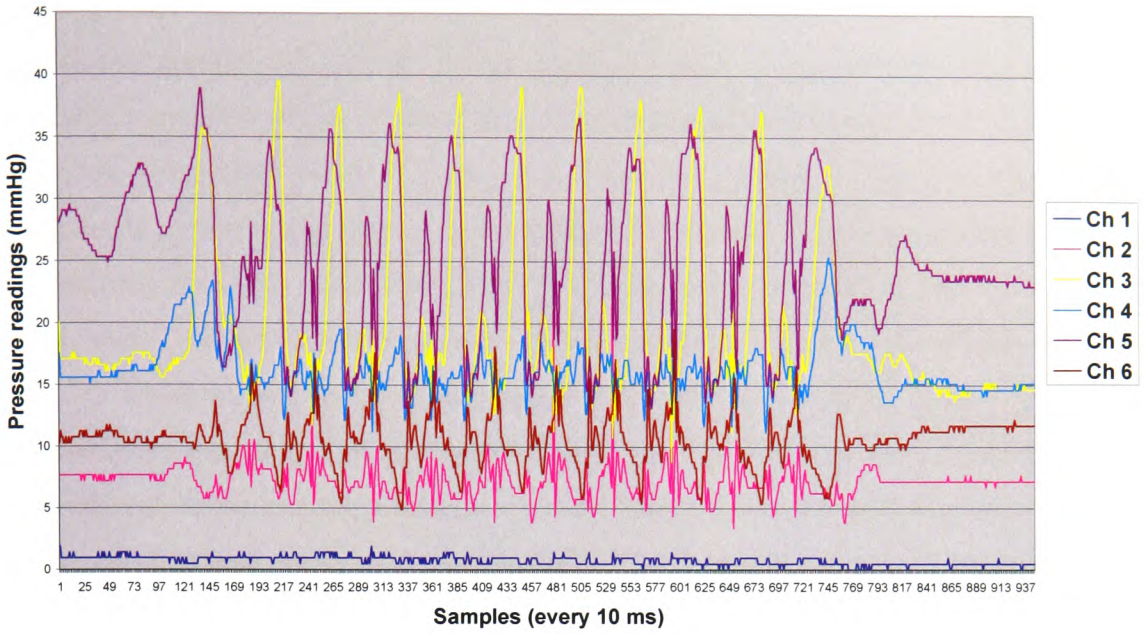

Figure 5.19 Pressure generated under compression bandages during walking

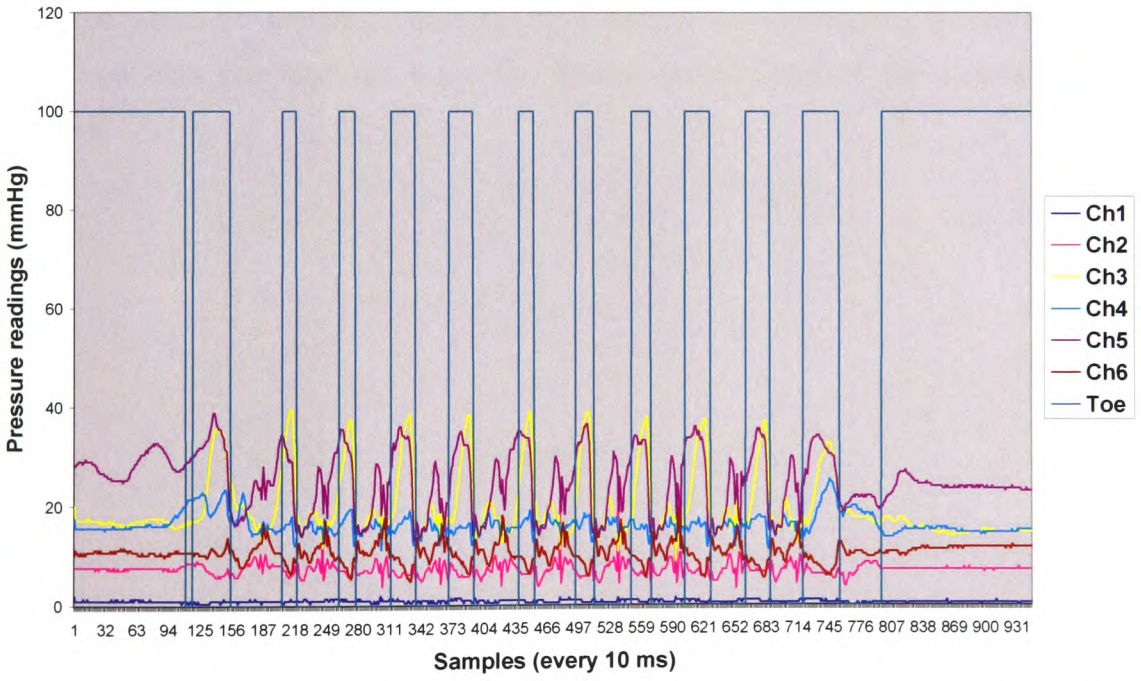

Figure 5.20 Pressures generated under compression bandages during walking combined with the gait signal produced by the left big toe

The vertical axis represents the sub-bandage pressures in mmHg while the horizontal axis represents the number of samples (taken every 10 ms). It can be seen that there were considerable variations (about 30 mmHg) in sub-bandage pressures especially for the sensors in the middle anatomical points of the leg (i.e. channels 3, 4 and 5). This was expected since the calf muscle increases and decreases in volume considerably at these points during walking. On the contrary the other 3 sensors (placed at the top of calf muscle, on the ankle and 4 cm above the ankle) did not experience major volume changes of the leg. From Figure 5.20 it can be seen that when the big toe touches the ground the calf muscle starts increasing in volume until a maximum pressure value is reached. Before the big toe leaves the ground the pressure readings of each sensors is at its minimum value. Hence the foot plantarflexion produces the maximum sub-bandage pressures during walking. These results agree with the measurements from previous studies (can be compared with Figures 3.1/p59, 3.5/p63), although these trials do not provide any specific information about the exact foot movement or any other kind of gait indicators. However, the values of variation of sub-bandage forces agree with previous studies (i.e. about 30 mmHg). These results indicated the satisfactory fundamentals of the process and thus provided the basis for further development of the wound assessment laboratory.

5.5 Phase 3 - Development of prototype original measurement system

The experience gained and the disadvantages of the initial system (volume, weight, trolley requirement, volume of cables and number of sensors) led to a different development approach. This new design approach aimed to:

i) Minimize volume and weight

ii) Increase the number of Fontanometer sensors to 10

This aim was accomplished by designing a miniature circuit board that would:

- Eliminate the need for the interface box since the signal multiplexing would be accomplished on the board
- Replace the circuits (that also existed in the interface box) designed to set the FSRs' gains. Instead these circuits were included on the board.
- Provide power, excitation, signal processing and multiplexing for 4 FSRs and 10 Fontanometer sensors in a small enclosure

The circuit is shown in Figures 5.21, 5.22 and 5.23.

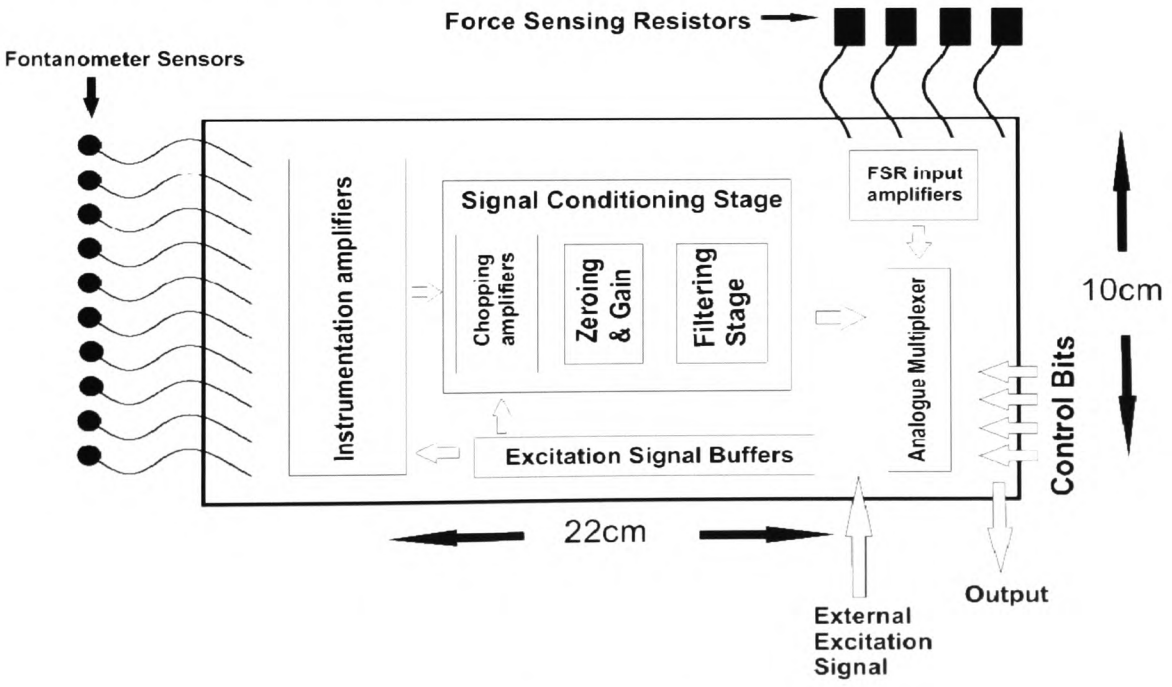

Figure 5.21 Prototype amplifier board

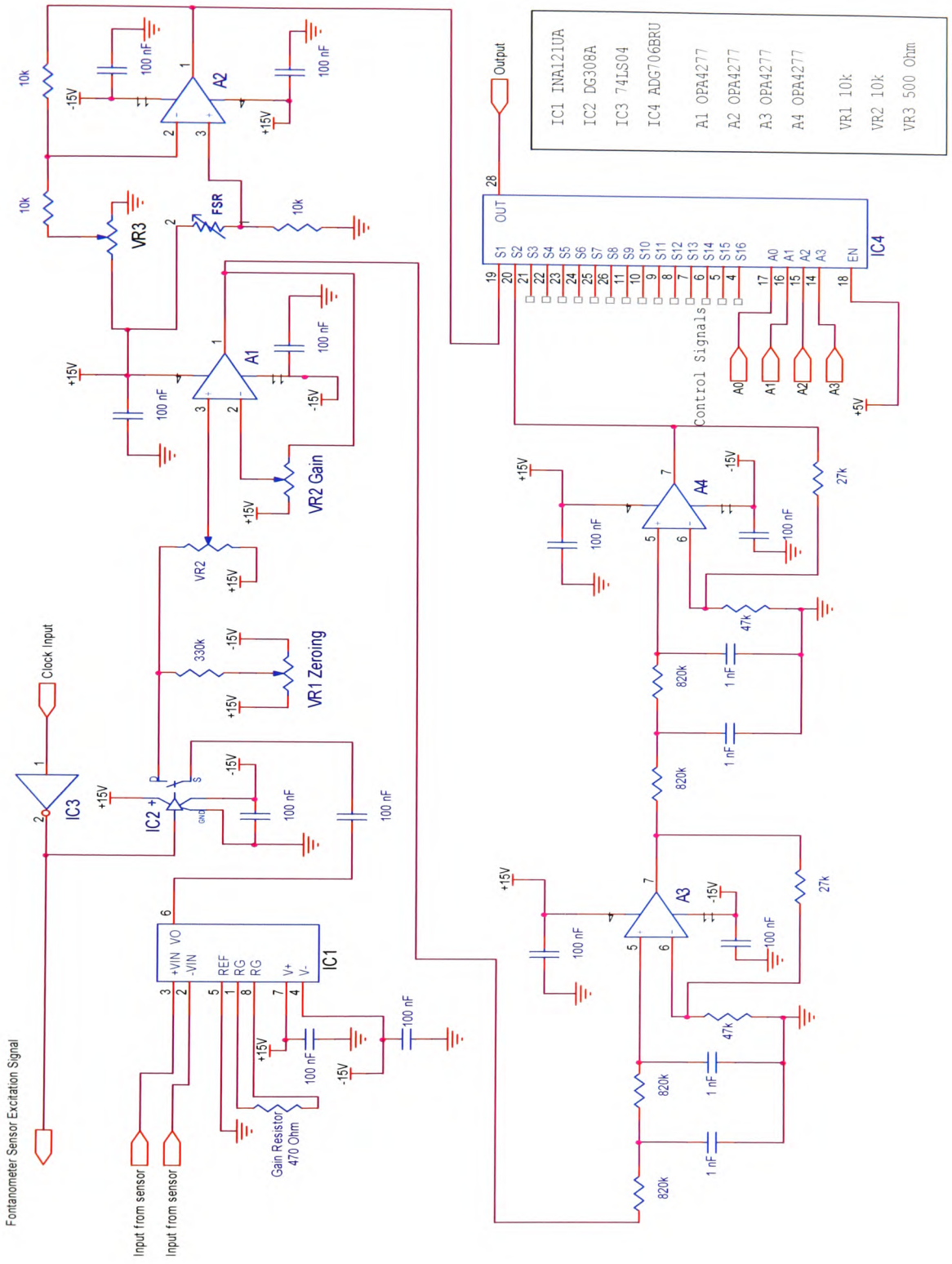

Figure 5.22 Prototype amplifier circuit diagram

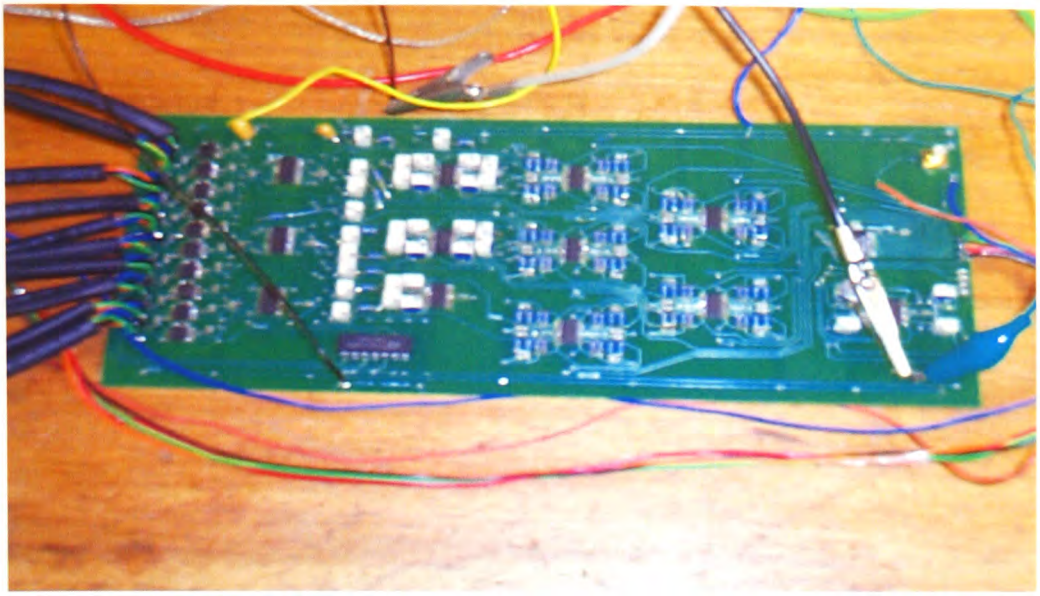

Figure 5.23 Prototype amplifier circuit board

Each Fontanometer sensors is connected to the amplifier circuit using a 6 PIN LEMO series 2 connector. According to the manufacturer, the required excitation signal for the sensors (arranged in full bridge strain gauge configuration) can be either 1 V DC (maximum) or 5 V rms AC (maximum). It was decided to apply a 5 V rms square wave (2 kHz) which produced a higher amplitude signal than the output produced by the 1 V DC for the same applied pressure. The principle of operation of a single channel is as follows:

The input from a sensor is connected to IC1 (instrumentation amplifier), whose gain is set to 19, sufficient to produce a clear signal for applied pressures between 0-100 mmHg (peak amplitude 2.8 V). The output of IC1 is AC coupled and connected to IC2 (analogue switch) whose switching frequency is the same as the frequency used for the excitation signal (i.e. 2 kHz). This stage allows only the positive part of the signal to go through and acts as the demodulator of a chopper amplifier configuration (the pressure signal is already modulated by the excitation signal). The purpose of this stage is to reduce drift. The output is connected to VR1 which can increase or decrease the signal is DC offset (zeroing stage). The signal gain can be set by VR1, VR2 and A1. From here the signal is fed to a four pole low pass filter (A3 and A4), cut off frequency 194 Hz, eliminating noise and spikes produced by the chopping part of the circuit. Finally the output of each discrete channel is fed to IC4 (analogue multiplexer). The control bits of the multiplexer are set by the data acquisition card (DAQ700,

National Instruments) and LabView (National Instruments) test program. The output of each channel was observed using the same LabView test program. The inputs from the gait indicators (FSRs) are connected to A2, using a simple voltage divider circuit. VR3 is used to set the gain of the gait indicator circuits. The circuit is powered by an external power source. The excitation signal for the Fontanometer sensors (2 kHz square wave) and the analogue switches is produced by a signal generator (as seen in Figure 5.21). This signal is buffered by IC3.

5.5.1 Performance tests and discussion

The apparatus and methods used for the performance tests are described in 5.1. The system was tested in a temperature controlled laboratory environment. The results are shown below:

- Resolution: By using the oscilloscope and the LabView test program it was determined the average system resolution was 0.118 mmHg. A summary is given in Table 5.17.

Channel	Resolution (mmHg)
1	0.12
2	0.11
3	0.1
4	0.12
5	0.13
6	0.13
7	0.12
8	0.12
9	0.11
10	0.12
Average	0.118

Table 5.17 Resolution results (in mmHg) – Prototype original measurement system

- Accuracy: Table 5.18 shows the summary of results. No channel exceeded the required accuracy (i.e. ±2 mmHg).

Channel	Maximum Positive difference (mmHg)	Maximum Negative difference (mmHg)
1	1.94	1.97
2	1.1	1.88
3	1.4	1.88
4	1.77	1.98
5	1.94	1.75
6	0.96	1.77
7	1.97	0.85
8	1.85	1.99
9	1.23	1.65
10	1.52	1.99
Average	1.57	1.96

Table 5.18 Maximum positive and negative differences from the fixed initial applied pressures (in mmHg) – Prototype original measurement system

- Linearity: The envelope created by the red and blue lines includes all the trend lines produced by the linearity measurements. The maximum positive error was 1.99 mmHg while the maximum negative error was 1.82 mmHg, therefore in agreement with the specified limit (±2 mmHg). A typical trend line is shown in green colour (channel 6).

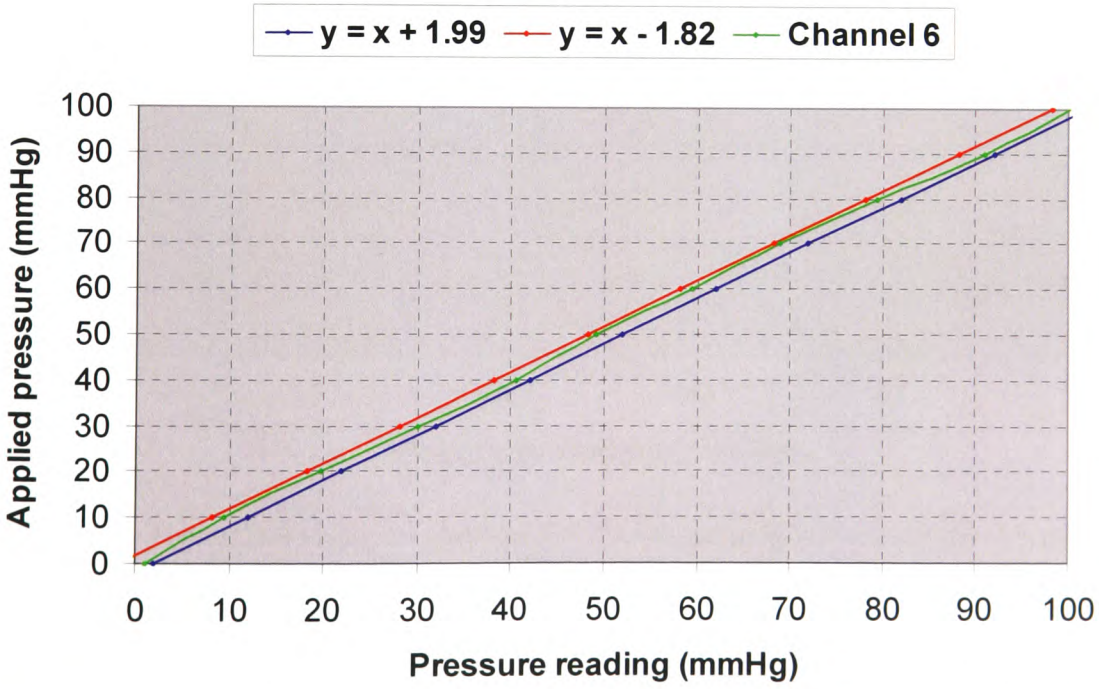

Figure 5.24 Linearity measurement – Prototype original measurement system

- Hysteresis: Maximum hysteresis error is shown in Table 5.19. Figure 5.25 shows a typical measurement (channel 2).

Channel	Maximum difference (mmHg)
1	1.4
2	1.83
3	1.39
4	1.91
5	1.44
6	1.44
7	1.84
8	1.87
9	1.52
10	1.37
Average	1.6

Table 5.19 Hysteresis error – Prototype original measurement system

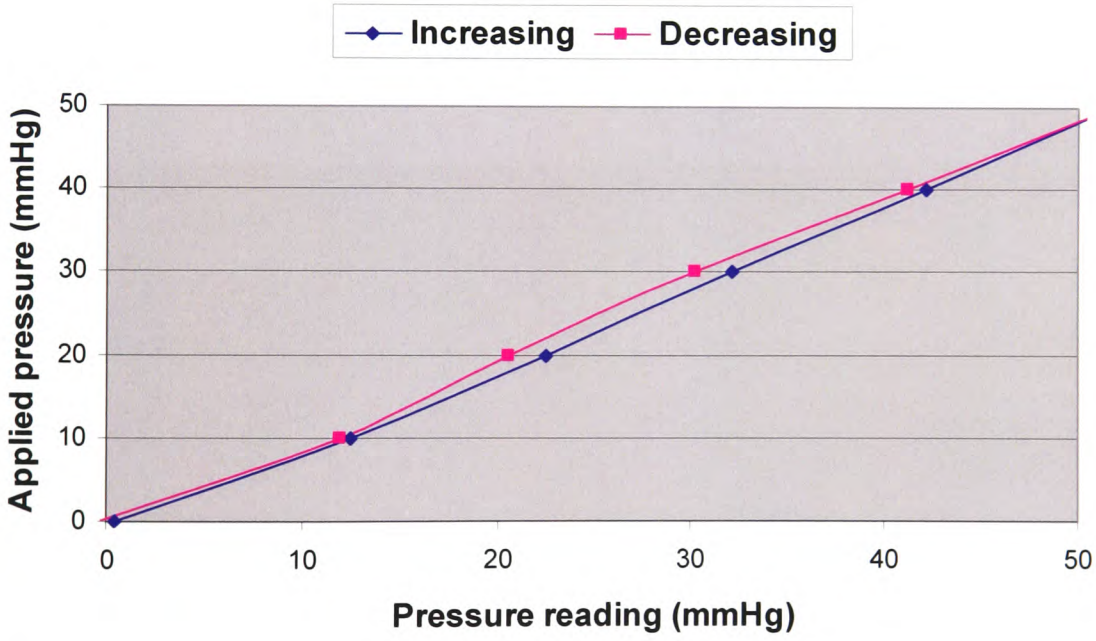

Figure 5.25 Hysteresis error on channel 3 – Prototype original measurement system

- Drift: The system drift was measured following the method described in section 5.1.5. One measurement was completed for each channel. The results are shown in Table 5.20 and Figure 5.26. It can be seen from Figure 5.26 that it takes about 250 seconds for the majority of

the signals to reach a relatively stable stage. Therefore this time can be considered as the settling time, i.e. about 4 to 5 minutes.

Channel	Initial applied pressure (mmHg)	Average pressure (mmHg)	Maximum positive drift (mmHg)*	Maximum negative drift (mmHg)*	Final drift (mmHg)
1	40.76	41.33	0.95	0	0.03
2	40.9	40.94	0.29	0.09	0.24
3	41.5	41.85	0.83	0.31	-0.31
4	40.08	39.37	0.09	1.37	-0.93
5	40.22	41.74	1.99	0	-1.44
6	38.85	38.78	0.29	0.34	-0.07
7	39.82	40.02	0.89	0.35	-0.26
8	40.76	42.19	1.98	0.21	1.63
9	42.29	42.16	0.43	0.67	0.11
10	40.78	40.98	0.67	0.23	-0.26
Average	40.59	40.94	0.84	0.36	0.53

*From initial pressure reading

Table 5.20 Drift measurements outcomes in mmHg – Prototype original measurement system

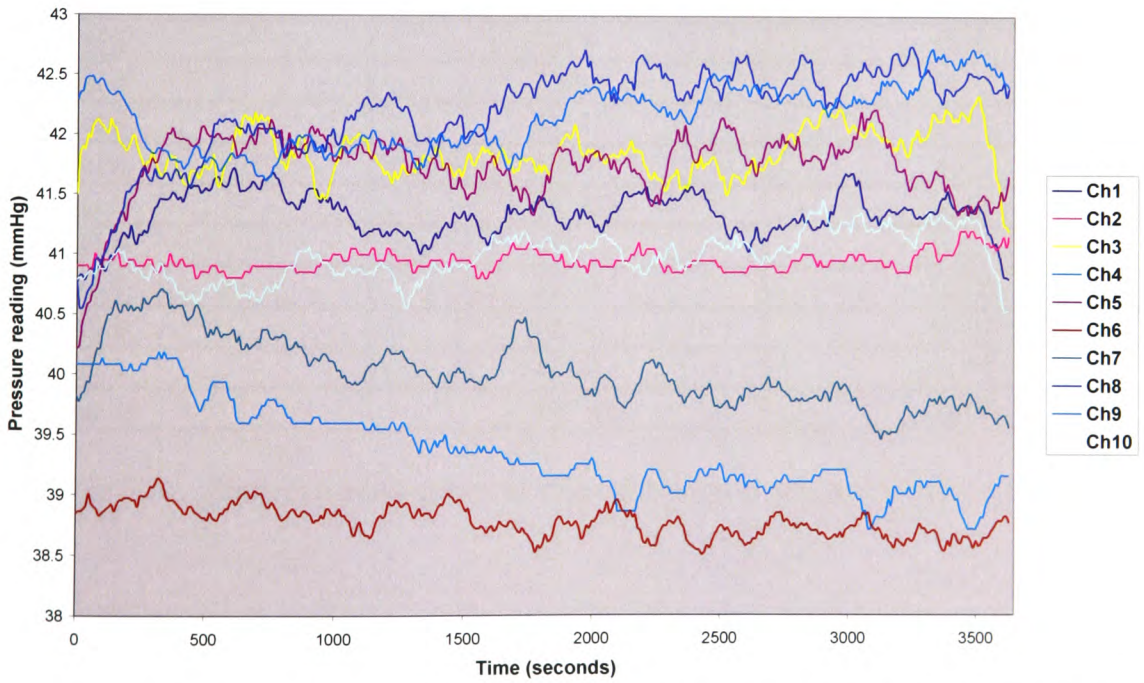

Figure 5.26 Drift measurements – Prototype original measurement system

- Noise: Initially the nature of noise was determined. The use of the spectrum analyser revealed that there were no frequency components at the lower frequency spectrum. As expected at higher frequencies (i.e. above 200 Hz) the frequency components originating from the excitation signal (2 kHz) were eliminated by the 4 pole low pass filter. Therefore it can be concluded that noise was of thermal origin. Table 5.21 summarises the average equivalents (in mmHg) of the noise levels measured on each channel. Figure 5.27 illustrates a typical measurement while Table 5.22 shows the signal to noise ratios acquired from the noise measurements. There has been an attempt to further filter the output signal by placing a simple low pass filter (cut off 100 Hz) at the output of the board. However there has not been significant change at the level of noise. Table 5.23 illustrates the signal to noise ratios (for 3 channels) before and after the application of the low pass filter

Average noise (mmHg)	Ch1	Ch2	Ch3	Ch4	Ch5	Ch6	Ch7	Ch8	Ch9	Ch10
	0.32	0.34	0.3	0.33	0.25	0.28	0.3	0.26	0.26	0.3

Table 5.21 Average noise levels in mmHg – Prototype original measurement system

	40 mmHg	80 mmHg
Channel 1	43.9	44.85
Channel 2	39.14	44.51
Channel 3	41.04	47.72
Channel 4	40.18	46.8
Channel 5	42.78	48.83
Channel 6	41.16	49.29
Channel 7	39.34	50.06
Channel 8	39.66	49.94
Channel 9	42.37	51.97
Channel 10	41.89	48.06

Table 5.22 Signal to noise ratios in dBs – Prototype original measure system

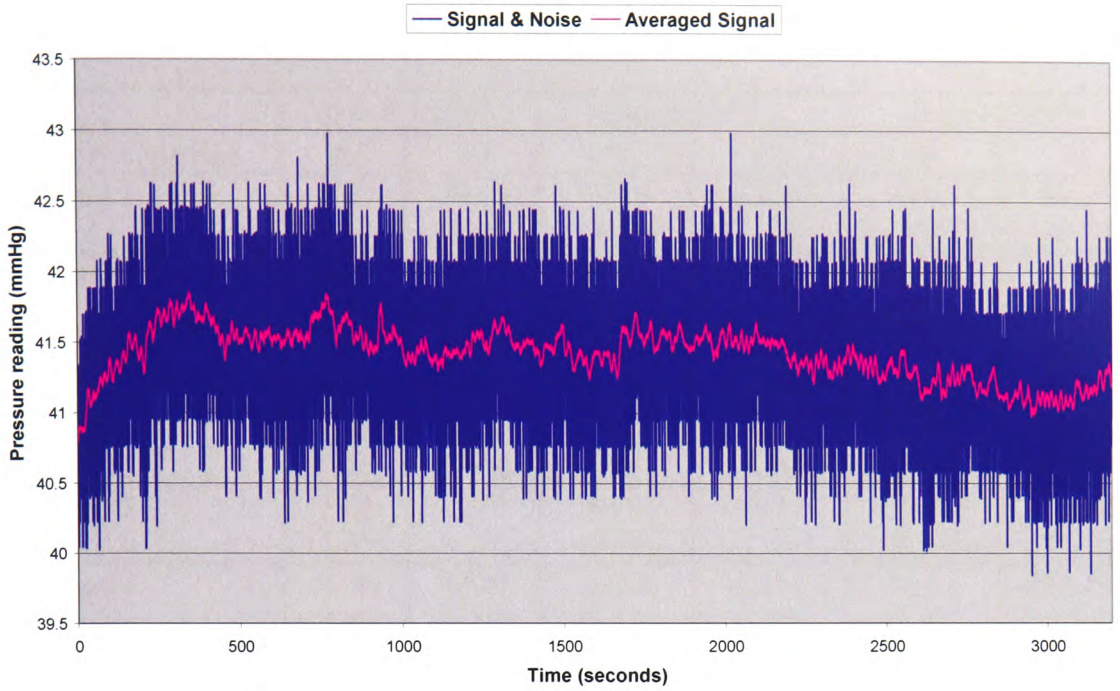

Figure 5.27 Noise measurement for Channel 6 (40 mmHg applied pressure) – Prototype original measurement system

Channel	Before 40 mmHg	After 40 mmHg
1	43.9	43.85
5	42.78	42.85
10	41.89	42.32

Table 5.23 Low pass filter application effects expressed in dBs – Prototype original measurement system

- Repeatability: Repeatability measurements are given in Table 5.24.

	Day 1 (20°C)		Day 2 (21°C)		Day 3 (21°C)	
Pressure (mmHg)	**40**	**80**	**40**	**80**	**40**	**80**
Channel 1	40.51 (1.13)	79.68 (0.85)	40.16 (0.96)	80.34 (0.85)	40.2 (0.98)	80.31 (0.99)
Channel 2	39.61 (0.82)	79.69 (0.84)	40.67 (1.22)	80.22 (1.19)	40.12 (0.57)	80.1 (0.12)
Channel 3	40 (0.94)	80.65 (0.97)	40.7 (1.18)	80.08 (1.49)	40.23 (1.02)	80.07 (0.68)
Channel 4	40.69 (0.99)	80.34 (0.96)	40.49 (1.05)	80.4 (1.36)	39.97 (0.68)	79.88 (1.01)
Channel 5	39.2 (1.07)	79.19 (1.01)	40.8 (1.05)	80.24 (1.56)	39.68 (0.98)	79.68 (0.35)
Channel 6	40.84 (0.96)	80.87 (0.89)	40.88 (1.14)	80.11 (1.32)	40.01 (1.03)	80.72 (1.04)
Channel 7	39.88 (0.97)	81.64 (0.87)	41.29 (0.78)	80.15 (1.53)	40.31 (1.12)	79.68 (0.46)
Channel 8	40.39 (1.12)	78.63 (1.24)	40.96 (0.94)	80.81 (1.15)	39.95 (0.55)	79.76 (0.86)
Channel 9	40.41 (1.11)	79.1 (1.1)	40.82 (0.92)	80.24 (1.1)	39.67 (1.11)	80.13 (0.9)
Channel 10	40.47 (1.07)	79.3 (0.97)	40.43 (1.11)	80.45 (1.3)	40.15 (0.99)	80.4 (1.12)
Coefficient of variation (average)	0.025	0.012	0.025	0.016	0.022	0.009

Table 5.24 Summary of repeatability measurements – Prototype original measurement system

- Crosstalk: Crosstalk was measured using the method described in 5.1.8. There was no significant change to the signal to noise ratios. Table 5.25 shows the signal to noise ratios for channels 1, 5 and 10. The initial SNR value (in dBs) corresponds to the value acquired during the system noise measurement.

Channel	Initial SNR	Crosstalk SNR
1	43.9	43.7
5	42.78	42.69
10	41.89	41.85

Table 5.25 Crosstalk effects (results in dBs) – Prototype original measurement system

Table 5.26 shows a summary of results acquired for the prototype original measurement system.

	Prototype original measurement system
Resolution	Average 0.118 mmHg
Accuracy	±1.99 mmHg
Linearity	Maximum positive error 1.99 mmHg/ maximum negative error 1.82 mmHg over the 0 – 100 mmHg range
Hysteresis	Maximum error 1.91 mmHg over the 0 – 100 mmHg range
Drift	Maximum positive 1.99 mmHg / negative 1.37 mmHg
Noise	Equivalent to 0.294 mmHg (average – all channels)
Repeatability	Maximum standard deviation 1.56 mmHg
Crosstalk	Negligible

Table 5.26 Results summary – Prototype original measurement system

The analysis of the results derived from the performance measurements shows that the system performed adequately in relation to the required specification. System accuracy, linearity, hysteresis, drift and repeatability experienced lower error than ±2 mmHg, while the crosstalk effect was negligible. System noise corresponded to 0.294 mmHg (average), while the added low pass filter did not reduce noise. The measured average resolution was 0.118 mmHg.

By comparing these outcomes with the results of the previous development phases (see Tables 5.7 and 5.1.5), it can be commented that:

i) The overall performance of the prototype original measurement system was worse than the initial system (whose performance results were almost identical with the benchmark tests – section 5.3). More specifically maximum positive and negative drift was 1.99 and 1.37 mmHg compared to the 0.12 and 0.93 mmHg of the initial system. Also the average noise was 0.294 mmHg compared to the 0.235 mmHg of the initial system, while linearity and hysteresis errors were increased by 0.3 mmHg (positive)/ 1.19 mmHg (negative) and 0.14 mmHg respectively.

ii) Although the overall performance was worse than the initial system, the volume and weight were considerably decreased. The inputs increased from 10 (6 Fontanometer sensors and 4 gait indicators) to 14 (10 Fontanometer sensors and 4 gait indicators),

while the miniature board included signal processing section and multiplexing. Finally the overall development cost was considerably decreased since each S7b amplifier cost £600 (£2400 total) while the expenditure for the measurement system was about £200.

iii) The use of the chopper amplifier demodulation part (explained in 5.5) was reconsidered since it did not produce the anticipated outcomes (i.e. drift decrease), rather produced spikes due to bad synchronisation between the pressure and excitation signals. Therefore it was decided to remove this section from the final design in order to reduce power and space (on board) requirements.

It can be concluded that the original measurement system exhibited acceptable performance (within the required specification) while the board was significantly smaller than the initial system and included 14 inputs (10 Fontanotmeter and 4 gait indicators). However, further development was required in order to overcome the limitation of this design (generation of excitation signal, power generation, and wireless transmission). The following sections describe the final stage of development.

5.6 Phase 4 - Execution of final design and its validation

The third phase required the transformation of developments to date into a clinically practicable system. The final design aimed to:

i) Further decrease volume and power requirements
ii) Utilize battery power
iii) Include wireless data transmission
iv) Maintain system performance characteristics

The following description focuses on the final design and addresses the principle of operation, the data collection system and the analogue and digital electronics circuitry.

5.6.1 Principle of operation

As stated in the previous sections a wireless, battery powered system would be most suitable for sub-bandage pressure measurements, since it allows free subject movement with few cables. The idea behind this design was to develop a system that could handle 14 inputs (10 pressure sensors and 4 gait indicators) and transmit data through a single transmission channel, using a multiplexer, an FM transmitter and a data collection system able to display the data real time.

Figure 5.28 shows the main blocks of the sub-bandage pressure measurement system. The principle of operation (described below) is very similar to the previous design, although this design aimed to include the excitation signal generator as well as the IC (PIC16F84) responsible for controlling the multiplexer on a single circuit board. The principle of operation is as follows: The application of pressure causes the sensors (excited by a TTL square wave) to produce signals, initially amplified by 10 instrumentation amplifiers. The outputs are connected to the signal conditioning part of the circuit that sets the signal offset, gain and filters the unwanted excitation AC component. The parallel outputs (combined with the FSR signals) are connected to the multiplexer that selects one channel at a time (controlled by a microcontroller). The single output is digitized by the analogue to digital converter (included in a second microcontroller) and is connected to the FM transmitter. The FM receiver accepts

the signal and sends it to the data acquisition card where it is demultiplexed by the LabView software and ultimately displayed and recorded for further processing.

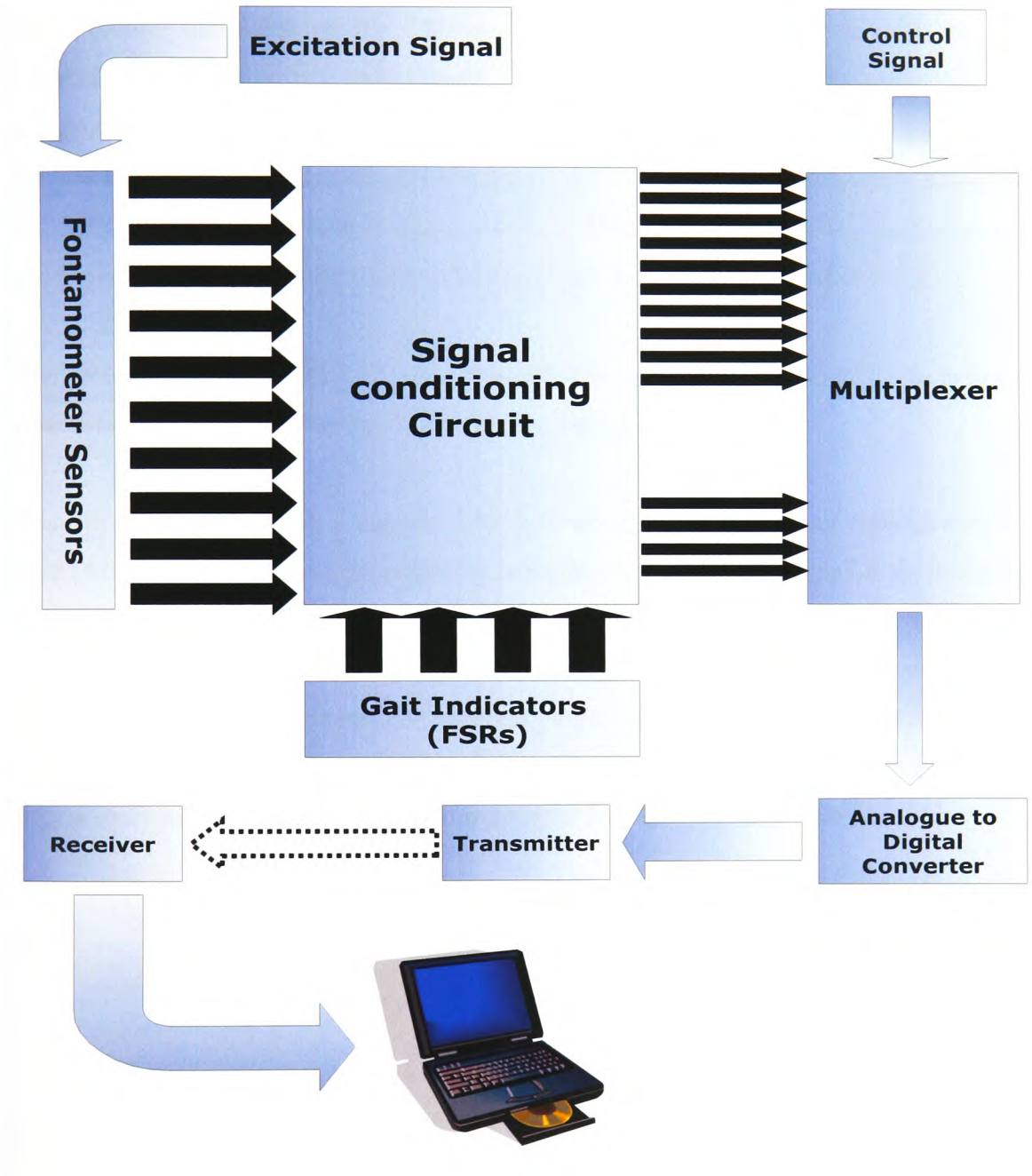

Figure 5.28 The proposed measurement system

5.6.2 The data collection system

The data collection part of the electronic instrumentation consists of a portable computer (Dell 8100), a LabView program (National Instruments), a data acquisition card (DAQ700) and a small circuit consisting of the FM receiver, indicators and the connector for the data acquisition card (Figure 5.29). Figure 5.30 illustrates the receiver circuit diagram. All components are powered by the data acquisition card. Two LEDs present on the board are used as indicators. More specifically the green LED indicates when the system is on, while the red LED shows that the data is being recorded. ICs 1 and 2 represent 2 analogue switches, used to switch on and off the LEDs (utilising digital outputs DOut2 and DOut3).

The receiver operates at 433.92 MHz and includes automatic gain control, super heterodyne receiver and double RF filtering. It can receive data at 50 kbps.

The FM receiver provides 2 signals. The first signal, connected to an analogue input of the card (ACh1), is a DC output proportional to the strength of an incoming RF signal on its input. For example a signal with RF strength of -120 dBm produces a voltage of 1.27 V, while a dBm value of -40 produces a voltage of 2.63 V. The RF signal strength is displayed by the LabView program. The second FM receiver output corresponds to the incoming data sent by the ambulatory system. This signal that contains the sub-bandage pressure information is in digital form and is connected to one of the digital inputs of the card (DIn1).

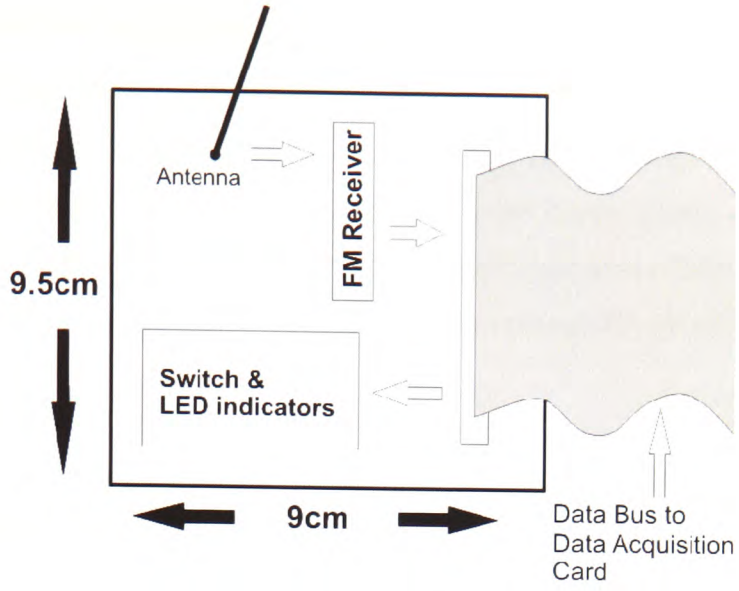

Figure 5.29 Receiver board

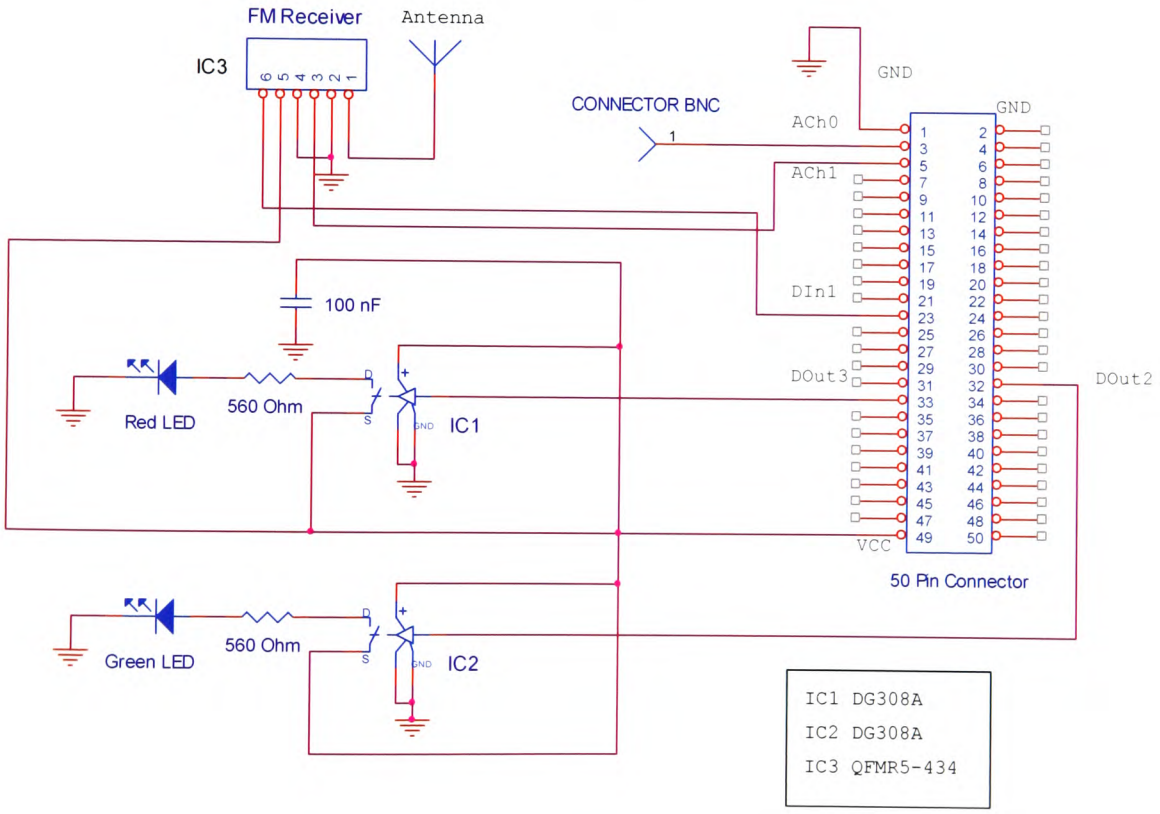

Figure 5.30 Receiver circuit diagram

5.6.3 Analogue electronics circuitry

The analogue circuitry of the system contains all the electronics required for the amplification gain, zeroing, filtering and multiplexing of the incoming signals (Figure 5.31). There are 10 identical channels that process the signals produced by the Fontanometer sensors and another four channels that handle the signal coming from the gait indicators (FSRs) which consist of 4 simple voltage dividers connected to 4 amplifiers with appropriate gain circuitry (set by four 500 Ω miniature variable resistors).

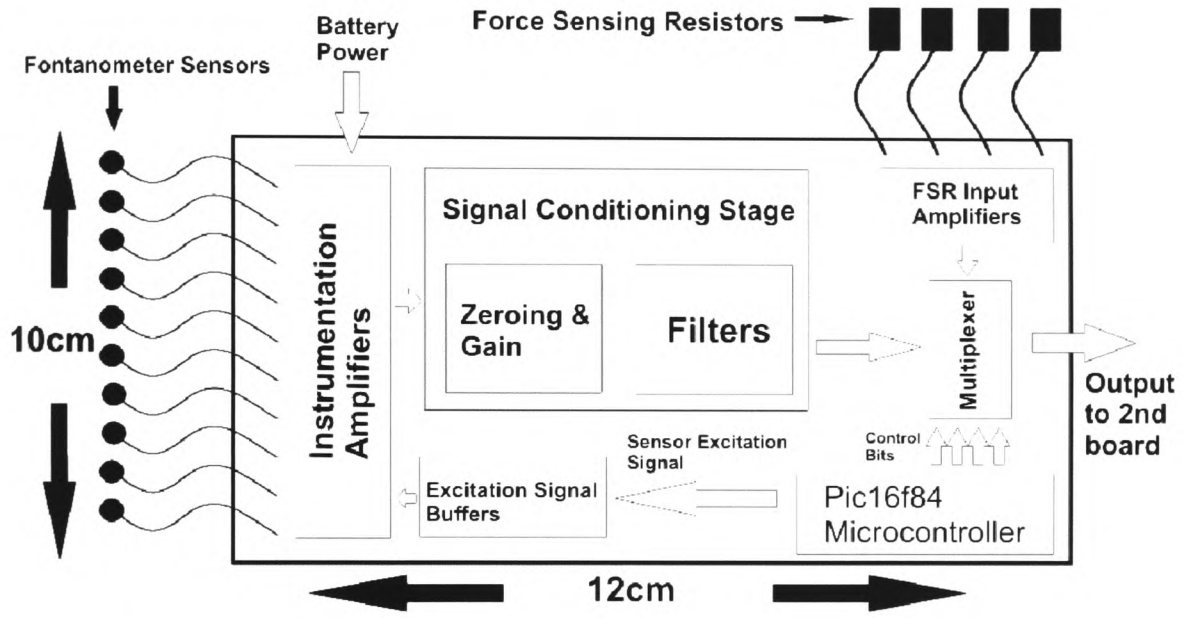

Figure 5.31 Analogue circuit board

The operation of the final system is very similar to the operation of the prototype amplifier board (shown in Figure 5.8). By referring to Figure 5.32, a single channel operation is as follows:

Initially a 2 kHz TTL excitation signal is supplied to the Fontanometer sensor. The signal from the sensor is picked up and amplified by IC1. A summing amplifier (A1) is responsible for adjusting the DC offset of the signal by means of VR1.

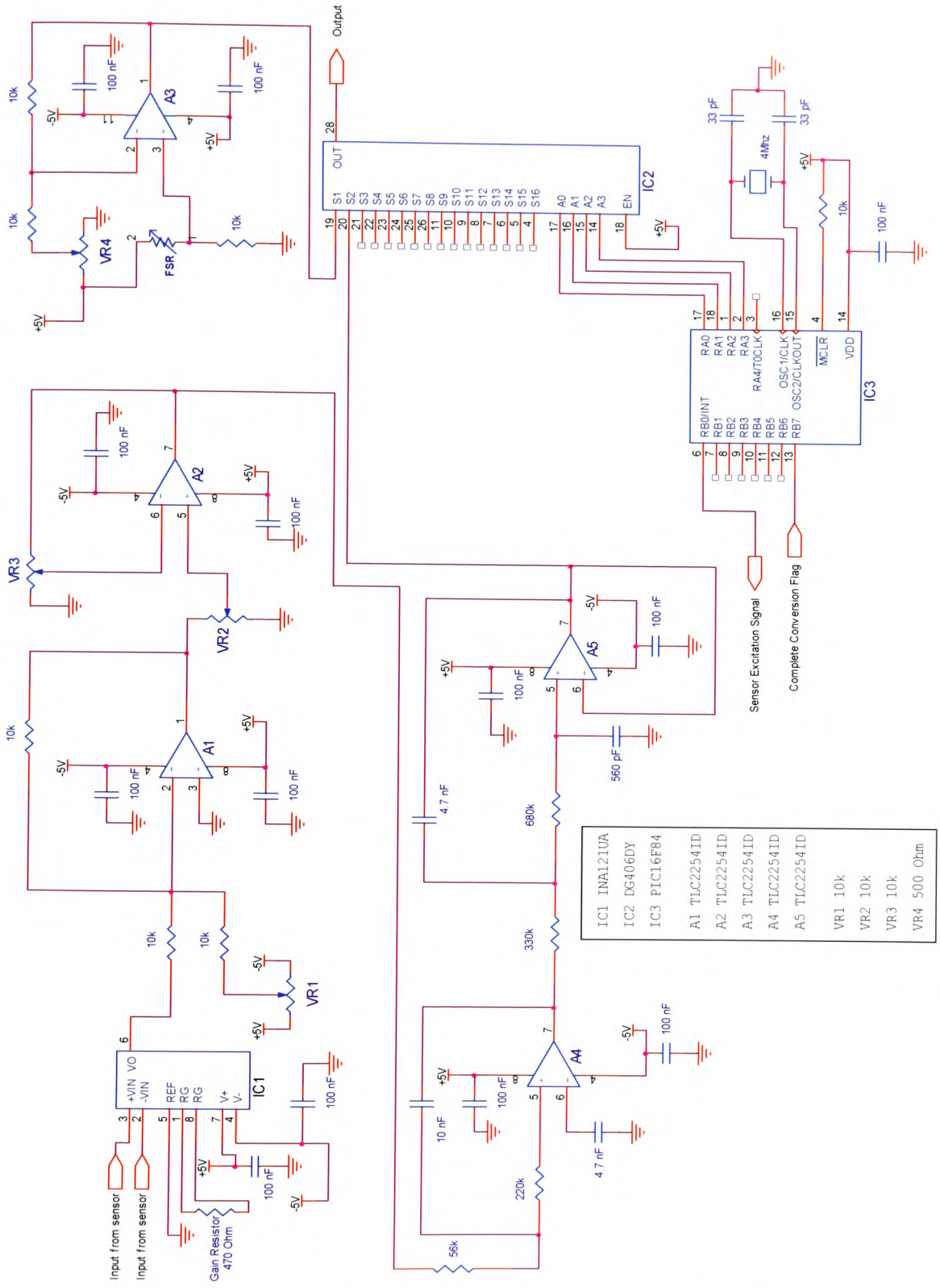

Figure 5.32 Single channel diagram and FSR inputs

The signal gain may be adjusted by the non-inverting amplifier configuration created by A2. The gain range is from 1 to 20. A4 and A5 form a 4 pole Sallen and Key filter with 207 Hz corner frequency (aiming to eliminate excitation frequency). For the purposes of gain, zeroing and filtering the TLC2254ID (Texas Instrument) quad amplifiers were selected. These amplifiers are ideal for battery power systems since they consume very little power (typically 35 μA per channel) and produce low noise (19 nV/√ Hz at f = 1 kHz).

The output of filtering section is connected to IC2 (multiplexer) address bits of which are controlled by IC3 (microcontroller). The output is connected to IC6 (Figure 5.33) which digitizes the signal and sends it to the FM transmitter.

The system is powered by a series of regulators (ICs 1,2,3,4 and 5) powered by two 9 V rechargeable batteries connected in series. The arrangement is shown in Figures 5.33 and 5.34.

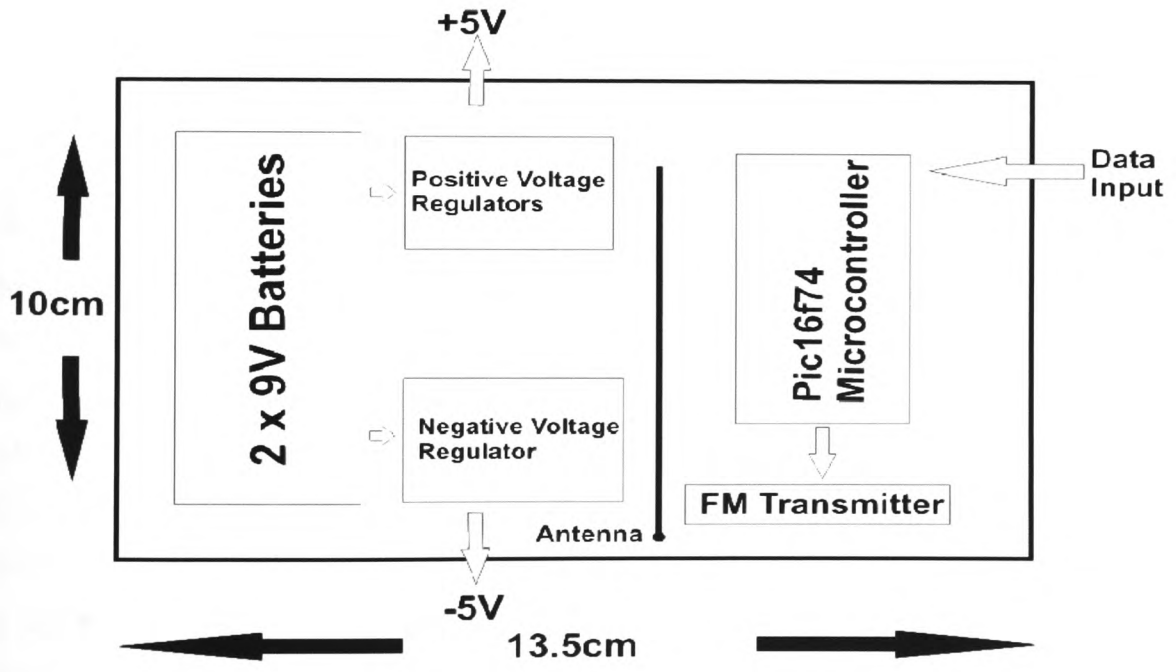

Figure 5.33 2nd board including power source, microcontroller and FM transmitter

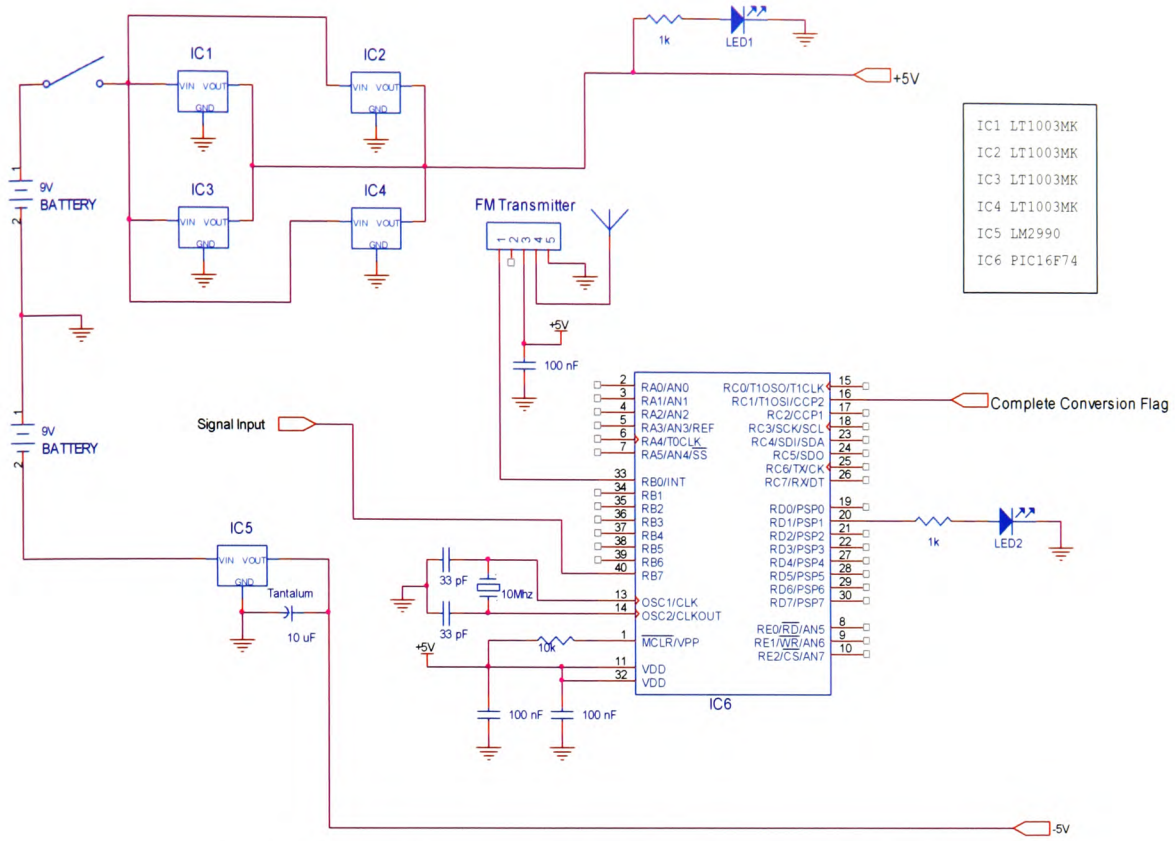

Figure 5.34 Power supply and FM transmitter circuit

5.6.4 Digital electronics circuitry

The digital electronics circuitry of the system consists of two microcontrollers (PIC16F84, PIC16F74) and the FM transmitter and receiver (data link modules utilizing FM transmission). Figure 5.35 details the connections between the PIC16F84 (clocked at 4 MHz) microcontroller and the multiplexer. Figure 5.36 shows the connections between the PIC16F74 (clocked at 10 MHz) microcontroller and the FM transmitter module. The following pages describe the operation of each circuit and how the two microcontrollers communicate in order to complete an analogue to digital conversion before the data is transferred to the transmitter. Both microcontrollers are programmed in assembly language using the MPLAB compiler (MPLAB IDE v8.20 – Microchip).

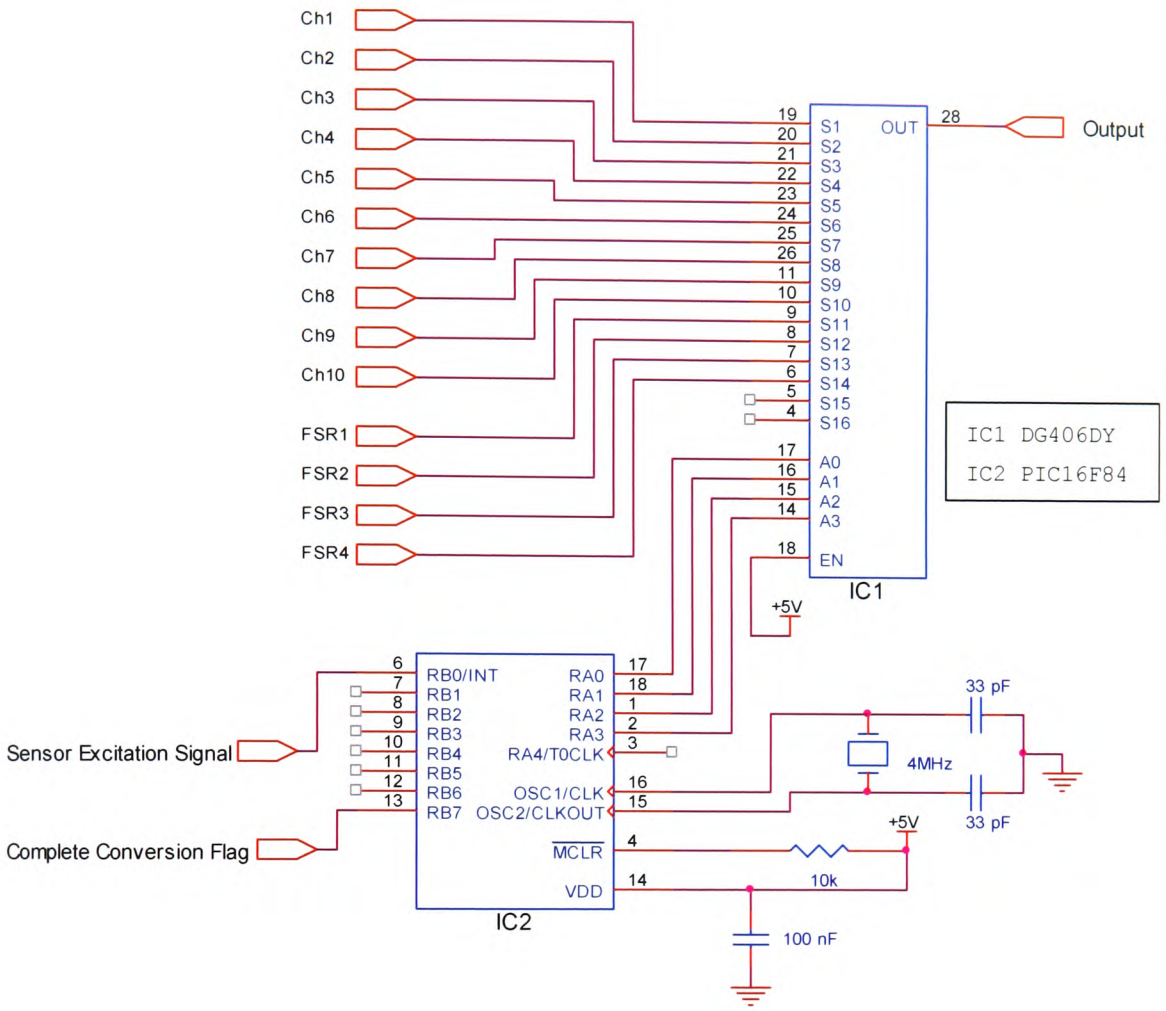

Figure 5.35 PIC16F84 circuit diagram

The role of the PIC16F84 microcontroller (IC2 – Figure 5.35 is twofold: i) to produce the excitation signal (2 kHz square wave) required for the Fontanometer sensors and ii) to control the address bits of the multiplexer. The excitation signal is produced using the internal timer (TIMER0). Control of the address bits is carried out by combining the actions of PIC16F84 (IC2 – Figure 5.35) and PIC16F74 (IC1 – Figure 5.36) and is described later in this section.

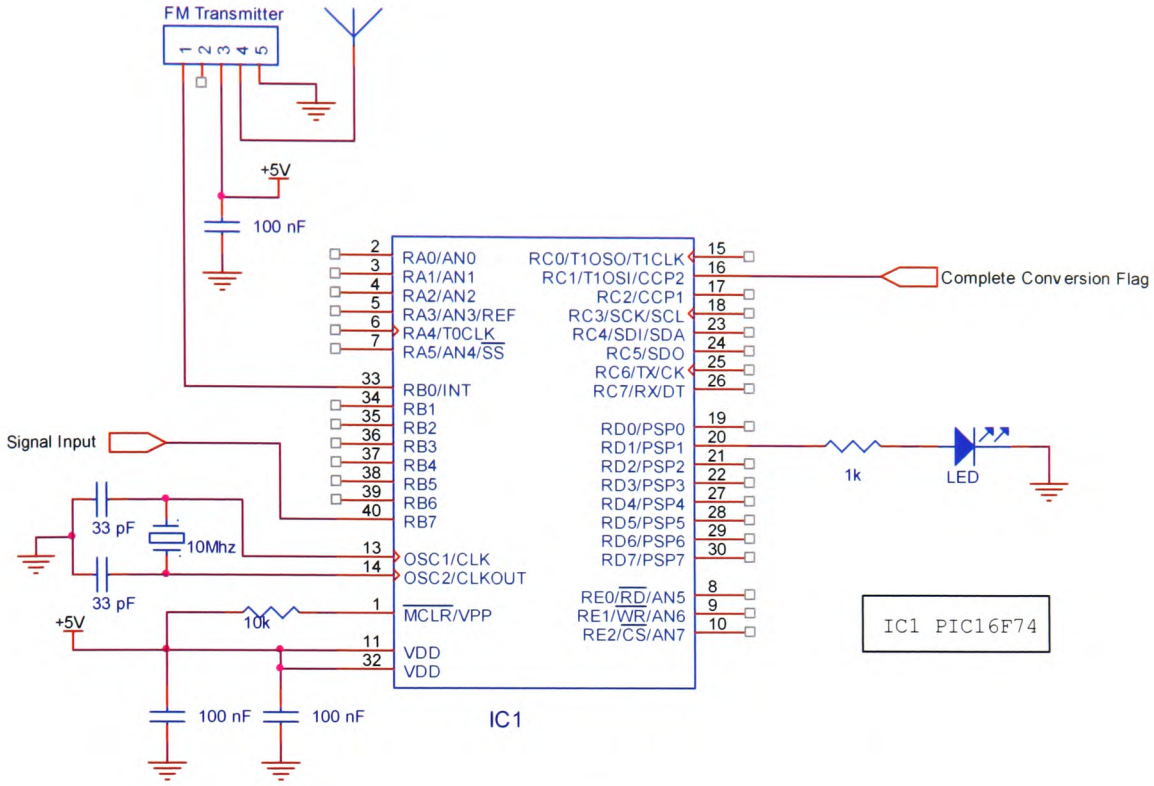

Figure 5.36 PIC16F74 circuit diagram

The PIC16F74 (IC1 – Figure 5.36) microcontroller is responsible for digitizing the output of the multiplexer. The internal 8-bit analogue to digital converter has programmable A/D acquisition time (default $\leq$ 16 μs). When in digital form, the serial signal is sent to the FM transmitter (data link module). Figure 5.37 shows a block diagram that describes the way that the two microcontrollers communicate in order to successfully finish an analogue to digital conversion of a selected signal (incoming from the multiplexer).

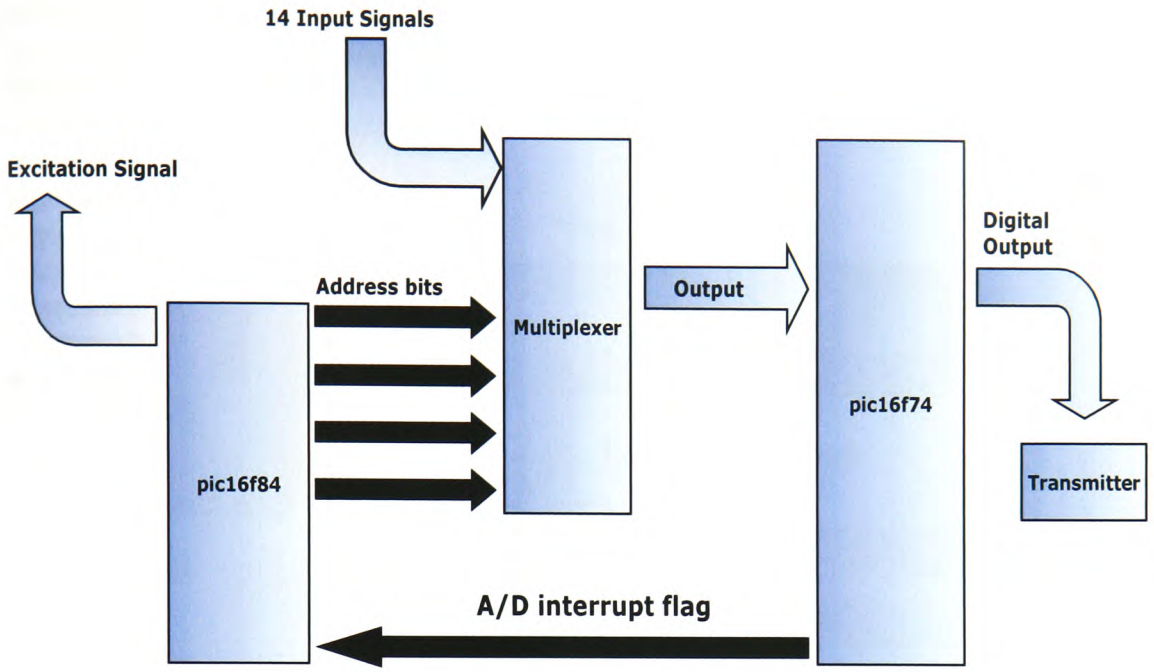

Figure 5.37 Data transmission components

All input signals (both from the Fontanometer sensors and the gait indicators) are connected to the multiplexer. When the system is switched on there is a wait time of 30 seconds before the PIC16F84 selects the first channel of the multiplexer and 35 seconds before the A/D module of the PIC16F74 is turned on. In this 5 second gap when the 2 chips initialise, a high signal is sent to the receiver in order to synchronise it with the transmitter (discussed in section 5.3.5). After this wait time the selected multiplexer output is sent to PIC16F74 where is converted into a digital signal, i.e. ready to be transmitted by the FM transmitter.

In order to complete successful data transmission the two microcontrollers and the multiplexer have to be synchronised. When an analogue to digital conversion is complete an A/D interrupt flag is produced that can be sent to the PIC16F84 in order to change the address bits and select the next system channel on the multiplexer. The address bits of the multiplexer are selected on a continuous loop by the PIC16F84, starting from the 1st channel up to the 14th and back to the 1st. This loop continues until the system is turned off.

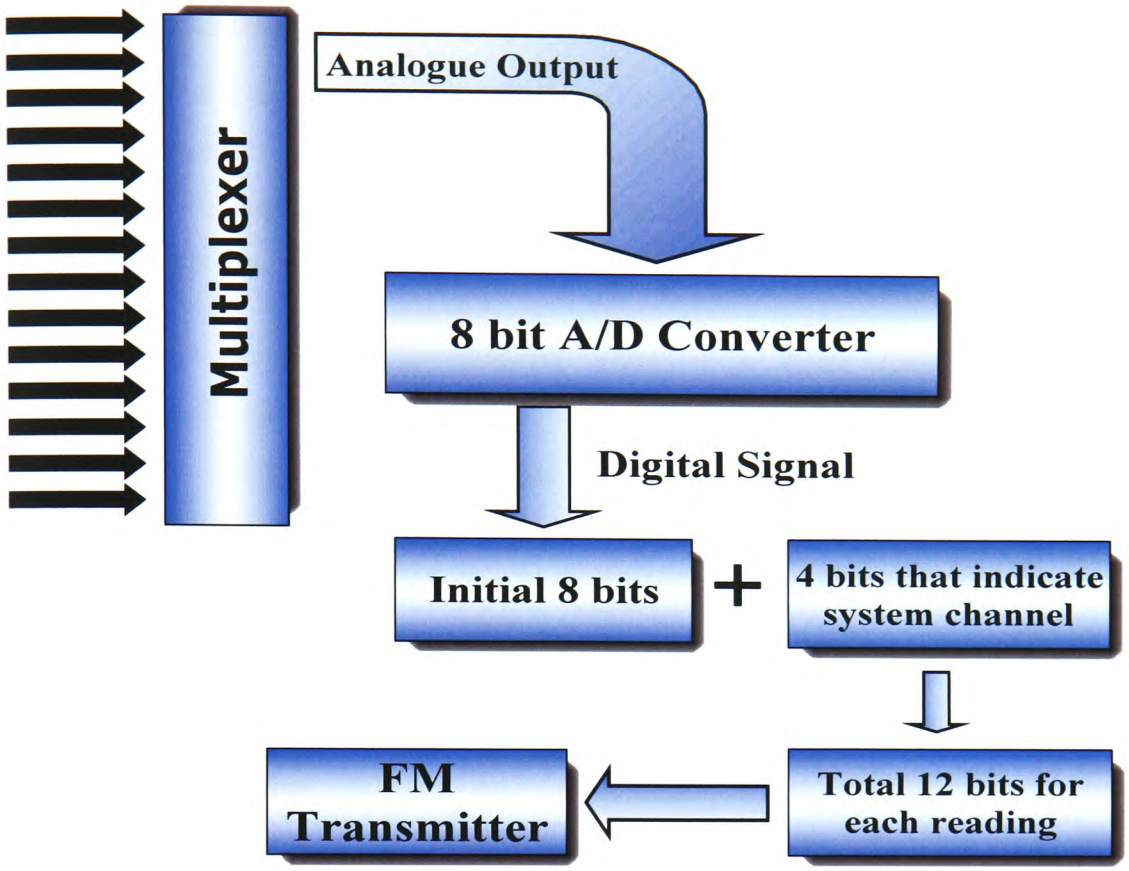

Figure 5.38 Signal encoding procedure

Figure 5.38 describes the encoding procedure that is used when an A/D conversion is completed. This procedure ensures that when the signal is received by the FM module and processed by the portable computer, the software will be able to recover the channel number and place it in the appropriate array. More specifically after each conversion the digital data is stored in a general purpose register of the microcontroller. Another four bits are added before the converted bits in order to indicate the number of the channel. Therefore in total 12 bits are being produced in every conversion (i.e. 8 bit from the A/D and 4 bits as channel indicators). Knowing that the FM transmitter is capable of achieving 50 kbps it can be calculated that about 297 samples can be transmitted every second for each channel. However, because the A/D module of the PIC16F74 can convert data much faster than this rate, a delay has to be introduced in order to cope with the FM transmission speed.

5.6.5 Data collection system hardware and software

The host computer was a Dell 8100 Laptop with 1.2 GHz processor and 256 MB of RAM. When the program is loaded, it performs a check of the functionality of the data acquisition card (DAQ-700) by turning both LEDs (of the receiver board) on for 5 seconds. The data collection software is responsible for the following processes:

- Signal demultiplexing – The incoming signal is in serial form and needs to be demultiplexed in order to acquire the sub-bandage pressure information
- Data display – The pressure information is displayed for observation of the variation of sub-bandage forces (quasi real time) and monitoring of the system operation
- Data recording – Data need to be stored (as spreadsheet) for further analysis

A flow chart illustrating the key functional processes is shown in Figure 5.40. When the signal is captured by the receiver the information is in serial digital form. The role of the software is to demultiplex the signal, store the data in the appropriate array (corresponding to each channel), display the samples as pressure values and store these values (if required by the software user). This procedure can be divided into 2 stages:

i) The first stage concerns the synchronisation of the receiving part (FM receiver, DAQ700 and software) and the transmitting circuit. As stated in 5.6.4 when the system is turned on, the two microcontrollers attempt to synchronise. PIC16F84 is initiated after 30 seconds while the PIC16F74 waits another 5 seconds before it starts communicating with the PIC16F84. In this 5 second gap a high signal is sent to the receiving part of the system in order to let it know that pressure values will be sent. When this wait time is ended the software will know that the first received sample corresponds to a pressure value captured by channel 1 and so on (as explained in 5.6.4).

ii) When a sample is received (consisting of 12 bits), the software reads the first 4 bits, and uses them as a guide in order to place the remaining 8 bits to the appropriate array (shown in Figure 5.40). Thereinafter, the appropriate mathematical expression (as calculated using the performance and calibration measurements) is used in order to

translate the digital value and transform it into a pressure sample allowing the data to be displayed. This process is repeated continuously until the system is turned off.

Referring to the technical characteristics, the card is capable of sampling signals at up to 100k samples per second. The FM modules can transmit maximum 50k bits per second allowing therefore enough time to the data acquisition card to process the samples.

This LabView program is created as an executable file and it can run on every laptop (with PMCIA input) as long as the Runtime Engine LabView v6.1 is installed. The program code is given in Appendix B, while a screenshot is shown in Figure 5.39.

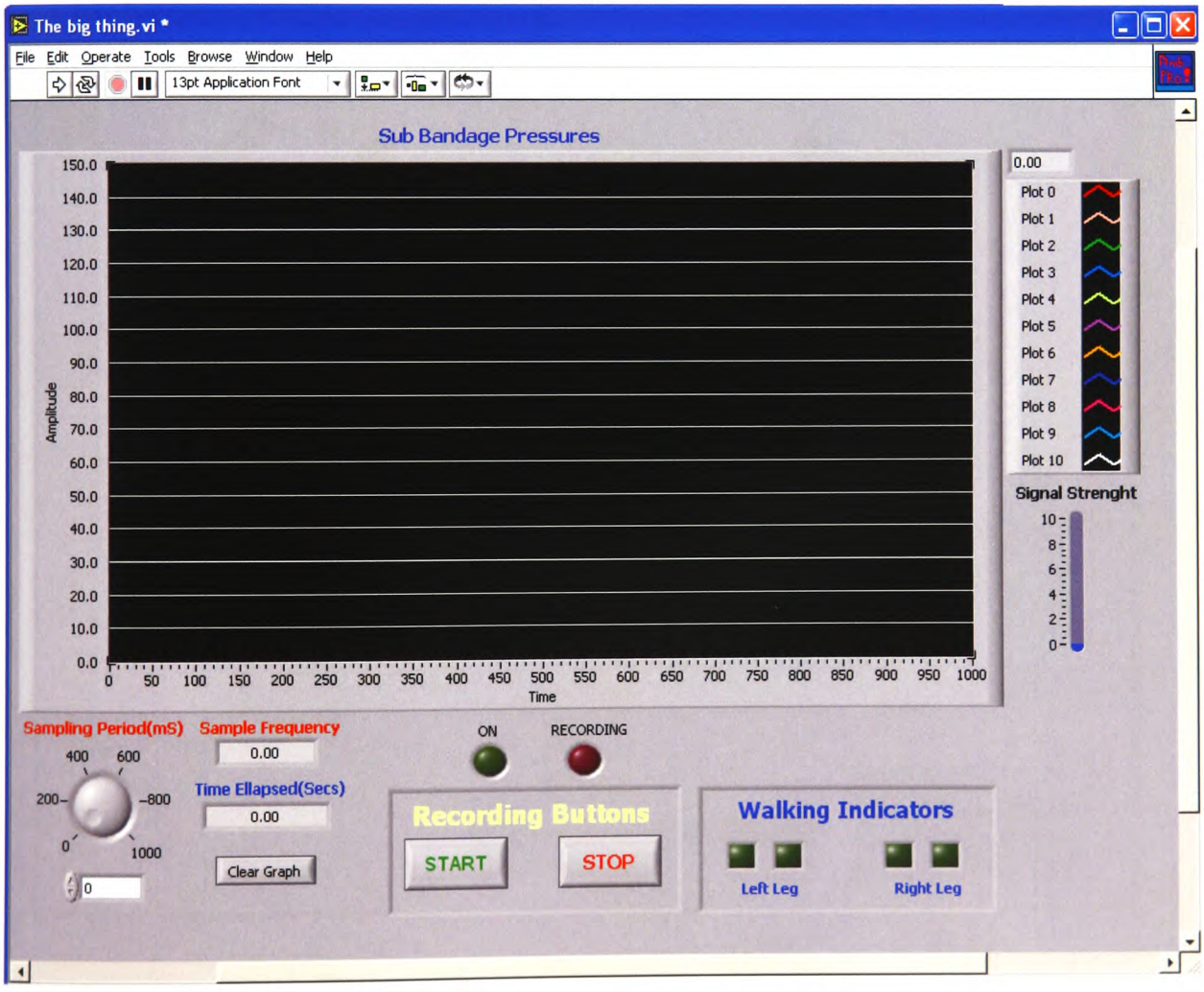

Figure 5.39 LabView program screenshot

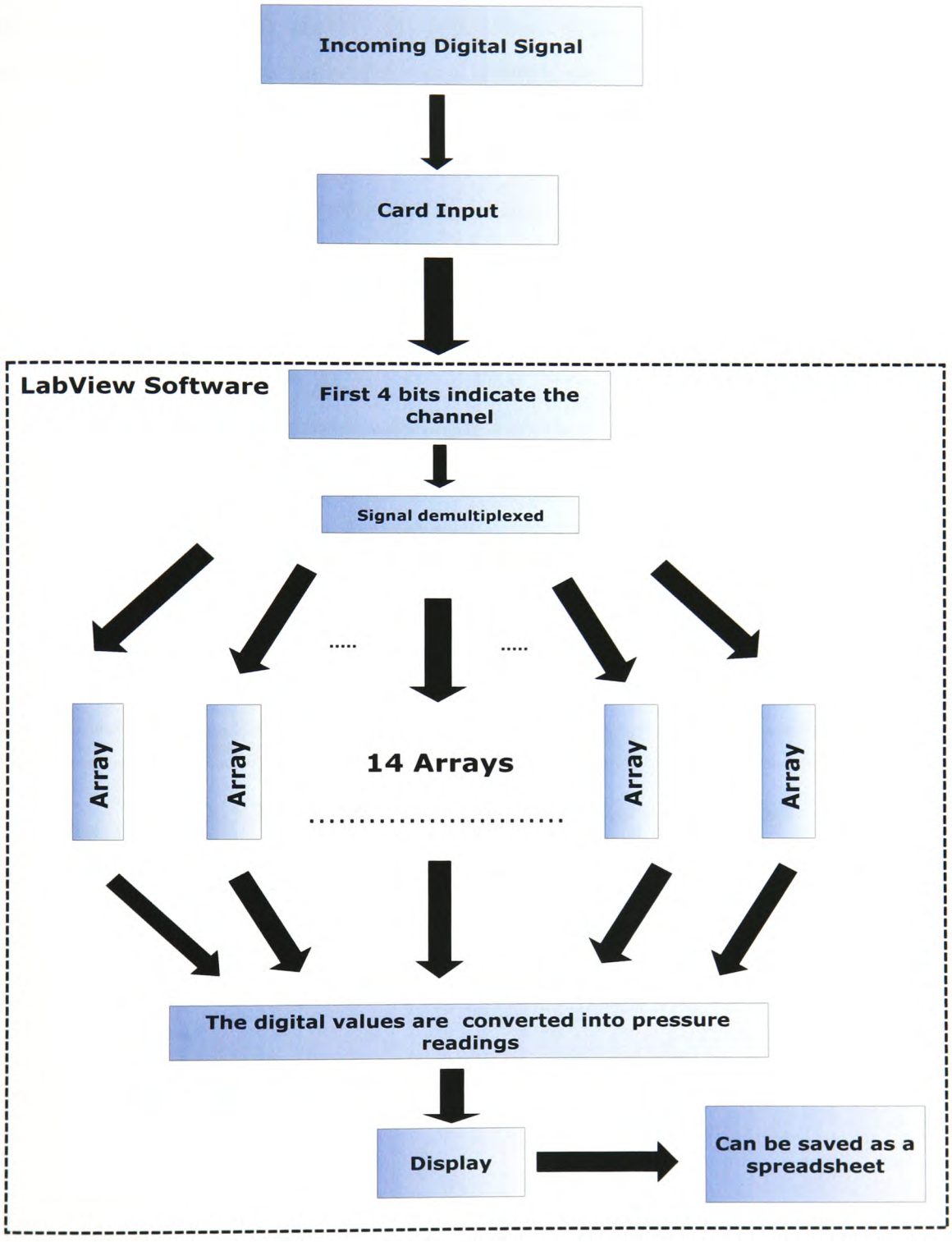

Figure 5.40 LabView program structure

5.6.6 Performance tests without RF

The apparatus and methods used for the performance tests are described in 5.1. The system was tested in a temperature controlled room environment. It has to be mentioned that these tests were undertaken without connecting the RF part of the circuit, for this reason only the analogue part was tested. The problems faced with the RF transmission prohibited the test of the complete system (discussed in 5.6.7). The results were:

- Resolution: Table 5.27 illustrates the measured resolution for each channel and the system average.

Channel	Resolution (mmHg)
1	0.1
2	0.11
3	0.11
4	0.12
5	0.11
6	0.12
7	0.12
8	0.1
9	0.1
10	0.11
Average	0.11

Table 5.27 Resolution results (in mmHg) – Final design

- Accuracy: Table 5.28 shows a summary of the results. It can be seen that there is no positive or negative value that exceeded 2 mmHg.

Channel	Maximum Positive difference (mmHg)	Maximum Negative difference (mmHg)
1	1.65	1.97
2	1.54	1.22
3	1.23	1.89
4	1.44	1.56
5	1.88	1.45
6	0.37	1.88
7	1.41	1
8	1.1	1.88
9	1.12	0.85
10	1.03	1.88

Table 5.28 Maximum positive and negative differences from the fixed initial applied pressures (in mmHg) – Final design

- Linearity: The envelope created by the red and blue lines includes all the trend lines produced by the linearity measurements (Figure 5.41).The maximum positive error was 1.95 mmHg while the negative maximum error was 1.93 mmHg, i.e. within the specified limit (±2 mmHg). A typical trend line is shown in green colour (channel 6).

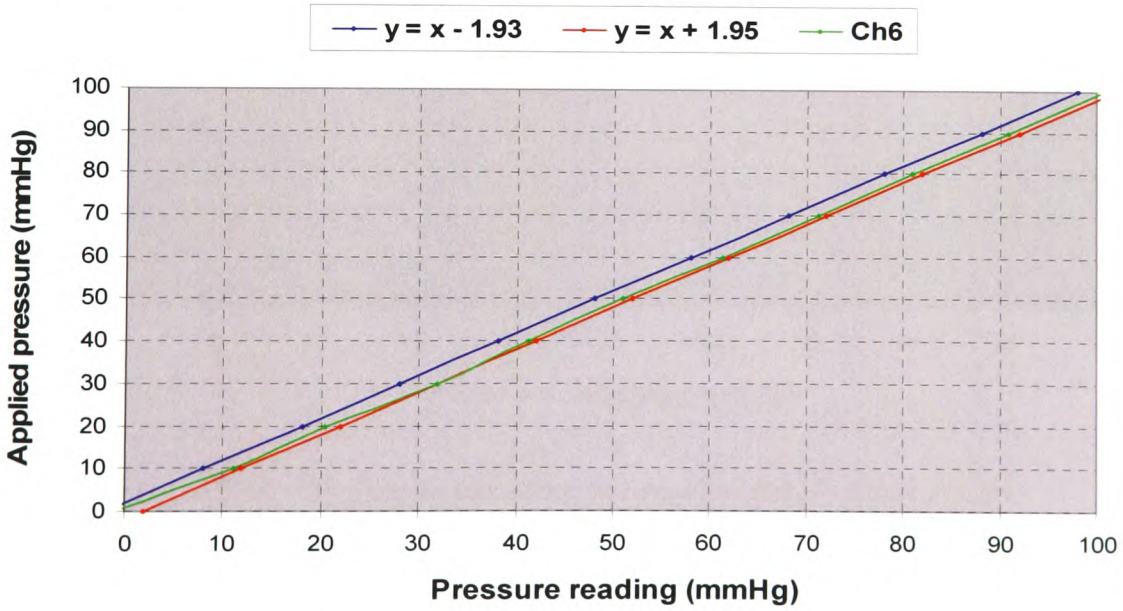

Figure 5.41 Linearity measurements – Final design

- Hysteresis: Table shows the maximum differences between increasing and decreasing pressures for each channel while Figure 5.42 illustrates a typical hysteresis error.

Channel	Maximum difference (mmHg)
1	0.58
2	1.24
3	1.29
4	1.13
5	0.91
6	1.49
7	1.52
8	1.49
9	1.2
10	1.47
Average	1.232

Table 5.29 Hysteresis error – Final design

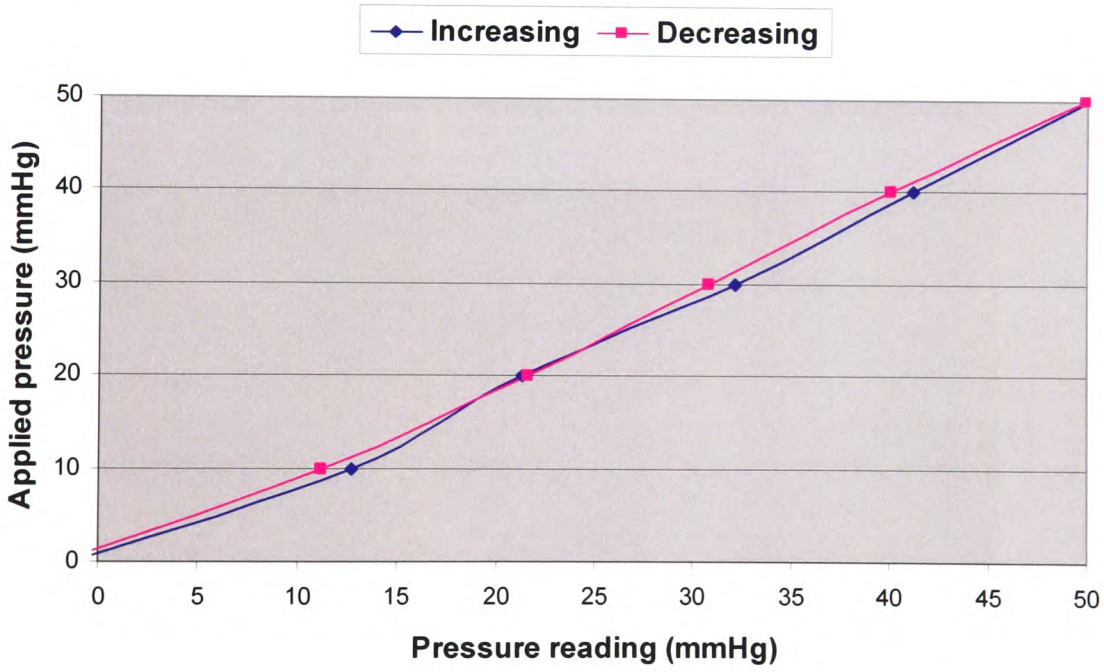

Figure 5.42 Typical hysteresis error on channel 1 – Final design

- Drift: Table 5.30 illustrates the drift measurements results while Figure 5.43 shows graphically the filtered drift. It can be seen that it takes about 4 to 5 minutes for the pressure readings to reach a relatively stable value. This period of time is considered the settling time.

Channel	Initial applied pressure (mmHg)	Average pressure (mmHg)	Maximum positive drift (mmHg)*	Maximum negative drift (mmHg)*	Final drift (mmHg)
1	40.82	41.24	1.13	0.04	1.13
2	38.96	39.89	1.47	0.25	1.05
3	40.29	39.93	0.19	0.68	-0.36
4	41.13	41.39	0.57	0.16	0.02
5	40.76	41.31	0.95	0	0.63
6	40.34	40.76	0.69	0	0.46
7	40.79	40.55	0.26	0.79	-0.79
8	40.78	40.86	0.5	0.23	0.47
9	41.12	40.74	0.2	0.89	-0.27
10	39.95	40.02	0.65	0.38	-0.38
Average	40.49	40.67	0.66	0.34	0.55

* From initial pressure reading

Table 5.30 Drift measurement results in mmHg – Final design

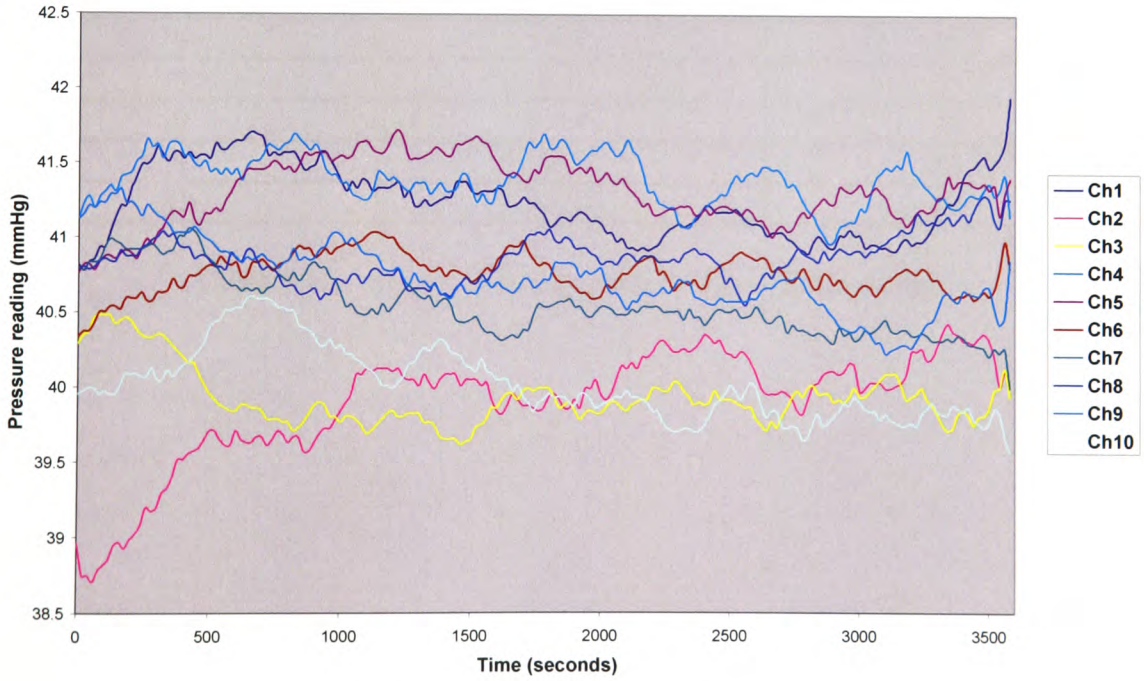

Figure 5.43 Drift measurements – Final design

- Noise: The nature of noise was determined by using a spectrum analyser. It was noted that regardless of the pressure stimulus the frequency spectrum remained uniform suggesting that noise was of thermal origin. Table 5.31 illustrates the average noise level translated into mmHg while Figure 5.44 shows a typical noise measurement (channel 10). Noise amplitude was stable regardless of the amount pressure applied to the pressure. Finally, a low pass filter (cut off 100 Hz) was applied to the output in order to further reduce noise. However, as it can be seen from Table 5.32 there was no reduction of noise with the application of this extra filter.

Average noise (mmHg)	Ch1	Ch2	Ch3	Ch4	Ch5	Ch6	Ch7	Ch8	Ch9	Ch10
	0.26	0.26	0.26	0.24	0.27	0.25	0.25	0.25	0.25	0.26

Table 5.31 Average noise levels in mmHg – Final design

Channel	40 mmHg	80 mmHg
1	42	50
2	41.6	49.7
3	41.6	50
4	43	49.9
5	42.3	49.3
6	44	50.3
7	43.7	50.3
8	44	48.2
9	42.4	48.9
10	42.7	49.9

Table 5.32 Signal to noise ratios in dBs – Final design

Channel	Before 40 mmHg	After 40 mmHg
1	42	42
5	42.3	42.4
10	42.7	42.7

Table 5.33 Low pass filter application effects expressed in dBs – Final design

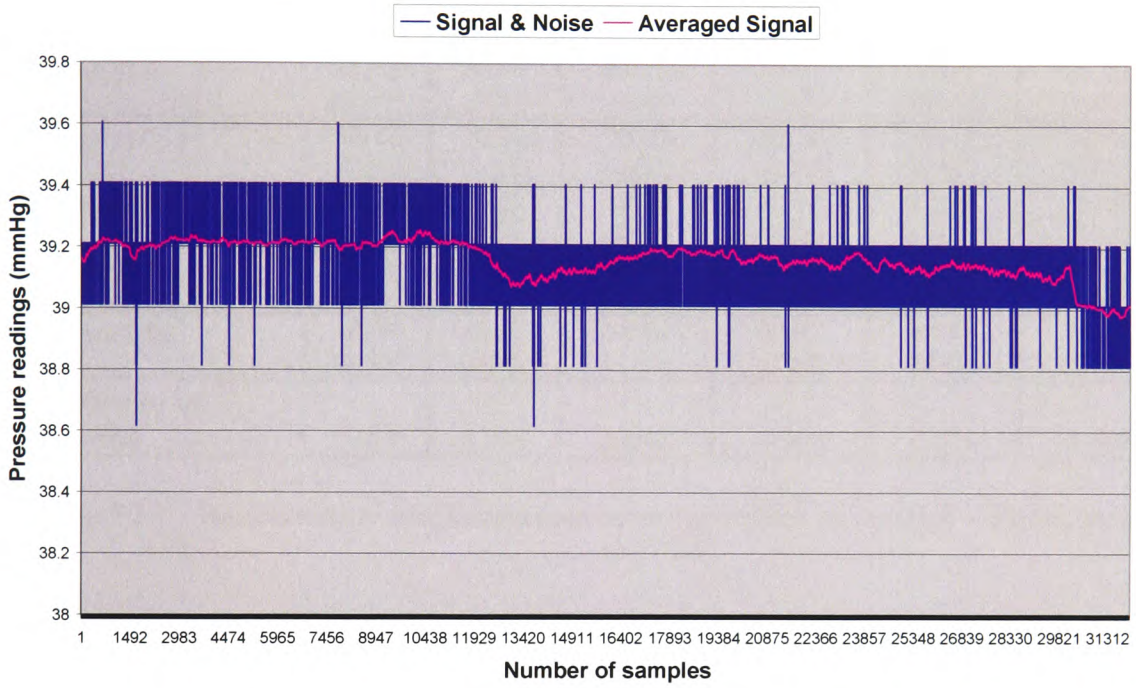

Figure 5.44 Typical noise measurement (channel 7) – Final design

- Repeatability: Table 5.34 summarizes the repeatability measurements. The results reveal a repeatable system. A warm up time of 6 minutes was allowed before the commencement of the measurements each day.

	Day 1 (20°C)		Day 2 (21°C)		Day 3 (21°C)	
Pressure (mmHg)	**40**	**80**	**40**	**80**	**40**	**80**
Channel 1	41.58 (0.56)	81.21 (0.99)	40.51 (0.44)	78.96 (0.34)	40.59 (0.87)	80.85 (1.12)
Channel 2	41.12 (0.74)	81.04 (0.41)	41.09 (1.1)	80.38 (1.05)	41.15 (0.98)	81.78 (0.75)
Channel 3	39.97 (0.87)	80.88 (1.24)	40.99 (1.34)	79.46 (1.06)	40.14 (0.45)	79.55 (0.28)
Channel 4	41.17 (1.25)	80.44 (0.85)	40.68 (0.51)	80.31 (0.14)	40.98 (1.42)	80.42 (0.75)
Channel 5	40.99 (0.71)	81.31 (0.12)	40.99 (0.74)	80.54 (0.34)	40.27 (1.01)	80.17 (0.41)
Channel 6	41.72 (0.51)	80.82 (0.74)	41.12 (1.4)	80.87 (1.37)	41.13 (0.41)	81.92 (1.02)
Channel 7	40.12 (0.57)	79.72 (0.62)	39.48 (0.62)	80.14 (0.79)	40.11 (0.68)	79.78 (0.62)
Channel 8	40.84 (0.52)	80.27 (0.24)	39.74 (0.67)	79.59 (0.58)	40.13 (0.51)	78.89 (0.14)
Channel 9	40.65 (0.41)	81.99 (1.03)	41.08 (1.24)	80.85 (1.09)	40.45 (0.89)	79.12 (0.99)
Channel 10	40.47 (0.95)	80.87 (0.84)	39.91 (1.31)	80.93 (0.29)	40.56 (0.86)	80.23 (0.76)
Coefficient of variation	0.017	0.008	0.023	0.008	0.019	0.009

Table 5.34 Repeatability measurements (average values in mmHg) – Final design

- Crosstalk: Crosstalk was measured following the process discussed in section 5.1.8. Table 5.35 shows the results. The measurements did not show any significant crosstalk effect between the channels either sharing the same ICs or any other combination of channels and pressures. Figure 5.45 shows how the pressure reading of channel 9 remained unchanged during the stepped increase of pressure on channel 10.

Channel	Noise SNR	Crosstalk SNR	Pressure Variation
1	42	42	Negligible
5	42.3	42.3	Negligible
10	42.7	42.6	Negligible

Table 5.35 Crosstalk effect (dBs) – Final design

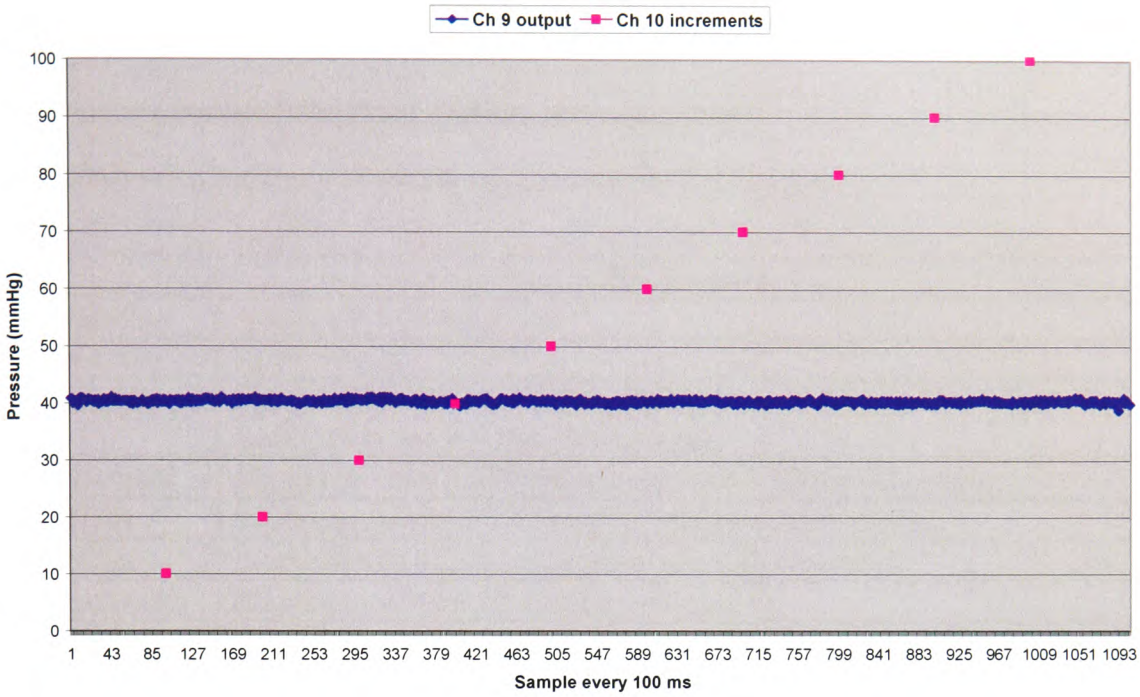

Figure 5.45 Channel 9 output during increase of pressure on channel 10 – Final design

Detailed discussion regarding the performance of the final design is provided in section 5.7.

5.6.7 Performance tests with RF

As stated in 5.6.4, data transmission requires the synchronisation of the 2 microcontrollers and the data recording software (within the transmission limits of the FM transmitter and receiver). This synchronisation protocol however was not fully completed at the development stage, therefore prohibiting the execution of measurements with a fully operational system, i.e. both analogue and digital parts. Further development and corrections are needed in order to achieve data transmission for a fully operational system.

5.7 Summary and discussion

5.7.1 Performance of the final system and outcomes

Table 5.36 shows a summary of results acquired for the final system.

	Final system
Resolution	Average 0.11 mmHg
Accuracy	±1.97 mmHg
Linearity	Maximum positive error 1.95 mmHg/ maximum negative error 1.93 mmHg over the 0 – 100 mmHg range
Hysteresis	Maximum error 1.49 mmHg over the 0 – 100 mmHg range
Drift	Maximum positive 1.47 mmHg / negative 0.89 mmHg
Noise	Equivalent to 0.255 mmHg (average – all channels)
Repeatability	Maximum standard deviation 1.42 mmHg
Crosstalk	Negligible

Table 5.36 Results summary – Final system

The development of the final system aimed to further decrease volume and power requirements, utilize battery power, include wireless data transmission and maintain (or improve) system performance characteristics. The following were achieved:

- Volume was decreased by removing the chopper amplifier demodulation section (explained in section 5.5) of the prototype design, which created considerable space on the board. Moreover, all components, excluding the 2 microcontrollers, were replaced by surface mount parts.
- Power requirements were reduced by replacing the OPA4277 quad amplifiers (used in the prototype design) with the TLC2254ID quad amplifiers, which reduced current consumption by 35 mA. Also, current consumption was reduced by removing the DG308 analogue switches (chopper amplifier demodulation).
- The system was powered by two 9 V batteries.
- Wireless data transmission was included in the system. However, there have been difficulties when attempted to synchronize the 2 microcontrollers with the LabView system. Due to lack of time the transmission protocol was not completed. This failure

prohibited the execution of ambulatory measurements. Further development is required to successfully achieve wireless data transmission.

- System performance results (shown in Table 5.36) were in agreement with the required specification. More specifically, accuracy and linearity were just within the required values while maximum hysteresis error was 1.49 mmHg. Maximum drift was 1.47 mmHg, while noise level was low (0.255 mmHg), slightly higher than the Gaeltec S7b amplifier. The system was repeatable since the maximum standard deviation of measurements (over 3 days) was 1.42 mmHg. Finally crosstalk effect was negligible. In general the final system performed better than the prototype design (also discussed in 5.7.2).

5.7.2 Effects of development on systems' performance

Table 5.37 provides a comparison between the results acquired in each development phase.

	Benchmark tests	**Existing technology**	**Prototype system**	**Final system**
Resolution (average)	0.1 mmHg	0.108 mmHg	0.118 mmHg	0.11 mmHg
Accuracy	±1.14 mmHg	±1.94 mmHg	±1.99 mmHg	±1.97 mmHg
Linearity error (0-100 mmHg) Max positive/ negative	1.35 mmHg/ 1.04 mmHg	1.69 mmHg/ 0.63 mmHg	1.99 mmHg/ 1.82 mmHg	1.93 mmHg/ 1.95 mmHg
Hysteresis max error (0-100 mmHg)	1.88 mmHg	1.77 mmHg	1.91 mmHg	1.49 mmHg
Drift maximum Max positive/ Max negative	0.26 mmHg/ 0 mmHg	0.12 mmHg/ 0.93 mmHg	1.99 mmHg/ 1.37 mmHg	1.47 mmHg/ 0.89 mmHg
Noise (equivalent)	0.22 mmHg	0.235 mmHg	0.294 mmHg	0.255 mmHg
Repeatability Max standard deviation	0.51 mmHg	1.27 mmHg	1.56 mmHg	1.42 mmHg
Crosstalk	N/A	Negligible	Negligible	Negligible

Table 5.37 Performance comparison, all systems

These findings lead to the following conclusions:

i) All performances were in agreement with the required specification.

ii) The best performance results were produced during the preliminary tests. With the exception of the hysteresis error (maximum 1.88 mmHg) all other results were better than the ones acquired during the other development phases.

iii) The system that utilized existing technology produced (as expected) similar results to the benchmark tests. The introduction of the interface box did not degrade system's performance.

iv) The worst results were produced by the prototype design since accuracy, linearity, hysteresis error and drift were just within the specified values. Noise was also elevated compared to the previous phases being equivalent to 0.29 mmHg. However volume and weight were considerably reduced when compared to the trolley configuration.

v) The final design performed better than the original prototype with hysteresis error being the lowest of all development phases. Maximum drift was 1.47 mmHg (less than prototype) while noise level decreased (prototype 0.29 mmHg, final design 0.25 mmHg). In general the system performed better than the prototype design but worst than the system that used existing technology

vi) Even thought the overall performance is degraded, the final design has some significant advantages. For example, volume and weight are considerably reduced, while a single circuit board provides inputs to 10 Fontanometer sensors and 4 gait indicators. Wireless transmission allows comfortable movement for the subject compared to the trolley that had to be next to the connected (with many wires) volunteer. Moreover, cost is significantly reduced. One S7b amplifier costs around £400 while the final system cost £300 including board manufacture, batteries, case and components.

Therefore taking under consideration the acceptable performance of the final design and these advantages, it can be concluded that this approach could unexceptionably allow the execution of studies involving the measurement of ambulatory sub-bandage pressure for relatively low cost.

5.7.3 Recommendations for further work

The following recommendations are based on the performance outcomes, the ultimate experience with the system and some suggestions for possible circuit alterations. More specifically:

i) Further development should aim to reduce drift (if possible, to the level of the S7b amplifiers). The chopper amplifier method could be included in a future development but special attention should be paid to the signal demodulation part in order to avoid synchronization issues.

ii) During the development it was noted that the gain section caused, in some cases, instability with the signal amplitude, requiring reset of gain before the commencement of a measurement. This could be avoided by either designing a circuit with fixed gain or altering this part by leaving only one very stable variable resistance.

iii) Each microcontroller requires 40 mA to operate. A different design should aim to implement just one microcontroller that would be able to handle all operations. This approach would also minimise synchronisation problems.

iv) The major problem of the final design regarded its inability to transmit data. An alternative approach should aim to simplify the transmission method and increase data rates. This could be accomplished with the application of more transmitters, taking under consideration the power requirements. Also, a Bluetooth transceiver could be used. This approach could also allow the establishment of links between the system and other devices (for example a palmtop).

v) Volume and weight could be further reduced by using smaller components (for example SO and SOIC parts)

6 Discussion and conclusions

6.1 Summary of the research programme

The aim of this study was to investigate the assessment and monitoring of sub-bandage interface pressure during leg movement. This would include background research followed by the development of an ambulatory measuring system. The planned research packages were, in summary:

i) To conduct a critical review of studies concerning compression therapy application in relation to venous leg ulcer formation. Particular aspects to be examined included the amount of compression that various bandage systems and stocking apply to the limbs during leg movement.

ii) To identify and justify key parameters and develop an initial specification for the required measurements of sub-bandage interface pressure in the laboratory and on human subjects.

iii) To undertake a critical review of available measurement technologies and commercial systems.

iv) To develop and validate the instrumentation system and application protocols using laboratory and human volunteer testing.

v) To design and execute a set of trials in the laboratory and on human volunteers for a defined set of compression bandage systems and materials in common use.

vi) To develop and initiate studies to attempt to correlate the understanding developed in (v) with the effect of compression therapy.

The anticipated outcomes were:

i) The identification of studies concerning sub-bandage pressure variation and determination of gaps in knowledge.

ii) A prototype measuring system capable of monitoring the variation of sub-bandage forces under ambulation.

iii) The execution of a set of trials and studies that might point to a better understanding of the physiological dynamics of the leg beneath a bandage system, during limb movement.

iv) Publication of results and observations

6.1.1 Execution of the research packages

In general, a large proportion of the project was completed. Objectives (i) to (iv) were significantly completed and some work was completed towards (v).Whilst consideration was given to package (vi) and some preparatory work involving ethical approval submissions was carried out, it was not possible to complete this aspect. The development work in (iv) could not be taken to its ultimate outcomes and this in turn impacted upon the objectives (v) and (vi). It was anticipated, from the outcome that these investigative studies package may be ambitious in terms of scope and time. Further details are provided in the discussion below.

6.1.2 Summary of achievements and outcomes

i) Literature review - An extensive review was completed that resulted in the identification of key indicators for system development and gaps in knowledge.

The literature review showed that compression bandages remain the commonest treatment for venous leg ulcers although the mode of action is yet not completely understood. Multilayer compression can be more effective than single layer bandages and can sustain pressure for longer periods.

In the context of interface pressure and stiffness measurements it was suggested that measurements are very commonly used as a tool to characterise support surfaces or investigate the forces that are exerted by various compression systems. The majority of the published studies involved measurements of interface pressure and stiffness while the subjects stood still (there have been very few attempts to characterise the dynamic behaviour of compression bandages). The review of measuring systems showed that commercially available and prototype devices and sensors have been tried extensively to monitor interface pressure, both

in static and dynamic conditions. Based on these outcomes, the key messages influencing the development of ambulatory sub-bandage measurements were found to be:

- There has been minimal work which compared the dynamic behaviour of bandage systems and stockings.
- There has been no presentation of correlation between the ambulatory sub-bandage interface pressure and the walking speed or walking time; while stiffness (both dynamic and static) is simulated in only one study.
- There is no commonly agreed measuring system while sensors are generally located at different anatomical points making comparisons very difficult.
- The measurement systems used demonstrated good electrical characteristics without however being developed with an appraisable number of sensors.
- Systems able to record pressure continuously are preferred from those producing on demand single readings.
- Measuring systems need to become smaller, lighter and portable.

These messages determined that the measurement requirements for a wound assessment laboratory must include:

- A device that would be able to record sub-bandage interface pressure during ambulation at various anatomical points simultaneously; in quasi real-time.
- The ability to characterise of the effect of walking speed and walking duration on sub-bandage pressures.
- A means of comparison of the pressure produced by various bandages and stockings during exercise.
- The identification of the dynamic stiffness indices for single layer bandages and bandage systems.

A significant output from the review was an article in the Journal of Wound Care (Bethaves, 2002)

ii) Initial specification and prototype development - From the review it was possible to specify and justify the requirements of a measurement system.

A prototype measurement system, having performance in agreement with the required specification, was produced. This emerged through 4 phases of development (chapter 5). The system was not completed due to lack of time. However, only the wireless FM part remained incomplete. This however did impede the completion of the human study objectives.

The following was achieved:

- Phase 1

Having confirmed the suitability of the Fontanometer sensor for sub-bandage pressure measurements (see 5.2), it was decided to execute certain tests that would provide information about the electrical characteristics of the sensors. The outcomes (Tables 5.7 and 5.37) showed that the sensor (and S7b amplifier) performance agreed with the set specification. Also, these results were used as a basis for comparisons with the performance results of the systems that would be developed.

- Phase 2

The aim of this development phase was to illustrate the feasibility of ambulatory sub-bandage pressure measurements and to test different software approaches. Both aims were achieved since the assembled system (which included a portable computer with the LabView program) allowed the execution of ambulatory sub-bandage measurements. The performance results (see Table 5.16) were very similar to the original benchmark results, which were expected since no extra signal processing was added to the Gaeltec amplifiers.

- Phase 3

The development of the original measurement system aimed to minimize volume and weight and increase the number of Fontanometer sensors. System volume and weight were considerably reduced. A large trolley (weighting more than 15 kg) was replaced by a single board (utilizing surface mount components) weighting less than 400 g. In addition the number of inputs was increased from 10 (6 Fontanometer, 4 gait indicators) to 14 (10 Fontanometer, 4

gait indicators). However system's performance (see Table 5.26) was worse than the initial system since both noise level and drift were increased.

- Phase 4:

The development of the final system aimed to further decrease volume and power requirements, utilize battery power, include wireless data transmission and maintain (or improve) system performance characteristics. The following were achieved:

- Volume was decreased by removing a problematic signal processing section of the previous design
- Power requirements were reduced by introducing micro power components to the new design
- Wireless data transmission was included in the system but could not be fully established. This development did not allow the execution of clinical trials
- System performance results (section 5.7.1) were within the set specification while noise level and drift were improved in relation to the prototype design. Detailed discussion is provided in sections 5.7.1 and 5.7.2

iii) Trials and studies

As stated in ii) the final system development was not completed forbidding the execution of trials and studies that would provide useful information about the interaction of sub-bandage forces. Despite this failure, the initial system provided a general picture of the variation of sub-bandage pressures. The results were consistent with findings from other studies that measured such forces.

iv) Literature and conference contribution

As a result of this research this author has published a number of papers. These are shown in Appendix A. A directly relevant journal paper is shown in full together with a list of related publications.

6.2 Discussion

The literature review suggested that 30 to 40 mmHg of compression appeared sufficient to promote healing, although this figure has a poor evidence base, particularly in relation to other studies that suggest that higher pressure may be needed to reverse venous hypertension. Also, multilayer compression appears more effective than single layer bandages and can sustain pressure for longer periods.

The assessment of the properties of bandages and bandage systems is based on the measurement of interface pressure, which is established as a commonly used tool in research. The review suggested that the validity of interface pressure measurements depends on many issues, for example sensor characteristics (both electrical and geometrical) and the manner of the measurement (leg shape and posture).

The majority of published sub-bandage pressure measurements were executed in static conditions. This left many unanswered questions about dynamics. For example how does walking affect pressure, is pressure sustained during exercise, is the pressure exerted by stockings similar to that of a bandage and what are the dynamic stiffness indices of such systems and their effect?

The review of available measurement technologies and commercial systems suggested that much technology approach tends to portable systems that utilize multiple sensors, battery power and continuous monitoring of pressure. However the published work did not have consisted reporting of the electrical characteristics of the devices used in clinical measurements. The general tension of the review seemed to emphasize the need for objective study such as was the requirement for an effective Wound Assessment Laboratory.

The hardware specification was based on the literature review key indicators and the contemporary clinical input that was provided at the Wound Healing Research Unit. As a result, the system (that would enable the execution of the objective study) was specified such as to include elements of the literature review (electrical characteristics and design issues) and clinical input (bandage type, sensor location and type of sensor).

Previous studies shown that sub-bandage measurements could be carried out by using available commercial devices or manually made systems. The initially available resources for this project included 6 Gaeltec S7b amplifiers and 6 Fontanometer sensors. The volume, weight and cost of the devices made clear that the monitoring of sub-bandage pressure required a different and more cost effective development approach, which was eventually executed in 4 phases. This approach was followed because the initially available amplifiers (considering the issues mention before) did not allow execution of systematic measurements and trials. In addition, the original prototype system entailed further development to meet the requirements of the specification, leading to another development phase.

It is noteworthy that the development of each phase was influenced by the outcomes of the previous phase. For example the reduction of the large volume and weight of the initial system was set as the main aim of the prototype design. Thereinafter the final design aimed to overcome the limitations of the previous system regarding power dependency, data transmission and low (compared to the other systems) performance.

In general every system had some advantages and disadvantages. The initial system allowed the execution of ambulatory measurements, had probably the best performance characteristics but had 6 pressure inputs, had to be placed on a trolley, was heavy, had to be pushed next to the subject and was expensive. The prototype design minimised volume and weight significantly, reduced cost, increased number of pressure inputs (to 10) but had the worst performance characteristics, could not be used in a clinical trial since it was powered by an external source and the data transmission was accomplished using cables. The final design further minimized volume and weight, improved performance characteristics (compared to the prototype system), included wireless transmission and utilised battery power. However the wireless transmission was problematic and consequently did not allow the execution of ambulatory sub-bandage measurements.

The overview of performance results suggests that the overall performance was affected by the development procedure. The prototype design was worse than the initial system. The final design was better than the prototype but still worse (in some measurements) than the initial

prototype. On the contrary the practicability was improved since volume and weight were reduced, wireless transmission included and battery power was utilized.

It can be concluded that:

- There are many questions regarding the dynamic behaviour of bandage systems and stockings. Further research in this area could provide a better image of ambulatory sub-bandage pressures.
- The literature review combined with the clinical input shaped the hardware specification and provided the basis for future human volunteer ambulatory measurements.
- The development approach was beneficial since each phase influenced the next one by providing solutions to hardware and software issues and setting the design aims for the following system.
- The final design, taking under consideration its transmission problems, had significant advantages (volume, weight, inputs, power, wireless transmission) compared to the initial trolley system and the prototype design. By adding the cost effectiveness, it can be concluded that the approach was successful. Recommendations for further development are given in the next section.

6.3 Further work and recommendations

In order to complete the development of the WAL the following work is required:

i) Improvement of the assembly language program (for the 16f74 microcontroller) in order to overcome the synchronisation problems that cause the problems in the transmission

ii) Further development of the LabVIEW program in order to correctly demultiplex the incoming signals and to synchronise with the transmission circuit

iii) Trials and studies with subjects in order to investigate the gaps in research (discussed in chapter 3). Ethical approval has been acquired for such measurements, but they

could not be completed due to the errors described in chapter 5. It is recommended that these trials should include:

- The dynamic stiffness of medical stockings and bandages
- The effect of speed on sub-bandage pressure
- The effect of walking on how the sub-bandage pressure is sustained and for how long
- Monitoring the sub-bandage pressures for an ulcerated patient at various walking speed

v) Due to system design it is possible to modify it so as to utilise different types of sensors (for example temperature or humidity sensors) and monitor the effect of walking and other body movements on these parameters.

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Appendix A

Publications

Interface pressure measurement: testing and selecting sensors

Interface — or contact — pressure measurements play a key role in the design of many patient support surfaces aiming to protect areas vulnerable to pressure ulceration. But testing and selecting appropriate devices can be problematic

pressure ulcer prevention; mattresses; cushions; capacitance, resistive, pneumatic and fluid-filled sensors

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Pressure ulcers still present a major challenge to both clinicians and health-care systems. Effectively targeting preventive resources to patients at greater risk of developing pressure ulcers is complicated by the myriad extrinsic and intrinsic interactions that give rise to these wounds. The many patients affected, and the greater number requiring preventive care, make prevention and treatment expensive.[1,2]

A common way of managing pressure ulcers is to provide pressure-distributing support surfaces. Many are commercially available. Over 100 support surfaces were available in the marketplace in the early 1990s.[3] Evaluation of the efficacy of these devices[4] has been limited, with fewer than 40 randomised controlled trials.

One common approach in the design and marketing of support surfaces is to measure the interface pressure while the subjects are lying on their backs on the support surface.

It is generally assumed that low interface pressures at key anatomical sites prone to developing pressure ulcers indicate that a support surface is likely to be effective. However, virtually no evidence exists to support this.[5]

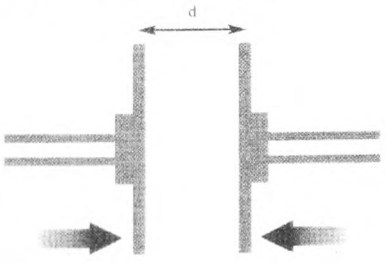
Several types of sensor provide measurements of the perpendicular force or pressure applied to the sensor and, if these are mounted in an array or matrix, they can provide information on pressure-distribution patterns. These allow for pressure-mapping of full-body interface pressure distribution between the patient and the support surface.[5]

Many pressure-measurement systems exist, but four technologies are commonly used to measure pressure between different parts of the anatomy and their supporting surfaces:

- Capacitive sensors
- Resistive sensors
- Pneumatic sensors
- Fluid-filled sensors.

The characteristics of these devices, and their limitations when used to measure interface pressure, are discussed here.

Fig 1. Forces applied to capacitor



What devices have been used?

Table 1 highlights several commonly available pressure-measuring technologies and their operating characteristics. Modes of action are reviewed below.

Capacitive sensors

Capacitors are electrical elements that store energy in the form of an electrical field. This energy is supplied to the capacitor by a power supply and can be transformed into a useful reading with the appropriate circuitry. Usually, very small capacitors are put into mats or other transducers and then change their electrical characteristics (described below) in response to external pressure or another physical parameter.

In their simplest form, capacitors consist of two metal plates that are opposite-charged and do not let any current pass through them (Fig 1). The amount of the electrical charge that can be stored depends on the physical dimensions of the plates and the dielectric material (the material between the metal plates, which could be porcelain [ceramic], mica, glass, plastic and the oxides of various metals).

The general formula that applies is:

$$C = \varepsilon_r \varepsilon_0 \frac{A}{d}$$

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1 Collier, M. Pressure Sore Development and Prevention. Cambridge: Wound Care Society Educational Leaflet, 1995.

2 Waterlow, J. Pressure sores and their management. Care Critical Illness 1995; 11: 3, 121-125.

3 Clark, M. Problems associated with the measurement of interface (or contact pressure). J Tiss Viab 1994; 4: 2, 37-42.

4 Cullum, N., Deeks, J., Sheldon, T.A. et al. Beds, mattresses and cushions for pressure sore prevention and treatment (Cochrane Review). The Cochrane library 4. 2001. Oxford: update software.

5 Harstall, C. Interface Pressure Measurement Systems for Management of Pressure Sores. Edmonton: Alberta Heritage Foundation for Medical Research, 1996.

6 Sternheim, M.M., Kane, J.W. (eds). General Physics. New York: John Wiley & Sons, 1986.

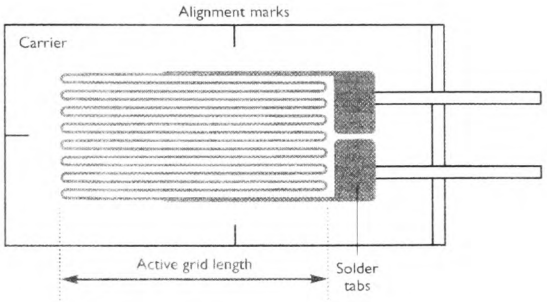
7 Geddes, L.A., Baker, L.E. (eds). Principles of Applied Biomedical Instrumentation. New York: John Wiley & Sons, 1975.

Table 1. A selection of commercially available interface pressure measuring systems

Measuring device	Pliance (Novel Germany)	Xsensor (Crown Therapeutics)	Oxford Pressure Monitor MKII (Talley Medical)	S7b (Gaeltec)	FSA (Vista Medical)	Clinseat (Tekscan)
Sensor type	Capacitive transducer	Capacitive sensor	Pneumatic	Metal diaphragm with directly deposited resistive strain gauges	Piezoresistive sensors	Resistive technology
Pressure range (mmHg)	NS	0–220	0–300	0–300	0–100* or 0–200**	0–200 0–1000
Sample rate samples/second	10,000	Up to 5000	2.7 at 300mmHg 6 at 0mmHg***	Continuous readings	3072	NS
Resolution (mmHg)	NS	1mmHg	1mmHg	2mmHg	1mmHg	1mmHg
Accuracy	NS	Approximately 10mmHg	±4mmHg	2mmHg	Variation coefficient**** less than 10% at manufacture	NS

NS=not specified in manufacturer's technical literature
*Bed system
**Seat and back system
***Single-cell sampling rate
****Variation coefficient is the standard deviation expressed as percentage

Fig 2. Metal wire bonded strain gage (adapted from National Instruments)



where ε_0 is the dielectric constant of free space, ε_r is the relative dielectric constant of the insulator, d is the distance between plates and A the area of the plates. Usually, an insulator or dielectric material is introduced between the plates to increase the sensitivity of the sensor.[11]

By changing one of these parameters, it is possible to observe a change in the capacitance. The easiest way is to change the area of the plates or the distance between them. The latter is the easiest, and the one most commonly adopted.

Advantages of capacitive transducers include their flexibility (their size differs from large to very small) and the fact that the capacitance does not depend on the conductivity of its plates. This results in extremely small errors as the dimensions of the plates are not independent of temperature.

Resistive sensors

Resistive technology uses resistive elements, such as strain gauges and force-sensing resistors (FSRs), to map the force and translate it into pressure readings. The alternation of resistance (the change of resistance of the electrical component) has been used extensively to transmute temperature and displacement into electrical signals. The resistance of a conductor, regardless of its physical form, depends on three factors:

- Type of material
- Geometric configuration
- Temperature.

The resistive elements, which are called 'piezoresistive', can change their resistance under physical pressure or mechanical work. If these elements are strained or deflected, their internal resistance will change and stay changed until the material's original position is restored.

Strain gauges, which are commonly used in pressure-measuring devices, are constructed using piezoresistive materials. These comprise fine wires that change their resistivity when deformed. They

can measure extremely small displacements but are affected by temperature. To reduce this problem, pairs of strain gauges are employed in bridge circuits, and strains in the opposite directions are applied to adjacent arms of the bridge.[8] A bonded metallic strain gauge is illustrated in Fig 2.

The basic formula that applies in this case and describes the resistivity of fine wires is:

$$R = \frac{\rho L}{A}$$

where R is the resistance, ρ is the resistivity of the wire, L the length of the wire and A the cross-sectional area. By appropriate mathematical transformation this relationship becomes:

$$G = \frac{D\,R/R}{D\,L/L}$$

Here, G is the gauge factor and characterises the magnitude of the piezoresistive effect. It must be noted that the gauge factor for semiconductor materials is approximately 50–70 times that of metals. However, semiconductor strain gauges are more sensitive to temperature.[8]

Pneumatic and fluid-filled sensors

These sensors use either hydraulic or pneumatic technology. In the first case, a bladder is filled with liquid and the pressure causes the liquid to be displaced. It is translated afterwards by the device.

Pneumatic sensors use the same principle, but fill the bladder with gas instead of liquid. Reger et al.[9] commented on one commonly used pneumatic device, the Oxford Pressure Monitor MKII (Talley Medical, UK), which has 12 sensors arranged either as a four by three matrix array or as individual pressure sensors. Airflow into the sensors is suddenly increased until the external pressure is balanced by the pressure within it. According to Reger et al., pneumatic pressure measurement systems eliminate the need for extensive circuitry, reducing the possibility of malfunctions.[9]

Air-filled sensors have been used in a number of studies.[10,11] For example, Taylor et al.[13] used them within a simple measuring system designed to record pressures underneath compression bandages. The pressure sensors used were latex anorectal catheter balloons and the applied pressure was converted into voltage. The system was found to be accurate (typically less than ±0.5mmHg) and reproducible over a 12-month period, showing the potential value of air-filled sensors.

Use of pneumatic sensors is not without problems. Ferguson-Pell and Cardi[14] reported two challenges. The first source of potential error derived from a tendency of the output to 'creep'. This occurs when a sensor is loaded with a known weight and the measured pressure does not remain constant. Ferguson-Pell and Cardi[1] also discussed hysteresis, where sensors may record different pressures, depending on whether the sensor is being unloaded or loaded.[14]

Three pressure measurement systems were compared: the Force Sensing Array (FSA) (resistive), the Talley Pressure Monitor 3 (TPM3) (pneumatic) and the Tekscan 'seat' system (resistive).[14] All provided a linear response to increasing pressure (0–160mmHg in steps of 20mmHg). In all cases, the regression coefficient was better than 0.99 (that is, the response of the systems was almost 100% linear). However, the Tekscan and FSA demonstrated marked hysteresis and creep.

For the same applied pressure increments, the hysteresis for FSA was ±18.7% and that for the Tekscan system was ±21.7%. Hysteresis was calculated as the maximal difference in average measured pressure as a percentage of applied pressure at the point of the maximal difference.

Creep (or instability) was also reported to be high for both the FSA and Tekscan systems. Two constant loads were applied (50 and 100mmHg) and two readings were made after two and 10 minutes. Tekscan had an instability of 17.9% after two minutes and 26% after 10 minutes for the 50mmHg load. For the same conditions FSA showed 3.3% and 4.6% instability. Finally, Tekscan had a creep of 7.5% and 13.5% for the 100mmHg load at the two- and five-minute intervals. For the same load FSA had a creep of 2.2% and 7.6%.

Other considerations

Other issues regarding pressure-measuring devices are their accuracy, precision and resolution. Accuracy is defined as the difference between the true value of the measure and the measured value indicated by the instrument,[15] with the true value being interpreted in reference to some absolute or agreed standard. For instance, the Oxford Pressure Monitor MKII has a specified accuracy of ±4mmHg, which means that the output for an applied pressure of 10mmHg could be either 6 or 14mmHg.

A system is precise when it can display the same reading every time the same physical effect is applied to the sensor, although this does not mean the reading is necessarily correct. For instance, it is possible to obtain a linear response from a device, but this will shift if the temperature changes. In this case, the device is still precise but not accurate because the shifted response does not give the actual magnitude of the physical parameter.

Resolution describes the degree of detail the system can display. It could be defined as the smallest incremental quantity that can be measured with certainty.[8] Most systems described in this paper have a resolution of 1mmHg.

8 Webster, J.G. (ed.). Medical Instrumentation: Application and design. New York: John Wiley & Sons, 1998.

9 Reger, S.I., McGovern, T., Chung, K.C., Stewart, T.P. Correlation of transducer systems for monitoring tissue interface pressures. J Clin Eng 1998; 13: 5, 365-370.

10 Isherwood, P.A., Robertson, J.C., Rossi, A. Pressure measurements beneath below-knee amputation stump bandages: elastic bandaging, the Puddifoot dressing and a pneumatic bandaging technique compared. Br J Surg 1975; 62: 12, 982-986.

11 Danielsen, L., Madsen, S.M., Henriksen, L. et al. Sub bandage pressure measurements comparing a long stretch with a short stretch compression bandage. Acta Derm Venereol (Stockh) 1998; 78: 3, 201-204.

12 Stockport, J.C., Groarke, L., Ellison, D.A. et al. Single layer and multi layer bandages in the treatment of venous leg ulcers: comparison of sub bandage pressures. J Wound Care 1997; 6: 10, 485-488.

13 Taylor, R.J., Taylor, A.D. Construction and calibration of a low cost bandage pressure monitor. J Wound Care 1998; 7: 3, 125-128.

14 Ferguson-Pell, M., Cardi, M. Prototype development and comparative evaluation of wheelchair pressure mapping system. Assistive Technology 1993; 5: 2, 78-91.

15 Webster, J.G. (ed.). The Measurement, Instrumentation and Sensor Handbook. New York, NY: CRC Press LLC, 1999.

16 Fletcher, J. Selecting pressure-relieving equipment. J Wound Care 1995; 4: 6, 254.

17 Clark, M., Defloor, T., Haai, B. et al. Physical effects upon human soft tissues produced by pressure-redistributing beds and mattresses. EUAP Review 2000; 2: 1, 7-9.

18 Campbell, K. Pressure point measures in the operating room. J Enterostomal Ther 1989; 16: 3, 119-124.

Table 2. A selection of investigations/studies highlighting the difficulty of measuring interface pressures

Study	Volunteers	Instruments	Position	Accuracy reported	Sensors attached	Clothing
Pressure point measures in the operating room[18]	20 patients	Gaymar pressure gauge	Supine	NS	Occipital right Left scapula Thoracic spine Sacral Left-right heel	NS
The effect of position and mattress on interface pressure[20]	62 healthy (50 females, 12 males) MA = 38.3	Ergocheck measuring system	Supine, 30° semi-Fowler Lateral Prone	Measuring error of 1.7–3.7%	Sensor pad	Night clothes
The effect of small shifts in body weight on blood flow and interface pressure[21]	50 subjects 31 females 19 males Ages: 67–97	Mini Texas interface pressure evaluator	Lateral oblique Supine	Reliability of 95% or greater	Trochanter Sacrum	NS
A comparison of pressure-relieving surfaces using two measures of pressure[22]	20 patients 11 females 9 males MA = 51	Electro-pneumatic device	Laterally inclined	NS	Left/right ischial areas	NS
Relationship between body weight, body position, support surface and tissue interface pressure at the sacrum[23]	18 patients	Gaymar pressure sensor system	Supine Semi-Fowler Fowler	2mmHg	Sacrum	NS

NS= not specified; ; MA=mean age

Other issues include linearity and thermal effects. A system is linear when the output signal or measurement varies in direct proportion to the input signal (applied force).[7] In a linear device, the output-input ratio is always the same for the region if the input does not exceed the manufacturer's recommended value.

In addition, quite a few sensors can be affected by temperature. These thermal side-effects alter the output, which usually depends on the sensor material. This problem is usually overcome by using software with the appropriate algorithms to calculate the shift in pressure, or by using more complex circuits that eliminate these effects.

Interface pressure measurement problems

Several reviews have highlighted the technical challenges and fundamental limitations of interface pressure measurement. Despite these limitations, interface pressure measurements are often seen as an 'easy' method of comparing patient support systems. These have been discussed in detail elsewhere,[3,16,17] so this review will not repeat the arguments. However, Box 1 provides an overview of the nature of the problems encountered.

Over the years sporadic comments have been made about the effect of the clothing worn by subjects participating in research on interface pressure measurements. Campbell[18] reported how sacral interface pressures change as the number of layers of material between the subject and the support surface diminished. Her study aimed to evaluate the interface pressure at various body points (occipital, right and left scapula, thoracic spine, sacral right and left heel) of patients undergoing peripheral vascular surgery.

She noted that the pressure-relieving capabilities of the mattress were reduced for every extra piece of cloth added between the patient and the support surface. Furthermore, in the nine subjects, there was an increase of 16mmHg when all the layers and the clothes were added.

Various options exist during interface pressure measurement, from subjects wearing no clothing or having only a sheet between the skin and the support surface, through to subjects wearing normal everyday clothes during the study. Perhaps in an ideal scenario all measurements would be performed with no intervening clothing or bedding, as was reported by Clark and Rowland[19] in 1989 and in other studies by the same research group. However, this may not be possible or practical in many environments, while there is potential to embarrass both the subject and researcher as most

19 Clark, M., Rowland, L. Preventing pressure sores: matching patient and mattress using interface pressure measurements. Decubitus 1989; 2: 1, 34-39.
20 Defloor, T. The effect of position and mattress on interface pressure. Appl Nurs Res 2000; 13: 1, 2-11.
21 Oertwich, P.A., Kindschuh, A.M., Bergstrom N. The effects of small shifts in body weight on blood flow and interface pressure. Research in Nursing & Health 1995; 18: 6, 481-8.
22 Colin, D., Desvaux, B., Saumet, J.L. A comparison of pressure relieving surfaces using two measures of pressure. J Wound Care 1995; 4: 7, 302-304.
23 Rondorf-Klym, L.M., Lagnemo, D. Relationship between body weight, body position, support surface, and tissue interface pressure at the sacrum. Decubitus 1993; 6: 1, 22-30.

Box 1. Challenges reported in the performance and interpretation of interface pressure measurements

Validity — do these measurements provide information on the likely development of pressure ulcers on different support surfaces?

Validity — do these measurements help clinicians decide which patients are most likely to develop pressure ulcers?

What subjects are appropriate? Young volunteers, elderly patients, elderly volunteers?

Can mannequins overcome the variability inherent in human populations?

What posture should be adopted during tests and how should this be reported?

Should subjects be stratified on the basis of their age, weight and sex?

How should the instrument be calibrated? Are the sensors appropriate for the measurements to be performed? Are they too rigid, too small or too large?

How will the test results be reported?

interface pressure measurements are performed around the pelvis.

The effect of different clothing on interface pressure measurements is unclear, and this is one area ripe for further exploration. The likely effects of this single aspect of interface pressure measurement on the generated data need to be defined.

Table 2 illustrates representative studies and shows some of the deficiencies that make them non-comparable. This is not an exhaustive list, but has been selected to highlight particular study design flaws.[18,20–23]

Most recent laboratory studies comparing patient support surfaces have focused on interface pressure and tissue compression (examples are listed in Table 2). Other parameters, such as temperature and humidity, could also be explored. For example, Ferguson-Pell et al.[24] examined several parameters (temperature, humidity, pressure) at the patient cushion interface and suggested potential methods of measuring them. He noticed that most pressure sensors used showed a higher value than the known stress that he applied.

Additionally, Ferguson-Pell et al. measured temperature using thermocouples (temperature sensors), and humidity using moisture-sensitive sensors. The results suggested that foams and viscoelastic foams tend to increase skin temperature and that cushions with impermeable covers elevate interface humidity.

Kemp[25] reviewed the role of humidity in pressure-ulcer formation and suggested that its measurement would provide a comprehensive picture of the patient's environment. Such studies could help to understand the interactions of many of the parameters that affect pressure ulcer formation.

Conclusion

This paper has identified the main difficulties and limitations that are encountered when measuring interface pressures. Particular emphasis is placed on the selection of sensors and their use in clinical situations and environments.

The challenges faced when attempting to achieve reliable, repeatable measurements lie in the performance characteristics of the various sensor technologies, the presence of hysteresis and creep, and the manner in which sensors are applied to volunteers or patients.

While these techniques are commonly used, clinicians and researchers lack awareness of their limitations.[12] This is compounded by the lack of conventions on how interface pressure should be measured, reported and interpreted.[11] Further investigations are needed to explore the influence (if any) of subject posture and clothing on measured interface pressures.

Despite emphasis on tissue compression and the measurement of interface pressures, other factors are involved in pressure ulcer development. There remains a need to characterise each of the potential factors (such as temperature) and to determine how they act independently and in combination to produce or catalyse pressure damage.

In conclusion, what seems to be a relatively simple procedure — the measurement of interface pressure — is in fact complex, with many unresolved issues. Before we can even attempt to evaluate the role of tissue compression in pressure damage, we need to agree how this parameter should be measured. ■

Box 2. Summary of the main points

Many patient support surfaces, such as beds, mattresses or cushions, are designed to redistribute loading away from parts of the anatomy vulnerable to pressure ulcers. As part of the process of designing them, interface or contact pressure measurements play an important part

Many pressure measurement systems exist, but four technologies are commonly used: capacitance, resistive, pneumatic and fluid-filled sensors

When these devices are tested, findings can be affected by a number of factors. What appears to be a simple procedure, which is frequently used in a clinical setting, can be influenced by unforeseen problems. These include the type of clothing the volunteer or other subject testing the device is wearing, the posture of the subject and their age, weight and sex, compared with those occurring in real-life situations

Temperature and humidity can also influence the true accuracy of readings, sometimes by what appears to be very small, yet significant, margins

The devices themselves can vary their readings, depending on the presence of hysteresis and creep

More research is needed to establish common agreement on how this parameter can be measured

24 Ferguson-Pell, M., Reddy, N., Stewart, S.F.C. et al. Measurement of physical parameters at the patient-support interface. In Whittle, M., Harris, D. (eds). Biomechanical Measurement in Orthopedic Practice. Oxford: Clarendon Press, 1985.

25 Kemp, M.G. Protecting the skin from moisture and associated irritants. J Geront Nurs 1994; 20: 9, 8–14.

All data pertaining to the interface pressure measurement systems have been drawn from company product specifications available on the internet or from company publications

List of project relevant publications to which this author contributed:

Bethaves T, Clark M, Williams RJ, Melhuish JM, Harding KG (2001). Evaluation of the role of support surfaces in pressure ulcer formation and treatment. All Wales Medical Physics & Clinical Engineering Summer Meeting, Llandeilo 15-16 June, Wales.

Bethaves T, Melhuish JM, Krishnamoorthy LK, Harding KG (2001). A novel method for assessing the microcirculation through intact bandages. Innovations in Wound Care, Cardiff, Wales.

Melhuish JM, Bethaves T, Williams RJ, Harding KG (2001). Assessment of sub-bandage forces applied by eight long stretch bandages to six leg models. 11th ETRS Annual Conference, Cardiff, Wales.

Melhuish JM, Bethaves T, Williams RJ, Harding KG (2001). Bandaging technique, sub-bandage pressure and shear. 11th ETRS Annual Conference, Cardiff, Wales.

Melhuish JM, Bethaves T, Williams RJ, Harding KG (2001). Pressure relief for heels: an effective innovation. Innovations in Wound Care, Cardiff, Wales.

Melhuish JM, Krishnamoorthy LK, Bethaves T, Harding KG (2001). Reductions in local perfusion upon application of compression bandages. 11th ETRS Annual Conference, Cardiff, Wales.

Melhuish JM, Bethaves T, Clark M, Williams RJ, Harding KG (2002). Quantifying lower limb perfusion under intact compression bandages. 2002 Joint Conference of the Wound Healing Society and the European Tissue Repair Society, Baltimore, Maryland USA.

Melhuish JM, Bethaves T, Krishnamoorthy LK, Clark M, Williams RJ, Harding KG (2003). Changes in the microcirculation of the application of compression bandages in the lower limb. Harrogate 2003, Harrogate, UK.

Melhuish JM, Bethaves T, Krishnamoorthy LK, Clark M, Williams RJ, Harding KG (2003). Lower limb microcirculation an application of compression bandages using a novel laser Doppler approach. ETRS 2003, Amsterdam, Holland.

Melhuish JM, Clark M, Bethaves T, Oduncu H, Williams RJ, Harding KG (2003). Measuring interface pressure. Harrogate 2003, Harrogate, UK.

Melhuish JM, Krishnamoorthy LK, Bethaves T, Clark M, Williams RJ, Harding KG (2004). "Measurement of the skin microcirculation through intact bandages using laser Doppler flowmetry " Medical & Biological Engineering & Computing **42**(2): 259-263.

Appendix B

Circuit Diagrams and Photographs

Table of contents

Wound Assessment Laboratory, final system circuit diagram **B1**
The circuit diagram of a single channel of the main board of the final system, including the PIC16F84 microcontroller, the multiplexer and the circuitry for a single gait indicator (FSR)

Transmitter and battery power circuit diagram **B2**
The circuit diagram of the board responsible for powering the system, digitizing the incoming pressure signals and transmitting the data

Receiver circuit diagram **B3**
The receiver circuit board including the FM receiver, the indicator LEDs and the 50 pin connector for the data acquisition card (DAQ700)

Amplifier prototype circuit diagram **B4**
This circuit diagram illustrates a single channel of the 2nd prototype (amplifier board)

Receiver board image **B5**

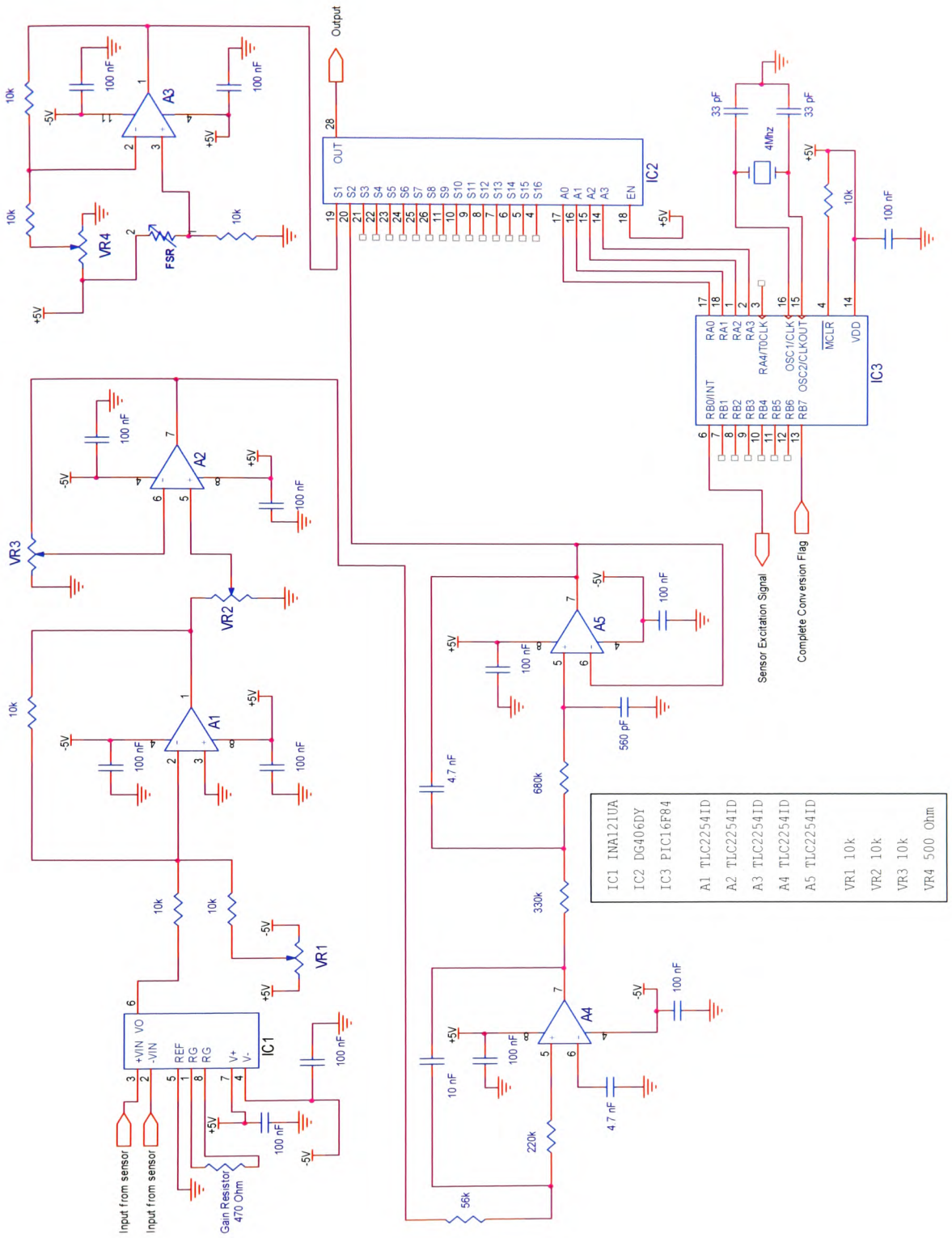
Testing configuration image **B6**

Fontanometer sensor attached to the sphygmomanometer **B7**

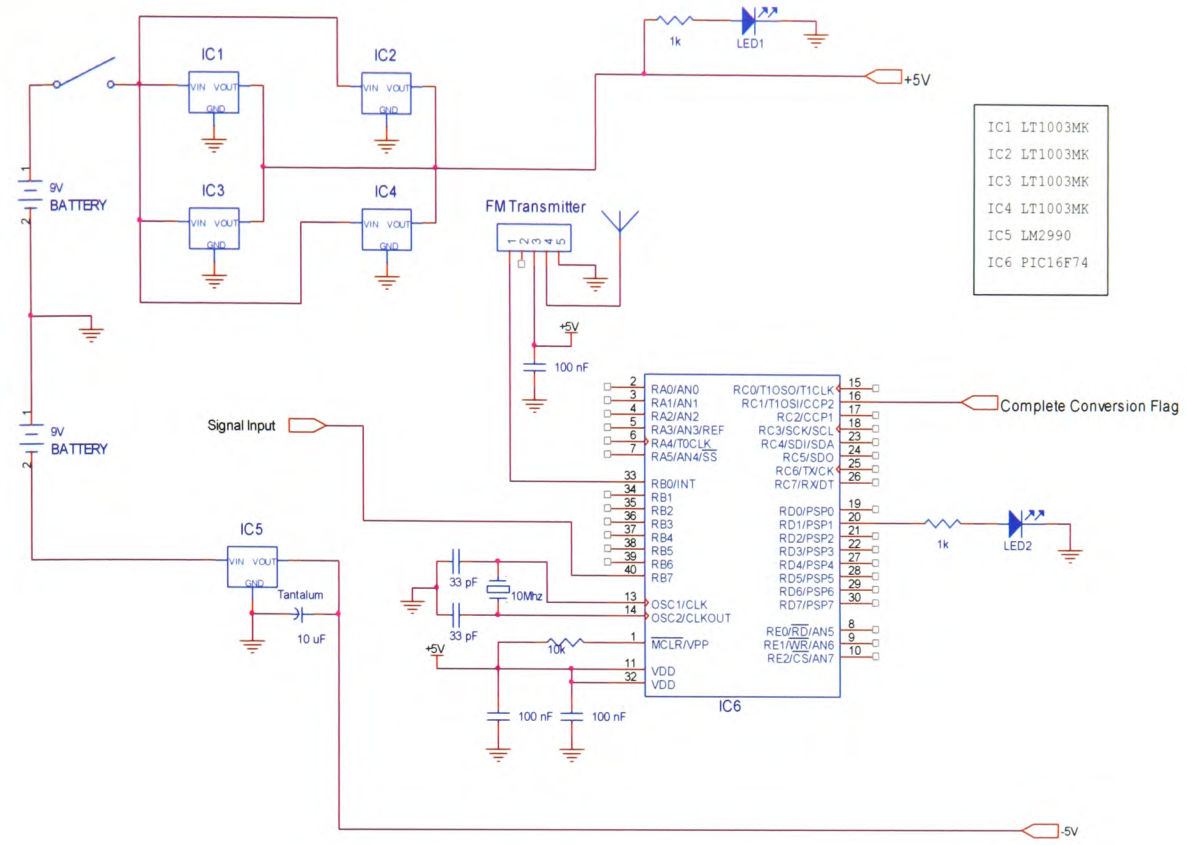
Sub-bandage measurement system image **B8**

Sub-bandage measurement system detail diagram **B9**

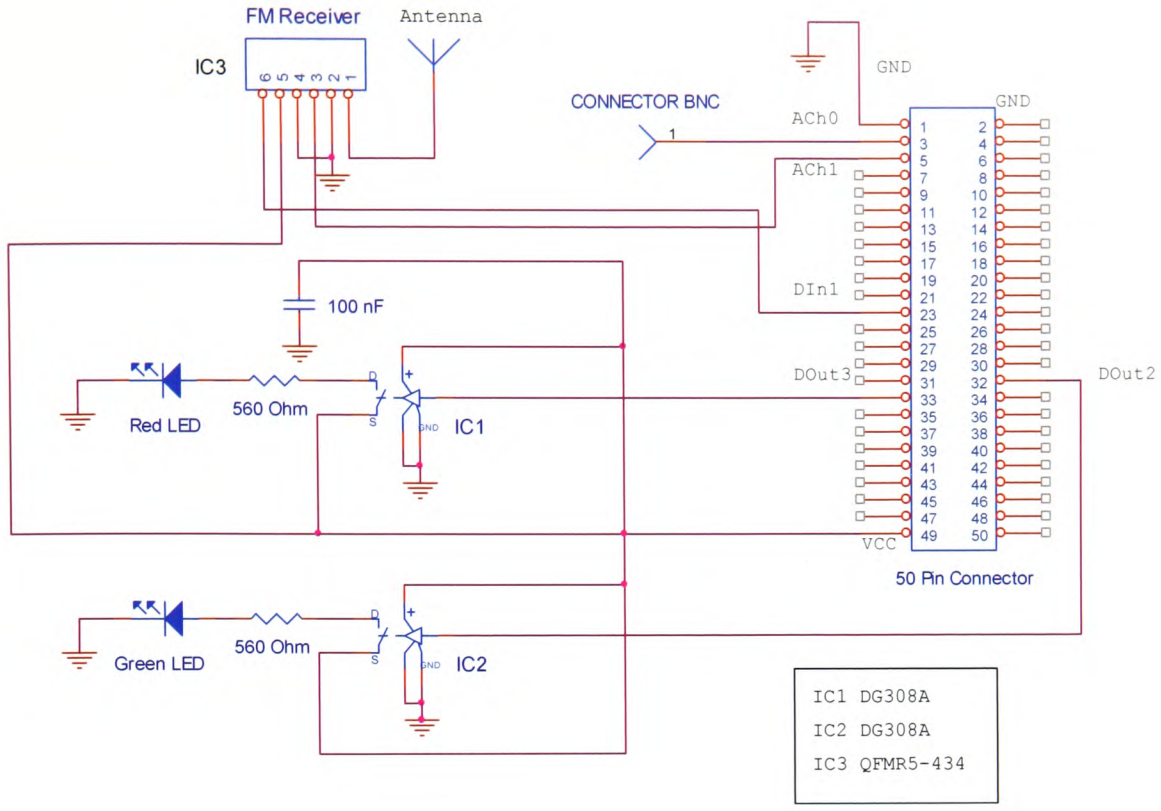
LabView final program code **B10**



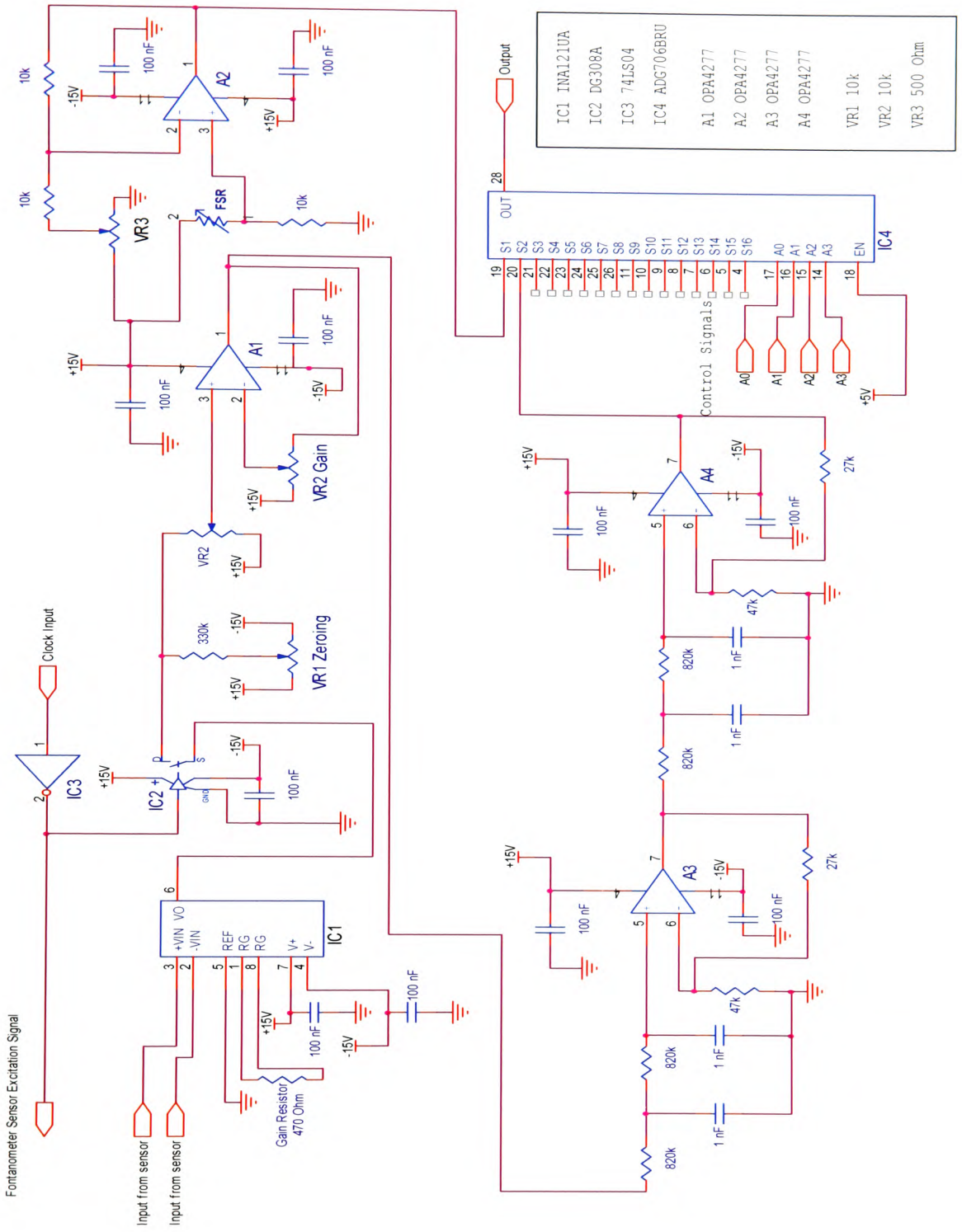
B1 - Wound Assessment Laboratory, final system circuit diagram (single channel)



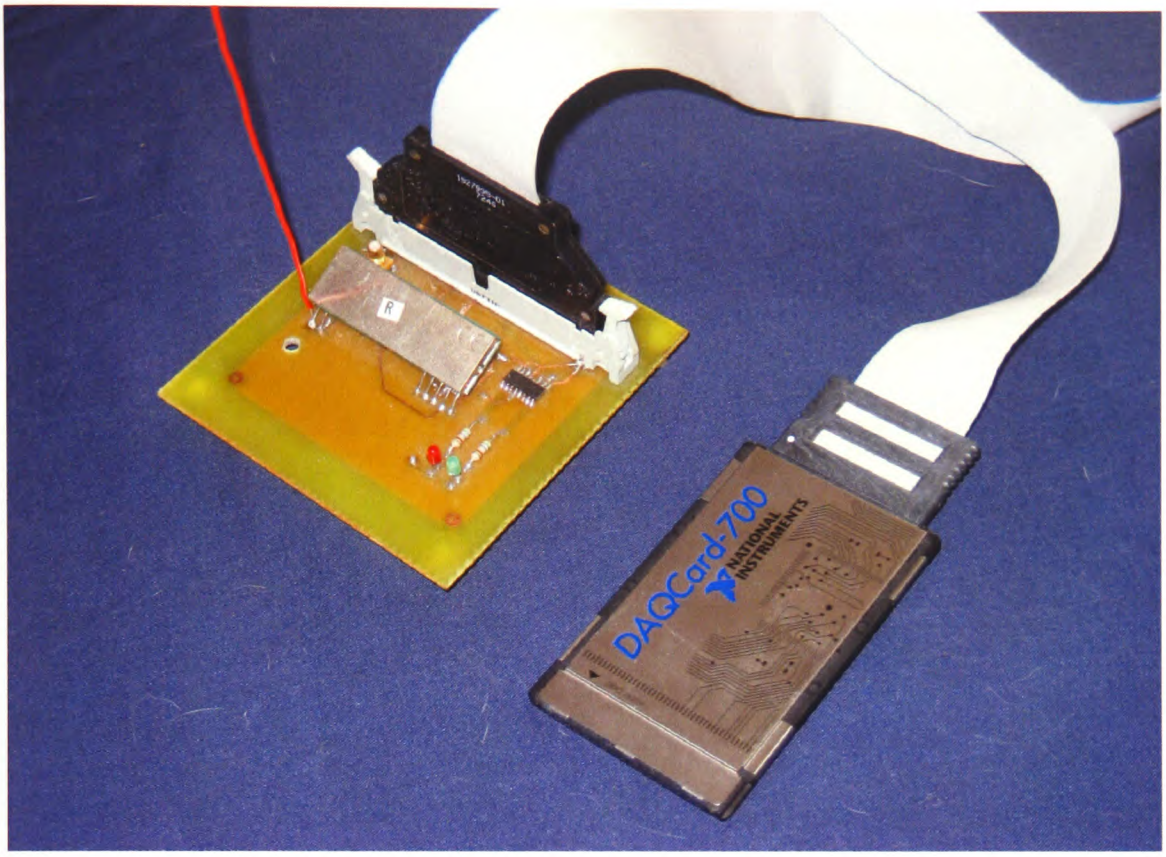
B2 - Transmitter and battery power circuit



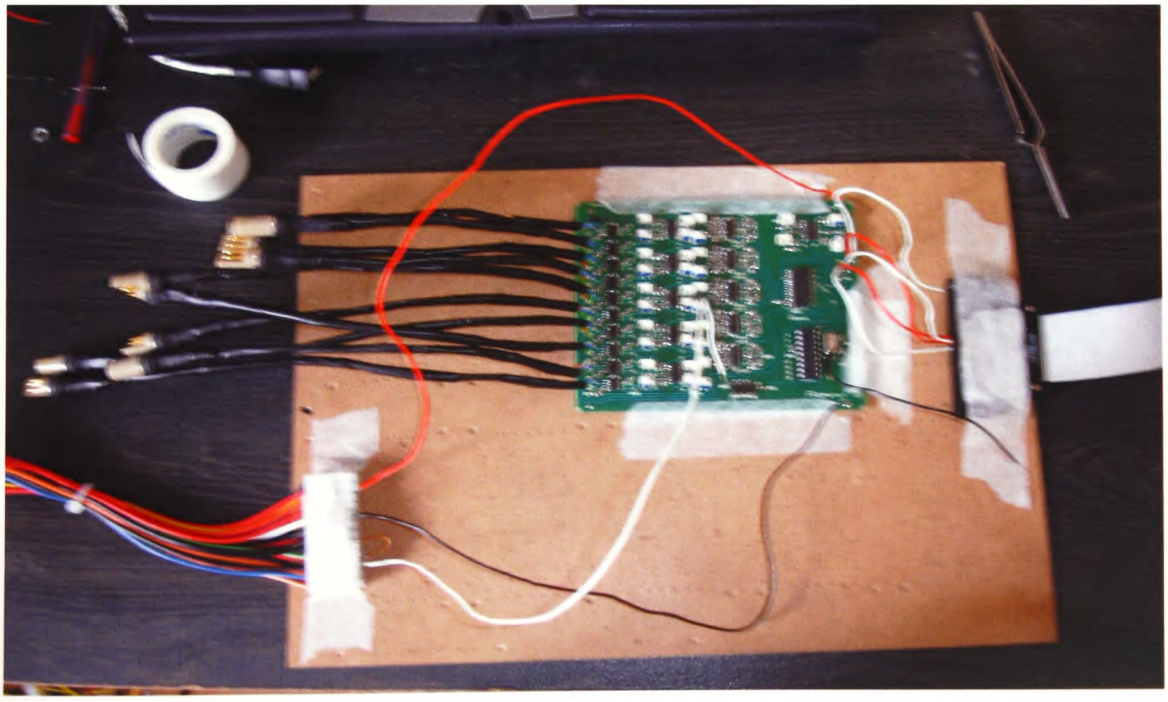
B3 - Receiver circuit



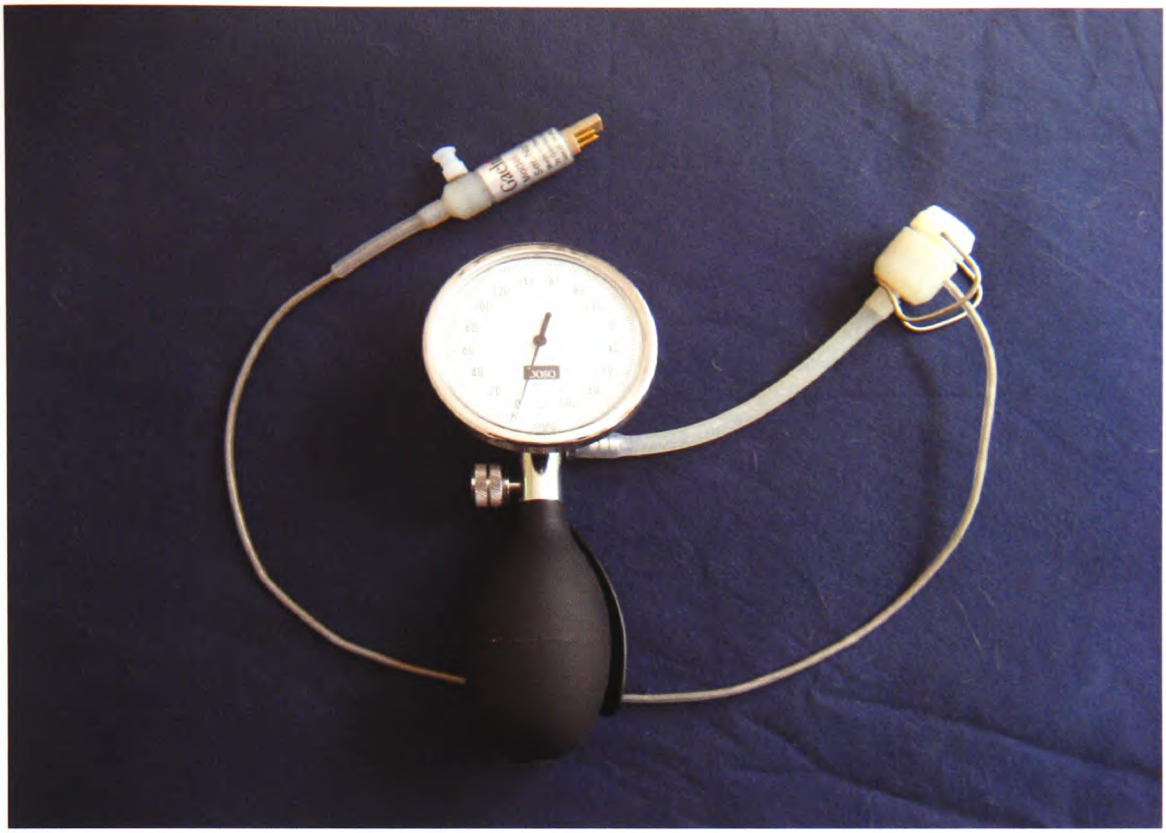
B4 - Amplifier prototype circuit diagram



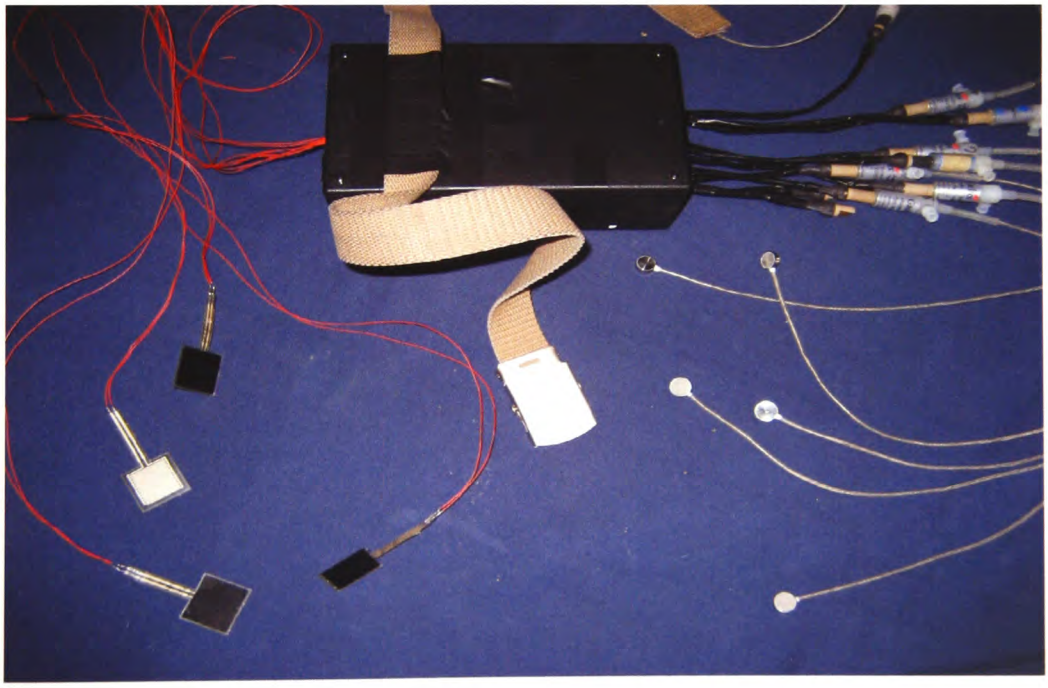
B5 - Receiver Circuit



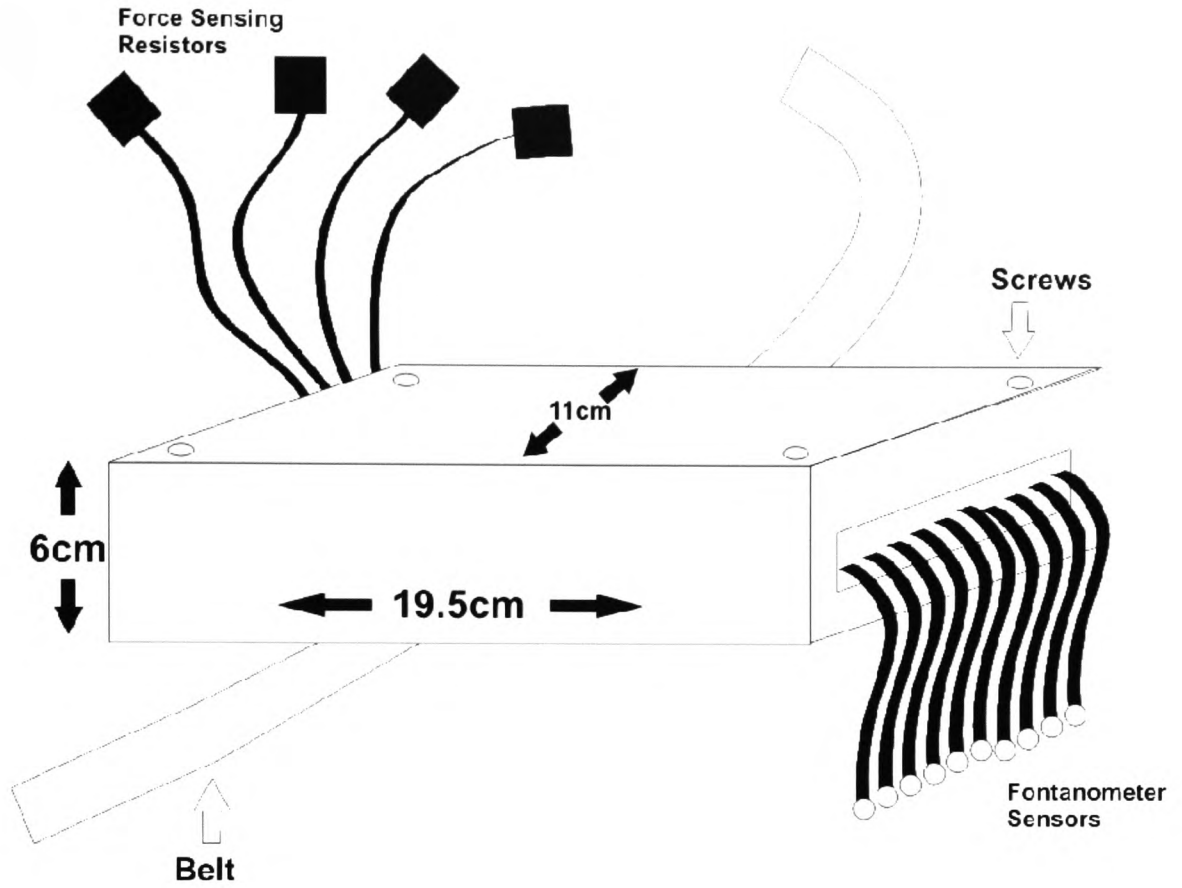
B6 - Testing Configuration



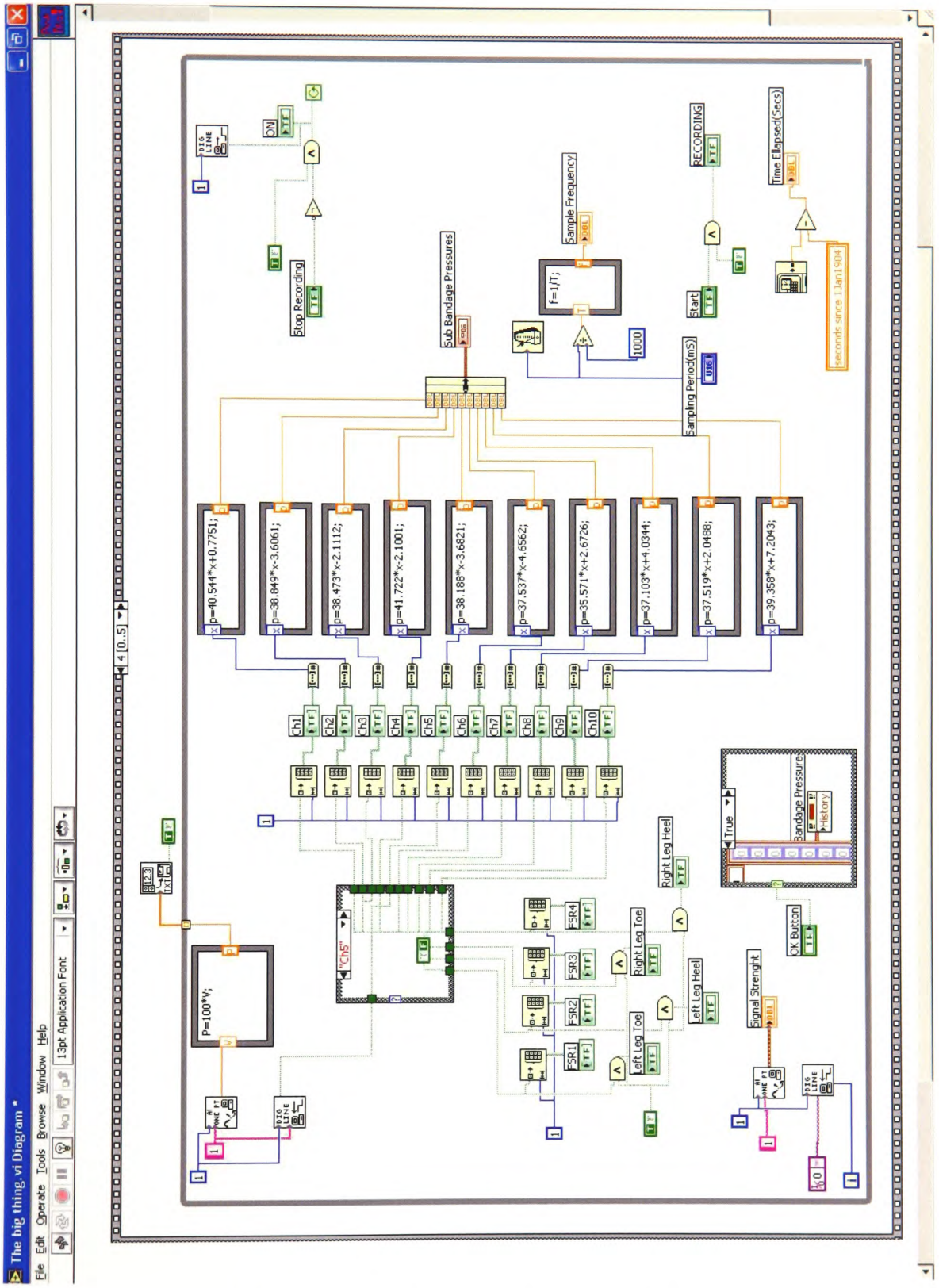
B7 - Fontanometer Sensor attached to the sphygmomanometer



B8 - Complete Sub-bandage pressure measurement system



B9 - Complete System detail diagram



B10 – LabView program code screenshot

Appendix C

Background Work

Table of Contents

Aetiology and Assessment **C1**
This section discusses the aetiology of venous ulcers and the assessment methods commonly used

Prevalence of venous leg ulcers **C2**
The prevalence of venous leg ulcers in UK and other developed countries is discussed

Economic implications **C3**
This section analyses the economic implications of venous ulcers for health care organisations

Management and healing methods **C4**
This part discusses the management approaches when dealing with venous ulceration and describes common healing methods, excluding compression therapy

References and Bibliography **C5**

C1 – Aetiology and Assessment

The aetiology of venous ulceration is not completely understood. There are 3 theories that attempt to determine the aetiologic factors. These are:

Fibrin cuff theory:

Browse and Burnand (1982) introduced the fibrin cuff hypothesis in 1982. They suggested that the high ambulatory venous pressure within the calf muscle pump is transmitted through communicating veins to the superficial veins within the skin and subcutaneous tissues of the lower leg. As a result the local capillary bed is distended and the endothelial pores are widened, eventually allowing large molecules to escape into the interstitial fluid. This in turn allows fibrinogen to accumulate within the tissues, which polymerizes to form insoluble fibrin complexes. These complexes are hard to break down since there is inadequate fibrinolytic activity in both blood and tissue fluid. A barrier, created when the fibrin is deposited around the capillary, prohibits the passage of oxygen and other nutrients to the cells of the epidermis leading directly to cell death and ulceration. The authors suggested that this development can be reversed by reducing the venous pressure either by surgery or compression treatment. Furthermore the fibronolytic activity of the cells can be enhanced with drugs. On the contrary if the process is not stopped then the situation is irreversible since there is permanent tissue damage from the fibrosis and as a result the ulceration can be persistent.

White blood cell trapping theory:

This theory is thought to be the best explanation of venous ulcer formation. It is suggested that raised pressure in the venous system during standing or ambulation reduces the capillary perfusion pressure, resulting in capillary flow rate reduction and cause trapping of white cells. The trapped white cells release toxic oxygen metabolites and proteolytic enzymes damaging the capillaries and becoming more permeable to large molecules. Furthermore capillary loops are occluded occurring in a reduction of blood flow to various parts of the skin (receive blood only by diffusion from the functioning capillaries) leading to ulceration. (Coleridge Smith, 1988; Saharay et al., 1997).

Trap hypothesis:

Falanga and Eaglstein (1993) brought forward the trap hypothesis. They stated that:" fibrin and other macromolecules that leak into the dermis "trap" growth factors and other stimulatory or homeostatic substances and render them unavailable for the maintenance of tissue integrity and the repair process". Furthermore they signified that the venous ulcer microenvironment is hostile or non conductive to the repair process.

Successful treatment of leg ulcers requires throughout assessment to allow the diagnosis of the underlying pathology. This detailed assessment in turn provides the foundation for further diagnostic evaluation, determination of the origin of the ulcer, and development of an appropriate treatment method. The initial assessment of a patient should include parameters that characterise patient's general condition. Furthermore the following assessment methods are commonly used:

- Doppler Ultrasound (Rajendran et al., 2007a)
- Tourniquet Testing (Bryant, 2000)
- Plethysmography (Rudolph, 1998; Bryant, 2000; Fernandes Abbade and Lastoria, 2005)
- Colour Doppler Ultrasound (Bryant, 2000)
- Magnetic Resonance Imaging (Nelzen, 2007).
- Phlebography (Vowden and Vowden, 2001c)
- Ambulatory venous Pressure (Nelzen, 2007).

C2 - Prevalence of venous leg ulcers

Prevalence is the proportion of population with the disease (i.e. an active venous leg ulcer) at a particular point in time and can be determined by cross sectional surveys of the population (Cullum, 1995).

Leg ulcer prevalence has been studied by many researchers. For example Callam et al. (1985) undertook a survey that took place in the neighbouring health board areas of Lothian and Health Valley (in Scotland) of a total population of 1 million. They reported a prevalence of 1.48/1000, while the ratio of men to women was:

$$\frac{Men}{Women} = \frac{1}{2.8}$$

Cornwall et al. (1986) studied the population of Harrow Heath District (with population of about 200,000). The authors recorded 357 patients with 424 ulcerated legs yielding a prevalence of 0.18% (this value increased for population over 40, becoming 0.38%).

A second study by Callam et al. (1987a) examined other aspects of leg ulceration like recurrence rates and ulcer sites. They demonstrated that venous leg ulcers constitute the majority of leg ulcers and that recurrence is a major problem for the population. Figure I illustrates recurrence of episodes of ulceration, while Table 1 demonstrates ulcer sites.

Site	Calf	Gaiter	Foot
Number of ulcers	154	731	51
Percentage	19%	88%	6%

Table 1 Site of ulceration in 827 legs

Baker et al. (1991) examined a large metropolitan area (Perth, Australia with population of 238,000 in 1988). The prevalence of chronic venous ulceration was 0.62 per 1000, while male to female ration was 1/1.8.

In a review study Wienert (1999) commented on the epidemiology of leg ulcers. He included studies, which investigated leg ulcer prevalence figures, with populations from 12000 to

434,699. Figure 2 demonstrates the prevalence rates included in this review. These studies however are rather old and the type of leg ulcer is not reported.

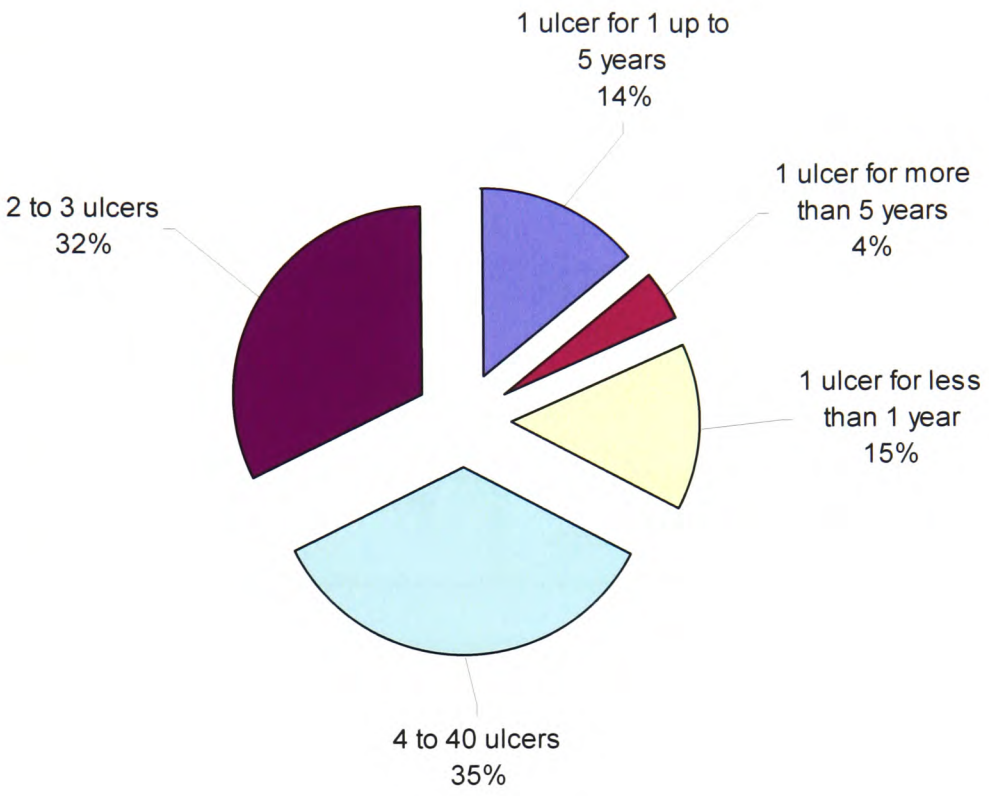


Figure 1 Recurrence and number of episodes
[Adapted from Callam et al., 1987a]

In another review Fowkes et al. (2001) produced a table that includes the prevalence of venous ulcers in adult males and females in selected epidemiological surveys. They reported that prevalence values vary greatly because of different sampling methods, ages of the populations and definitions of chronic ulceration (i.e. sometimes all ulcers are included or only venous ulcers which are the majority). Table 2 summarises some of their findings.

Year	Location	Sample Size	Type of ulcer	Prevalence	
				Male	Female
1973 (Coon et al., 1973)	Tecumseh, USA	6,389	Venous, Active or healed	0.1%	0.3%
1985 (Dale et al., 1985)	Edinburgh, Scotland	586	Chronic	0.8%	
1986 (Henry, 1986)	Ireland	2,012	Chronic active	1%	1.2%
1992 (Lindholm et al., 1992)	Malmo, Sweden	232,908	Chronic	0.12%	
1993 (Andersson et al., 1993)	Gothenburg, Sweden	5,140	Chronic active	3.3%	1.5%

Table 2 Venous ulcer prevalence from Fowkes et al. (2001)

[Adapted from Fowkes et al., 2001]

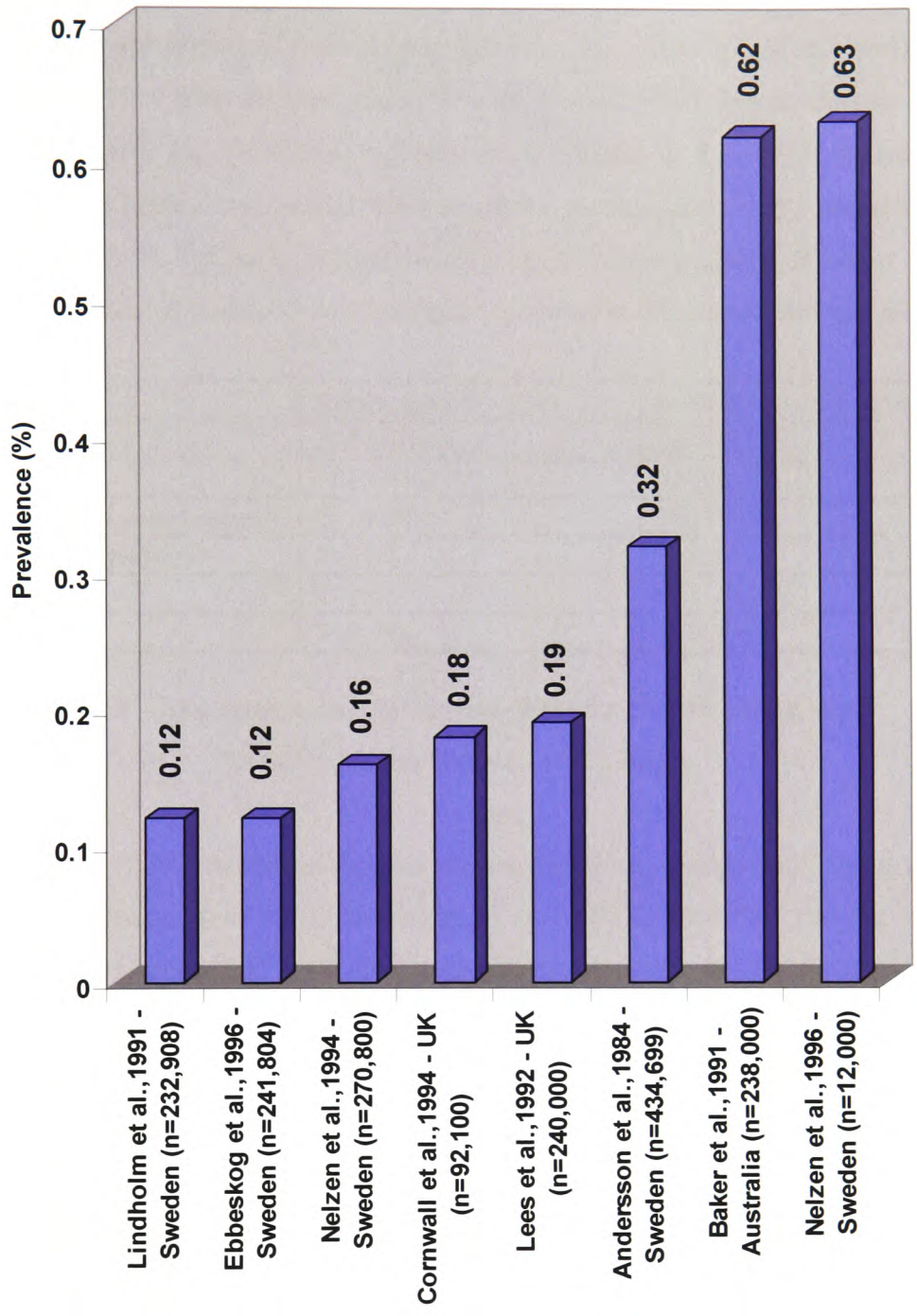


Figure 2 Studies on leg and foot ulcer prevalence

[Adapted from Wienert, 1999]

O'Brien et al. (2000) investigated the aetiology and prevalence of leg ulcers in the Mid Western Health Board region of Ireland (population of 317,069). This study demonstrated a prevalence of 0.12%, 0.09% for men and 0.16% for women while venous disease accounted for 81% of all ulcers (as illustrated in Table 3). Marklund et al. (2000) investigated the prevalence of non healed and healed chronic ulcers in an elderly rural population. They conducted the study in Brålanda, a rural Swedish area with population of about 4000. The prevalence rate of healed and non healed chronic leg ulcers in this population was 8.5%.

Aetiology	Limbs n=399 n(%)	Patients n=352 n(%)
Venous	324 (81%)	282 (80%)
Arterial	38 (9.5%)	37 (10.5%)
Mixed (arterial and venous)	27 (6.8%)	25 (7.1%)
Diabetic neuropathy	4 (1%)	3 (0.9%)
Malignancy	4 (1%)	4 (1.1%)
Rheumatoid	2 (0.5%)	1 (0.3%)

Table 3 Leg ulcer aetiology in Mid-Western Health Board study [Adapted from O'Brien et al., 2000]

Wipke-Tevis et al. (2000) described the prevalence, incidence, management and predictors of venous ulcers in residents of certified long term care (LTC) facilities. For the dates from January 1st 1996 to October 30th 1998 the prevalence on admission to LTC facilities was 2.5%, while the authors commented that this number is greater than other studies where large populations are investigated and vary from 1% to 2%. Margolis et al. (2002) estimated the prevalence and incidence of venous ulcers among the elderly, utilizing data from the General Practice Research Database (GPRD) in the UK, from 1988 to 1996. For a population of 50,000 elderly, the annual prevalence rate was 1.69%. For general population of 200,000 the prevalence value ranged from 1.13% to 1.2% per year. It was concluded that venous ulcers are more likely to occur in women than in men and the incidence of leg ulceration increases with age.

Graham et al. (2003) published a systematic review that aimed to determine the prevalence of leg ulcers, searching online databases (Ovid, MEDLINE, CINAHL and EMBASE). The populations included in the studies ranged from 4,000 to 1 million, while the prevalence values differed from 0.12% to 1.8%. The authors stated that the reviewed studies varied in methodology and concluded that more high quality research is required to determine the various factors that could affect prevalence results.

Briggs and Josè Closs (2003) published a review paper that commented on issues regarding leg ulcer epidemiology studies (i.e. definitions, variations in cases, choice of age groups, patient identification). Their findings included the following:

- Prevalence of patients with open leg ulcers being treated by health professionals is in the region of 0.11% to 0.18%.
- 1% to 2% of the population suffers from recurrent leg ulceration.
- Venous disease is the most common cause of leg ulceration and accounts for the 37% to 81%.

In a recent publication Moffatt et al. (2004) determined the prevalence and cause of leg ulceration in a defined geographical population (London, Wandsworth Community NHS trust and population of 256,000). The prevalence was reported to be 0.045% (64% for women and 36% for men). Table 4 details the aetiology of the identified ulcers.

Also venous ulcerations significantly affect lifestyle because of chronic pain sometimes combined with discomfort, inability to work and frequent clinic or hospital visits. The studies by Walshe (1995), Hofman et al. (1997), Persoon et al. (2003), Hareendran et al. (2005), Stevens (2006) and Bentley (2006) investigated the impact of ulcers on patients' daily life. Significant problems reported are: pain, itching, altered appearance, loss of sleep, leakage and smell, functional limitations and disappointments with treatment.

Cause	Number	Percentage
Venous	59	43%
Mixed Venous/Arterial	14	10%
Mixed Arterial/Venous	7	5%
Arterial	5	4%
Arterial and Diabetes	1	1%
Diabetes	1	1%
Pressure(Bandage induced) trauma	3	2%
Multifactorial	3	2%
Traumatic	0	0

Table 4 Aetiology of leg ulceration in Moffatt et al. study [Moffatt et al., 2004]

Estimating the prevalence of leg ulceration for a certain population or heath district appears to be challenging. The studies described in this section included prevalence values ranging from 0.062% (Baker et al., 1991) to 8.5% (Marklund et al., 2000), while the populations studied varied from 4000 (Brålanda, Sweden Marklund et al., 2000) to 1 million (Lothian and Health Valley, Scotland Callam et al., 1985). The variations of prevalence values originate from factors that are also documented by both Graham et al. (2003) and Briggs and José Closs (2003) in two review studies. One of the commonest problems is the absence of a clear definition of ulceration. Briggs and José Closs (2003) noted that there should be two methods to identify leg ulcers. Firstly by approaching general population (or a representative sample) and ask directly whether they have or have had an ulcer and secondly by approaching health care professionals. Obviously by selecting a sample population it is possible to identify people that lives with an ulcer but doesn't visit a GP or a clinic. In addition the lack of validation of ulcer cases by clinical assessment and diagnostic procedures could increase prevalence values. The inclusion criteria are sometimes broad, for example inclusion of foot ulcers. Graham et al. (2003) also stated that there have been studies where there has been misreporting and contributed to wide range of values. Finally, choice of group age, country profile, treatment rates, healing rates and other sociodemographic factors (like economical, social or marital status) could significantly affect prevalence values (Moffatt et al., 2006). Therefore all these variables should be considered, noted and analysed when epidemiology studies are conducted. In general the studies described, demonstrate how venous ulceration occurs in a significant

proportion of the population, thus affecting lives and consuming noteworthy resources from health services. However further studies are needed to more clearly reflect prevalence of venous leg ulcers (Kantor and Margolis, 2007). In addition, patients' life quality is significantly affected with pain being the most important issue.

C3 - Economic implications

The management and treatment of venous leg ulceration consumes considerable recourses from health care services.

Costs related to venous ulcers could be divided into "direct" and "indirect" ones. The first category involves the treatments to the patient (for example NHS or nursing home). The second category includes costs related to society (i.e. lost production by patient or family members, poor life quality that could affect mobility etc.) (Franks and Bosanquet, 2007).

There have been studies that investigated the economic implications of venous ulcer in large scale. For example Wilson (1989) found that the treatment costs range between £150 to £650 million per annum. A more recent estimation by Laing (1992) has shown that treatment costs were between £294 to £650m per year in the UK. Bosanquet (1992) found that the cost for ulcer care to be between £230 and £400 million for 1990-1991 prices.

Other studies examined cost implications in a smaller scale. For example Franks et al. (1995a) calculated the costs of treating 200 patients with venous leg ulcers over a 24 week period to be more than £193,000 and the cost per healed limb to be £1964. Furthermore Farejsö et al. (1997) analyzed the costs of treating leg ulcers at different level of care. The costs were calculated in a socioeconomic basis and were divided into direct costs (i.e. mainly costs to the health services) and indirect (i.e. loss of income to the patient). It was estimated that the amount of money spent per week in the region was £65,800 with direct costs being £52,700 and indirect ones being £13,100. This estimate becomes £3.4m per year in the region and according to the authors this amount becomes £197m in Sweden for treatment of leg ulcers.

Morell et al. (1998) conducted a randomized controlled trial in which they compared patients treated in clinics with high compression bandages to those treated home by nurses. It was found that for patients treated in clinics the expenses were £878 compared to £859 (all 1995 prices) for the other group. Furthermore the 12 week healing rate was 34% in clinics rather than 24% in homes. Marston et al. (1999) undertook a study that followed a series of patients who underwent treatment with outpatient compression without adjuvant techniques to determine healing rates and costs of treatment. The average cost for 10 weeks of outpatient treatment was $2198 ± $445, ranging from $1444 to $2711. Furthermore factors that increased treatment costs in this study were ulcer size and amount of ulcer drainage. The cost to heal ulcers less than $5cm^2$ averaged $1327, ulcers 5 to $20cm^2$ averaged $1978 and finally ulcers more than $20cm^2$ averaged $5289.

Ellison et al. (2002) assessed the costs of leg ulcer care in two large UK health authorities (Stockport and Trafford) with a population of 540,000. In Trafford the total expenditure of care over 13 weeks (including material cost, in patient care, staff cost, patient travel) was £120246.24 in 1993, £151375.35 in 1994 and decreased to £53176.96 in 1999. In addition in Stockport health authority the costs were £110891.83 in 1993, £65545.76 in 1994 and reduced to £83344.30 in 1999. An international study by Tenvall and Hjelmgren (2005) estimated the cost of treating patients with venous leg ulceration in Sweden and in the UK during 1 year. Having calculated the amounts according to the price level of 2002 in Euros, it was found that the average cost of treating an ulcer varied between €1332 and €2582 in Sweden and from €814 to €1994 in the UK.

These studies illustrate the magnitude of the economic implications of leg ulceration and demonstrate the significance of the problem for health care authorities with treatment costs ranging from £150m to £650m per year.

C4 - Management and healing methods

Correct management and treatment of patients with a venous leg ulcer can lead to faster healing, save important resources of health services and significantly improve patient's quality of life. Management and healing of venous ulcer is achieved by addressing the underlying aetiology (i.e. venous and capillary hypertension) and consequently improve venous return, which reduces oedema formation and increases the velocity of blood flow (Bryant, 2000).

Dowsett (2005) has suggested 3 points that relate to ulcer management:

- Reduce blood pressure in the superficial venous system.
- Aid venous return of blood to the heart by increasing the velocity of flow in the deep veins.
- Reduce oedema by reducing the pressure differences between the capillaries and the tissue.

The main treatment technique which effectively manages the underlying factors of leg ulcers is compression therapy and is extensively detailed in the next paragraph. The following sections summarize the various treatment methods of venous ulceration, excluding surgical and drugs management, two methods that are not part of the purpose of this thesis:

Dressings: Dressings are materials with protective or therapeutic capabilities that are applied on an ulcer. The aim of a dressing is to keep the ulcer clean and free from contamination and promote healing, particularly in chronic ulcers where there may be significant tissue loss (Bradley et al., 1999). The ideal dressing should provide an environment at the surface of the ulcer in which healing may take the maximum rate consistent with the production of a healed ulcer with an acceptable cosmetic appearance. There have been studies that reviewed or compared the characteristics and healing rates achieved by various dressings, without however finding any significant difference in their efficiency (Franks et al., 2007; Palfreyman et al., 2006 and 2007; O'Donnell and Lau, 2006).

Low Intensity Laser Therapy: LASER (which stands for "Laser Amplification by the Stimulated Emission of Radiation") is created when a photon interacts with an energized atom (Miller, 1996).

The LASER beam has the following characteristics:

- Monochromatic i.e. single wavelength (this feature is of interest in ulcer healing)
- Collimated i.e. non-divergent light rays
- Coherent i.e. the beam is in phase

The exposure of ulcer cells to the photon energy produced by the LASER beam is believed to enhance tissue repair. Young et al. (1990) suggested that affected cells show a temporary increase in permeability of their cell membranes, which might initiate the mechanism that stimulates healing. The activity that takes place next to the implementation of LASER beam includes cell proliferation, protein synthesis and growth factor production. Other effects of Low intensity Laser Therapy includes stimulation of:

- ATP production
- Mast cell recruitment and degranulation
- Growth factor release by macrophages
- Keratinocyte proliferation
- Collagen synthesis
- Angiogenesis
- Vasodilatation mediated by increased synthesis of nitric oxide

Furthermore there is an acceleration of the resolution of acute inflammation which results in rapid formation of granulation tissue (Dyson, 2007).

Studies by Bihari and Mester (1989), Crous and Malherbe (1988), Ashford et al., (1997) and Gupta et al., (1998) supported the suggestion that laser therapy stimulates ulcer healing. Flemming and Cullum (1999) having reviewed laser related studies, stated that future low

intensity laser therapy research should consist of better and clearer methodologies, improved sample sizes and aiming to compare various laser types mentioning co-interventions such as compression therapy.

Electrical Stimulation: Electrical stimulation of the ulcer is achieved by placing one electrode in contact with the peri-ulcer skin and one contacting the ulcer bed. The electrodes are connected to a power source (usually battery driven) and a circuitry board generates the desired type of electrical current. This stimulating current can either be Direct Current (DC), Alternating Current (AC) and pulsed (AC or DC but in pulses) (Moore, 2007). When epidermis is intact it maintains a potential (an electronegative charge of about -23mV). An injury however disrupts this potential and produces small currents that flow from the epidermis to the damaged areas. This current activity commences wound healing and is ended when healing is complete or arrested. The mechanism by which electric stimulation acts in the healing process is unknown. Is has been suggested however that it may imitate the injury current and therefore imitate and stimulate healing (Dyson, 2007).

Topical Negative Pressure Therapy: The aim of application of topical negative pressure is to create a sanction force enabling the drainage of excessive fluid and reducing the mechanical effects of tissue on ulcer healing. Negative pressure is achieved by inserting reticulated foam dressing in the ulcer (sealed in place with the help of an adhesive dressing). A sanction force is then applied by using appropriate electronic equipment. Furthermore by applying polyurethane (PU) or polyvinylalcohol (PVA) foam which is cut to fit the wound cavity exactly, negative pressure is best achieved. Finally an adhesive dressing is applied over the foam sealing it from the environment and creating conditions for moist healing. This dressing should be changed every 48 to 56 hours. Topical negative pressure is known to increase blood flow and reduce oedema and bacterial colonisation rates. This kind of treatment can be either continuous or intermittent and within a range of negative pressure options (-50mmHg to -125mmHg) in order to provide optimal fluid level, tissue tension and capillary flow to enhance vascular profusion. While rental charges for the electronic equipment can be high, this treatment method has been shown to work and be beneficial to ulcer healing by promoting

stimulation of granulation tissue and reduction of the reconstruction requirements of the healing area (Jones et al., 2004; Sibbald et al., 2003).

Surgical and other types of debridement: Surgical debridement is conducted when a venous ulcer shows signs of infection like cellulitis, persistent or increased exudates, fever, increased drainage or delayed healing (ulcer area decreases less than 10% over a 2 week period). The aim of this procedure is to remove non viable tissue and decrease bacterial burden while contraction and epithelialisation is stimulated (Brem et al., 2004; Fernandes Abbade and Lastoria, 2005). Rajendran et al. (2007b) presented the latest techniques in debridement in 2007 paper. These are:

- Autolytic debridement: In this method the necrotic tissue is dissolved by utilizing the body's own enzymes and moisture. Safe and virtually painless procedure which however can take several weeks.
- Enzymatic debridement: This method involves the use of topical gels and solutions which dissolve and remove necrotic tissue. The enzymes used are categorized as proteolytics, fibrinolytics and collagenoses that target specific components of tissue.
- Mechanical debridement: this kind of debridement is achieved with:
- Use of wet to dry dressings. Saline-moistened gauze is applied over the ulcer and allowed to dry. The necrotic tissue is the adhered to the dressing and the debridement occurs when the gauze is removed.
- Hydrotherapy is carried out in a whirlpool bath that loosens and removes surface debris bacteria, necrotic tissue and ulcer exudates.
- Wound irrigation is accomplished with the use of water streams under high or low pressure to remove bacteria, particulate matter and necrotic debris for the ulcer.
- Maggot debridement: This therapy is attained with the use of the green bottle fly larvae (the only species used in the UK). This method is fast, highly selective and effective. The maggots produce proteolytic enzymes that have the ability to breakdown necrotic tissue which is then consumed by the larvae. Their activity also stimulates healing and inhibits bacterial and other pathogen growth.

Plastic surgery: In some cases immediate healing may be necessary or even requested by the patient. In such cases plastic surgery takes place, which incorporates autologous skin grafts or muscle flaps (Araujo et al., 2003).

Limb elevation: Limb elevation contributes to the improvement of microcirculation and reduces oedema. Leg elevation in hospital also enhances healing (Simon et al., 2004).

Ultrasound therapy: Ultrasound is the sound that propagates at a frequency which is above the limit of the human ear. Frequency values, typically between 0.5 and 3 MHz have been used to stimulate healing (Peschen et al., 1997). Ultrasound stimulates healing by increasing the permeability of the plasma membranes of cells to calcium ions following the exposure to non thermal levels of ultrasound waves. Cells affected by these waves undergo migration, division, differentiation, growth and synthesize materials like collagen, all of them activities that stimulate healing (Dyson, 2007). Flemming and Cullum (2000) stated in a review that there may be some improvement in the healing rate of venous ulcers associated with the use of ultrasound therapy; however the poor quality of some studies that worked on this subject does not support the routine use of therapeutic ultrasound in practice.

Other methods: Bradbury (2003) published a paper that commented on modern techniques that battle chronic venous insufficiency (which may result to hypertension and venous ulceration). These are:

- Radio frequency ablation.
- Endovenous laser therapy.
- Powered phlebectomy.
- Foam sclerotherapy.

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