Development and Initial Evaluation of Wireless Self-Monitoring Pneumatic Compression Sleeves for Preventing Deep Vein Thrombosis in Surgical Patients

by

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Abstract

This thesis describes the successful development and initial evaluation of a proof-of-concept wireless monitoring system for improving the effectiveness and safety of pneumatic compression therapy to help prevent deep vein thrombosis (DVT). In the development, an important objective was to make feasible the practical and commercial deployment of such improved therapy systems in future, by focusing on a cost-effective design and implementation.

Over the years, pneumatic compression has been shown to be an effective solution for the prevention of DVT. However, different problems and complications related to the use of commercial pneumatic compression devices that typically include automatic pressure controllers and pneumatic compression sleeves have been reported. For example, one study reported a high percentage of improperly applied or nonfunctional pneumatic compression devices in routine usage. Technical problems, non-compliance, and human error were identified as the causes behind the failed therapies. Also, it was reported that dedicated in-service instruction did not improve the proper use of the pneumatic compression controllers and sleeves. In another study, significant unanticipated variations between expected and delivered pneumatic compression therapy were reported: expected therapy delivered only an average of 77.8% of the time during the therapy, and much of the time key values related to the outcome of the therapy were found to have

variations great than 10%. Specific hazards have also been reported. For example, one patient developed acute compartment syndrome after wearing a pair of pneumatic compression sleeves with faulty pressure release valves. In another case, epidural analgesia masked a malfunction resulting from a reversed connection between four-way plastic tubing of the sleeves and the controller, exposing a patient to a hazardous pressure of around 300mmHg, blocking all blood flow for a prolonged period of time.

Newer models of pneumatic compression sleeves and controllers from various manufacturers claim to improve therapy by, for example, increasing the peak blood flow velocity. However, there is no evidence in the published literature to support such claims. A published review of the literature from 1970-2002 reached the conclusion that the most important factors in improving therapy with pneumatic compression devices, particularly during and after surgery, were the degree of conformance of delivered therapy to the prescribed therapy, patient compliance, and the appropriateness of the site of compression. The inability to monitor delivered therapy and patient compliance remains a problem in efforts to improve pneumatic compression therapy.

The above-described problems were addressed in the successful development of the innovative prototype described in this thesis. This wireless monitoring system should improve the effectiveness and safety of pneumatic compression therapy. Also, innovative aspects of the system design allow for cost-effective integration into existing commercial controllers and sleeves. For example, an innovative and potentially patentable usage and reprocess indicator was developed for pneumatic compression sleeves to significantly improve their safety and to reduce their cost of use per patient.

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Medical Terminology

- **acute compartment syndrome** - a progressive painful loss of function of muscles and nerves that happens most often in the leg or arm
- **arthroplasty** - orthopaedic surgical procedure in which a joint is constructed, i.e. the joint is replaced by a prosthesis
- **deep vein thrombosis (DVT)** - the formation of a thrombus (blood clot) within a deep vein, usually in the lower extremities
- **epidural analgesia** - a form of regional anesthesia involving injection of drugs through a catheter placed into the epidural space (a part of the human spine); the injection can cause both a loss of sensation (anaesthesia) and a loss of pain (analgesia), by blocking the transmission of pain signals through nerves in or near the spinal cord
- **pneumatic compression devices** - consists of pressure controllers and pneumatic compression sleeves, commonly used for the prevention of DVT
- **proximal** - nearer to the heart
- **pulmonary embolism (PE)** - blood vessels of the lung blocked by dislodged thrombus, which is potentially fatal

- **total joint replacement** - an arthritic or damaged joint is removed and replaced with an artificial joint called a prosthesis

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Chapter 1

Introduction

1.1 Motivation for the Research

Pneumatic compression devices, typically including controllers and pneumatic sleeves, are commonly used in surgical patients to apply intermittent pressure to the surface of the limb, thereby simulating muscular contraction to prevent the development of deep vein thrombosis (DVT) through a decrease in venous stasis and increase in fibrinolysis. The use of pneumatic compression therapy for the prevention of DVT has proven to be effective in helping to prevent DVT and pulmonary embolism (PE) [1–8].

The effectiveness of pneumatic compression therapy is highly dependent on the delivered pressure waveform and the extent of conformance of the delivered therapy to the expected therapy. Several studies reported failed therapies due to patient and staff non-compliance and other reported variations between the expected and delivered therapies due to design limitations of current pneumatic compression devices [9–11]. In previous attempts to deliver the expected delivery more accurate and reliably, new designs that incorporated dedicated pressure monitoring means were developed to monitor the actual pressure to delivered each air chamber on a pneumatic limb compression sleeve [10]. These pressure measurements were used to form a closed-loop control to reduce variations in the pressure waveform that was

actually delivered. Although these designs could reliably improve the aforementioned therapy, the delivery of pressure was still highly dependent on the extent of compliance by staff and patients, which is defined in this thesis to be the extent of conformance of the actual application of the compression sleeves to an optimal application. If the pneumatic compression sleeves were inappropriately applied by staff, or they were removed and re-applied by a patient, then the expected pressure waveform could not be delivered despite the presence of the closed-loop control. A motivation therefore exists to improve the compliance of the therapy such that the expected therapy can be delivered more accurately and more reliably. In addition, because such improved systems required the use of numerous additional dedicated pressure monitoring lines, their design reduced the practicality of such systems and so a second motivation exists to replace these additional monitoring lines with wireless monitoring means to improve the feasibility of a practical deployment of such monitoring solutions for the pneumatic compression sleeves, devices and controllers.

In addition to the variations in delivered therapy, the use of pneumatic compression sleeves and controllers is associated with the risk of tissue and nerve injuries due to technical problems of these devices and due to human errors [12–15]. Although the incidence of complications is low, the consequences of hazardous compression can be very serious, resulting in severe obstruction of venous blood flow and thus increasing the risk of developing DVT and potentially fatal PE in surgical patients. The safety of a pneumatic compression therapy for preventing DVT is increased if the pressure levels within the pneumatic compression sleeves are continuously monitored, and the operators are alerted when abnormalities of the therapy are detected. A third motivation therefore exists to implement a reliable safety and protec-

tion mechanism for pneumatic compression therapy.

Because many previous designs of pneumatic compression devices have significantly increased the cost per use due to additional complexity and hardware, practical deployment of such previous designs in commercial products did not occur. A fourth motivation is therefore to implement a cost-effective solution that lowers the cost per use, or averages out over multiple uses any additional costs arising from additional monitoring components.

1.2 Scope of the Research

A desired outcome of this thesis project was to develop a proof-of-concept monitoring system that improves the effectiveness and safety of pneumatic compression therapy for preventing DVT. The specific objectives to be achieved were: (1) to provide reliable means to monitor the compliance and pressure delivery of the therapy through a wireless medium, (2) to develop a protection mechanism for the detection of abnormal operations, (3) to implement the above in a cost-effective manner, in order to improve the feasibility of a practical deployment of the monitoring system, and (4) to initially evaluate whether this new monitoring system would result in a more effective and safer pneumatic compression therapy for preventing DVT.

1.3 Thesis Overview

The following chapter outlines background information related to the development of the wireless monitoring system and presents a review of previous research in the area of pneumatic limb compression to help prevent DVT. Topics discussed are the construction, clinical use, complications and

problems associated with existing pneumatic compression devices. Previous attempts to improve pneumatic limb compression therapy are reviewed, and the chapter concludes with the proposed features and improvements of the new monitoring system.

Chapter 3 contains the details of design and implementation of a prototype to achieve the above objectives. Considerations such as the type of parameters to be monitored, wireless medium to be used, and conformance to relevant governing regulations are included. Chapter 4 discusses an improvement for the prototype: a power management scheme which allows reliable and continuous operation of the prototype throughout its life. Details on the analysis of different power management approaches are included, and the projected improvements in operating life are presented. Chapter 5 describes another improvement for the prototype: a usage and reprocess indicator, which potentially lowers the cost per use of the prototype, or averages out the increase in cost due to the additional hardware components by allowing multiple uses on different patients. Chapter 6 presents the methods and results from the initial evaluation of the improved prototype, and also discusses some of the technical problems which were experienced in this study.

Chapter 7 identifies and explains possible extensions of the improved prototype to other medical applications. In Chapter 8, the contributions of the research are outlined. Chapter 8 also provides suggestions on topics for further investigation.

Chapter 2

Background and Review of Previous Research

This chapter starts with a description of deep vein thrombosis, and the apparatus and clinical use of pneumatic compression devices for its prevention. The complications and problems associated with the use of pneumatic compression devices are also presented, as well as the limitations and previous attempts to improve the current pneumatic compression devices.

2.1 Description of Deep Vein Thrombosis

Deep vein thrombosis (DVT) refers to the formation of a thrombus (blood clot) within a deep vein, usually in the lower extremities. A thrombus either arises spontaneously or is caused by conditions such as surgery, trauma and immobilization. DVT may damage the valves in the veins, so instead of flowing upwards, the blood begins to pool and build up below the site. This can result in pain, swelling, and ulcers on the limb, severely impairing a person's ability to live a full, active life. If the thrombus dislodges and travels to the lung, the blood vessels may be blocked, leading to pulmonary embolism (PE), which is potentially fatal and can kill within hours [16]. More than 600,000 people in the United States have a pulmonary embolism each year, and more than 60,000 of them die [17]. Most of those

who die do so within 30 to 60 minutes after symptoms start. Pulmonary embolism is one of the most common causes of death in hospitalized people who must remain in bed for a long time.

Development of DVT in surgical patients is a serious concern. Previous studies have reported that 90% of clinical PE arise from proximal DVT. Approximately 30% to 80% of patients who underwent a total joint replacement developed DVT when prevention therapy was not used. The rate was ranged from 14% to 29% for patients after total hip arthroplasty [7]. The incidence of DVT and subsequent PE in patients undergoing neurosurgery has been reported to be as high as 25%, with a mortality rate from PE between 9% and 50% [18]. As a result of the high morbidity associated with these postoperative complications, preventative therapy for DVT is imperative and commonly used.

2.2 Pneumatic Compression for the Prevention of DVT

2.2.1 Apparatus and Clinical Use

A number of methods for DVT prevention are available, including pharmacological methods such as aspirin, low-molecular-weight herapin, warfarin and mechanical methods such as pneumatic compression devices. Although pharmacological methods for preventing DVT are commonly used, they are associated with side effects and significant costs. On the other hand, pneumatic limb compression devices are relatively inexpensive and safe. Over the years, pneumatic compression has been shown to be an effective measure for the prevention of DVT [1–8].

Pneumatic compression devices consist of an inflatable compression garment for the arm, leg, or foot and an electrical pneumatic controller (the instrument) that fills the inflatable garment with compressed air. The inflatable garment simulates the pumping action of muscle contraction (Figure 2.1) by compressing the limb to enhance venous blood movement and to help prevent the formation of thrombus in the veins of immobilized patients. The compression can be intermittent or sequential; for example, for a thigh-length (three chambers: ankle, calf, and thigh) compression sleeve, an intermittent compression is characterized by the simultaneous inflation of all the pneumatic chambers, and in contrast, a sequential compression is characterized by initial inflation of the ankle chamber. The inflation of the ankle chamber is then sustained while the calf chamber is also inflated. The thigh chamber is then inflated while the ankle and calf chamber inflations are maintained. After this inflation cycle, all three chambers are allowed to deflate to allow the leg veins to refill with blood. As the pressure delivered by these devices generally ranges from 20-60 mmHg, which is lower than the normal diastolic pressure level, the blood circulation in the extremities can be accelerated without disturbing the blood flow in the arteries [19].

Due to a their widespread use and popularity, and due to a larger set of potential problems, the focus of the thesis is on thigh-length sequential compression devices (SCD). A typical clinical setup of the SCD is shown in Figure 2.2.

2.2.2 Key Parameters

The key parameters of a compression therapy for preventing DVT include: (1) the level of pressure delivered to the patient, (2) the inflation

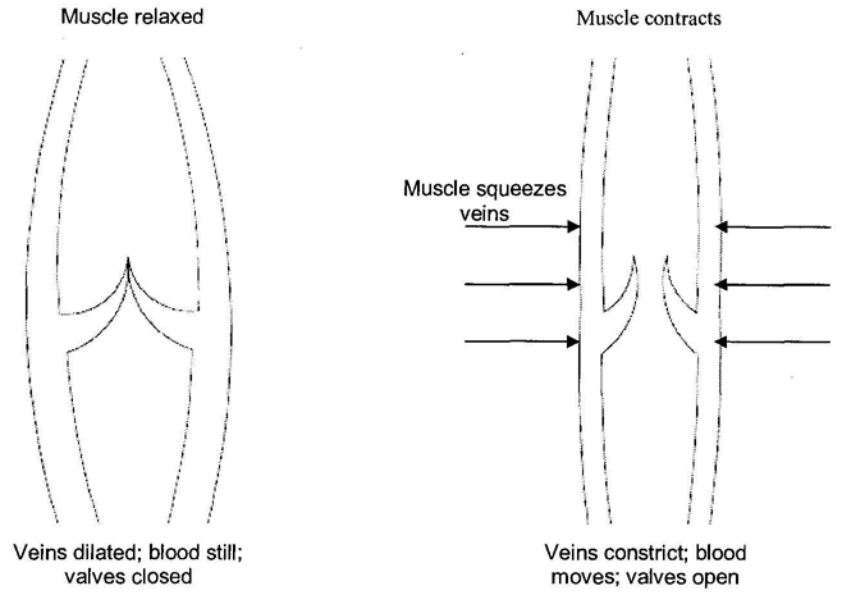

Figure 2.1: The pumping action of muscle contraction that helps to push the blood up through the veins

rate, (3) the duration of pressure hold period, (4) the duration of deflation, and (5) compliance, which is defined to be the extent of conformance of the actual application of the compression sleeves to an optimal application by clinical operators and patients [9]. These parameters are heavily related to the effectiveness of the compression therapy for preventing DVT. Despite the introduction of newer models from various manufacturers claiming to increase the peak blood flow velocity, there is no evidence in published literature that the peak venous velocity produced by such systems actually reduces the incidence of DVT and PE.

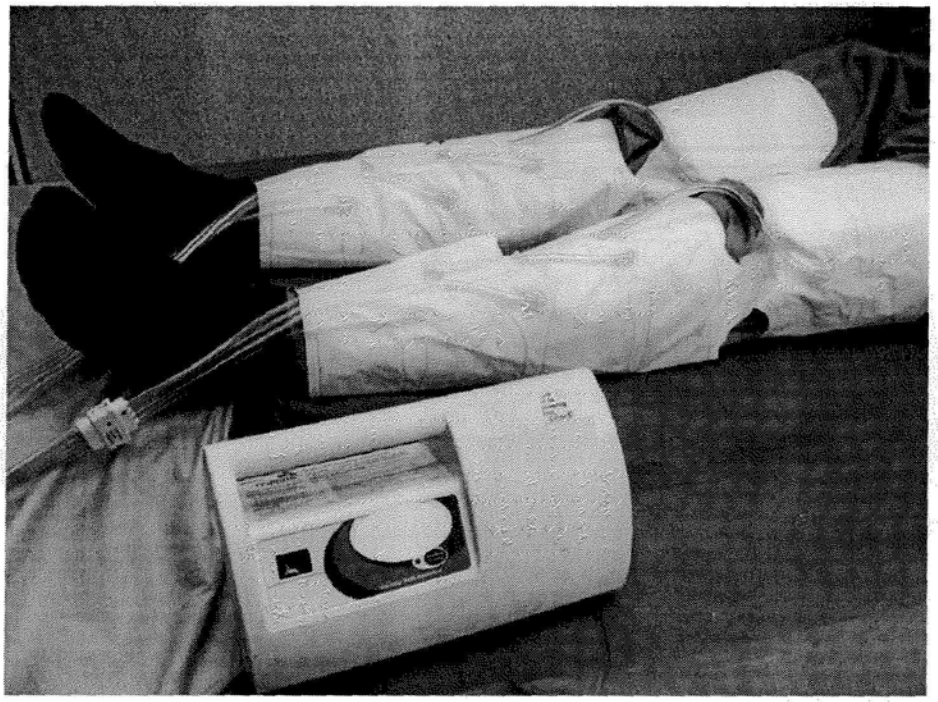

Figure 2.2: A typical clinical setup of pneumatic compression device for the prevention of DVT

2.2.3 Complications and Problems Associated with the Use of Compression Devices

In this section, the complications and problems associated with the use pneumatic compression devices are presented. In the mid eighties, a patient developed acute compartment syndrome after wearing a pair of intermittent compression boots with faulty pressure release valves [15].

Later, Comerota et al. observed a high percentage of improperly applied or nonfunctional units in routine nursing units [11]. Technical problems, non-compliance, and human error were reported as the causes behind failed therapies. In the same paper, it was reported that dedicated in-service in-

struction did not improve the proper use of the devices, and the authors commented that this could be partly explained by the removal of the sleeves by patients due to discomfort when a nurse was not in attendance. Haddad et al., in 2001, reported unanticipated variations between expected and delivered pneumatic compression therapy [9]. Expected therapy was reported to be delivered only an average of 77.8% of the time during the therapy. Also, it was reported that most of the time, key values related to the outcome of the therapy had variations greater than 10%. Again, the authors found that medical or nursing education did not reduce the variations.

In the same year, a market-leading manufacturer of pneumatic compression devices recalled connection tubing sets that connected SCD controllers to pneumatic sleeves. The sets had a reversed connector and pose a serious hazard. Although it is unknown whether the manufacturing problem caused any injury, a reversed connector changes the sequence of inflation and connects the cooling feature to the calf chamber. Activation of the cooling feature under this condition causes the SCD becomes a tourniquet, a medical device for *obstructing circulation*, by causing up to 200 mmHg pressure to be applied around the extremity [12]. This hazardous condition can persist even after the machine is turned off, and in a pain-controlled patient, can go unnoticed for several hours, leading to permanent tissue damage.

Two years ago, Mitchell reported a case where epidural analgesia masked a malfunctioning pneumatic compression device [13]. The connection between four-way plastic tubing and the controller was connected in the reverse order and consequently a patient was exposed to a pressure of around 300 mmHg for prolonged period of time. It is important to note that the patient was treated using an advanced model of a sequential compression device.

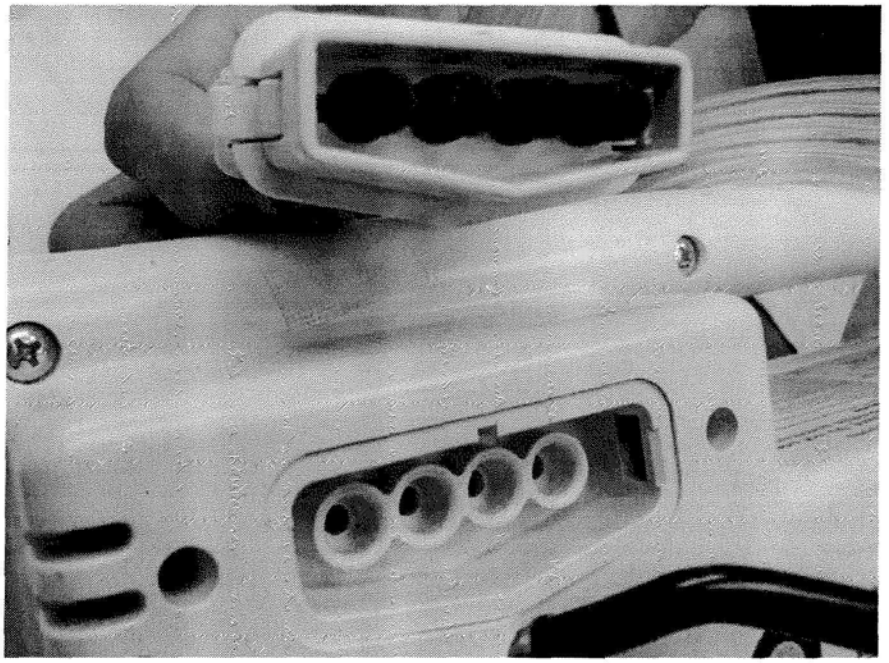

Figure 2.3: Pneumatic connector of the SCD

2.2.4 Limitations of Current Compression Devices

Older pneumatic compression devices offer little or no monitoring mechanisms for the applied pressure. In newer devices, some monitoring mechanisms exist but are indirect and minimal (as seen from the above where two cases involved a newer SCD model). Also, the devices generally do not provide meaningful audiovisual feedback to staff with respect to detected problems [20]. As seen in Figure 2.4, the LED displays do not have enough space to provide detailed information on the problem. In this thesis, "meaningful" audiovisual feedback is defined as feedback that provides clear description of the problem so the user does not have to check the service manual for interpretation on the warning code, and meaningful feedback

should also indicate possible solutions to solve the detected problem.

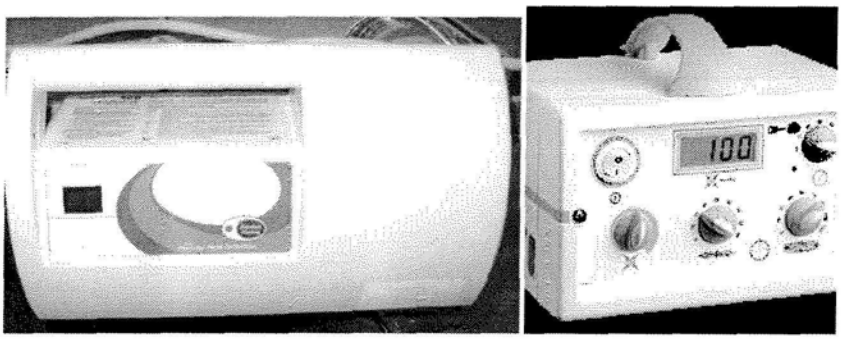

Figure 2.4: Two models of SCD controllers

As the current design of the most commonly used SCD controllers measures the chamber pressure using the same pneumatic connections for gas delivery, the accuracy of such measurements is compromised due to flow-related pressure drop along the pneumatic tubing. Also, in such controllers a single flow control valve is used for controlling pressure delivered to all chambers; as a result, the delivered pressure is strongly related to the application of the compression sleeves; if the snugness of the compression sleeves is uneven on both limbs, then the manufacturer's specified pressure cannot be achieved. A previous study has also stated that it is inaccurate for the current designs of SCD controllers to measure the chamber pressure without taking into account the chamber temperature [21].

2.3 Review of Previous Research in Improving Pneumatic Compression Devices

Previously, Haddad et al. developed a system for acquiring pressure waveforms from the sleeve chambers using dedicated pressure monitoring

lines [9]. The purpose of the development of that system was for evaluating possible reasons for unanticipated variations in the delivered therapy compared to the expected or prescribed therapy. Accordingly, the objective of the work reported by Haddad et al. was not to improve existing pneumatic compression devices. In that study, dedicated pressure monitoring lines were used, i.e. pneumatic connections (with no gas-flow inside) that connected transducers and pneumatic chambers through separate ports on the chamber. The system accurately monitored the delivered pressure but it did not have other therapy monitoring and protection features, and does not provide meaningful audiovisual feedback to the operator. Instead, the investigators adjusted the fitting of the sleeves based on their manual comparison between the acquired and desired pressure.

Later, Masri et al. developed a new SCD prototype in an effort to correct the variations in pressure waveform delivery found in the study by Haddad et al. [10]. The device used dedicated pressure monitoring lines and flow-control valves for each individual chamber, which created a feedback loop allowing dynamic control of the pressure and rate of inflation of each chamber. The prototype successfully reduced the variations in delivered pressure among therapies. But again, other than controlling the delivered pressure, the prototype did not provide any therapy monitoring and protection mechanism.

Even if the unanticipated variations in delivered pressure waveforms are largely corrected, problems such as reversed sequence of inflation, lack of compliance and pressure delivery problems due to instrument and human errors are not preventable with these measures. As a result, the development of improved apparatus to detect instrument-related and human errors could be of significant value for improving the effectiveness, reliability and safety

of pneumatic compression therapy for preventing DVT.

2.4 Summary

In this chapter, a brief description on DVT and PE was provided, together with a description of the fundamental operating principles and the key parameters of pneumatic compression therapies for the prevention of DVT. Complications and problems associated with the use of pneumatic compression devices reported in the literature, and the limitations of current devices were also discussed. Finally, a summary of the key aspects of the previous attempts to improve pneumatic compression devices was given to identify further actions that might be taken to improve the overall quality of limb compression therapy for preventing DVT.

Chapter 3

Development of the Initial Prototype

3.1 Objective

In this Chapter, a wireless monitoring system is presented as a cost-effective solution for improving the safety and effectiveness of a compression therapy for preventing DVT. The design considerations and justifications of a wireless monitoring system are first presented, followed by a detailed description of the system architecture and the actual implementation.

3.2 Monitoring of Therapy-Related Parameters

The proposed monitoring system analyzes the key parameters of a compression therapy through the monitoring of pressure and temperature of the sleeve chambers.

To understand that the monitoring of pressure and temperature is valuable for the application, the reasons of why a compression therapy fails or becomes ineffective are first discussed. First, instrumentation failure can be a cause; a faulty pump or a leakage along the pneumatic hoses or at the chamber reduces the pressure delivered to the patient or the rate of pressure rise during the inflation. Second and more often, the sleeves are not

applied appropriately. Instruction manuals often indicate that the sleeves should be applied to the patients' limb "snug but not too tight" and that the "snugness" should be even on both limbs. These instructions create an ambiguity on an appropriate fitting of the sleeves, and perhaps can be an explanation of a previous finding where dedicated on-site training to the nurses did not raise the percentage of appropriate fittings of the sleeves among the patients. And even if the sleeves are well applied initially, the sleeves may become loose after hours of inflation and deflation, or due to movement of the patient; this may often go unnoticed as the nurses are generally too occupied with other tasks to inspect the fitting of the sleeves.

Although a previous design of the pneumatic compression device successfully reduces variations in the delivered therapy by introducing dedicated pressure monitoring to individual chambers, it does not solve problems related to human errors and instrumentation failure such as the ones above. Therefore, a monitoring system that detects, reports and provides users with guidelines to identify and solve these problems is of significant value to improve the overall quality of compression therapy for preventing DVT. In fact, Haddad et al. have stated in their study that [9]:

> "...the manufacturer's specifications could be achieved to within 10% by monitoring delivered pressure cycles and by iteratively reapplying and adjusting the sleeves using feedback from the monitored pressure cycles..."

and when commenting on the lack of improvement from nursing education, they stated that:

> "...the SC devices do not provide meaningful audiovisual feedback to staff with respect to these key parameters..."

The pressure within compression sleeves is the first parameter selected to be monitored. Besides providing the user with information regarding the level of delivered pressure and the rate of inflation, it is also an indirect measure of compliance and the operating condition of the instrument. For example, an overly-tight fitting of compression sleeve introduces an excessive force on the limb, which may collapse the veins and limit the venous blood flow; if the fitting is too loose, the contact area between the sleeve and the limb is reduced, the force exerted on the limb may also be lower than desired, and thus may result in a less effective therapy. As the sleeve pressure is a function of force exerted on the limb and the contact area, both of the above scenarios can be detected by the monitoring of pressure, i.e., a detection of an overpressure of the sleeve may indicate that the fitting is too tight, and conversely a detection of an under-pressure of the sleeve may indicate that the fitting is too loose, or that a leakage exists along the pneumatic tubing of that particular chamber. If no pressure rise is observed at all, it is highly possible that the instrument is out-of-order.

Besides improving the quality of a therapy, another significant value of the monitoring system is the improvement of the patients' safety. By monitoring the sequence of pressure rise, the peak pressure, and the duration of inflation, injury due to prolonged exposure to high pressure or reversed sequence of inflation can be prevented.

The temperature of a sleeve chamber is the second parameter to be monitored. A rise in skin temperature can be a sign of complication, but is often unnoticed by the clinical operators during the course of a compression therapy. Although the temperature of the sleeve chamber is not equivalent to the that of the skin underneath, it reflects the skin temperature to a certain extent; and so if a significant difference in temperature is observed among

the chambers, then the operator can be alerted to check the condition of the limb to prevent further development of the complication. The chamber temperature also ensures that the acquired pressure readings are temperature compensated and are more accurate [21].

Each sleeve chamber on the pneumatic compression sleeve is identified by an unique address. The identification of the sleeve chambers helps the prototype and the operators to locate the detected problems accurately, and as it will be seen in a later section, technically it is these unique addresses of the chambers that allow detection of the sequence of inflation.

3.3 Wireless Communication of Therapy-Related Parameters

3.3.1 Justification

An accurate measurement of the delivered pressure can be achieved by using dedicated pressure monitoring lines, as in the prototype reported by Bassam et al: However, the design may not be very practical. In the original design of the compression sleeves, each of the sleeve chambers is connected to the instrument via a pneumatic tubing, resulting in 6 hoses for gas delivery; and including the 2 additional connections for cooling of the sleeves, 8 pneumatic connections exist by default. Therefore, the prototype with dedicated monitoring lines consists of 8 + 6 pneumatic hoses. The drawbacks of this design are: (1) higher cost of manufacture due to the additional ports and hoses, (2) major redesign of the sleeves and instrument are involved, (3) higher chance of human error due to the additional connectors, and (4) although special connectors can be made to ease the connection, this

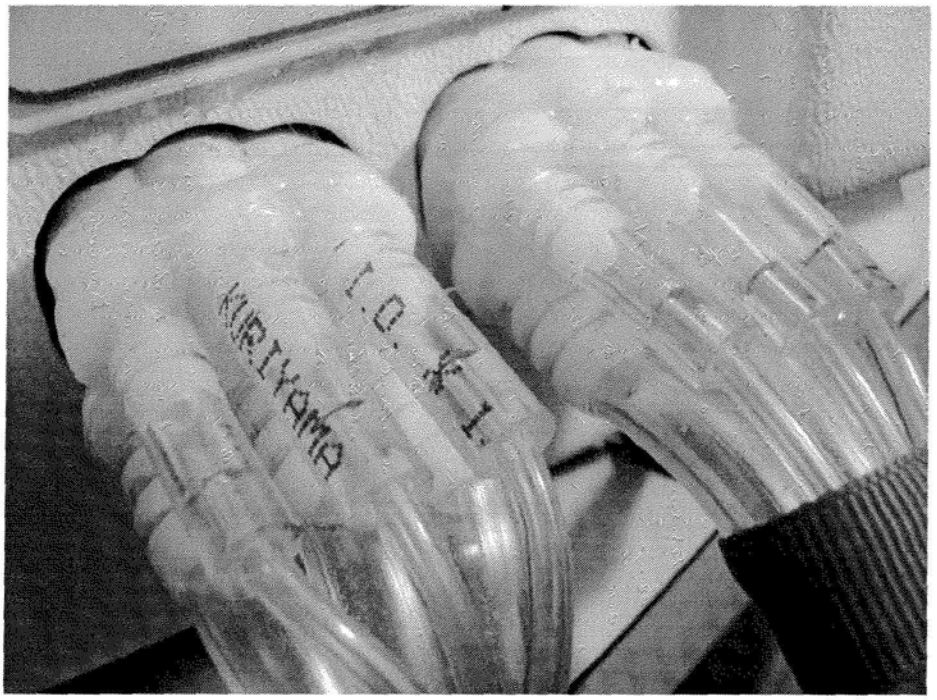

Figure 3.1: A previously reported prototype

again will increase the cost of the design. One may argue that the improved sleeves presented in this thesis will also increase the cost of the therapy due to the hardware involved; however, it will be seen in Chapter 5 that the cost per therapy can be reduced by allowing safe reuse of the improved sleeves. This clearly requires that the compression sleeve can be cleaned reliably. The design with additional hoses and electrical wires that run between the instrument and the sleeves has a higher complexity of cleaning due to the increased surface area, and also creates a potential reliability problem due to the degradation of electrical connectors. A wireless design of the monitoring system allows the sensor modules to be placed inside the sleeve chambers, and has several advantages: (1) it has a lower complexity of cleaning and is

less obstructive as no additional ports, hoses and electrical connectors are required on the compression sleeves, (2) it has a faster setup time and a lower chance of connection errors, and (3) no major redesign of the sleeves is needed, allowing quick integration of the prototype into existing sleeve designs.

3.3.2 Selection of a Wireless Communication Medium

Wireless communication is available in the form of infrared (IR), ultrasound, and radio frequency (RF). IR communication is inexpensive, but requires line-of-sight between the transmitter and the receiver to operate efficiently. Also IR devices do not work very well in bright light. As line-of-sight is not always possible in a clinical environment, and bright surgical lamps are commonly used in operating theaters, IR communication is not suitable for the application. Ultrasonic data communication is also impractical because of echoes and data errors from ambient noise, and it only provides low data rates due to the low ultrasonic bandwidth. RF communication has several advantages over the other two choices; it has an ability to transmit data at a faster rate, does not require line-of-sight, can be made omni-directional, and due to its popularity, there are more products available for selection and the cost of development is continuing to decrease. It is therefore reasonable for the monitoring system to use RF as the data communication medium.

3.3.3 Selection of a Radio Frequency Communication Band and Technologies for Use in a Clinical Environment

An RF monitoring system comprises at least one receiver station and one remote sensor module. The receiver station is usually responsible for

issuing communication commands, receiving and processing the incoming data. The sensor module is usually responsible for the acquisition of sensory information of interest, and its transmission of which to the receiver station. The design of such systems requires the following initial considerations: (1) source of power, (2) frequency band, and (3) RF technology.

Source of Power

The sensor modules can either be powered by batteries or by energy from the receiver station if no continuous DC power is present. Batteryless or passive systems use inductive coupling for data communication, and are often used in applications such as logistic tracking, product identification, and security access controls. Inductive coupling refers to the transfer of energy from one circuit component to another through a shared magnetic field, and is characterized by the mutual inductance of the receiver station (energy supplier) and sensor module (energy receiver) antennas. The mutual inductance is high when the antennas are placed close to one another, but falls much more rapidly than the inverse square of distance when the separation becomes large compared to the size of the antennas. As a consequence, inductive coupling systems work reliably when the receiver station and the sensor modules are close to one another, but the read range is generally limited to a distance roughly comparable to the diameter of the receiver station antenna [22]. Large antennas have larger inductance and consequently larger induced voltage, but generally, the size of antenna is limited by the available space in the application. An example of a passive RF monitoring system is an anti-theft radio identification (RFID) system used in retail stores. 1-bit transponders are placed on shelf items, when they

are brought through the receiver station antenna near the exit, the receiver station provides the transponders with energy and the latter responds with a 1-bit data through load or capacitive modulation. The receiver station will decide whether the item has been paid using the incoming signal and turn on the alarm if necessary.

On the other hand, battery powered or active systems are used when a close coupling between the receiver station and the sensor modules is not always possible, a higher data communication rate is needed, sensory data has to be acquired when an energy provider is not present, or when the sensor modules need an ability to initiate a communication without the receiver station. A milk-temperature monitoring unit is an example of an active system; sensor modules with an integrated temperature sensor are placed on milk cartons, and temperature is recorded at a predefined interval during the transportation from the farm to the distributor. Upon arrival at the distributor, the receiver station issues a command to the sensor modules to report any temperature abnormality.

Passive communication was initially considered for the monitoring system. However, several limitations have prevented a practical deployment of such systems in a clinical environment. Below is an description on the intraoperative use of compression sleeves during a total hip replacement [8]:

> "After preparing the skin over the hip and the proximal part of the thigh and draping the lower extremity with stockinette, wrapped snugly with an elastic bandage, the surgeon placed a sterile, thigh-high compression sleeve around the leg and distal part of the thigh. The end of the sterile tubing from the compression sleeve was passed off the operative field to the cir-

> culating nurse, who attached it to the compression pump on the floor near the operating table. The sterile compression sleeve has an extra length (one and a half meters) of sterile connecting tubing to allow the lower extremity to be moved without restriction during the operation. It is important to attach the sterile connecting tubing to the operative drapes so that the unsterile portion of the tubing cannot be pulled onto the operative field by manipulation of the lower limb. The compression pump was started immediately after the draping was completed."

As an unsterile receiver station cannot be brought into the operative or sterile field, the distance between the receiver station (on the pneumatic connector) and the furthest sensor module (in the thigh chamber) is less than 1 meter. Based on the results from previous research, powering of sensory modules by inductive coupling is reliable only up to several centimeters [23, 24]. As a result, the lack of a reliable coupling and readily available low power transducers at the time of development decrease the feasibility and reliability of using a passive design for the monitoring system. The current design uses lithium-ion coin-cell batteries as the power source for the sensor modules because of their long shelf-life and small self-discharge rates.

RF Technology

The transmission frequency is selected to be in the 2.4GHz industrial, scientific, and medical (ISM) license-exempt band because of of the wide availability of transceivers in this band, high possible data rates, and suitable operating range. As the antenna size decreases with an increase in the frequency of operation, transmitting at 2.4GHz allows a smaller antenna

than the 915MHz; for example, a quarter-wavelength printed antenna in the 2.4GHz band is approximately 3cm, comparing to 8cm in 915MHz. The reduction in size in the circuit board reduces the cost of the prototype (more modules can be fit on the same panel), and lowers the potential of blocking the air flow in the sleeve chamber. The available wireless communication technologies that operate in the 2.4GHz ISM band are Bluetooth, ZigBee, and proprietary solutions.

Bluetooth wireless technology is a short-range communications technology intended to replace the cables connecting portable and/or fixed devices while maintaining high levels of security. The Bluetooth specification defines a uniform structure for a wide range of devices to connect and communicate with each other. The technology is well fitted for widely compatible communications on a personal area network comprises of personal digital assistants, headsets, cellular phones, personal computers, for example, where the standard eliminates much of the design challenge.

ZigBee wireless technology is a short-range communications technology complemetary to Bluetooth. The protocol suits industrial and domestic monitoring and control applications where a scalable network comprising multiple nodes communicating infrequently is required. The major difference between ZigBee and Bluetooth is power consumption; ZigBee is designed for very low duty cycle, ultra long life applications where battery life is measured in years, whereas continuous Bluetooth communications typically drain batteries in a matter of hours.

At first glance, these technologies appear to be the optimum choice for the application; however, adhering to these standards comes at a price. As the standards are designed with the concept of networking, there is significant data packet overhead simply to ensure compatibility between the wire-

less network nodes and the expandability of the network, which increases data transfer time and power consumption. This is reasonable when the network nodes are from different manufacturers and when the number of nodes are not predictable at the time of the system design. But if these factors are known beforehand, such as the ones for the current application, the additional overhead and power consumption becomes an unnecessary expense [25, 26]. Power management is important for embedded applications due to a limited supply of energy, and is especially the case for this application because the batteries are not replaceable once the monitoring modules are sealed inside the sleeve chambers. At the time of the development, Bluetooth and ZigBee modules typically consume 17mA or more for transmission and reception at 0dBm output power. As the current draw of a proprietary solution can be as low as approximately 12mA at 0dBm output power, has less data packet overhead, and higher flexibility in protocol design, a non-standard proprietary technology is selected for the monitoring system.

3.4 Regulations and Recommendations

3.4.1 Emission and Immunity Standards in North America

The prototype system, as other RF devices, are required to comply with emission regulations for RF devices from Industry Canada (IC) and the Federal Communication Commission (FCC). Many aspects of the IC Radio Standards Specifications 210 (RSS-210) [27] and FCC Part 15 are harmonized [28]. RSS-210 and Part 15.247 state that the maximum conducted output power of a radio frequency device operating in the 2400 - 2483.5MHz ISM band should not exceed 1 Watt (30dBm) if digital modulation is used.

Maximum conducted output power is defined as the total transmit power delivered to all antennas and antenna elements averaged across all symbols in the signaling alphabet when the transmitter is operating at its maximum power control level. Power must be summed across all antennas and antenna elements. The average must not include any time intervals during which the transmitter is off or is transmitting at reduced power level. The United States Food and Drug Administration (FDA) does not have its own regulatory standard for radiated immunity. For immunity to electromagnetic interference (EMI), the FDA recognizes the IEC 60601-1-2:2001 standard "Medical Electrical Equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests" and considers the standard as a baseline for all electrical medical devices, except for active implanted devices. The testing level of electromagnetic immunity for a non-life supporting medical device is 3V/m at a distance of 3m from the radiator.

3.4.2 A Guideline from FDA

In January 2007, the FDA published a draft guidance on radio frequency wireless technology in medical devices. The draft guidance is developed to assist industry, systems and service providers, consultants, FDA staff, and others in the design, development, and evaluation of radio frequency (RF) wireless technology in medical devices. Although the guideline does not establish legally enforceable responsibilities, the FDA recommended the address of the following issues regarding expected characteristics of the electromagnetic environment where a medical device will be used: (1) performance of wireless functions, (2) wireless coexistence, (3) wireless quality of service,

(4) integrity of data transmitted wirelessly, (5) security of data transmitted wirelessly and wireless network access, and (5) electromagnetic compatibility (EMC).

Performance of Wireless Functions

Medical electrical equipment following the IEC 60601-1-2:2001 standard is presently exempt from the electromagnetic immunity provisions in the passband of RF frequencies where the medical device RF wireless receiver or transmitter operates. This means that IEC 60601-1-2:2001 is presently inadequate to assess if the wireless link will operate properly in the presence of in-band electromagnetic disturbance (EMD). FDA recommends that the testing should be performed to demonstrate the wirelesss functions will operate safely and effectively in the intended use environment.

Wireless Coexistence, Quality of Service, Integrity and Security

The limited amount of RF spectrum available and potential competition among wireless technologies for the same spectrum is a key factor contributing to a wireless medical device's safety and effectiveness. And as many different RF technologies can be present in a clinical environment: RFID, wireless local area network, and FCC part 15 devices for example, FDA recommends that the selection of wireless technologies should be addressed in the design and development process, and should be included as part of the risk management process. Additionally, the quality of service for medical functions is often higher than that of other services such as cellular networks and internet services. Connections lost without warning and

failure to establish connections may have serious consequences, especially when wireless communication is used for the transmission of critical medical device alarms. Therefore, mitigations for these problems is essential for an effective and reliable operation of a medical device.

3.4.3 Electromagnetic Compatibility

A state of EMC exists when the electromagnetic susceptibility (EMS) of a device is less than the level of electromagnetic interference (EMI) due to emissions from other devices located nearby. Electromagnetic interference may be passed from the interferer to the victim by conduction, induction, or radiation. Such interference may take place at radio, audio, and power-line frequencies. Static discharges can also disrupt the performance of devices.

EMI problems with medical devices can be very complex, not only from the technical standpoint but also from the view of public health issues and solutions [29]. While short-range wireless technologies offer many advantages over conventional wired devices, hospital staff are often reluctant to introduce new radio-frequency telemetry systems in the medical environment due to their concerns about reliability and potential EMI issues between the new and existing devices or networks.

Each hospital and different area within a hospital can present very different EM environments, and the field strength is reported to be especially high in OR due to limited space and high equipment density in a study by Boivin et al. [30], when electrical surgical units are in operation, the field strength was measured to be over 30V/m and 12.9V/m at 50cm. In addition, a study conducted by Davis et al. has shown that the risk of EMI is time varying and dynamic, and unexpected EMI sources due to unpre-

dicted use of mobile devices operating at the same frequency band can be difficult to predict [31]. In a recent study, Furahata et al. has summarized the indications of EMI, which include: (1) artifacts in images, (2) noise on waveforms of physiological signals, (3) error in the displayed numerical value of the transducer readings, (4) sensor malfunction, and (5) change in operation mode [32]. Based on these findings, it is obvious that: (1) potential problems in medical devices due to EMI should not be underestimated, and (2) mitigations of EMI problems are necessary for successful implementation and deployment.

Due to limitation in time and resources, the thesis will focus on the *preliminary* evaluations on EMI effects on medical devices in the intended use environment due to the radiated RF energy from the monitoring system, and the mitigation of EMI problems from external in-band RF interference that may affect the performance, integrity and the quality of wireless functions. Additionally, these issues are investigated from a biomedical engineering perspective, where dedicated RF testing equipments and expertise are not always present, and the FDA recommendations for preliminary evaluation of wireless medical devices are followed. It is important to note that the preliminary evaluation in this thesis do not substitute for testing in accredited laboratory, and that other issues such as the immunity to conducted RF electromagnetic energy, electrostatic discharge (ESD), and magnetic fields are equally important and must be considered if the prototype system goes to commercialization.

3.5 System Architecture

The prototype system is composed of a receiver station, 6 battery-operated sensor modules located in the sleeves, and an user application.

3.5.1 Receiver Station

The receiver station is the controller unit of the monitoring system. It is responsible for initializing and terminating the compression therapy, controlling the communication schedule of the sensor modules, computing additional process parameters based on the received pressure and temperature data, and relaying both the processed sensory data and the important system messages to the user application. The receiver station is controlled

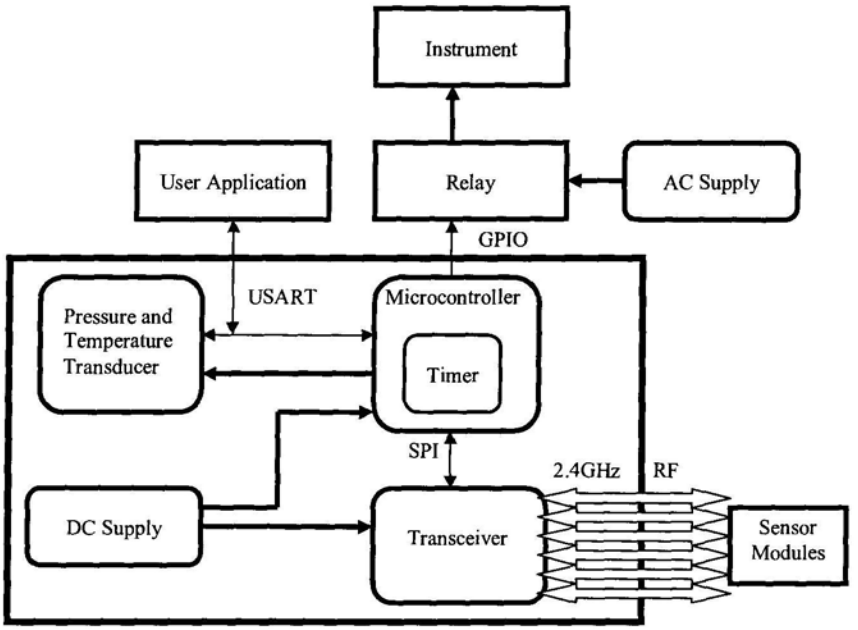

Figure 3.2: Architecture of the receiver station showing data flow (thinner arrows) and power flow (thicker arrows)

by an onboard microcontroller unit (MCU) optimized for low power operation. User commands and system messages are transferred between the user application and the MCU through an onboard universal synchronous and asynchronous serial receiver and transmitter (USART) communication device, which is also shared for acquiring data from the pressure and temperature transducer. The MCU controls the transceiver through a serial peripheral interface (SPI), and the transceiver communicates to the sensor modules according to a communication schedule controlled by the internal timer of the MCU. The MCU starts and stops the AC supply to the instrument via a relay that operates with a 3V DC output. The MCU and the transceiver receive power supply from an independent power line to prevent the coupling of analog and digital noise; each power line has two decoupling capacitors to filter the noise in the power supply.

The receiver station is placed at the pneumatic connector between the instrument and the compression sleeves (Figure 3.3), and is approximately 1

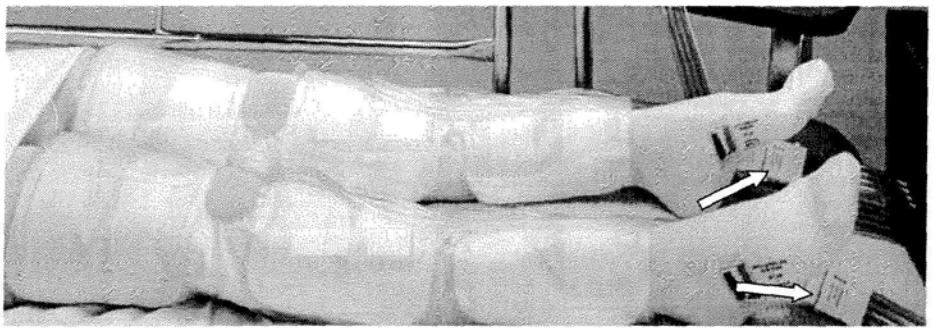

Figure 3.3: Pneumatic connectors as indicated by the arrows

meter away from the thigh chamber. Although the receiver station can communicate with the sensor modules at a greater distance, the transmission power of the sensor modules can be reduced by decreasing the communica-

tion distance, resulting in longer battery lives of the sensor modules. The probability of the sensor modules interfering other medical equipments in surrounding environment is also reduced as a result of reduction in transmission power. The receiver station is connected to the relay in the instrument and the user application through a wired interface along the pneumatic connector. One may argue that the wired interface will defeat the purpose of utilizing wireless communication; but the idea here is that wireless technology allows the separation of the instrument and the disposable portion of the apparatus after a monitoring means is integrated (such as the previous and current prototype), and through this separation, limited-reuse of the sleeves becomes feasible, thus reduces the cost per therapy and averages out the cost of the monitoring means. A key value of the use of wireless communication in this application is the significant improvement in the feasibility of a practical deployment of the monitoring system through the reduction in cost per therapy, leading to a higher potential of benefiting a larger population. More details on this will be provided in Chapter 5.

3.5.2 Sensor Modules

A sensor module acquires pressure and temperature data from the transducer, temporarily stores the data, and transmits it to the receiver station for further analysis. It operates mostly in a power down mode to conserve energy, and wakes up periodically by the internal timer to perform data measurement and communication. The architecture of a sensor module is almost identical to that of a receiver station, except that an USART interface is not required for user communication, and that an instrument control interface is not required. An addition functionality of the sensor modules is the ability

to detect the battery voltage through an onboard analog-to-digital (ADC) converter. More details on the detection of battery voltage will be discussed in a later section. The high similarity between the architectures of the two components allow reduction in development cost and time.

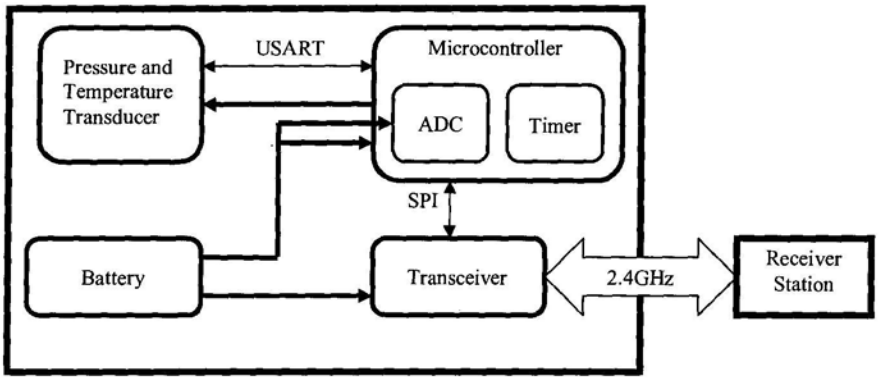

Figure 3.4: Architecture of the sensor module showing data flow (thinner arrows) and power flow (thicker arrows)

The MCU and the transceiver receive power supply from an independent power rail to prevent the coupling of analog and digital noise. And the MCU controls the power supply to the digital transducer, and turns it off when the measurement of pressure and temperature is not required to conserve energy.

3.5.3 User Application

The user application provides the operators with the ability to interact with the monitoring system. The user interface displays therapy related parameters and appropriate system messages and alerts based on the commands from the receiver station. It also provides simple start-stop control on the therapy, and allows recording of the therapy related parameters. The

user application can be hardware based, using a LCD display and capacitive buttons for example, or software based, which is the approach chosen for the current thesis. The user application is written with LabView and C#.NET for fast prototyping, and communicates to the receiver station via an RS-232 interface.

3.5.4 Pressure and Temperature Transducer

As mentioned in the previous chapter, the use of additional pneumatic tubing, ports and connectors in previous designs increased the complexity of cleaning and the cost of manufacturing; as a result, the sensor modules of the current prototype system are sealed inside the sleeve chambers to eliminate the additional hardware required. Due to a lack of pressure reference in the sleeve chamber, a transducer that measures absolute pressure is selected instead of a relative pressure transducer (In Chapter 5, it will be seen that an absolute pressure transducer is also required for detecting the pressure of a reprocess or sterilization chamber). A pressure transducer is required on both the receiver station and the sensor modules. The transducer on a sensor module acquires the pressure delivered to the patient, and the transducer on the receiver station provides the system with a reference atmospheric pressure (P_a) to calculate the relative pressure of the sleeve chambers. In addition, the components of a sensor module must operate at or below 3V because a CR2032 battery can only source a maximum voltage of 3V.

The MS5534BM from Intersema Sensoric SA (Bevaix, Switzerland) is selected as the absolute pressure transducer on the prototype. The MS5534BM was a rare sub-3V transducer (operates from 2.2 to 3V) that was available at the time of the development; another possible choice has been the SCP1000

from VTI Technologies Oy (Vantaa, Finland), but was not selected as it was not yet in mass production.

The MS5534BM is a surface mount device including a piezoresistive pressure sensor and an ADC-interface integrated circuit. It provides an SPI for communicating pressure and temperature data in a 16-bit word format. The conversion time for a pressure or temperature reading is 35ms, which gives a maximum sampling rate of approximately 30Hz; and this satisfies the requirement of a 10Hz sampling rate for the monitoring application. A sampling rate of 10Hz is required to accurately capture the rate of inflation. Additionally the transducer allows accurate software calibration of the sensor through 6 preprogrammed calibration coefficients. The transducer is operable from -40 to +125°C and its pressure measurement range is from 7.5 to 825mmHg absolute at an accuracy of ±0.5mmHg. The pressure measurement range fits the application as the chamber pressure ranges from 0 to 45mmHg relative to P_a. The lower end of the pressure measurement range of the MS5534BM is very useful for a critical improvement for the prototype, which is covered in Chapter 5. The IC consumes 1mA in active mode, 0.1μA in standby mode and is turned off when no conversion is needed. The current consumption into the master clock pin is 0.5μA, and the total active time during a 35-ms conversion is 2ms [33].

3.5.5 Transceiver

The transceiver on the receiver station and sensor modules is the nRF24L01 from Nordic Semiconductor ASA (Tiller, Norway), which is optimized for low-power operation (operable from 1.9 to 3.6V) and features a 0.9μA in the power down mode (register retention). It is programmed via an SPI

and is capable of 2Mbps transmission at 2.4GHz. Due to the fast data rate, the actual on-air time of the radio is very short during transmission (the manufacturer uses the term "Shockburst" for the short on-air time). The IC drains 11.3mA of current at 0dBm output power for transmission, and 12.3mA and 11.8mA of current at 2Mbps and 1Mbps respectively for receiving operation. This level of current drain is much lower than that of the Bluetooth and ZigBee ICs available at the time of development. For the antenna on the prototype, an design provided by Nordic Semiconductor was used [34].

3.5.6 Microcontroller

The MCU utilized in the wireless monitoring system is the ATmega88V from Atmel (California, U.S.). It is operable from 1.8V to 5.5V, can operate at either 1MHz and 8MHz using the internal RC oscillator, and has different measures for power reduction, including the active, idle, and power-down modes. The MCU operates at 1MHz on the sensor modules to reduce power consumption, and the current drain in the active, idle, and power-down modes are 0.4mA, 0.07mA, and 3.8μA (watchdog timer enabled) respectively [35]. As the receiver station operates with continuous DC supply, the MCU runs at 8MHz and is responsible for therapy related parameters calculation. Another choice of the MCU is the MSP430 from Texas Instruments (Texas, U.S.), which offers comparable low power operation and features. The ATmega88V is selected over the MSP430 due to the availability of development tools and parts in the lab. Figure 3.5 is a picture of the overall design of the system.

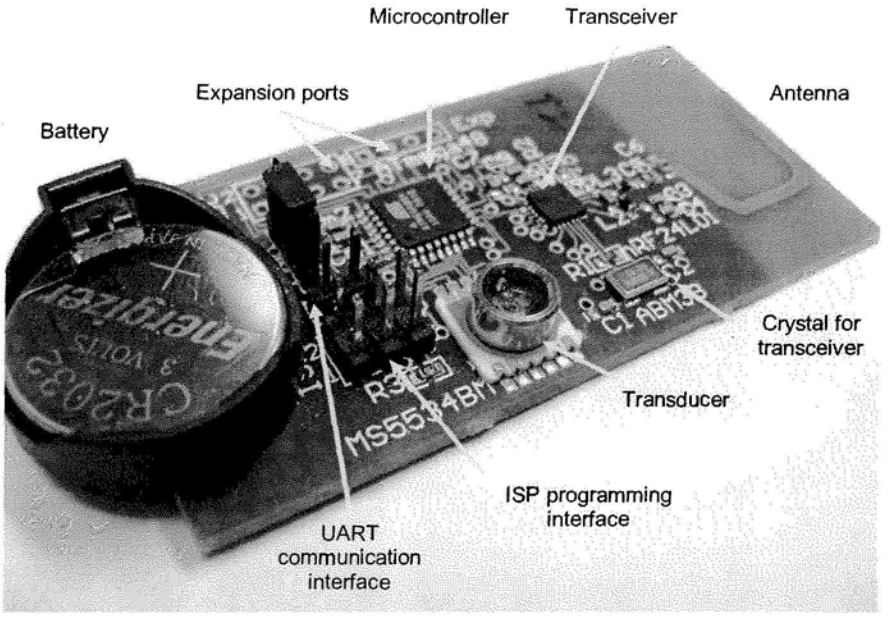

Figure 3.5: The completed design of the prototype system

3.6 Implementation of Monitoring Functions

Safety and risk management is an integral part of the design of medical devices. A medical device is expected to operate as specified, perform in a safe manner, and recover from problems with the least intervention from the operators. Although the ISO 14971 standard defines a general process of risk assessment, the acceptable risks of a medical device still depend on the specific application and its operating environment [36]. Both acceptable and unacceptable risks must be clearly identified and mitigated during the design stage to minimize the potential risk to the patients. Human factors should also be considered in the process. In this section, the potential problems and the corresponding mitigations of the compression therapy and the

monitoring system are presented.

3.6.1 Therapy Related Problems

The main function of the prototype system is to ensure that a compression therapy for preventing DVT is delivered effectively to the patients. In this thesis, therapy related problems are defined as those that may affect the performance of a compression therapy, and creates potential hazards to the patients. For problems related to instruments external to the monitoring system, pressure leakage along pneumatic tubing for example, an acceptable mitigation include audiovisual warning messages to the clinical operators, clearly identifying the nature and location of the problem, and an immediate termination of the therapy if a direct threat to the patient is present. For other internal problems, audiovisual warnings are used as a last resort if auto-recovery fails. It is unacceptable for the prototype system to terminate its operation without notifying the clinical operators.

Under-pressurization of the sleeve chambers

The sleeve chambers are under-pressurized when the instrument is unable to deliver a maximum pressure within 5% of the specification to the sleeve chambers (Table 3.1) [10]. Although the problem does not bring an

Position	P_{max}(mmHg)
Ankle chamber	45
Calf chamber	40
Thigh chamber	27

Table 3.1: Peak pressure values of the sleeve chambers

immediate risk to the patient, the chance of developing DVT will be in-

creased due to a sub-optimal compression therapy. The problem can be caused by a leakage in the hoses or sleeve chambers, a faulty pump on the instrument, kink(s) along the hoses, faulty transducer, the design limitations of the current instrument, and a loose fitting of the sleeves. An acceptable mitigation include the inspection and replacement of faulty instruments, hoses, and sleeves, and most often, the refitting of the compression sleeves. Upon detection of such problems, the system alerts the users and provide them with clear details regarding the possible source and locations of the problems.

No inflation in the sleeve chambers

The maximum duration of a sleeve chamber in a deflated state is 60 seconds. Therefore, the system will issue an audio and visual alarm if no inflation is observed for more than 60 seconds. The alarm is accompanied by system messages with clear details on the sources and locations of the problems. An audio alarm is often necessary because in a surgical environment, the nurses and surgeons are usually occupied by other tasks. The problem can be caused by a faulty pump in the instrument, or disconnected hoses between the instrument and the sleeves. The patients are not under immediate risk of being injured, but they may have a high chance of developing DVT without the compression therapy, and thus the problem must be solved as soon as possible.

Temporary over-pressurization of the sleeve chambers

In this thesis, a temporary over-pressurization of the sleeve chambers is defined as an occasional, non-sustained detection of the chamber pressure

higher than the maximum pressure specified in Table 3.1. It can be caused by transducer error, instrument problem, or a sudden movement by the patient which temporarily increases the pressure of the sleeve chamber. This occasional problem brings no immediate and long term risks to the patients; however, as the temporary over-pressurization of the sleeve chamber may accelerate the deterioration of the structure of the sleeves, the number of occurrences of the problem has to be recorded and used for calculating the remaining usable life of the sleeves.

Sustained high pressure in the sleeve chambers

The maximum duration of a sleeve chamber in an inflated state, defined as pressure greater than 10mmHg relative to P_a in this thesis, is approximately 15 seconds. Therefore a hazard exists if the pressure of a sleeve chamber is held above the 10mmHg for over 15 seconds. Sustained high pressure can be caused by a faulty release valve or pump on the instrument that prevents the release of pressure, or by an incorrect positioning of the sleeves so that the patient's limb is pressed on the transducer. In the first case, the blood flow of the patient's limb can be severely obstructed, leading to a higher chance of DVT. In the second case, the pressure spot developed on the limb of an immobile patient may lead to pressure ulcers. Complications developed during a compression therapy are not easily detectable because: (1) direct inspection of the patients' skin is not possible as the sleeves are opaque, and (2) surgical patients under anesthesia cannot feel any pain or discomfort and so cannot communicate with the clinical operators. Besides the audiovisual alarms, the monitoring system will also stop the therapy because an immediate threat of serious injury is present to the

patients.

Sequence of inflation

Under a normal operation, the compression of the sleeves starts with an inflation at the ankle chamber, follows by an inflation at the calf chamber, and finally at thigh chamber. A faulty connector or a connection error corrupts the sequence of inflation, and is a serious risk to the patient. A compression sleeve with a reversed inflation sequence acts like a tourniquet, so instead of promoting blood flow in the veins, the normal flow is severely obstructed. Assume that the sensor modules are named as RS1, RS2, RS3 for the ankle, calf and thigh chamber respectively, the detection criteria is presented in Table 3.2.

Sensor Module	**Correct Sequence**
RS1	No previous detected pressure rise in RS2 and RS3
RS2	Previous detected pressure rise in RS1 No previous detected pressure rise in RS3
RS3	Previous detected pressure rise in RS1 and RS2

Table 3.2: Detection criteria for corruption of the sequence of inflation

The therapy will be stopped upon detection of such problem due to the immediate risk, and the clinical operators are alerted both visually and audibly. As the sequence of inflation cannot be detected without identifying the sleeve chambers, this justifies the decision of programming each sensor module with an unique address.

Temperature abnormality

Complications during the course of a compression therapy is often difficult to detect [12, 13, 15]. Although many complications are symptomless, for symptomatic complications, symptom often includes localized elevated temperature [37–39]. Although a monitoring module cannot determine the exact skin temperature, the temperature of a sleeve chamber still partially reflects the temperature of the skin underneath. Therefore, if the measured temperature of a particular chamber is observed to be different (1^oC) from the average temperature of other chambers, the system will advise the clinical operator to check the skin condition of the patient and perform further analysis if necessary.

3.6.2 Wireless Communication Problem

For problems that involve wireless communication, the monitoring system will first attempt to solve the problem without users' intervention. The receiver station will first attempt to reconnect with the sensor modules; if the source of interference is from a frequency hopping system, the interference is expected go away within a short period of time due to the random hop in frequency; and if the reconnection attempt fails, the receiver station will detect stationary disturbance through the internal "carrier detect" function of the transceiver. The receiver station will then issue a change channel command if a stationary disturbance exists. If the problem remains after changing channel, the receiver station and sensor modules will increase the output power and lower the data communication rate to increase the sensitivity of the transceiver. If all these measures do not recover the communication, the monitoring module will issue a warning message clearly identifying the

problem and the sensor modules to the clinical operator.

3.6.3 Battery Supply Problem

The operating voltages of the MCU, transceiver, and the transducer are 1.8 to 5.5V, 1.9 to 3.6V and 2.2 to 3.6V. Therefore, if the battery voltage drops below 2.2V, the clinical operator will be warned to change the sleeves to prevent interruption of the therapy monitoring. The sensor modules detect the battery voltage by using the internal ADC. The system voltage supply is fed into one of the ADC ports and is compared to a 1.1V internal band-gap reference. The battery voltage is then calculated with Equation 3.1 [35].

$$V_{batt} = \frac{ADC_{register} * V_{ref}}{1024} \tag{3.1}$$

3.7 Summary

In this chapter, a proof-of-concept monitoring system was presented with the overall objective to improve the safety and effectiveness of the therapy. The technical specifications and details were also included. The monitoring features of the wireless monitoring allows a continuous monitoring of various parameters related to pressure and temperature in a compression therapy. It also localizes and identifies potential problems that may happen in duration and provides the clinical operators with sufficient information to solve the problems and maintain the effectiveness of the therapy. The wireless monitoring system is self-managed, and does not require user intervention unless an unrecoverable or patient-threatening problem has occurred.

The use of wireless technology allows the separation of the instrument and the disposable portion of the apparatus after the integration of the

monitoring system; and through this separation, limited-reuse of the sleeves becomes more feasible, thus reduces the cost per therapy and averages out the cost of the monitoring means. This significantly improves the feasibility of practically deploying the monitoring system, and the potential of benefiting a larger population.

Chapter 4

Development of a Novel Power Management Scheme for an Improved Prototype

4.1 Objective

In this chapter, a novel power management scheme tailored for the application will be introduced. Power management is an important addition to the remote sensor modules due to the following reasons: (1) it is difficult to replace batteries of the sensor modules which are sealed inside the sleeve chambers; in other words, the battery of a sensor module must last long enough for the specified duration of a compression therapy, (2) in the next chapter, we will see that the average cost of the prototype can be reduced by the limited-reuse of the compression sleeves, and thus it is important to control the power consumption of the remote sensor modules so that the proposed features of the prototype can operate uninterruptedly for multiple uses, and (3) by programming the sensor modules to operate under the same power management scheme in which the sleep and active cycles are well defined, the power consumption of the modules, as well as the remaining operating life of the system, become deterministic. This improves the

overall reliability of the proposed prototype as well as reduces the variations of operating life among the remote sensor modules.

4.2 Design Criteria

The software-based power management scheme shall allow the prototype to operate continuously for 3 weeks while providing a shelf-life of 2 years. The scheme shall not interfere with the accuracy and the transmission reliability of the sensor modules. It shall also be an universal solution for all the sensor modules so that no modification of the power management algorithms is required upon integration. The other advantages of having an universal solution include reduced software complexity, and reduced variation of operating life among different sensor modules. Additional requirements will be presented in the next chapter when the concept of limited-reuse of the sleeves is introduced, but for this chapter, the above criteria are used.

4.3 Implementation

Although hardware-based power management solutions may be able to extend the battery life of the prototype, such as the selection of hardware with lower power consumption, and batteries with higher capacity, these solutions may not be optimum for product development due to the higher cost involved. Recalling that the price of medical products is often marked up 4 times before reaching the end user, a $20 dollar increase in the manufacturing cost of an improved device will cause the end user to pay $80 dollars; as a result, the improved device may not be able to reach and benefit as many people as desired. On the other hand, a software-based method is relatively

cost-effective and more flexible, and is therefore selected as the approach for power management.

Power consumption of an embedded system can be reduced by using the following techniques: (1) program the components to run at the lowest possible speed, (2) use power reduction modes such as the "idle", "standby" and "powerdown" modes whenever active operation is not required, (3) turn off partial or all components on the system whenever possible, and (4) program the input-output pins to a tri-state level when not used to prevent unintentionally current draw. Before different approaches for power management are introduced, the battery life of the prototype without any power management is discussed. To begin with, Table 4.1 summarizes the level of current draw of the components in various operating modes.

Components	**Mode of operation**	**Current(mA) at 3V**
MCU	Active(1MHz)	0.4
	Idle	0.07
	Powerdown	0.0038
Transceiver 1Mbps	Transmit	11.3
	Receive	11.8
	Powerdown	9nA
Transducer	Conversion (2ms - active)	1.005
Transducer	Conversion (33ms - standby)	0.006

Table 4.1: Level of current consumption of various components in the prototype

And the average current consumption over a period (I_{avg}) and operating life of the prototype ($L_{prototype}$) can be calculated by:

$$I_{avg} = \frac{\sum_{i=0}^{2}\sum_{j=0}^{n} I_{i,j}t_{i,j}}{t_{total}} \tag{4.1}$$

$$L_{prototype} = \frac{battery\ capacity}{I_{avg}} \tag{4.2}$$

where $I_{i,j}$ represents the current consumption of the component i in operating mode j and $t_{i,j}$ represents the duration that the component spends in that particular mode. The symbol i represents components on the prototype, including the MCU, transducer, and transceiver; and j represents various operating modes that a component can operate in, such as the "active", "power-down", and "idle" mode.

4.3.1 Without Power Management

The simplest solution to control the sampling rate and to keep track of the timings of pressure acquisition is to rely on the base-station. For a steady 10Hz sampling rate, the base-station issues a command to the remote sensor modules to start a pressure conversion at 65^{th}ms of a 100ms monitoring cycle. After the conversion finishes approximately 35ms later, the sensor modules starts the transmission of data to the base-station; assuming that the base-station is ready for receiving data and no error has occurred, the transmission will take approximately 1ms. As the sensor modules have no knowledge of the base-station's clock, the transceivers are kept in the receiving mode before receiving a command. The MCU is left in the active mode for the whole cycle.

Using Equation 4.1 and 4.2, the average current draw of the sensor module and its operating life are calculated in Table 4.2 assuming that the effective capacity of a 225mAh battery is 175mAh.

Without power management, the operating life of the sensor modules is well short of the required 3 weeks of use. In fact, the modules will defi-

Components	Mode	Current(mA)	Duration(ms)	I*t
MCU	Active(1MHz)	0.4	100	40.0
	Idle	0.07	0	0.0
	Powerdown	0.0038	0	0.0
Transceiver	Transmit	11.3	0.2	2.26
	Receive	11.8	66	778.8
	Powerdown	9nA	32	0.0
Transducer	Active	1.005	2	2.0
	Standby	0.006	33	0.2
			$\sum_{i=0}^{2}\sum_{j=0}^{n} I*t$	823.3
			t_{total}	100ms
			I_{avg}	8.2mA
			$L_{prototype}$	21.3hrs

Table 4.2: Average current draw and operating life of the prototype without power management

nitely not be able to sit on the shelf for 2 years and still provide any usable operating life. As a result, we can see that a power management scheme that controls both the power consumption while on the shelf and during the actual use is mandatory.

4.3.2 Power Management - I

From the analysis above, it is observed that during a 100ms cycle, most power is consumed by the transceiver in the receiving mode. Therefore, the first proposed power management solution is to limit the power consumed by the transceiver.

In this approach, a sensor module uses an internal timer to keep track of the time elapsed since the last transmission, and set up the transceiver 5ms before the next communication slot, with reference to its own clock,

for the incoming command. The average current draw of the sensor module and its operating life are presented in Table 4.3. Although there is some improvement over the last approach (no power management), this approach still does not provide the required operating life.

Components	Mode	Current(mA)	Duration(ms)	I*t
MCU	Active(1MHz)	0.4	100	40.0
	Idle	0.07	0	0.0
	Powerdown	0.0038	0	0.0
Transceiver	Transmit	11.3	0.2	2.26
	Receive	11.8	5	59.0
Transducer	Active	1.005	2	2.0
	Standby	0.006	33	0.2
			$\sum_{i=0}^{2}\sum_{j=0}^{n} I*t$	123.8
			t_{total}	100ms
			I_{avg}	1.2mA
			$L_{prototype}$	7days

Table 4.3: Average current draw and operating life of the prototype with power management I

4.3.3 Power Management - II

For a monitoring application, a short latency of data arrival at the base-station is tolerable. This approach introduces a communication cycle of 500ms - a sensor module transmits 1 data packet containing 5 pressure and 1 temperature measurement every 500ms, with reference to the base-station's clock, at its own predetermined 10ms transmission slot. The sensor modules are resynchronized every second. To further limit power consumption, the MCU is put into: (1) "deep sleep" power reduction mode between each sampling period of pressure and temperature, (2) "idle" power reduction mode

during each conversion of data, and (3) "active" mode only for calculation, uploading and downloading of data and command from the transceiver and transducer.

The MCU is active for 1ms during each sampling of pressure and pressure, and 1ms for each setup of the transceiver. Within a second, there are 2 transmissions, 1 reception, and 12 measuring periods; therefore, the MCU is in the active mode for 16ms each second. The total transmission time of the transceiver was calculated to be approximately 200μs at 1Mbps. The average current draw of the sensor module over 1 second and its operating life are calculated in table 4.4. The operating life is significantly improved, and exceeds the requirement of 3 weeks of operating life.

Components	**Mode**	**Current(mA)**	**Duration(ms)**	**I*t**
MCU	Active(1MHz)	0.4	1*15	6
	Idle	0.07	35*15	36.8
	Powerdown	0.0038	460	1.7
Transceiver	Transmit	11.3	0.2*2 transmissions	4.52
	Receive	11.8	5*1 transmissions	59
Transducer	Active	1.005	2*12 samples	24.1
	Standby	0.006	33*12 samples	2.4
			$\sum_{i=0}^{2}\sum_{j=0}^{n} I*t$	134.5
			t_{total}	1000ms
			I_{avg}	0.13mA
			$L_{prototype}$	7.7weeks

Table 4.4: Average current draw and operating life of the prototype with power management II

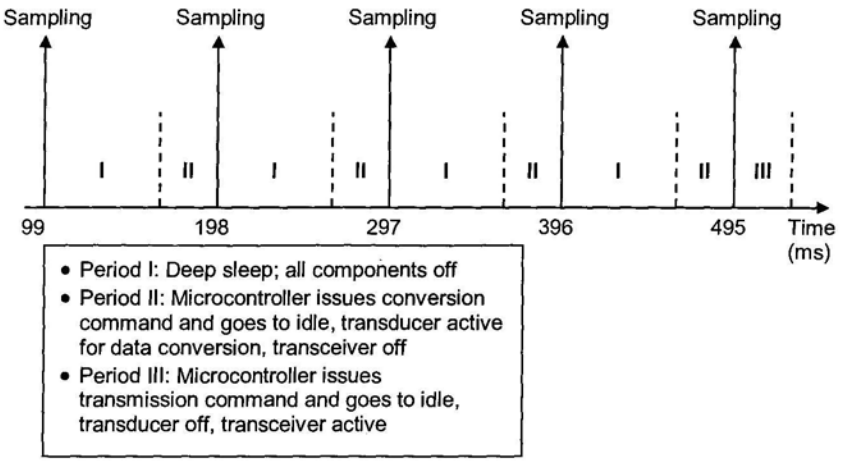

Figure 4.1: Power management scheme II

4.3.4 Power Management - III

To implement an optimum power management scheme, we have to go back to the details of a therapy cycle. A therapy cycle consists of a 11-second inflation period, and a 60-second rest period. At the start of a therapy cycle, the sleeve chambers are rapidly inflated to different levels of pressure depending on their locations (rapid inflation period). The chambers are kept inflated for the remaining of the 11-second period; after that, the chambers are deflated and will remain deflated for 60 seconds.

The timings of the acquisition of pressure during the rapid inflation period must be known so that the rate of inflation, a key parameter affecting the effectiveness of a therapy, can be calculated accurately. Therefore, during this period, the sampling rate of the sensor modules is set at 10Hz to accurately capture the inflation rate; at other times, a sampling rate of 1Hz is adequate and the monitor modules communicate with the base-station

only when therapy related problem is detected. A sampling rate lower than 1Hz is not recommended, because the reaction time of the prototype to change its sampling rate to higher sampling rate from a lower setting depends on the lower sampling interval. For example, if the lower sampling rate is set at 0.5Hz, by the time the prototype switches from the lower sampling rate to a higher sampling rate, the inflation of pressure may have already completed,and thus results in an inaccurate calculation of the rate of inflation.

The average current consumption of the 10Hz interval is equivalent to the one shown in Table 4.4. And that of the 1Hz interval is shown in Table 4.5. The calculations are based on the fact that within a second, there is no transmission (no problem detected), 1 reception, and 2 measurements.

Components	**Mode**	**Current(mA)**	**Duration(ms)**	**I*t**
MCU	Active(1MHz)	0.4	1*2 samples	0.8
	Idle	0.07	35*2 samples	4.9
	Powerdown	0.0038	928	3.5
Transceiver	Transmit	11.3	0.2*0 transmission	0.0
	Receive	11.8	5*1 transmission	59.0
Transducer	Active	1.005	2*2 samples	4.02
	Standby	0.006	33*2 samples	0.4
			$\sum_{i=0}^{2}\sum_{j=0}^{n} I*t$	72.6
			t_{total}	1000ms
			I_{avg}	0.07mA

Table 4.5: Average current draw and operating life of the prototype with power management III at 1Hz

The average current over a complete therapy cycle (the inflation, defla-

tion and rest period) can be calculated as:

$$I_{avg} = \frac{I_{avg\ 10Hz} \times t_{10Hz} + I_{avg\ 1Hz} \times t_{1Hz}}{t_{therapy}} \quad (4.3)$$

At a later section, we will look at an algorithm that detects the rapid inflation period (or the "10Hz period") of a therapy cycle. For the purpose of estimating the operating life of the prototype, the inflation rates specified by the manufacturer are used.

Position	P_{max}(mmHg)	Rate(mmHg/s)	Duration(s)
Ankle chamber	45	13.6	3.3
Calf chamber	40	9.7	4.1
Thigh chamber	27	4.8	5.6
		Avg. duration	4.3

Table 4.6: Duration of pressure rise of sleeve chambers

Therefore, equation 4.3 becomes:

$$\begin{aligned} I_{avg} &= \frac{0.13 \times 4.3 + 0.07 \times 66.7}{71} \\ &= 0.08mA \\ L_{prototype} &= \frac{175mAh}{0.08mA} \\ &= 2290\ hours\ or\ 95\ days \\ &= 13.6\ weeks \end{aligned}$$

By using a power management scheme with adaptive sampling rate, the operating life of the sensor modules increases significantly from approximately 21 hours without power management to 95 days. In the next section, the effect of power consumption of the sensor modules in the "sleep" mode (while on-shelf) is presented; but before that, we now look at an algorithm

for the detection of the rapid inflation period, and the adjustment of the sampling rate of the sensor modules.

4.3.5 Rapid Inflation Detection Algorithm

The algorithm for detecting the rapid inflation of a therapy cycle has the following design requirements, the algorithm shall: (1) have a fast response to the rise in pressure, (2) change the sampling rate from 1Hz to 10Hz upon detection so that enough pressure data is captured for the calculation of the inflation rate, (3) have a fast response to the end of rise in pressure, and (4) change the sampling rate from 10Hz to 1Hz upon detection so that power is not wasted (Figure 4.2).

The simplest yet effective way of detecting the rapid inflation period is to compare 2 consecutive pressure readings; if the current reading (P_{new}) is higher than the previous reading (P_{old}) than a predefined threshold (P_{thresh}), then the rapid inflation period has started. As a result, the pseudocode of the detection algorithm is:

Algorithm 1 Detection of the rapid inflation period

```
1: Acquire P_new
2: Run at every sampling period
3: if (P_new − P_old) ≥ P_thresh then
4:     Inflation period has started
5:     Sampling rate ← 10Hz
6: else
7:     P_old ← P_new
8: end if
```

The selection of a proper threshold is critical to the application, because if the threshold is too low, then a false detection may occur, and if the threshold is too high, a rise in pressure may not be detected. As the sampling

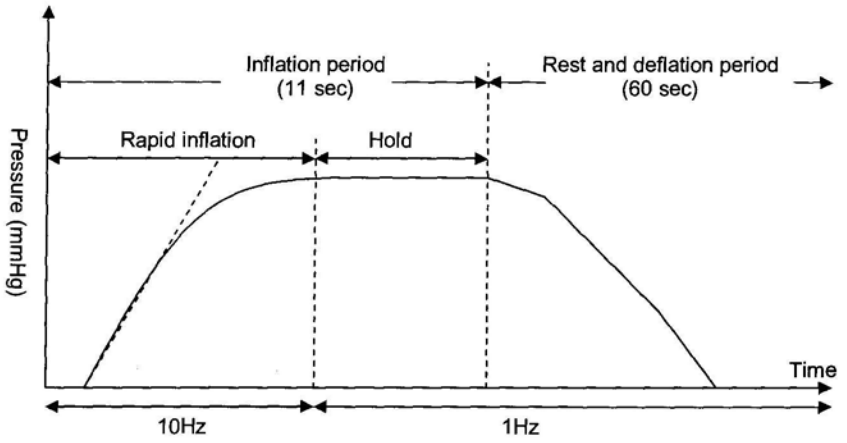

Figure 4.2: Power management - adaptive sampling rate

rate is 1Hz in the rest period, we have to consider the pressure rise in the sleeve chambers within a second; based on the information in Table 4.6, the rise in pressure within a second of the rapid inflation period is calculated in Table 4.7. As mentioned previously, the original compression system may

Position	Rise in 1s(mmHg)
Ankle chamber	13.6
Calf chamber	9.7
Thigh chamber	4.8

Table 4.7: Pressure rise in one second in different chambers

not be able to provide the specified rate of inflation; the proper thresholds for the ankle, calf, thigh chambers shall take into a 20% error margin, and therefore are approximately 11.0, 8.0, and 4.0mmHg respectively. Thus when such pressure rise is observed, a sensor module changes its sampling rate from 1 to 10Hz. On the other hand, if such pressure rise is not observed over 1 second when the sampling rate is at 10Hz, the sampling rate will be

changed from 10 to 1Hz.

Algorithm 2 Detection of the completion of the rapid inflation period

1: Acquire P_{new}
2: Run at every sampling period
3: **if** $(P_{new} - P_{old}) \leq P_{thresh}$ **then**
4: Inflating period has completed
5: Sampling rate $\leftarrow$ 1Hz
6: **else**
7: Continue sampling at 1Hz
8: **end if**

4.4 Power Management in Sleep Mode

When the compression sleeves are on-shelf before the first use, the power consumption of the sensor modules must be carefully controlled so that there is enough power remaining for 3 weeks of operation. The proposed power management scheme in sleep mode is the following: (1) the sensor modules automatically wake up every 4 minutes to monitor incoming commands for 64ms, (2) in between the wakeup, the MCU is in power down energy reduction mode, the transducer is turned-off, and the transceiver is in the power down mode, and (3) the MCU uses the internal watchdog timer to keep track of the timings; the watchdog timer has the lowest power consumption among the internal timers, and because it operates on a separate 128kHz internal oscillator, it is the only timer that is operative in the power down mode of the MCU. The average current consumption is calculated as before in Table 4.8.

Assume that the compression sleeves have sat on the shelf for two years, the total energy consumed is 122mAh. Therefore, the remaining battery life is 175 – 122 =53mAh. Using the average current calculated from above,

0.07mA, the remaining operating life is $\frac{53mAh}{0.08mA}$ =4 weeks. Therefore, the requirement is met.

Components	Mode	Current(mA)	Duration(ms)	I*t
MCU	Active(1MHz)	0.4	1	0.4
	Idle	0.07	63	4.41
	Powerdown	0.0038	239936	911.8
Transceiver	Transmit	11.3	0	0.0
	Receive	11.8	64	755.2
Transducer	Active	1.005	0	0.0
	Standby	0.006	0	0.0
			$\sum_{i=0}^{2}\sum_{j=0}^{n} I*t$	1671.8
			t_{total}	240000ms
			I_{avg}	7μA
			Energy consumed	61mAh/yr

Table 4.8: Average current draw of the sensor module in sleep (on-shelf) mode

4.5 Practical Difficulties

In this section, the challenges encountered in the implementation of the power management scheme and the solutions to the problems are discussed.

4.5.1 Synchronization

The first challenge is to synchronize the receiver station and the sensor modules. Synchronization allows the samplings of data to occur at a predefined period of time without relying on a continuously-running timer on the sensor module, which in turns reduces the power consumption of the device. Every second, the receiver station sends out a synchronization

signal including the current cycle time to each sensor module; the sensor module will use this information to determine how long it should wait until the first sampling interval. For example, if a sensor module receives synchronization information stating that the current cycle time is 45ms, then the sensor module will go into power down mode for another 54ms, before the watchdog timer interrupts the MCU to wakeup and measure the first pressure sample.

4.5.2 Clock Skew

After a preliminary testing of the power management scheme, it was observed that the remote sensor modules frequently missed its predefined communication slot, sometimes as much as 30ms. After some investigations, it was determined that the system clock of the remote sensor modules, running at 1MHz, is derived from an 8MHz internal RC oscillator by using an 1/8 clock divider. According to the MCU's specification, the accuracy of the internal 8MHz RC oscillator is $\pm 10\%$. Assuming that the sensor module's RC oscillator is skewed from 8.0MHz by -10%, then the clock of the sensor modules will be running at 8.0MHz $\times$ $(1 - 0.1)$ = 7.2MHz, for which the single clock interval is 1.11μs. For the initial design, the number of cycles that a sensor module is in the power down mode between each sampling of pressure is determined with reference to an 8.0MHz/8 clock (reference clock). To make this clear, the sensor module is programmed to sleep for $\frac{270ms}{1\mu s/cycle} = 270,000$cycles every 500ms. However, due to the clock skew, the sensor module will have actually slept $270,000$cycles $\times$ $1.11\mu s$ = 297ms. Another interpretation of this is that the clock of the sensor module is 27ms slower than the receiver station clock if there is a 10% difference between the

two clocks. It can also be calculated that every percentage in clock difference between the receiver station's and sensor module's clock will introduce a 2.7ms clock difference every 500ms.

Another cause of the problem is that as no continuous clock is present on the sensor modules (to conserve power), the internal watchdog timer is configured and turned-on to keep track of the time between measurements, and wakes up the MCU every 100ms. As time is required for the setup and configuration of the internal timer, and a short delay is present to startup the system clock of the MCU from a power-down state, the actual "sleeping" time is longer than expected.

The problem is further complicated by the variation of the internal oscillator speed at different voltage levels, and this has made it virtually impossible to pre-calculate a value to offset the clock skew. Although an on-board voltage regulator may prevent clock skew due to varying battery voltage, it does not prevent clock skew due to manufacturing variations of the internal oscillators; furthermore, the additional hardware leads to an increase in power consumption, which is highly undesirable for this application. To solve these problems, a versatile software solution that reliably detects the clock skew and corrects the problem at various operation voltage levels is required.

A Solution to the Problem

In the proposed solution, the rceiver station determines the clock-skew and provides the sensor modules with adequate information to correct the problem. First, the local clock of the receiver station is selected as the master clock of the system because:(1) as the receiver station does not rely on bat-

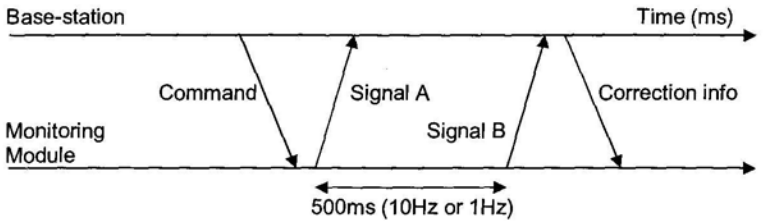

Figure 4.3: Clock correction scheme

tery power, the speed of the oscillator is more steady and so is its clock, (2) the receiver station can use a more accurate, but a higher power consuming 16-bit timer to keep track of the timings; compared to the watchdog timer that is used during the sleep modes of the sensor modules, the 16-bit timer provides higher resolution on timing and has an actual register for accessing the timer counters; the watchdog timer does not have a counter register and only interrupts the system when it times out at predefined intervals, (3) as the clock skew of the sensor modules cannot be predicted, upon measuring the clock differences, the receiver station has to turn on its transceiver for a period of time longer than usual; clearly the battery-operated sensor modules cannot afford to do so. Under this approach, a sensor module is not aware of the actual timing of the system, instead it performs correction of its timings based on the relative difference to the receiver station's clock. At the start of a therapy, the receiver station sends out a command for the estimation of clock skew to a particular sensor module. Upon receiving the command, the sensor module sends out a replying signal (signal A) back to the receiver station. After signal A has been acknowledged by the receiver station, the sensor module goes on to run a complete 500ms measurement cycle with a sampling rate of 10Hz (5 samples during the 500ms period) before sending out a second replying signal (signal B) to the receiver sta-

tion, indicating the end of the cycle. When the sensor module receives an acknowledgment from the receiver station after sending out signal B, it goes into receive mode and waits for incoming information regarding the clock skew. For the receiver station, an internal timer is started upon receiving signal A, and is stopped as soon as signal B from the same sensor module is received. The amount of clock skew is the difference between the time that signal B is received and 500ms. Due to the difference in the duration of sleep between a 10Hz and 1Hz cycle, the estimation process is repeated with the sensor module completing another 500ms cycle at 1Hz.

During the compression therapy, the receiver station will send out a clock-skew estimation command every hour, or whenever it detects more than 5 occurrences of communication errors. A complete operation cycle of a sensor module under the power management scheme can be found in Figure 4.4.

4.6 Summary

In this Chapter, a novel power management scheme was presented to extend the battery life of the sensor modules to meet the requirement of 2 years of shelf life and 3 weeks of usage. It was calculated that the proposed method with an adaptive sampling rate feature, extends the battery life from 21 hours without power management to 13.6 weeks. As the timings of the measurements are predefined under the scheme, the rate of inflation can be reliably calculated. The proposed method also prepares for the introduction of another improvement for the prototype, which will be discussed in the next chapter.

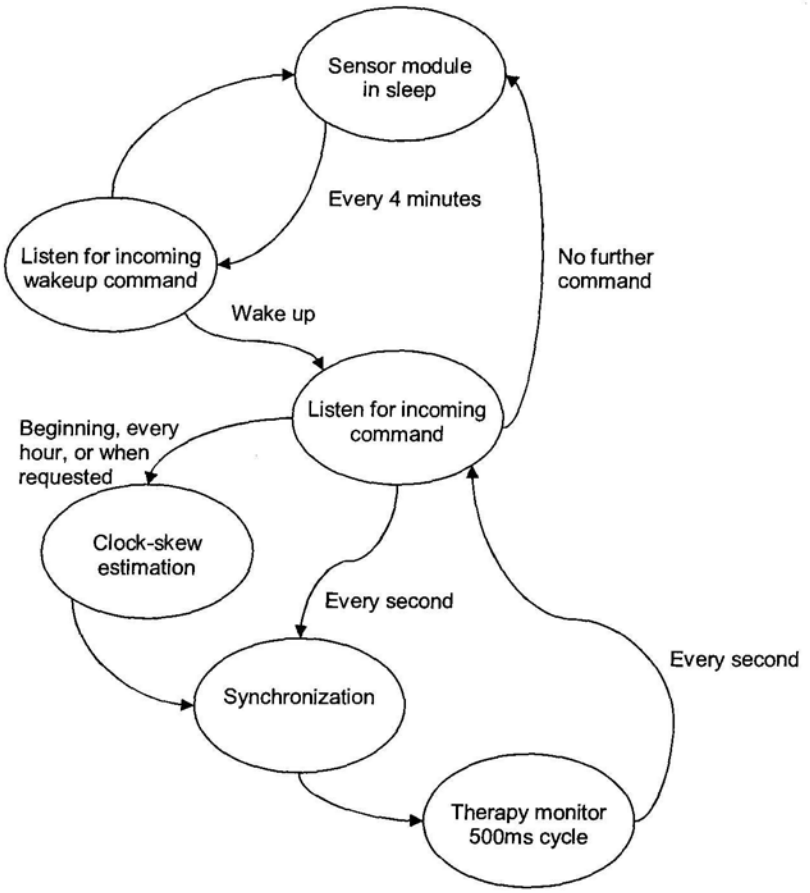

Figure 4.4: Complete operation cycle of a sensor module with power management

Chapter 5

Development of a Novel Usage and Reprocess Indicator for an Improved Prototype

5.1 Objective

According to a private market research report, the sequential compression market for preventing DVT in the United States was estimated to be approximately at least $150 million per year [40]. It was also estimated that a multi-hospital system could save $250,000 to $300,000 annually on sequential compression therapy for the prevention of DVT by reusing the single-use disposable compression sleeves. The Food and Drug Administration (FDA) has classified reprocessed compression sleeves as low risk and non-critical (intended to make topical contact and not penetrate intact skin) devices according to their risk priority scheme (RPS); and this indicates that reprocessed sleeves or multi-use sleeves are generally safe if they are properly reprocessed before each use. The debate on whether or not to reprocess the compression sleeves has been on-going for years between manufacturers

and third-party reprocessing companies, and is out-of-scope of the thesis. However, if the reprocessed compression sleeves are used, some measures will be necessary to monitor the usage and the state of reprocessing of the sleeves so that the quality of the prevention therapy and patients' safety are not compromised. And in fact, the financial benefits in using reprocessed or multi-use compression sleeves can allow further investments in safety and quality control features such as those presented in Chapter 3.

Currently, aside from printed confirmation on the package and labels that showed a change in color when exposed to certain chemicals used for reprocessing, there are no embedded means of determining whether a reprocessed medical device was actually reprocessed [41]. Consequently, this may lead to the following problems that can compromise patients' safety: (1) unauthorized repackaging of used, non-sterilized sleeves, (2) mix-up of new/reprocessed and used compression sleeves - which are often indistinguishable when out of their packages, (3) deterioration of the sleeves from being overly reused or reprocessed, and (4) inappropriate reprocessed.

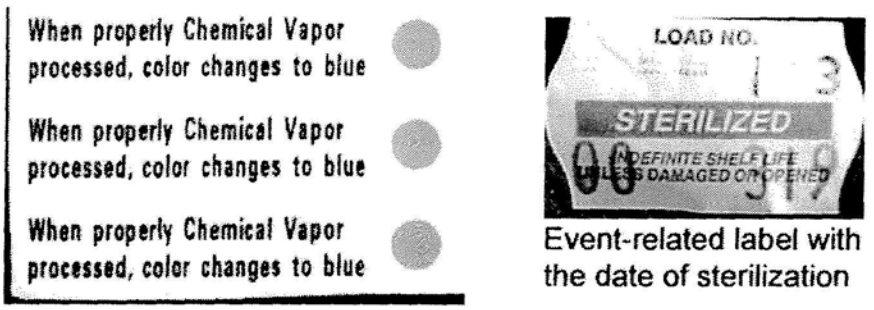

Figure 5.1: Sterilization detector: color changing labels (left) and printed confirmation (right)

This chapter will introduce a novel proof-of-concept usage and reprocessing indicator to solve the above problems, and to lower the average cost per

therapy by allowing safe, limited-reuse of the improved compression sleeves.

5.2 Introduction to Reprocessing Methods for Pneumatic Compression Sleeves

Various methods are available to reprocess medical devices; however, as the non-woven material used on the compression sleeves and hoses are heat-sensitive, high temperature methods such as autoclaving and dry heat are not suitable for reprocessing these sleeves. Instead, Ethylene oxide (EtO), hydrogen plasma (H_2O_2), and gamma radiation sterilization methods are chosen by the medical industry to reprocess the sleeves due to their material compatibility.

5.2.1 Ethylene Oxide

Among the sterilization (or reprocessing) technologies currently available, sterilization by ethylene oxide (EtO) remains as one of the most popular. According to the Association of Medical Device Reprocessors(AMDR), EtO is currently chosen as the method to sterilize compressible limb sleeves due to material compatibility.

EtO was first used as a gaseous sterilant for medical applications by Phillips and Kaye during the late 1940s while they were working at Fort Detrick. In 1950s, McDonald obtained a patent describing processing parameters of a sterilization process using an EtO/chlorofluorocarbon gas blend. The efficiency of EtO was subsequently demonstrated and validated in many sterilization applications for medical devices. EtO has been chosen over other gaseous sterilant due to its lower toxicity, greater diffusion rate, com-

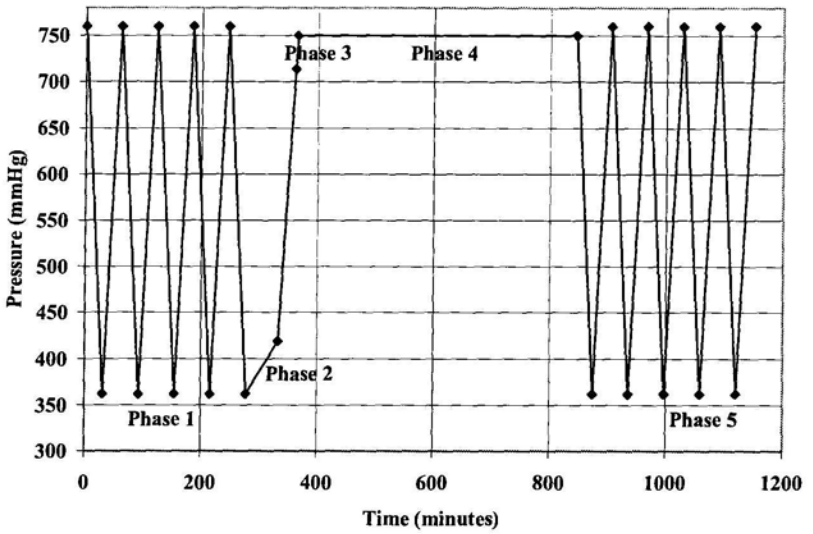

Figure 5.2: A generic (shallow type) EtO steriliation process

patibility with a wide range of packaging and product materials, and efficient microbial inactivation properties.

A generic EtO process can be broken down into five stages: (1) initial evacuation, (2) conditioning and humidification, (3) charging with gaseous sterilant, (4) exposure dwell, and (5) post-cycle sterilant evacuations [41–43]. The gas blend of an EtO process will also determines the level of pressure inside the sterilization chamber as shown in the Figure 5.2.

Initial Evacuation

After the medical device is placed inside the sterilization chamber, the internal chamber space is heated to a temperature range between 37.8 and 60°C. When the target temperature is reached, a partial vacuum is drawn on the loaded vessel to remove residual air which may dilute the sterilant

gas; in the case of flammable sterilant such as 100% EtO, this step will reduce the potential for ignition. Use of 100% EtO generally requires a deep level of vacuum (down to ~100mmHg absolute) to minimize flammability and explosion risks, but a shallow level of vacuum (down to ~350mmHg absolute) is possible if an inert gas such as nitrogen is introduced to displace residual air for the same purpose. Removal of residual air will also lower the air pressure within the medical device and packaging to the same level as the chamber; the created diffusion gradient will act as the molecular driving force for steam and EtO into the device at the later stages. To improve the efficiency of the evacuating residual air, instead of keeping pressure at a static low value, some EtO processes uses pressure pulsing such as the one in Figure 5.2.

Conditioning and Humidification

Following the initial vacuum, water vapor (in the form of low temperature steam), is injected into the chamber to achieve a chamber relative humidity of 40 to 80%. Steam injection is followed by a dwell period to allow the moisture to diffuse into the medical devices being sterilized. Relative humidity is an important factor affecting the effectiveness of microbial inactivation by EtO.

Charging with Gaseous Sterilant

After the humidification period, EtO is introduced into the chamber. EtO is usually heated up before being injected so that the internal temperature will not alter significantly. The pressure at this stage is determined by the gas blend, and the desired EtO operating concentration.

Exposure Dwell

Following the injection of the gas sterilant to a predefined operating pressure, an exposure dwell period is initiated. This allows for diffusion of the sterilant through the medical products for complete sterilization. The dwelling time varies upon factors such as load density, material diffusion properties, sterilant concentration, and temperature. Typically, dwell periods can last from 2 to 12 hours.

Postcycle Sterilant Evacuations

Upon completion of the exposure dwell period, the sterilant gas is evacuated from the chamber using a number of post-vacuum pulses. The evacuation time, again, depends on the same factors as stated above [41–43].

5.2.2 Hydrogen Peroxide Plasma

Hydrogen peroxide was first reported for use in medical device sterilization in 1987. The process uses a combination of hydrogen peroxide vapor and low temperature gas plasma to sterilize medical devices. As the load temperature is maintained at 45^oC to 55^oC, the process is suitable for heat and moist sensitive products. The overall cycle time is around 75 minutes [44, 45].

A Typical Process

After the medical devices are placed inside the sterilization chamber, the internal chamber is evacuated to 0.3mmHg. The duration of this stage is from 5 to 25 minutes. Following initial evacuation, an aqueous solution of hydrogen peroxide is then injected into the chamber raising the pres-

sure in the chamber by 0.01mmHg. The injection of the sterilant typically lasts 6 - 12 minutes. The hydrogen plasma remains in the chamber for another 42minutes to allow the sterilant to come in intimate contact with the items being sterilized. Plasma is then generated at a power level sufficient to achieve sterilization. The power is then kept on for 5 to 50 minutes to complete sterilization, depending on the concentration of the hydrogen peroxide. Finally, the chamber will be vented and return to atmospheric pressure. During the whole process, temperature is maintained at 45°C to 55°C [44, 45].

5.3 Design Criteria

5.3.1 Indication of Usage

Relevant usage information are the parameters that may affect the structural quality of the compression sleeves, and thus the overall effectiveness of the DVT prevention therapy. These parameters include: (1) the number of uses of the compression sleeves,(2) total duration used on patients, (3) number of occurrences of pressure-related problems in the past, and (4) the total sleep time.

A physician can use the usage information to estimate the effectiveness of the therapy on the patient under treatment; and the indicator can adjust the operation of the instrument based on the comparison between these information and a set of predetermined operating limits. For example, if the indicator senses that the compression sleeves have been reprocessed 3 times, which is over the 2-time reprocessing limit (or 3-use limit), the indicator will send out a warning message conveying the information; however as the risk of patients developing DVT without any compression therapy

was significantly higher than that with non-optimal therapies, the usage and reprocessing indicator will only halt or prevent a compression therapy from starting only when the situation poses a high risk to the patient under treatment. One may question that this approach may indeed have harmful consequences if the overly-reprocessed sleeves have pressure-related problems (such as pressure built-up due to material failure); however, if this occurs, the monitoring mechanisms introduced in Chapter 3 can detect the problem and provide adequate warning regarding the situation.

Typically, a surgical patient continues to wear the compression sleeves for 1 week after the surgery. And assuming that compression sleeves can have 3 uses or be reprocessed twice, the proper operating limits of these sleeves will be 3 uses, or 3 weeks maximum.

5.3.2 Indication of Device Reprocessing

A requirement of the reprocessing indicator is to detect whether a pair of used compression sleeves has been reprocessed. The second requirement is to detect the type of the reprocessing method using a robust detection algorithm. The last and the most important requirement, is to use these information to control the compression pump based on the status of the sleeves. Again, the indicator will terminate a compression therapy if non-reprocessed sleeves are detected due to the high risk of cross-contamination.

5.3.3 Power Management

Power management is a critical component of the usage and reprocess indicator. First, power must be conserved to allow uninterrupted detection of reprocessing, and secondly, the proposed operating life should not be af-

fected regardless of the presence of the indicator. In other words, with this new module, the prototype must last long enough to stay on shelf for two years before providing 3 uses, and reliably detect reprocessing in between. The average wait between a pair of compression sleeves is used and reprocessed is approximately 1.5 month, and thus a 3 month waiting period is included in the calculation of power consumption.

5.4 Implementation

5.4.1 Usage Indicator

As a compression therapy may be temporarily paused during the transportation of surgical patients from the operating room to the ward, a reasonable definition of a use in this context is: (1) a therapy duration of longer than 20mins, and (2) when a pause in the therapy is longer than 10 minutes. When the user pressed the button "stop" on the user application, the receiver station starts an internal stopwatch, counting down from 10 minutes. If the therapy is restarted before time is up, the stopwatch is reset and the status of use of the compression sleeves will not be altered. However, if the therapy is not restarted in 10 minutes, the status of the compression sleeves will be changed from "new" or "reprocessed" to "used". Users will not be able to start or restart a therapy with a pair of compression sleeves marked as "used".

The memory for storing the total usage time on a sensor module is designed to update every second, after the completion of a communication cycle. And during which, the sensor module also updates its internal counter for pressure-related problems. The total sleep time is updated every 4 minutes when the sensor modules are waken up from the sleep mode.

5.4.2 Reprocess Indicator

5.4.2.1 Sampling Rate

The evacuation stages of an EtO process are shorter than the gas dwell stage, and have more variation in pressure and temperature. Moreover, the pulsing of pressure in the evacuation stages of an advanced EtO process makes it more difficult to detect the start of such processes. As a result, the selection of the sampling interval will be based on the evacuation stages, rather than the gas dwell stage. Also as pressure varies more intensively than temperature in a reprocessing procedure, pressure variation will have more weight on the selection of the sampling rate. Generally, a H_2O_2 process keeps its pressure at a more constant level, therefore the focus is put on EtO processes.

The implementation of the reprocess indicator starts with a careful selection of the sampling interval, so that the "appropriate" pressure of the evacuation cycle is captured for identifying the type of the reprocessing method. The pulsing period of an evacuation cycle can be as short as 20 minutes for an EtO process, and thus a proper sampling interval should be less than 10 minutes. For this thesis, the sampling interval is set to 8 minutes, which is twice the wakeup interval of the prototype in the sleep mode, to minimize power consumption in between wake-ups. More details on the analysis of power consumption are presented in Section 5.4.2.4.

5.4.2.2 Reprocessing Detection Algorithms

A deep vacuum EtO, shallow vacuum EtO, and a H_2O_2 plasma process have similar stages, but the pressure and temperature values at various stages are very distinctive.

The initial evacuation stage of an EtO and H_2O_2 sterilization process is characterized by a decrease in pressure and an elevation in temperature. At each scheduled wakeup, the reprocess indicator compares the current pressure and temperature readings to the predefined detection thresholds. If both the sampled pressure (P_{samp}) and temperature (T_{samp}) are within the detection threshold for 2 consecutive readings, which is equivalent to 16 minutes with an 8 minute sampling interval, the detection algorithm will declare that the initial evacuation stage has started.

The vacuum levels of a shallow type EtO, deep type EtO, and a H_2O_2 sterilization process are approximately 350, 100, 10mmHg respectively. The temperature may range from 37.8 to 60°C for an EtO process, and 45 to 55°C for a H_2O_2. Based on these information, a reliable decision condition for pressure and temperature is set at $P_{samp} \leq 450$mmHg and $T_{samp} \geq 30°C$, and the pseudocode for detecting the initial evacuation cycle is shown below:

Algorithm 3 Detection of the initial evacuation cycle

```
1: Acquire P_samp and T_samp
2: P_min ← 1000mmHg at the beginning of the reprocessing mode
3: if (P_samp ≤ P_L) ∧ (T_samp ≥ T_L) then
4:     Increment evacuation counter (C_evac)
5:     if (C_evac > 2) ∧ (¬ Gas contact occurred) then
6:         Initial evacuation occurred
7:     end if
8:     if P_samp ≤ P_min then
9:         P_min ← P_samp
10:    end if
11: end if
```

This distinctive pattern of pressure and temperature cannot be triggered by air transportation because the cabin pressure was often kept at 565mmHg

- a pressure level equivalent to 8000ft, and even if not, the temperature would not be as high as 35^{o}C at that altitude.

After the evacuation and nitrogen purge phase, pressure gradually increased. In this phase, the pressure can range from 488mmHg to 1atm depending on the gas blend, and the temperature would further increase by another 5^{o}C due to steam and EtO injection. As the shortest gas contact phase is approximately 2 hours, therefore if the indicator has previously detected the presence of the initial evacuation stage, and that the sampled pressure and temperature are above 487mmHg and 40^{o}C for 14 consecutive indicator cycles (equivalent to 112 minutes) , then it can be concluded that gas contact phase has occurred. As the pressure variation pattern for an H_2O_2 process is quite different, more details on its detection will be given at the end of the current section. The pseudocode for detecting this phase is shown below.

Algorithm 4 Detection of the gas contact phase

```
1: Acquire P_samp and T_samp
2: if (P_samp ≤ P_H) ∧ (T_samp ≥ T_H) then
3:     Increment gas contact counter (C_gcontact)
4: end if
5: if (C_gcontact > 14) ∧ (Initial evacuation occurred) then
6:     Gas contact occurred
7: end if
```

At the end of the reprocessing, pressure and temperature was reduced due to post-cycle evacuation. As pulsing may be present as in the initial evacuation cycle, a reliable detection condition is again P_{samp} <= 450 mmHg (P_L) and T_{samp} >= 30^{o}C (T_L). Two consecutive measurements of pressure and temperature that pass the above criteria indicate the completion of reprocessing of the device and thus the indicator can change the

status of the device from "used" to "reprocessed". Finally, the indicator determines the type of the reprocessing method based on the minimum sampled pressure (P_{min}). The pseudocode for detecting the post-cycle evacuation and reprocessing type is actually an modified version of the algorithm for detecting initial evacuation:

Algorithm 5 Detection of the initial and post-evacuation cycle

```
1: Acquire P_samp and T_samp
2: P_min ← 1000mmHg at the beginning of the reprocessing mode
3: if (P_samp ≤ P_L) ∧ (T_samp ≥ T_L) then
4:     Increment evacuation counter (C_evac)
5:     if P_samp ≤ P_min then
6:         P_min ← P_samp
7:     end if
8:     if (C_evac > 2) ∧ (¬ Gas contact occurred) then
9:         Initial evacuation occurred
10:        if P_min < 100mmHg then
11:            Medical Device is reprocessed by H2O2
12:            Goto normal listen mode
13:        end if
14:    else if (C_evac > 2) ∧ (Gas contact occurred) then
15:        Medical Device is reprocessed
16:        if P_min ∈ (100, 350)mmHg then
17:            Reprocessed by deep vacuum EtO
18:        else if P_min ∈ (350, 450)mmHg then
19:            Reprocessed by shallow vacuum EtO
20:        end if
21:        Goto normal listen mode
22:    end if
23: end if
```

To prevent false detection, if the sampled pressure is detected to be high continuously for an unreasonable period of time, the detection algorithm will reset all counters and flags to their default values. The reset limits for low and high pressure readings are 360 minutes and 900 minutes due to the

fact that all phases in an EtO or H_2O_2 processes are shorter than the above durations.

Algorithm 6 Prevention of false detection

1: **if** $(C_{evac} > 45) \vee (C_{gcontact} > 113)$ **then**
2: $C_{evac} \leftarrow 0$
3: $C_{gcontact} \leftarrow 0$
4: Initial Evacuation $\leftarrow$ FALSE
5: Gas contact $\leftarrow$ FALSE
6: Post-cycle Evacuation $\leftarrow$ FALSE
7: **end if**

The complete flowchart of the detection algorithm is shown in Figure 5.4 and Figure 5.5 at the end of the chapter. The current design of the reprocessing indicator, has several advantages over a previous design [46]: (1) the current design allows the detection of multiple reprocessing methods through the monitoring of variation pattern of both pressure and temperature, whereas in the previous design, the use of temperature fuse limits its ability to differentiate between reprocessing types, (2) the current reprocessing indicator can be reused multiple times; in contrast, the temperature fuse must be replaced after each use, and (3) the current reprocessing indicator is easily re-programmable, but the old design requires a fuse-change for detecting different reprocessing methods. For more details on the previous design, please go to Appendix A.

5.4.2.3 A New Mode of Operation

The indicator provided a new mode of operation to the prototype - the reprocessing detection mode. After each use, a sensor module automatically goes into this mode, and alter the status of reprocessing of the sleeves based on the results from the detection algorithm introduced in the previous

section.

In this mode, the indicator is scheduled to wakeup at two occasions: (1) measurement of pressure and temperature, and (2) monitor for incoming signal from the receiver station. The purpose of (1) obviously is to provide data to the detection algorithm for analyzing the status of reprocessing, and (2) is to allow the indicator to communicate with the receiver station in the reprocessing mode. The latter situation can arise when an user attempts to use a pair of used but non-reprocessed sleeves. A complete 8-minute cycle of the reprocessing mode was illustrated in Figure 5.3.

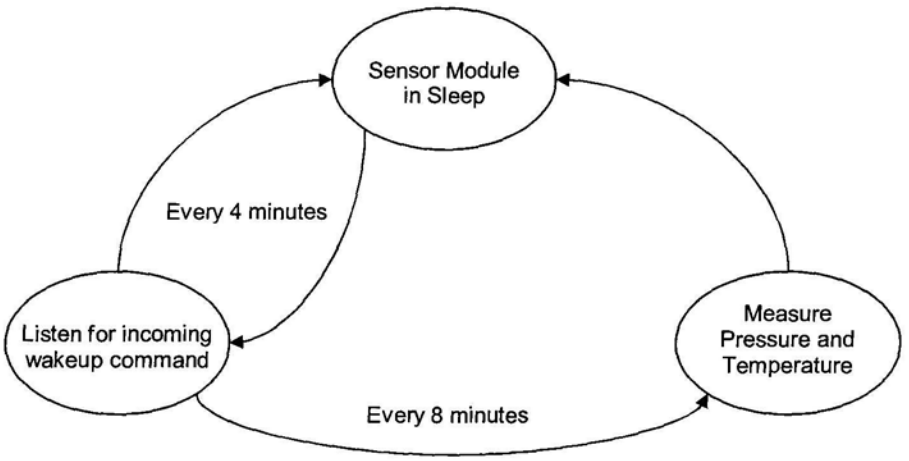

Figure 5.3: A complete 8-minute cycle of the reprocessing mode

The aforementioned functions of the indicator requires a reliable power source, and as a receiver station is not always available within a reprocess chamber, this is another major reason why a battery is used instead of relying on passive inductive coupling power transfer.

5.4.2.4 Power Management

The power consumption of the reprocess indicator is minimized by controlling the current draw in each phase of the reprocessing mode. The power management scheme is identical to the one for the sleep mode, except that a measurement of pressure and temperature is carried out every 8 minutes.

Following the same methods introduced in the last chapter, the current consumption and duration of each phase of the reprocessing mode is summarized in Table 5.1.

Components	**Mode**	**Current(mA)**	**Duration(ms)**	**I*t**
MCU	Active(1MHz)	0.4	1	0.4
	Idle	0.07	63	4.41
	Powerdown	0.0038	239936	911.8
Transceiver	Transmit	11.3	0	0.0
	Receive	11.8	64	755.2
Transducer	Active	1.005	2*0.5	1.0
	Standby	0.006	33*0.5	0.1
			$\sum_{i=0}^{2}\sum_{j=0}^{n} I*t$	1672.9
			t_{total}	240000ms
			I_{avg}	7μA
			Energy consumed	61mAh/yr

Table 5.1: Average current draw of the sensor module in reprocessing mode

Assuming that the overall delay between each use of the compression sleeves is 2 months, and the overall on-shelf duration is 2 years, the power consumption is: 61mAh/year $*$ 2.25year $=$ 137.3mAh. Recalling that the average current drain of the prototype with the adaptive sampling rate feature is 0.08mA, the remaining operating life is then $\frac{(175-137.3)\text{mAh}}{0.08\text{mA}}$, which is equal to 3.4 weeks. Therefore, the requirement set earlier is still met.

5.5 Summary

In this chapter, a novel usage and reprocess indicator for the wireless monitoring system prototype was presented. The indicator improved the overall reliability and safety of the compression therapy by providing usage related information and preventing non-reprocessed sleeves from being used. In addition, the feasibility of a practical deployment of the prototype was significantly improved through the safe reuse of the disposable compression sleeves.

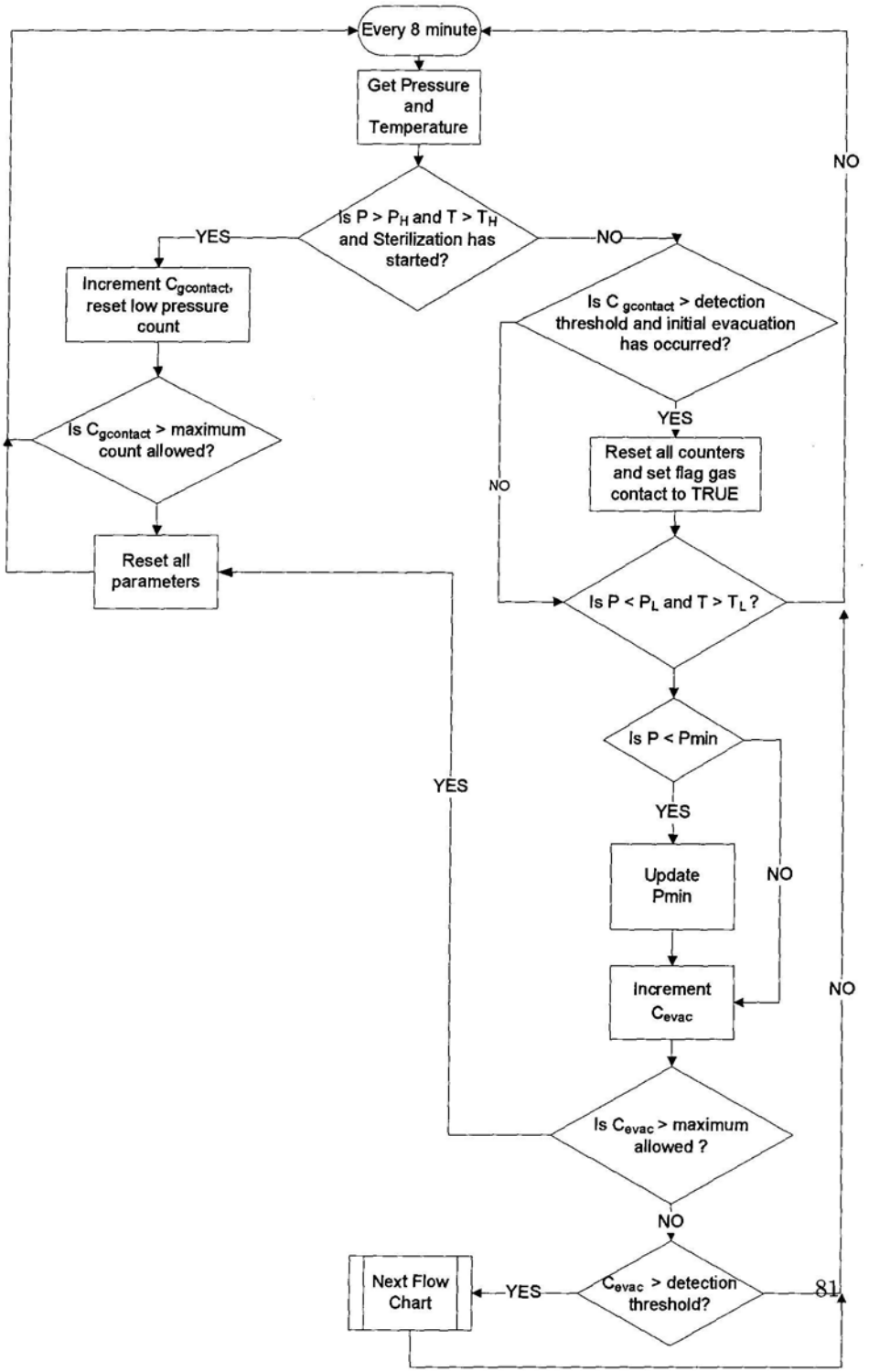

Figure 5.4: Reprocessing indicator detection algorithm - Part I

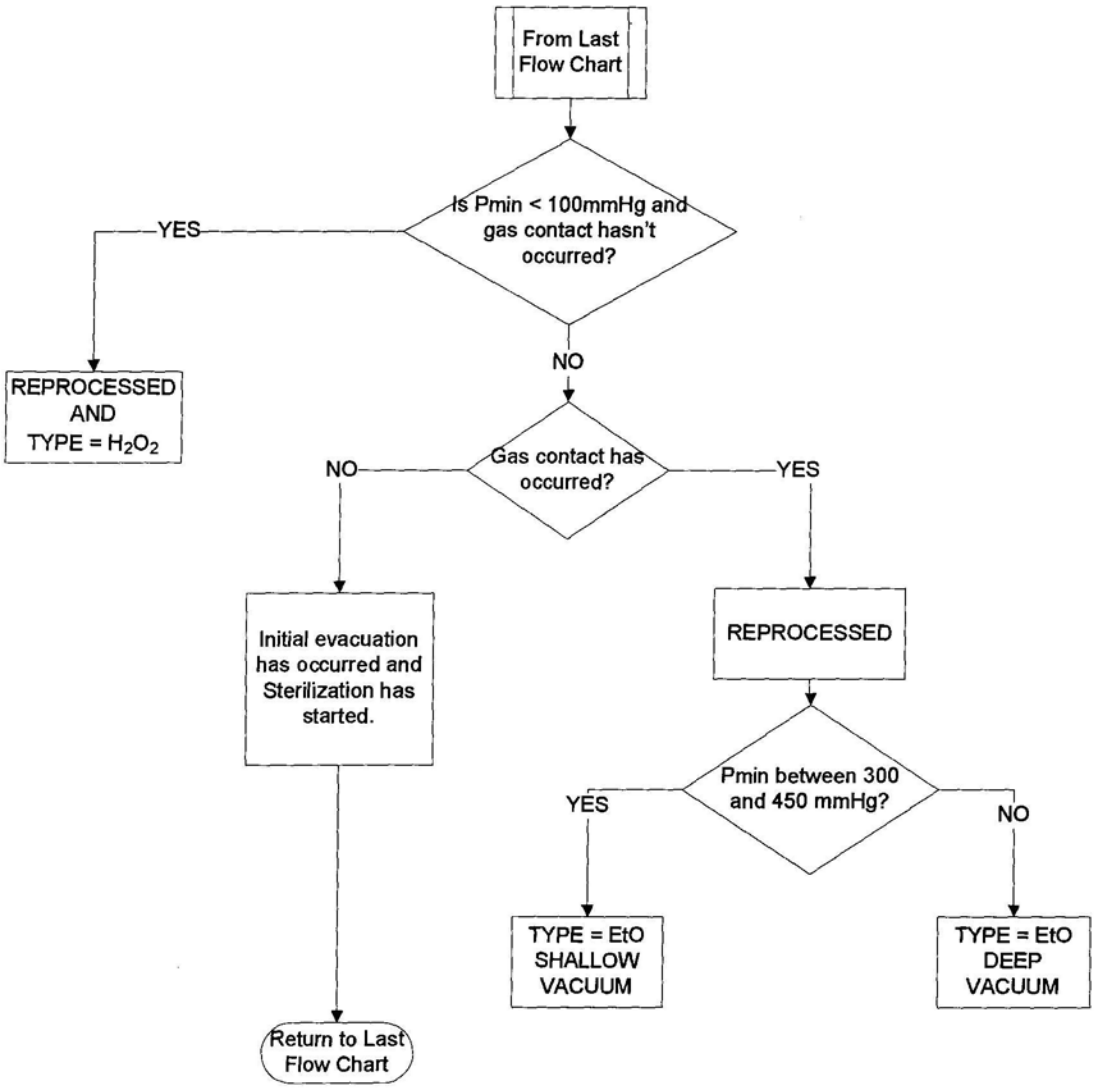

Figure 5.5: Reprocessing indicator detection algorithm - Part II

Chapter 6

Initial Evaluation of the Improved Prototype

6.1 Objective

The features and improvements proposed in previous chapters must be tested thoroughly to ensure a high reliability of the complete monitoring system. In this chapter, the evaluation methods and results of different components are presented.

6.2 Evaluation of Self-Monitoring Functions

6.2.1 Wireless Communication

For evaluation of the performance of wireless communication, the receiver station and a sensor module was put into normal therapy monitoring mode, with the sampling rate fixed at 10Hz. The maximum distance for reliable operation, defined as the distance when no unrecoverable wireless communication occurred within an hour, was observed to be further than 3 meters when the sensor module was placed on a non-conducting trolley; when the sensor module was placed near a human body, the distance varied with different body positions and locations of the module, and was decreased

to 1 meter (separation between the antenna and the human body was less than 1 centimeter). It was also observed that the reliable communication distance increased as the sensor module was moved away from the human body. For the current application, the receiver station is placed at the connector between the compression sleeves and the instrument (the connector is shown on Figure 6.8), and the separation between the furthest sensor module in the thigh chamber and the receiver is less than 1m. The measured distance for reliable operation is thus acceptable for the application; however it is expected that an antenna optimized for body-worn applications could significantly improve the maximum operable distance.

For evaluation on the emission power, the testing for compliance to the RSS-210 and FCC 15.247 emission regulations must be carried out in an anechoic chamber at an Industry Canada or FCC certified test center. Testing for compliance with these standards is critical to the commercialization of the proposed prototype, but is not very feasible within the scope of the project. However, it seems reasonable to assume that the emitted power of the prototype is less than 0dBm. The reasoning is based on the following facts: (1) the maximum configurable output power of the transceiver is 0dBm, and (2) as the printed antenna is not optimized, it is highly probable that its gain is much less than 0dBi. As a result, the effective isotropic radiated power (EIRP) of the system, which is the sum of the antenna gain and the transceiver output power, is expected to be less than 0dBm.

6.2.2 Sensing of Pressure and Temperature

Method

Each sensor module was evaluated individually on the accuracy of pressure and temperature measurement. A sensor module was placed inside a pressure chamber connected to a compressed gas source (Figure 6.1), and a separate relative pressure transducer accurate to ±0.1mmHg was used for providing a calibrated reference on the chamber pressure (actual pressure). The module-under-test was configured to sample the chamber pressure at a fixed sampling rate of 10Hz, and wirelessly transmit the data to a nearby receiver station outside the pressure chamber, where the acquired pressure

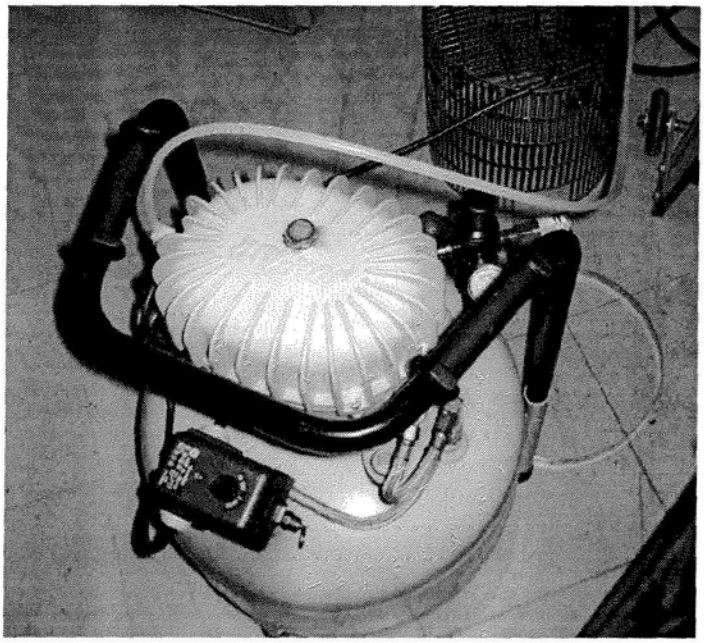

Figure 6.1: A compressed gas source

was subtracted from the atmospheric pressure (reference pressure) to obtain

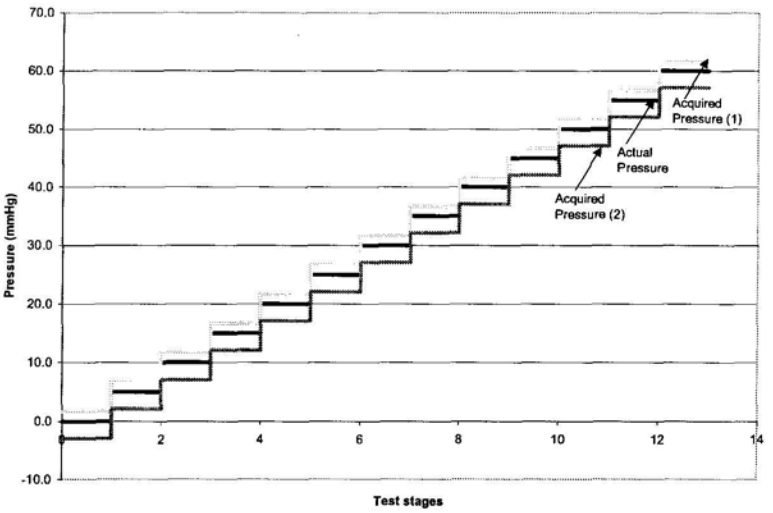

Figure 6.2: Test results of evaluation of sensor module accuracy (two sets of data shown)

a relative pressure reading. The chamber pressure was increased step-wise from 0mmHg to 60mmHg, at 5 mmHg per step; the acquired pressure from the sensor module was compared to the actual pressure at each step.

Results and Discussion

The results from an initial evaluation showed a large discrepancy between the actual and acquired pressure. The maximum discrepancy was observed to be ±3mmHg. As the measured chamber pressure was observed to have shifted uniformly away from the actual pressure, this indicated that the discrepancy was caused by zero offsets among the transducers on the receiver station and the sensor modules. Upon further investigations, it was discovered that the six calibration coefficients allow the calculation of temperature compensated pressure, but these coefficients do not provide any information related to zero offset.

A solution was developed to include the zero offset error (within 0.1mmHg) in the calculation of relative pressure within the sleeve chambers; recall that to counter the clock-skew problem, the receiver station estimates the clock skew of the sensor modules by having the latter run two complete measurement cycles at 1Hz and 10Hz before the start of the therapy. Ideally, if there is no offset problem, the pressure reading obtained during these cycles should be equal to the reference pressure because the sleeves are in a deflated state; practically, a difference exists and is caused by the zero offset of the particular transducers. Therefore, the firmware was modified to store the zero offsets of the sensor modules on the receiver station for the calculation of zero-offset compensated pressure.

The above testing procedures were repeated for all sensor modules, and with the new firmware in place, there was no observable discrepancy between the measured and actual pressure.

6.2.3 Detection of Potential Problems

6.2.3.1 Methods

Therapy related problems

One of the main features of the monitoring system is its ability to detect potential therapy related problems. Having tested the performance of the wireless communication and the accuracy of the transducers, the reliability of the detection algorithms for problems that may happen during a compression therapy was tested with the same equipment as above. Pressure in the chamber was variated to simulate the therapy-related problems and the response of the monitoring system was observed. The simulation conditions are listed in Table 6.1.

Tests	Pressure Variation
Under-pressurization	40mmHg, ankle 35mmHg, calf 22mmHg, thigh $\leq$-5% of max pressure
Over-pressurization	50mmHg, ankle 45mmHg, calf 32mmHg, thigh $\geq$+5% of max pressure
No inflation	0mmHg, $\geq$60 seconds
Sustained high pressure	10mmHg,$\geq$ 11 seconds

Table 6.1: Test conditions of the evaluation of detection for potential problems

For evaluating the detection of a corrupted sequence of inflation, the sensor modules of the same sleeves were tested as a group. For demonstration purposes, the sensor modules at the ankle, calf, and thigh chambers are named as RS1, RS2, and RS3 respectively in this section, and the details of the testing conditions used in the evaluation are presented in Table 6.2.

Sensor Module	Testing procedures
RS1	(1)Increase pressure on RS2 and RS3 (2)Increase pressure on RS1
RS2	(1)Increase pressure on RS3 (2)Increase pressure on RS2
RS3	(1)No pressure increase on RS1 and RS2 (2)Increase pressure on RS3

Table 6.2: Testing procedures for corrupted sequence of inflation

For evaluating the detection of temperature abnormalities, each of the sensor modules was placed in turn under a volunteer's limb in a lying position. The measured temperature of a sensor module under the limb was expected to be higher than the other modules in the same group; the setup

simulates conditions where a patient develops a local increase in skin temperature or when an inappropriate application of the sleeves has occurred (in an appropriate application of the sleeves, the patient's limb is not rested on the module).

Wireless communication problems

Other than therapy related problems, wireless communication problems may also exist. The recovery measures of the prototype in response to loss of communication due to clock-skew or synchronization problems, and due to external interference were evaluated. To simulate the first type of communication problem, a sensor module and the receiver station were first brought to normal operation, then the power supply of the sensor module was cut-off for a short period of time. The second type of communication problem was simulated by first configuring the communication power of the system at a lower level, -5dBm for example, followed by moving a sensor modules away from the receiver station to a separation where the output power was too low for a reliable operation. The procedure was repeated different sensor modules, and the responses of the monitoring system was recorded.

Battery supply problems

To simulate battery supply problems, batteries of 3V (new), 2.8V (after a period pulsing drain), 2.5V (50mAh remaining), 2.1V (approaching the end of life) were used. First, a sensor module with a RS-232 interface was programmed with the battery voltage sensing algorithm and was configured to report the battery voltage every second; the measured voltage was

compared with the one measured by a digital multimeter to evaluate the accuracy of the voltage sensing algorithm. Second, the sensor modules and the receiver station were put into normal operation during the evaluation, and the system response was observed at different battery voltage levels.

6.2.3.2 Results and Discussion

Therapy related parameters

Under the simulation conditions, the monitoring system was observed to be able to detect and identify therapy related problems, and provide the appropriate warning messages upon detection.

Wireless communication problems

The auto-recovery mechanism of the system in response to the simulation conditions for loss of communication due to clock-skew and synchronization was observed to be the following: (1) when the battery supply of the module-under-test was removed, the receiver station was unable to transmit synchronization information to the module, and the system reported a synchronization error, (2) when the battery supply remained unplugged, more synchronization errors were reported, (3) when more than 5 synchronization errors were detected, the receiver station was observed to exit the therapy monitoring mode, and changed to the clock-skew estimation mode, (4) when the battery supply was plugged back to the sensor module, clock-skew estimation was able to proceed, (5) after the clock-skew estimation was completed, the receiver station went back to a normal therapy monitoring after synchronizing with the sensor modules, and (6) the system was observed to run without problems after the simulation.

The auto-recovery mechanism in response to the simulation conditions for loss of communication due to external interference was observed to be the following: (1) when the sensor modules are moved away until the receiver station was unable to transmit synchronization information to the module, and the system reported a synchronization error, (2) when more than 5 synchronization errors were detected, the receiver station was observed to exit the therapy monitoring mode, and change to clock-skew estimation, (3) after 5 clock-skew estimations failed, the receiver station increased the output power to 0dBm, (4) the receiver station was observed to successfully wakeup the sensor module, and went back to normal operation after clock-skew estimation and the synchronization procedures, and (5) the system was observed to run without problems after the simulation.

Battery supply problems

The prototype successfully detected different levels of battery voltages; however, during the test, unrecoverable wireless communication problems were observed when a 2.5V battery was used. The transducer was not observed to have any problem at that voltage level. After investigation, the source of the problem was found.

Recalling that the operating voltages of the MCU, transceiver, and the transducer are 1.8 to 5.5V, 1.9 to 3.6V and 2.2 to 3.6V, it may appear that the transducer will be the first component to stop operating due to the decrease in battery voltage, but the was not the case. Let us consider the voltage and internal resistance of a CR2032 battery from Energizer (Missouri, U.S.) in Figure 6.3 [47]. When there is a pulse drain of current, the battery voltage temporarily drops. As the transceiver and the microcon-

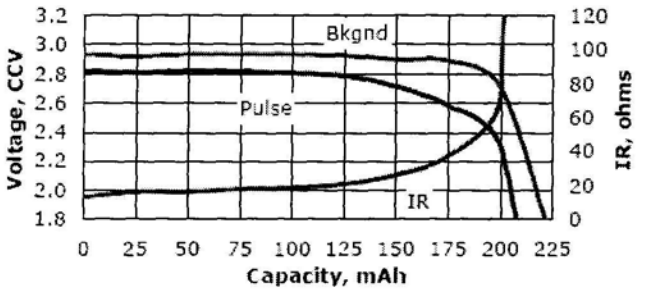

Figure 6.3: The voltage and internal resistance characteristics of a CR2032 battery, CCV: closed circuit voltage, IR: internal resistance

troller drain 11.8mA and 0.07mA of current in the receive mode, and the transceiver stops working at 1.9V, the closed circuit battery voltage that is too low for the transceiver to operate normally can be calculated using:

$$\begin{aligned} V_{batt\ min} &= 1.9V + V_{drop} \\ &= 1.9V + I_{drain} * R_{internal} \\ &= 1.9V + (0.0119 * 50)V \\ &= 2.5V \end{aligned}$$

The internal resistance of the CR2032 battery at 2.5V is approximately 50Ω, which leads to a temporary voltage drop of 0.6V to 1.9V; and as the current drain of the MCU and the transducer is much lower than that of the transceiver, the voltage drop will be much less than 0.6V at 2.5V. Therefore, at 2.5V, the transceiver will stop working due to its current drain, and the transducer will remain operable. This agrees with the observation above.

An appropriate detection threshold was thus 2.5V. After the modification, the monitoring system was observed to provide appropriate warning messages at 2.5V, and prevented unrecoverable communication problems

from occurring.

6.3 Evaluation of Power Management Scheme

Method

As power consumption was a function of current drain and draining time, the evaluation of the power management scheme includes the measurement of: (1)the current drain of the sensor modules in sleep mode and different phases in monitoring mode, (2)the duration of the transmission and reception phase (3)the performance of the clock-skew correction and synchronization algorithms, and (4)the reliability of the rapid inflation detection algorithm.

For (1), a digital multimeter was connected in series between the battery and the power rail of a sensor module to measure the current drain; the sensor module under test was programmed into: (a) continuous transmission mode for measuring current drain in the transmission phase, (b)receive mode for measuring current drain in the command-listening phase, (c)deep sleep power reduction mode for measuring sleeping current drain, and (d)continuous pressure or temperature sampling mode to measure current drain in the data acquisition phase.

For (2), the battery on a sensor module was replaced by a DC supply; a resistor of 1kΩ was connected in series between the supply and the power rail of the sensor modules. The two ends of the resistor were connected to a differential amplifier on an oscilloscope. After the transceiver was programmed into continuous transmission or receive mode, the active time ("on-time") of the transceiver was observed on the oscilloscope as the time between a rise and drop in voltage. The testing was focused on the transceiver because the

current drain was the main contributor to the overall power consumption.

For (3), the sensor modules and the receiver station were put into normal operation, and the system time was recorded when a sensor module reports the pressure and temperature data, which was then compared to the proposed timing of the communication slot of that particular sensor module. The sensor modules and the receiver station were placed 10cm apart to prevent communication problems due to attenuated RF transmission power and the effects of external interference.

For (4), the algorithm was evaluated with two sensor modules at a time; one was put into normal operation (with dynamic sampling rate adaptation), and the other was programmed to sample at a fixed 10Hz. The calculated rate of inflation was then compared to the manually calculated inflation rate based on the data from the latter.

Results and Discussions

The calculated and measured current drain are listed in Table 6.3. The measured results matched closely to the ones obtained from the specification sheets. The on-off timings of the transceiver also matched with the designed values. Based on these findings, it can be reasonably assumed that the calculations presented in Chapter 4 were valid.

Recall that each sensor module has a 10ms dedicated communication slot for the transmission of data to the receiver station, and the sensor modules are configured by the receiver station to start a communication half way through the slot. For example, a sensor module "n" (n goes from 0 to 5) was configured to start communicating at (505 + 10n) ms , and its communication slot goes from (500 + 10n) to (510 + 10n)ms of a monitoring

	Current Drain(mA)	
Mode	**Calculated**	**Measured Average**
Sleep	0.0038	0.0037
MCU active	0.4	0.39
Continuous transmission	11.3	11.3
Receive Mode	11.8	11.8
Data acquisition	1.0	1.0

Table 6.3: Measurement of current drain in different modes

cycle. With the clock-skew and synchronization algorithms installed, the sensor modules were observed to communicate in their own communication slot in a timely manner, meeting the mid-point of a communication slot with a maximum discrepancy of $\pm$2ms.

The initial evaluation of the rapid inflation detection algorithm revealed a problem. Although the detection algorithm responded quickly to the pressure rise and successfully captured a rate, the sampling rate was changed from 10Hz to 1Hz prematurely, which results in a wrong detection of the maximum delivered pressure.

Ideally, the sleeve chambers inflate at a rate specified by the manufacturer and stop immediately when the maximum pressure was reached; practically, approaching the end of the pressure rise, the rate of inflation gradually falls off until the maximum pressure is reached. The decrease in the rate of pressure rise caused the detection algorithm to calculate that a maximum pressure was reached. To overcome this initial problem, a new algorithm was developed so that the sampling rate was changed from 10Hz to 1Hz only when the pressure rise was less than 0.5mmHg (the minimum detectable pressure including error) over the past 0.5s. The pseudocode of the new algorithm was:

Algorithm 7 Detection of the completion of the rapid inflation period

```
1: Acquire P_new
2: Run at every sampling period
3: if (P_new − P_old) ≥ P_thresh end then
4:     Increment counter
5: else
6:     Reset counter
7: end if
8: if counter ≥ 5 then
9:     Inflating period has completed
10:    Sampling rate ← 1Hz
11: end if
```

With the new algorithm in place, a reliable detection of the end of a rapid inflation period and the maximum delivered pressure was observed.

6.4 Evaluation of Usage and Reprocess Indicator

6.4.1 Usage Indicator

The usage indicator was first tested on its accuracy of capturing the total therapy time and total sleep time. The sensor modules and receiver station was first put into normal operation for 2 hours, and the recorded and actual total therapy time were compared. The sensor modules were then put into sleep mode and were wakened up after another 2 hours, before comparing the actual and recorded total sleep time. Under these conditions, the usage indicator was observed to record the total therapy time accurate to the closest second, and the total sleep time was accurate to the closest 4 minutes. The discrepancy was due to the software structure; in the therapy monitoring mode, the memory for storing the total therapy time is updated every second (every cycle), and and the memory for storing the total sleep

time is updated every 4 minutes in sleep mode, when the sensor modules wake up to monitor a start command.

The response of the prototype to a pair of used but not reprocessed sleeves was then examined. After the memory for storing the overall therapy duration was erased, the prototype was put into the therapy monitoring mode for 20 minutes, stopped and restarted after 5 minutes; then the prototype was stopped again for over 10 minutes and restarted. The 20-minute spent in normal operation was expected to change the status of the sleeves from "new" to "used but not reprocessed". The first start-stop sequence was to test whether the prototype allows a restart from a temporary pause of the therapy, which was defined to be a paused less than 10 minutes, and the second start-stop sequence was to test whether the prototype prohibits a restart from a permanent termination, which was defined as a pause longer than 10 minutes.

The usage indicator under the simulation performed as expected; it prevented the therapy from starting after the pause longer than 10 minutes, and allowed a restart after a temporary pause.

6.4.2 Reprocess Indicator

6.4.2.1 Simulated Reprocessing Environment

Before carrying out the evaluation in an actual EtO chamber, the reprocess indicator was tested in a simulated environment. A sensor module was placed inside a vacuum chamber as shown in Figure 6.4. The vacuum chamber simulated different levels of vacuum encountered in reprocessing, and a heat source was used to simulate the temperature rise during the reprocessing of the sleeves.The simulation conditions are shown in Table 6.4.

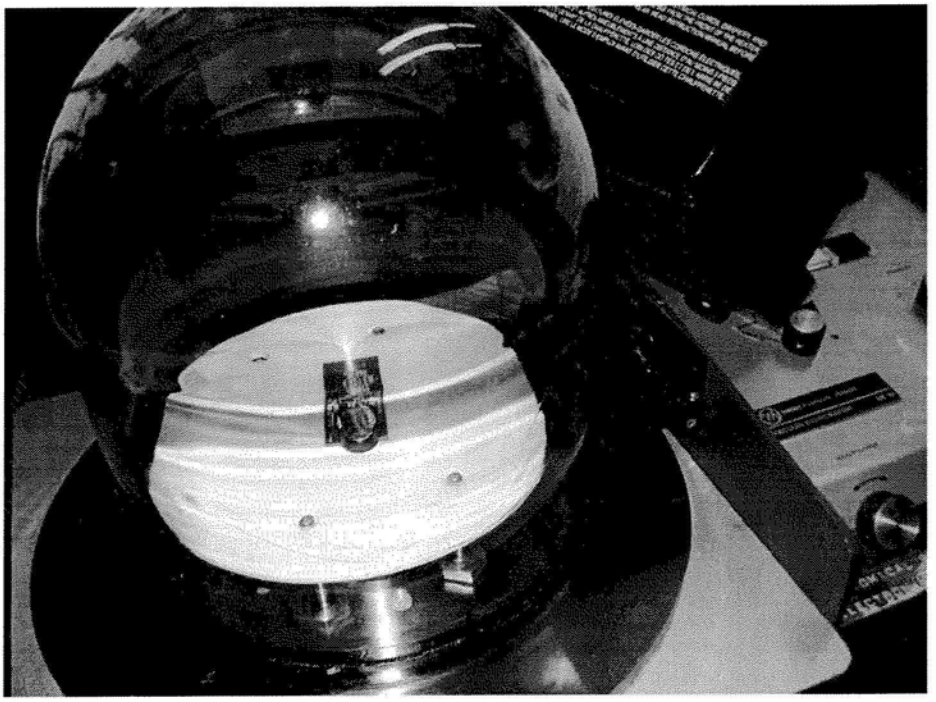

Figure 6.4: Simulated reprocess environment: a sensor module (middle) was placed in a vacuum chamber (glass jar) with a heat source(top right, black)

Several non-reprocess related patterns were also used to test whether the indicator will give a false detection: (1) A drop in pressure accompanied by a stationary or decreased temperature; this condition was to simulate a situation that may happen in a non-pressurized air cabin, (2) a normal EtO pressure pulsing pattern that lasts longer than the maximum allowed duration (temperature set at 30^oC), and (3) a correct pressure pulsing pattern, followed by a high pressure period (close to 1atm) that lasts too long (temperature set at 40^oC). For tests (2) and (3), the maximum allowed duration was temporarily reduced from 360 and 900 minutes respectively to 60 and 120 minutes to accelerate the testing process.

Process Type	Simulation Conditions		
	Pre-evacuation	Gas contact	Post-evacuation
EtO	30 minutes of pressure pulsing (370↔750mmHg), temperature≥35°C	300 minutes of pressure at 750 ±10mmHg, temperature≥40°C	30 minutes of pressure pulsing (370↔750mmHg), temperature≥35°C
Deep Vacuum EtO	Minimum pressure: 110mmHg		
Shallow Vacuum EtO	Minimum pressure: 370mmHg		
H_2O_2	Minimum pressure: 20mmHg Temperature: 30°C for 30 minutes		

Table 6.4: Simulation conditions of different reprocessing procedures

Under these simulation conditions, the reprocess indicator was shown to be able to detect and identify the type of reprocessing methods. It was also observed that the internal counters were reset after a pulsing pattern or high pressure was continuously detected over the maximum allowed duration.

6.4.2.2 EtO Process in Vancouver General Hospital

According to Graham Wickham of the Biomedical Engineering Department at Vancouver General Hospital (VGH), the EtO process in VGH consists of the following steps: (1) vacuum cycle (103mmHg or 2.0 psia) for about 20 minutes, (2) steam and EtO injected into chamber, temperature controlled to 55 degrees C, held for 2 hours, (3) exhaust, a 12 hour process, comprising vacuum cycles to 103mmHg absolute, followed by 20 minutes aeration, then repeat. Based on the definition above, the process is a deep vacuum type EtO process.

Two sensor modules were programmed with identical reprocess detection software and a status of sterility of "used (but not reprocessed)", and were

packed in a plastic box and a sterilization bag before being sent to the Sterile Supply Department at VGH (Figure 6.5). The reprocess indicator on both sensor modules successfully detected the presence and the type of the reprocessing method, deep vacuum type EtO process, and the status of sterility was changed from "used" to "reprocessed".

Figure 6.5: The packaging of sensor modules for evaluation at VGH

6.5 Evaluation of the Improved Prototype in the Operating Room

After the above tests, the overall reliability and effectiveness of the improved prototype was evaluated in the operating room at Cambie Surgery Center (Vancouver, Canada). The operating room selected was among the biggest in the Center, and was equipped with various medical equipments,

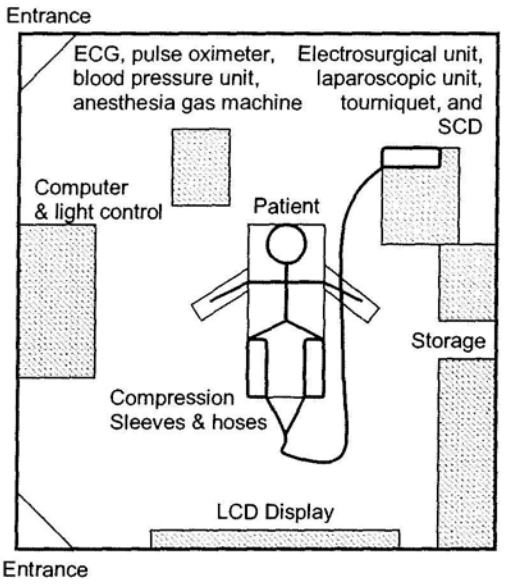

Figure 6.6: A sketch of the operating room and a typical setup of a surgical patient wearing a pair of pneumatic compression sleeves

including the electrocardiogram (ECG), pulse oximeter, blood pressure unit, anesthesia gas machine, tourniquet, electrosurgical unit (ESU), laparascopic unit and the sequential compression device (SCD). It was also equipped with surgical lamps, desktop computer, and a LCD panel. At the time of the evaluation, three 802.11g wireless networks with strong signal levels were detected. Figure 6.6 is a sketch of the operating room and the typical setup of a surgical patient wearing a pair of pneumatic compression sleeves.

All medical equipments, the LCD panel, computer monitor and surgical lamps were turned on and placed into the appropriate locations to simulate a surgical environment. The volunteer, wearing a pair of compression sleeves, was positioned on the operating table. A pulse oximeter, blood pressure cuffs, and ECG electrodes were also connected to the patients.

First, the prototype was put into normal operation for 10 minutes, during which the wakeup process of the sensor modules, clock-skew estimation, synchronization, and the actual therapy monitoring were observed. During the period, there were no observable problems with either the monitoring of the compression therapy or the wireless communication.

The second test evaluated the prototype under external interference from the movement of intraoperative personnel. The possible path of movements are shown in Figure 6.7. Usually an anesthetist will be monitoring the ECG and blood pressure readings, a nurse may move along the path near the LCD for transporting surgery related items. The surgeon most likely stays near the operating table, but the actual position of the surgeons depends on the type of surgery. The surgeons may move the patient's limb as required. To simulate the potential interference, an assistant was first asked simulate

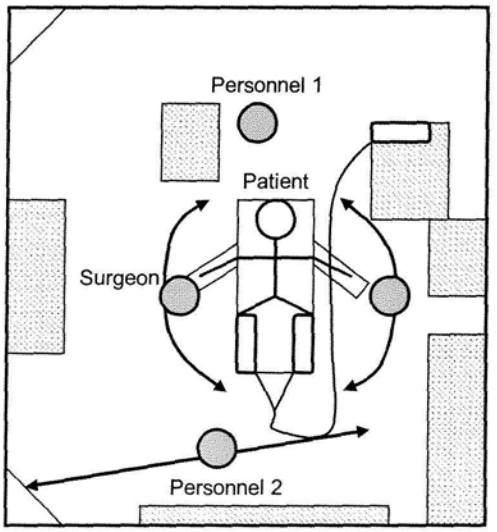

Figure 6.7: Possible movements of intraoperative personnel

a surgeon's movement, which was to walk around the operating table, and

move or touch the compression sleeves when requested by the investigator. The assistant was then asked to move a metallic trolley along the path close to the LCD screen and place the trolley at the end of the operating table close to the receiver station. During these tests, the performance of the prototype was observed by the investigator, who was 2 meters away from the prototype.

During the two sections of the simulation, no indication of problems was observed in the prototype.

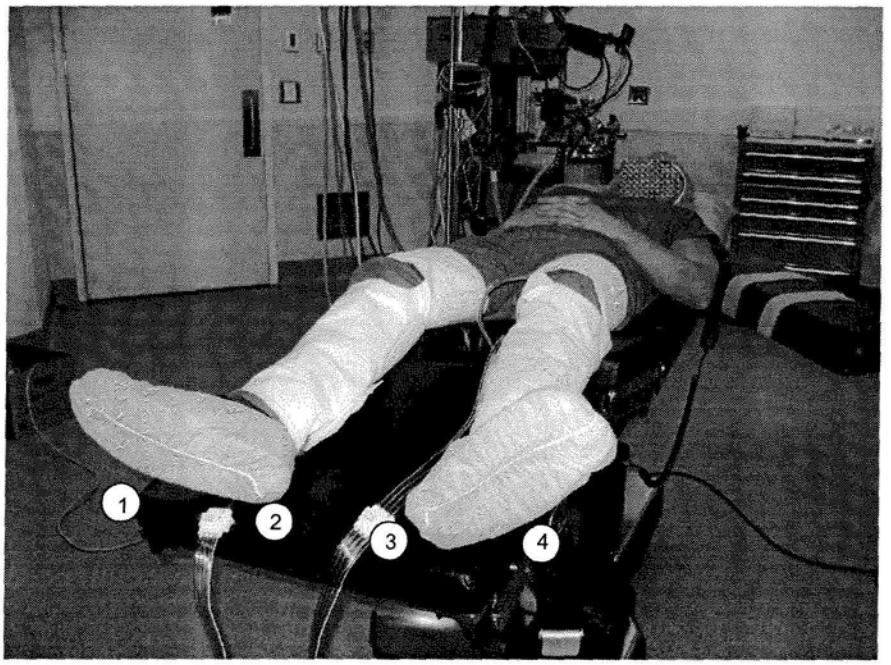

Figure 6.8: Possible receiver station position

The third test evaluated the performance of the wireless communication when the receiver station was positioned at various positions. Depending on the type of surgery, the receiver station, located on the pneumatic connec-

tion, can be placed at positions shown in Figure 6.8. The sensor modules in the compression sleeves are not fixed in position in order to accommodate various operating positions. For example, sensor modules fixed at the front of the limb are not appropriate for a back surgery when the patient may be lying on his or her chest. To simulate an actual intra-operative use of the improved compression sleeves, the assistant was only provided with instructions to apply the sleeves as usual and he also had to make sure that the sensor modules did not slip under the patient's limb. The positions of the sensor modules, after the sleeves were applied by the assistant, were observed to be: (1) left thigh - outer side of the limb (outer), close to the bottom of the thigh (bottom), and vertical to the axis of the limb (vertical), (2) left calf - top of the limb (top) and vertical, (3) left ankle - top and along the axis of the limb (horizontal), (4) right thigh - top and horizontal, (5) right calf - outer, side, and vertical, and (6) right ankle - outer, bottom, vertical, and partially covered by the under side of the ankle. Sensor positions (2) and (3) were shown in Figure 6.9.

At position 1, the receiver station was on the outer side of the patient's limb and the line-of-sight between the receiver station and the sensor modules at the right ankle and left limb was blocked by the metallic operating table; no communication problem (startup, clock-skew estimation, synchronization, and monitoring of therapy) was observed.

At positions 2 and 3, the receiver station was on the inner side of the patient's limb, and the limb was in the way among most sensor modules and the receiver station; no communication problem was observed.

At position 4, the receiver station was on the outer side of the patient's limb; as no communication problem was observed in the other 3 positions, the receiver station was pulled further down from the surface, and towards

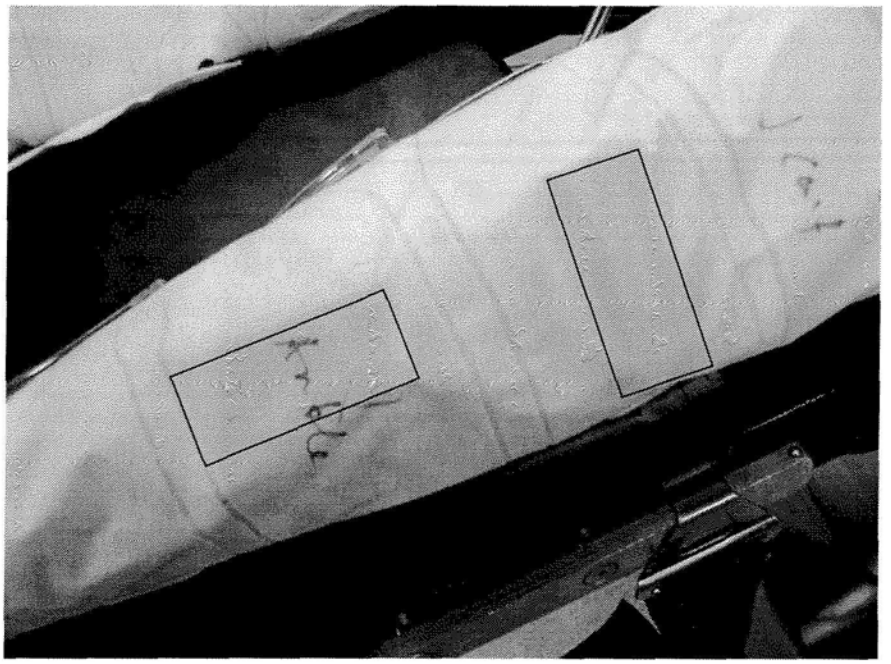

Figure 6.9: Positions of sensor modules in left calf and ankle chamber

the underside of the operating table. No communication problem was observed when the receiver station was out of the underside of the operating table; however, as the receiver station was placed on the underside of the operating table, an intermittent synchronization problem was observed with the sensor module in the right thigh chamber, even at the maximum output power. It is likely that the metallic operating table has caused a significant attenuation in the RF signal and thus lead to this communication problem.

The final test in the operating room preliminarily evaluated the EMI effects on the ECG, pulse oximeter, and blood pressure measurement unit. The evaluation method is based on ANSI C63.18, "American national standard recommended practice for an on-site, ad hoc test method for estimat-

ing radiated electromagnetic immunity of medical devices to specific radio-frequency transmitters". This method is recommended by the U.S. FDA for preliminary on-site testing of EMC among medical device, and can be performed by biomedical engineers in any clinical environment.

Although the C63.18 test method does not replace the testing required for meeting the legal requirements as discussed before, it provides an inexpensive and relatively reproducible test method for understanding the level of compatibility of the new device with existing devices which can be performed by clinical or biomedical engineers without complex equipments. To test whether an existing device is compatible with the new wireless device (radiator), the radiator is first placed at a recommended initial distance (1m for radiator with output power less than 600mW) away from the device under test (DUT). Any signs of interference are recorded. If no interference is observed, the radiator is moved closer to the DUT and again any deviation from normal operation is recorded. The evaluation is stopped at the minimum testing distance (0.25m for radiator with output power less than 600mW). As soon as interference is encountered, the radiator is moved away from the DUT until interference ceases, and the separation distance is recorded. The same procedure is repeated for each axis, and with the antenna placed vertically and horizontally [48]. Following this exact procedure, the EMC between the prototype and the sensitive medical equipments in the operating room, such as the ECG, pulse oximeter, blood pressure measurement unit was evaluated. There was no observable EMI problems on the medical equipments tested during our visit to the operating room.

As most medical equipments follow the IEC-60601-1-2 standard and are immune to a field strength of 3V/m (note that if manufacturers do not meet the 3V/m limit, they may still ship their product but must specify at what

level their equipment does comply), it was of interest to find out how far away from the medical equipment the prototype needs to be in order to generate field strength of 3V/m; or in other words, the distance at which the prototype may cause EMI problems.

The field strength equation 6.1, combines with the power density equation 6.2, gives equation 6.3, where E is the field strength in volt/meter, P is the power density in watt/meter^2, and P_t is the overall output power of the radiator in watts.

$$E = \sqrt{120\pi P} \tag{6.1}$$

$$P = \frac{P_t}{4\pi r^2} \tag{6.2}$$

$$E = \frac{30P_t}{r^2} \tag{6.3}$$

A distance of 3m is used in Equation 6.3 because that is the testing distance specified by the IEC regulation. The calculated field strength is 0.06V/m, and due to the symmetry of the equations, the distance at which a field strength of less than 3V/m is also 0.06m or 6cm based on the assumption that the antenna provides a gain of 0dBi. This explains why our test conducted in the operating room did not generate any EMI problem at 25cm. On the other hand, as it is highly improbable that a medical equipment will be positioned closer than 6cm to the prototype, and thus one can be fairly confident that the prototype will not have EMC problems with other medical devices in a typical operating room setting. This explanatory approach was also used in a previous study by Dempsey, where the calculated results matched closely with the measured results in a hospital

[49].

Finally, Equation 6.2 is used to evaluate whether the prototype complies to IEEE C95.1-2005, "Standard for safety levels with respect to human exposure to radio frequency electromagnetic fields, 3 kHz to 300 GHz" [50] and RSS-102, "Radio frequency exposure compliance of radiocommunication apparatus (all frequency bands)" [51]. The IEEE and IC maximum permissible partial body power density exposure (MPE) limits are $4mW/cm^2$ and $1mW/cm^2$ (radiator very close to the body) in an uncontrolled environment (no RF safety scheme is present). The calculated power density of the prototype, placed at 1cm away from the body, is $0.08mW/cm^2$. As this is significantly lower than the limits, it can be concluded that the prototype is very safe from a thermal heating perspective.

6.6 Summary

Individual components of the improved prototype were evaluated. Evaluations of the self-monitoring features of the prototype, the power management scheme, and the usage and reprocess indicator were performed, followed by an evaluation of the overall effectiveness and reliability of the improved prototype in an intra-operative setting. The prototype was observed to pass most of the evaluations on the first run; at other times when the prototype failed to meet the requirements, the causes of failure were found and solutions were implemented to fix the problem. The prototype successfully passed the remaining tests with the updated implementation.

Finally, EMC of the prototype was observed in the operating room following ANSI C63.18. As no observable EMI effect on other medical devices was present, the distance at which a field strength of 3V/m is generated

was calculated to show that the testing result matches with the theoretical predictions. Based on the calculated result of power density and the IEEE C95.1-2005 limits, the prototype is very safe for use close to the body.

Chapter 7

Identification of Possible Extensions of the Improved Prototype to Other Medical Applications

7.1 Objective

In this chapter, possible extensions of the wireless monitoring system to other medical devices and applications are identified. The features of the novel wireless monitoring system that was developed are first summarized. An outline of some similar applications then follows. Finally, a specific example is identified in which the use of a wireless monitoring system based on the improved prototype developed in this thesis research may be beneficial, resulting in improved performance, safety and cost-effectiveness.

7.2 Review and Analysis of the Features of the Improved Prototype

The monitoring features of the improved prototype allow a continuous monitoring of various parameters related to pressure and temperature during compression therapy. The improved prototype also localizes and identifies potential problems that may happen during the therapy and provides an operator with sufficient information to solve such problems and maintain the effectiveness of the therapy. The prototype is self-managed, and does not require user intervention unless an unrecoverable or patient-threatening problem has occurred.

The power management scheme in the improved prototype allows the sampling rate of the monitoring system to adapt to the actual need, and enhances the battery life of the in-sleeve sensor modules where the batteries are not conveniently replaceable. The extended battery life allows limited reuse of the disposable compression sleeves on multiple patients, and the embedded usage and reprocess indicator enhances the safety and reliability of such reuse. The cost per patient is thus reduced, making it feasible to deploy the improved prototype commercially.

7.3 Generalization of Applications for Possible Extensions

Because the thresholds used for detecting application-related problems are easily reprogrammable, the monitoring features can be adapted to a number of similar medical applications, especially when parameters related to pressure and temperature have a key role in the overall effectiveness and

safety of the application.

Also, the prototype that was developed may be very suitable for applications where the sensor modules must operate in a sealed environment to provide protection. In such applications, the batteries of the sensor modules are not conveniently replaceable, and the power management scheme can significantly enhance battery life by adjusting the sampling rate to adapt to the operating need.

The improved wireless monitoring system is especially suitable for applications where one or more disposable components are connected to an instrument to carry out a desired medical function, such as the current application in which a pair of disposable compression sleeves are connected to a pressure controller to provide a therapy for preventing DVT. The usage and reprocess indicator of the prototype thus provides a self-monitoring means to keep track of the status of sterility or cleanliness (for non-sterile applications) of the disposable portions, and the cost per application is reduced through limited reuse of such components. Some examples of similar types of medical devices are: (1) alternating pressure mattresses for preventing bed sores and skin ulcers in long-term patients in intensive care, where a controller is pneumatically connected to the mattress, and sequentially inflates and deflates different chambers of a multi-chamber pneumatic mattress (Figure 7.1a), (2) automatic blood pressure monitoring and measuring devices, for which a controller monitors and determines the blood pressure through the variation of pressure within the disposable or reusable pneumatic cuff (Figure 7.1b), (3) pneumatic anti-shock trousers for preventing and treating severe blood loss, where a controller delivers compressed gas to a pair of pneumatic pants and by compression of the legs decreases the blood flow in the lower body, and to increase availability of blood to the rest

of the body (Figure 7.1c), and (4) surgical tourniquets, described in more detail in the next section to demonstrate the method of adaptation and the actual advantages resulting from the extension of the prototype system.

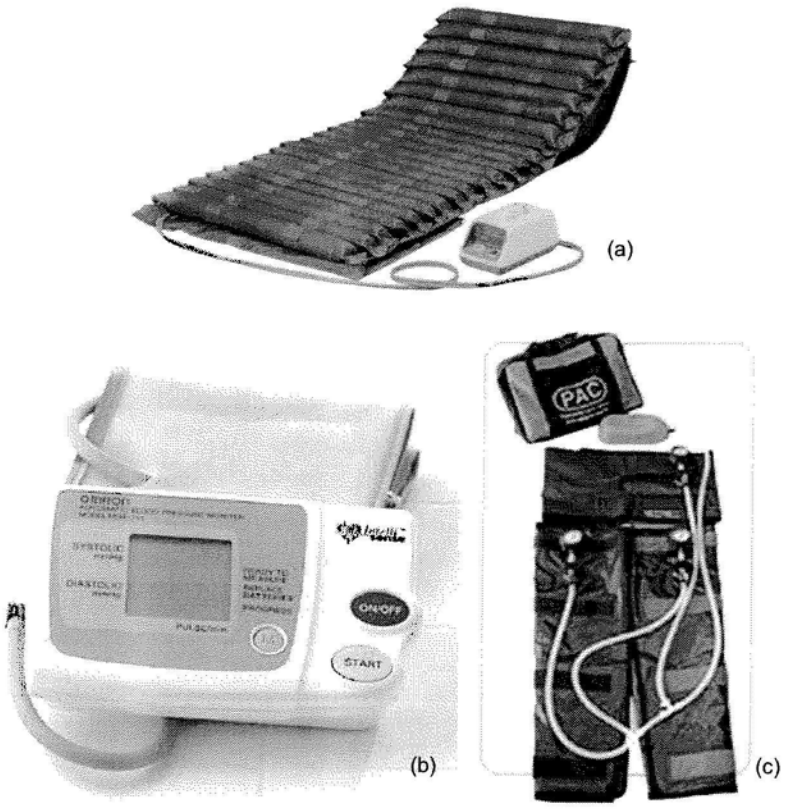

Figure 7.1: Pneumatic medical devices: (a) an alternating pressure mattress, (b) automatic blood pressure monitoring and measuring device, (c) pneumatic anti-shock trousers

7.4 An Example

One of the most suitable applications is surgical tourniquets. A surgical tourniquet can be defined as a constricting or compressing system used to control arterial and venous circulation to an extremity for a period of time. Pressure is applied circumferentially upon the skin and underlying tissues of a limb encircled by a tourniquet cuff; this pressure is transferred to the walls of underlying blood vessels, causing them to become temporarily occluded. In surgical settings, the tourniquet is used following exsanguination to produce a relatively bloodless operative field over a time period suitably long for the performance of a surgical procedure.

A tourniquet system typically includes a disposable inflatable cuff and a controller for supplying compressed gas to the cuff. Pressure is applied to the limb encircled by the inflated and pressurized cuff. The pressurized gas is contained within an inflatable bladder of the tourniquet cuff. All bladders have one or two pneumatic connectors for the attachment of connecting tubing.

The key parameter of circulation control is the cuff pressure; if the cuff pressure is too low, circulation will not be completely stopped and the system will fail to produce a bloodless operative field; conversely, if the applied pressure is too high or if the application time is too long, muscles and nerves may be injured or damaged. Because the inflation of a tourniquet cuff relies on a pneumatic pressure controller, similar to the source used for compression therapy for preventing DVT, problems similar to those described in Chapter 3 can occur. Therefore, the features of the improved prototype that was developed and presented in this thesis could be adapted and integrated into a tourniquet system to provide continuous protection

Figure 7.2: Components of a tourniquet system

over pressure problems. This could be done by placing a sensor module in the bladder of single-use, sterile tourniquet cuff to periodically acquire and transmit pressure data to a receiver station, thus ensuring that there is no problem such as overpressure, under-pressure, or excessive periods of pressurization. The power management scheme provides an extended battery life for the sensor module, and thus the usage and reprocess indicator could allow monitoring of the status of sterility of such tourniquet cuffs. The cost per application of these tourniquet cuffs might thus be reduced by allowing safe, reliable and limited re-use of these cuffs on multiple patients.

7.5 Summary

Possible extensions and adaptations of innovative aspects of wireless monitoring system were identified in this Chapter. The features of the improved prototype were reviewed, a generalization of applications where the system may be beneficial was provided, and an example of such an extension was given to illustrate the method of adaptation and the actual advantages resulting from such an extension.

Chapter 8

Conclusions and Recommendations

8.1 Summary of Contributions

The primary contributions of this research study apply to pneumatic compression devices for the prevention of deep vein thrombosis (DVT). The most important contributions of this research were:

8.1.1 The Successful Development of an Innovative Wireless Monitoring System

A prototype of an innovative wireless monitoring system for improving the reliability, safety and effectiveness of pneumatic compression therapy for preventing DVT was successfully developed and initially evaluated. Besides providing continuous monitoring of key parameters of therapy such as the level of delivered pressure and the rate of inflation, the innovative system also detects, identifies and localizes therapy-related problems and certain indications of possible complications. Upon detection of such problems, audiovisual alerts, as well as meaningful indications of the problems are provided by the prototype system to the clinical operators. Additionally, this wireless monitoring system is self-managed, and does not require

user intervention unless an unrecoverable or patient-threatening problem is detected. To minimize the severity of harm to the patients, the system also provides basic instrument control functionality so that compression therapy can be halted as soon as a significant hazard is detected. Compared to previously reported designs, the current prototype system eliminates the needs for additional pressure monitoring lines, ports and connections, and thus is easier to clean and maintain. As no major redesign of the pneumatic compression sleeves and controllers is required, quick integration of the system into existing sequential compression devices supplied by different manufacturers is possible, and thus potentially benefits a larger population.

8.1.2 The Successful Development of a Novel Power Management Scheme

To maximize the storage and operational life of the wireless monitoring system, a novel power management scheme was successfully developed and initially evaluated for the application. This allows the monitoring features of the prototype system to operate without interruption over time periods suitably long for the application. The scheme carefully controls the power consumption of the system at different phases, so that the system can have up to 2 years of storage life, 3 weeks of continuous usage, and an overall 6 months of wait in between uses on a 225mAh coin-cell battery. This eliminates the need to replace batteries in the sensor modules, which must necessarily be sealed inside the sleeve chambers and thus are not accessible. The novel power management scheme for the application thus significantly improved the overall reliability, convenience and feasibility of a practical deployment of future commercial systems based on the design of the proto-

type.

8.1.3 Development of an Innovative Usage and Reprocess Indicator

A novel usage and reprocess indicator was developed and evaluated to detect the exposure of the sleeves to reprocessing between successive patients, based on the pattern of alteration of key parameters related to the reprocessing. Temperature and pressure changes are key parameters of common reprocessing techniques. The novel usage and reprocess indicator prevents the start of a compression therapy if it detects that the pneumatic sleeves have been used previously but have not been properly reprocessed. The indicator also monitors key parameters of continued clinical usage, such as the duration of the current therapy on a specific patient and the cumulative duration of use of the sleeves on multiple patients. These parameters are crucial to the safety and the overall effectiveness of the therapy. Furthermore, the reprocess detection algorithm is re-programmable to allow quick adaptation to a variety of different reprocess procedures and techniques. The usage and reprocess indicator facilitates safe and reliable reuse of the otherwise single use, disposable pneumatic sleeves on multiple patients, thus allowing a reduction and averaging of any additional cost associated with the prototype system.

8.1.4 Identification of Extensions of the Monitoring System and the Usage and Reprocess Indicator

It was discovered that the versatile design of the wireless monitoring system would permit adaptation and integration of key aspects into other

commonly used medical devices. Possible extensions of the wireless monitoring system were identified in this study. The features of the improved prototype were reviewed, a generalization of applications where the integration of the system may be beneficial was provided, and an example of such extension was included to illustrate the method of integration and the actual advantages brought by the monitoring system.

8.2 Recommendations and Future Work

8.2.1 Integration of the Current Prototype System with Previously Proposed Controllers

The current prototype system can be integrated with previously proposed but impractical closed-loop controllers. The combined system potentially maximizes the level of protection and effectiveness of pneumatic compression therapy for preventing DVT, and minimizes the complexity and cost due to any additional cost of the closed-loop controllers. Although a major redesign of the system architecture of the current prototype is not necessary, as the required sampling rate of a control application is much higher than that of a monitoring application, a different low power pressure transducer may have to be used.

8.2.2 Inductive Coupling and Power Scavenging

Although a design employing inductive coupling is not feasible at the moment, it remains as an attractive future option. In future, as the power consumption of new transducers and microcontroller units continues to drop, it may be possible to transfer adequate power from the receiver station to

the sensor modules. Although a battery may still be needed for the reprocess indicator, the battery life will be significantly extended by a hybrid design. A related and interesting research topic is energy scavenging: it might be possible to provide the sensor modules with adequate energy harvested from the surrounding environment such as pressure variations. Although energy harvesting devices exist nowadays, most of the devices cannot provide adequate energy for measurements at a high sampling rate.

8.2.3 Optimization of the Antenna

During the initial evaluations, the human body to which the prototype was attached was observed to affect the communication range of the antenna. Therefore, an antenna design optimized for close-to-body applications and different body positions might be investigated to maximize the communication range. Additionally, the power consumption may further decrease due to an optimized antenna because the transducer may use lower output power for communication.

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Appendix A

Appendix

Proceedings of the 29th Canadian Medical and Biological Engineering Conference: An Radio Frequency Identification and Monitoring System for Improving Pneumatic Compression Devices used in Deep Vein Thrombosis Prevention Therapy

Abstract

A radio frequency identification and monitoring system for improving pneumatic compression devices used in the prevention of deep vein thrombosis is currently being developed and evaluated. While existing commercial devices encountered unanticipated variations between expected and delivered therapies, monitoring of individual chamber using multiple pneumatic hoses and electrical wires is cumbersome, impractical, unreliable, and may carry potential risk to patients.

By incorporating wireless technology, several parameters of the therapy such as pressure, humidity, temperature and attachment of sleeves can be simultaneously monitored without the need of excessive wires and hoses. This leads to an opportunity to eliminate problems and complications due to human or system errors as reported in previous literatures. Moreover, the quality of the therapy can be improved as battery operated transducers

can be placed inside the chambers for accurate measurement without any connection and reliability concern. The number of uses and the state of sterilization can also be monitored to prevent unauthorized re-use or allow limited re-use of such devices; the latter potentially reduces costs of medical centers and hospitals.

The wireless identification and monitoring architecture is not limited to pneumatic therapies of deep vein thrombosis, but any medical application that requires continuous monitoring of multiple parameters. In addition, as technology further matures, battery operated transducers can be replaced by passive transducers which further decrease the size and cost of the system.

Introduction

Over the years, pneumatic compression has been shown to be an effective prophylaxis for the prevention of deep vein thrombosis (DVT) [7]. However, different problems and complications related to the use of such devices are reported in the following literature:

In the mid eighties, a patient developed acute compartment syndrome after wearing a pair of intermittent compression boots with faulty pressure release valves [15].

Later, Comerota et al. observed a high percentage of improperly applied or nonfunctional units in routine nursing units [11]. Technical problems, incompliance, and human error were the causes behind failed therapies. Also, dedicated in-service instruction did not improve the proper use of the devices, and the authors have commented that this could be partly explained by the removal of the sleeves by patients due to discomfort when a nurse is not in attendance.

Haddad et al., in 2001, reported unanticipated variations between expected and delivered pneumatic compression therapy. Expected therapy was reported to be delivered only an average of 77.8% of the time during the therapy and most of the time, key values related to the outcome of the therapy have variations greater than 10%. Again, authors have found that medical or nursing education did not reduce the variations.

One year ago, Mitchell reported a case where epidural analgesia masked a malfunctioning pneumatic compression device [13]. The connection between the four-way plastic tubing and the controller was connected in the reverse order and consequently a patient was exposed to a pressure of around 300 mmHg for prolonged period of time. It is important to note that the patient was treated using an advanced model of sequential compression device (SCD).

Despite the introduction of newer models from various manufacturers claiming to increase the peak blood flow velocity, a study completed by Morris et al., based on literature from 1970-2002, has reached a conclusion that "the most important factors in selecting a mechanical prophylactic system, particularly during and after surgery, are patient compliance and the appropriateness of the site of compression. There is no evidence that the peak venous velocity produced by a system is a valid measure of medical performance" [52]. Moreover, as seen from above, the lack of dedicated monitoring measures remains a problem in pneumatic compression therapy.

In this study, a proof-of-concept radio frequency identification and monitoring system (RFIMS) is currently under development and evaluation with the overall objective to improve the quality and effectiveness of the therapy, reduce the risk of complications of patients, and to lower the cost of using pneumatic compression devices (PCDs).

Why Wireless?

Although previous literature has shown that a new design of the sleeves, which uses dedicated pressure monitoring lines, can improve the effectiveness of the therapy, the design may not be very practical [10]. Fundamentally, PCDs control the inflation and deflation of the sleeves by means of delivering pressurized gas via tubing; as a result, introducing additional electrical wires or pneumatic tubing as well as ports and incisions for transducer signals will make the device more cumbersome. This is especially a problem in an intra-operative environment, where the obstruction from wiring should be brought to a minimum. For a description of intra-operative setup of PCDs, readers are referred to Woolson and Watt [8].

Additionally, electrical wires also introduce reliability problems and potential risks - signal degradation resulting from worn out wires and connectors can lead to a suboptimal prophylaxis, and an unexpected short in the system may bring life-threatening current dangerously close to a patient or health professionals during the application of PCDs. In general, less wire or tubing also means faster set-up time and less chance of misconnection.

Therefore a wireless approach, without these disadvantages, is a better approach to tackle the existing problems.

System Description

The RFIMS consists of a base-station, battery operated multiple monitoring modules, and a communication protocol that allows low-power and reliable data transmission.

Base-station

The base-station is responsible for commanding the monitoring modules, receiving and processing data from the monitoring modules, and requesting required adjustment from the controller unit. For prophylactic application for DVT prevention, the station must also be able to handle data at a rate of around 10Hz.

The base-station consists of a microcontroller ATmega48V from Atmel (California, US), a transceiver (to be discussed in a later section), and a pressure transducer. The pressure transducer measures the barometric pressure which is then used for calculating the actual gauge pressure in the chambers.

Monitoring modules

The monitoring modules are responsible for the sensing of important parameters that affect the outcome of the therapy, and wirelessly transmit these data back to the base-station for further analysis. Similar to the base-station, each module consists of a transceiver, a microcontroller, and transducers for different measurements.

A module is placed inside each of the compression sleeve chambers for the following reasons. First, it prevents any direct contact to the electronic devices which may affect the reliability and performance of the system. Secondly, measurements of pressures delivered to the patients can be measured more accurately as the effect of pressure drop along the narrow pneumatic tubing is minimized.

Thus, the modules must be small and have low power consumption so that the battery will not need to be replaced during the life-time of the sleeves. The following are key-parameters to be monitored:

I. Pressure

Absolute pressure transducers are used to monitor the pressure waveform delivered to the patients. In the case of SCDs, the sequence of inflation will also be monitored to prevent any risk to patients due to misconnections, as well as manufacturing problem . Problems related to the sequence of inflation are difficult to observe, but can have serious consequences. Should any major abnormality be recorded, an alarm will sound at the base-station and the device will be automatically turned off.

II. Compliance detection and guidance

Instruction manuals often indicate that the sleeves should be wrapped around a limb snugly but not too tight. However, the definition of "snug but not tight" varies from one person to another, and this may result in an improper application of the sleeves and affect the outcome of the therapy.

Thin and flexible piezoresistive force sensors are used as an indicator of how snug the sleeves were applied. The readings are checked periodically against a predetermined range of forces for an optimal pneumatic therapy and sound instructions will be provided to the users as a feedback.

III. Complication detection

When the limbs of a patient are covered with the compression sleeves, any problems with the skin underneath are difficult to be observed. Humidity and temperature can be indicators for these problems; a sudden rise in

either of the parameters may well indicate a complication underneath.

IV. Usage

While the RFIMS has the potential to improve the therapy, the cost of each pair of sleeves will increase due to the additional monitoring measures. If some of the sleeves can be reprocessed or reused a limited number of times, the added cost can be averaged-out, and this will also reduce the expenditure of hospitals and clinics on PCDs by a large factor. Obviously, this has to be done without sacrificing the safety of patients; in other words, the usage of sleeves must be monitored to prevent any unauthorized reuse.

In this aspect, using temperatures in A.1 as an example, binary switches made of low melting temperature (M.P.) fusible alloys such as LOW117 (M.P. at 47°C) or LOW136 (M.P. at 58°C) are used as an indicator of exposure to a predetermined temperature level in a sterilization process. If the binary switch must be located on the outside of the sleeve, signals can be inductively coupled back to the transceivers inside the chamber, using the same principle of transmission in passive radio frequency identification (RFID) devices. It should be mentioned that the original idea was to supply power to the monitoring modules (transceivers, microcontrollers and transducers) by inductively coupling; however, the idea was limited by inadequate power at the required operating range. In the future, as technology matures, ultra-low power electronic components will allow battery to be removed, allowing a further reduction in size and cost of a similar system.

Sterilization methods	Temperature (^oC)
Sterrad - H_2O_2 plasma	45-50
Steris System 1	50-56
EtO Gas	50-60

Table A.1: Temperatures for sterilization methods

Wireless communication and protocol

During the application of PCDs, the compressor unit is typically placed within 3 meters from the limb. Thus the base-station and monitoring modules must work reliably within this distance. To implement a reliable transmission link, a protocol with hand-shaking is required. Hand-shaking between the base-station and monitoring modules prevents unnecessary retransmission due to data collision and in turn preserves battery power. Another advantage is that the monitoring modules can be sleeping most of the time to lower power consumption and wake up only as required. As the basic requirement for hand-shaking is two-way communication, the monitoring modules and base-station in the system are equipped with transceivers.

Under the current protocol, the monitoring modules wake up every second to search for wake-up signals from the base-station. Before receiving any data, the base-station will update the number of uses for that particular sleeve and check the input from the binary switch.

As soon as the monitoring modules are active, they will wait for a ready-to-send signal from the base-station, a command to start the transmission of acquired data. While waiting, modules will gather transducer readings through its analog-to-digital converter and input ports. Upon the reception of data, the base-station will send out an acknowledge signal to the sender and request the next module to send its data. As each module has a

distinguishable identification number, the order of inflation can be observed.

When the whole therapy is completed, the monitoring modules will be signaled to return to hibernation. It is important to note that a refresh rate of 10Hz is required; subtracting data acquisition time and other required delays, and assuming a pair of thigh-length three-chamber sleeves, an estimated 10ms interval is available for transmissions of data and handshaking signals from a monitoring module.

The operating frequency band of the transceivers is chosen to be the 2.4-2.4835 GHz industrial, scientific, and medical (ISM) band due to its global availability. Additionally, the antenna size is inversely proportional to frequency; higher frequencies allow smaller antennas to be used.

For the system prototype, a wireless module purchased from SparkFun Electronics with surface mounted chip antennas from Linx Technologies (Oregon, US) and the nRF2401A device from Nordic Semiconductor (Tiller, Norway) were used in the initial evaluation. For a comparison between the proprietary standard used in the transceiver and other technologies such as Bluetooth and Zigbee, readers are referred to Heggabo [25].

Testing

A preliminary range test has been carried out in the lab with a single base-station and monitoring module operating under the current protocol. The pair is configured to perform a single cycle that consists of three stages: 1) Wake-up 2) Active 3) Acknowledge. The functional communication distance is defined as the distance at which 18 of 20 cycles performed are successfully completed.

Limited by the indoor space where a line-of-sight can be established,

the functional communication distance is recorded to be over 5 meters. A functional distance of 3 meters is recorded as one of the modules is placed behind a wall located in the middle of the lab. Movement of people did not appear to affect the transmission within the required distance. The preliminary testing has shown that the selection of major components, i.e. microcontroller, transceivers and antennas, is justified.

The next step will be to evaluate the range and integrity of the radio frequency (RF) link in a clinical environment. Besides the test above, monitoring modules will be configured to send out 100 consecutive data packets and the number of successful transmitted data packets will be recorded.

After the integrity of the RF link is ensured, transducer readings, key parameters including the rate of monitoring will be individually recorded and evaluated. Simulated malfunctions, such as reverse order of inflation, and occluded tubing will be carried out to test the warning system. Perhaps the most interesting function to be tested is the usage and sterilization transducer as it demonstrates an integration of a passive and active RF system. The functional coupling range will first be determined, followed by the testing of the transducer under simulated sterilization conditions.

Finally, the overall quality of the compression therapy with the new system will be evaluated. Results will be discussed during the Canadian Medical and Biological Engineering Conference in June 2006.

Summary

A proof-of-concept radio frequency identification and monitoring system is currently under development and evaluation with the aim to improve the quality and effectiveness of the therapy, reduce the risk of complications

of patients, and to lower the cost of using pneumatic compression devices. The preliminary test has shown that the selected wireless devices successfully transmitted data within the required distance no matter whether a line-of-sight can be established or not. Further experiments will be carried out to demonstrate the usefulness of the device and its potential application in the field of medical devices.