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Enhancing Medical Devices and Personal Healthcare Products with Force Sensing Technology

Abstract: *The medical field presents special challenges to equipment manufacturers. High reliability is an essential characteristic of equipment and instrumentation that may be used in life-or-death situations. This, in turn, places similar reliability requirements on every component used in the manufacture of such equipment, particularly the electro-mechanical components that constitute the Human-Machine Interface (HMI). One category of HMI components is the force sensor – a component that is also used widely in the related and rapidly expanding market for personal healthcare monitoring devices. Sensor devices collectively provide the technology that underlies the recently coined term 'Quantified Self' (1). This paper examines current applications of force sensors in medical and healthcare products, and shows that evolving sensor technologies may be the key to controlling the ever-increasing cost of the healthcare system.*

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The Importance of Feedback

A common goal of medical practitioners as well as individuals interested in managing their own health is to obtain feedback on their healthcare activities. Before the advent of today's digital sensor-based technology, the only options available to doctors were manual – such as taking a patient's pulse, visually checking for consistent flow of an intravenous drip or taking an analog reading of a patient's temperature with a thermometer. Such measurement methods were both time-consuming and, more significantly, non-continuous. The cessation of the heartbeat of a patient in intensive care might have been missed, simply because of the inattention of an overworked nurse.

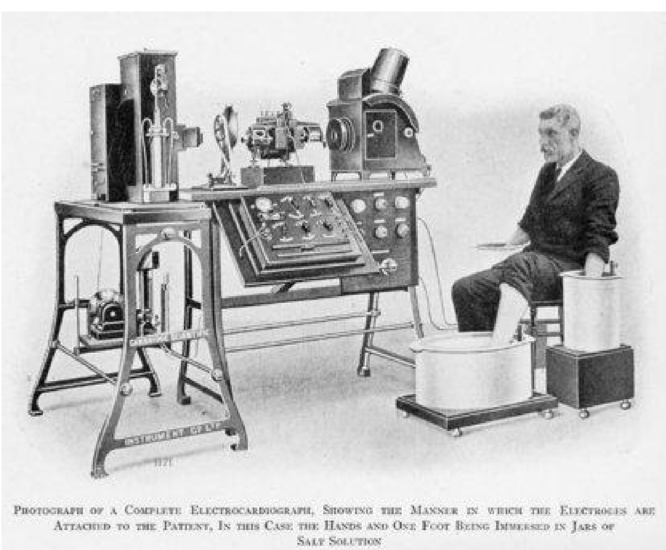

Fig 1. Early Electrocardiograph

The earliest examples of automated heart rate monitoring date back to the start of the twentieth century [2] with the invention of electrocardiography (ECG). The underlying principle of ECG is the continuous detection of very small voltage changes between different parts of the patient's body as their heart beats. In today's ECG systems small disposable electrodes (sensors) are self-adhered directly to the patient's body to transfer the minute electric currents to the monitor itself; but in those early systems, the 'sensors' were containers filled with salt water into which the patient placed their limbs, and the printout showing the heartbeat was to a photographic plate (Figure 1). Cumbersome indeed! But for the first time, doctors were able to obtain continuous feedback about a patient's heart function in response to administered treatments.

Hospital and Medical Office Applications

As electromechanical technologies progressed through the following decades, new types of sensors emerged that in turn gave birth to a continually widening range of instruments and systems available to the medical community. By the middle of the twentieth century, it had become possible for hospitals to continuously monitor the vital signs of patients with systems that automatically generated alarms in the event that any of the measured values moved outside their normal range. Prior to this, the only method for such rigorous monitoring was to dedicate a nurse to each and every patient in intensive care.

Fig 2. Diverse Types of Force Sensing Resistors

The second half of the twentieth century saw the evolution of the computer age and the transition from analog measuring devices to digital. As digital processors became increasingly powerful yet smaller, so too did sensor devices. Miniaturized versions of traditional sensors such as load cells and strain gauges emerged, along with new types of sensors invented during that period. One such device was the force sensing resistor (Figure 2). Developed in the nineteen seventies and patented by Interlink Electronics a few years later, the force sensing resistor (FSR®) soon became widely adopted in diverse industries, including medical instrumentation, because of its cost effective performance.

FSR devices are reliable and durable, both of which are essential characteristics for components used in medical equipment. Failure of such equipment in emergency situations is unacceptable, since it could result in loss of life.

Force sensing resistors have a thin form factor and are available in many different shapes and sizes, including custom designs. Their function is to detect variations in force applied anywhere over their upper surface, and in some implementations they can also signal the relative location at which the force has been applied. This gives them the added ability to operate as linear potentiometers. The current flowing through an FSR is in direct correlation to the applied force, and the analog output from the sensor can be used in various ways to provide functionality for the equipment in which it is installed.

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In general, FSR's can be dedicated to specific functions in the human-machine interface, or they can be used in conjunction with other sensor technologies to enhance the quality of data delivered. For example, they can be used to initiate haptic feedback such as a 'click' sound or a vibration when sufficient pressure is applied to a button or key.

Of particular note in the context of medical applications is that Interlink Electronics offers special versions of its sensors with anti-microbial protection. In the following sections, we will review some of the numerous implementations of force sensing technology in equipment used in hospitals and in doctors' offices.

Position and Movement Sensing at the Human-Machine Interface

Various types of equipment require contact (or non-contact) between a surface of the device and some part of a patient's body. One example is equipment used for radiation treatment of tumors, such as the Clinac and Truebeam systems offered by Varian Medical Systems (Figure 3). To ensure pinpoint targeting of a tumor, the beam must be positioned and focused precisely. This is accomplished during treatment setup using a touch guard detector that incorporates a force sensing resistor supplied by Interlink Electronics. The unique characteristic of the FSR that makes it an ideal fit for this application is its ability to distinguish between a touch and a firm press.

Fig 3. Radiation Treatment System

Bed Monitoring

Another application for which FSRs are well-suited is hospital bed monitoring. Not only can force sensing be used to detect the presence or absence of a patient from their bed, but it can also be used to identify pressure points resulting from the patient's specific position in bed (Figure 4A). A matrix of sensors, like the Recora Bed Occupancy Sensor (BOS) shown in Figure 4B, is used for this purpose. The Recora BOS utilizes a custom FSR developed by Interlink Electronics.

Fig 4A. Hospital Bed with Integrated Monitoring

There are various reasons why a patient may leave their hospital bed, some perfectly normal and some not. Going to the bathroom – normal; exiting the hospital without the knowledge and approval of the patient's doctor – abnormal! Equipped

Fig 4B. Recora BOS

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with bed occupancy sensors using FSR technology, a bed can alert medical staff whenever a patient gets into or out of bed, whatever the reason.

In practical terms, monitoring for pressure points is even more important. By generating programmable alerts, the bed's monitoring system can notify a nurse when it is time to change the patient's position. Prolonged pressure on a wounded area of a patient's body is undesirable, and even lying on a normal area for too long can result in pressure ulcers. A study conducted under the auspices of the National Institutes of Health [3] revealed that the average hospital charge per pressure ulcer patient was reported to be $48,000 in 2006. This represents a minimum annual outlay of 11 billion dollars to the U.S. health care system, excluding nursing home and home health care costs. The study concluded that halting the progression of early stage pressure ulcers has the potential to eradicate enormous pain and suffering, while saving thousands of lives and reducing health care expenditures by millions of dollars.

Advances in wireless communications now present the potential for remote monitoring, still further reducing costs and suffering by taking bed monitoring technology outside the hospital to the home or nursing home environment. The same technology can also be utilized in wheelchairs, especially for people whose sole means of local mobility is their wheelchair.

Feeder Tube Position Sensing

Another requirement for position sensing is exemplified by the Baxter infusion pump shown in Figure 5. An infusion feeder tube is routed through the pump by a qualified medical operator, and must be positioned precisely to ensure that the flow of liquid through it is fully and accurately under the control of the pump. To accomplish this, the pump mechanism contains custom FSR components from Interlink Electronics, which initiate alarm signals if the tube is not positioned correctly.

Fig 5. Infusion Pump

Occlusion Detection

Although the position sensing method for flow control works well as an integrated element of a regulated pump device, there exists a more general need for ascertaining satisfactory flow in feeder tubes. For example, in portable infusion pumps, failure to detect occlusions could be life threatening. To prevent such a possibility, these pumps are usually equipped with sensors that measure back pressure in the pump assembly. If the upstream pressure falls below a preset level, or the downstream pressure rises above its preset limit, then appropriate alarms will be triggered. The force sensing resistor is ideal for this application because of its small size and thin, flexible form factor.

Fig 6. Occlusion Detector

Introtek International offers one such solution that can be used independently of the particular source of the tube's contents. Its Pressure-Occlusion Detector (PRO) is designed to detect subtle changes in positive and negative air pressure in soft tubing and to produce a corresponding passive resistive output signal (Figure 6). If that signal drifts outside of its normal range, an alarm can be generated. For example, it can be used in conjunction with an intravenous drip-feed (IV) to raise an alarm if a blockage has occurred anywhere in the tube. Conversely, it can also raise an alarm if the IV liquid source has reached empty.

To sense the changes in the tube's internal pressure, the PRO uses an Interlink Electronics' FSR. Originally, the PRO Detector was the result of a steadily growing interest in the global community of medical device manufacturers because it offers a unique solution to accurately monitor tubing occlusion. However, its applications have now extended to clinical laboratories, pharmaceutical manufacturing and automated packaging applications.

Bionic Limb Feedback

Some of the most advanced applications for force sensing lie in the field of prosthetics. The human brain controls limbs through an extraordinary system of minute electrical signals and feedback sent to and from muscles through the body's nervous system. When a person suffers the loss of one or more limbs, the brain continues to send output signals to the points at which the limb(s) were severed; it does not, of course, receive any feedback from the missing limb(s). Today's leading edge research in the field is focused on developing artificial limbs that are capable of accurately simulating the movements triggered by these signals from the brain, as well as providing proportional feedback to the brain that continuously reflects the results of those movements. The feedback is essential for ensuring that just the right amount of movement and pressure are applied for the intended purpose. For example, an excessively powerful handshake could result in the recipient's hand being crushed!

Enormous advances have been made over the past decade in prosthetic technology (Figure 7), but the cost of the resulting artificial limbs is still prohibitively high for many would-be recipients. Among the more expensive components used in the technology are the myoelectrodes used to sense the degree and strength of muscle movements in associated residual limb parts. Consider, for example, a prosthetic hand attached to a person's arm. Brain activated movements of the hand work in conjunction with corresponding muscular activity in the forearm and upper arm. Myoelectrode sensors attached to the arm provide the necessary electrical feedback that allows the brain to dynamically regulate the hand's function.

Fig 7. Prosthetic Arm

Recent development work has enabled much lower cost force sensing resistors to be used in place of the myoelectrodes [4]. Instead of providing direct electrical signals from the skin surface, force sensing resistors vary the strength of battery driven signals in response to changing pressure from the muscles over which they are attached.

Rehabilitation Systems

Another emerging application of force sensing resistors is in rehabilitation systems. During recovery from a broken limb or from a stroke, for example, a patient must undergo physical therapy to retrain and strengthen affected parts of the body. Recent research [5,6] has shown that robot-assisted therapy can improve motor and gait recovery more effectively than conventional therapy alone[7]. As a result of these studies, several robot-assisted exoskeleton devices have become available in the medical marketplace, in recent years. For walking therapy, these include the Hocoma Lokomat® (Figure 8), BAMA RoboGait®, and the newest entry, the Tibion® Bionic Leg (Figure 9).

Fig 8. Walking Therapy

Tibion's product differs from its predecessors in that it is a wearable, battery-powered robotic device that is activated by the patient's ***intent*** to move. In other words, it is force sensing feedback that initiates and controls the degree of assistance it provides.

Fig 9. Bionic Leg

Fig 10. Arm Therapy

For arm and hand therapy, Hocoma offers the Armeo family of devices, while other products include the InMotion Robots family from Interactive Motion Technologies and the SEM™ Glove from Bioservo Technologies AB (Figure 10). The SEM Glove provides powered assistance to the wearer's hand grip, utilizing FSRs from Interlink Electronics to help regulate the grip strength. In all of these systems, sensor feedback ensures that the degree of assistance stays within preset limits.

Enhanced HMI Control

Having reviewed some of the more advanced and specialized medical applications of force sensors, we should not forget their most fundamental application – namely, enhanced functional control at the human-machine interface (HMI). One such example is the Philips Respironics V60 Ventilator (Figure 11) which is used to assist patients who have breathing difficulty. It comprises a microprocessor-controlled pneumatic system that delivers a mixture of air and oxygen to the patient via a mask or tube. Intended for use by qualified medical personnel only, the operator provides inputs to the ventilator through a touchscreen, keys, and a navigation ring. These inputs become instructions for the pneumatics to deliver a precisely controlled gas mixture to the patient. The navigation ring enables the operator to adjust values and navigate the graphical user interface by rotating their finger on its touchpad – a ring sensor supplied by Interlink Electronics. This is much like the input method used on Apple's iPod, but without the limitations of a capacitive input device.

Fig 11. Respiratory Ventilator

As in many industries, numerous medical monitoring and management products have adopted a keyboard and some kind of pointing device as their primary method for data input and control functions. In some such products, the "pointing device" is a micro joystick, while in others cursor movement is effected via a touchpad. A micro joystick offers more precise, full 360-degree control than a touchpad, while the touchpad is easier to use with gloved hands.

Fig 12. Patient Monitor with Touchpad Control

For non-medical applications, touchpads may be based on either resistive or capacitive technologies. However, capacitive touchpads are typically unacceptable for medical applications, because they do not function reliably – or even at all – when operated by a doctor or nurse with gloved or contaminated hands. Resistive touchpads do not have that problem, but until recently they lacked the two-finger gestures available on capacitive devices. However, Interlink Electronics now offers resistive touchpads that do support two-finger functions such as pinch and zoom.

Fig 13. Panasonic Toughbook

One example that uses the original Interlink Electronics touchpad is the Mindray V21 patient monitor. As can be seen in Figure 12, it can be operated through a combination of soft keys at the bottom of the screen and the touchpad below it. A second example is the Panasonic Toughbook ruggedized laptop (Figure 13) used by many first responders such as ambulance drivers and paramedics. Again, a capacitive touchpad was not acceptable for the Toughbook, for the same reasons cited above.

The added support for two-finger gestures in the next generation of VersaPad® touchpads will be very useful for applications where viewing medical imaging, including 3-D images, is required.

Quantified Self Applications

In 2007, two editors of Wired Magazine, Gary Wolf and Kevin Kelly, coined the term "quantified self" to serve as the foundation for "a collaboration of users and tool makers who share an interest in self-knowledge through self-tracking." In essence, they formalized an idea that had by then existed for many years in piecemeal fashion. Pedometers were not new; heart rate monitors were not new; nor were sleep monitors. However, users of these devices purchased them typically to fulfill a singular purpose. A fitness enthusiast might have owned a heart rate monitor, but not a sleep monitor. A walker might have owned a pedometer, but not a heart rate monitor.

In the years since then, numerous new devices and systems have emerged that integrate multiple functions both for fitness enthusiasts and for those interested in their own well-being. The popularity of these devices has grown so rapidly that a recent study by ABI Research [8] forecasts that the market just for wearable devices that can connect to the Internet will grow to $6 billion by 2018.

Furthering the cause for "quantified self" applications, Qualcomm and the XPRIZE Foundation launched a global competition in January 2012 with a prize of $10 million for development of a device similar to one that was commonplace in all the *Star Trek* series, but hasn't yet crossed the final frontier from fantasy to reality – the medical Tricorder [9]. The objective of the competition is to make available to everyone a portable wireless device that can monitor and diagnose the owner's state of health, enabling them to take pre-emptive action in the event that a potential health risk is detected.

In this section, we will examine some of the quantified self applications that have emerged since the term was first introduced, and the part that force sensors play or could play in these exciting new products.

Wearable Activity Trackers

In 2006, Nike launched what may be considered the first multi-function activity tracker and the pre-cursor to the quantified-self movement. In collaboration with Apple Computer, they introduced the Nike+ iPod Sports Kit, comprising a small piezoelectric accelerometer/wireless transmitter unit, a receiver that plugged into an iPod Nano, and an iTunes membership. At the same time, Nike introduced a new line of shoes designed to accommodate the transmitter unit under the insole, as well as a new website (nikeplus.com) where users could store their workout data in perpetuity. This system enabled users to track and display data such as the elapsed time of the workout, the distance traveled, pace, and calories burned.

Fig 14. SportBand

Despite its small size, the iPod Nano was not the most ergonomically satisfactory wearable device for runners. So in 2008, Nike introduced the SportBand (Figure 14) – a wristband with built-in display, USB connector and wireless receiver (for communicating with the in-shoe sensor). Upon completing a workout, the user could connect the SportBand to their computer via a USB port, in order to upload their workout data to nikeplus.com.

Several new companies also entered the market in 2008. Fitbit, a new player in the "quantified self" arena, introduced its first product, now known as the "Classic". Using a micro-miniature accelerometer and a wireless base station, it could not only measure steps taken, distance traveled, calories burned, and activity intensity, but also sleep quality. With the advent of Bluetooth connectivity to cell phones, even more functionality became possible, including three-dimensional mapping of a runner's path utilizing the built-in GPS tracking available in many such phones in conjunction with a micro-miniature altimeter built into the device.

Fig 15. Nike Fuelband

Once the potential market for activity tracking devices was recognized, a flurry of new entries emerged, including products from BodyMedia, Jawbone, Withings and Polar. To maintain their market share, Nike added several new products to their line in 2012, including the Fuelband (Figure 15) and the SportWatch GPS which comes with a Nike+ in-shoe sensor included. In addition, they introduced new digitally enabled footwear for athletic training and basketball. The sensors in these shoes enabled the implementation of advanced new features such as jump height and quickness, made possible by the fusion of multiple sensor technologies including force sensing.

Since 2008, major technology advances have been made and the state-of-the-art activity tracker as of late 2013 is the Amiigo fitness bracelet (Figure 16) which works with either iPhone or Android devices. It goes beyond tracking step count, distance, calories burned and sleep quality; it can also be used in the gym due to its remarkable ability to recognize and track dozens of different types of exercises, as well as to measure body temperature and pulse rate. To accomplish this, the Amiigo system comprises two elements – the bracelet plus a small ancillary unit that attaches to a shoe lace. The system contains five different sensors, and the bracelet is waterproof so that it can also be used for tracking swimming exercises.

Fig 16. Amiigo fitness bracelet

Fig 17. Smartwatch

2013 saw the arrival of another new category of wearable devices – the smartwatch. Although not specifically directed at the personal healthcare market, several of the new smartwatch start-up companies have also incorporated activity tracking features in their products. Examples include the Pebble Smartwatch (Figure 17), the Dew Motion iStick Playtime and the Kreyos Meteor.

Integrated Activity Trackers

Activity tracking devices that depend on walking, jogging or running over distance, are not useful for people who like to work out in a gym or fitness club, since the equipment is stationary. To make the nikeplus.com service available to indoor exercisers, Nike and Apple have licensed their technology to the manufacturers of most of the major brands of gym equipment. Nike+ Gym compatible cardio machines include stationary bikes, stair climbers, elliptical trainers, treadmills, and other cardio equipment. These machines include an iPod docking connector usually located in or near the cardio equipment's tray.

Other companies offering cloud-based services similar to nikeplus.com have since followed suit; among them are iFit, FitLinxx and RunKeeper.

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Wellness Monitors

In contrast to the continuous monitoring of activity trackers, personal wellness monitors are generally designed to take spot checks of specific parameters that relate to the user's health. These parameters include heart rate, respiratory rate, and blood pressure. One cutting edge example is the Zensorium Tinké which comes in both iPhone and Android connectable versions (Figure 18). The iPhone unit plugs in directly and does not require its own battery, whereas the Android unit communicates with its phone via Bluetooth wireless and it does require a battery.

The Tinké uses red and infrared light to measure heart rate, respiratory rate, blood oxygen saturation and heart rate variability. The user grips the unit with their thumb placed over the source and detector apertures, and the reflected light contains the waveform that is analyzed and displayed by the associated smartphone app. This method of analysis is known as "photoplethysmography". The thumb pad surrounding the apertures uses a force sensing resistor supplied by Interlink Electronics to ensure that the user is applying the proper thumb pressure while the measurement is being taken. This in turn ensures that the surface of the user's thumb is just the right distance from the light source and detector for an optimum reading, and serves as another example of the successful fusion of different sensor technologies.

Fig 18. Zensorium Tinké

What's Next?

As this paper has illustrated, remarkable progress has been made in applications of sensor technology in the medical and healthcare fields during the past decade. Even so, many new applications continue to emerge. Consider for example, the "haptic hand" shown in Figure 19. This strange-looking array of force sensing resistors (from Interlink Electronics) and associated processors, forms the basis of a sensorized glove that is being used to help in our understanding of joint movement and hand stiffness in arthritic patients. Developed at the Tyndall National Institute at University College Cork, Ireland, the glove provides data from which can be built 3-D simulations of a patient's joint mobility over time, and from which their degree of arthritis can be assessed.

Fig 19. Haptic Hand prototype

The researchers at Tyndall also expect that the same technology will be of value in other areas such as rehabilitation of a patient's hand movement following a stroke, and as a tool in the training of surgeons.

Specific applications such as the haptic hand are certainly of great value, but perhaps the most important area now evolving is that of "wireless health". Professor Hassan Ghasemzadeh at San Diego State University and a Research Manager at the UCLA Wireless Health Institute, estimates that through the use of remote health monitoring systems such as those discussed in this paper, savings of as much as 71% of the cost of hospital re-admissions could be realized [10].

Working with doctors, nurses and researchers at a half dozen of California's major medical centers, his team is working on the complex challenges of developing cost-effective, practical monitoring systems and the meaningful analysis of the massive amounts of real-time data gathered by them. His work is in its infancy, but his recent studies have already resulted in substantial improvement in the accuracy of intervention prediction for monitored patients. In other words, the percentages of false positives and false negatives with regard to the need for medical intervention have been dramatically reduced.

The annual cost of the healthcare system in the U.S. currently stands at $3 trillion, and is rising every year. Approximately 80% of the cost accrues from patients with chronic conditions such as heart disease and diabetes, which are conditions whose indicators are well-suited to monitoring. Professor Ghasemzadeh believes that early intervention for monitored patients with chronic illnesses may be the only way to save the healthcare system from financial collapse.

Conclusions

In this white paper we have reviewed the impact that sensors and sensor fusion are having in the area of medical equipment and related personal healthcare monitoring devices. There is a rapidly growing demand for sensors that can be used for enhancing the Human Machine Interface, as well as for sensors which can provide data that can be used in new and interesting ways to quantify the self. FSR's are playing and will play a significant role in meeting these needs. They are cost effective, thin form factor, easy to measure, low power consumption, and easy to customize printed electronic devices. They are easily combined with other sensing technologies to enhance haptic feedback and can also be used to enhance the quality of data from other sensors. This makes them extremely appealing to product designers and engineers as they seek to create the next generation of innovative medical devices and products. What kind of future can you imagine?

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