Bluetooth™

The Wireless Ecosystem for Health, Fitness and Assisted Living.

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Executive Summary

Bluetooth is already the de facto wireless standard for health and fitness devices. Whether that's a defibrillator, a weight scale, a heart rate belt, a glucose meter or a Wii Fit Balance Board, manufacturers have been enthusiastic in choosing Bluetooth to solve their connectivity issues. Altogether, over 20 million Bluetooth health and fitness devices have been sold, from hundreds of different manufacturers.

That success hasn't come by chance. Bluetooth[1] offers advantages that other wireless options, whether standard or proprietary, are not capable of providing. Key amongst these are:

- Excellent resistance to interference
- Best in Class Security.
- Low Power operation
- A RANDZ license-free regime which gives manufacturers the confidence to use it without being sued.
- Low Cost. Both as a result of the design of the specification and the economy of scale accruing from the production of billions of silicon chips by multiple vendors.
- Security of supply from that same range of silicon vendors.
- Being the short range radio of choice in mobile phones.
- Support from a community of over 11,000 member companies.

Medical devices are still not perfect; they have an Achilles' heel, which is that the manner in which data is formatted remains proprietary, so similar devices from different vendors cannot talk to the same application. That is already changing. Bluetooth has worked with the Continua Alliance and the IEEE 11073 Personal Health Devices group[2] to bring its Health Device Profile to market. Chosen as the wireless transport by the Continua Health Alliance[3], it is a first joint step to remove this proprietary barrier and bring interoperability to the medical market.

However, we are only looking at the tip of the healthcare iceberg. The next, vital step in this market, which will change its scale by multiple orders of magnitude, will appear as we make health and fitness devices cheaper and connect them to the web using mobile phones. Today over half of the world's population owns a mobile phone, the majority of which include Bluetooth. The next Bluetooth standard, known as Bluetooth low energy will enable a new generation of battery powered health and fitness devices to talk directly to web based applications. Using a gateway technology, every new phone will be able to work with every Internet ready Bluetooth low energy device. Using the power of the scale and customer reach of the mobile networks and handset manufacturers, Bluetooth low energy has the potential to bring health monitoring to the entire world.

It cannot come soon enough. The demographics of the world's population are changing. Advances in hygiene and medicine have brought us longer life, but with it increasing years of ill-health and a growing incidence of long term chronic conditions. The models on which we have built healthcare for the last few centuries cannot stand up to these pressures, which drain an ever greater part of our GDP every year.

To address these issues we need to harness technology to help people stay well, promoting a healthy, independent lifestyle. Technology may not necessarily cure people – that may or may not prove to be economic or even possible for the growing number of long term chronic conditions that we collect. But it can be

used to inform and help the population to look after their own health, whether that is as an active teenager, parent, or grandparent.

Life and health is a continuous spectrum. In our youth, it may involve information about the way we play and our social interactions. As we grow and have children, it's about staying fit to cope with the pressures of work, mortgage and family. Getting older, more and more of us are contracting long term chronic diseases and we need to find the best way to manage them as part of our everyday lives. And as we watch our grandchildren grow up, we need help to manage our surroundings, to help us live independently with peace of mind for ourselves and our families.

Bluetooth is key to making this possible because of its capabilities and, most importantly, because of its ubiquity. The latest version of the standard can support complex medical sensors as well as simple detectors for assisted living which need to run for years on a single battery. By making the connection to the internet simple, using the established ubiquity of mobile phones and the internet, it will also give developers, whether they are medics, researchers, or enthusiasts within disease support groups, the opportunity to write software and web applications that help us to stay healthier.

Bluetooth provides the platform for the innovation we need in healthcare. There is no other connectivity option that has the scale to let us progress from today's deployments of a few thousand users to a global deployment of hundreds of millions. It is the only route to universal, connected healthcare.

This report examines the changes in population demographics, explaining the reasons for the problem of funding healthcare in the future. It discusses the ensuing requirements for a wireless means of transferring data from health and wellness devices to a remote patient record and explains why Bluetooth is best suited for this application.

It will need many pieces of the puzzle to be solved to move us from the position we are in today to a future of sustainable personal healthcare. The medical industry and Bluetooth are working together to solve the connectivity and interoperability parts of that puzzle. Together they can help make that future a reality.

Background

Bluetooth is one of the most amazing phenomena in the area of wireless standards. From its inception just over ten years ago, it has grown to become the most widely used short range wireless standard. Each year it is incorporated in more than one billion products. That number is growing every year, and by 2011, there will be more Bluetooth products on our planet than there are people.

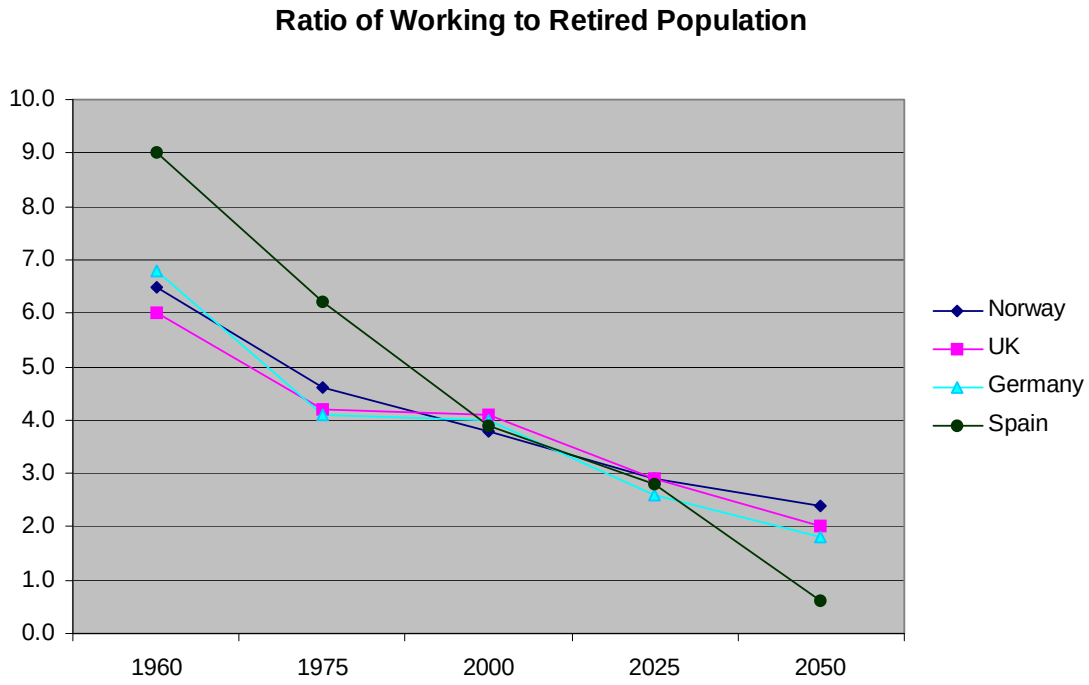
Although most people think of Bluetooth as either a wireless headset or a way of transferring data between devices (its popularity is so great that the word Bluetooth has entered many languages as both a noun and adjective to describe these uses), it is routinely used in a vast number of less visible applications, from credit card readers to defibrillators, agricultural implements to blood pressure meters. Over 12,000 companies and institutions, including universities, health providers and insurers have become members of the Bluetooth Special Interest Group (SIG), contributing their knowledge and expertise to the standard. The membership is a Who's Who of multiple industry sectors.

As well as developing the most successful short range wireless standard, the Bluetooth SIG has worked with regulatory bodies around the world to open up the 2.4GHz frequency band for unlicensed devices. The result is that almost all Bluetooth devices can be used without modification in any country in the world, in sharp contrast to most other wireless technologies operating in this frequency band, which need to ship versions customised to suit particular geographic areas.

Bluetooth has proven itself to be robust; in terms of performance, reliability, interoperability and also in intellectual property. Whereas other standards leave licensing risks to each manufacturer, the Bluetooth standard operates a RANDZ policy, giving manufacturers the confidence to incorporate the technology into their products without the need to pay license fees, and virtually free from the risk of being sued for patent infringement. That overall level of confidence has been instrumental in making it the success it is today. With the backing of its members it is moving forward to provide the wireless ecosystem for many more applications in the future.

Introduction – the driving demographics

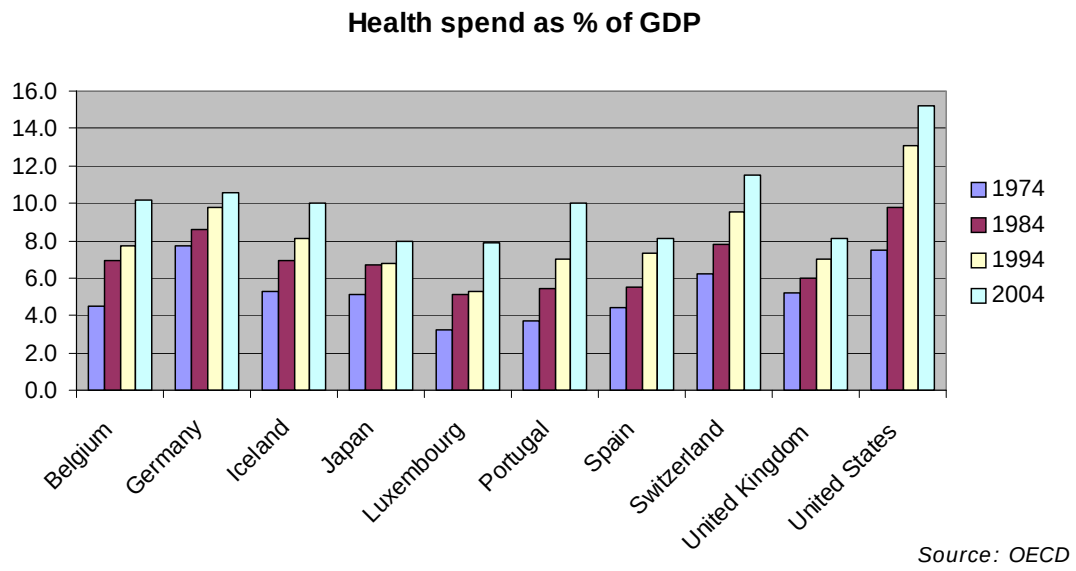
The demographics of the world's population are changing. People are living longer and are having fewer children. That change is progressing at different rates in different countries and cultures, but it is a problem that will beset every nation. As life expectancy increases, and birth rate falls, the ratio of those in work to those who are retired or who need medical or social support will fall. That ratio determines who will pay. As it falls, the societal cost of healthcare become less and less sustainable.



Source: European Commission

Unfortunately the world is facing a double whammy. As our life expectancy increases, so does the number of years that we will be ill. Despite medical advances, the percentage of our lives that will be blighted with disease stays relatively static – older age means more years with long term chronic conditions. Moreover, changes in lifestyle exacerbate this, as previously uncommon diseases such as diabetes and asthma affect a growing portion of the population for more of their lives.

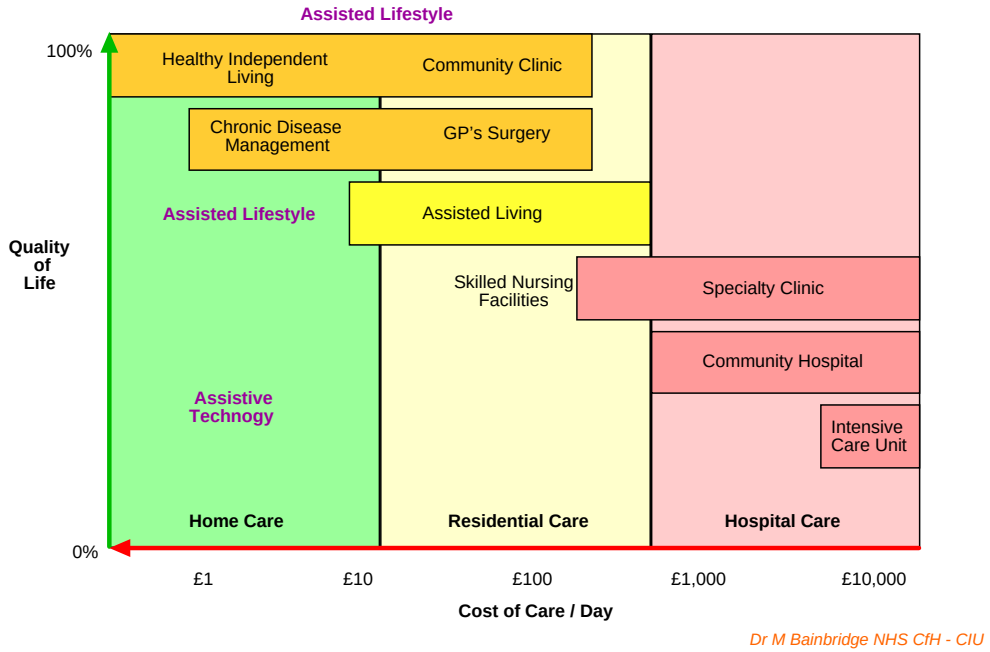
The effect of these trends is that we are spending an ever increasing portion of our income on healthcare. Worldwide, nations are already struggling to cope with these costs, whether they are met by private insurance or public funding. As the demographics start to bite, the current form and structure of healthcare will become impossible to support.



Source: OECD

There is no magic solution. What is clear is that steps need to be taken to control the costs of supporting a population that is increasingly ageing and prone to long term chronic disease (LTC)[4]. That involves a combination of promoting healthier lifestyles, supporting people to manage their medical conditions themselves or within communities, and in enabling independent living, which helps to keep people out of hospital or residential care.

Many analyses of care costs have shown that prevention can produce vast savings. A report by the NHS in the UK graphically indicates the benefits of keeping people well and independent:



Dr M Bainbridge NHS CfH - CIU

Tipping the balance towards prevention, support and self management is not a simple job. It requires the combination of sensor technologies that can monitor patients and their health, software that can analyse the data and provide pertinent and compelling feedback to the user to help them modify their

behaviour, and a wireless technology that can transfer the patient data from the sensors to the software, regardless of where the user may be. Bluetooth, and the infrastructure that contains and support it, is the only solution that can provide the ubiquitous data connectivity that the future of healthcare requires.

Supporting the Life Cycle of Healthcare

The new paradigm of healthcare as something that a patient embraces throughout their life places stringent requirements on the technologies that will support it. It requires an infrastructure that will measure what we do and how we interact with our environment and which then places that information securely into our health records. Depending on where we are in our lives, that may be personal data for our own use, data that we share with our clinicians, data which is shared with support communities, or with our families. It may be generated when we are at home, at work, at play, or within a medical environment. It's important that a technology can support that range of lifestyle options. If it does not, then we run the risk of moving from the old position of being institutionalised by a hospital to becoming institutionalised by a technology.

Supporting an active and independent life

Remote Health solutions need to allow seamless coverage as people move through their lives and as their situations change. As well as the spectrum of requirements – having fun, keeping fit, maintaining quality of life, through to independent living with peace of mind for ourselves and our family, people will expect technical solutions to be simple, reliable and interchangeable to accommodate the way they choose to live.

Bluetooth – a Healthcare Ecosystem

With over three billion deployed products, Bluetooth has not only proven that it can support a wide range of applications, it has assembled a community that knows how it needs to evolve. It is already incorporated within a wide range of medical and fitness devices; if one takes a broad definition which includes all of the Nintendo Wii products as fitness devices, the combined total exceeds 100 million, with devices in the home, as wearable sports gear, in ambulances and all the way through to FDA approved equipment[5]. However, up until now, each manufacturer has designed their own, proprietary implementation, so that the data from different manufacturer's devices is incompatible. In January 2006, the

Bluetooth SIG inaugurated a Working Group dedicated to developing a standard to support existing and emerging medical devices and to bring compatibility and interoperability to this market. Membership came from medical device manufacturers, silicon suppliers and other supporters of the Bluetooth standard, who worked together to produce a Health Device Profile that was approved in 2008. This was adopted by the Continua Health Alliance as their wireless health option in the first version of their own standard.

The Bluetooth Health Device Profile works with the Bluetooth chips that are in production today, which support streaming data rates of up to 2.1 Mbps. That means that it can support medical devices as complex as ECGs, which need to stream data. It is equally applicable for simple devices such as weight scales that only need to transmit small quantities of information. It builds on the underlying capabilities of the Bluetooth standard, which include:

- Excellent resistance to interference from Wireless LANs, through the use of Adaptive Frequency Hopping.
- Best in Class Security, including immunity from "man-in-the-middle" attacks, by utilising Secure Simple Pairing with elliptic curve Diffie-Hellman public key cryptography.
- Low Power operation, utilising sniff sub-rating modes to allow devices to enter power saving sleep states.
- A rigorous qualification program to ensure interoperability.
- A license-free regime which gives manufacturers the confidence to use it.
- Excellent range – up to 1km range products are available.
- Global Applicability, using the 2.4 GHz band, which was negotiated worldwide by the Bluetooth SIG for Bluetooth technology.
- Low Cost. Both as a result of the design of the specification and the economy of scale accruing from the production of billions of silicon chips by multiple vendors. This also gives security of supply for medical device manufacturers, whose products typically have much longer lives than those of consumer products.

Enabling Interoperability

Much of the development work within medical standards is being driven by a key requirement of purchasers – hospitals and clinicians, which is a demand for interoperability. When medical devices were not connected and only provided a local display that was written down by the user or a clinician, interoperability was not important. All that mattered was that the measurement was accurate.

With the advent of connectivity, whether by a cable to a network, or via a wireless link, it is important that medical data from different devices speak the same language. As they feed data into a central Electronic Health Record it is vital that the information gathered from different makes of monitor is consistent. To help achieve that, a group within the IEEE standards body has been defining a set of "device specialisations", which mandate the way in which data is represented by specific types of medical device. Products that conform to these standards, known as IEEE 11073, provide the confidence that the patient data is consistent, whatever make or combination of devices is being used. The IEEE 11073 family of standards already covers blood pressure monitors, thermometers, weight scales, glucose meters, pulse oximeters and heart/pulse rate monitor and more are being added to this list.

The Bluetooth Health Device Profile integrates these IEEE 11073 device specialisations, giving the assurance that Bluetooth medical devices not only

connect in a consistent manner, but also provide a guarantee of the quality and format of information that is transferred over the wireless link. Products that meet this requirement can be further certified to carry a Continua logo to indicate their compliance.

Adding Mobility to Medical Devices

Traditionally most medical devices are designed to be used within a medical environment. They are used by trained medical staff and provide information in a medical language and format. As public interest in personal healthcare increases, and as governments attempt to persuade people to be more aware of their health, we will see these products being supplemented by a rapid growth in personal medical devices, sold directly to consumers.

These devices will initially offer similar readings to the current range of medical products, covering parameters such as blood pressure and glucose, but will need to evolve to offer more compelling personal feedback. Most users are not experienced in interpreting medical data – they would prefer feedback on trends that provide information they can use to improve their wellness. This argues for devices that can interact easily with web applications, as that will open the path for rapid innovation in novel forms of health feedback. As yet it is impossible to tell whether that will come from medical suppliers, from support groups, from device manufacturers or from other developers. What is important is to adopt standards that will bring a critical mass of devices to the market place, providing the opportunity for innovation. That critical mass need not be constrained to medical devices. It should reflect the continuum of our health requirements, which means that it will extend seamlessly into the sports and fitness market.

Today the first wireless sports devices using Bluetooth are already available, in the form of heart rate monitors and pedometers. They herald an important trend in the health device market, as it develops into a full spectrum of devices that span wellness, sport, fitness and disease. As populations feel the financial pressures to take better care of themselves they will increasingly use a variety of such devices, which need to aggregate their results into the patient's personal medical record.

This change transforms the way that products need to connect. If they are going to allow the freedom of use which purchasers will require, they will need to be as mobile as our lifestyle. That mandates two important design factors:

- They will need to be connectable wherever they are, and
- They will need to be small, hence ultra low power.

If this market is to be successful, it is likely to innovate with sensors that fit within clothing and sports equipment and which are so power efficient that they can run off coin cells for years. They will also need a wireless link that can meet these requirements at the same time as communicating the user's health data through a mobile phone and back to their personal health record. Interoperability with mobile phones is vitally important to the growth of the market and critically requires a technology that is supported by handset vendors.

Because there was no technology that all of these requirements, it became necessary to develop one. That new technology is part of the Bluetooth family of wireless standards and is called Bluetooth low energy. It has been designed specifically to meet the needs of mobile health devices.

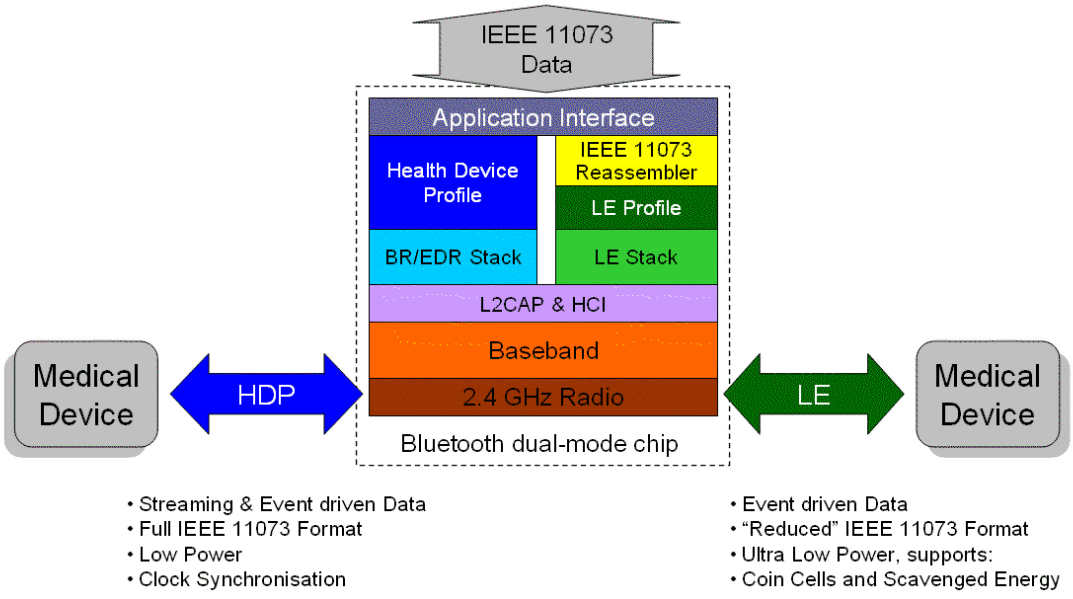
Bluetooth low energy

The Bluetooth low energy standard[6] is a further evolution of the current Bluetooth technology. It starts from the point of acknowledging that almost every mobile phone contains a Bluetooth chip. This allows mobile phones to connect to existing health devices which use the current Bluetooth Health Device Profile.

Although these devices are low powered, they cannot be made sufficiently low power for some applications. To obtain the absolute lowest power consumption, where even coin cells can power a device for years, you need to change the way in which a radio operates, so that it stays asleep for most of its life, consuming almost no power, then wakes up at the point that it has data to send, sends the data as quickly as possible and returns to its low power sleep mode.

The Bluetooth low energy chips that are destined for medical devices have been designed to perform in this manner. The specification has the potential to enable wireless devices operating in the 2.4GHz spectrum to have the lowest power consumption of ANY wireless standard. It achieves this without sacrificing the features that have made Bluetooth so successful – robustness to interference, excellent security, interoperability and a licence-free technology.

One of the most attractive aspects of this new Bluetooth technology is the way in which it will be implemented in mobile phones, PCs, residential gateways and home medical centres. These are devices that will connect Bluetooth health devices to a web based application. Within these, a single Bluetooth chip can share its radio to act both as a conventional Bluetooth HDP controller and a Bluetooth low energy controller at the same time.



Bluetooth's Dual-mode advantage. One chip supports all types of medical device.

The new specification has been designed to allow chip manufacturers to reuse most of the features of the Bluetooth chips which they are currently building. The advantage this confers is twofold:

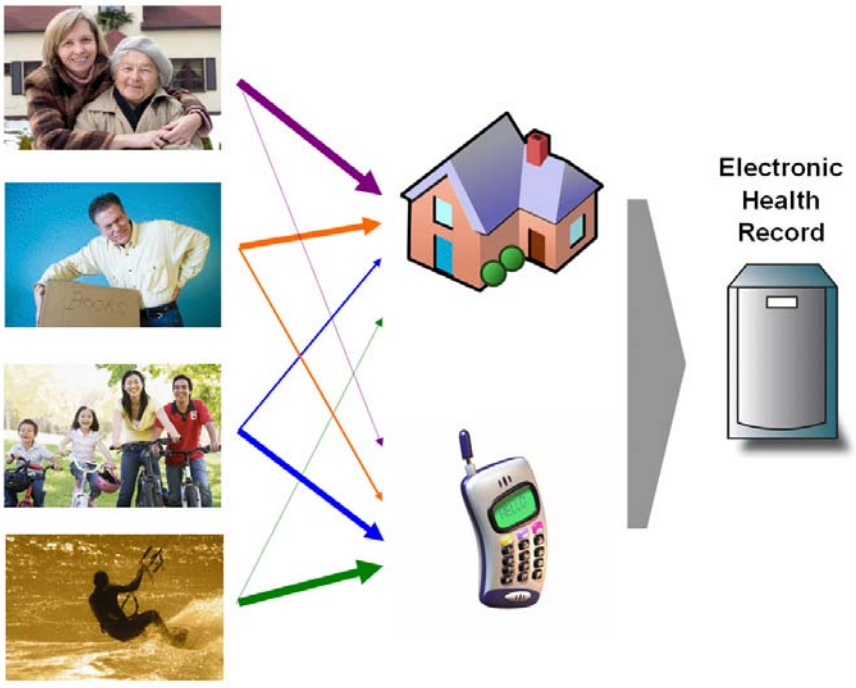
- There is so little new circuitry required within these chips that they will cost no more than the chips currently being used within mobile phones. That means that they will rapidly find their way into new phone and laptop designs, so that in a very short space of time, all new mobile phones will support both standard Bluetooth and Bluetooth low energy devices.

- Any company designing a medical home hub can use one of these chips in the knowledge that it will work with anything from an ECG to a door sensor. One design will support any device in the wireless ecosystem, bringing the advantage of future-proofing to product manufacturers.

An ecosystem for whole life monitoring

As we move through life, our medical needs change. They rarely change rapidly, but evolve with us as we age. As our health and wellness become more connected, we are likely to want to gather different data for different purposes. That will include wellness information, such as weight; achievement information, such as how well we play our favourite sports, moving to disease management as we acquire long term conditions, through to independent living assistance as we enter old age.

Although the evolution is common to all populations, the way that we each progress through it is personal. It is important that any life-time medical monitoring technology appreciates that. In order to do that it demands a flexibility of approach that can provide a wide range of different monitors that we will use throughout our lives, but equally supports a range of different topologies for connecting them.



The way we connect
(As we age, the way we connect our health devices evolve, independently to the devices.)

When we are young and active, the mobile phone is likely to be the prime instrument of connectivity for these devices. As we settle down and start families, some of this connectivity will transfer to a home gateway of some form. And when we are retired more of our medical devices and the assisted living sensors that will be installed around our homes will connect most of the time to a static gateway in the home. How this evolves and at what stage things change will be as individual as we are. Collectively our use of technology and our mobility may form part of a larger demographic, but still remains personal to each of us. What is important is that the infrastructure supports the way we want to live, rather than institutionalising us with the technology.

Some proponents of eHealth attempt to divide the connectivity of health devices into different topologies - Local Area Networks (LANs) for static devices, Personal Area Networks (PANs) for devices we wear inside the home and Wide Area Networks (WANs) for those that we take outside. It's a false and dangerous classification as it ignores the way we live our lives today. It is a classification that is only really relevant to engineers. Users do not care about topology – they just want the products they have bought to work. Mobility is something that exists as long as we can move, and whether a device is static or mobile, the only thing that counts is that it can get its data back to the appropriate health record. Accepting this means that the connectivity hubs of personal healthcare should support one radio for all health devices.

The reason that Bluetooth is the ideal wireless solution for a medical ecosystem comes from the power that it provides for collector devices, whether they are mobile phones, or home hubs, to support any combination of medical or fitness device. Our lifestyle means that we will want to place our health data into a personal health record in different ways at different times throughout our lives. Bluetooth allows us to do that with no restraint on lifestyle. It is the only wireless solution that does not come with a straight-jacket.

Enabling today and the future

The current version of the Continua standard has an architecture where data is consumed by collecting devices before it is transmitted on to the next participant in the chain en route to the eventual health record. This is the paradigm which is derived from existing clinical devices, where a local monitor will display the results of the sensor attached to the patient for the nurse or doctor to see before storing it in the hospital database. It is the paradigm that is supported by the Bluetooth Health Device Profile and is used in today's Continua certified products.

For mobile devices that need small batteries it has a few disadvantages. Firstly, it requires a large amount of data to be transferred, which will reduce the battery life of a personal health sensor. Secondly, it requires the collector device to contain enough processing power to act on that information – usually to display it. For laptops and phones that's not a problem, but for other devices, like watches, it may be.

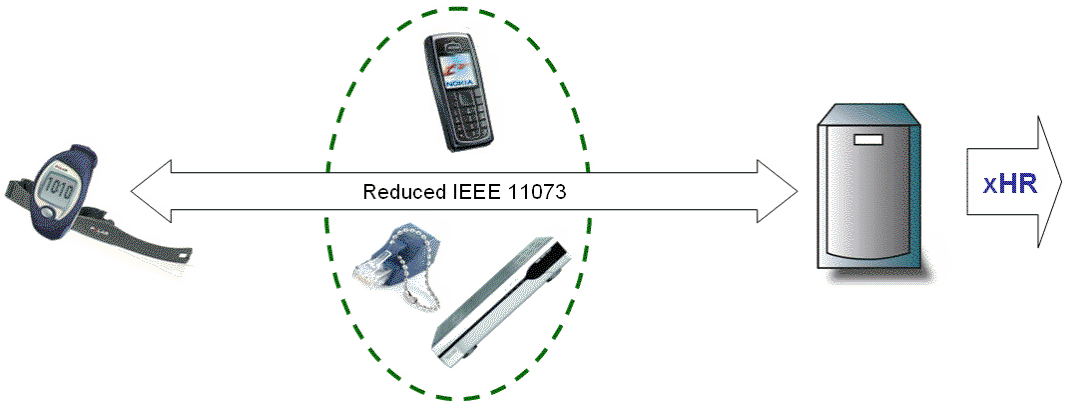
Aggregator

Aggregators collect the data before forwarding to the WAN. This creates a two part process to get data from device to server. Aggregators need to understand all of the supported IEEE 11073 device specialisations.

Typical devices include PCs and home health centres.

For many medical products this is not a problem. But for the lowest powered ones, such as pedometers fitted inside running shoes, it requires more data to be transmitted than is strictly necessary. (It may also be a problem for some of the lowest powered collector devices, such as watches and wall displays.)
It also puts the onus on phone manufacturers to provide application programs that understand the whole range of different sensors that might be attached.

For the simplest, and lowest powered sensors it is more attractive to treat the phone or gateway as no more than a secure data transmission pipe that can send the data directly to a remote server. With this approach the intelligence is within the server, rather than the phone. Bluetooth low energy can take advantage of this by allowing the server to talk to the sensor the first time it is connected and determine how it works. They can then negotiate with each other to reduce the amount the data that is transferred over the wireless link, so that only events or changes are reported.



Gateways

Gateways provide a secure tunnel to allow servers to interact directly with devices. They allow reduced data sets, which are required for low power, coin cell based sensors. Data is reconstituted at the server.

Typical gateways include phones, Ethernet adaptors for DSL and cable modems and set top boxes. Gateways do not need to understand IEEE 11073 formats.

Although the first and most prolific gateways will be mobile phones, they can equally be Ethernet adaptors for cable and DSL modems, set-top boxes, PCs or any other device that supports a back-link to an IP address. Whether they are transmitting data from sports equipment, lifestyle monitors, assisted living or early onset dementia monitors, they provide a ubiquitous infrastructure to make sure that our health data ends up within our health records.

This approach substantially reduces the quantity of data that is transmitted, compared to a full IEEE 11073 exchange, but the server is able to faithfully reconstruct it into a full IEEE 11073 format for the Health Record. It also benefits the owners of gateway products, as less data needs to be transmitted, lowering costs if the gateway is passing data over a cellular network. An additional benefit is that it may also improve response times and give a better user experience. At the device itself, the lower data transmission load means extended battery operating life, opening up the possibility of designing wireless monitors and sensors that run on coin cells.

For phone manufacturers, they gain the enormous advantage of only needing to write a generic gateway application that will work with any health device (or any other Bluetooth low energy product that utilises the gateway function), instead of having to write numerous, device specific applications. If data needs to be displayed on the handset, this can be sent back to a web based, generic application from the server, once again simplifying deployment and speeding up innovation. All of this feeds the virtuous circle of deployment, critical mass and application development.

The Bluetooth Medical Working Group is currently working on this solution as a parallel development to the Health Device Profile for devices. It will complete the ecosystem requirement of supporting the full range of medical, health and assisted living devices, even those which need to operate at the lowest possible power. It is a further commitment to providing a complete tool kit for a wireless medical ecosystem.

Conclusion – an ecosystem built on flexibility and ubiquity

Choosing a wireless technology for medical devices needs to take into account the lifetime requirements of users. It needs to support a variety of different connection topologies, including Local Area Networks (LANs), Personal Area Networks (PANs) and Wide Area Networks (WANs) if it is to become ubiquitous. Otherwise it constrains the way we live and any technology that does that will fail to gain user acceptance.

To achieve success eHealth needs a critical mass of devices. Today there are just over 3 billion Bluetooth devices in existence. In 2011, there will be more Bluetooth devices than people. From the start of 2010, mobile phones will incorporate chips which support standard Bluetooth as well as low energy Bluetooth. No other wireless technology can begin to emulate this.

The ability of the new generation of Bluetooth chips to support any Bluetooth medical device gives designers of mobile phones, PCs, Gateways and home medical hubs unrivalled power to build devices that can talk to any personal Bluetooth medical device. The twin standards of Bluetooth low energy and Bluetooth cover the full diversity of products that range from simple sensors in Assisted Living (which need battery lives of many years), to complex monitors

that stream waveform data. The options of full or reduced IEEE 11073 data transport will also enable innovation in the development of web based applications for simple consumer wellness and sports requirements, stimulating development and further driving the ecosystem forward.

Over the last three years the medical and sports community has come together within the Bluetooth working groups to define a wireless technology for the future. The first Bluetooth HDP products are now available to buy. With the help of Bluetooth, the revolution in wireless healthcare is about to begin.

Nick Hunn
May 2009

References and Links:

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