Taking a Wireless Medical Product to Market

Tomorrow's wireless personal healthcare product?

Wireless technology has long been exploited by the healthcare sector, in devices such as pagers and hand-held instruments. However, scepticism of the risks associated with wireless has prevented widespread adoption, particularly in life critical applications. Now, significant advances in radio sophistication and performance have eroded these perceived risks to the point where wireless technology is now in widespread use in high integrity medical systems.

Combining a world-renowned expertise in wireless design with over twenty five years experience in medical product development, Cambridge Consultants provides one of the most advanced wireless medical device design teams in operation today.

Wireless Medical Products

Today's medical devices face an increasingly demanding and competitive market. As performance targets within the sector continue to rise, new ways of increasing efficiency, productivity and usability are sought. Wireless technology provides tangible and recognised benefits for medical products - and is a key technology that few manufacturers are ignoring.

However, it is far from trivial to harness the benefits of wireless without a strong background in the technologies available for use. Key performance factors that must be considered include frequency band, data rate, range, power consumption, interoperability and regulatory constraints. In addition, methods to ensure link quality, resilience to interference, latency, and security must also be addressed.

To meet today's performance expectations, radio technology has progressed significantly in recent years. The availability of low cost microprocessor intelligence has enabled radios to be far more sophisticated. Devices can monitor available frequency spectrum to minimise interference and maximise capacity, can employ robust protocols to maximise link integrity, and can encrypt data to provide privacy. Furthermore, standardisation has created an economy of scale and also new medical frequency bands have been established, within which strict rules govern use of the spectrum for sensitive medical applications.

As a result of these advances, there are a wide variety of wireless medical devices on the market today, from ambulatory monitoring systems that transmit real time patient data to a central station in the hospital, to swallowable pills that transmit measurements to an external reader. All have very different performance requirements, from both technical and commercial perspectives.

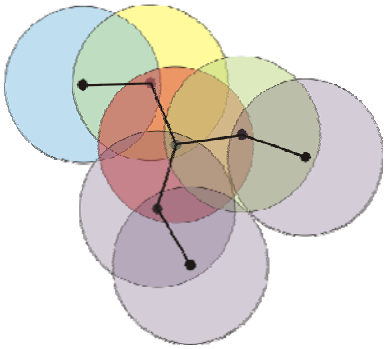
Wireless Design

Cambridge Consultants adopts a 'technology agnostic' approach, having expertise in the vast majority of wireless technologies available today. Based on this strong foundation of fundamental radio principles, we are able to select the optimum technology for a particular application.

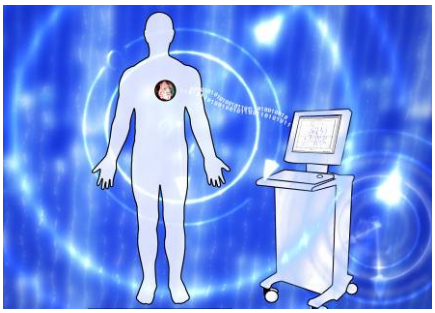
In some cases a 'standard' technology may be appropriate, whilst in others a proprietary solution can be adopted to achieve superior performance. An interesting mix involves customisation of a standard technology to achieve specific requirements and in doing so, exploiting the economy of scale of the underlying technology, while derisking the product development.

A brief selection of relevant wireless technologies available today include:

- **Bluetooth® -** A 'Personal Area Networking' (PAN) technology that originally targeted simple 'cable replacement' solutions. Bluetooth® satisfies the need to transmit 'moderate' amounts of data within the immediate vicinity of a person or object. Now, with enhanced data rates and other functionality it is a dominant standard in personal computers and mobile telephones. Bluetooth® operates in the 2.4GHz licence-free band at aggregate data rates up to 723kbit/s and, now, 2.2Mbit/s in its Enhanced Data Rate (EDR) version.



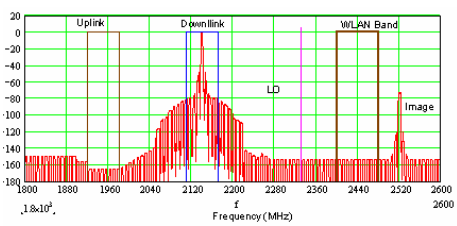
- **ZigBee® -** A 'Mesh Networking' technology that is a key driver towards wireless automation and ubiquitous computing. ZigBee® is optimised for low current consumption. It can form networks that self-configure and even self-heal in the event that a node fails. ZigBee® operates at 868, 902MHz and 2.4GHz with peak data rates to 250kbit/s for the 2.4GHz version.
- **Wi-Fi® / 802.11 -** A 'Local Area Networking' (LAN) technology often referred to as the 'wireless extension of ethernet'. Wi-Fi® is a high data rate packet-based system, originally optimised for data transmission. It enables higher data rates to be transmitted than Bluetooth®, but with a corresponding increase in power consumption and, indeed, cost. Dependent on the variant, Wi-Fi® operates in the 2.4GHz and 5GHz licence free bands at peak data rates up to 54Mbit/s. To overcome limitations in its packet based approach, enhancements are provided for increased 'Quality of Service' and also for improved security.
- **Cellular -** A 'Wide Area Networking' (WAN) technology that is enabling the mobile phone revolution. Cellular systems depend upon a 'basestation' infrastructure with a service administered by operators. Nevertheless, cellular allows transmission over large distances without need to create an infrastructure (as long as it exists). Systems operate between 450MHz & 2.1GHz with low data rates in the current generation (circa. 14.4kbit/s) up to 2Mb/s for the third generation systems being deployed today.
- **DECT -** A relatively mature 'Cordless' technology used domestic digital cordless handsets. DECT is a 'connection-orientated' technology originally developed for uninterrupted transmission of voice. It therefore provides a high quality service for continuous data. It does, however, require an infrastructure in its standard form, which does nevertheless allow roaming. DECT operates at 1.9GHz (or 2.4GHz) at aggregate data rates up to 552kbit/s with multiple timeslots.



- **Proprietary –** Customised wireless solutions for specific applications, perhaps based on simpler RF technology operating in licence-free bands. An example being Cambridge Consultant's own "SubQore" architecture optimised for ultra-low power consumption in implantable radio devices.

RF Systems Design

For wireless medical devices, it is important to compensate for the intermittent nature of the RF link. Although the simpler radio chip designs are capable of sending data over-the-air, they rarely include protection for dropped links or bad fading conditions caused by indoor RF propagation. Cambridge Consultants understand these problems in great detail, and ensure the integrity of the wireless system is not compromised. Data integrity is vital for most wireless medical applications and several techniques are needed to compensate for intermittent links and improve resilience to interference. These range from low-level data protection, through packet handling and message verification. In addition our concepts for self-configuring and self-healing RF networks have been used to avoid coexistence problems with other transmitters in the same band.



Radio Regulations

When choosing a wireless technology and frequency band for a new device, the first engineering concern is to achieve desired data rates, power consumption, interference levels and radio propagation characteristics. However, national radio regulations also have a major role in constraining that choice. National regulations typically dictate physical limits (power, bandwidth, time occupancy etc) on signals in a given band, and sometimes dictate spectrum etiquette to ensure co-existence between neighbouring systems.

Despite these constraints, regulation changes often support new market opportunities by allowing specific medical applications in new frequency bands. For example, the USA's introduction of the Wireless Medical Telemetry Service (WMTS) in 2000 has allowed licensed primary medical use at 600MHz and 1400MHz. The FDA encourages use of the WMTS bands to improve patient safety by reducing risk of RF interference from other radio systems.

Another example for medical devices is the 402-405MHz Medical Implant Communications Service (MICS), which was established by the FCC in 1999 and is currently emerging as a global standard for implantable wireless devices.

While the USA, Japan and Europe mostly lead the development of radio regulations, other countries typically follow their lead with a delay of a few years. For example, New Zealand is currently considering introducing an equivalent to the USA's WMTS, also at 1400MHz.

RF radiation exposure limits also apply to medical wireless devices, as they are frequently in close proximity to patients. These safety limits are relevant for transmission powers above about 100mW and at microwave frequencies where the Specific Absorption Rate (SAR) in human tissue becomes important.

Fortunately, most wireless medical devices only need to operate indoors and at short range, so typical transmitter power levels are much lower than the safety limits. Indeed, in many cases, intentional wireless transmissions may in fact create a lower field strength than unintentional transmitters.

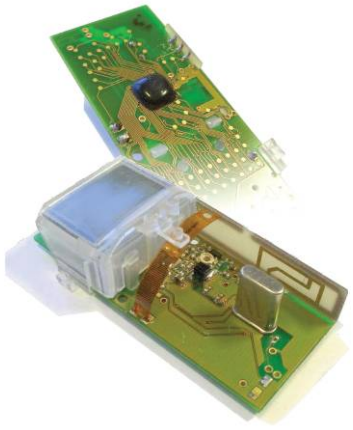
Medical Regulations

The development of medical devices is regulated in both the US and the EU and is managed by a mandatory development process. The reason for this approach is that the range of technologies used in medical devices is vast and fast moving. Thus a standards based approach, whilst it has its applications in healthcare, is not appropriate for novel, disruptive applications and technology that are encouraged in this market. Cambridge Consultants adopt a proven risk-based approach to novel medical device development, where risks are identified up front and throughout the development programme. This approach termed “Design for Validation” and was developed by Cambridge Consultants with Cambridge University. The aim is to ensure regulatory compliance with the least burden on development. For example, we took the “Thermosense” system, a novel invasive cardiac diagnostic device, from concept to regulatory approval in only 18 months. We have a track record of success with “Design for Validation” and our development philosophy has been adopted by many of our satisfied clients.

Wireless Medical Product Development

Medical product development is governed by the Quality Systems Regulation (QSR) in the US and the Medical Devices Directive (MDD) in Europe. Most other countries operate approvals regimes that recognise conformance to QSR and MDD.

The wide range of medical device types and the need to allow swift introduction of innovative products means that both QSR and MDD dictate the development process that needs to be followed, rather than calling up specific technical standards. The international standard ISO 13485 dictates the particular requirements for the application of quality standard ISO9001 to medical device development. Conformance to ISO13485 provides presumptive evidence that the development conforms to the MDD and is instrumental in gaining certification from the FDA in the US.



The development process invoked by the regulations involves rigorous hazard analysis and risk assessment throughout the design cycle. It is not easy simply to bolt the medical process requirements onto a standard wireless product development programme.

Cambridge Consultants uses development processes that conform to ISO 9001 and has successfully completed projects to ISO 13485, designing products that

have been released as conforming to both the QSR and the MDD.

We understand the particular needs of the medical marketplace, as well as the technical details of the various radio standards.

The Challenge

There is a clear opportunity to capitalise on advances in wireless technology for application in the medical industry today. Significant advances in radio sophistication and performance are now at a point where wireless connectivity can be added to medical products, using the latest technology and controlled development processes.

Wireless technology can provide ubiquitous connection across medical systems, improve co-ordination across hospitals and offer specialist application for implantable devices. The high-speed and high data integrity offered by the latest wireless technology improves usability of medical devices, monitors patients and assets, and removes the high installation costs associated with wires.

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