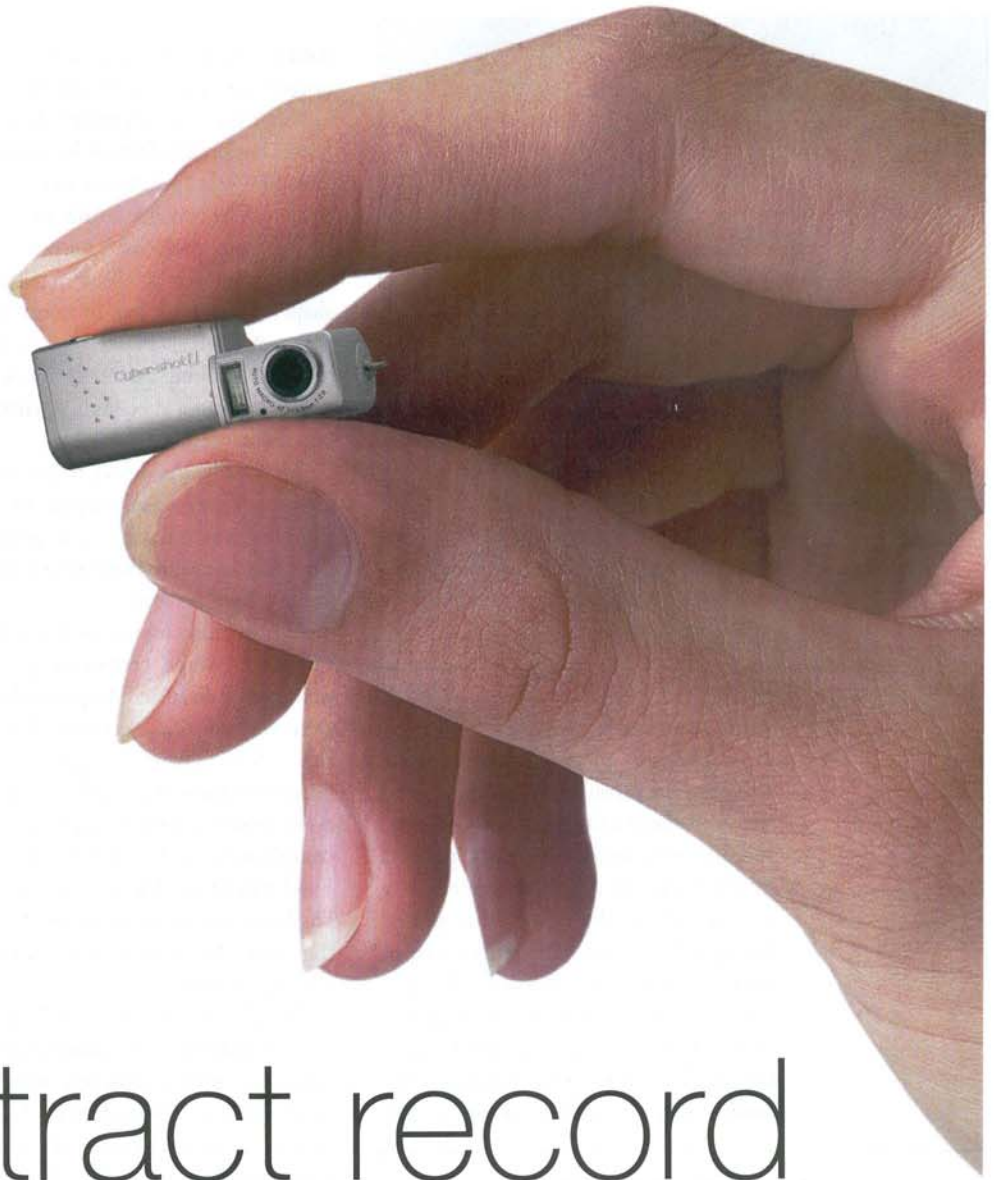


Wireless endoscopy is proving that it isn't a novelty medical technique. **Vanessa Knivett** reports.

Anyone who has had a traditional endoscopy will know the procedure is an unpleasant experience. A pill sized capsule is certainly a more preferable way to capture pictures of your insides, particularly if it replaces the need for a Barium meal, push endoscopy or xray. And signs are it could be more effective.

The M2A capsule was conceived by Given Imaging's Dr Gabriel Iddan, formerly a senior engineer at Rafael, the R&D group of the Israeli Ministry of Defense. Dr Iddan had set out to develop an imaging technique that would enable examination of the small intestine without subjecting the patient to pain or discomfort and legend has it that a defence project involving the development of electro optical devices for missiles provided



A new tract record

Dr Iddan with the necessary inspiration.

Given Imaging, an Israeli medical equipment specialist, designed the prototype for a wireless endoscope in 2000. But, like any medical breakthrough, M2A has taken much time and effort to get it to its current state.

Today, the technology is expanding the ability to diagnose certain diseases – such as Crohn's disease and small intestinal tumours not visible with current radiological imaging techniques – and its application to a broader patient pool, including 11 to 18 year olds.

But the design challenges were not insignificant. A particular challenge, and

one that Given Imaging decided to hand over to low power specialist Zarlink, was providing sufficient power for the camera to take enough pictures to provide an accurate representation of the entire gut.

Steve Swift, Zarlink's general manager of ultra low power communications, explains: "Given Imaging had incorporated a cmos imager chip with a transmitter and controller circuit designed by another Israeli company, plus batteries. It had done some clinical trials and realised it had a good product, but that more functionality was needed."

Zarlink was charged with designing a new circuit that would add features, as

well as reduce power consumption. The design, carried out by Zarlink's team in Sweden, took approximately 14 months from first specification to completion.

The M2A capsule consists of a microchip camera, leds that act as a flash, an antenna and two silver oxide batteries. And there is the transmitter asic that Zarlink designed for Given Imaging, offering particularly low power consumption.

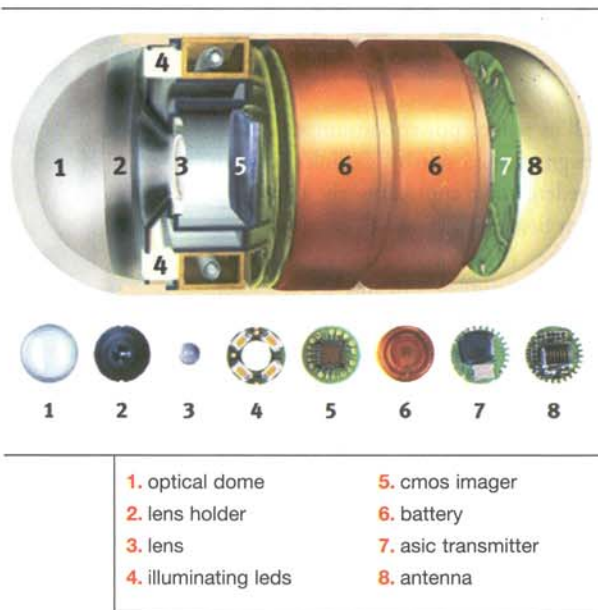
As Swift explains: "Lower power consumption means being able to take more images over a longer period." During a typical 8 to 12 hour examination of the gastrointestinal tract, M2A will take two pictures a second – some 60,000 images



At 11 x 26mm and weighing less than 4g, the M2A is swallowable. Given Imaging suggests it is taken with water so the camera's view is not obscured.

of the gut/mucosa.

As patients go about their normal activities, the capsule collects images and transmits them using rf. A vest mounted antenna array picks up the images and stores them on a belt mounted data recorder. After the camera has passed through the system, the patient returns the vest and the data recorder to the doctor, who then downloads the images to Given's RAPID (Reporting and Processing of Images and Data) software. This produces a 20minute video of the



patient's gastrointestinal tract, which the doctor can then scan for abnormalities.

Chip size was the primary design limitation, as the capsule must be swallowable. The capsule is 11 x 26mm and weighs less than 4g. The circuitry is fully encapsulated in a plastic enclosure. Recounts Swift: "The capsule is a specific mechanical shape, which took lots of research. As it moves through gastrointestinal tract, it self cleans by rubbing against the walls of the vessel, clearing away anything that might obscure its view."

Mercifully, the device is not reusable! In fact, a key specification by Given Imaging was circuitry that guarantees single use to ensure there is no black market for these devices.

Whilst many aspects of the design are still under wraps, certain design limitations can be discussed. In particular, there were very specific electrical characteristics. Says Swift: "Peak envelope power/transmitted power has to be low – no so much because of spectral frequency compliance, but because the US Food and Drug Administration sets limits for the amounts of rf that can be transmitted from

The device transmits in the ism band. "It's unregulated, so you don't need licence and there are no channels within that band that you have to abide by. However, there are spectral properties that you have to be careful of," says Swift. These include maintaining frequency stability within the band and making sure the device doesn't produce spurious emissions.

Medically significant

The advantages over traditional endoscopic techniques are for patients and doctors alike. The typical small intestine is like a 21ft long coil and has been very hard in the past to examine using traditional endoscopic methods. Already, the M2A is establishing a reputation for finding obscure gastrointestinal bleeding. The M2A moves through the gut just like a piece of food would – by relying on the normal peristaltic (or contracting) movement of the gut. Once swallowed, it operates autonomously – the only preparation

required is a six to eight hour fast and ingestion of a clear liquid that won't obscure the camera's view.

There are one or two challenges which Given Imaging is addressing. For example, there isn't a way of identifying the precise location – or pathology – of the problem. However, the M2A Plus has software that creates a graphical representation of the patient's gastrointestinal tract. By correlating data points, the doctor can locate a problem more accurately.

It is also relatively costly. However, notes Swift: "The diagnostic yield for capsule endoscopy is extremely high – I have seen rates of up to 90%, whereas traditional techniques have a 40 to 50% diagnostic yield. It seems to be a viable approach which has good patient compliance. Every indication is that this is going to be a worthwhile future technology."

According to Kevin Rubey, coo of Given Imaging: "The platform technology that we have developed is a basis for diagnostic solutions for other areas of the gastrointestinal tract, including the oesophagus, the stomach and the colon. Our long term objective is to establish the Given system as a diagnostic tool for the detection of abnormalities of the whole gastrointestinal tract."

Meanwhile, Zarlink's experience with companies like Given Imaging is reaping rewards outside its custom asic business. Whilst the transmitter chip Zarlink designed for this system is exclusive to Given Imaging, the IP used to develop it and some of circuit elements can be reused in other applications.

Zarlink is expecting silicon from the fab for a newly developed transceiver for implanted devices with application in a range of medical devices, including pacemakers, defibrillators, neural stimulators and drug infusion devices. Swift sees much potential in this: "This transceiver will allow an implanted device to communicate wirelessly through the patient's skin to the physician. This has all kinds of applications and we are having active discussions with major medical device manufacturers about that technology." **NE**