



Plextek

Case Study

Controller for Home Male Fertility Test

Medical device company Genosis has developed a new Over The Counter (OTC) fertility home test kit that will assist couples with early diagnosis of problems when trying to conceive children.

To be sold as a kit containing both a female and a male tester device, the essential diagnosis of both is achieved using chemical test strips but, for the male test, a small electronics package is needed to control part of the process, Genosis came to Plextek for assistance.



Genosis Fertell

Throughout the industrialised world there is a considerable increase in the number of women deferring childbearing until after 30 years of age, and this has a marked effect on fertility. A couple's fertility is dependent on the age of the female partner, with fertility rates halving as women age from 30 to 38. However, the commonest cause of infertility, representing 40 percent of all cases, is due to male factors, with problems such as sperm inadequacy.

Against this time-dependent background, couples are currently screened for infertility by being told to try to conceive for 12 months. If after this year they are still unsuccessful, they are deemed clinically infertile and subsequently offered a more detailed diagnosis. This protracted evaluation results in substantial anxiety and frustration for the couple. Additionally, their natural fertility decreases month by month thereby reducing their chances of successfully conceiving upon treatment.



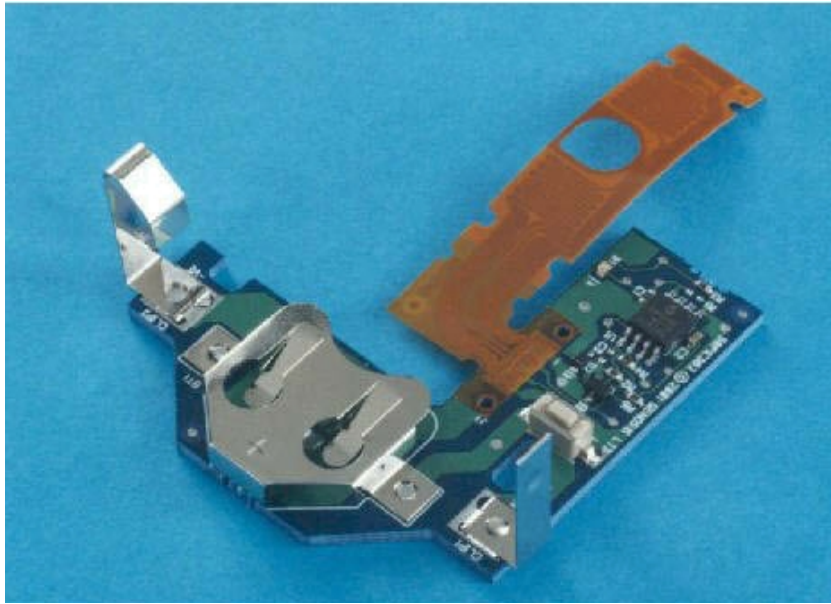
The availability of an accurate, simple to use OTC screening test for both male and female fertility, will afford couples earlier diagnosis which translates into a greater number of couples successfully conceiving and having healthy babies upon treatment. The home use also has the benefit of avoiding the embarrassment of unnecessary third party involvement.

The *Fertell* male test mimics nature by separating the motile (active) sperm from the non-motile (non-active) sperm and then measures them using the chemical test strip.

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Controller for Over The Counter Medical Test

To separate the motile from the non-motile sperm, the tester contains a column of fluid up which the motile sperm are encouraged to swim. This is where the Plextek electronics comes in. The embedded microcontroller accurately regulates the temperature of this column at normal body temperature, the best conditions for the motile sperm.

“Plextek has been able to provide Genosis with a full spectrum of consultancy services for the electronics in the *Fertell*”, said Andrew Scholan, Plextek’s Project Manager for the Genosis development work. “They initially came to us with a requirement for heating a small volume of chemical reagents, and since then we have been able to provide assistance throughout the product development cycle.”

Plextek initially undertook a design study for Genosis which examined the potential options available for the heater: whether to use a simple discrete controller or a more flexible microprocessor based solution. When all of the options had been considered, development using an ultra-low cost microcontroller was embarked upon.

The microcontroller solution allowed Genosis to incorporate both heater control and timing controller requirements of the product with great flexibility. The basic functions were easily augmented so that temperature limit checking and module health functions were incorporated at no additional material cost, allowing a test to be aborted if proceeding in an abnormal way.

Working with human technology designers Pearson Matthews Design, Plextek designed the electronics for ease and simplicity of use, with a clear system for patient prompting during the test.

Extensive work was undertaken to characterise the device’s thermal properties, testing various designs of heater and then selecting the optimal lowest cost design.

Throughout the development cycle, the hardware and software design and manufacturing engineering was always undertaken in a way to minimise the final factory gate cost. The software was efficiently coded in assembly language and every component selection was analysed to see if there was an alternative,

Design for low cost manufacturing:

- single sided PCB design
- 100% surface mount technology for automated assembly
- minimal component count
- ultra-low cost microcontroller
- optimised assembly language software
- zero adjustment assembly process
- no calibration required
- in-built Power On Self Test
- MOSFET switch power dissipation control software

more cost-effective component or manufacturing approach.

“Early diagnosis and treatment of infertility increases a couple’s chances of successfully conceiving and having a healthy baby,” said Genosis CEO Paul Bateman.

“Plextek’s electronics design expertise has enabled us to provide a reliable and robust solution for temperature control at a cost acceptable to an over-the-counter, disposable device.”

So far, the device has been tested in the laboratory on over 100 men, and a full clinical trial is underway.

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