

## ASX ANNOUNCEMENT

### PeriCoach® Clinical Trial Reveals Marked Improvement in Quality of Life, Sexual Function and Continence

- Analytica concludes post-clearance, randomised, controlled clinical trial on version 2 product.
- Superior results to control group in quality of life improvements.
- Superior results to control group in sexual satisfaction scores.
- Resources diverted to gathering evidence of version 3 product performance for licensing deal.
- Trial results to be presented to international urological and sexual health conferences.

**21<sup>st</sup> February 2017 - Brisbane, Australia - Analytica (ASX:ALT).** Analysis of PeriCoach clinical trial data conducted by an independent contract research organisation shows significant improvements in quality of life and sexual function, in conjunction with reduced urinary incontinence and improved pelvic floor strength.

The post-approval randomised clinical trial was held in Australia at five specialty continence clinics. The trial studied women undergoing clinician-guided pelvic floor rehabilitation (control) and women engaged in clinician guided pelvic floor rehabilitation with PeriCoach (version 2) to support home exercise between visits. The robust study design included women with predominantly stress urinary incontinence and required 8 visits to the clinician study site over 20 weeks. The level of clinical intervention in both groups far exceeds that of a normal UI sufferer seeking treatment, but this level of oversight was necessary to independently collect data.

Quality of life measurements showed statistically significant superior results (p-value = 0.015) for the PeriCoach group over the control group. Internationally recognised surveys assessed the areas of avoidance of behaviour, psychosocial impact, and social embarrassment, each of which PeriCoach scored better than the control group. Important to also note, that the PeriCoach group had higher scores at baseline and maintained even higher scores throughout the course of the trial which supports the thesis that effective biofeedback provides positive reinforcement and encouragement between clinical visits during treatment.

To analyse changes in continence, a 24-hour pad weight test was utilized, and the pelvic floor strength of all participants was assessed via Oxford Scale through digital examination by clinicians. Both groups did experience reduction in pad weight which did not produce a statistically significant difference (p=0.8034). This is to be expected as established data notes that 70% of women will see improvement with guided pelvic floor muscle exercise. For pelvic floor strength the data trend was in favour of the PeriCoach group, participants were twice more likely to have a 30% or better reduction in pad weight as well as earlier improvements of pelvic floor muscle strength during first four weeks of pelvic floor muscle rehabilitation. It should be noted that a 30% reduction in pad weight is considered a large change and pelvic floor measurements by Oxford Scale are not linear as many women stay at middle level for long periods of time.

Sexual satisfaction analysis for sexual active participants was highly significant (p-value = 0.0061), for the PeriCoach group satisfaction increased significantly while the control group pointedly worsened over the 20 weeks. Specifically, areas around emotional state during sexual activity showed improved shame and fear score, and reduced scores with relation to fear of urine leakage during sexual activity. This area too suggests that the biofeedback of the PeriCoach leads to improved overall confidence.

Based on the findings during the interim analysis, a final data review was completed and enrolment concluded at



47 of the initial target of 90 participants. The trial has demonstrated the efficacy of PeriCoach in the core areas for pelvic floor rehabilitation and these learnings are to be presented at clinical forums in coming months. Abstracts have been developed and accepted for presentation at the Urological Society of Australia and New Zealand in Canberra the and International Society for the Study of Women's Sexual Health in Atlanta USA, with submissions also underway for additional international urology and gynaecology conferences.

Analytica's version 3 PeriCoach has significant improvements over the version 2 product used in this clinical study. The PeriCoach version 3 has a patent-pending onboard accelerometer and gyroscope which, in combination with the force-sensors allows the system to identify whether or not a woman is performing her exercises correctly. It is estimated that about 50% of women do not perform their pelvic floor exercises correctly and there are several different incorrect techniques. The version 3 will be capable of providing real-time feedback to a woman on whether or not she is exercising correctly. As the PeriCoach movement library grows the system will be then able to provide increasingly customised training to correct a woman's technique. The version 3 system also has superior quality of life monitoring features and a more structured exercise program, which can gather real-world data at a similar level of rigour to that in the clinical trial.

"This controlled trial was originally designed to provide evidence to drive clinical acceptance of the PeriCoach," said Geoff Daly, CEO of Analytica Ltd. "We met this objective and now look to additional studies with the new version 3 which engage the everyday consumer. Having already achieved regulatory clearances in all major markets, collecting credible, publishable, real-world data is underway. Clinical evidence established through strong study designs, as well as how the product performs in the hands of consumers are essential in partner discussions. Over the last year the landscape has shifted and our technology advanced with additional data capture and analysis functionality. All the enhancements and investment into the version 3 PeriCoach have been designed with this focus."

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For more information about the PeriCoach System, visit: [www.PeriCoach.com](http://www.PeriCoach.com)

For more information about Analytica, visit [www.AnalyticaMedical.com](http://www.AnalyticaMedical.com)

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#### About Analytica Limited

Analytica's lead product is the PeriCoach® System – an e-health treatment system for women who suffer Stress Urinary Incontinence. This affects 1 in 3 women worldwide and is mostly caused by trauma to the pelvic floor muscles as a result of pregnancy, childbirth and menopause.

PeriCoach comprises a device, web portal and smartphone app. The device evaluates activity in pelvic floor muscles. This information is transmitted to a smartphone app and can be loaded to a cloud database where physicians can monitor patient progress via web portal. This novel system enables physicians to remotely determine if a woman is performing her pelvic floor exercises and if these are improving her condition. Strengthening of the pelvic floor muscles can also potentially improve sexual sensation or satisfaction and orgasm potential in some women.

PeriCoach has regulatory clearance in Australia, and has CE mark and USFDA 510(k) clearance. The product is available for sale from [pericoach.com](http://pericoach.com) in Australia, New Zealand, UK and Ireland, and the USA.

