

Outstanding results achieved from Joondalup Health Campus delivering clinical and functional validation of HeraBEAT

- Independent clinical study at JHC completes and confirms the accuracy of the HeraBEAT device is comparable to professional hospital grade CTG machine
- Outstanding results from the study:
 - 100% Foetal Heart Rate detection by both expectant mothers as well as clinicians on 81 users and 126 recordings
 - Very high level of accuracy with a 0.3 beats per minute mean difference and a total accuracy rate with minimal deviation of between -1.5 and +0.9 beats per minute (95% limits of agreement) from the industry standard benchmark
 - Exceptional user satisfaction and usability score of 96-100% using international SUS (System Usability Score) ranking
- Outstanding results validate and support HeraBEAT device for remote monitoring of foetal heart rate
- Clinical validation from top tier healthcare providers underpins the Company's commercialisation strategy and can now be leveraged into all existing and future commercialisation opportunities
- The Study is now being expanded to explore additional applications for HeraBEAT

HeraMED Limited (ASX: HMD) ("HeraMED" or the "Company"), a medical data and technology company leading the digital transformation of maternity care with its proprietary in-home maternity care platform, is pleased to announce outstanding clinical study results that confirm the accuracy of the HeraBEAT device against a hospital grade Cardiotocography CTG machine.

Furthermore, the results confirmed the ease of use and user satisfaction by expectant mothers at the clinic, and at home, as well as the effective electronic transmission of the foetal heart rate (FHR) trace by the mother to the antenatal care team for review and consultation.

The clinical study was undertaken at Joondalup Health Campus (JHC), Western Australia and led by Associate Professor Paul Porter (the "Study"). The Study was designed to evaluate the usability, accuracy, and reliability of the HeraBEAT device, by expectant mothers, initially at the antenatal clinic and then at home.

HeraMED CEO and Co-founder Mr David Groberman, said: "These results mark the culmination of many years of hard work by the HeraMED team to develop a clinically validated foetal and maternal heart rate monitor for pregnant women to be used remotely and in telehealth consultations.

"I believe these results represent an important milestone in HeraMED's history as they represent the first comprehensive, independent clinical validation of the accuracy and usability of our technology which can now be leveraged into all existing and future commercialisation opportunities."

About the Study

The Study was conducted by a highly experienced clinical and research team that specialises in innovative technology focused on obstetrics and paediatrics.

The Study enrolled 81 pregnant women, from 12-week gestation with diverse placental positions, body mass index (BMI) and obstetric histories. The Study evaluated:

- Accuracy - completed by a clinician, comparing HeraBEAT to a hospital CTG machine and confirms HeraBEAT's ability to effectively detect Foetal HR and differentiate from Maternal HR;
- Usability by expectant mothers - evaluating ease of use and user satisfaction at the clinic and at home; and measured by the international medical standard System Usability Scale (SUS); and
- Utility for remote home monitoring - using the HeraBEAT device for recording continuous FHR trace by the mother, electronically transmitted to the antenatal care team for review and consultation. An assessment of the transmission, including data clarity and clinical utility, was made by the clinical team.

About the Results

The accuracy of the HeraBEAT device was found to be excellent when compared to the industry gold standard CTG (Phillips Avalon) machine. The device was used 126 times and the limits of agreement (95%) were between -1.5, +0.9 BPM and a mean difference of approximately -0.3 BMP.

The FHR was detected on 100% of occasions by clinicians (n=52) and importantly, the FHR was detected on 100% of occasions by the expectant mothers when using the device without assistance. These results were achieved both in the clinic (42 occasions) and at home (32 occasions).

The average time to locate the FHR by expectant mothers at home was 1.1 minutes with an average total FHR tracing time of 4.4 minutes.

The FHR trace was deemed clinically interpretable (as assessed by obstetric staff) in 100% of clinician performed assessments and in 97% of maternal home use.

Using the international medical standard System Usability Scale (SUS) to usability of expectant mothers, the device was very well-reviewed by the pregnant women, ranking in the 96-100% percentile for usability and user satisfaction.

Associate Professor Paul Porter who led the study at JHC commented: "The results of this study show that the HeraBEAT device is accurate and easy to use by clinicians in the hospital and expectant mothers at home. The foetal heart rate data obtained with the HeraBEAT device, both at home is equivalent to that obtained in the antenatal clinic using current assessment protocols for low-risk pregnancies and allows for the device to be used in telehealth consultations. The research team is finalising a detailed manuscript for peer review."

Commercialisation Strategy

The HeraBEAT device forms the backbone of HeraMED's comprehensive HeraCARE SaaS and IoT platform, a digital hybrid maternity care solution. HeraMED's proprietary technology has already obtained TGA (Australia) and CE (Europe) approvals for OTC (over the counter) home use as well as FDA 510K clearance for home use under prescription in the US.

The clinical study undertaken by Joondalup Health Campus reflects the Company's well-defined strategy to align itself with leading healthcare providers and medical institutions to gain medical validation and to complement and improve the care currently offered by obstetricians and healthcare providers. HeraMED is in discussions with many leading healthcare providers around the world to undertake paid pilots to assess the HeraCARE platform to enhance their existing care models for expectant mothers.

These results can now be leveraged into all future commercial opportunities and strengthen the Company's position when discussing future commercial agreements

-ENDS-

This announcement was authorised by the Board of HeraMED Limited.

HeraMED Limited

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HeraMED is an innovative medical data and technology company leading the digital transformation of maternity care by revolutionising the prenatal and postpartum experience with its hybrid maternity care platform. HeraMED offers a proprietary platform that utilises hardware and software to reshape the Doctor/Patient relationship using its clinically validated in-home foetal and maternal heart rate monitor, HeraBEAT, cloud computing, artificial intelligence, big data and a digital social networking dashboard.