

## Outstanding results achieved in the second JHC clinical trial delivering clinical and functional validation of HeraBEAT as a full CTG monitor

- Joondalup Health Campus (JHC) has completed a second, independent clinical study that specifically examined the accuracy, reliability, usability and acceptability of the HeraBEAT smart foetal heart rate monitor in prolonged monitoring sessions.
- Professionally referred to as Non-Stress Test (NST) or Cardiotocography (CTG), longer Foetal Heart Rate (FHR) monitoring sessions are often required for more detailed medical assessment in cases of high-risk pregnancies or when there is an increased concern for the health of the baby.
- The results further validate and support HeraBEAT's superiority for extended, CTG-equivalent remote and home monitoring of FHR.
- Clinical validation from top-tier healthcare providers underpins the Company's commercialisation strategy and can now be leveraged to unlock additional business models and opportunities requiring high-risk, CTG-level monitoring capabilities.
- This second clinical study was designed to:
  - Evaluate the accuracy and clinical utility of HeraBEAT when used to record FHR over time scales consistent with NST examinations (around 20 minutes or more)
  - Assess the ability of pregnant women to record these NST measurements unsupervised at home without diminishing results accuracy and clinical utility.
  - Assess the obstetrician's ability to review the NST recordings remotely using the HeraCARE platform and analyse it clinically compared to a paper-based, in-hospital professional CTG machine.
- The study results are:
  - The foetal heart rate (FHR) was **detected on 100%** of the occasions.
  - High level of accuracy compared to industry-leading, hospital-grade professional CTG machine (Philips Avalon): 95% limits of agreement were +0.72 (CI 0.4 to 1.0) and -1.78 (CI -2.1 to -1.5), with a mean difference of **-0.53 ±0.64 Beats Per Minute (BPM)**. This accuracy far exceeds the guidelines of ± 8 BPM and replicates the excellent results seen in JHC's first HeraBEAT study.
  - When using the special HeraBEAT CTG adaptor, **95% of HeraBEAT recordings showed a Signal-Loss-Ratio (SLR) of <20%** (as the global standards require) with an **average SLR of only 8.5%**.
  - HeraBEAT accurately detects the essential clinical features present in CTG's needed for obstetricians to make clinical decisions - **100% concordance for detection** of FHR, ability to determine FHR baseline, variability, presence of variables and **90% concordance for the presence of accelerations** (35/39 paired recordings).
  - Time taken to detect FHR on smartphones ranged from less than 15 seconds to 1 minute (n = 62) to 6 minutes (n=1).

- Average duration of HeraBEAT monitoring was 32.4 minutes.
- Average Foetal Heart Rate (FHR) was 141.5 BPM, and Maternal Heart Rate (MHR) was 87.4 BPM.
- Clinical Baseline FHR estimation is equivalent between the Phillips and HeraBEAT:
  - Baseline FHR of the Philips Avalon 136.97 (SD 5.81)
  - Baseline FHR HeraBEAT 136.53 (SD 6.77)
  - Mean difference 0.45 (95% CI -0.61-1.50).
- Women were able to use the device independently at home and were satisfied with the experience.
  - System Usability Scale (SUS) parameters **show A/A+ (Excellent) ratings** for Total Scale, Usability and Learnability
  - **Overall rating 6/7** (adjectival enhancement of SUS).

**HeraMED Limited (ASX:HMD)** (“HeraMED” or the “Company”), a medical data and technology company leading the digital transformation of maternity care, is pleased to announce outstanding results of the HeraBEAT Cardiotocography (CTG) extended clinical trial at the Joondalup Health Campus (JHC), located in Western Australia. The HeraBEAT device is one of the core components of the Company’s HeraCARE, a larger, holistic, digital, remote monitoring pregnancy platform.

#### **JHC’s first HeraBEAT clinical trial involved shorter duration monitoring sessions**

The first clinical trial of HeraBEAT by JHC focused on evaluating HeraBEAT for monitoring sessions that were 1-5 minutes in duration, which are suitable for low-risk pregnancies. The trial, led by Associate Professor, Dr Paul Porter, showed excellent results that were peer-reviewed and published in an article appearing in the ACOG’s (the American College of Obstetricians and Gynaecologists) formal scientific journal, known as the “green journal”. The link to this article follows: [https://journals.lww.com/greenjournal/Fulltext/2021/04000/Accuracy, Clinical Utility, and Usability of a.18.aspx](https://journals.lww.com/greenjournal/Fulltext/2021/04000/Accuracy,_Clinical_Utility,_and_Usability_of_a.18.aspx). HeraMED also reported the finding of this trial to investors in an ASX Announcement, dated 16 March 2021 (a link to this Announcement, follows: [https://cdn-api.markitdigital.com/apiman-gateway/ASX/asx-research/1.0/file/2924-02353885-6A1024771?access\\_token=83ff96335c2d45a094df02a206a39ff4](https://cdn-api.markitdigital.com/apiman-gateway/ASX/asx-research/1.0/file/2924-02353885-6A1024771?access_token=83ff96335c2d45a094df02a206a39ff4)). The monitoring sessions conducted in the trial, also known as FHR auscultations, represent an important part of the standard of care for pregnancy surveillance and are conducted regularly on every antenatal visit – whether it is a physical meeting at the clinic or now also with the adoption of the virtual OB HeraCARE-based solution (that is, a remote visit).

#### **Second Trial - prolonged, CTG-equivalent monitoring sessions required in higher-risk pregnancies**

While FHR auscultations are a powerful preliminary screening tool for assessing foetal wellbeing, there are several, significant and common scenarios of more complex medical situations in which there is a medical standard requiring longer and more detailed foetal Heart Rate evaluation. In cases such as a high-risk pregnancy, late gestational ages or when there is an increased concern about the foetal wellbeing or a pregnancy complication, longer measurements of the FHR are necessary. At least 10 minutes of consecutive FHR trace is required, and, in most cases, a 20-minute session is the standard. During these more prolonged examination periods, measurements known as Non-Stress Test (NST) or Cardiotocography (CTG) are taken. These are crucial to maintaining a stable FHR signal, and the examining

physicians need to be able to analyse different aspects and characteristics of the FHR trace such as variability, accelerations, decelerations and more.

### **JHC trials HeraBEAT's value in cases where longer monitoring sessions are needed**

Given many pregnancies with additional complexities required more detailed medical examinations, the professional team of researchers, led by associate professor, Dr Paul Porter in collaboration and support of Dr Cliff Neppe, Head of Obstetrics at JHC and Dr Kym Jones OBGYN specialist and the clinical lead for the HeraCARE project at JHC, decided to undertake a second independent clinical study to examine the accuracy, reliability, usability and acceptability of the HeraBEAT device. This compared the device to professional, hospital-grade CTG machines during prolonged FHR monitoring sessions. This second trial initially occurred in the antenatal clinic and later shifted to the home before recommended use in routine clinical protocols. In this second clinical study, JHC evaluated the accuracy and clinical utility of HeraBEAT when used to record FHR over time scales consistent with NST examinations. The study also assessed the ability of pregnant women to record these measurements unsupervised at home without diminishing results accuracy and clinical utility.

The study was performed over two phases:

- Phase 1 at JHC's antenatal clinic (involving 63 pregnant women) and generated 6,982 pairs of data points, for professional comparison analysis.
- Phase 2 at the patient's private homes (involving 40 pregnant women) for assessing remote monitoring capabilities.

The trial was conducted during the second half of 2021 and into early 2022.

Phase 1 of this study assessed accuracy and usability while women had dual simultaneous recordings of FHR greater than 15 minutes by HeraBEAT and a Phillips Avalon CTG (Hospital standard of care). Accuracy was determined by comparison to literature standards ( $\pm 8$  BPM) and previous work (specifically, JHC's first HeraBEAT study). Clinical utility was determined by the recognition of FHR patterns and features between the CTG and HeraBEAT devices.

Phase 2 of the study assessed clinical usability and patient satisfaction when the HeraBEAT device was used unaided at home to produce FHR traces of greater than 15 minutes, which were then automatically sent by the HeraCARE system and uploaded to a medical cloud for the evaluation by a physician.

Key results of JHC's second study follow

1. The HeraBEAT device accurately measured the FHR when used over long recording times compared with industry-standard CTG machines. The device was used 63 times and 95% limits of agreement were  $+0.72$  (CI 0.4 to 1.0) and  $-1.78$  (CI -2.1 to -1.5), with a mean difference of  **$-0.53 \pm 0.64$  BPM**. This accuracy far exceeds the guidelines of  $\pm 8$  BPM, and replicates the excellent results seen in JHC's first HeraBEAT study.
2. HeraBEAT achieved a very good signal quality of the FHR recordings measured as Signal Loss Ratio (SLR). Compared to the International Federation of Gynaecology and Obstetrics Guidelines (FIGO) threshold of 20% signal loss for adequate signal quality, the mean SLR for

- HeraBEAT was 8.5% compared to 3.4% with Phillips CTG. 38 of the 40 FHR records with HeraBEAT exceeded SLR ratio of greater than 20%.
3. HeraBEAT traces accurately reflected formal CTG traces for the important FHR features needed for clinicians to make decisions, including the presence of the FHR; baseline FHR; and the presence of variability, variables and accelerations:
    - a) 100% concordance for detection of foetal heart, ability to determine FHR baseline, and the presence or absence of variability and variables
    - b) 90% concordance for the presence or absence of accelerations (35/39 paired recordings).
  4. Clinical (Obstetrician reported) Baseline FHR estimation (beats per minute) was equivalent between Phillips and HeraBEAT.
  5. Women were able to use the device independently, at home, and were satisfied with the experience.
    - a) System Usability Scale (SUS) parameters showed A/A+ (Excellent) ratings for Total Scale, Usability and Learnability
    - b) Overall rating of 6/7 (adjectival enhancement of SUS)
    - c) The clinical features and utility report are to be finalized.
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**HeraMED CEO and Co-founder, Mr. David Groberman said:** “We are delighted with the results coming out from JHC’s second trial of our revolutionary HeraBEAT and HeraCARE solutions. It demonstrates that the Smart FHR monitor can not only be used as a screening tool for assessing foetal wellbeing, but it is also highly valuable in pregnancies where more detailed medical examinations are required, including high-risk pregnancies when there is an increased concern about the foetal wellbeing.

The study clearly indicates that the HeraBEAT device accurately measured the FHR when used over long recording times compared with industry standard CTG machines. Its traces also accurately reflected formal CTG traces for the important FHR features needed for clinicians to make decisions. But importantly, the study also concludes that our technology is simple and easy to use by patients at home away from ‘bricks and mortar’ medical facilities, with women in the trial able to use the device independently, at home. And, what’s more, they were well satisfied with the experience. The fact that the trial is independent, i.e not sponsored by the Company, gives another level of credibility to the results. We are extremely proud of our technology and thankful for the professional team at JHC for a meticulous, professional, and uncompromising trial that complies with the highest standards of the medical community.

With these excellent results, we are now ready to bring this capability to a commercial level, expanding our offering and unlocking new business models and new commercial opportunities.

**Associate Professor Paul Porter who led the study at JHC commented:** “The results of this second study clearly show that the HeraBEAT in its CTG configuration is accurate and easy to use by clinicians in the hospital and expectant mothers at home. The extended CTG foetal heart rate data obtained is equivalent to that obtained in the antenatal clinic using current assessment protocols for high-risk pregnancies and allows for the technology to be used in telehealth consultations via the HeraCARE platform. I believe that the technology will be useful in situations of high-risk pregnancies and when there is an increased concern for the wellbeing of the fetus. The research team is finalising a detailed manuscript for peer review, and we believe additional insights will be provided in the near future.”

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-ENDS-

This announcement has been authorised by the Board of HeraMED Limited.

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**About HeraMED Limited (ASX:HMD):**

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 and big.

**About HeraCARE:**

The Company's proprietary offering, HeraCARE, has been engineered to offer a fully integrated maternal health ecosystem designed to deliver better care at a lower cost, ensure expectant mothers are engaged, informed and well-supported, allow healthcare professionals to provide the highest quality care and enable early detection and prevention of potential risks.

**About Joondalup Health Campus:**

Joondalup Health Campus (JHC) is a general hospital in Perth's northern suburbs that offers a comprehensive range of medical and surgical services including emergency, intensive care, maternity, neonatal and paediatric services, aged care and rehabilitation and mental health.

The hospital is also the state-wide referral service for bariatric and peritonectomy surgeries. The 722-bed campus is comprised of a standalone 146-bed private hospital and a co-located hospital that provides services to public patients living in its catchment area.

JHC is managed by Australia's largest private hospital operator, Ramsay Health Care, and has a long-standing public-private partnership agreement with the WA State Government.