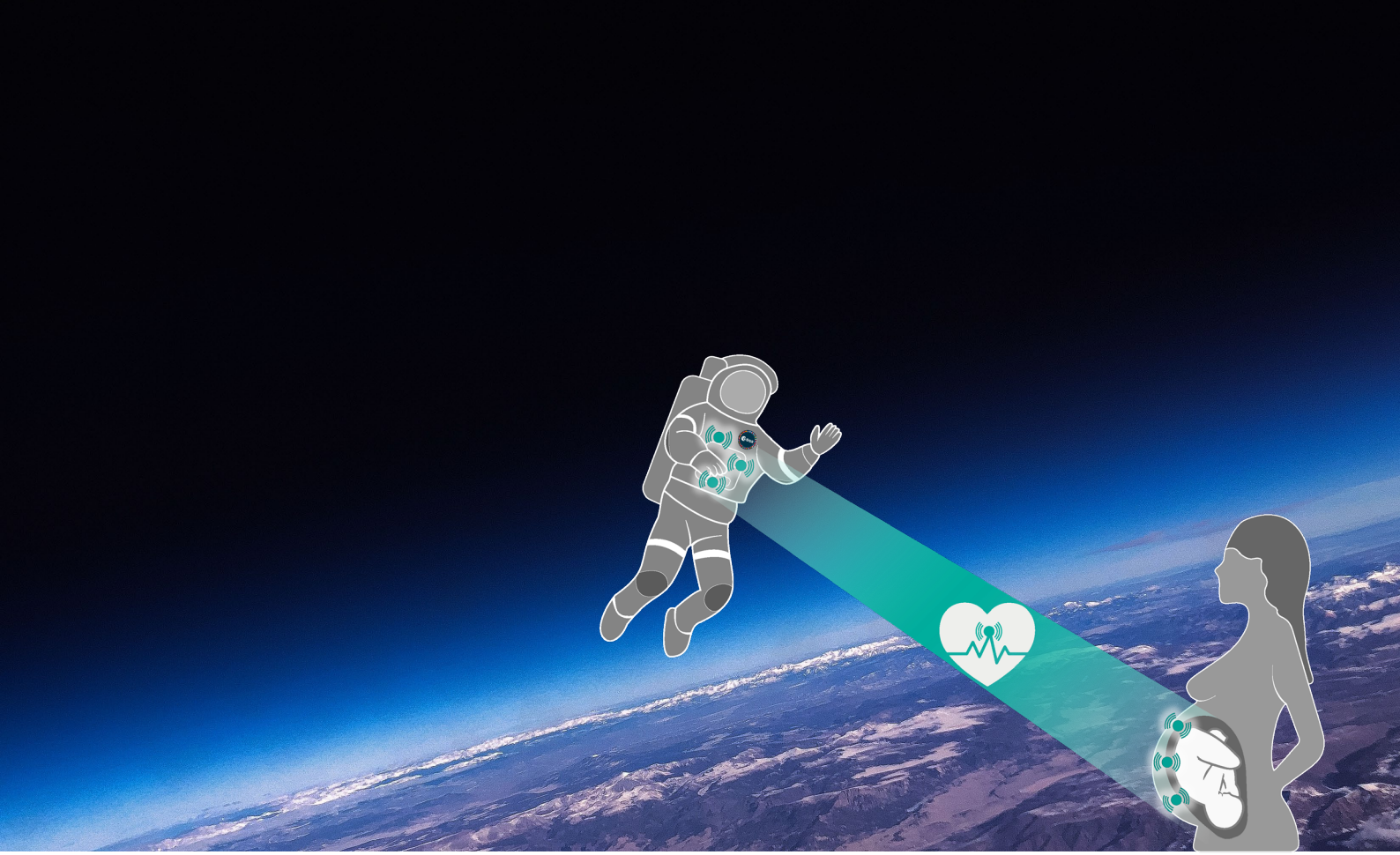

Socio-economic benefits from ESA Technology Transfers

A report for esa

CASE STUDY: Electronic Foetal Monitoring System

know.space

July 2022

Dry electrodes to monitor vital signs: From astronauts in space to foetuses in utero

With astronauts spending prolonged periods of time in zero gravity on the ISS, it is essential to monitor their vital signs from Earth. A conventional ECG requires astronauts to clip themselves up to an ECG device with a maze of wires and electrodes, which must be gelled to adhere to the skin, whilst not catching on objects or equipment as they float around[1].

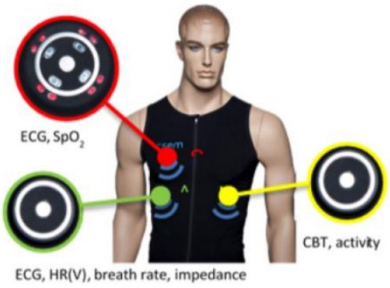

Image: CSEM

Under ESA contract, CSEM developed the LTMS system, designed to monitor astronauts' vital signs using an easy to wear vest fitted with three dry electrodes. The technology is capable of monitoring ECG, respiration rate, pulse oximetry, blood pressure, body core temperature, activity and posture, and weight and body composition, 24 hours a day[2]. **This same technology is now being applied to foetal monitoring.**

Before labour, it may be necessary to monitor the foetus' heartbeat for any irregularities, whereas during labour it is recommended to perform regular monitoring of the foetal cardiac activity. At present, classical cardiotocography (CTG) is widely used to monitor the foetal heartbeat. This requires expectant mothers to visit the hospital and stay in bed for the duration of the monitoring, with a series of wires connected with a bedside device. As such, foetal monitoring is intermittent, and mothers cannot move freely during monitoring (especially problematic during labour). In addition, electrodes must be attached to the stomach by a professional and may require frequent adjustment. **CSEM saw an opportunity to develop a technology using the dry electrodes that would provide a more comfortable wireless solution, using ECG technology rather than CTG's ultrasound solution.**

Space technology brought down to Earth …

CSEM is a private, non-profit organisation for research and innovation, supported by the Swiss government. They started work on the LTMS technology nearly 20 years ago under ESA contract and worked with ESA's Technology Transfer and Patent Office (TTPO) to develop the **Electronic Foetal Monitoring System (ELAINE).**

The ELAINE system uses dry electrode technology to record full foetal ECGS (fECGs), as well as broader range of cardiac foetal biomarkers. Unlike CTG which uses a large belt, **ELAINE is comprised of 8 electrodes which are attached individually to the abdomen and**

[1] NASA (2012) *Spinoff - Dry Electrodes Facilitate Remote Health Monitoring*. Available at: https://spinoff.nasa.gov/Spinoff2012/hm_4.html#:~:text=The%20dry%20electrode%20may%20be,dive%20suits%20for%20scuba%20divers
[2] ESA, 2022. Available at: https://www.esa.int/Science_Exploration/Human_and_Robotic_Exploration/Research/Long_Term_Medical_Survey_System

connect via just two cables to a small master unit. This unit is battery powered and transmits signals to a PC via wi-fi, which allows the wearer freedom of movement.

ELAINE has successfully undergone two phases of hospital testing, the first being a small trial of 10 pregnant women, followed by a further trial of 15 women. A key challenge for CSEM was to differentiate the foetal heartbeat from the much stronger maternal heartbeat. Engineers successfully identified the foetal heartbeat in most cases, although detection remains difficult in women with more adipose tissue, a question that will be addressed in the upcoming third phase of its development. Both initial phases took place at the University Hospital (Inselspital) of Bern and focused on late-stage, uncomplicated pregnancies. Further testing is planned, including on earlier stage pregnancies and women with other underlying health issues. It is hoped that ELAINE could soon be used to supplement CTG machines and potentially be a replacement solution within the next decade.

... monitoring foetal cardiac health from home

ELAINE may have the potential to supplement or replace classical CTG machines in a hospital setting, but furthermore, this technology could also pave the way for high-accuracy, at-home foetal monitoring. CSEM are developing a **portable device which could be used by women at home to monitor their baby using a mobile phone app**. Doctors could remotely monitor the foetus and call mothers in to the hospital only when abnormalities are detected.

Potential for significant socio-economic benefits

Whilst the technology transfer of the dry electrodes for ECG monitoring is **still in the late development stage**, some initial socio-economic benefits have begun to emerge, with the promise of many larger, global benefits to come through its successful commercialisation, for the organisation, their customers, and for broader society and the environment.

Developing dry electrodes for use in foetal heart monitoring

Commercial opportunities

The commercialisation of ELAINE through **supporting a European SME** or the **creation of a spin-off company** has the potential to bring about **job creation** and **economic growth**

CSEM is looking for **commercial opportunities** utilising the ELAINE system, with a variety of proposed approaches. Since it is itself a private non-profit organisation, one of its missions is to enhance the competitiveness of industry by developing new technology platforms and then transferring it to the industrial sector. CSEM does this by collaborating with existing companies or providing licensing models to existing companies. For the ELAINE system, CSEM aims to explore the business model of collaborating with a European SME to transfer the technology to market, industrialising and commercialising the product.

Currently, CSEM is in ongoing discussions with a Spanish SME; however, the organisation is also considering creating a spin-off company, or indeed applying both approaches of collaboration and company-creation. With either approach, commercialisation of ELAINE will bring **job creation**, through growth and expansion of the SME, or by the creation of a new company within the European landscape.

Through the collaboration of CSEM and its partnering SME, there will also be potential **revenue streams** bringing economic growth:

For CSEM: a licensing scheme on the hardware and/or the algorithm.
For the SME: Selling the device as a standalone hardware; subscription service for enhanced data analytics, usage of data acquired from patients in research studies with hospitals.

New telemedicine market opportunities

Whilst CSEM has developed a variety of wearable medical device technologies over the years, the dry electrode technology they are utilising within **ELAINE would not have emerged without ESA funding and support**, helping direct them towards the **creation of a new product.** This product has then opened up the capabilities to develop innovative end user cases, such as monitoring foetal ECGs, **entering a new domain** where they previously had no real experience and would not necessarily have considered before the introduction of this technology and its potential.

Offering a solution based on the ELAINE system will also position them to offer a new product within the **telehealth market**, which is expected to reach **€190 billion globally by 2025**.[3]

New collaborations

CSEM has a long history in working on the dry electrode technology thanks to its support from ESA and its experience in the space domain, first forming a collaborative relationship with the **Bern University Hospital (the Inselspital)** for validating this technology in 2008 in the form of the LTMS-2, followed by validation projects in the Concordia Station (Antarctica). For the specific use case of ELAINE and seeking to enter a new market domain, CSEM again collaborated with Bern University Hospital to perform clinical studies for validation purposes, this time with **new expertise** on board for the project to address the niche area of foetal heart monitoring. Furthermore, CSEM's discussions with an SME about commercialising the product has built a potential **collaboration/relationship between the organisation and a new company**.

By entering into a new market, CSEM has also seen opportunities to network in areas they didn't previously; an example of this is being invited to join a European workshop on foetal signal processing: **"Signal Processing and Monitoring in Labour".**

Supporting hospitals in providing supplementary solutions

Reduce resource pressure

An increase in **home monitoring** by the patient means **fewer hospital visits**, **shorter stays** at the hospital, and a **decreased risk of exposure** of the patient to diseases such as COVID-19

The introduction of a simple-to-use and reliable way to separate the foetal heartbeat from that of the mother's for monitoring purposes paves the way for increased **home monitoring**.

The current advice for women is that if they sense decreased foetal movement, or if there is a change in the foetus's usual pattern of movements, then they must seek out monitoring of the baby's heartbeat to ensure its wellbeing. There is no set 'number of movements' a woman should feel, since every foetus and every stage of the pregnancy is different. Furthermore, if there is a woman with a higher risk pregnancy, such as one with intrauterine foetal growth restriction, a history of intrauterine foetal death, foetal malformations, or identified foetal heart arrythmia, then

[3] The Business Research Company, 2021. *Telehealth Global Market Report 2021: COVID-19 Growth And Change*. Available at: https://www.reportlinker.com/p06036653/Telehealth-Global-Market-Report-COVID-19-Growth-And-Change.html?utm_source=GNW

there is a high level of close outpatient monitoring, including daily foetal kick count, nonstress tests, and multiple prenatal visits to the clinic.

A reliable home monitoring solution where the mother can do a simple check of the foetal heartbeat in order to alleviate some of their concerns could **decrease the number of times she would have to go in-person to the hospital**. It also has the potential to **decrease the length of time** a woman would have to remain at a hospital for monitoring purposes.

During the recent **COVID-19 pandemic**, there has also been an additional risk of becoming seriously ill from the virus for pregnant women, and dangers for babies in late-stage pregnancies have been postulated, in certain cases not directly connected with the severity of the symptoms, providing a strong example of how fewer hospital visits can be beneficial.

Each hospital has a **limited/specific number of CTG machines** and licences, and so being able to provide supplementary solutions would also alleviate the **resource pressure** on the CTG machine availability.

Ease of application

One of the key selling points of the ELAINE system is that by using dry electrode technology, it is **simple to use and apply, with a standardised application** format of where to apply the electrodes to the skin. Additionally, the patients do not have to remain connected to a large machine with cables and wires, providing freedom for the mothers to move around rather than remain stationary.

Therefore, it is **not necessary to have a specially trained nurse** to set up a complex machine and apply sensors to the patient, as well as providing the ability for patients to set it up themselves at home for monitoring.

New processes developed

Using dry electrodes for ECG in foetal heart monitoring has the potential to be a **wide-reaching supplementary solution in 2-3 years**, and a **possible replacement method within 10 years**

There are currently two methods used in order to electronically monitor a foetus's heart rate. The non-invasive **cardiotocography (CTG)** measures the baby's heart rate together with the mother's uterine contractions, via means of ultrasound technology, or the **electrocardiogram (ECG)**. The latter can be performed non-invasively through the woman`s abdomen, or invasively by performing foetal heartbeat assessment through the foetal scalp, implying an open amniotic sack (thus the woman being in labour). The non-invasive method offered by other providers by using different electrodes than those of the LTMS technology has not yet found a broad application in clinics, and is still under development. Only the invasive strategy is well established, yet rarely used, since an electrode has to be passed through the mother's cervix and attached to the baby's head.

The technology underpinning CTG has not changed since its implementation over 60 years ago – instead, only the protocols for its usage are changed every few years. One of its challenges is that **interpretation of a CTG can be subjective, based on human interpretation**, and there **are limited safeguards against getting this interpretation wrong**. Common errors include incorrect interpretation of deceleration of heartbeat, leading to unnecessary (and morbidity creating) medical interventions, or misidentification of the maternal heart rate (MHR) recording as the foetal heart rate (FHR), masking issues for the foetus[4].

[4] Di Tommaso, M. et al., 2019. *Errors and pitfalls in reading the cardiotocographic tracing.* Minerva Ginecol. Apr;71(2):91-96. doi: 10.23736/S0026-4784.18.04336-8.

The invasive ECG meanwhile is a procedure that cannot be used before labour, and brings risks of potential **bruising** of the baby's scalp, with important consequences in the case of unidentified foetal coagulopathy.

The use of dry electrode sensors offers a **new process**, providing an ECG but from a **non-invasive method**, whilst being **wireless** and **simple to apply**, unlike the CTG. It has the potential to be a great supplementary method for the CTG, and can hopefully decrease the need for invasive methods whilst still providing ECG data.

Data for research

Since the ELAINE system uses dry electrodes and a cable-free device, it can potentially provide longer monitoring times than CTG machines in a comfortable, user-friendly manner, since for CTG the mother is limited in movement, strapped to a large device, this being one of the reasons why monitoring times are intermittent. There is even potential with ELAINE for 24/7 monitoring in more serious cases, or at least monitoring happening more frequently.

An **increase in data gathering** means that the large pool of data can be utilised in **research studies**, especially for those exploring the topic of foetal heart arrythmia, or seeking to build a wider profile on how foetal hearts act over longer periods of time.

Support for decision-making process

Currently, at the end-stage of labour and sometimes during earlier stages, the foetus will need "continuous CTG" due to risk of complications such as lack of oxygen, and medical personnel will need therefore to **make decisions about whether or not to deliver the baby early** by caesarean or instrumental vaginal birth.

Due to the discomfort of the mothers in having to be hooked up to cables for the CTG during labour, it is difficult to leave the woman connected to the machine for a very long time. As a cable-free solution that provides the woman freedom to move around and more comfort, the dry electrode solution could provide **earlier insight** on the patient and be used for a longer period of time, allowing for **additional data for the decision-making process**.

Providing benefits to a wider societal landscape

Foetal arrythmia monitoring solutions

ELAINE can provide additional supplementary monitoring solutions for pregnancies displaying **foetal arrythmia**, which account for **1-2% of all pregnancies**, and **10-20% of all referrals to foetal cardiologists**

Foetal arrythmia refers to any abnormality identified in the heart rate of the foetus, including tachycardia (increased heart rate) or bradycardia (slowed heartbeat). It accounts for 1-2% of all pregnancies[5], as well as 10-20% of referrals to foetal cardiologists[6]. If a risk has been determined for the pregnancy due to foetal arrythmia, treatment has to be undertaken predominantly at the hospital, with **close outpatient monitoring** that can be time consuming and difficult, including daily foetal kick count, prenatal visits 2-3 times a week, and nonstress tests.

[5] American Pregnancy Association, 2021. *Fetal Arrhythmia*. Available: https://americanpregnancy.org/healthy-pregnancy/pregnancy-complications/fetal-arrhythmia/
[6] Saileela, R. et al. *Ventricular Tachycardia in a Fetus: Benign Course of a Malignant Arrhythmia*. J Obstet Gynaecol India. 2019;69:383–6.

Since the ELAINE system can be used in home monitoring, it could be a useful **supplementary solution in the outpatient treatment** of these risky pregnancies.

Improved patient well-being

Utilising a solution for foetal heart monitoring that uses the dry electrode technology brings about a wide range of advantages for the patient herself, for her comfort, mental health and flexibility.

As mentioned, some labours currently require the use of "continuous CTG" in order to track the baby's health. However, a challenge of this method is the discomfort to the mother, since she cannot move freely during labour, change positions easily or use a birthing pool, which can **impact the stress levels and coping techniques** for the woman in labour. Continuous CTG has also been associated with an increased number of caesarean sections and instrumental births, which carry a **risk to the mother**.[7] By introducing the use of wireless dry electrodes to carry out some of this monitoring process instead, the **mothers will be more comfortable** whilst medical personnel will still receive the required data. This could be especially useful for **high-risk pregnancies** (around 6-8% of all pregnancies[8]).

Sometimes, an **invasive internal monitoring process is required** if the external signal is interrupted, where an **electrode is placed directly onto the scalp of the baby whilst it is still in the womb.** Whilst this provides higher accuracy (direct monitoring of the heart as opposed to auscultation), risks are associated with the process, including bruising of the baby's scalp and the restriction of movement for the mother. The ELAINE system could be used as a supplementary external monitoring process to help **avoid the need for invasive internal procedures** or **provide additional insight** as to whether medical intervention is required.

Additional benefits for the well-being of the mothers are of course the simplicity of application for the electrodes, and the ability to carry out home monitoring.

Support to isolated and rural communities

The introduction of a simple-to-apply ECG technology such as the dry electrodes can provide remote monitoring solutions for pregnant women living in isolated rural communities

There are places around the world where women live in isolated communities, far away from medical support, having to **travel for hundreds of miles** to get to a hospital in order to hear their baby's heartbeat. They are therefore unable always to have the proper ongoing monitoring required for the health of their foetus.

This issue is also present at a smaller scale in Europe. For example, in France, **7% of births** occurred to women residing at **≥30 km from a maternity unit** and 1% at ≥45 km in 2014.[9] Furthermore, the **global COVID-19 pandemic** meant that many women have had to remain isolated at home for safety reasons, thereby not getting the frequency of monitoring needed.

[7] Alfirevic, Z. et al (2017) *Continuous cardiotocography (CTG) as a form of electronic fetal monitoring (EFM) for fetal assessment during labour*. Available at: https://www.cochrane.org/CD006066/PREG_continuous-cardiotocography-ctg-form-electronic-fetal-monitoring-efm-fetal-assessment-during-labour

[8] University of California (2022) *High-risk pregnancy*. Available at: https://www.ucsfhealth.org/conditions/high-risk-pregnancy

[9] Pilkington, H. et al (2014) *Where does distance matter? Distance to the closest maternity unit and risk of foetal and neonatal mortality in France*. Eur J Public Health. 2014 Dec; 24(6): 904–909

Wider applications

The use of dry electrodes for monitoring purposes is not limited to foetal heart monitoring; indeed, there is a wide variety of potential applications.

An example of this currently under development at CSEM is that of an ultra-long-term electroencephalography (EEG) monitoring system of **epilepsy seizure detection**. Other potential applications are for monitoring the **health of elite athletes and scuba divers**, and for **babies** – especially those born to parents who have previously lost a baby to sudden infant death syndrome (SIDS), requiring home monitoring solutions.

Would these benefits have been realised without ESA?

With **ESA's Technology Transfer Programme**, CSEM has been able to assess the feasibility of the Electronic Foetal Monitoring System through a validation process with the University of Bern, and this initial phase paved the way for continued development and validation phases for the technology, **setting the stage for future commercialisation**. CSEM has had **a long history of working with ESA**, initially starting the design for the LTMS system with dry electrodes in 2003, with several prototypes delivered and tested over the years. Without the ESA Technology Transfer programme support to help them pivot towards using the same dry electrode technology for foetal monitoring, CSEM would have had to search for funding elsewhere, which would have made the development process much slower and more complicated.

"**ESA was fundamental** in this technology development. It isn't the first time people have tried to develop an application for ECG foetal heart monitoring, but this innovative line of thinking – using cooperative sensors – was thanks to ESA."

Ricard Delgado, CSEM

… with further development and benefits to come

ELAINE can differentiate between the maternal and foetal heartbeats, though further work is needed to refine this technology and ensure accurate detection in all women (or to identify the best user group). CSEM is also working to make the device more compact and minimise noise. A **third larger phase of testing is planned** (awaiting ethical approval), this time looking at women with other health issues complicating their pregnancies (e.g., diabetes), as well as how ELAINE performs in the earlier stages of pregnancy. Testing on women during labour will also be required before ELAINE can be routinely used in a hospital setting. Concurrently, CSEM is working to **develop an at-home product and app in the next few years**, which could transform the system of foetal monitoring.