

# HOME CARE

# DETERMINATION OF THE DATE OF BIRTH



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## EXECUTIVE SUMMARY

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Home birth prediction for premature and normal births increases the chances of survival and improves the quality of life for many premature babies and is a great help with many small problems surrounding one of life's most beautiful moments.

Prof. Dr. Ernst Rainer Weissenbacher

In the past years WPmed has developed a scientific idea for the prediction of the date of birth through various studies and from this a technical device has been developed, which can answer this question for parents and doctors.

The technical implementation has been internationally patented and is therefore available for exclusive use.

The goal is to either sell/license the technical solution to a leading manufacturer of medical technology or to implement the use of the technology as a stand-alone or within a wearable platform such as the Apple Watch within 18 months.

# 1. FOUNDERS

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Our founding team consists of Prof. Dr. Ernst-Rainer Weissenbacher and Dr. Oliver Pressmar. They met many years ago in the course of scientific work and have since become friends.

Prof. Weissenbacher is professor emeritus of the Ludwig-Maximilians University and practicing gynecologist from Munich. In the course of his medical work, he has repeatedly been confronted with the question of when the longed-for offspring will be born.

Dr. Pressmar first came into contact with the topic of birth and in particular premature birth when his son was born. Since then, he has not let go of this topic and, together with Prof. Weissenbacher, is in the process of developing a technical aid for the many parents.



Prof. Dr. Ernst-Rainer Weissenbacher

## Foundation motivation

### Qualification & Competencies

Prof. Dr. Ernst Rainer Weissenbacher is a German gynecologist and was the head of the Polyclinic for Gynecology and Obstetrics at the University of Munich Hospital, Grosshadern Campus.

Ernst Rainer Weissenbacher is considered a national and international specialist in the care of high-risk pregnancies and the treatment of genital infections. He was awarded the Heinz Spitzbart Award - Prize for the Advancement of Infection Immunology in Gynecology and Urology, the Janssen-Cilag Award - Prize for the Advancement of Med. Mycology and the Medal of the Working Group Infectiology and Infection - Immunology of the German Society of Gynecology and Obstetrics. He is author and member of different working groups and societies



Dr. Oliver Pressmar

## Foundation motivation

### Qualification & Competencies

Dr. Oliver Pressmar studied mechanical engineering at the Technical University of Munich and specialized in medical technology at an early stage. He deepened his expertise during an MBA at the TU Munich with a focus on intellectual property and innovation research. He concluded his academic career with a dissertation on innovations in medical technology.

He is self-employed with his engineering office in different fields but has been working together with Prof. Weissenbacher on innovations in medical technology for years.

## 2. TARGET CUSTOMER

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### Target Customer

The [patented product](#) appeals to parents and especially mothers [worldwide](#). However, the target group can be further differentiated on the basis of the product functions:

#### Parents at increased risk of preterm birth or miscarriage

The percentage of premature births in Germany is about 8.9% and worldwide the number is about 15 million babies per year and these numbers only consider the successful births. Any parent who has had experience with preterm birth and/or miscarriage would be very grateful for a product that can detect an impending birth before labor begins. This brings the [time advantage to reach an appropriately equipped clinical facility](#) and thus also [increases the intervention possibilities](#), e.g. implementation of a medicinal lung maturation and finally also the chances of survival or the quality of survival of the babies.

#### Parents with organization desire and needs

In addition, the product is also of great help to all parents who do not want to be surprised by the sudden onset of labor. Only [3-4% of babies are born on the due date](#). However, 95% in the period of two weeks around the calculated date. However, there is a great desire of parents to [determine the date of birth closer for professional, private or logistical reasons](#). A lead time of about 3 days to the birth date would be a great help here. The product is also another building block to the trend of self-tracking like fitness trackers or wearables.

## 3. CUSTOMER BENEFITS

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### Customer benefits

Predicting the date of birth can [significantly increase the chance of survival and quality of life of premature infants](#), as appropriate medical measures can be initiated and the time window also allows them to reach places with better medical infrastructure (NICUs). [Our product can indicate birth according to current study findings 24-48 hours before delivery and thus before the first contractions.](#)

Signaling in the resting phase even before the start of the activation phase (onset of labor) of pregnancy [reduces the uncertainty and anxiety of parents](#) and [reduces the stress](#) of sudden onset of labor. It also simplifies all other logistical problems around the birth and makes the birth [plannable](#).

### 3.1 Independent product

The product can be produced as a stand-alone product such as a pregnancy or fertility test such as the Clearblue Advanced Fertility Monitor. The [basic version](#) of the device includes the evaluation unit and the necessary test strips for 4 weeks. This package covers the customers who only want a higher accuracy of the date determination in the range of 3 weeks before and 1 week after the calculated date.



For the parents with increased risk of miscarriage or premature birth, the monitoring period of the basic version of four weeks can be extended by [4 weeks at a time via an extension package](#). Thus, for example, monitoring of the complete 3rd trimester would also be possible.

Technically, the device determines two vital signs daily and compares their course over the time of pregnancy. The evaluation algorithms can then either be executed on the device or within the cloud in a central unit with pattern recognition. The data exchange should be done from the device e.g. via the Bluetooth interface of the cell phone. The central randomized and anonymous evaluation, enables the continuous improvement of the pattern recognition e.g. via artificial intelligence and thus leads to increasing prediction qualities.

### 3.2 Own wearable

The second product variant is the version as a [stand-alone wearable](#), such as the AVA wristband or the OvulaRing. Here, the determination of the two vital parameters takes place via the built-in sensors. The continuous determination (every 5min) of data points can [significantly increase the prediction quality](#) in contrast to the daily determination and [smooth measurement errors and outliers](#). The data transfer and the user interface would be implemented in an app.

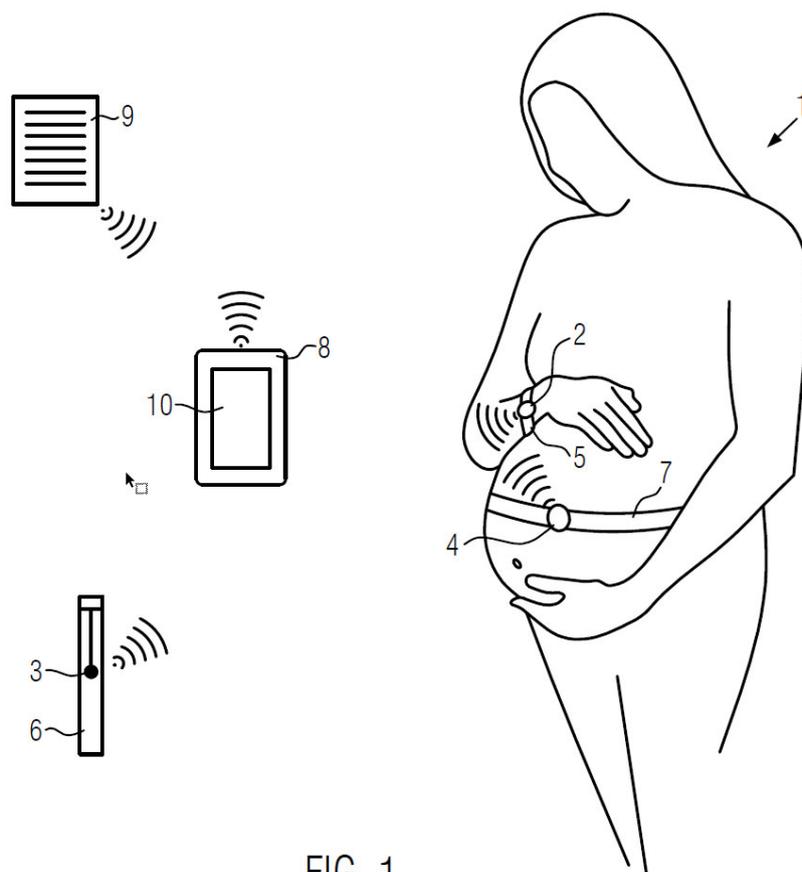
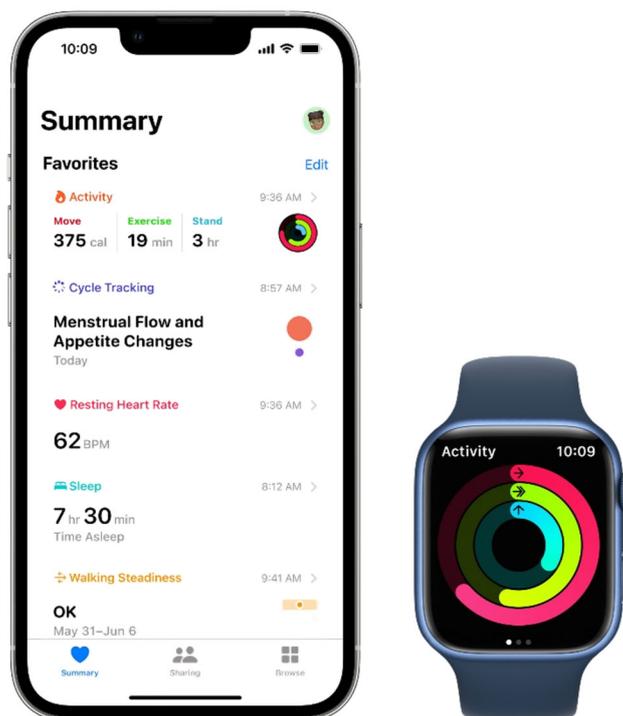


FIG. 1

### 3.3 Integration in wearable-platform

The third product variant is the [use of an existing wearable platform](#) such as the [Apple Watch](#). The integrated biosensors can be used to determine vital parameters. If necessary, the biometrics function could be supplemented, for example, via newer sensors from Rockley Photonics.



## 4. MARKET ANALYSIS

### 25 million potential customers per year

Across Europe, 7.32 million children will be born each year by 2040, according to data from the UN (World Population Prospects UNDATA). Worldwide, this figure is 132 million per year. Looking at the main Western markets (USA, France, Germany, Italy, Spain, UK, Japan), birth rates are expected to be around 30 million babies per year. These figures do not yet include growth markets such as India.

Based on these figures, the annual market in the industrialized nations alone is 29.6 million basic units and 6.6 million extension packs. Based on the recommended retail prices of Clearblue (SPD joint venture of Procter & Gamble and Alere) for their Clearblue Fertility Monitor Advanced (single unit price 139.00 Euro) including extension pack (price for 24 units 48.50 Euro), which is comparable in complexity, this would result in potential total sales of 4,121 million Euro for the basic unit and an additional 323 million Euro for the extensions.

With a 2% market share, this would correspond to sales of around 88.9 million euros per year. According to surveys, however, market penetrations of 10-20% with correspondingly higher sales figures (400-800 million euros) are also possible.

### Number of birth, both sexes combined (thousands)

Source: World Population Prospects UNDATA

	2010-2015	2015-2020	2020-2025	2025-2030	2030-2035	2035-2040
Europe	40.215	38.847	36.606	34.635	33.795	34.055
US	19.753	19.503	20.180	20.617	20.670	20.631
JP	5.387	4.766	4.391	4.234	4.195	4.166
CN	88.181	84.889	77.100	71.651	69.185	67.936
RU	9.361	9.287	8.243	7.374	7.082	7.372
KR	2.244	1.897	1.736	1.701	1.709	1.588
Total	165.141	159.189	148.256	140.212	136.636	135.748
prematurity rate	7,50%	7,50%	7,50%	7,50%	7,50%	7,50%
market penetration	0,00%	0,00%	2,00%	7,50%	10,00%	10,00%
basic units			2.965.000	10.516.000	13.664.000	13.575.000
extension units (3pc.)	-	-	667.000	2.366.000	3.074.000	3.054.000
price per basic unit			139 €	139 €	139 €	139 €
price per extension unit			49 €	49 €	49 €	49 €
turnover per year			88.902.000 €	315.293.000 €	409.669.000 €	407.006.000 €

## No competing products and patent protection

Currently, there are **no competing products** worldwide. However, after a successful market launch, there will be increased competitive pressure. However, **comprehensive patent protection** has been obtained in the PCT system to secure market share. The globally recognized and award-winning **patent law firm Grünecker** from Munich developed and implemented the intellectual property protection strategy for this purpose. The patents are filed under EPO PCT/EP2020/074094 & USPTO 17638276.

## Monopoly position and first to market

According to the company idea "We turn ideas into inventions, inventions into patents, patents into profit" our innovation, product and profit is protected by patenting. After market introduction, a monopoly position will develop.

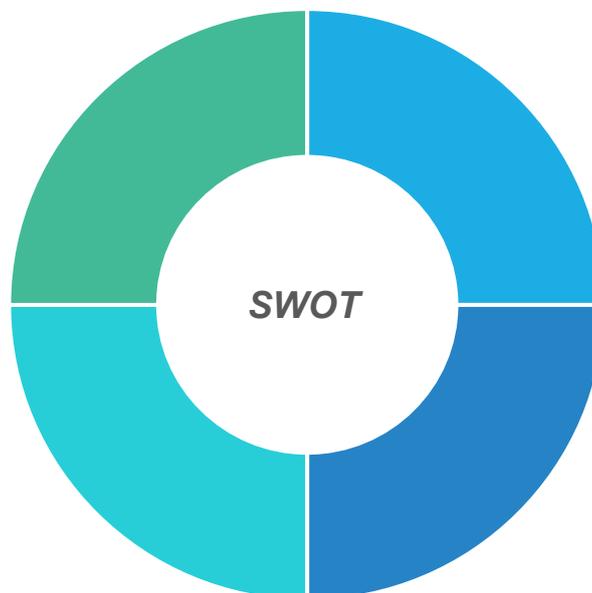
Should another company enter the market despite **high market entry barriers**, the product will continue to have all the advantages of first-to-market.

### STRENGTHS

- unique, new and innovative product
- high professional competence

### OPPORTUNITIES

- Development of a new market segment
- Expansion of a monopoly position
- worldwide high number of births / pot. Customers
- growing market self-diagnostics



### WEAKNESSES

- Prototype and further Product development necessary
- Establishment of a central data structure with high data protection requirements

### THREATS

- Circumvention of patent protection

## 5. MARKETING

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Depending on the selected product version as a stand-alone device, own wearable or via integration into a wearable platform, the marketing goals and strategy also differ. Basically, the medium-term goal must be that [every pregnant woman worldwide is aware of the product and its benefits](#). This requires two steps: informing healthcare professionals and informing expectant mothers.

### Information for medical professionals

Prof. Weissenbacher and Dr. Pressmar will introduce the product to the medical community with further study and lectures, highlighting in particular the benefits for high-risk births and primiparous and multiparous babies with a history of prematurity. This is to inform medical professionals and midwives about the product. A [recommendation of the medical professionals](#) and possibly an [inclusion in the benefit catalog of the health insurers](#) would be a very big step towards a high market share.

### Information for the expectant mothers

In addition to the recommendation of scientific professionals (gynecologists, midwives, etc.) all normal marketing tools are entitled. First of all, it must be communicated that there is an innovation for pregnant women which increases the (over-)quality of life of the babies, especially in the case of premature babies, and which can solve further problems in the environment of the beginning and planning of birth.

The high differentiability of the target groups is an advantage here:

- Women between the ages of 20-50 years with a desire to have children or in pregnancy. Special emphasis should be placed on older mothers because of the higher risk of preterm birth and usually higher family incomes and mothers who have already had a preterm birth.
- Technically interested men and women between the ages of 20-50 who see advantages in a technical, digital product and already use other such products such as fitness trackers or wearables.

When integrated into an existing wearable platform such as the [Apple Watch](#), a new target group can be developed in addition to those already interested in such products, as this function adds a [completely new USP for this platform](#).

## 6. MILESTONES

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The founders had the first idea in 2017 and conducted initial scientific work on medical-biological background. They developed the idea to develop a corresponding product. The next year was characterized by the evaluation of the study and the development of the idea and possible products. The company WPmed would be founded in 2019 and filed an international patent for the idea in 2020.

In 2021, improvements to the concept were made and tested in further studies. The founders decided to manufacture the product with a partner or integrate it into a wearable platform in 2022. In the next 18 months, prototypes will be created together with the partner and the algorithms will be refined in a field test. The product is then to be launched on the global market.

