quantus
PREMATURITY

A revolution in ultrassound-based diagnosis

The first test for early detection of preterm birth

AN UNSOLVED CLINICAL NEED

Prematurity * is the leading cause of death for children and newborns in developed countries, the second worldwide, and presents an approximate global prevalence of 10%.
Each year more than 15 million of preterm babies that can suffer complications due to this condition are born globally. Prematurity contributes to long-term growth impairment and significant long-term morbidity such as cognitive, visual and learning impairments.
More than 50% of the total of preterm births are spontaneous preterm births (sPTB): unpredictable situations beyond a routine follow-up of pregnancy.
Prematurity prevalence has remained stable during the last decades because the current standard test for its detection is based on the measurement of the cervical length (CL) **.
CL measurement performs very low in general population. For this reason, there is an open debate about its application between the guidelines which are defined among the different scientific societies (SMFM, ACOG and ISUOG).

quantusPREMATURITY: the first fully automatic test for early detection of spontaneous preterm birth (sPTB)

- **Early detection:** quantusPREMATURITY is the first test that allows an early detection of the risk of sPTB before cervical shortening has already occured through the automatic analysis of an ultrasound image of the cervix. quantusPREMATURITY brings the opportunity to avoid the variability when measuring cervical length, simplifying this process, and being more efficient thanks to the advanced image processing techniques and the Artificial Intelligence (AI).
- **Multi-Result:** quantusPREMATURITY allows sPTB prediction at two levels of pregnancy (before 34 and 37 weeks) for being able to foresee different scenarios of pregnancy's monitoring.
- **Reliable:** quantusPREMATURITY results presented better performance and greater strength than those test based on the CL.

Comparison of quantusPREMATURITY with the Cervical Length (CL):

	CL [A]	quantusPREMATURITY [A]	CL [A]	quantusPREMATURITY [A]
Sensitivity	10.3%	16.5%	10.0%	35.2%
Specificity	99.1%	99.6%	98.8%	99.7%
PPV	32.9%	52.2%	10.0%	50.7%
NPV	95.7%	95.9%	98.4%	98.9%

[A] Average values in trials (references 9-10)

* Defined as a condition suffered by babies born before 37 weeks of gestational age.
** Transvaginal ultrasound-based technique which allows to evaluate cervix characteristics (uterine cervix) by measuring its length to determine the risk ofpreterm birth. Also known as cervical length.

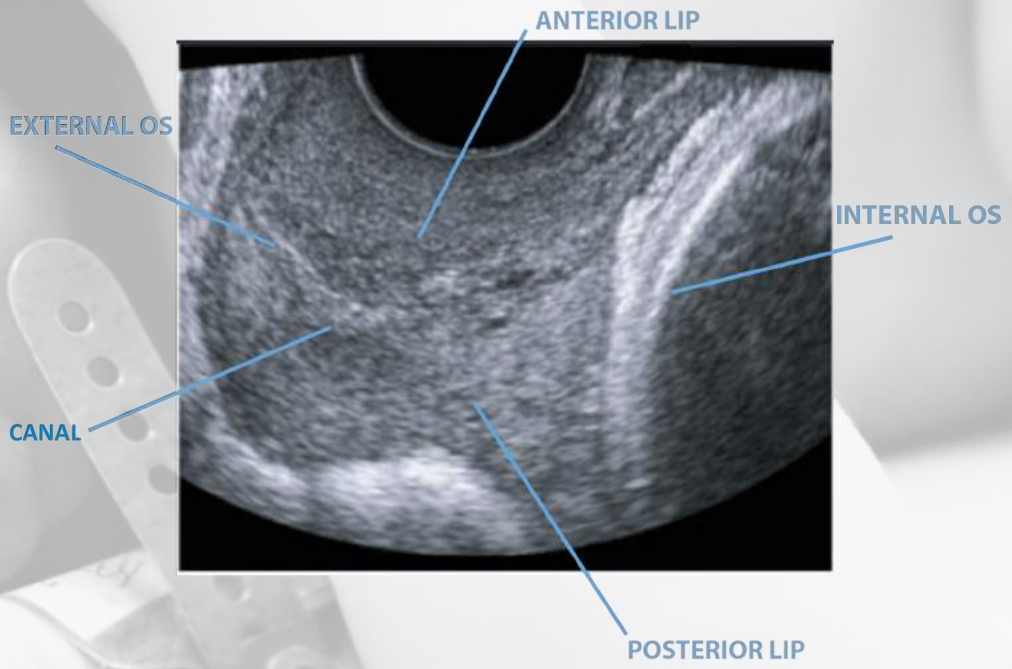
HOW TO USE quantusPREMATURITY?

Using quantusPREMATURITY is very easy, only 3 simple steps are required:

1. Acquire an ultrasound image
2. Upload the image to the web application
3. Recieve the results report

Step 1: Acquire an ultrasound image

quantusPREMATURITY requires a transvaginal ultrasound image of the uterine cervix in DICOM format. A simple guide that shows how to make acquisitions is available in the application.



Step 2: Use the web application of quantusPREMATURITY to analyze the image

This application is a simple tool that allows you to send the image that you want to analyze.
To do this, just follow these four simple steps and complete the analysis.

Upload

The DICOM image. More than one image according to convenience are allowed

Identify

The clinical information

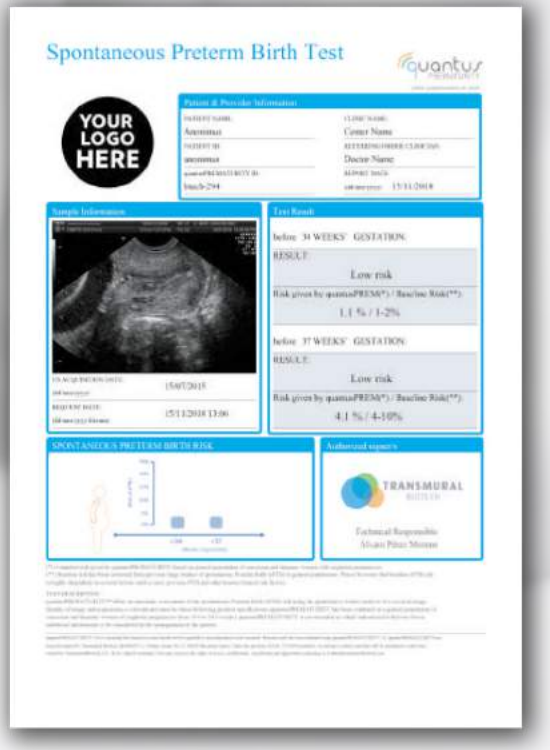
Select

The desired image to be analyzed

Send

The sample to be analyzed

Step 3: Obtain the result from the application in few minutes



¿WHEN TO USE quantusPREMATURITY?

During the 2nd trimester ultrasound-based morphological screening, the transvaginal scan to assess the risk of sPTE may be useful to estimate the need to carry out additional checks or launch specific therapeutic strategies for reducing this risk. sPTB risk prediction before the week 34 is especially relevant at clinical level, since it represents the gestational age with the largest number of fetal complications associated with prematurity.
quantusPREMATURITY is indicated for single pregnancies between 19 and 24 weeks of gestation to determine the risk of sPTB as a consequence of a premature cervical remodelling.
It is designed to be used as a tool for universal screening in general population, regardless of presenting risk factors associated with preterm birth.

However, those patients with increased risk of sPTE WITH previous sPTB, background of conization and/or presence of uterine malformation, could particularly benefit from this test in order to adapt its follow-up or treatment in a personalized way.

For example, during ultrasound scanning of a first pregnancy of 20 weeks gestation, where measurement of cervical length is 25 mm and directed anamnesis, the patient does not present any other risk factor for preterm birth, the basal risk for sPTB < 34 weeks is 1.7% and < 37 weeks is 4.8%. A transvaginal ultrasound to evaluate the risk of PPE, together with the morphological ultrasound, is performed. A result of 'low risk' using quantusPREMATURITY would reduce the risk of sPTB < 34 weeks at 1.1% and < 37 weeks at 4.1%, while a 'high risk' result would increase the risk at 51.6% for sPTB < 34 weeks and a 73.3% for sPTB < 37 weeks. Therefore, early knowing the risk of sPTBy using a simple transvaginal ultrasound can clearly.

quantusPREMATURITY OFFERS AN EXPERIENCE WITHOUT LIMITS

- Unrestricted 24/7 access: only having internet connection, you can use quantusPREMATURITY and check the results at any time and from anywhere.
- No installation is required: quantusPREMATURITY has been designed thinking about a simple initial use and does not require any software download or installation.
- Great compatibility: quantusPREMATURITY is compatible with most of the web browsers, as well as with the most common ultrasound machines used in obstetrics and Gynaecology.

quantusPREMATURITY OFFERS A HIGH ECONOMIC VALUE

- Does not require any initial investment in infrastructure.
- Pay per use: pay only per analysis. Without mandatory minimum consumption or fee of monthly maintenance.
- 15 days freeTest available without commitment for adapting our technology to your clinical practice.

For further information please contact us at:
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WHY DOES quantusPREMATURITY WORK?

Changes that occur at histological level in a tissue (proportion of collagen, fat or water, among others) affect the dispersion of ultrasonic signals. These signals constitute the basis for generation of ultrasound images. Quantitative analysis of ultrasound images, together with the advanced techniques based on Artificial Intelligence, allows to detect very subtle changes in tissues that are not visible to the human eye.
These changes could be relevant information from tissue microstructure related to a pathology.

The uterine cervix is a potential candidate for the application of this type of technology, since a cervical remodelling must occur during pregnancy. Cervical remodelling process consists of microstructural changes of the cervix which starts within the first trimester of pregnancy and lasts until term. An early or premature cervical remodelling may precede sPTB. Therefore, an early identification of a premature cervical remodelling could reduce potential maternal and perinatal complications associated with sPTB.

quantusPREMATURITY provides an alternative to the early detection for the prediction of the sPTB risk reliably; reaching levels of precision, performance and reproducibility without precedent in the state of the art.

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quantus PREMATURITY

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RELIABLE

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CSQ MED ISO 13485:2016

CE

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