



**A revolution in ultrasound-based diagnosis**

*The first test for early detection  
of spontaneous 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 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 occurred 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 Artificial Intelligence (AI).
- **Multi-Result:** quantusPREMATURITY allows sPTB prediction at two levels of pregnancy (before 34 and 37 weeks) to be 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):

	sPTB risk < 34 weeks gestation		sPTB risk < 37 weeks gestation	
	CL <sup>A</sup>	quantusPREMATURITY <sup>B</sup>	CL <sup>A</sup>	quantusPREMATURITY <sup>B</sup>
Sensitivity	10.0%	32.4%	10.3%	13.2%
Specificity	98.8%	99.5%	99.1%	98.7%
PPV	10.0%	52.7%	32.9%	36.8%
NPV	98.4%	98.8%	95.7%	95.8%

<sup>A</sup> Average values in trials (references 4-8)  
<sup>B</sup> Reference 10 (under review)

\* 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 of preterm birth. Also known as cervical length.

## HOW TO USE quantusPREMATURITY?

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



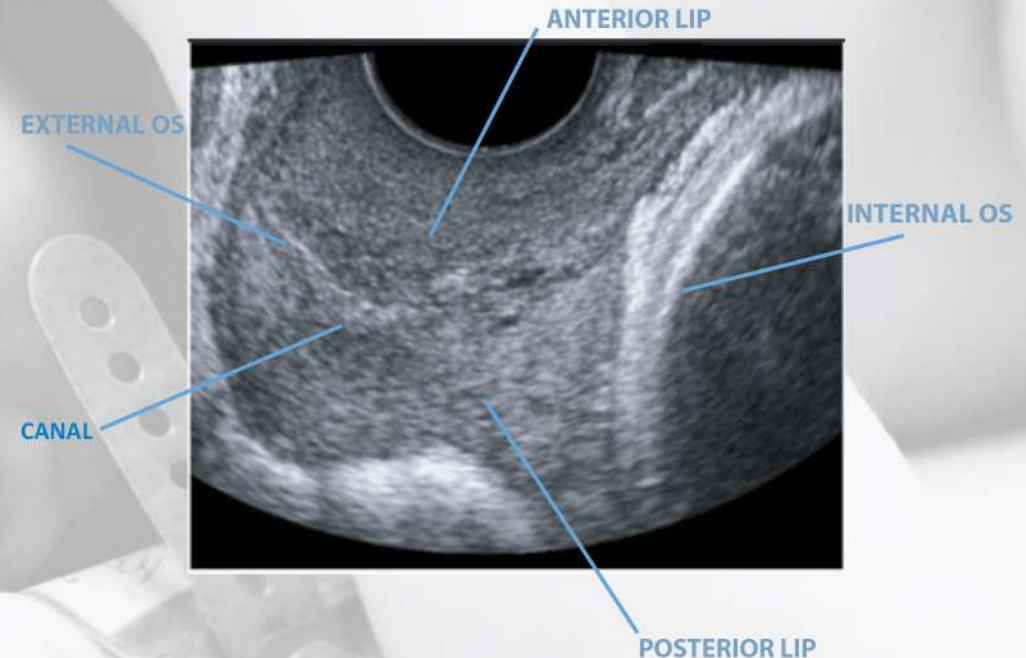
1. Acquire an ultrasound image

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.



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**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 can be selected for convenience



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

**Spontaneous Preterm Birth Test**

**Patient & Provider Information**

PATIENT NAME:	CLINIC NAME:
Address:	Center Name:
PATIENT ID:	REFERRING PHYSICIAN:
Address:	Doctor Name:
PHYSICIAN ID:	REFERRAL DATE:
Branch-204	DATE RECEIVED: 15/11/2018

**Sample Information**

US-IMG IDENTIFIER: 15072015

PHYSICIAN: 15112018 13:06

**Test Result**

before 34 WEEKS' GESTATION:

RESULT: **Low risk**

Risk given by quantusPREMAT<sup>®</sup> / Baseline Risk(\*\*): 1.1 % / 1-2%

before 37 WEEKS' GESTATION:

RESULT: **Low risk**

Risk given by quantusPREMAT<sup>®</sup> / Baseline Risk(\*\*): 4.1 % / 4-10%

**SPONTANEOUS PRETERM BIRTH RISK**

Bar chart showing risk levels for gestational weeks 34 and 37.

**Authorized signatory**

TRANSMURAL HEALTH

Technical Responsible: Alicia Pérez Sainza

## WHEN TO USE quantusPREMATURITY?

During the 2nd trimester ultrasound-based morphological screening, the transvaginal scan to assess the risk of sPTB 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 whether the patient presents risk factors associated with preterm birth. However, those patients with increased risk of 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 sPTB, 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 25.8% for sPTB < 34 weeks and a 46.7% for sPTB < 37 weeks. Therefore, knowing the risk of sPTB early, by using a simple transvaginal ultrasound image, can clearly have an impact on the clinical management of the case to assess follow-up controls or initiate personalized treatments.





## 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:  
sales@transmuralbiotech.com

## 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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ROBUST



RELIABLE



FOR ALL WOMEN



Transmural Biotech S.L., CIF: B65084675.

C/ Beethoven 15 Planta 4 Desp. 18 08021 Barcelona, Spain

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quantusPREMATURITY is a medical device according  
to the EU regulations for CE mark