



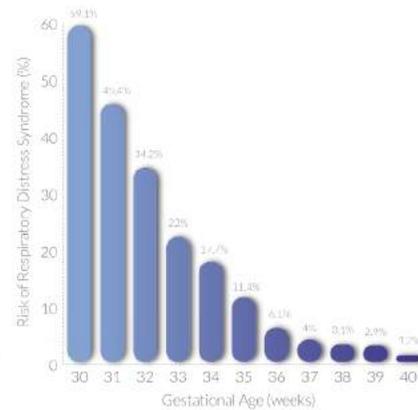
A Revolution in Ultrasound-Based Diagnosis

The First 100% Non-Invasive test to predict
Neonatal Respiratory Morbidity Risk



AN UNSOLVED CLINICAL NEED

- Preterm Birth Rate is increasing year by year in developed countries.
- Neonatal Respiratory Morbidity* remains as the leading problem in preterm babies despite prenatal and postnatal treatments.
- Current tests for the assesment of Fetal Lung Maturity** (FLM) require an amniocentesis, wich limits their practice due to the associated risks and discomfort.



Data extracted and adapted from different publications: JAMA 2010, JAMA Pediatr. 2013 and Paediatr Perinat Ep. 2013

HOW TO USE quantusFLM?

Using quantusFLM is easy only with 3 simple steps:



Step 1: Acquire an ultrasound image

Obtain ultrasound images of the fetal thorax at the level of the cardiac 4-chamber view in DICOM format. A clear guideline on how to acquire optimal images is available inside quantusFLM web application.

quantusFLM – the First 100% non-invasive Fetal Lung Maturity test

- Non-invasive: quantusFLM is the first Fetal Lung Maturity test in the market based on analysis of an ultrasound image of the fetal lungs. It gives the opportunity to avoid the need for an invasive technique to predict Neonatal Respiratory Morbidity in the clinical practice.
- Fast: quantusFLM can provide accurate results in just a few minutes.
- Reliable: The results of quantusFLM are as reliable as any other commercial test.

Comparison of quantusFLM and other commercial FLM test:

	Sensitivity	Specificity	PPV	NPV
L/S Ratio ^A	74,6%	82,5%	34,1%	96,4%
PG ^A	82,7%	54,4%	18,0%	96,3%
Lamellar body ^A	84,2%	74,4%	27,9%	97,6%
quantusFLM ^B	71,0%	94,7%	67,9%	95,4%

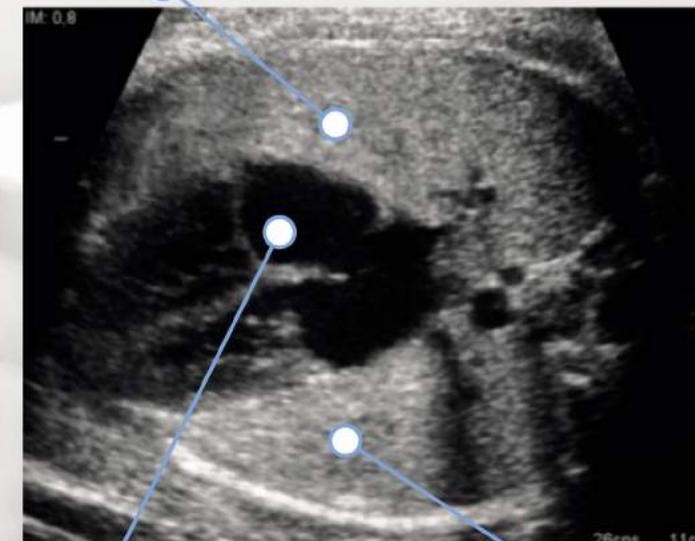
L/S: Lecithin / Sphingo myelin
PG: Phosphatidol Gl ycerol

^A Average reported values (references 4-9) in clinical studies
^B Data extracted and adapted from Scientific Reports 2019 (ref. 23)

*Defined as either Respiratory Distress Syndrome or Transient Tachypnea of the newborn that require his admission to a special unit and the use of medical respiratory support.

**The term "Fetal Lung Maturity" is universally used by the scientific and medical community to define the capacity of fetal lungs to achieve normal respiratory function if the fetus is born.

PROXIMAL LUNG



HEART

DISTAL LUNG

Step 2: Use quantusFLM web application to analyze the image

quantusFLM web application is a simple tool that allows you to send to the system the image you want to analyze. You just need to follow 4 simple steps to complete the analysis:



Upload

The DICOM image. More than one image can be upload for your convenience.



Label

Introduce clinical data to be analysed.



Select

The desired image to be analysed.



Send

The sample to be analysed.

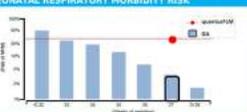
Step 3: Get the results from the web application in just a few minutes.

Fetal Lung Maturity Test

YOUR LOGO HERE

Patient & Provider Information	
PATIENT NAME: Patient Name	CLINIC NAME: Clinic name
PATIENT ID: Patient ID	REPORTING PHYSICIAN: Doctor Name
quantusFLM ID: XXX1-14969	REPORT DATE: 16/04/2020

Sample Information	Test Result from NIRM
 GESTATIONAL AGE: 37 WEEKS 0 days US ACQUISITION DATE: 03/10/2014 REQUEST DATE: 16/04/2020 17:48	quantusFLM ID: XXX1-14969 Baseline risk by gestational age: 4 % Risk adjusted by quantusFLM(*): 28.1 %

NEONATAL RESPIRATORY MORBIDITY RISK	Authorized signers
	 Technical responsible: Alvaro Pérez Moreno

(*)This test indicates the probability of Neonatal Respiratory Morbidity (NRM), which is defined as respiratory distress syndrome or treatment for any of the children, diagnosed by means of adjusting the baseline risk by the gestational age by the positive or negative likelihood ratio obtained by the presence of advanced lunging features.

TEST DESCRIPTION
quantusFLM offers an automatic assessment of the Neonatal Respiratory Morbidity (NRM) by using the quantitative feature analysis of a fetal lung image. Quality of image and availability to measure area that is under normal or present (quantusFLM) has been established in pregnant women from 28 to 38.3 weeks with normal FM-C2 and no fetal structural or chromosomal abnormalities. quantusFLM is not intended as a final test for delivery, but as additional information to be considered in the management of the patient. NRM is defined as respiratory distress syndrome in newborn background of the newborn.

quantusFLM is a medical device that is subject to the provisions of the Spanish Royal Decree for the implementation of quality control of medical devices. It is a medical device, subject to the provisions of the Spanish Royal Decree for the implementation of quality control of medical devices. It is a medical device, subject to the provisions of the Spanish Royal Decree for the implementation of quality control of medical devices. It is a medical device, subject to the provisions of the Spanish Royal Decree for the implementation of quality control of medical devices.

WHEN TO USE quantusFLM

quantus FLM can be particularly useful where elective delivery could be an acceptable option but the risk of Neonatal Respiratory Morbidity should be known.

In many clinical situations the decision of whether to deliver or wait is in a "grey zone", particularly in late preterm to early-term (34+0 to 38+6 weeks) pregnancies. Typical examples can be:

- Difficult-to-control hypertension or diabetes,
- maternal fluid retention with edema,
- very symptomatic cholestasis,
- previous history of unexplained fetal death or abruption,
- and any situation where an elective cesarean section <39+0 weeks is considered.

In these and other circumstances delivery may be a reasonable, but not an absolute, option to avoid danger to mother or fetus. Knowing the risk of Neonatal Respiratory Morbidity can be a critical information in the decision-making process, either to confirm or otherwise delay delivery.

For instance, in a 36+0 week pregnancy, the baseline risk of morbidity and NICU admission for respiratory support is 6.1 %. However, a risk adjusted by quantusFLM below the baseline risk might reduce the chances of morbidity to 5.2%, while if the risk adjusted by quantusFLM is above the baseline risk, the probability of respiratory morbidity might be 33.7%. Thus, knowing FLM (without the need of an invasive technique) may have a clear impact in the clinical management of this case.



quantusFLM OFFERS TIMELESS AND BORDERLESS USER EXPERIENCE:

- ✓ **Unrestricted and 24/7 access:** As long as there is Internet, you can use quantusFLM and review the results ANYTIME, ANYWHERE.
- ✓ **No installation required:** quantusFLM is designed to give new users an easy start because neither downloading nor installation of any software is required.
- ✓ **Great compatibility:** quantusFLM is compatible with the main web browsers as well as the most commonly-used Obstetrics and Gynecology Ultrasound Machines.

quantusFLM OFFERS GREAT ECONOMIC VALUE:

- ✓ **NO initial infrastructure investment is required!**
- ✓ **Pay per Use: You pay for each analysis you order!**
- ✓ **30-day FREE trial available, no conditions!**

Get your
30-day
FREE Trial

To sign up for a 30-day FREE trial,
contact us at
sales@transmuralbiotech.com

WHY DOES quantusFLM WORK?

Changes occurring at the histological level of a tissue, including the proportion of collagen, fat or water, among others, affect ultrasound backscattering signals. This constitutes the basis for ultrasound image reconstruction. Computerized quantitative ultrasound analysis detects extremely subtle changes, unperceivable by the human eye, in order to accurately infer relevant information of tissue microstructure.

Fetal Lung Maturity constitutes an obvious candidate for the use of quantitative ultrasound solutions as it results from the combination of the evolving changes in lung airways and alveoli during gestation, and the concentration of surfactant. Over the last 30 years research has focused on the extraction of quantitative information about tissue characteristics from ultrasound images.

Transmural Biotech's quantusFLM software uses a combination of cutting-edge image analysis technologies that make individualized predictiveness of the risk of Neonatal Respiratory Morbidity. quantusFLM reaches unprecedented levels of accuracy and reproducibility for a completely non-invasive ultrasound-based test.

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NON INVASIVE



RELIABLE



FAST



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