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Acquisition guide of fetal lung ultrasound images for the use of quantusFLM



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CE 0051

DATE: 06.11.2023
EDITION NUMBER: 42

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1.- About this guide for acquisition of fetal lung ultrasound images

This guide is a reference work for **quantusFLM** product users. The document has been conceived for persons and users acquainted with ultrasound imaging techniques. Ultrasound training and clinical practice are not provided in this guide.

The guide includes the specifications of the transducer and image mode characteristics that must be applied for the proper use of **quantusFLM**. If you desire more exhaustive information about the Ultrasound Machine functionalities, you must consult its user's manual (Manufacturer's instructions of the ultrasound machine).

The guide contains advice for the proper acquisition of the optimal image in order to use **quantusFLM** (detailed in the chapter 5: "Optimal image obtaining").

If you need a printed copy of this manual, please request it at info@transmuralbiotech.com. TRANSMURAL BIOTECH will send you the copy at no extra cost for you.

2.- Symbols and terms used in this guide for the acquisition of fetal lung ultrasound images

The following standards will be used in this guide for the acquisition of fetal lung ultrasound images:

- The steps of the functional instructions will appear numbered when the functional instructions must be executed in a determined order.
- The bulleted lists present information in a list, without involving a sequence.
- Warnings: Warnings are intended to alert to the importance of following the proper procedures when there is risk of injury for the system's user or patients.
- Cautions: Cautions are intended to alert to the importance of following the proper operating procedures in order to avoid the risk of system damage.
- Note: Notes contain information about the appropriate use of the system and/or the proper execution of a procedure.

3.- Warnings and cautions

The use of **quantusFLM** presents no risks for the user and/or the patient. Read carefully the chapter about warnings and cautions provided by the ultrasound machine's manufacturer for the proper and safe use of the ultrasound machine.

WARNINGS:

- In order to avoid patient discomfort or minor risks, keep hot surfaces away from the patient.
- In order to avoid risks, only certified sonographers will be authorized to use the ultrasound machine. This fact doesn't include transducer's face.
- To avoid the risk of electric shock or injury, don't open the boxes of ultrasound.
- To avoid the risk of damage, do not use the system in the presence of gases or flammable anesthetics since these could cause an explosion.
- To avoid the danger of electric shock, only use ultrasound machines on appropriate grounding.
- To prevent the risk of electrocution, examine the face, box and wire of the transducer before using it. Don't use the transducer or wire if they present some damage.
- To avoid the danger of electrical shock, only use the recommended accessories and peripherals for your ultrasound machine.
- To avoid the danger of electrical shock for the patient/individual, do make sure the wires are properly mounted.
- To protect the patient or subject against electrical discharge, refrain from touching the system battery contacts while these are touching said patient or subject.
- To avoid any damage to the operator/spectator, the transducer must be removed from the patient before applying a pulse of high voltage defibrillator.

CAUTIONS:

- Do not use the system if an error message appears when an image is presented: carefully observe the error code, phone the technical support service of your ultrasound machine and turn off the ultrasound machine.

- To avoid an increase in temperature of your system and transducer connectors (To prevent your system and transducer connectors from overheating,), do not block the air flow towards the ventilation holes of the ultrasound machine.

ALARA (As Low As Reasonably Achievable) criterion:

ALARA is the guide criterion for the use of the diagnostic ultrasound image. Qualified sonographers establish the lowest exposition level that is reasonably possible based on their professional criterion and experience. There are not enough completed rules to dictate a proper answer against any situation. In this manner, the sonographer maintains the lowest levels of exposure in order to obtain minimal biological levels and diagnostic images.

4.- General preparation

This chapter exposes the general preparations for the ultrasound image acquisition and storage in a generic way. The provided information is general. User's manual of the ultrasound machine (from the manufacturer) must be consulted for specific data about the functionalities of the ultrasound machine.

Characteristics of the ultrasound machine

Functional validation and compliance of the intended purpose of **quantusFLM** was made by using images obtained with the following ultrasound machines:

Brand	Model
Siemens	Antares
	Acuson X300
	Acuson S2000
	NX2
	NX3
Samsung Medison	Accuvix A30
	Accuvix A35
	Accuvix V10
	Accuvix V20
	Accuvix XG
	Accuvix XQ
	SonoAce X6
	SonoAce X8
	SonoAce R7
	SonoAce Pico
	SA8000
	HS40
	UGEO WS80A
	UGEO HM70A
General Electric	V 730
	E10
	E8
	E6
	Logiq E9
	LogiqP5
	LogiqP6
	LogiqP9
	Logiq3
	Logiq C5
	Logiq S8

		Voluson i
		Voluson P
		Voluson S6
		Voluson S10
Aloka		Arietta 70
		ALPHA 7
		ALPHA 6
		F37
		SSD-3500
Toshiba		Aplio
		Xario
		Xario 100
		Xario 200
		Aplio 300
		Aplio 400
		Aplio 500
Philips		HD9
		HD15
		Epiq 5
		Epiq 7
		ClearVue 550
		ClearVue 650
		Affiniti 50G
		Affiniti 50W
		Affiniti 70G
		Affiniti 70W
		iU22
Mindray		DC-3
		DC-N3
		DC-7
		DC-70
		DC-8
Sonoscape		S11
		X5
Alpinion		Ecube7
		Ecube 8
		Ecube15
Esaote		My Lab Eight
Hitachi		Ascendus

Table 1. Compatibility chart

Any ultrasound machine that allows for the acquisition of images which match the characteristics defined in the chapter “Characteristics of the image mode” should be

compatible with **quantusFLM**. The Compatibility chart (Table 1) shows the list of ultrasound machines compatible with **quantusFLM**.

In case of using other ultrasound machines or acquisition parameters that are not present in the list of supported ultrasound machines, consult with the sales department of **quantusFLM** in order to perform a previous qualification of the ultrasound machine that will ensure a proper operation of the system.

Characteristics of the transducer

A variety of ultrasound probes (transducers) with different shapes and sizes acquire ultrasound images of different regions of the body. The transmitted signal from the transducer comprises different ultrasound pulse bursts. In turn, the probe receives the echo (returned signal) from the original signal; this signal is used to build the final image which depends on the various tissues the signal goes through.

Tissue attenuation is directly related to transducer's frequency. The transducers used for acquiring images must be capable of working in the required frequency ranges by **quantusFLM**: 2-6MHz. Transducer must be compatible with the ultrasound machine, consult ultrasound machine's manufacturer manual for more information.

Acoustic coupling gel must be used for image acquisition. While most of the gels provide adequate acoustic coupling, some are not compatible with some transducer materials (refer to manufacturer's instruction of the ultrasound machine).

Characteristics of the image mode

Most of the ultrasound machines allow safe settings of acquisition (presets). In this manner, ensuring the repetitiveness of the acquisition parameters becomes easier for the distinct users of an ultrasound machine. However, **quantusFLM** system allows for the use images that have been acquired with the modification of some acquisition parameters according to technical criterion, subject to compliance with:

- Presented requirement in chapter 5, "Obtaining of the optimal image".
- The following settings:
 - Smoothing must be deactivated (Smoothing=Off)
 - Adaptive image processing must be deactivated (AIP=Off)
 - Frame correlation must be deactivated (Frame Correlation=Off)
 - Automatic Gain Control must be deactivated (AGC=Off)
 - Mostly, any parameter which applies imaging post-processing must be deactivated. For instance, if available, Speckle Reduction Imaging parameter must be deactivated (SRI = Off)

- System must save the images without any compression

Mostly, the acquired image must not be post-processed (or as little as allowed by the ultrasound machine) for the use of **quantusFLM**.

It is recommended to create a specific setting of the ultrasound machine for the acquisition of the images that will be analyzed by **quantusFLM**. In this manner, the proper obtaining of the image and the deactivation of the non-desired parameters is ensured. Settings for cardiovascular studies accomplish most of the previously mentioned specifications. These settings could constitute a good base for adjusting needed parameters that will allow acquired images to be analyzed with **quantusFLM**.

In case of ignoring setting parameters for the acquisition, consult with the sales department of **quantusFLM** to perform a previous qualification of the ultrasound machine and its settings that will ensure the proper operation of the system.

5.- Obtaining the optimal image

An ultrasound image corresponding to a specific anatomical plane (reference plane) which displays fetal lung is required for the use of **quantusFLM**.

This chapter presents how to acquire an image of the reference plane and establishes guidelines to obtain the optimal result from **quantusFLM**.

Plane of interest

Previous knowledge of the user about the image modes, transducer functionalities, settings and exploration techniques are supposed for the acquisition of the ultrasound images. The image must be acquired by means of abdominal echography using 2D-mode (or B-mode) images. The mode is similar to the one used to obtain fetal ultrasound images for screening which allow the evaluation of fetal anatomy.

Plane of interest must show fetal thorax in an axial section in the same way as fetal cardiac studies do. Plane level must correspond to the same that allows seeing a four chamber heart view (see Figure 1).

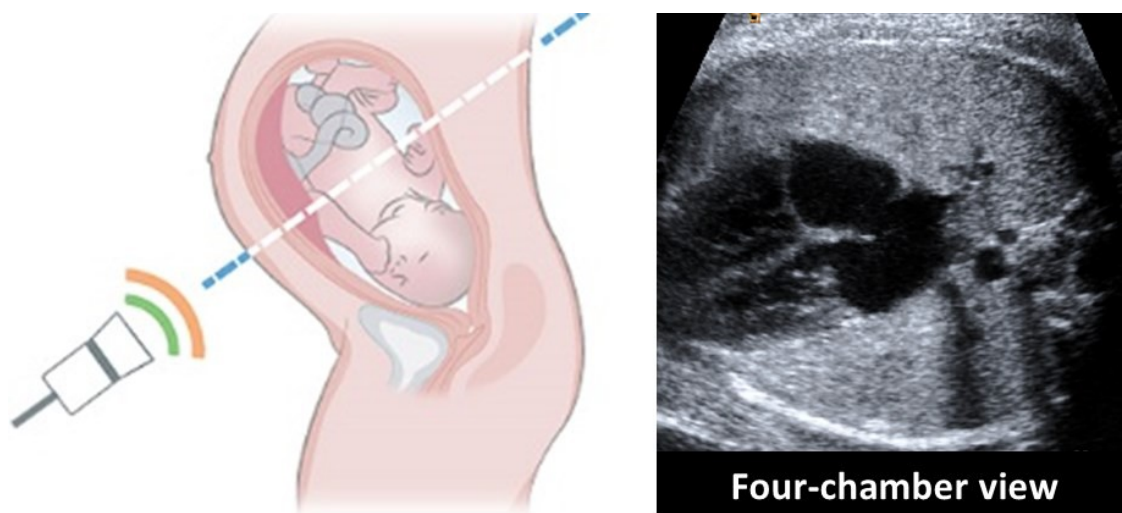


Figure 1. Cutting plane that allows obtaining the 4-cardiac-chamber view.

Reference image must show complete fetal thorax. Heart must be oriented horizontally to facilitate the proximal lung identification. To this aim, fetal spine must be oriented at 3 or 9 o'clock. Figure 2 shows an example of an optimal image:

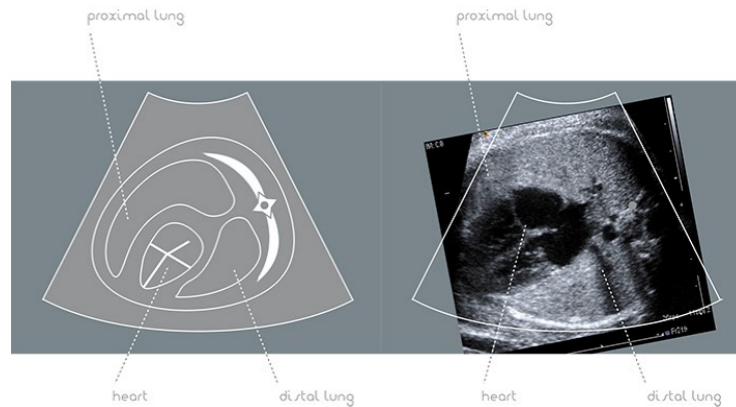


Figure 2. Optimal fetal thorax image for the use of **quantusFLM**.

Mostly, the best possible image of the lung parenchyma must be obtained avoiding shadows (for instance, from the ribs) or high contrasts.

Quick guide to obtaining the optimal image

In order to ensure the proper operation of the system, the image must meet the following requirements:

- Acquisition frequency must range within 2 and 6 MHz.
- When possible, harmonics must be activated during acquisition.
- No specific settings are required for the acquisition, but pre-settings for cardiac applications are usually optimal for **quantusFLM** requirements.
- Semi-lateral section at 4-chamber view level (see Figure 1).
- Fetal spine must appear in the horizontal axis (3h or 9h) of the image.
- Fetal thorax must take up the complete ultrasound image. Avoid the use of zoom in order to achieve thorax occupation across the whole screen (use depth). Avoid shadows caused by bone structures (especially in the proximal lung). Avoid saturations or dark zones due to extreme gains. Avoid image artifacts caused by:
 - Filtered options (smoothing)
 - Image measurements
 - Calipers and pointers
 - Colour (Colour Doppler, etc.)
 - Other artifacts

Figure 3 shows graphical examples of the aforementioned requirements.

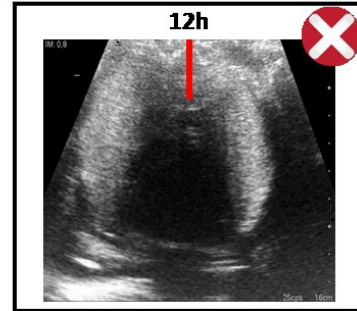
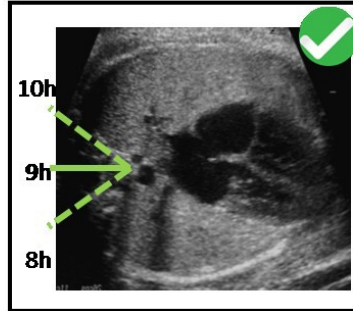
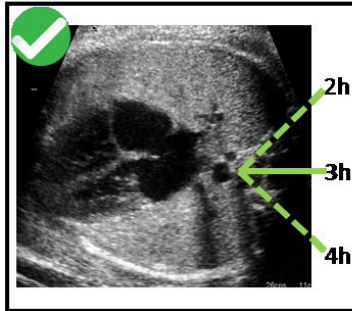
It is recommended to have these guides near the ultrasound machine in order to consult it.

NOTE: Anatomy, physiology and physical conditions of the patient are factors that must be taken into account during the acquisition. Moreover, exploration technique depends on knowledge and experience of the sonographer that performs the acquisition.

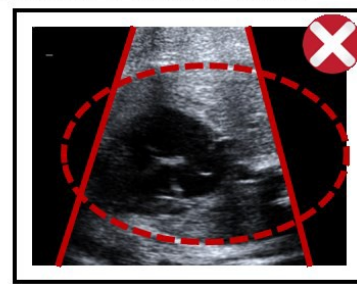
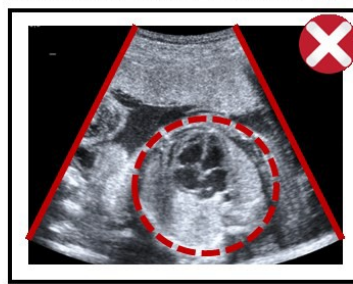
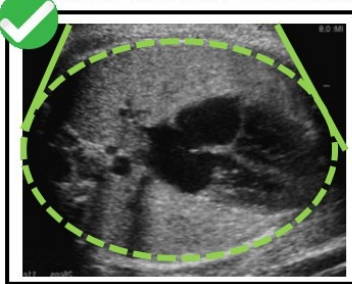


- Preferred Probe frequency: 2-6MHz.
- Fetal spine located horizontally, at 3h or 9h.
- Avoid post-processing artifacts: smoothing, on-line measurements, pointers, color Doppler images, etc.
- Entire thorax structure has to be shown.
- Avoid saturation and shadows.
- Preferred use of harmonics. (Cardiac presets recommended)

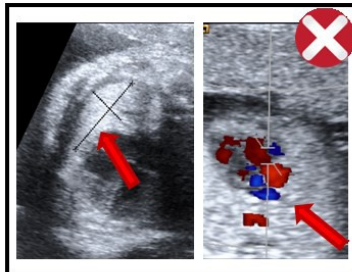
Spine located horizontally (9h or 3h $\pm$ 1 hour)



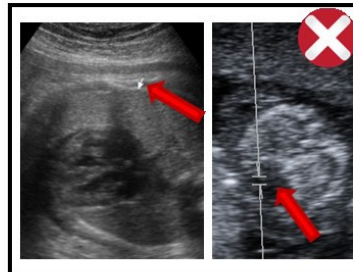
Entire Thorax structure must be shown. Thorax limits right and left scan (no more or less zoom allowed)



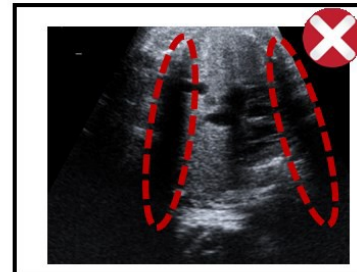
Avoid Doppler, Color, on-line measurements or similar artifacts



Avoid pointers or markers



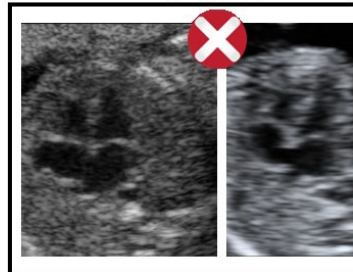
Avoid shadows (from ribs, spine or other limb bones)



Avoid saturation (over exposure)



Avoid smoothing or post-processing



Avoid not use harmonics



Figure 3. Acquisition guide

6.- Storage in ultrasound machine

In order to store an image in the ultrasound machine, it is necessary to previously freeze the screen. Most ultrasound machines save configuration data of the ultrasound machine and the data introduced by the user (for instance: patient identification, etc.) with the image. In case of doubt, consult the specific procedure in the ultrasound machine guidelines of manufacturer.

Stored images must be saved to be analyzed by **quantusFLM**.

Information associated with the image can be useful to the user for identification.

Warning: Check the information related to the patient and the acquisition for any error. This can prevent possible errors in the acquired image identification.

NOTE: Once images are saved, these are selected from **quantusFLM** application in order to be analyzed (see User's Manual). Data associated with each image can be automatically read by means of the **quantusFLM** application. The acquired data, both automatically and manually introduced to **quantusFLM**, shall comply with the applicable laws for data protection (LOPD).

7.- Recording

Images must be saved in DICOM format (without any compression option activated). In this manner, DICOM format will allow to **quantusFLM** to automatically fill out most of the fields required by the system.

Most common devices for recording and storing are:

- Internal network
- USB
- CD/DVD
- Picture Archiving and Communication System (PACS)¹

General steps for saving images are:

- If the copy can't be performed by means of the internal network or the PACS connection, it must be introduced using a storage device (USB or CD).
- Desired images must be selected. The button or tab that starts the copy must be clicked. In some cases, both destination unit (red/usb/cd/dvd) and DICOM format files must also be selected.
- Images will be copied in the device. If you select CD/DVD, images are usually copied as internal memory, it is therefore necessary to indicate again that a copy is wanted into the device.
- Extracting storage device.

NOTE: It is important to identify the files path where images will be saved since the exact location of the image files to be analyzed shall be selected from **quantusFLM** application.

¹ quantusFLM® is integrated with a third-party provider that allows the client to connect the ultrasound machine with quantusFLM. For more information, please contact us at support@quantusflm.com

8.- Frequently Asked Questions

Can any ultrasound machine be used?

Any ultrasound machine which acquires images that match the characteristics defined in the “Characteristics of the image mode” chapter should be compatible with **quantusFLM**. The “Compatibility Chart” shows the list of ultrasound machines which are compatible with **quantusFLM**. Before using ultrasound machines or acquisition parameters not listed as compatible, consult with the sales department of **quantusFLM**. A preliminary qualification of the ultrasound machine will be performed in order to ensure the proper operation of the system with the new ultrasound machine.

Can any transducer be used?

Transducers to acquire images must be able to work within the frequency range required by **quantusFLM**: 2-6 MHz.

Is any pre-setting valid?

quantusFLM system allows using images that have been acquired with the modification of some acquisition parameters according to technical criteria, subject to compliance with:

- Presented requirement in chapter 5, “Obtaining the optimal image”.
- The following settings:
 - Smoothing must be deactivated (Smoothing=Off)
 - Adaptive image processing must be deactivated (AIP=Off)
 - Frame correlation must be deactivated (Frame Correlation=Off)
 - Automatic Gain Control must be deactivated (AGC=Off)

Mostly, the acquired image must not be post-processed (or as little as allowed by the ultrasound machine) for the use of **quantusFLM**.

Settings for cardiovascular studies accomplish most of the aforementioned specifications. These settings could constitute a good base for adjusting needed parameters that will allow acquired images to be analyzed with **quantusFLM**.

Is it necessary to create a new pre-setting?

It is recommended to create a specific ultrasound machine setting for the acquisition of the images that will be analyzed with **quantusFLM**. In this manner, proper image obtaining and deactivation of non-desired parameters is ensured. Moreover, ensuring the repetitiveness of the acquisition parameters becomes easier for the distinct users of an ultrasound machine.

NOTE: In case of doubt during the creation of the settings, consult your ultrasound machine technician for configuration.

How is a fetal thorax image acquired?

The image must be acquired by means of abdominal ultrasound image using 2D-mode (or B-mode). Firstly, it is necessary to recognize the fetal position. For the acquisition of the plane, ultrasound beam must be perpendicular to fetal thorax.

User's previous knowledge of image mode, transducer operation, system's configuration and exploration technique is required for image acquisition of fetal thorax suitable for **quantusFLM**.

What must be seen in a 4-cardiac-chamber view?

Displayed cardiac structures change according to the fetal thorax level in which ultrasound cutting is performed. The 4 fetal cardiac chambers and part of lung parenchyma must be seen in the 4-chamber view plane.

Is it difficult to acquire the 4-chamber-view plane?

The image must be acquired by means of abdominal ultrasound image using 2D-mode (or B-mode). The mode is similar to the one used to obtain fetal ultrasound images for screening which allow the evaluation of fetal anatomy.

Can I save the image in any format?

Images must be saved in DICOM format. Other formats are not supported by the system.

If I keep many images together, how will I know which image is good?

quantusFLM application will request the exact location of the image files to be analyzed. The application allows previewing the images in order to be able to select the desired image.

How can I connect to the PACS?

To connect the ultrasound machine to quantusFLM through the third-party provider's PACS please contact us at support@quantusflm.org .

9.- Contact

For further information you can contact us at:

support@quantusflm.org

or visit:

www.quantusflm.org

