

Obstetric Guidance

Understanding the Exam

An obstetric ultrasound is performed to assess one or more fetuses. This exam can be performed in the 1st trimester of the pregnancy or later in the 2nd/3rd trimester. This exam is typically performed with the transducer placed on the abdomen/pelvis to evaluate the pregnancy within the uterus. A transvaginal probe can also be used if it is very early in the pregnancy and the pregnancy is too small to be viewed transabdominally, or if the cervix needs to be evaluated for competency later in the pregnancy.

Reasons that a 1st trimester obstetric ultrasound might be performed:

- Viability: Evaluate for a heartbeat and general health of the fetus
- Dating: Acquire a crown-rump length (CRL) measurement to determine/confirm the gestational age (GA) of the fetus
- Rule-out ectopic pregnancy: Confirm that a pregnancy is intrauterine. Ectopic
 pregnancies are life-threatening pregnancies that occur outside the uterus (excervical, ovarian)
- Nuchal Translucency: Measurement of fluid behind the neck of the fetus. A thickened nuchal translucency can be a marker for genetic abnormality
- Early anatomy screening: Anatomical screening completed late in the 1st trimester to evaluate for genetic abnormality

This exam typically lasts about 15-30 minutes.

Reasons that a 2nd/3rd trimester obstetric ultrasound might be performed:

- Anatomy: Evaluate the anatomy of a fetus for findings that indicate genetic abnormality or other physical abnormality
- Growth: Evaluate the EFW by obtaining biometry measurements to check for intrauterine growth restriction (IUGR) or larger than average fetuses.
- AFI: Check the amniotic fluid index as too much or too little fluid can impact a pregnancy.
- BPP: Evaluate fetal movement. Too few movements might prompt further tests or even delivery if the fetus remains inactive for a long period of time.

This exam typically lasts about 15-90 minutes depending on what is being evaluated. Limited exams, for example a $2^{nd}/3^{rd}$ trimester ultrasound for AFI, can take 15 minutes. A detailed anatomy scan can take up to 90 minutes.

Performing and Approving Users

		Required Credentials	Common Additional
			Credentials
Performed by	General/Obstetric	One of the following:	
	Sonographer	 General sonographers 	
		credentialing: Registered	
		for Diagnostic Medical	
		Sonography (RDMS):	
		Certified by the American	
		Registry for Diagnostic	
		Medical Sonography	
		(ARDMS) or Certified by	
		the American Registry of	
		Radiologic Technologists	
		(ARRT)	
		Obstetric sonographers	
		must be Registered for	
		Diagnostic Medical	
		Sonography by (ARDMS)	
		and have a subspecialty	
		certification in Obstetrics	
		and Gynecology (OB/GYN)	
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Read by	Radiologist,	ABR (American Board of	
	Maternal Fetal	Radiology) certified radiologists	
	Medicine (MFM)	hold certifications in DR	
	Provider	(diagnostic radiology) or IR/DR	
		(interventional	
		radiology/diagnostic radiology).	
		Gynecology (OB/GYN)	

Facility Types

This type of study is performed in these facility types:

- Community hospitals
- Outpatient imaging centers
- Public health facilities
- University-affiliated teaching hospitals and medical institutions
- Government and private research institutes
- Medical imaging facilities
- Private physician offices
- Maternal Fetal Medicine (MFM) office
- Women's Health facilities

Worksheet

Protocol

Selecting one of the four protocols (1^{st} trimester, $2^{nd}/3^{rd}$ trimester, $2^{nd}/3^{rd}$ trimester limited, $2^{nd}/3^{rd}$ trimester detailed anatomy) will adjust the worksheet to accommodate for the imaging technique used.

Items in the measurements and observations sections will change when you select a different protocol.

The 1^{st} trimester protocol includes 1^{st} trimester measurements such as the crown-rump length, nuchal translucency, gestational sac size and yolk sac size. It also includes observations specific to the 1^{st} trimester, such as early anatomy observations.

The $2^{nd}/3^{rd}$ trimester protocol includes different biometry measurements such as the biparietal diameter (BPD), head circumference (HC), abdominal circumference (AC), and femur length (FL). There are more extensive anatomy observations available as the fetus is more developed than in the 1^{st} trimester. Additionally, a BPP and AFI can be documented in the $2^{nd}/3^{rd}$ trimester.

The 2nd/3rd trimester limited protocol does not include any fetal anatomy observations by default, as this protocol is used to answer a specific clinical question. This protocol might be used to document weekly AFIs if a patient has hypertension or to document biometry measurements to check the growth of a fetus that is not growing as guickly as expected.

The 2nd/3rd trimester detailed anatomy protocol includes all fetal anatomy observations and is used to document a more comprehensive anatomy assessment. This protocol might be used for a patient that had an abnormal result on a genetic test or is at an advanced maternal age (>35 years old) and is often used at Maternal Fetal Medicine (MFM) sites or sites that perform high-risk ultrasound.

Measurements and Observations

This section contains the three standard tabs (Report Images, Report Attachments, Report Recipients), and three study-type-specific tabs for a pregnancy with one gestation. If more than one gestation is documented, an additional tab will be added for each additional gestation.

General & GA Tab

- Contains dates of previous ultrasound, last menstrual period (LMP), current ultrasound, and conception date. Estimated date of delivery (EDD) is calculated based on these values.
 - Best Assessment: The highlighted EDD is considered the 'best assessment' by the user to calculate the EDD and fetal age most accurately. The EDD best assessment default is "EDD by LMP" but users can select a different EDD by clicking on the preferred EDD. Selection of a different EDD impacts the fetal biometry percentile calculations. Percentile calculations are based on the GA indicated by the Best Assessment.
 - You can choose to always hide any EDD assessment from the final report (even if data is present) via a My Choices Form option configurable per client/division.
- Para represents the number of times the patient has given live birth. For a pregnancy to count as a "birth," it must go to at least 20 weeks' gestation (the midpoint of a full-term pregnancy) or yield an infant weighing at least 500 grams, irrespective of whether the infant is live born or not.
- Gravida represents the number of times a patient has been pregnant regardless of the pregnancy outcome.
- Pregnancy is either Intrauterine (in the uterus), Ectopic (an abnormal place or position), or Unknown.

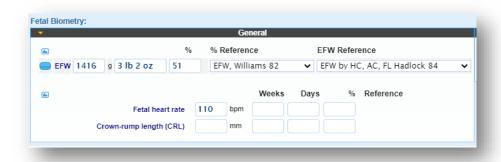
Fetus Tab

- Contains measurements and observations on the growth and development of the fetus
- Contains dropdowns to indicate the fetal biometry model reference used to determine growth percentile.
- In the Fetal Anatomy Observations section, multiple fields can be selected at the same time. Observations can then be applied to all selected fields, reducing the time it would take to select each individually.
- Growth charts can be toggled on/off on the report by clicking the blue bubble to the left of the data.

Understanding EFW, Percentile Reference, and EFW Reference in Fetal Biometry

EFW (Estimated Fetal Weight) is the estimated weight of the fetus in both g and lb/oz. The weight of the fetus will always be an estimation because, unlike other fetal biometry values like femur length or head circumference, weight cannot be measured during the

ultrasound.



Obstetric References

Studycast includes references for estimating gestational age, fetal weight, and percentiles.

The Help page explaining these references can be found here:

http://192.168.70.207/coreweb/assets/help/obstetric-references.html

Studycast Advisor

The Studycast Advisor prompts the user when the study that they are working on is part of a pregnancy and should be added to a case or used to create a new case. There are several benefits to creating cases that represent pregnancies.

Note: The Advisor can be disabled for one or all divisions in a facility.

Reports

Accreditation

Reports are designed to meet requirements from AIUM (American Institute of Ultrasound in Medicine)

My Choices form options

The My Choices form containing the worksheet options can be found here: https://www.cognitoforms.com/CoreSoundImaging1/mychoicesobstetric

Study Description

The study description appears as part of the title on the final report. The format is 'STUDYDESCRIPTION' Obstetric Study Report. In the Studycast obstetric worksheet, the study description defaults to Transabdominal. The default list includes three selections, Transabdominal, Transvaginal, and Transabdominal and Transvaginal. Users can modify the select list from the worksheet. Through the My Choices form, a client can set a protocol-specific default as well. The default can be blank.

Demo Path

When training, insert this demo path after you've covered basic worksheet orientation.

If the training is for a technologist

- Study Quality defaults to Excellent (default can be something else)
- Study Description defaults to Transabdominal (but the client can specify default based on protocol – prep for this training should include confirming client default;

- understanding of client workflow/facility should determine if further discussion on this is needed)
- Protocol is set automatically, based on the EDD/GA indicated from several fields in the structured report. If the GA is indicated to be less than 14 weeks, the protocol will be set to 1st trimester. Otherwise, the protocol will be set to 2nd/3rd trimester when a technologist first opens the worksheet
- Gestation defaults to 1 unless additional gestations are indicated in the structured report (if new client, did we confirm samples with multiple gestations were received in training prep)
- Procedure defaults to blank (this should be covered in the My Choices call. It is very likely the client will have custom procedure statements/should be noted in training prep)
- Informed Consent can be checked or unchecked by default

Open the report to show how Study Quality, Protocol, Procedure, and Informed Consent affect the procedure statement on the report.

For all trainees

To document your exam, we can begin with a review of the General and GA tab. The information here has transferred from your ultrasound machine and/or has been set based on Studycast options. Note that the EDD by Current US is highlighted in yellow. This indicates it is the Best Assessment method for EDD. You can complete the para and gravida observations. The pregnancy observation defaults to "Intrauterine" and Diabetes defaults to "No". Select only if they need to be changed.

On the Fetus A tab, you can document fetal activity [set 3 observations here].

The AFI values will transfer from your ultrasound machine. BPP values can be documented and the BPP score will calculate based on these values.

The fetal biometry measurements will transfer from your ultrasound machines. The GA and growth percentile references will be set if applicable, resulting in the GA by weeks and days and the growth percentile values being populated. The growth chart for a given parameter will be included on your report if the growth chart indicator is selected.

In the Fetal Anatomy Observation section, you can check 'all' and click 'seen'. Now you can document any abnormalities. For example, you can document the Aorta as Abnormal.

Now, you can click 'Generate all' and all findings statements based on the selections we have made so far will appear in the corresponding findings section. Findings statements are generated for all observations that are not blank, or do not appear in another format on the report.

When we generate Conclusions, you will see the GA information and a summary of abnormal findings appear in conclusion statements.

You can see conclusion statements related to the abnormal aorta and when you click 'preview report', you see the normal fetal anatomy observations in a tabular format.

If you are satisfied with how you have documented the exam, at this point you can click 'set preliminary' and this moves to the doctor's list for approval.

Now let's take a deeper look at additional functionality.

Studycast Advisor & Cases

Open a study that meets the criteria to be added to a case. Click on the illuminated advisor and add the study to a case. Show the information that populates on the General & GA tab including the EDD from the previous ultrasound. Navigate to the Fetus A tab and demonstrate in-worksheet Compare functionality.

Note: Prior Viewpoint users will be used to calling a case a "pregnancy"

Key Studycast Benefit

Creating or adding a study to a case will:

- Populate the EDD from the previous study in the pregnancy
- Plot the EFW and other relevant values from previous studies on growth charts
- Enable in-worksheet access to the Compare function for studies in a case

In the Fetus A tab, show the measurements pre-populated. Explain that the default references can be defined by the client and show how to select a different reference.

Show how the radio buttons control which growth charts display on the reports, and that data from previous ultrasounds are displayed on the growth chart when the study is part of a case.

Explain that the anatomy observations available can be defined by the client. Set all anatomy observations as 'seen' from the top row of the section. Hold down shift and select three individual pieces of anatomy. Set to 'abnormal', again from the top row of the section.

Show collapsing a Uterine Arteries Doppler section and explain that the collapsed state of sections on the Fetus A tab will save per user.

Navigate to the Maternal Anatomy tab. Measurements will populate from the machine - show ovarian measurements and add an observation of 'unremarkable'. Generate findings and conclusions.

Demonstrate Previous Results functionality and how findings and conclusions can be appended or replaced with information from the previous study. Demonstrate how to add, delete, and reorder statements and preview the report.

SWOT Analysis

Strengths	Weaknesses
 All obstetric studies are consistent with AIUM guidelines Allow for percentile calculations from multiple references, including references for specific patient populations such as WHO, Intergrowth and NIHCD Multiple growth chart options available Ability to add a study to a case with one click to populate the EDD from previous study, plot previous 	 Competitors have a larger market share of Women's Health market and are in more MFM locations Some functionality that Viewpoint has that Studycast does not: Tumor classification based on IOTA MFM risk assessment Invasive procedures Genetic counseling Pregnancy outcome

measurements on charts, and enable in-worksheet Compare functionality

- Integrates with all EMRs
- CPT/ICD-10 codes built in
- Preset favorites allow for efficient documentation of common ICD-10/CPT/Indication/Procedure statement combinations
- Efficient documentation of fetal anatomy observations
- Reporting efficient enough for OB clinics and robust enough for MFM sites
- Report layout configurable for facilities
- Share images to patient smart phone included
- Anywhere access to images
- Single portal for all images across enterprise
- Compare data across exams
- Post-exam full calculation tools
- Image archiving until patient is age 28 (10 years for GYN exams)
- Workflow automation for report delivery

Opportunities

- Promote the use of cases to further reduce manual data entry
- Create additional protocols for Limited studies (ex: growth, AFI)
- Promote CoreShare as many practices still rely on modality report printouts and thermal paper for image printing.
 Better workflow and cost savings.
- Dominant player makes focused messaging possible

Threats

- Perception of longtime users of other products that Studycast is not built for OB/MFM studies because it is different or uses different verbiage (ex: Viewpoint users are used to calling cases "pregnancies")
- Portion of industry satisfied with modality driven reporting