INTERBIO-21st

International Fetal and Newborn Growth Standards for the 21st Century

The International Fetal and Newborn Growth Consortium

UPDATE TO THE INTERGROWTH-21ST ULTRASOUND OPERATIONS MANUAL

- Pregnancy Dating
- Cervical length measurement
- Doppler measurements

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Please read this manual carefully and refer to it throughout the study if any clarification is needed.

This is a supplementary Operations Manual for INTERBIO-21st, part of the INTERGROWTH-21st project. It was prepared by the INTERGROWTH-21st Ultrasound Coordinating Unit, led by Aris Papageorghiou with input from Raffaele Napolitano.

INTERGROWTH-21st is a large project involving health institutions from geographically diverse countries. It is therefore essential that the participating institutions follow the same data collection procedures.

This manual is designed to familiarize all staff involved with the techniques for those aspects that are different from the Fetal Growth Longitudinal Study (FGLS) of the INTERGROWTH-21st project.

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1. Differences and similarities between the INTERBIO-21st and INTERGROWTH-21st ultrasound manuals

DIFFERENCES: The ultrasound methods of the INTERBIO-21st are identical to those of the Fetal Growth Longitudinal Study (FGLS) in all respects except:

- Pregnancy dating: In INTERBIO-21st the gestational age of the pregnancy will be assigned by measurement of the fetal Crown Rump Length (CRL) at 9^{+0} to 13^{+6} weeks gestation, as the study allows recruitment of women with no known LMP. — Section 2
- Cervical length is measured once at 19-24 weeks — Section 3
- Uterine arter Doppler is measured once at 19-24 weeks. — Section 4
- Umbilical artery Doppler is measured after 24 weeks. — Section 5
- Quality criteria for Doppler signals — Section 6

SIMILARITIES: All other aspects including remain the same as in the INTERGROWTH 21st protocol:

- Serial measurement of the Biparietal Diameter (BPD), Occipito Frontal Diameter (OFD), Head Circumference (HC), Transveres Abdominal Diameter (TAD) Antero-Posterior Abdominal Diameter (APAD), Abdominal Circumference (AC) and Femur Length (FL)
- 3D volumes of the fetal head, abdomen and femur.
- Measurement of amniotic fluid volume.
- Documentation of placental localization.
- Documentation of fetal presentation.
- Data management
- All Quality control aspects

This Ultrasound Protocol update should be read in conjunction with the existing INTERGROWTH-21st Ultrasound manual

2. Initial Ultrasound Examination and Dating of Pregnancy: Measuring the Crown Rump Length

All mothers will have a transabdominal ultrasound scan to date the pregnancy and confirm they are between 9^{+0} to 13^{+6} weeks of gestation.

2.1 Aims

- To confirm intrauterine pregnancy, viability and singleton gestation.
- To confirm gestational age.

2. 2 Dating

- **Gestational age will be calculated from the CRL.**

  Unlike the FGLS study (where only women with strict LMP criteria were recruited), INTERBIO will recruit women at high risk of perinatal complications, including those in environments of poor nutrition. Therefore the LMP may be unreliable.

  Because of this the gestational age from the CRL will be used.

  This is calculated automatically by the study ultrasound machine using established charts. If the dating scan is done on another machine ensure you use the attached chart to look up the estimated gestation.

2. 3 How to do it:

The fetal CRL will be measured as described in the INTERGROWTH-21st Ultrasound protocol.

The same elements of training, standardisation and quality control will be carried out.

3. Assessment of maternal cervical length

3.1. Aims

- To measure the maternal cervical length.
- This is carried out once, at the 19-24 week scan.
- Transabdominal measurement is performed
- The measurement is transcribed onto the ultrasound form (there is no field in the ultrasound machine for uploading it directly)
- If transvaginal measurement is performed for other reasons this can be used in the form (but this is not part of the study)

3.2 Obtaining and Measuring the Cervical Length

- The cervix has to be visualised in the sagittal plane to obtain a full length of the cervical canal (CL), with a nearly empty bladder and without applying fundal or suprapubic pressure.
- Measurement of the cervical length has to be taken from the internal os to the external os incorporating only that length that is bordered by endocervical mucosa.
- A single linear measurement is to be taken from the internal to the external os. When the cervical canal is curved the single longest measurement should be taken.
- Funnelling does not need to be recorded. The length in this case should be measured from the lowermost border of the funnelling to the external os.
- The measurement is manually recorded in the ultrasound form. If it is not possible to obtain the measurement, this is also recorded.

[There is not a facility to measure the CL on the HD9 Philips machine. The measurement should be therefore acquired on the “Review” mode. The CL picture should be stored. Press on the “review” bottom, select the appropriate image, select the calipers facility and place the calipers. Record the measurement on the notes as it won’t be]

Figure: Transabdominal measurement of the uterine cervix

4. Assessment of Uterine Artery Doppler

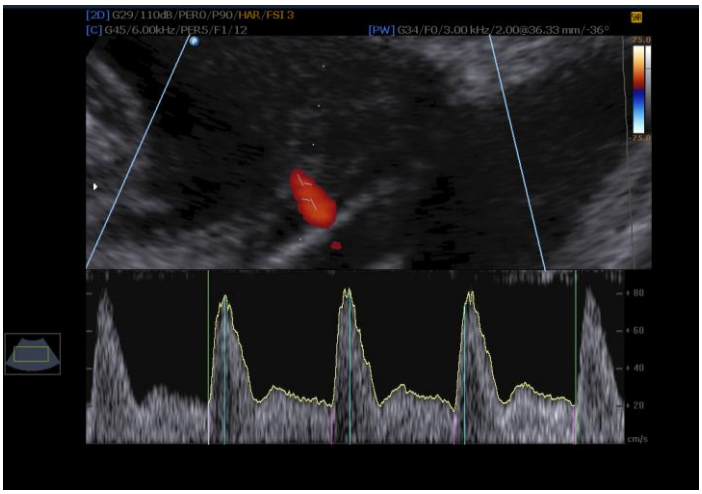
4.1. Aims

- To use Doppler to measure the impedance to maternal uterine artery blood flow.
- This is carried out once, at the 19+0 to 23+6 week scan.
- Transabdominal measurement is performed.
- The measurement is transcribed onto the ultrasound form (there is no field in the ultrasound machine for uploading it directly).

4.2 Obtaining and Measuring the Doppler Signal

- Appropriate setting adjustment should be performed before obtaining the final trace. Please see "**Doppler Quality Criteria"** below.
- Uterine artery Doppler signal should be obtained at the apparent crossover with the external iliac artery using Color Doppler.
- If the correct anatomic site cannot be identified (anatomical variation), the uterine artery closest to the iliac artery should be insonated. In case of an early bifurcation of the uterine artery It should be measured before the bifurcation. Where this is not possible to identify, the larger vessel should be insonated between the two.
- Once 4 - 6 similar waveforms are obtained, select ”Left” or “Right Uterine Artery”

- The presence of an early diastolic “notch” should be recorded for each vessel; A notch is present when there is a clearly defined upturn of the flow velocity waveform at the beginning of diastole in all the waveforms. (see Figure)



- PI: Pulsatility index (PI), Resistance index (RI), Systolic / Diastolic ratio (S/D) should be measured via autotracing of three or more consecutive similar waveforms, from the beginning of the systolic to the end of the diastolic signal, selecting the “limited trace” or “automatic trace” options on the ultrasound machine.
- In case the signal is poor due to background noise and a clearer image trace cannot be obtained, a manual trace can be used for the indices calculations.

5. Assessment of Umbilical Artery Doppler

5.1. Aims

- To use Doppler to measure the impedance of blood flow through one umbilical artery.
- This is carried out from 24+0 weeks at each scan.
- Transabdominal measurement is performed.
- The measurement is transcribed onto the ultrasound form (there is no field in the ultrasound machine for uploading it directly).

4.2 Obtaining and Measuring the Doppler Signal

- Appropriate setting adjustment should be performed before obtaining the final trace. Please see "**Doppler Quality Criteria"** below.
- Umbilical Artery Doppler signal should be obtained from the sampling of a free loop of the umbilical cord.
- Ensure fetal quiescence i.e. absence of significant limbs/breathing movements.1
- Once 4 - 6 waves are obtained “Umbilical artery” should be selected.
- PI: Pulsatility index (PI), Resistance index (RI), Systolic / Diastolic ratio (S/D) should be measured via autotracing of three or more consecutive similar waveforms, from the beginning of the systolic to the end of the diastolic signal, selecting the “limited trace” or “automatic trace” options on the ultrasound machine.
- In case the signal is poor due to background noise and a clearer image trace cannot be obtained, a manual trace can be used for the indices calculations.
- The end diastolic flow (EDF) should be considered as present if no discontinuation between the end of the diastolic signal and the beginning of the following systolic signal is seen.
- Absent or reversed EDF should be reported in case of absence/reverse signal.

6. Quality Criteria for Doppler measurements

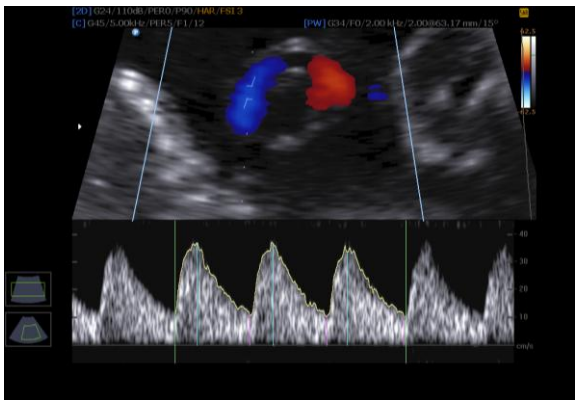
Doppler ultrasound require a careful technique so that reproducible measurements are taken.

The table highlights specific quality measures that should be undertaken:

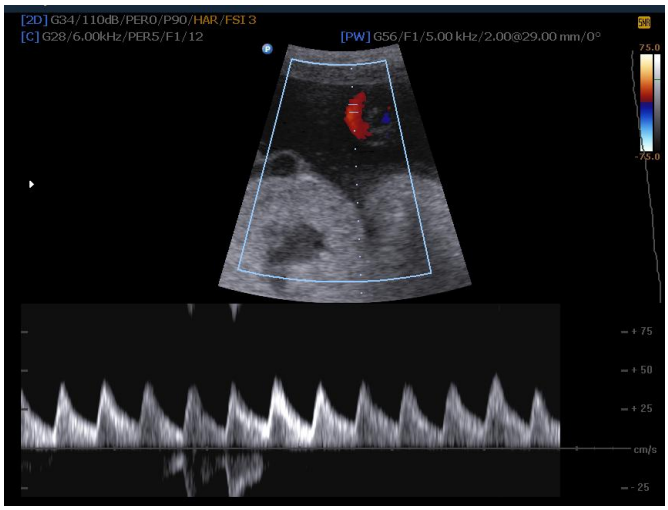
Doppler Quality Criteria to be used for both Uterine and Umbilical artery examination

Magnification	50% of the screen with zoom box and sample gate in the centre of the vessel
Angle of Insonation	less than 30%
Sweep speed	4 - 6 waveforms with consistent and similar signal
Clarity of the image	PRF and color gain correction (avoid venous signal)
Anatomic site of the Sample	Uterine artery: before the bifurcation above the Iliac vessels. Umbilical artery: free loop
Velocity Scale	75% of the peak systolic velocity

A clear umbilical artery Doppler signal

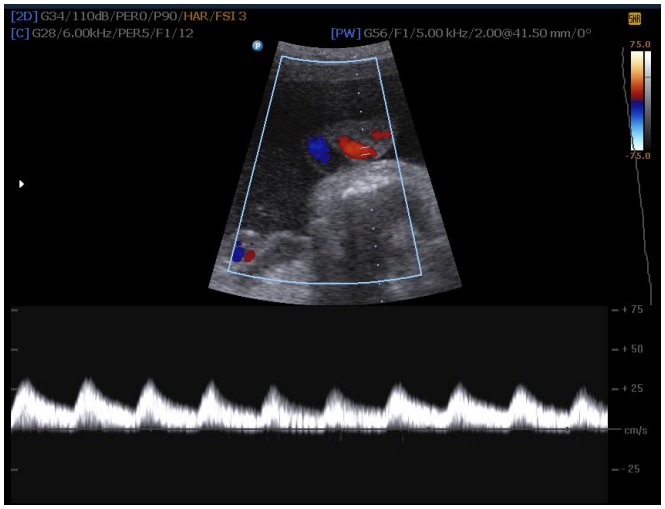


COMMON ERRORS



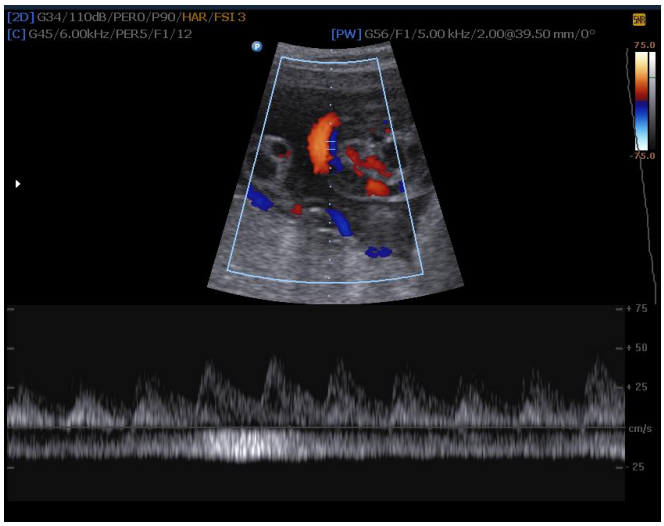
Low sweep speed results in many waveforms on the screen

In addition there is low pulsatility repetition frequency (PRF, other specified as “scale or “velocity” in different machines) scale



PRF less than 30% of the peak velocity

Poor angle - more than 30%



Gate not in the centre of the vessel, background noise of the umbilical vein