(11)

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[54] FETAL ANATOMIC SEX ASSIGNMENT BY ULTRASONOGRAPHY DURING EARLY PREGNANCY

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#### Related U.S. Application Data

[63] Continuation of Ser. No. 372.234, Jun. 26, 1989, abandoned, and a continuation of Ser. No. 282.824, Dec. 7, 1988, abandoned, which is a continuation of Ser. No. 65,128, Jun. 19, 1987, abandoned, which is a continuation of Ser. No. 914,568. Oct. 2, 1986, abandoned, which is a continuation of Ser. No. 525,781, Feb. 3, 1986, abandoned, which is a continuation of Ser. No. 662,877, Oct. 19, 1984, abandoned.

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1581	Field of Search	128/660.07-660.10.
11		1287881 01

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57) ABSTRACT

A method and apparatus are disclosed for fetal anatomic sex assignment by ultrasound during early pregnancy based on pattern recognition that allows identifiestion of external genitalia during the gestational age range of 12 to 14 weeks. The pattern recognition derives from knowledge of the embryology of the developing external genitalia of the fetus and the relationship between embryologic events and recognizing patterns specific for male and female obtained by ultrasonic imaging. Fetal anatomic sex has been accurately diagnosed using high resolution digital linear-array real-time ultrasound in over 500 pregnancies that were scheduled for ultrasound except for detected cases of sex reversal, sex chromosome mosaicism, prior to genetic amniocentesis, and ambiguous sex chromosomes, except as noted. ultrasonic imaging of the penils or clitoral structure corresponded to later sex determination by karyotype. Imaging of the external genitalia can be included as part of a complete fetal anatomic survey, which includes gestational age dating and inspection for gross abnormalities. Sex assignment requires 30 seconds to 10 minutes. Fetal anatomic sex assignment can be performed by ultrasound early in pregnancy, that is, during the twelfth to fourteenth weeks from the last menstrual period of the mother, yet the results are as accurate as those obtained by chromosome analysis from genetic amniocentesis which can be safely performed only after the sixteenth week of pregnancy. Fetal anatomic sex assignment is particularly useful in genetic counseling with regard to X-linked disorders and can be clinically important when either sex reversal, sex chromosome mosaicism, or ambiguous sex chromosomes are detected by prenatal diagnosis. Other features are also disclosed.

20 Claims, 4 Drawing Sheets

SCAN PLANES OF ORENTATION

