

# WHITE PAPER

# HeartAssist™: The Automatic Classification and Measurement Tool for Fetal Heart Assessment

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# **Abstract**

**Objectives:** The paper aims to evaluate the feasibility and reliability of HeartAssist<sup>™</sup>, which automatically provides complex fetal heart view image classifications and fetal heart structural measurements.

Methods: Expert examiners obtained 10 fetal heart view images and measured each parameter manually and using HeartAssist™. HeartAssist™ automatically classified the acquired fetal heart view images and measured the parameters. The acceptance rate of classification and the accuracy of annotation were evaluated. The automatic segmentation and measurement was also compared with that of manual measurement.

**Results:** Fetal heart view images from 4,000 fetuses were acquired and analyzed at Asan Medical Center. The range of gestational ages acquired was between 20 and 40 weeks. HeartAssist™ provided the following results; The acceptance rate of classification of the 10 fetal heart view images was 95.5%. The accuracy of annotation by ViewAssist™ was 100%. Dice similarity coefficient of 84.8% was sufficient for the measurement of the structures, and HeartAssist™ reduced the processing time by 87% compared to the manual process.

**Conclusion:** HeartAssist<sup>™</sup> provides automatic classification of fetal heart view images and measurement of fetal heart parameters, leading to the diagnosis of congenital heart disease (CHD) with a significant reduction in the processing time. HeartAssist<sup>™</sup> is expected to be of great assistance in the evaluation and detection of CHD.



# Introduction

Congenital heart disease (CHD) is the most common severe congenital abnormality, with an incidence of 8 to 9 per 1,000 live births<sup>(1)</sup>. CHD is a leading cause of infant morbidity and mortality. Accurate prenatal detection of CHD allows for improved neonatal outcome and better pregnancy counseling. Fetal echocardiography is the most crucial method of diagnosing CHD in the second-trimester of pregnancy. Fetal echocardiography should be performed on women with recognized increased risks for fetal cardiac anomalies<sup>(2)</sup>. One of the most crucial steps in the diagnosis of CHD is the accurate acquisition of fetal ultrasound standard planes. This assessment involves a sequential segmental analysis of four primary areas including the situs, atria, ventricles, great arteries and their connections. From these four areas, the examiner should evaluate ten fundamental scanning planes and Doppler findings for diagnostic information about the fetal heart<sup>(3)</sup>.

Although several guidelines discussed the parameters of the essential scanning planes and common indications, fetal echocardiography remains a challenging method, and the prenatal detection rate of CHD varies widely. Structural cardiac anomalies are among the abnormalities most frequently missed during pregnancy<sup>(4)</sup>. Several factors account for missing the abnormalities; 1) the fetal heart is small with indistinct anatomical structural appearance, 2) the fetus moves with relative movement of the probe, 3) fetal heartbeats are fast, 4) contrast artifacts such as shadowing, enhancement, speckle, and specular reflections make imaging difficult, 5) some examiners lack expertise in fetal echocardiography. These factors result in an extended time in the acquisition of clear images for consistency in viewing the plane and location of the heart. Thus, there has been much effort to improve the quality of the acquired images and to reduce the processing time.

HeartAssist™ automatically classifies 10 fetal heart view images from two-dimensional images and measures structures by segmenting them. HeartAssist™ is a state-of-the-art technology for detecting the fetal heart and classifying each frame as belonging to one of the standard viewing planes using the residual neural network (ResNet)-based model. It has the advantage of reducing the processing time as it is automatically implemented from classification to measurement.

The purpose of this study is to introduce HeartAssist<sup>™</sup> and to verify its reliability in providing automatic classification and measurements of fetal heart view images.





# **Materials and methods**

This study was a retrospective analysis using collected data of the normal fetuses at Asan Medical Center, Seoul, Korea. All prenatal sonographic evaluations were performed using an HeartAssist™ equipped WS80A and HERA W10 (Samsung Medison Co., Ltd, Seoul, Korea) with a transabdominal probe (Table 1).

**Table 1.** Environment for development and evaluation

Items	Contents
Institution name	Department of Obstetrics and Gynecology, Asan Medical Center, Seoul, Korea
Principal investigator	Hye-Sung Won M.D., Ph.D.
Sponsor organization	Samsung Medison Co., Ltd, Seoul, Korea
Target sample size	4,000 fetuses
Primary purpose	To verify the reliability of fetal heart evaluation using HeartAssist <sup>TM</sup>

For study inclusion, fetuses were:

- 1. from singleton pregnancies confirmed by prenatal ultrasonography,
- 2. required to undergo detailed high-resolution ultrasonography, including echocardiography by several specialists in maternal-fetal medicine, and
- 3. between 20 and 40 weeks gestational age (GA).

The recorded data included ten classified views: transverse abdominal view (TAV), four-chamber view (4CV), left ventricular outflow tract (LVOT) view, right ventricular outflow tract (RVOT) view, three-vessel view (3VV), three-vessel trachea (3VT) view, three-vessel view pulmonary artery (3VV) PA), aortic arch (AArch) view, ductal arch (DArch) view and bicaval view. Additionally, from the ten classified views, seven classified views were used to measure the 44 parameters and divided into three categories: 1) Measurement data points (34): cardiac axis, thoracic area, heart area, thoracic circumference (thoracic circ), heart circumference (heart circ), thoracic transverse diameter, heart transverse diameter, left atrium (LA) width, right atrium (RA) width, left ventricle (LV) width, right ventricle (RV) width, LV length, RV length, LA area, RA area, LV area, RV area, tricuspid valve (TV) annulus diameter, mitral valve (MV) annulus diameter, aortic valve (AV) annulus diameter, ascending aorta diameter (Asc. Ao diam), pulmonary valve (PV) annulus diameter, pulmonary artery diameter (PA diam), aorta diameter (Ao diam), superior vena cava diameter (SVC diam), thymus diameter (thymus diam), aortic isthmus diameter (Ao isthmus diam), ductus arteriosus diameter (DA diam), main pulmonary artery diameter (MPA diam), right pulmonary artery diameter (RPA diam), transverse aortic arch diameter, and descending aorta diameter (Desc. Ao diam), 2) Calculation data points (8): cardiothoracic area ratio (CTAR), cardiothoracic circumference ratio (CTCR), cardiothoracic ratio (CTR), left to right ventricular width ratio [LV/RV (W)], left to right ventricular length ratio [LV/RV (L)],

left to right ventricular area ratio [LV/RV (A)], aortic valve to aorta ratio (AV/Ao), aortic to pulmonary valve ratio (AV/PV), 3) Judgment data points (2): 3VV alignment and 3VT-V shape (Table 2).

HeartAssist<sup>™</sup> also included Z-scores as a qualitative measurement method. The Z-scores were expressed as a multiple of the standard deviation. The measurement deviates from the mean, allowing the comparison of cardiac sizes' growth. Among the 44 parameters, 14 parameters were calculated by Z-scores: Ao isthmus diam in 3VT view<sup>(5)</sup>, DA diam in 3VT view<sup>(5)</sup>, heart transverse diameter (width), heart circumference (heart circ), and heart area<sup>(6)</sup>, CTR<sup>(7)</sup>, LA width<sup>(8)</sup>, RA width<sup>(8)</sup>, LV width<sup>(8)</sup>, RV width<sup>(8)</sup>, LV/RV (W)<sup>(8)</sup>, AV annulus diameter<sup>(8)</sup>, PV annulus diameter<sup>(8)</sup>, and AV/PV<sup>(8)</sup>.

**Table 2.** The list of 10 classified views; 7 views for the 44 parameters and annotations, 3 views for annotation only.

View	Parameter	View	Parameter	
	Cardiac axis		AV annulus diameter	
	Thoracic area	LVOT view	Asc.Ao diam	
	Heart area		AV/Ao	
	CTAR	PVOT view	PV annulus diameter	
	Thoracic circ	ICVOT VIEW	AV/PV	
	Heart circ		3VV alignment	
	CTCR		PA diam	
	Thoracic transverse diameter	3VV	Ao diam	
	Heart transverse diameter		SVC diam	
	CTR		Thymus diam	
	LA width		3VT-V shape	
	RA width	3VT view	Ao isthmus diam	
4CV	LV width		DA diam	
	RV width	3\/\/ DΛ	MPA diam	
	LV/RV (W)	JVVPA	RPA diam	
	LV length		Asc.Ao diam AV/Ao  PV annulus diameter AV/PV  3VV alignment PA diam SVC diam Thymus diam 3VT-V shape Ao isthmus diam DA diam RPA diam Arch view Ao isthmus diam Transverse aortic arch diameter Ao isthmus diam Desc.Ao diam Arch view Only annotation Only annotation AV Only annotation Only annotation	
	RV length	A Arch view	Transverse aortic arch diameter	
	LV/RV (L)	RVOT view  AV/PV  3VV alignment PA diam SVC diam Thymus diam 3VT-V shape Ao isthmus diam DA diam  RPA diam  ASC.Ao diam Transverse aortic arch diameter Ao isthmus diam Desc.Ao diam Darch view DArch view DArch view DArch view Only annotation Only annotation		
	LA area		Desc.Ao diam	
	RA area	DArch view	Only annotation	
	LV area	Bicaval view	Only annotation	
	LA area RA area	TAV	Only annotation	
	LV/RV (A)	1		
	TV annulus diameter			
	MV annulus diameter			

Please refer to the "materials and methods" text for abbreviations.

HeartAssist™ was trained by deep learning algorithms and designed to have the ability to classify, annotate, segment, measure and calculate from the acquired fetal heart images. The ResNet-based model was based on deep learning algorithms to classify and annotate. The dice similarity coefficient (DSC) was the statistical method of segmentation to measure, calculate, and evaluate. The DSC was calculated as 2 x area of overlapped area between predicted area and ground truth area / total area (predicted area + ground truth area)<sup>(9, 10)</sup>. The measurement parameters included diameter, area, circumference and Z-scores according to each parameter' reference. The sequence of processes implemented by HeartAssist™ was the same as that of the specialist as follows. The total processing time was defined from when the examiner pressed the freeze button until when the annotation or measurement was completed. On the other hand, when using the automation process, the total processing time was defined from when the image was loaded for measurement until when the annotation or measurement was finished.

When the described process results were presented, the analyst focused on classification and measurement and also conducted verification. The first verification method was interpreted as 'success' if the fetal heart images classified by HeartAssist<sup>TM</sup> matched the expert's results, or 'failure' if they didn't match the expert's results. The second verification method measured the consistency between the area of the fetal heart structures segmented manually by an expert and automatically by HeartAssist<sup>TM</sup>.

# **Results**

The ResNet-based model was trained on about 20,000 randomly sampled frames (10 views and 44 parameters) and tested on 10% of total images from 4,000 fetuses. HeartAssist™ has successfully achieved a series of processes to classify the acquired images and measure each structure's parameters.



### **Automatic classification**

Acquired fetal heart images were classified by HeartAssist™ automatically. The automatic classified fetal heart images matched the expert's classified answers by 95.5% on average. Table 3 shows the acceptance rate. In the case of RVOT view, 3VV, 3VT view, and 3VV PA, the acceptance rate was calculated with redundant answers, as it tends to be observed with similar images depending on the expert's handling.

Table 3. The results of the acceptance rate

	TAV	4CV	LVOT view	RVOT view	3VV	3VT view	3VV PA	AArch view	DArch view	Bicaval view
Acceptance rate (%)	95.5	93.0	97.1	100.0	100.0	99.0	100.0	90.5	90.2	91.2

Please refer to the "materials and methods" text for abbreviations.

# **Automatic annotation**

(\* Automatic annotation is activated when the ViewAssist™ option is available on the system)

According to clinical standards, when the ViewAssist<sup>™</sup> option is available on the ultrasound system, for each frame, HeartAssist<sup>™</sup> automatically annotated the anatomy in the center of the structures and also added a label indicating its view from the list of 10 views. Experts validated these annotations. All labels are correctly annotated (Figure 1).

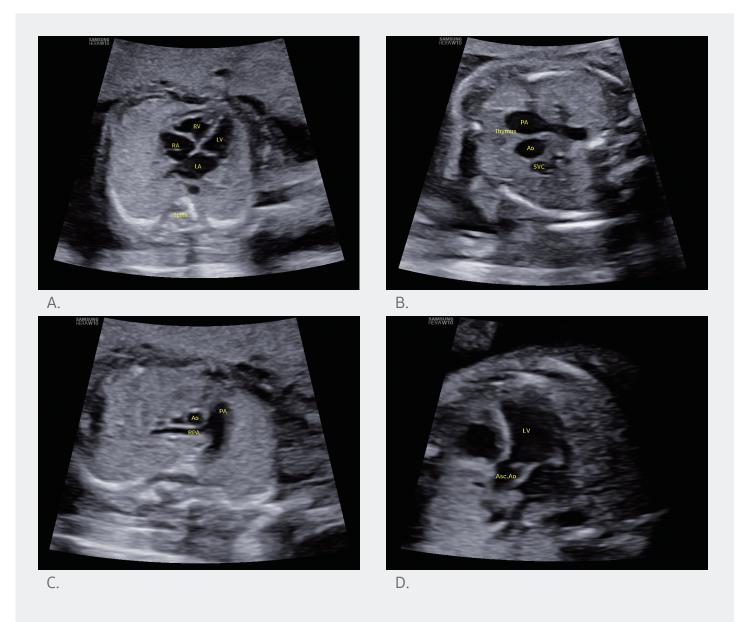


Figure 1. The results of automatic annotation using ViewAssist™. A. four-chamber view (4CV); B. three-vessel view (3VV); C. three-vessel view pulmonary artery (3VV PA); D. left ventricular outflow tract (LVOT) view. RV, right ventricle; LV, left ventricle; RA, right atrium; LA, left atrium; PA, pulmonary artery; Ao, aorta; SVC, superior vena cava; RPA, right pulmonary artery; Asc.Ao, ascending aorta.

# **Automatic segmentation and measurement**

The automatic segmentations by HeartAssist<sup>™</sup> consistently generated cross-sectional regions similar to that of manual raters (Figure 2). The DSC averaged 84.8% when the automatic segmentation of fetal heart structures was compared to the expert's measurements (Table 4).

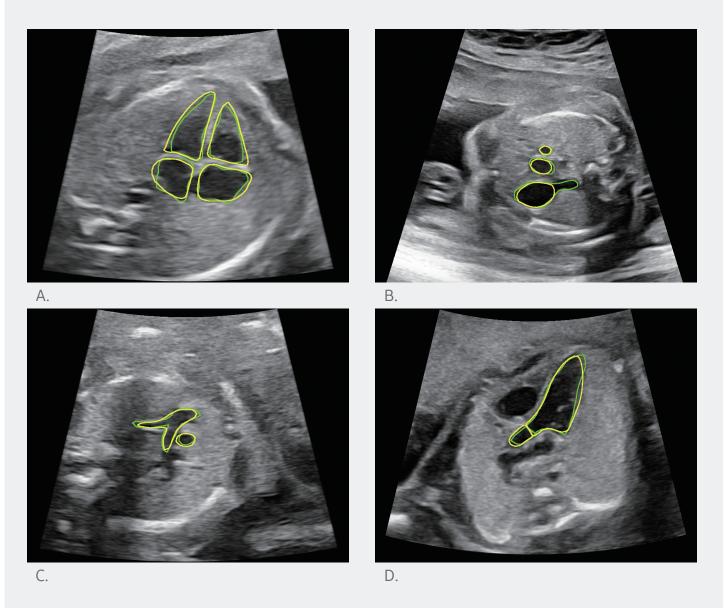


Figure 2. The results of automatic segmentation. A. four-chamber view (4CV); B. three-vessel view (3VV); C. three-vessel view pulmonary artery (3VV PA); D. left ventricular outflow tract (LVOT) view. The manual segmentation was indicated with green lines. HeartAssist™ segmentation was indicated with yellow lines.

Table 4. The results of automatic segmentation using dice similarity coefficient

	TAV	4CV	LVOT view	RVOT view	3VV	3VT view	3VV PA	AArch view	DArch view	Bicaval view
DSC (%)	94.5	90.5	85.8	83.6	81.6	85.3	82.9	79.3	82.8	82.1

DSC, dice similarity coefficient

The Z-scores graph helps interpret the results (Figure 3). The Z-scores of HeartAssist™ helps quantify the growth of cardiac structures compared to overall fetal development. The previous studies of normal fetal cardiac dimensions have allowed quantitative assessment of fetal cardiac growth using centiles of the GA. However, the Z-scores are an alternative method to centiles for evaluating cardiac structures because it is more related to fetal growth than to the GA<sup>(5, 6, 11-13)</sup>.

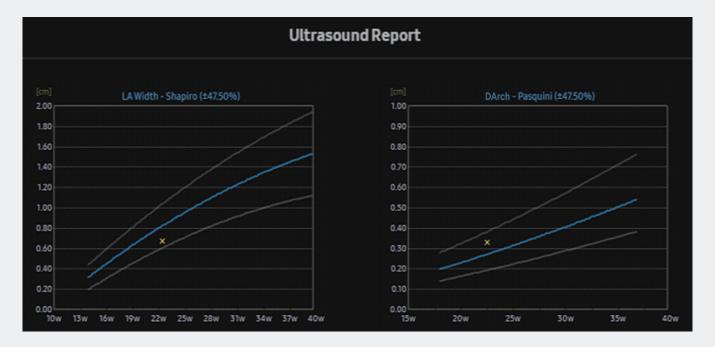


Figure 3. The graph with the yellow mark (x) of the measured values using the Z-scores. The grey lines indicate ±2 standard deviations (SD). The blue line displays the mean. LA, left atrium; DArch, ductal arch.

# The comparing of processing time between manual and automatic measurement

The automatic annotation and measurement saved an average of 87% of the processing time over manual measurement. For example, the manual annotation time of the TAV was 7,060 milliseconds (ms). On the other hand, the automatic annotation time of HeartAssist™ was only 842 ms.

### The difficult cases

Occasionally, the results of using HeartAssist<sup>TM</sup> with uncertain images were interpreted into two separate categories. The first category was that HeartAssist<sup>TM</sup>'s results were considered acceptable similar to that of expert when classifying RVOT view, 3VV, 3VT view, and 3VV PA. As previously mentioned, those views had only minimal differences (Figure 4). The second category was that HeartAssist<sup>TM</sup> could classify even a problematic image correctly as the result of deep learning (Figure 5).





В.

Figure 4. A is an uncertain image. HeartAssist<sup>™</sup> can classify this image into the right ventricular outflow tract (RVOT) view with 25% possibility (B). According to the expert's point of view, this image can be classified as the RVOT view or the three-vessel tracheal (3VT) view. RV, right ventricle; PA, pulmonary artery.





B.

Figure 5. Application of HeartAssist™ in uncertain images (A and B). DArch, ductal arch.

# **Discussion**

HeartAssist™ is a novel program developed to reduce the processing time of fetal echocardiography. Additionally, it helps examiners diagnose CHD with high accuracy by classifying fetal heart view images and measuring parameters of the fetal heart structures. The importance of fetal echocardiography in the detection and diagnosis of CHD was key to the development of HeartAssist™.

Fetal echocardiography can be performed at any time during the second trimester when cardiac anatomical details can be adequately visualized. According to the International Society of Ultrasound in Obstetrics and Gynecology (ISUOG) published practice guidelines, analyzing a 4CV of the fetal heart and examining the size and relationships of both arterial outflow tracts should be performed even in fetuses at low-risk for cardiac anomalies<sup>(2)</sup>.

Prenatal echocardiography plays a vital role in diagnosing CHD as it allows for better neonatal outcomes. It also calls for an increasingly complex examination by examiners. Thus, 10 grayscale images, eight color Doppler ultrasounds, five pulse-Doppler ultrasounds, heart rate and rhythm assessment, and nine cardiac biometrics are recommended to diagnose CHD according to the American Institute of Ultrasound in Medicine (AIUM)<sup>(3)</sup>.

It is important to note that many examiners are busy and fatigued in their daily practice and may produce inconsistent results due to the number of parameters that need to be measured. Therefore, a consistent automation system was developed to resolve these problems. Computer-aided analysis of the fetal heart may assist the examiners in identifying CHD. Detecting the fetal heart's location and viewing the planes for classification are critical steps where automation would be of great assistance. HeartAssist™ compensates the limitations of manual examination by providing several key advantages. It provides automatic classification and measurement for 10 fetal heart views obtained from fetal echocardiography. It also enables a shorter processing time compared to manual processing. These capabilities allowed enhanced performance, better validation, and faster operation without the in-examiner variability experienced when performing manual examinations.

# Conclusion

In conclusion, HeartAssist™ is best used as a tool to facilitate the analysis of the fetal heart. This program is recommended for use to overcome limitations of manual examination arising from inter-examiner variability and for examiners who lack expertise in fetal heart ultrasonography and are unable to easily obtain measurement data in their practice. Finally, the examiner will achieve consistent results using HeartAssist™, which may be contributing to the increase in detection rate of CHD, ultimately leading to improved perinatal outcomes.

\* Remark: ViewAssist<sup>TM</sup> & HeartAssist<sup>TM</sup> are two separate optional features.



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