

Obtaining accurate peri-procedure measurements of the TV annulus

AI-powered 3D Auto Tricuspid Valve Quantification (3D Auto TV)

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Overview

The semiautomated 3D Tricuspid Valve quantification tool (3D Auto TV) provides 14 automated 3D measurements of the complex tricuspid valve annulus (TA) anatomy in a complete heart cycle.

Background

Tricuspid regurgitation (TR) represents a distinctive entity with clear adverse prognostic implications, which are independent of left ventricular function and pulmonary hypertension.^{1,2} Due to increased mortality from isolated tricuspid valve (TV) surgery,³ the number of transcatheter TV interventions is rapidly expanding, with new percutaneous devices emerging. This growth of transcatheter TV interventions demands precise assessment of the complex anatomy and function of the TV.

Functional TR is the primary cause of TV insufficiency, marked by changes in the geometry and dynamics of the tricuspid annulus. In addition, TA dilation impacts clinical outcomes in both severe and moderate TR cases and can complicate interventional procedures.^{4,5}

Current guidelines recommend measuring the TA diameter in the 2D apical four-chamber view at end-diastole.⁶ Tricuspid annular measurements are underestimated by 2D echocardiography compared with 3D measurements, raising concerns regarding the need to potentially reassess the cutoff values for surgical intervention, which are currently based on 2D evaluation of the tricuspid annulus.^{7,8} Using 3D methods considers all three dimensions, which allows capture of the complex saddle shape of the TV annulus.

The Philips 3D Auto TV software was developed to support accurate clinical evaluation of the tricuspid valve annulus in 3D and provide users with fast and reproducible results.*

*Clinical Validation Study and Internal documentation D001636834

Workflow

The 3D Auto TV application workflow follows the chart depicted in Figure 1.

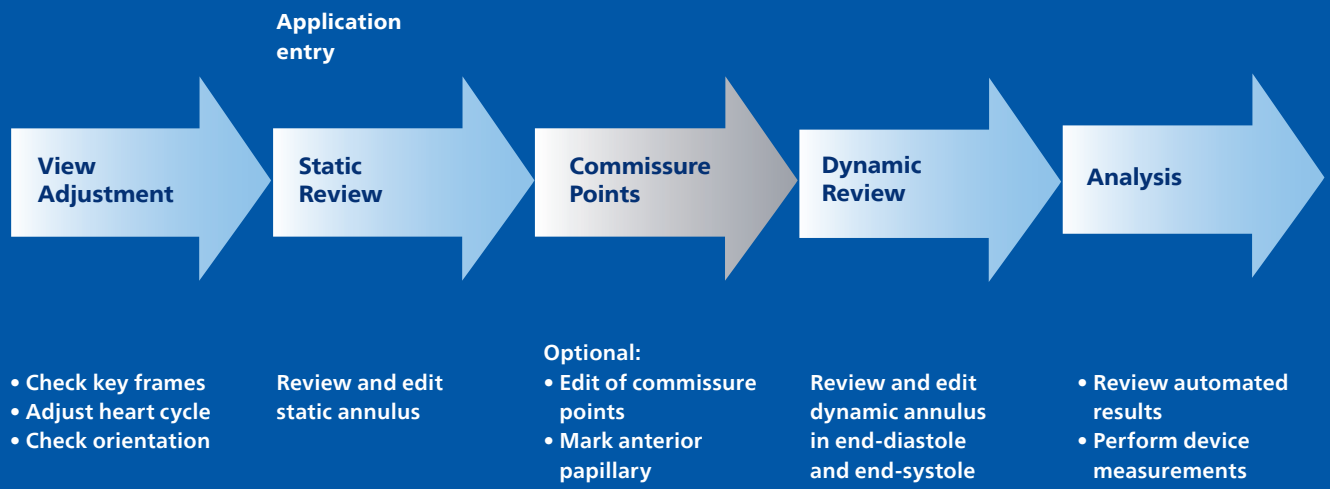


Figure 1 Flow chart demonstrating 3D Auto TV application workflow and functional steps.

| Abbreviation | Term |
|--------------|------------------------------------|
| AP | Anterior-posterior |
| AS | Anterior-septal |
| AV | Aortic valve |
| BSA | Body-surface area |
| CS | Coronary sinus |
| ED | End-diastole |
| ES | End-systole |
| ICC | Intraclass correlation coefficient |
| LAX | Long axis |
| LOI | Lines of intersection |
| MPR | Multi-planar reconstruction |
| RA | Right atrium |
| RV | Right ventricle |
| SL | Septal-lateral |
| SP | Septal-posterior |
| TR | Tricuspid regurgitation |
| TA | Tricuspid valve annulus |
| TEE | Transesophageal echocardiography |
| TEER | Transcatheter edge-to-edge repair |
| TTE | Transthoracic echocardiography |
| TTVR | Transcatheter valve replacement |
| TV | Tricuspid valve |
| VR | Volume rendering |

The software performs a semiautomated segmentation of the tricuspid annulus in a mid-systolic reference frame.

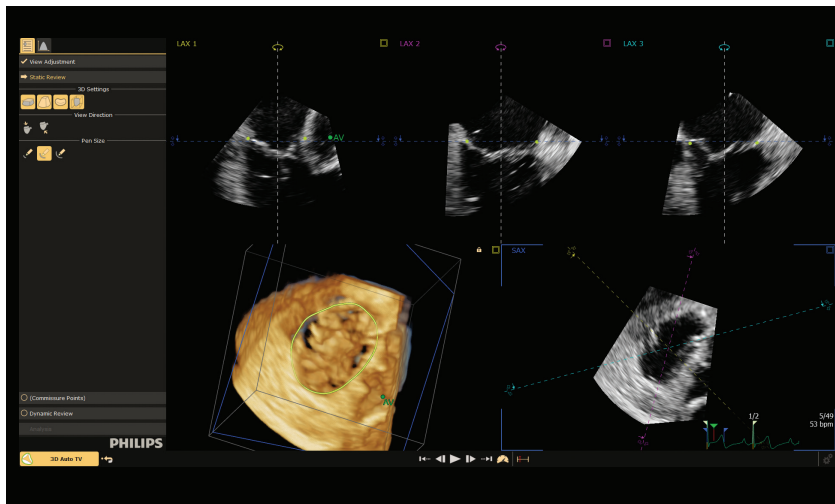


Figure 2 “Static Review” workflow step.

The “Static Review” workflow step is the default entry point for the user. Here, the user can review and edit the tricuspid annulus 360° in the mid-systolic reference frame.

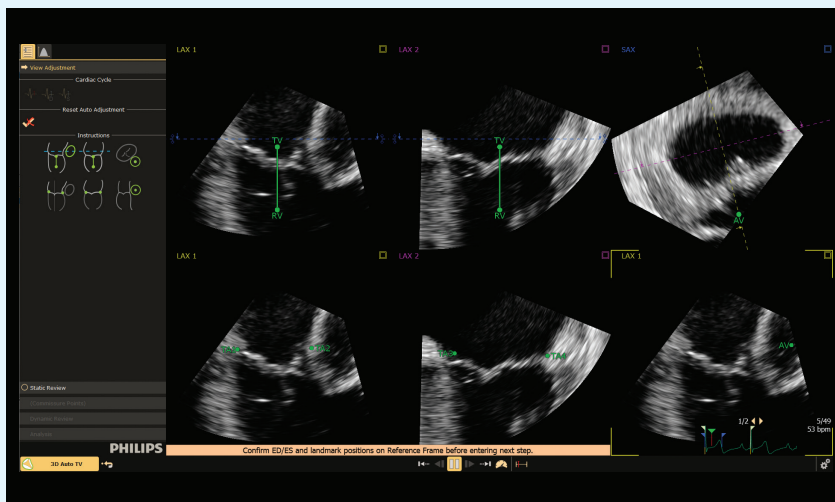


Figure 3 “View Adjustment” workflow step.

In most cases, the Philips HeartModel* algorithm identifies the tricuspid annulus automatically. Nevertheless, the “View Adjustment” workflow step gives the user the opportunity to manually adjust ED, ES and reference frame, to change the heart cycle and orientation, as well as initialize the annulus to support the algorithm in cases where the automation was insufficient.

*<https://www.usa.philips.com/healthcare/resources/feature-detail/ultrasound-heartmodel>

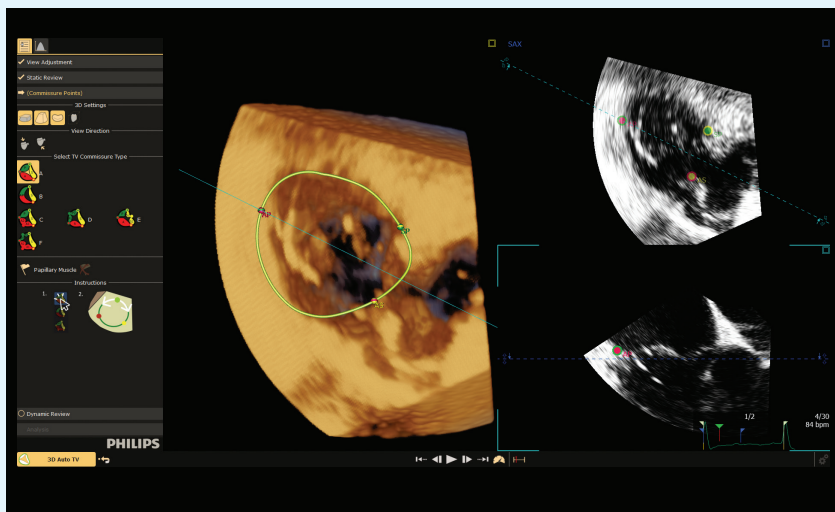


Figure 4 “Commissure Points” workflow step.

The optional “Commissure Points” workflow step allows the user to choose a TV leaflet morphology model, edit the commissure point landmarks and mark the anterior papillary muscle based on standard echocardiographic tricuspid valve nomenclature.⁹ The standardized nomenclature potentially simplifies the communication in the interventional team before and during TV transcatheter edge-to-edge repair procedures (TEER).

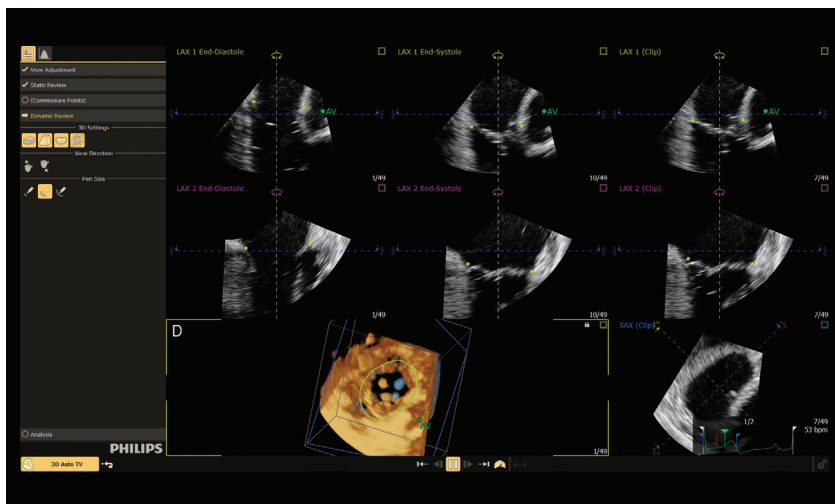


Figure 5 “Dynamic Review” workflow step.

After entering the “Dynamic Review” workflow step, the annulus is dynamically tracked over the complete heart cycle end-diastole to end-diastole (ED-ED). In the ED and ES frames, 360° review and editing can be performed by the user. These frames are most important because the automated annulus measurements will be computed on the respective TV segmentations in the ED and ES frames.



Figure 6 “Analysis” workflow step.

The “Analysis” workflow step provides annulus-characteristic measurements calculated based on the dynamic tricuspid annulus in ED and ES under the category “Annulus.” Additionally, it is possible to perform manual device-specific measurements, useful for valve replacement and annuloplasty under the category “Device,” as well as manual free-form measurements under the category “General.”

Measurements

Annulus – Tricuspid valve annular measurements

In the “Analysis” workflow step, the following measurements are derived automatically from the segmented tricuspid annulus.

| Measurement label | ED/ES | Description |
|-------------------------------|-------|---|
| TV ann perimeter (3D) | ED/ES | Circumference of the annulus, with elevation |
| TV ann perimeter (2D) | ED/ES | Circumference of the projected 3D perimeter on the annular best fit plane, without elevation |
| TV ann max diam | ED/ES | Absolute maximum diameter through center of the projected perimeter |
| TV ann min diam | ED/ES | Absolute minimum diameter through center of the projected perimeter |
| TV ann perimeter derived diam | ED/ES | Projected perimeter-derived diameter |
| TV ann height | ED/ES | Height of the annulus perpendicular to the annular best fit plane – distance between the highest and lowest elevation |
| TV ann area (2D) | ED/ES | Area inside the projected perimeter |

Device measurements

3D Auto TV allows the user to perform manual, predefined measurements intended for device sizing and preprocedural reassessment. These measurements are dedicated to transcatheter valve replacement (TTVR) and annuloplasty repair of the valve. They can facilitate procedure planning and preprocedural reassessment of the percutaneous device size.

Edwards Lifesciences Corporation uses these measurements as part of its sizing protocol for the EVOQUE Tricuspid Valve Replacement System* and the Cardioband* Annuloplasty Repair System.¹⁰ The measurements are activated by groups and are then adjusted manually.

| Measurement label | ED/ES | Description |
|--|-------|---|
| Group AP/SL diameter | | |
| TV ann AP diam (2D) | ED/ES | Anterior-posterior annulus diameter through center in the projected perimeter |
| TV ann SL diam (2D) | ED/ES | Septal-lateral annulus diameter through center in the projected perimeter |
| Group subvalvular plane 5 mm distance in the RV | | |
| Subvalvular 5 plane SL diam | ED/ES | Subvalvular parallel plane in RV direction with 5 mm distance from annulus plane – septal-lateral diameter, through projected center of the original annulus |
| Subvalvular 5 plane AP diam | ED/ES | Subvalvular parallel plane in RV direction with 5 mm distance from annulus plane – anterior-posterior diameter, through projected center of the original annulus |
| Group supralvalvular measurements in the RA | | |
| Supralvalvular C-shaped perimeter | ED | Supralvalvular measurement above the TA along the RA wall offset at 4 mm – C-shaped partial perimeter (excluding septal annulus) to be set at 45° angle parallel to 3D annulus segmentation; first aortic valve (AV) to last coronary sinus (CS) anchor points of the annuloplasty ring |
| Supralvalvular AV – AoCenter diam | ED | Supralvalvular measurement in RA direction – distance between center of the aorta (AoCenter) to the first AV anchor point |

General – Manual measurements

Additionally, the user can perform manual, free-form measurements (e.g., distance, spline, angle, area).

Measurements for valve replacement

Some replacement valves, like the EVOQUE system, rely both on leaflet capture and annular oversizing for adequate fixation.¹¹ These measurements are needed to initially size and reconfirm preprocedurally:

1. TV ann perimeter derived diameter (2D) ED determines the device size. This measurement is derived automatically from the annulus segmentation. The measurement has been validated against CT data in an internal study with n=82 subjects and shows a small relative bias of -1.5% between 3D Auto TV and CT for excellent comparability between modalities (Internal documentation D001815314).

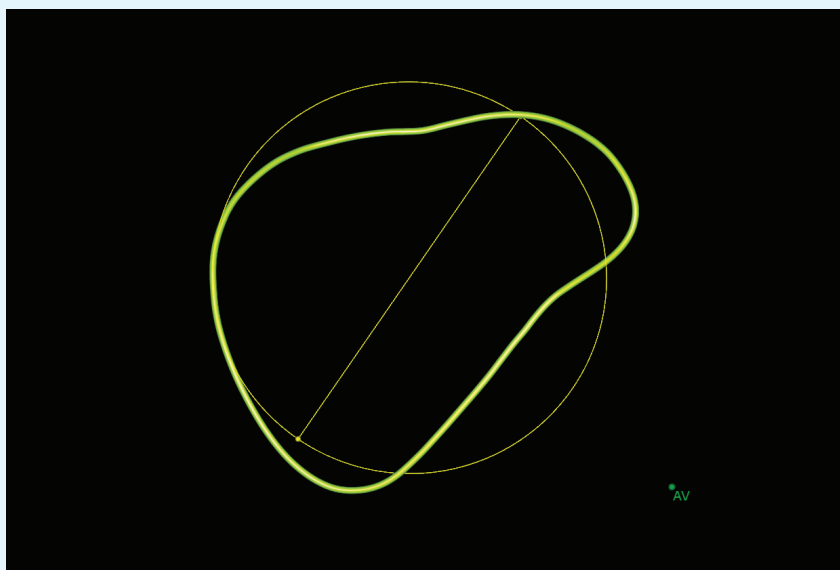


Figure 7 Perimeter derived diameter 2D.

The following measurements also assess the device fit:

2. TV ann AP/SL

Enables the user to define AP-SL diameters in the projected TV annulus to examine at least four anchors for leaflet capture. The septal point “S” is adjusted either in the short axis MPR or the 3D view (VR) to define the septal-lateral dimension through the center of the TV annulus. The anterior-posterior diameter is measured automatically as 90° perpendicular to the septal-lateral diameter through the TV center. The direction is kept for both ED and ES.

3. Subvalvular AP/SL

Enables the user to define the AP-SL diameters in a plane inside the RV parallel to the TV annulus plane at an offset distance of 5 mm below the annulus plane. The TV ann AP/SL measurement direction is projected onto the 5 mm distance plane and then manually adjusted to fit the RV wall. These measurements allow the user to assess the oversizing capacity of a valve replacement for a potentially better fit of the device through additional force/pressure on the valve annulus.

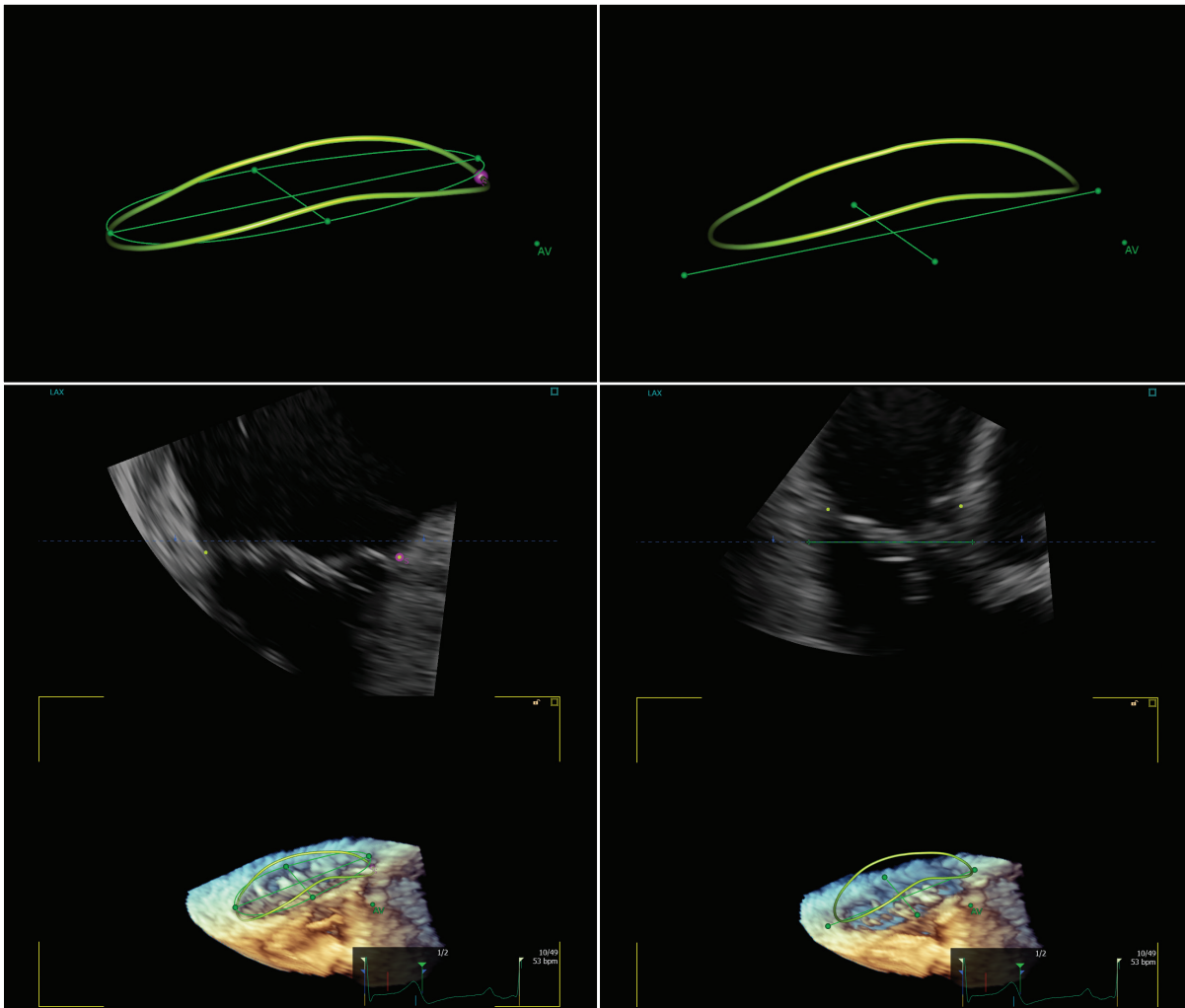


Figure 8 TV annulus and AP/SL measurements (left), TV annulus and subvalvular AP/SL measurements (right).

Measurements for annuloplasty

The annuloplasty device, such as Cardioband, is implanted with 4 mm from the TA hinge at an approximate 45° angle along the right atrial wall.

The supra-annular measurements enable the user to define the location of the annuloplasty device and measure its size. An initial suggestion for the device placement is presented and needs to be adjusted manually by the user.

1. Start with defining the exact location of the AV and CS anchor points in the 3D view (VR). Select and edit the anchor point position through click, drag and release.
2. Review the MPR views 360°, and adjust the exact location of the intended annuloplasty band placement. The controller is fixed with a distance of 4 mm from the annulus. Its angle can be adjusted through click, drag and release.

Resulting measurements:

1. **Supravalvular C-shaped perimeter:** a curve measurement defining the length of the annuloplasty device.
2. **Supravalvular AV - AoCenter:** the distance from the center of the aortic valve to the AV-anchor.

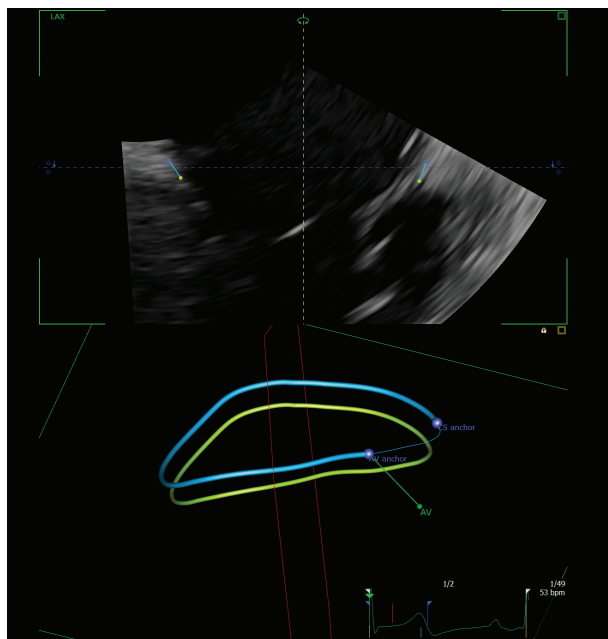


Figure 9 Supravalvular C-shaped perimeter and supravalvular AV – AoCenter.

Algorithm

The 3D Auto TV application uses two automation technologies: Philips HeartModel and dynamic speckle tracking. Our goal is to support the user by providing high quality automation, but leave the final say to the clinician.

Philips HeartModel

The Philips HeartModel is a model-based AI segmentation algorithm which provides anatomical context to the 3D ultrasound images of the heart. This means that position, orientation, size and shape of the heart (with a focus on tricuspid valve and surroundings) are determined in the image. For the 3D Auto TV application, the structure of highest importance is a segmentation of the tricuspid annulus.

Speckle tracking

Once the tricuspid annulus is detected and approved by the user in a reference frame, speckle tracking is used to track the tricuspid annulus through the complete heart cycle.

Validation

The 3D Auto TV software was developed to support accurate clinical evaluation of the tricuspid valve annulus and provide users with reproducible results for their consideration to assist them in validating their clinical evaluation. Reproducibility is measured as agreement between reviewers in a clinical performance validation study. In addition, agreement with previously validated tools is analyzed to ensure high performance of the new tool.

As a validated tool for the study, 4D CARDIO-VIEW was selected. 4D CARDIO-VIEW is a commercially available and FDA-cleared (K213544, initially introduced in K022824) software developed by Philips TOMTEC, which allows the simultaneous assessment and alignment of the TA in different imaging planes.

Validation study

A study was conducted to evaluate the algorithmic performance of the 3D Auto TV software, where transesophageal echocardiography (TEE) cardiac clips from 97 subjects and transthoracic echocardiography (TTE) cardiac clips from 100 subjects were used for TV annulus measurements by three clinical experts (reviewers). The reviewers used 3D Auto TV software for the measurements and the results were compared to the results of manual measurements by the same reviewers. The manual measurements, which were performed within the 4D CARDIO-VIEW application, were used as a ground truth for the study. Subjects, whose clips contributed to the study, represented a broad range of demographics, body habitus and severity of tricuspid regurgitation and thus were representative of the intended population.

Automation performance

A relative Bland-Altman analysis was performed to assess the agreement of size and shape measurements for tricuspid valve annulus between manual outputs from 4D CARDIO-VIEW (ground truth) and 3D Auto TV outputs obtained from three reviewers. Size and shape measurements for the primary endpoint included 2D perimeter in ES and ED and diameter parameters (MAX and MIN) in ES and ED output from two measurement methods. The primary endpoint was assessed separately for TTE and TEE arms of the validation study. Ground truth and 3D Auto TV measurements were provided by three reviewers and averaged for relative agreement assessment.

The results demonstrated high relative agreement of the 3D Auto TV software with the 4D CARDIO-VIEW software (ground truth) by producing 95% confidence intervals for the limits of agreement of less than $\pm 22\%$ for annulus size and annulus shape, respectively, within TEE and TTE arms.¹²

| 3D Auto TV vs. 4D Cardio-View | TEE subjects | | | TTE subjects | | |
|----------------------------------|---|----------------------------|-------------------------|---|----------------------------|-------------------------|
| | Mean difference (95% LCI, UCI) ± SD (n) | Lower LoA (95% CI) | Upper LoA (95% CI) | Mean difference (95% LCI, UCI) ± SD (n) | Lower LoA (95% CI) | Upper LoA (95% CI) |
| Annulus size | | | | | | |
| 2D perimeter in ED (%) | 3.75 (2.75,4.75) +/- 4.96 (97) | -5.97 (-7.64, -4.81) | 13.47 (12.31, 15.14) | -0.78 (-2.35,0.78) +/- 7.90 (100) | -16.26 (-18.86, -14.43) | 14.69 (12.86, 17.29) |
| 2D perimeter in ES (%) | 0.15 (-0.95,1.25) +/- 5.47 (97) | -10.57 (-12.40, -9.29) | 10.86 (9.58, 12.70) | 0.45 (-1.18,2.09) +/- 8.24 (100) | -15.70 (-18.42, -13.79) | 16.61 (14.70, 19.33) |
| Annulus shape | | | | | | |
| Max ED diameter (%) | 1.69 (0.49,2.89) +/- 5.95 (97) | -9.97 (-11.97, -8.58) | 13.36 (11.96, 15.36) | -1.13 (-2.93,0.67) +/- 9.09 (100) | -18.95 (-21.94, -16.84) | 16.69 (14.58, 19.68) |
| Min ED diameter (%) | 7.05 (5.79,8.31) +/- 6.26 (97) | -5.22 (-7.32, -3.75) | 19.31 (17.85, 21.41) | 0.68 (-0.95,2.30) +/- 8.21 (100) | -15.41 (-18.12, -13.51) | 16.76 (14.86, 19.47) |
| Max ES diameter (%) | -0.60 (-1.95,0.74) +/- 6.66 (97) | -13.66 (-15.90, -12.10) | 12.46 (10.89, 14.69) | 0.56 (-1.23,2.35) +/- 9.03 (100) | -17.13 (-20.11, -15.04) | 18.26 (16.16, 21.23) |
| Min ES diameter (%) | 1.38 (-0.02,2.77) +/- 6.91 (97) | -12.17 (-14.49, -10.55) | 14.92 (13.30, 17.25) | 0.67 (-1.05,2.40) +/- 8.69 (100) | -16.36 (-19.22, -14.34) | 17.70 (15.69, 20.57) |

Reproducibility study

The intraclass correlation (ICC) for interobserver reliability was assessed across the three reviewers for the semiautomated 3D Auto TV method and separately for the manual 4D CARDIO-VIEW method. The ICC was determined using a two way-mixed effect model (the clip is considered as a random effect and the readers are considered as a fixed effect).

Notably, the agreement was higher in the semiautomated 3D Auto TV measurements compared to the manual 4D Cardio-View measurements in both study arms (TTE & TEE). Excellent agreement between reviewers, for reproducibility, was reported for semiautomated annulus measurements with interobserver reliability ranging from 0.926 (95%CI 0.906, 0.942) to 0.956 (95%CI 0.944, 0.966) in the TEE arm and from 0.936 (95%CI 0.919, 0.950) to 0.955 (95%CI 0.942, 0.964) in the TTE arm, respectively. ICC values greater than 0.9 indicate excellent reliability.^{12,13}

Time savings

With the 3D Auto TV software, a significant reduction in time compared to the manual measurements was found. Experts report it takes them about 30 minutes per patient to complete the necessary measurements for peri- and pre-procedural assessment with a full measurement protocol. The average time to complete a full protocol of TV measurements, including annulus and device measurements, with 3D Auto TV is less than 4 minutes. 85% of the cases could be completed below 5 minutes, leading to an estimated time reduction over 80% for a majority of the cases (Internal documentation D001636834).

80%

estimated time reduction for a majority of cases

Normal values

3D Auto TV was used to measure normal values of the tricuspid valve annulus stratified by sex and age as part of the World Alliance Society of Echocardiography (WASE) study¹⁴ with n=789 subjects.¹² The results show that in general, men had slightly larger non-indexed TA measurements. However, indexing by body-surface area (BSA) showed larger TA diameters and perimeters in women because men had larger BSA. Additionally, most TA measurements were larger in the younger age group and decreased progressively with age.

In general, the dynamic analysis revealed that TA parameters change during the cardiac cycle, with their lowest values at ES and their highest in late diastole, not at the specific ED frame across sexes and age groups.

Conclusion

Philips 3D Auto TV is a tricuspid valve annulus quantification tool with 14 automated 3D annulus measurements and 10 dedicated measurements for percutaneous device procedure planning and size reconfirmation. The measurements are offered in a complete heart cycle ED to ED. Measuring the size and shape of the annulus is fast and excellently reproducible, as shown in the clinical validation study.

FAQs

On which frames in the heart cycle does 3D Auto TV perform the measurements?

The automated annulus measurements are calculated on all frames of the complete heart cycle and shown in the curve display. All measurements are reported either for ED/ES or only in ED in case of the supraavalvular measurements.

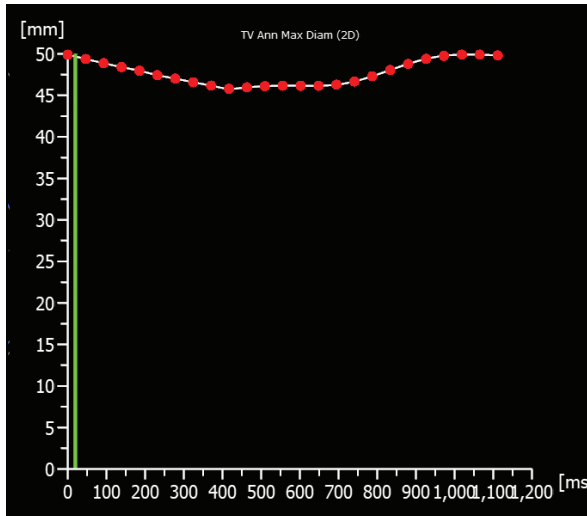


Figure 10 Curve display in analysis.

Which images does the 3D Auto TV application support?

The application supports 3D TEE and 3D TTE echocardiogram clips. 3D color and 3D contrast data are not supported.

What is a good acquisition for 3D Auto TV analysis?

The performance of the automatization depends on the quality of the image data that you intend to analyze. The following tips can improve the success of your quantification results:

- Ensure that the tricuspid valve is in the sector during the entire cardiac cycle.
- Ensure that at least part of the aortic valve is in the sector so the system can use it to initiate the automatic segmentation.
- Ensure the frame rate is ≥ 10 Hz and use multibeam acquisition if needed.
- Ensure the cardiac cycle has a minimum of 10 frames per cycle.
- Ensure the ECG provides a complete cardiac cycle and R-wave clearly. The recommendation is to acquire three heart beats.
- For transesophageal echocardiography (TEE), the automatization supports mid and deep esophageal views only; the automatization will not work for transgastric views or zoomed TTE views; the user needs to initiate the segmentation manually in these cases.

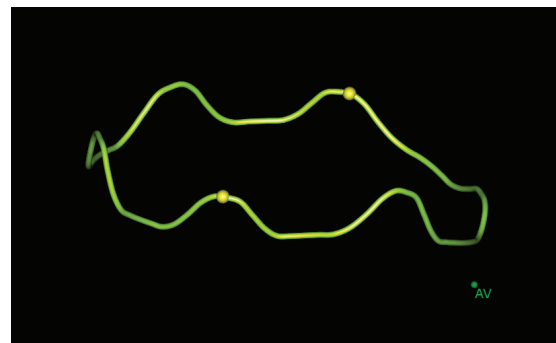
Why is there a minimum frame rate requirement?

To ensure the quality of the results, we require a minimum frame rate of 10 Hz and a minimum frame count of 10 frames per heart cycle.

Due to the physiology of cardiac motion, the volume-time-curve can be described by a few harmonics in the frequency domain. Thus, 10 sampling points per cardiac cycle are sufficient to avoid significant peak underestimation and smoothing. To support the majority of datasets and to ensure a minimal quality standard, a minimum of 10 frames/sec has been selected.

Why is the 3D annulus model not smooth but has a wavy shape?

In static review, three long axis (LAX) views are displayed as default. If the user edits only in these views with a small size pen, only these intersection areas in the model are affected. This results in a wave form.



- Please use the colored lines of intersection (LOIs) to navigate 360° around the complete model. Edit in all view planes where necessary.
- Choose the biggest pen to avoid waves and too many edits.
- Always check all angles in static review. Also check and rotate VR, especially when using the small pen.
- When the annulus model deviates too much from the actual annulus shape, consider going back to the "View Adjustment" workflow step, and initialize the annulus model again.

What shall I do when the dataset is not correctly aligned initially?

Go back to the “View Adjustment” workflow step. In case the alignment is only slightly off, adjust the landmarks for view alignment, aortic valve center and the four annulus points. In case the deviation in alignment is large, also consider pressing the “Reset auto adjustment” button to reset the image to the default position, if needed.

There are several possible reasons for incorrect initialization of the tricuspid annulus model:

- For zoomed TTE and transgastric TEE images, the automatic initialization is not implemented yet. These cases can still be processed but need to be initialized manually in “View Adjustment.”
- The field of view is not big enough. At least part of the aorta and the complete TV annulus need to be in the field of view during the whole heart cycle (see “What is a good acquisition for 3D Auto TV analysis?”). In these cases, the user should select another image.

What is the difference between the “Reset” button and the “Reject auto adjustment” button?

The “Reset” button in the “View Adjustment” workflow step resets the landmarks and image orientation to the automatically initialized state. When entering “View Adjustment” the second time, the “Reset” button resets the views and landmarks to the same state as when entered.

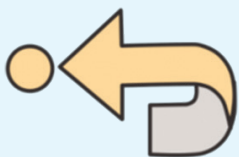


Figure 11 Reset button.

The “Reject auto adjustment” button resets the image orientation to the default image orientation as seen during acquisition.



Figure 12 Reject auto adjustment button.

Do we display tricuspid valve leaflets?

Leaflets are currently not displayed. TV leaflets are much thinner compared to the mitral leaflets and therefore harder to visualize and track. As an alternative, the user can mark the leaflet commissure points and the anterior papillary muscle in the “Commissure Points” workflow step. The nomenclature of the commissure points follows the suggested nomenclature from literature.⁹

Was 3D Auto TV validated against CT?

3D Auto TV was validated against CT measurements in an internal study (Internal documentation D001815314) with n=82 subjects. The results for all annulus measurements show an average relative bias of 5.2%, demonstrating that semiautomated results in 3D Auto TV slightly underestimate CT measurements.

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