# **Automatic Tablet-Based Monoplane Quantification of Stroke Volume and Left Ventricular Ejection Fraction: A Comparative Assessment against Computer-Based Biplane and Monoplane Tools**

Frederique M. de Raat, MSc1,2

P. Bingley, MSc2

S. Bouwmeester, MD PhD3

S.E.A. Felix, MD PhD3

Leon. J. Montenij, MD, PhD1,2

R.A. Bouwman, MD, PhD1,2

1 Department of Anesthesiology, Catharina Hospital, Eindhoven, the Netherlands

2 Department of Electrical Engineering, Technical University of Eindhoven, Eindhoven, the Netherlands

3 Department of Cardiology, Catharina Hospital, Eindhoven, the Netherlands

**Corresponding author**: Frederique M. de Raat, f.m.d.raat@tue.nl

**ORCID**

F.M. de Raat: 0000-0003-4157-2745

P. Bingley: 0009-0001-1921-1671

S. Bouwmeester, MSc 0000-0002-8358-2231

S.E.A. Felix, PhD 0000-0003-3733-0081

L.J. Montenij: 0000-0001-9001-3953

R.A Bouwman: 0000-0002-2051-5947

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**Conflict of interests**

The authors F.M. de Raat, P. Bingley, S. Felix, S. Bouwmeester, L.J. Montenij and A.R. Bouwman have declared to have no competing interest.

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**Keywords**: stroke volume, handheld ultrasound, point of care ultrasound, tablet-based, monoplane cardiac function quantification

# **Abstract**

**Purpose:** Point-of-care cardiovascular left ventricle ejection fraction (LVEF) quantification is established, but automatic tablet-based stroke volume (SV) quantification with handheld ultrasound devices is unexplored. We evaluated a tablet-based monoplane LVEF and LV volume quantification tool (AutoEF) against a computer-based tool (Tomtec) for LVEF and SV quantification.

**Methods:** Patients underwent handheld ultrasound scans, and LVEF and SV were quantified using AutoEF and computer-based software that utilized either apical four-chamber views (AS-mono) or both apical four-chamber and apical two-chamber views (AS-bi). Correlation and Bland-Altman analysis were used to compare AutoEF with AS-mono and AS-bi.

**Results:** Out of 43 participants, 8 were excluded. AutoEF showed a correlation of 0.83 [0.69:0.91] with AS-mono for LVEF and 0.68 [0.44:0.82] for SV. The correlation with AS-bi was 0.79 [0.62:0.89] for LVEF and 0.66 [0.42:0.81] for SV. The bias between AutoEF and AS-mono was 4.88% [3.15:6.61] for LVEF and 17.46 ml [12.99:21.92] for SV. The limits of agreement (LOA) were [-5.50:15.26]% for LVEF and [-8.02:42.94] ml for SV. The bias between AutoEF and AS-bi was 6.63% [5.31:7.94] for LVEF and 20.62 ml [16.18:25.05] for SV, with LOA of [-1.20:14.47]% for LVEF and [-4.71:45.94] ml for SV.

**Conclusion:** LVEF quantification with AutoEF software was accurate and reliable, but SV quantification showed limitations, indicating non-interchangeability with neither AS-mono nor AS-bi. Further refinement of AutoEF is needed for reliable SV quantification at the point of care.

**Non-standard Abbreviations and Acronyms**

AS-bi : Auto Strain-biplane

AS-mono : Auto Strain-monoplane

HAND : Handheld ultrasound

**Background**

Point of care bedside quantification of cardiovascular function is of special interest in the field of emergency and critical care. Indices used to assess cardiovascular function are stroke volume (SV) and left ventricle ejection fraction (LVEF). Transthoracic echocardiography (TTE) has the potential to provide real-time, non-invasive assessment of cardiac function, making it a valuable tool in guiding management decisions and optimizing care for critically ill patients. However, equipment availability, time constraints, and intra and interrater variability of standard TTE devices, form the limitations when it comes to point of care cardiovascular function assessment.

Over the past years, point of care ultrasound (POCUS) with miniaturized handheld ultrasound devices (HAND) made rapid bedside evaluations of cardiovascular function evaluation feasible [1], [2]. As a consequence, several tablet-based quantification tools have been developed which, in combination with HAND, can quantify LVEF at the bedside of the patient [3], [4], [5]. In our previous study we showed acceptable image quality, accuracy and precision for left ventricle function quantification based on a handheld device in comparison to conventional two-dimensional echocardiography [6]. Another study showed that LVEF quantification algorithms improve the intra and interrater variability [5].

However, automatic tablet-based quantification of SV with HAND devices is not yet described in literature. Recent data continue to emphasize the importance of SV quantification in predicting patient outcomes and selecting appropriate therapies[7], [8], [9]. Also, the LVEF quantification tools described in literature are based on biplane measurements which require acquisition of the apical four chamber (A4CH) and two chamber (A2CH) view [4], [5], [10]. Obtaining a A2CH view can be challenging, particularly with critically ill patients who aren’t optimally positioned. As a result, it’s more clinically feasible to use mono-plane measurements for quantifying cardiac function.

In this observational study, the interchangeability of a tablet-based automatic monoplane LVEF and LV volume quantification tool (AutoEF, DIA) is assessed against a computer-based monoplane and biplane quantification tool.

# **Materials & Methods**

This prospective, observational study was conducted from January 2021 till May 2022 in patients undergoing elective transthoracic echocardiography at the Cardiology department of the Catharina hospital, Eindhoven, the Netherlands. Exclusion criteria were age below 18 years, (supra)ventricular arrhythmias, moderate to severe valvular disease, moderate to severe pulmonary hypertension, and poor image quality precluding reliable assessment of the endocardial border. This study (W21.051) was approved by the institutional review board of the Medical Ethical Centre of Utrecht the Netherlands and carried out in accordance with the declaration of Helsinki. Written informed consent was obtained from all patients.

## Data acquisition

All acquisitions with the HAND were conducted by a certified cardiologist (S.B., S.F.) blinded to the post-processing results. During image acquisition patients were asked to perform an expiratory hold maneuver. Gain, focus, and depth settings were adjusted to maximize endocardial visualization.

HAND acquisitions were obtained with the Lumify S4-1 phased array transducer (1-4 MHz, Philips Ultrasound, Inc., Bothell, WA). This device does not support ECG triggered storage and looping of a single cardiac cycle, as it does not have ECG input capability. Instead, 8 second recordings of both the A2CH and A4CH views were acquired and the second heartbeat was used for analysis. HAND acquisitions were performed in triplicate without changing probe position. Total acquisition time was approximately 3-5 minutes. Images were saved as DICOM files for offline post-processing.

## Data quantification

As reference tool for LVEF quantification of the ultrasound acquisitions, the Auto Strain (AS) offline post-processing tool (*TOMTEC - ARENA Lot 50, TOMTEC Imaging Systems GmbH, Germany*) was used. End-diastole and end-systole frames were manually selected. End-diastole was defined as one frame before mitral valve closure. End-systole was defined as one frame before mitral valve opening or when end-systolic volume was deemed smallest by the operator. Next, based on the automatically traced LV blood-tissue boundaries (Figure.1), the modified Simpson’s method of discs was used to determine end-diastolic volume (EDV), end-systolic volume (ESV), SV and LVEF. The results were immediately saved without any manual correction of the tracing. Results based on quantification with AS based on the A4CH view only are referred to AS-mono and results based on both A2CH and A4CH views are referred to as AS-bi.

A collage of ultrasound images

Description automatically generatedFor AutoEF based quantification, the AutoEF tool (*AutoEF, ver 3.8.1, DIA Imaging Analysis Ltd., Israel*) was used. The AutoEF tool is able to automatically select the end-diastolic and end-systolic frame and trace the endocardial border (Figure. 2). Hence, no manual input or adjustments were needed. Based on the endocardial border tracings the EDV and ESV were determined. LVEF, EDV and ESV are calculated by the AutoEF algorithm and displayed. Stroke volume is not an output of AutoEF and is therefore manually derived by subtracting ESV from EDV. Results are referred to as AutoEF results.

**Fig. 1** This figure shows the delineation of the left ventricle (green line) throughout the heart cycle in images from the AS-mono and AS-bi dataset. a: A4CH view in diastole; b: A4CH view in systole; c: A2CH in diastole; d: A2CH in systole.

A close-up of ultrasound images

Description automatically generated**Fig. 2** This figure shows the delineation of the left ventricle (blue dots) throughout the heart cycle in images from the AutoEF dataset. a: A4CH view in diastole; b: A4CH view in systole.

## Statistical analysis

A sample size calculation was performed to limit the width of the 95% confidence interval (CI) around the standard deviation (SD) of the bias to 10%. Based on a mean SV of 60ml and a mean error of 30%, a sample size of 32 patients was calculated to be sufficient [11][12]. We included 43 patients in order to account for a potential drop-out rate of 25% due to insufficient image quality. Statistical analysis and data visualization were performed using IBM SPSS statistics (*version 22, IBM Corp, USA*) and MATLAB (*MATLAB 2020a, MathWorks, Inc. USA).* Data are shown as mean ± SD or median [IQR] as appropriate. The assumption of normality was confirmed using the Shapiro-Wilk normality test. Correlation calculations were performed using linear regression with Pearson’s correlation coefficient or Spearman’s correlation as appropriate. Correlation coefficients were considered poor (<0.4), moderate (0.4-0.7), strong (0.7-0.9), or very strong (>0.9) [13]. To determine the reliability for the quantification of LVEF the intraclass correlation coefficient of agreement (ICC) was calculated. ICC-was considered moderate (<0.75), good (0.76-0.9), or excellent (>0.9)[14]. Bland-Altman analysis was used to evaluate the agreement between AutoEF vs AS-mono, AutoEF vs AS-bi, and AS-mono vs AS-bi (Figure.3) in terms of bias as a measure of accuracy, and limits of agreement (LOA) and mean error as a measure of precision. Based on previous studies the clinically acceptable bias was set to 10% [12], [15].The precision of the reference technique and the experimental technique influence the mean error as explained by the following formula:

As a measure of precision the standard deviation of repeated measurements can be used, also known as repeatability and calculated as:

To determine the clinically acceptable mean error for LVEF and SV, the repeatability of each technique was calculated. The presence of proportional bias in the Bland–Altman plot was checked with regression analysis. To compare the means of the AutoEF, AS-mono and AS-bi quantification, a two-sided paired samples t-test was performed or a Mann-Whitney U test, depending on normality. P-values < 0.001 were considered significant according to the Bonferroni correction.

A logo with colorful arrows

Description automatically generated**Fig.3** Diagram of the different inter-technique comparisons; 1) AutoEF vs AS-mono (yellow arrow); AutoEF vs AS-bi (red arrow) ; AS-mono vs AS-bi (purple arrow)

# **Results**

Fourty-three patients participated in this study, of whom 8 were excluded because of poor endocardial delineation (3) and failure of quantification with the AutoEF tool (5). Therefore, 35 patients were included for analysis. The mean value of the triple measurements per patient is used in the analysis. The baseline characteristics of the patients are presented in Table 1.

**Repeatability**

The repeatability of LVEF was 14%, 13% and 8% for AutoEF, AS-mono and AS-bi, respectively. The repeatability of SV was 27%, 18% and 15% for AutoEF, AS-mono and AS-bi, respectively. Based on these repeatability’s, the clinically acceptable mean error for LVEF comparison between AutoEF and AS-mono was 11%, for AutoEF vs. AS-bi it was 10%, and for AS-mono vs. AS-bi it was 9%. The clinically acceptable mean error for SV comparison between AutoEF and AS-mono was 23%, for AutoEF vs. AS-bi it was 22%, and for AS-mono vs. AS-bi it was 17%.

**Correlation and Bland-Altman analysis**

The correlation between the AutoEF and AS-mono was strong for LVEF and moderate for SV (Table 2). Accuracy and precision were clinically acceptable for LVEF but not for the other parameters (Table 2, Figure 4). The correlation between the AutoEF and AS-bi was moderate for LVEF and SV (Table 3). Accuracy and precision were clinically acceptable for LVEF but not for the other parameters (Table 3). The correlation between the AS-mono and AS-bi was strong for LVEF and SV (Table 3). Accuracy and precision were clinically acceptable for all parameters (Table 3, Figure 5). The ICC was good for all parameters quantified with AutoEF. The ICC was lower for all parameters derived by the AutoEF quantification tool compared to AS-mono and AS-bi (Table 4). For the EDV en ESV results see appendix A.

**A graph of a line graph

Description automatically generated with medium confidenceFig.4** *Upper panel:* Correlation analysis of the AutoEF and AS-mono quantification for **(A)** LVEF, and **(B)** SV. *Lower panel:* Bland-Altman plots of AutoEF versus AS-mono for **(C)** LVEF, and **(D)** SV. LVEF = left ventricle ejection fraction; SV = stroke volume; R = correlation coefficient; R2 = Regression coefficient

**A diagram of a graph

Description automatically generated with medium confidenceFig.5** *Upper panel:* Correlation analysis of AutoEF and AS-bi quantification for **(A)** LVEF, and **(B)** SV. *Lower panel*: Bland-Altman plots of AutoEF and AS-bi for **(C)** LVEF, and **(D)** SV. LVEF = left ventricle ejection fraction; SV = stroke volume; R= Correlation coefficient; R2 = Regression coefficient

# **Discussion**

This study investigated the interchangeability of a tablet-based, monoplane LVEF and SV quantification tool for handheld echocardiography images with computer-based, monoplane (AS-mono) and biplane (AS-bi) references.

In recent years, several tablet-based quantification tools have been developed allowing LVEF quantification based on biplane measurements at the bedside. However, clinical practice could benefit from a quantification tool that can quantify LVEF and SV based on monoplane measurements. Therefore, this study provides a comprehensive analysis of the validity of an automatic tool referred to as AutoEF for LVEF and SV quantification based on monoplane A4CH views.

The assessment of left ventricular ejection fraction (LVEF) using the AutoEF tool demonstrated accuracy, precision, and reliability, exhibiting comparable results with both computer-based tools (AS-mono and AS-bi). Therefore, LVEF quantification with AutoEF can be deemed interchangeable with AS-mono and AS-bi. However, our findings indicate a lack of interchangeability between the AutoEF tool and AS-mono or AS-bi for stroke volume (SV) quantification.

It's important to emphasize that there is limited research conducted in the validation of automatic LVEF and SV algorithms, specifically for HAND echocardiography. Our results are in line with the study of V. Sachpekidis et al. which demonstrated that an AI-assisted automatic LVEF algorithm based on biplane measurements in a novel HAND device can be applied to a real-world patient population, yielding comparable results to cart-based echocardiography systems, and exhibiting a high sensitivity (90%) in detecting impaired LVEF below 50% [10]. In addition to this, the ICC values of AutoEF for LVEF quantification were comparable to those reported in the literature for the biplane Simpson's method used in standard echocardiography, with ICC ranging from 0.706 to 0.915 [5]. This has implications for various clinical scenarios, such as the monitoring of ICU patients.

However, our study showed that the AI-assisted AutoEF algorithm based on monoplane measurements cannot be used interchangeably for SV quantification (neither monoplane nor biplane). This could be explained by several reasons. First, the fact that LVEF is a relative measurement while SV is an absolute volumetric measurement. Second, as can be seen in appendix A, the EDV is underestimated by AutoEF compared to AS-mono and AS-bi. The underestimation of EDV leads to an underestimation of SV. Third, AutoEF utilizes only A4CH views and therefore makes more geometrical assumptions resulting in less accurate absolute measurements. Even though AS-mono also needs to make similar geometrical assumptions there is a difference: the algorithms for AS-mono and AS-bi come from the same vendor and are likely trained on the same dataset, while AutoEF was developed by a different company and likely trained on a different dataset with different assumptions on LV geometry. Fourth and most importantly, the end-diastolic and end-systolic frame selection are done automatically for AutoEF but manually for AS-mono and AS-bi, which could also lead to different results. Its important to note the lack of interchangeability cannot be attributed to the HAND device itself. An earlier study showed interchangeability between a HAND device versus a high-end ultrasound system (EPIQ) for LVEF and SV quantification. The quantification of LVEF and SV was done on computer-based software that required the examiner to define the end systolic and end diastolic frame for the left ventricle for HAND, making the method not fully automated [6].

This study provides a starting point for future research evaluating the clinical validity of tablet-based quantification tools for point of care assessment of LVEF and SV. The role of tablet-based ultrasound quantification is not to replace standard echocardiography but to enable quick and easy quantification of cardiac function at the bedside feasible and improve patient care, especially in critical care. It could be used by physicians who have received appropriate training but are non-experts in echocardiography, especially because there is no need to obtain an A2CH view which can be rather challenging in clinical practice. It's essential to consider the advantages of portability, availability and applicability of POCUS provided by monoplane AutoEF based ultrasound quantification, while acknowledging its current technological limitations when compared to fully equipped cart-based systems or biplane tools. Based on these advantages, it is a matter of debate whether to adjust the clinically acceptable bias and LOA, and thus except lower accuracy and precision. However, based on our results and the predefined clinically acceptable accuracy and precision, SV quantification with AutoEF is not yet of sufficient accuracy.

Our study has several limitations. First, the predefined clinically acceptable bias and precision, are a matter of discussion. [15]. Depending on the clinical situation and the advantages of the new tool, such threshold limits could be adjusted[16][17]. Second, this study was performed on relatively healthy patients. This is reflected in the relatively low BMI and the low number of exclusions due to insufficient image quality (3 out of 43). The relatively healthy population had limited ranges for LVEF and SV measured. In a patient group with a wider range of pathophysiological conditions a wider spread in the data is expected which could impact statistical significance of the results. Third, five patients were excluded due to failure of quantification of their images with the AutoEF tool. This did not seem to be related to image quality or endocardial border delineation as visually comparable images did quantify successfully. Improving the robustness of AutoEF would increase its applicability to more patients and should be realizable given that AS-mono and AS-bi could quantify the images of these 5 patients successfully. Fourth, expert sonographers conducted all examinations, giving rise to a high image quality. It is important to investigate whether image quality will decrease with less experienced sonographers and how this affects the quantification results. Finally, in this study the delineated borders as traced by the tools were not manually adjusted, although both tools provide this capability. This choice allowed for a true comparison of the automatically quantified results. However, in the case of certain outliers seen in the SV correlation plots in Figure 4 and 5, it was visible that the traced border was not correct. Manually adjusting the border in these cases is expected to improve the overall performance of the tools.

Future research should focus on a dedicated study which investigates the trending ability of SV. In the critical care setting relative changes in SV over time are used to monitor a patient’s condition or response to hemodynamic therapy. This study focused on absolute measurements at a single time point which are less clinically relevant in the ICU context. Furthermore, our study population consisted of relatively healthy, and slim patients, who were ideally positioned and breathing comfortably, which allowed for obtaining optimal acoustic windows and therefore adequate visibility of the endocardial border. In a follow-up study it is interesting to evaluate the performance of the AutoEF tool in a study population of critically ill patients or in a peri-operative setting, in which several conditions may be suboptimal. Finally, usage of handheld devices should also be investigated in patients who are mechanically ventilated to evaluate how this affects performance [18].

# **Conclusion**

LVEF quantification with the AutoEF tool showed accurate, precise and reliable results compared to both computer-based tools (AS-mono and AS-bi). LVEF quantification with AutoEF can thus be considered interchangeable with AS-mono and AS-bi. However, our results suggest no interchangeability between the AutoEF tool and AS-mono or AS-bi for SV quantification.

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**Financial interests**

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**Authors' contributions**

FM conducted the literature search, screened and analyzed all the patient data and has written the manuscript. FM had the leading role in the completion of this work. PB provided extensive support with writing the manuscript and the analysis of the data. SB offered his medical expertise regarding the screening of the patients and provided help with acquisition of data. SF had the leading role in data acquisition. RB was the initiator of this research and supported this work with his clinical expertise. He supervised together with LM the work of FM continuously throughout the drafting process and offered extensive feedback. The first draft of the manuscript was written by FM and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

**Ethics approval**

This study was in line with the principles of the Declaration of Helsinki. Approval was granted by the institutional review board of the Medical Ethical Centre of Utrecht the Netherlands on the 5th of March 2021 (W21.051) and was in accordance with the Medical Research Involving Human Subjects Act (WMO).

**Consent to participate**

Informed consent was obtained from all individual participants included in the study.

**Consent for publication**

Patients signed informed consent regarding publishing their data.

**Availability of data and materials**

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

**Corresponding author**: Frederique M. de Raat, **email:** [f.m.d.raat@tue.nl](mailto:f.m.d.raat@tue.nl), **Address:** Technical University of Eindhoven, De Zaale, Eindhoven, the Netherlands

**Author information, authors and affiliations**

Department of Anesthesiology, Catharina Hospital, Eindhoven, The Netherlands

Frederique M. de Raat, L.J. Montenij, R.A. Bouwman

Department of Cardiology, Catharina Hospital, Eindhoven, the Netherlands

S. Bouwmeester, S.E.A. Felix

Department of Electrical Engineering, Technical University of Eindhoven, Eindhoven, the Netherlands

Frederique M. de Raat, P. Bingley, L.J. Montenij, R.A. Bouwman

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| --- | --- |
| Table 1. Baseline demographic characteristics | |
| Total number of participants (N) | *35* |
| Male (%) | *46* |
| Age (yrs.) | *58 ± 14* |
| Body length (cm) | *172.6 ± 9.1* |
| Body weight (kg) | *76.2 ± 13.7* |
| BMI (kg/ m2) | *25.5 ± 3.6* |
| Body surface area (m2) | *1.9 ± 0.3* |
| Creatinine (µmol/L) | *82.3 ± 13.8* |
| Diabetes (%) | *9* |
| Hypertension (%) | *34* |
| Myocardial infarction (%) | *9* |
| Revascularization (%) | *9* |
| Valvular disease (%) | *0* |
| Peripheral disease (%) | *11* |
| COPD (%) | *0* |
| Values are presented as mean ± SD.  BMI = body mass index. COPD = chronic obstructive pulmonary disease. | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 2. Inter-technique comparison – AutoEF versus AS-mono | | | | | | | |  |  | | |
|  | **N** | **Averaged AutoEF** | **Averaged**  **AS-mono** | **Corr** | **95% CI of corr** | **Bias** | **95% CI of Bias** | **95% CI of LOA** | | |
| *LVEF, %* |  |  |  |  |  |  |  |  | |
|  | *35* | *58,99 ±* *3.69* | *53,79 ± 3.80* | *0.83* | *[0.69:0.91]* | *4.88* | *[3.15:6.61]*♦ | *[-5.50:15.26]*♦ | | |
| *SV, ml* |  |  |  |  |  |  |  |  | | |
|  | *35* | *52,44 ± 5,47* | *69,90 ± 16,69* | *0.68* | *[0.44:0.82]* | *17.46* | *[12.99:21.92]* | *[-8.02:42.94]* | | |
| Values are presented as mean *±* SD. \* p < 0.001  ♦ 95% CI within the clinical acceptable LOA or bias range  AS = AutoStrain; Corr = Correlation Coefficient; CI = Confidence Interval; LVEF = Left Ventricle Ejection Fraction; LOA = Limits Of Agreement; SV = Stroke Volume | | | | | | | | | | | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 3. Inter-technique comparison of AutoEF and AS-mono versus AS-bi | | | | | | | | | | |
|  | **N** | | **Averaged** | **Averaged**  **AS-bi** | **Corr** | **95% CI of Corr** | **Bias** | **95% CI of Bias** | **95% CI of LOA** |
| *AutoEF* | |  |  |  |  |  |  |  |  |
| *LVEF, %* |  | |  |  |  |  |  |  |  |
|  | *35* | | *53,79 ± 3.80* | *60,76 ± 2.50* | *0.79* | *[0.62:0.89]* | *6.63* | *[5.31:7.94]*♦ | *[-1.20:14.47]*♦ |
| *SV, ml* |  | |  |  |  |  |  |  |  |
|  | *35* | | *52,44 ± 5,47* | *73,05 ± 15,81* | *0.66* | *[0.42:0.81]* | *20.62* | *[16.18:25.05]* | *[-4.71:45.94]* |
| AS-mono |  | |  |  |  |  |  |  |  |
| *LVEF, %* |  | |  |  |  |  |  |  |  |
|  | *35* | | *58,99 ±* *3.69* | *60,76 ± 2.50* | *0.87* | *[0.76:0.93]* | *1.75* | *[0.05:3.45]*♦ | *[-8.44:11.95]*♦ |
| *SV, ml* |  | |  |  |  |  |  |  |  |
|  | *35* | | *69,90 ± 16,69* | *73,05 ± 15,81* | *0.88* | *[0.77:0.94]* | *3.16* | *[0.39:5.92]*♦ | *[-12.62:18.93]*♦ |
| Values are mean ± SD. \*p < 0.001  ♦ 95% CI within the clinical acceptable LOA or bias range  AS = AutoStrain; Corr = Correlation Coefficient; CI = Confidence Interval; LVEF = Left Ventricle Ejection Fraction; LOA = Limits Of Agreement; SV = Stroke Volume; | | | | | | | | | | |

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| **Table 4. Intraclass correlation coefficient of agreement (ICC)** | | | |
|  | ***AutoEF*** | ***AS-mono*** | ***AS-bi*** |
| ***LVEF*** | 0.837 [0.706:0.915] | 0.908 [0.839:0.951] | 0.907 [0.837:0.950] |
| ***SV*** | 0.907 [0.832:0.952] | 0.926 [0.869:0.960] | 0.952[0.916:0.974] |
| Mean value [95% Confidence Intervals]; ICC = Intraclass Correlation Coefficient | | | |