



# AI EJECTION FRACTION (EF) CLINICAL VALIDATION STUDY SUMMARY



KOSMOS  
by EchoNous

# Clinical Validation Study Summary

## Investigation Overview

- Study was conducted prospectively at Mercy Med Clinic (Columbus, GA, USA)

- Scanning performed in an outpatient setting on a challenging patient population

- Results were based on N=78 patients scanned in the study (powered for statistical and clinical significance)

- 4 echocardiographers (operators) scanned patients and were allowed to edit the automated left-ventricular endocardial tracings used for EF assessment

### **Each echo exam was manually annotated by 2 independent echo core labs using commercially available and FDA-cleared cardiac calculations software packages**

- Echo core labs had no access to the EF results produced by KOSMOS

- End-diastolic and end-systolic frames were manually selected, and corresponding left-ventricular endocardial tracings were manually generated by Massachusetts General Hospital (MGH) and University of California San Francisco (UCSF) echocardiography labs

- Volumes computed using Simpson's single-plane and bi-plane (if A2C is available) Method of Disks method using 20 disks

- EF computed as:  $EF = (EDV - ESV)/EDV$ 
  - EDV: end-diastolic volume
  - ESV: end-systolic volume

### **Average of the 2 echo core labs expert EFs was set as the gold standard EF and compared against KOSMOS EF**

- Both operator edited and non-user edited results were compared

- Primary endpoint: Root Mean Square Deviation (RMSD) between KOSMOS EF and Gold Standard EF < 10

- Statistical design and methodology performed by a professional biostatistician



# Manual EF vs. KOSMOS EF (ML Only)

## METRIC

## VALUE

### RMSD

Root Mean Square Deviation

7.12

### Bias

Average of sample-wise EF differences (green line in Bland-Altman plot)

-2.94

### Pearson Correlation

Measurement of linear correlation

0.86  
(very strong)

### Cohen's Kappa

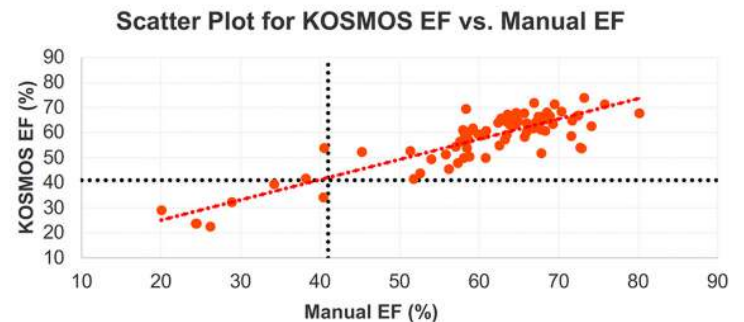
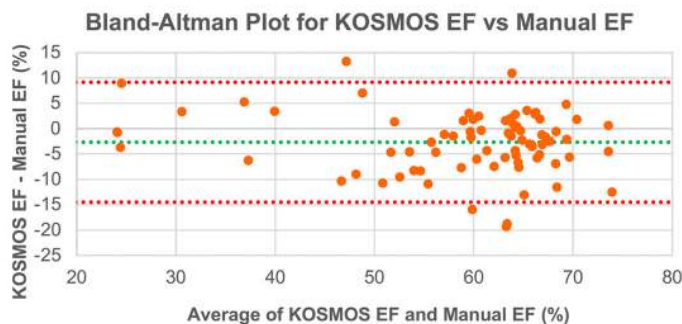
Robust measure of categorical agreement, where categories are defined as normal-mildly abnormal (EF > 41%) and moderately-severely abnormal (EF ≤ 41%). Categories are visualized with black dashed line in scatterplot

0.86  
(very strong)

### 95% Limits of Agreement

95% of EF differences are estimated to be within these bounds (red lines in Bland-Altman plot)

(-15.74, 9.85)



# Manual EF vs. KOSMOS EF

## (With User Adjustments)

### METRIC

### VALUE

#### RMSD

Root Mean Square Deviation

6.56

#### Bias

Average of sample-wise EF differences (green line in Bland-Altman plot)

-2.66

#### Pearson Correlation

Measurement of linear correlation

0.88  
(very strong)

#### Cohen's Kappa

Robust measure of categorical agreement, where categories are defined as normal-mildly abnormal (EF > 41%) and moderately-severely abnormal (EF ≤ 41%). Categories are visualized with black dashed line in scatterplot

0.86  
(very strong)

#### 95% Limits of Agreement

95% of EF differences are estimated to be within these bounds (red lines in Bland-Altman plot)

(-14.49, 9.16)

