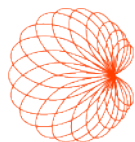# AI EJECTION FRACTION (EF) CLINICAL VALIDATION STUDY SUMMARY

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

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AI Ejection Fraction (EF) Clinical Validation Study Summary

Manual EF vs. KOSMOS EF
(ML Only)

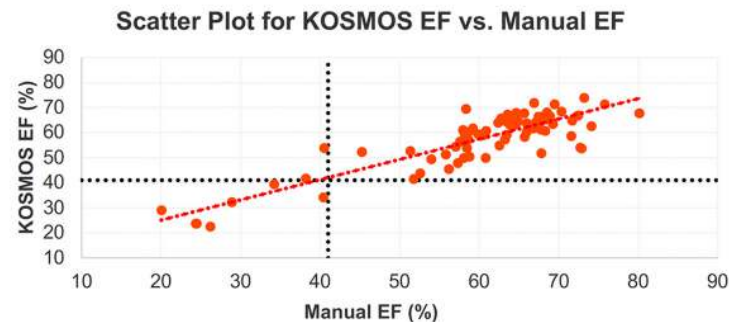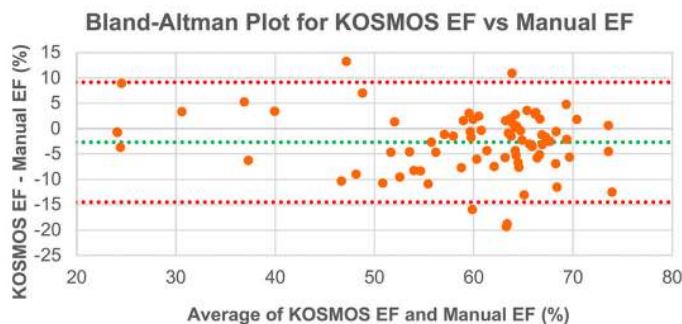| METRIC	VALUE
RMSD Root Mean Square Deviation	**7.12**
Bias Average of sample-wise EF differences (green line in Bland-Altman plot)	**-2.94**
Pearson Correlation Measurement of linear correlation	**0.86** **(very strong)**
Cohen's Kappa Robust measure of categorical agreement, where categories are defined 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)**

Bland-Altman Plot for KOSMOS EF vs Manual EF

Scatter Plot for KOSMOS EF vs. Manual EF

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AI Ejection Fraction (EF) Clinical Validation Study Summary

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)**

Scatter Plot for KOSMOS EF vs. Manual EF

Bland-Altman Plot for KOSMOS EF vs Manual EF

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AI Ejection Fraction (EF) Clinical Validation Study Summary