



# Kosmos<sup>®</sup> Bladder AI

## Clinical Performance and Non-Clinical Testing

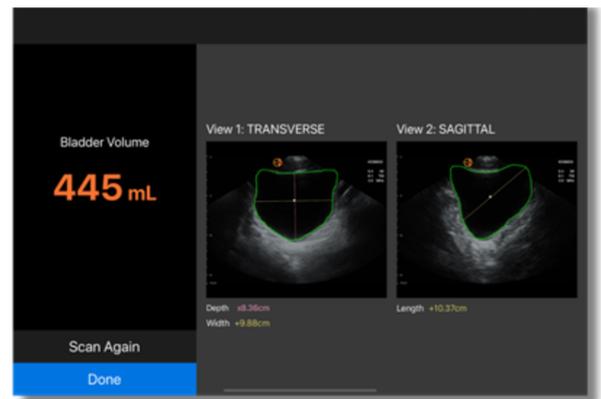
A prospective study was conducted to evaluate the correlation between manual bladder volume determination and Kosmos Bladder Biplane Caliper Volume AI (also referred to as Kosmos Bladder AI) algorithm in a clinical setting.

# Study Design

A total of 146 participants, 2 abdominal sonographers, and 4 nurses were enrolled in the study. Each participant underwent scanning by an assigned pair of healthcare professionals, comprised of a sonographer and a nurse. Three (3) independent sonographers were recruited to perform manual labeling of the bladder calipers on acquired videos that were used for evaluating the performance of Kosmos Bladder AI workflow. The participants in this study comprised of a well-rounded representation of demographic factors such as age, gender, BMI, ethnicity, and race. This diversity enriched the dataset and provided comprehensive insights.

Each acquired bladder video (transverse and sagittal) was labeled by three (3) sonographers. The average of these 3 measurements was considered the ground truth for assessment.

- Primary Endpoint:  
correlation coefficient  $\geq 0.90$



# Results

Results of the hypothesis testing of Kosmos Bladder AI software evaluating the performance of the algorithm against its objective performance goal of a correlation coefficient  $\geq 0.90$ . The performance goal was met.

Endpoint	Results (95% CI)	p-value
Correlation Coefficient	0.988 (0.986-0.99)	$< 0.0001$

# Software Verification and Validation Testing

Software documentation generated as part of EchoNous' design process include:

1. Software/Firmware Description
2. Device Hazard Analysis
3. Software Requirement Specifications
4. Architecture Design Chart
5. Software Design Specifications
6. Traceability
7. Software Development Environment Description
8. Verification and Validation Documentation
9. Revision Level History
10. Unresolved Anomalies
11. Cybersecurity

A comprehensive risk analysis was generated for the software with detailed description of the hazards, their causes and severity, as well as acceptable methods for control of the identified hazards. EchoNous developed a description, with test protocols including pass/fail criteria and report of results, of acceptable verification and validation activities at the unit, integration, and system level.

## Algorithm Testing

Comprehensive non-clinical performance testing of the deep-learning algorithms used in the device was performed to support their clinical performance. Specifically, the performance testing evaluated the performance of the following software functionality:

- Kosmos Bladder Biplane Caliper Volume Algorithm

Overall, the non-clinical performance testing results provide evidence in support of the functionality of Kosmos Bladder AI's algorithms.

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Note: Not all features are available in all markets, please check with your local representative for availability in your region.

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