

REAL-WORLD SAFETY AND PERFORMANCE OF THE COLOR DOPPLER ULTRASOUND SYSTEM: A MULTI-CENTER POST-MARKET CLINICAL FOLLOW-UP SURVEY

YuanBo Wang*, FuCheng Wang, Dan Wu, JieBing Ma, BaoLi Zhang, Wen Xie
Wuhan Zoncare Bio-medical Electronics Co., Ltd., Wuhan 430070, Hubei, China.

*Corresponding Author: YuanBo Wang

Abstract: Objective: To evaluate the real-world clinical safety and performance of the Color Doppler Ultrasound System (Model: M30/ViV 20, Manufacturer: Zoncare, China) across multiple centers and diverse operator profiles. Methods: This cross-sectional PMCF survey enrolled evaluators from 61 centers. A standardized questionnaire was used to assess device safety and performance across four domains: Safety (2 items), Image Quality (6 items), Operational Experience (4 items), and Stability (3 items). The primary endpoint was the acceptability rate (dichotomized as "Acceptable" vs. "Not acceptable") for each indicator, with exact 95% confidence intervals (CIs) calculated. The secondary endpoint comprised the distribution of original ordinal responses (Likert-scale) and median scores for each item. Results: A total of 76 valid questionnaires were returned. For the primary endpoint, the safety incidence (electric shock/skin burns) was 0% (95% CI: 0.0% - 4.7%). The overall acceptability rates for Image Quality, Operational Experience, and Stability were 99.3% (95% Bootstrap CI: 98.5% - 100.0%), 99.3% (95% Bootstrap CI: 98.3% - 100.0%), and 98.7% (95% Bootstrap CI: 97.0% - 100.0%), respectively, all exceeding the pre-defined performance goal of 84.4%. Secondary analysis revealed that the median scores for most items fell within the "High/Excellent" range (e.g., Resolution: 3 [IQR: 2-3]), indicating a generally positive perception. Detailed ordinal distributions highlighted that for image quality, focus and noise received the highest proportion of "Excellent" (Accurate/Low) ratings (89.5% and 81.6% respectively); for operational experience, button comfort rated best (65.8% Excellent); for stability, changes in device or probe performance rated best (85.5% Stable). Conclusion: The Color Doppler Ultrasound System demonstrates robust safety and high performance in real-world clinical settings, meeting the pre-specified performance criteria. Secondary analyses provided granular insights into specific strengths and minor areas for future optimization.

Keywords: Post-market clinical follow-up; Ultrasound; Real-world evidence; Safety; Performance; Acceptability rates

1 INTRODUCTION

Post-market clinical follow-up (PMCF) is a mandatory regulatory requirement to continuously confirm the safety and performance of medical devices throughout their lifecycle [1]. While pre-market clinical evaluation is conducted under controlled environments, it may not fully capture the variability of real-world clinical practice, including differences in operator expertise, patient characteristics, and clinical practice variability [2-4].

The Color Doppler Ultrasound System is a general-purpose US imaging system designed for fetal/obstetrics, gynecology, abdomen, pediatrics, small parts, musculoskeletal, cardiology (adult and pediatric), vascular, urology, nerve, and biopsy guidance. Although it has received regulatory clearance based on bench testing and controlled clinical evaluation, further real-world evidence is needed to comprehensively characterize its sustained performance in routine clinical practice.

Therefore, this PMCF survey was designed to evaluate the system in real-world settings. Specifically, we aimed to: (1) quantify the acceptability rate of key performance indicators using a binary endpoint (primary), and (2) characterize the detailed ordinal distribution of user evaluations to identify specific strengths and potential areas for refinement (secondary).

2 MATERIALS AND METHODS

2.1 Survey Design and Setting

This was a multi-center, cross-sectional, questionnaire-based PMCF survey conducted between April and August 2026. Participating sites included 61 clinical centers across 13 countries across Africa, Asia, and Europe. The diverse sites comprise a mix of large teaching hospitals, university medical centers, and advanced private cardiology clinics, collectively representing varied healthcare settings across urban and regional environments. This multi-country framework enables robust real-world evaluation of the device's performance, image quality, and operational characteristics in routine clinical practice.

2.2 Participants (Evaluators)

Eligible evaluators were licensed physicians or sonographers who had used the device (M30/ViV 20). They were required to have performed ultrasound examinations on applicable body parts (e.g., Fetal/Obstetrics, Abdomen, Vascular). Evaluators were recruited voluntarily.

2.3 Questionnaire (The Survey Tool)

A structured questionnaire was developed based on the essential performance requirements of ultrasound systems. It comprised three sections:

Evaluator Demographics: Years of experience, primary department, average monthly patient volume, and experience duration with the device.

Domain Assessments (Core Items): Covering Safety (Electric shock, Skin/tissue burns), Image Quality (Resolution, Artifacts, Contrast, Noise, Focus, Filling degree), Operational Experience (Button comfort, Operational smoothness, Workflow logic, Measurement accuracy), and Stability (Maintenance frequency, System crashes, Changes in device or probe performance). Each item utilized a 3- or 4-point ordered ordinal scale (e.g., High/Medium/Low; Excellent/Good/Fair/Poor).

Applicable Body Parts: A check-all-that-apply list for 11 intended clinical applications.

2.4 Survey Endpoints and Definitions

Primary Endpoint: The Acceptability Rate for each evaluated indicator. The original ordinal responses were dichotomized into "Acceptable" and "Not Acceptable" based on pre-defined clinical criteria:

For Safety items: "No" was defined as Acceptable; "Yes" was Not Acceptable.

For Image Quality (3-level): "High" and "Medium" were defined as Acceptable; "Low" was Not Acceptable.

For Operational Experience and Stability (4-level): "Excellent" and "Good" were defined as Acceptable; "Fair" and "Poor" was Not Acceptable.

Rationale: This stringent definition reflects a "fit-for-purpose" criterion, ensuring the device meets minimum clinical utility standards even in non-ideal situations.

Secondary Endpoint: The original ordinal score distribution for each item, presented as frequency counts, proportions, and median with interquartile range (IQR).

2.5 Statistical Analysis

All analyses were performed using SPSS Statistics 27 (IBM Corp., Armonk, NY, USA).

Descriptive statistics were used for evaluator demographics (frequencies and percentages).

For the Primary Endpoint: The safety incidence and its exact two-sided 95% confidence interval (CI) were calculated using the Clopper-Pearson method, which is appropriate for binomial proportions with zero observed events [5]. The performance acceptance rate and its 95% CI were estimated using the Bootstrap method to account for the sample size and the boundary nature of the estimates [6]. A pre-defined performance goal (PG) of 84.4% was set, corresponding to the lower bound of the 95% CI derived from the meta-analysis of literature data presented in the Clinical Evaluation Report (CER); the device was considered to have met the acceptable criterion if the lower bound of the 95% CI exceeded 84.4%.

For the Secondary Endpoint: Ordinal data were summarized as median (P25, P75). The distribution of responses across all grade levels (e.g., Low/Medium/High) was summarized using frequency/percentage table and visualized using bar charts [7-8].

Subgroup exploratory analyses were performed using the Mann-Whitney U test for comparisons by ultrasound model (two groups) and the Kruskal-Wallis H test for comparisons by years of experience (four groups). A two-sided $P < 0.05$ was considered statistically significant.

2.6 Sample Size

As this was an exploratory descriptive survey, no formal sample size calculation was performed. We aimed to collect at least 60 questionnaires (30 responses per model $\times$ 2 models) to obtain stable estimates of favorable rates. Although the sample size per model ($n \approx 30$) is generally considered adequate for the Central Limit Theorem to support approximate normality of sample means [9], given that many endpoints were proportions close to the boundary (0% or 100%), exact methods (Clopper-Pearson) and bootstrap confidence intervals were preferentially used for primary endpoint estimation.

3 RESULTS

3.1 Evaluator Demographics

Evaluators from 61 centers completed the survey. The baseline characteristics are presented in Table 1. The sample included operators with a broad range of ultrasound experience, covering both less experienced users (<3 years, 36.8%) and highly experienced clinicians (>10 years, 11.8%), with the majority (63.2%) having at least 3 years of professional experience. Most evaluators were active clinical users, as evidenced by 68.4% performing ≥ 100 examinations per

month. Primary departments were dominated by Radiology/Ultrasound (51.3%) and Obstetrics & Gynecology (52.6%), aligning with the main intended clinical applications of the device. Furthermore, 73.7% of evaluators had used the evaluated devices (M30/ViV 20) for at least 3 months, indicating adequate familiarity with system operation and clinical workflow. Collectively, these characteristics support the representativeness of the evaluator sample for the target user population in real-world clinical settings.

Table 1 Baseline Characteristics of Participating Evaluators

		N	Percent
BG1. Years of experience in ultrasound	<3	28	36.8%
	3-5	20	26.3%
	6-10	19	25.0%
	>10	9	11.8%
BG2. Primary departments ^a	Radiology/Ultrasound	39	51.3%
	Obstetrics & Gynecology	40	52.6%
	Cardiology	19	25.0%
	Other	8	10.5%
BG3. Average monthly patient volume	<100	24	31.6%
	100-200	36	47.4%
	201-300	10	13.2%
	>300	6	7.9%
BG4. Experience with the M30/ViV 20 device	<1m	3	3.9%
	1-3m	17	22.4%
	3-6m	24	31.6%
	>6m	32	42.1%

Note: a. Evaluators were allowed to select multiple primary departments to reflect real-world clinical practice. The distribution of departments was analyzed using multiple response analysis and presented as the percentage of cases (i.e., the proportion of all evaluators who selected each department).

3.2 Applicable Body Parts

The clinical applications for which the ultrasound system was used during the evaluation are summarized in Table 2. The most frequently examined body parts were Abdomen (59.2%), Vascular (47.4%), Small Parts (44.7%), Gynecology (42.1%), Cardiology (42.1%), and Fetal/Obstetrics (40.8%). Less commonly examined areas included Musculo-skeletal (19.7%), Nerve (18.4%), Pediatrics (17.1%), Urology (14.5%), and Biopsy Guidance (3.9%).

These findings indicate that the device was utilized across a broad spectrum of clinical indications, with a notable concentration in superficial and vascular applications, while maintaining a balanced representation across major specialties including obstetrics/gynecology and cardiology.

Table 2 Application Frequencies

		Responses		Percent of Cases
		N	Percent	
Applicable Body Parts ^a	A1. Fetal/Obstetrics	31	11.7%	40.8%
	A2. Gynecology	32	12.0%	42.1%
	A3. Abdomen	45	16.9%	59.2%
	A4. Pediatrics	13	4.9%	17.1%
	A5. Small Parts	34	12.8%	44.7%
	A6. Musculo-skeletal	15	5.6%	19.7%
	A7. Cardiology (adult and pediatric)	32	12.0%	42.1%
	A8. Vascular	36	13.5%	47.4%
	A9. Urology	11	4.1%	14.5%
	A10. Nerve	14	5.3%	18.4%
	A11. Biopsy Guidance	3	1.1%	3.9%
Total		266	100.0%	350.0%

Note: a. Dichotomy group tabulated at value 1.

3.3 Primary Endpoint: Acceptability Rates (Main Analysis)

The primary endpoint results are summarized in Table 3 and Table 4. Critically, the safety incidence was 0.0% for both electric shock and skin/tissue burns (95% CI: 0.0% - 4.7%), demonstrating an excellent safety profile in real-world use. For performance, all evaluated domains demonstrated high acceptability rates. Specifically, the overall Image Quality acceptability rate was 99.3% (95% CI: 98.5% - 100.0%), with all indicators exceeding the pre-defined PG of 84.4%. The Operational Experience domain also performed well, with the lowest indicators being Measurement accuracy at 97.4% (95% CI: 90.8% - 99.7%), which still met the performance goal. Stability indicators showed robust performance, except for maintenance frequency, which was slightly lower at 96.1% (95% CI: 88.9%-99.2%).

Table 3 Primary Endpoint: Acceptability Rates and 95% CI per Indicator (N=76)

Domain	Indicator	Acceptable Definition	Acceptable (N)	Acceptability Rate (%)	95.0% CI (%)	
					Lower	Upper
Safety	S1. Electric shock	No	76	100.0	95.3	100.0
	S2. Skin/tissue burns	No	76	100.0	95.3	100.0
Image quality	Q1. Resolution	High/Medium	75	98.7	92.9	100.0
	Q2. Artifacts	None/Mild	76	100.0	95.3	100.0
	Q3. Contrast	High/Medium	76	100.0	95.3	100.0
	Q4. Noise	Low/Medium	75	98.7	92.9	100.0
	Q5. Focus	Accurate/MOF	76	100.0	95.3	100.0
	Q6. Filling degree (color performance)	Full/Moderate	75	98.7	92.9	100.0
Operational experience	E1. Button comfort	Excellent/Good	76	100.0	95.3	100.0
	E2. Operational smoothness	Excellent/Good	76	100.0	95.3	100.0
	E3. Workflow logic	Excellent/Good	76	100.0	95.3	100.0
	E4. Measurement accuracy	Excellent/Good	74	97.4	90.8	99.7
Stability	ST1: Maintenance frequency	Excellent/Good	73	96.1	88.9	99.2
	ST2: System crashes	None/Rare	76	100.0	95.3	100.0
	ST3: Changes in device or probe performance	Stable/Minor	76	100.0	95.3	100.0

Note: CI = Confidence Interval, MOF = Mildly Out of Focus.

Table 4 Primary Endpoint: Acceptability Rates and 95% CI per Domain (N=76)

Table 4: Primary Endpoints: Acceptability Rates and 95% CI per Domain (N = 78)						
		Statistic (%)	Bootstrap ^a			
			Bias	Std. Error	95% Confidence Interval (%)	
					Lower	Upper
Image Quality	Mean	99.3	0.0	0.4	98.5	100.0
	Median	100.0	0.0	0.0	100.0	100.0
	Variance	10.7	-0.1	5.9	0.0	22.7
	Std. Deviation	3.3	-0.2	1.1	0.0	4.8
	Minimum	83.3				
	Maximum	100.0				
Operational Experience	Mean	99.3	0.0	0.5	98.3	100.0
	Median	100.0	0.0	0.0	100.0	100.0
	Variance	16.2	0.1	10.7	0.0	40.2
	Std. Deviation	4.0	-0.4	1.7	0.0	6.3
	Minimum	75.0				
	Maximum	100.0				
Stability	Mean	98.7	0.0	0.7	97.0	100.0
	Median	100.0	0.0	0.0	100.0	100.0
	Variance	42.7	-0.9	22.4	0.0	90.9
	Std. Deviation	6.5	-0.4	2.1	0.0	9.5
	Minimum	66.7				
	Maximum	100.0				
Performance (Weighted)	Mean	99.2	0.0	0.3	98.5	99.8
	Median	100.0	0.0	0.0	100.0	100.0
	Variance	8.8	0.0	4.0	1.6	17.1
	Std. Deviation	3.0	-0.1	0.7	1.3	4.1
	Minimum	84.6				
	Maximum	100.0				

Note: a. Unless otherwise noted, bootstrap results are based on 1000 bootstrap samples

3.4 Secondary Endpoint: Distribution of Original Ordinal Scores

The secondary analysis provided a granular view of user perceptions. Table 5 illustrates the percentage distribution for all ordinal items.

Table 5 Percentage Distribution for All Ordinal Items

Indicator	Median Score	Ordinal Rating and Percentage		
		Low	Medium	High
Q1. Resolution	3 [IQR: 2-3]	1 (1.3%)	31 (40.8%)	44 (57.9%)
Q2. Artifacts	3 [IQR: 2-3]	Significant 0 (0.0%)	Mild 25 (32.9%)	None 51 (67.1%)
Q3. Contrast	3 [IQR: 2-3]	Low 0 (0.0%)	Medium 29 (38.2%)	High 47 (61.8%)
Q4. Noise	3 [IQR: 3-3]	High 1 (1.3%)	Medium 13 (17.1%)	Low 62 (81.6%)

Indicator	Median Score	Ordinal Rating and Percentage			
Q5. Focus	3 [IQR: 3-3]	Out of Focus	MOF	Accurate	
		0 (0.0%)	8 (10.5%)	68 (89.5%)	
Q6. Filling degree (color performance)	3 [IQR: 2-3]	Low	Moderate	Full	
		1 (1.3%)	20 (26.3%)	55 (72.4%)	
E1. Button comfort	4 [IQR: 3-4]	Poor	Fair	Good	Excellent
		0 (0.0%)	0 (0.0%)	26 (34.2%)	50 (65.8%)
E2. Operational smoothness	4 [IQR: 3-4]	Poor	Fair	Good	Excellent
		0 (0.0%)	0 (0.0%)	34 (44.7%)	42 (55.3%)
E3. Workflow logic	4 [IQR: 3-4]	Poor	Fair	Good	Excellent
		0 (0.0%)	0 (0.0%)	37 (48.7%)	39 (51.3%)
E4. Measurement accuracy	4 [IQR: 3-4]	Poor	Fair	Good	Excellent
		0 (0.0%)	2 (2.6%)	48 (63.2%)	26 (34.2%)
ST1: Maintenance frequency	4 [IQR: 3-4]	Poor	Fair	Good	Excellent
		2 (2.6%)	1 (1.3%)	26 (34.2%)	47 (61.8%)
ST2: System crashes	4 [IQR: 3-4]	Frequent	Occasional	Rare	None
		0 (0.0%)	0 (0.0%)	27 (35.5%)	49 (64.5%)
ST3: Changes in device or probe performance	4 [IQR: 4-4]	Severe	Moderate	Minor	Stable
		0 (0.0%)	0 (0.0%)	11 (14.5%)	65 (85.5%)

Composite scores for Image Quality, Operational Experience, and Stability were calculated as the arithmetic mean of their respective items (6, 4, and 3 items, respectively), with higher scores indicating better performance. All three domains demonstrated high performance, with median scores of 2.8 (IQR: 2.5–3.0), 3.7 (IQR: 3.3–4.0), and 3.7 (IQR: 3.3–4.0), respectively, indicating a consensus on the "High/Excellent" performance. Notably, the Image quality domain achieved the highest proportion of maximum scores (71.7%, 95% CI: 67.3% - 75.8%) (Table 6), indicating exceptional device reliability in real-world use.

Table 6 Composite Scores Per Domain

Domain	Median Score	% of Maximum Score	95% CI (%)
Image quality	2.8 [IQR: 2.5-3.0]	71.7%	67.3% - 75.8%
Operational experience	3.7 [IQR: 3.3-4.0]	51.6%	45.9% - 57.4%
Stability	3.7 [IQR: 3.3-4.0]	70.6%	64.2% - 76.4%

However, a small proportion of evaluators gave "Fair" or "Poor" ratings to Measurement accuracy (2.6%) and Maintenance frequency (3.9%), suggesting these as potential areas for minor user-interface optimization in future iterations.

For the distribution of original ordinal performance scores, refer to Figure 1.

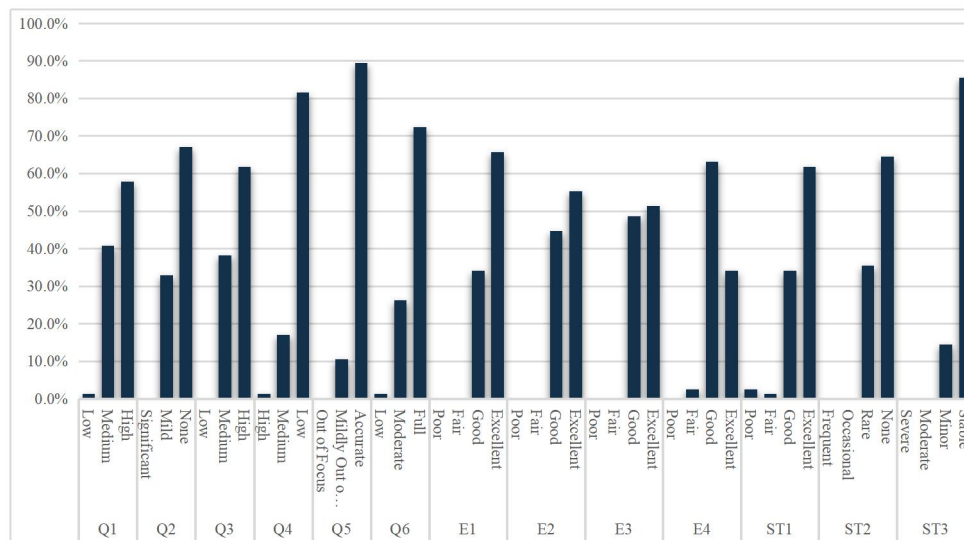


Figure 1 Distribution of Original Ordinal Performance Scores

3.5 Subgroup Exploratory Analysis

Subgroup analyses showed no significant difference in the weighted overall performance acceptability rate between the two ultrasound models (Mann-Whitney U test, $P = 0.34$) or across years of ultrasound experience (Kruskal-Wallis H test, $P = 0.38$). However, an exploratory stratified analysis suggested that the acceptability rate of the M30 model tended to be lower among evaluators with more than 10 years of ultrasound experience (98.1%), whereas the ViV 20 model showed relatively lower scores in the less experienced groups (< 5 years) (97.9%) (Figure 2).

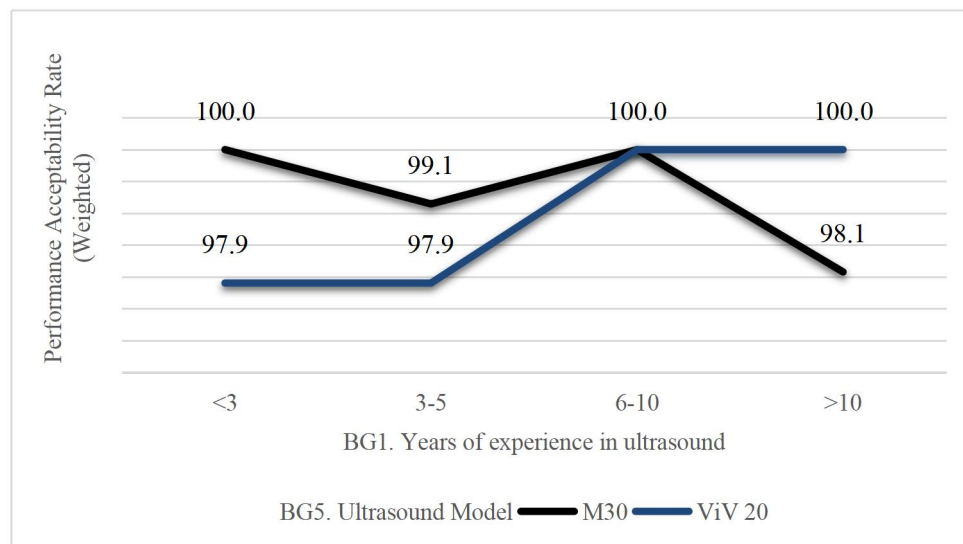


Figure 2 Acceptability Rate Across Experience Levels and Models

4 DISCUSSION

This multi-center PMCF survey provides robust real-world evidence supporting the safety and performance of the M30/ViV 20 Color Doppler Ultrasound System. The strength of this survey lies in its dual-endpoint design: the primary binary analysis offers a clear, rule-based conclusion regarding device acceptability, while the secondary ordinal analysis provides clinically meaningful nuance.

4.1 Safety and Performance

The zero incidence of electric shock and burns is a critical finding, confirming the device's adherence to stringent electrical and thermal safety standards in heterogeneous clinical environments. Furthermore, the high acceptability rates (with lower CI bounds exceeding 84.4%) across image quality and operational metrics indicate that the device consistently meets the daily diagnostic needs of clinicians, from obstetrics to cardiology.

4.2 Granular Insights from Ordinal Data

Secondary analysis of individual ordinal items revealed that while overall performance was excellent, several user-interface and operational aspects showed relatively lower top-box scores, particularly Workflow logic (51.3% Excellent) and Measurement accuracy (34.2% Excellent). These findings suggest opportunities for incremental improvement in workflow design and measurement consistency. These observations are consistent with current trends in ultrasound system development, where improvements in image quality, together with the rapid adoption of AI-driven automation, have highlighted workflow efficiency and usability as critical priorities for next-generation ultrasound systems [10-12].

In contrast, the System crashes indicator demonstrated high stability (None/Rare combined acceptability of 100%), which is an important reliability benchmark for point-of-care ultrasound systems.

4.3 Comparison with Performance Goals

Compared with pre-market controlled trials, real-world evaluations generally involve more heterogeneous patient populations, including individuals with higher BMI, complex pathology, and varying operator experience. Consequently, performance outcomes may be slightly lower or more variable than those observed under controlled trial conditions [13-14]. Nevertheless, our primary endpoint results, which strictly counted "Fair" as unacceptable, validate that the device remains effective even when not used under ideal conditions.

4.4 Limitations

Several limitations should be acknowledged. First, this was a cross-sectional survey based on subjective user perception rather than objective phantom-based or quantitative image quality measurements. Inter-rater reliability was not assessed (e.g., using Cohen's kappa or intraclass correlation coefficient). Second, the sample size may limit the generalizability of the findings to all clinical sub-specialties and geographic regions. Third, evaluator recruitment was voluntary, which may introduce selection bias and resulted in a limited number of questionnaires per center (though the diverse baseline characteristics of the evaluators help mitigate this concern).

5 CONCLUSION

In conclusion, the results of this PMCF survey demonstrate that the Zoncare Color Doppler Ultrasound System is both safe and effective in real-world clinical use. The primary endpoint confirmed high acceptability rates across all key performance domains, with a 0% safety incident rate. The secondary ordinal analysis provided valuable granular data, identifying specific strengths in image quality and stability, while highlighting minor workflow aspects that could benefit from future refinement. Ongoing post-market surveillance is warranted to monitor long-term device safety and performance.

COMPETING INTERESTS

The authors have no relevant financial or non-financial interests to disclose.

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