

PRODUCT MZS-5635	FREQUENCY ≥ 35 kHz	BATH TEMP. 18-70 °C	STANDARD TEST 5 min
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1. Intended use

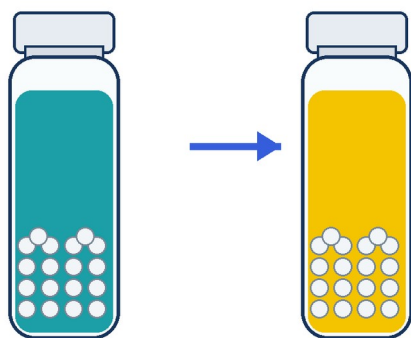
MZS-5635 is a single-use, sealed colorimetric vial for qualitative and comparative monitoring of cavitation activity in ultrasonic cleaning baths. It supports routine functional checks, periodic cavitation mapping and post-service checks in healthcare, laboratory and industrial ultrasonic cleaning systems.

Scope limitation: The indicator does not provide a calibrated acoustic value and does not directly verify instrument cleanliness, residual protein removal, disinfection or sterilization.

2. Product description

MZS-5635 Vial Construction

Not to scale



Before use **Acceptable endpoint**

2 mL clear glass vial | 31 mm high x 11 mm OD | 1.5 mL solution
 16-20 glass beads | bead diameter 3.0 +/- 0.2 mm

Vial	Clear glass, 2 mL nominal capacity
Dimensions	31 mm high x 11 mm outside diameter
Solution	1.5 mL blue-green reactive solution
Cavitation elements	16-20 glass beads per vial
Bead diameter	3.0 +/- 0.2 mm
Readout	Visual colorimetric endpoint

3. Test types

- Routine Cavitation Function Test - economical trending at one or more defined reference positions; normally performed daily or weekly according to facility policy.
- Periodic Cavitation Mapping Test - distributed assessment at initial setup, at planned intervals, after repair or when a routine result is unsatisfactory.
- MZS-5635 may be one component of qualification or requalification. Use of the vial alone does not constitute complete IQ, OQ or PQ.

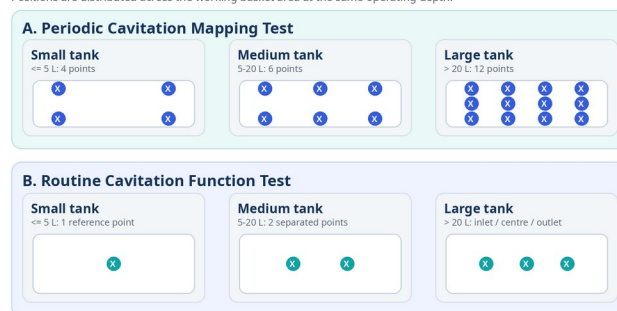
4. Preparation

1. Confirm that the vial is sealed, undamaged, within expiry and blue-green before use.
2. Prepare water and detergent according to the ultrasonic-cleaner and detergent manufacturers' instructions.
3. Fill to the defined operating level and degas the bath according to the equipment instructions.
4. Confirm the bath temperature is within 18-70 °C.
5. Use an empty basket or tray without instruments or production load.
6. For meaningful trending, keep liquid level, chemistry, temperature, degassing, basket, position and test time consistent.

5. Minimum recommended layouts

Minimum Recommended Test Layouts

Positions are distributed across the working basket area at the same operating depth.

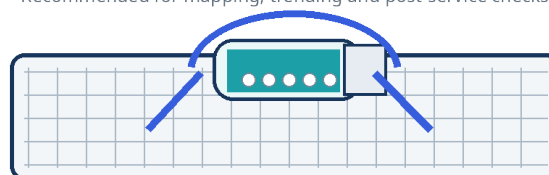


- Multi-level systems: for routine testing, use at least one vial in each basket on every level. For mapping, treat each level as a separate test plane.
- Multi-bay systems: treat each bay as an independent tank and apply the selected layout to each bay.
- Irregular geometry, independent transducer zones or equipment-specific protocols may require additional positions.

6. Positioning and holder

Reusable holder for a fixed test position

Recommended for mapping, trending and post-service checks.



A dedicated holder is not mandatory for basic use. The reusable MEDIWISH vial holder is recommended for mapping, trending and post-service checks to maintain a fixed, reproducible position and orientation.

Position requirement: Keep every vial sealed, fully submerged and horizontal for the entire ultrasonic cycle.

7. Test procedure

1. Place the required vial(s) at the defined position(s) in the empty basket or tray.
2. Start an uninterrupted 5-minute ultrasonic cycle.
3. Do not interpret an exposure shorter than 3 minutes. Short or interrupted exposure may produce a transient or unstable response.
4. Remove the vial(s) immediately after the ultrasonic stage.
5. Read and record the result as soon as practical - preferably within 1 minute and no later than 5 minutes after cycle completion.
6. Record cleaner ID, test position, bath temperature, cycle, REF, LOT, EXP, time to yellow, result, operator and corrective action.

8. Interpretation at the defined read time

OBSERVED STATE	RESULT	ACTION / MEANING
Blue-green before processing	UNPROCESSED	Initial state; do not use if the vial is not blue-green before exposure.
Transparent yellow by 5 min	ACCEPTABLE	Specified endpoint achieved at the tested location.
Green or light green at 5 min	UNSATISFACTORY	Incomplete or delayed response. Investigate conditions and repeat.
Blue-green / no visible change at 5 min	FAIL	No visible response under the applied conditions.

Delayed response (diagnostic only): If the solution becomes yellow only after 5 minutes but within 7 minutes, record DELAYED RESPONSE. This is not a standard acceptable result. Review degassing, temperature, chemistry, load, position and equipment condition. If yellow is not reached by 7 minutes, record FAIL.

Timing note: Color transition may begin within the first minute, but final interpretation is based on the defined cycle endpoint. Any later fading, drift or reversal must not be used to change the result recorded at the prescribed read time.

9. Comparative use of time-to-yellow

Under otherwise identical test conditions, a shorter time to the yellow endpoint generally indicates a stronger relative cavitation response at the tested location.

Do not directly compare time-to-endpoint values when the equipment, temperature, liquid, detergent concentration, degassing, load, position or test duration differ. The result is relative and is not a measurement in dB, W/cm² or another physical unit.

10. Troubleshooting

OBSERVATION	POSSIBLE FACTORS	ACTION
No change	Insufficient cavitation; poor degassing; incorrect level; equipment fault	Verify bath preparation, degas and repeat. Contact service if repeated.
Green at 5 min	Reduced response; poor degassing; temperature/chemistry/position variation	Standardize conditions and repeat; perform mapping if localized.
Different results by position	Non-uniform distribution or inconsistent placement	Use holder, repeat full mapping and inspect transducer zones.
Early/rapid yellow	Stronger relative response under the applied conditions	Continue the full defined cycle and record actual time-to-yellow.

11. Automated washer limitation

Ultrasonic stage only: MZS-5635 may be used in an automated washer only when a separately accessible ultrasonic cleaning stage operates within the specified product conditions. Remove the vial immediately after that stage and before thermal disinfection, high-temperature rinsing or drying. Do not process through a complete washer-disinfector cycle unless that exact cycle has been specifically validated by MEDIWISH.

12. Safety and precautions

- For professional use only. Keep out of reach of children.
- Single-use product. Do not reuse, open, puncture or intentionally empty the vial.
- Do not use a cracked, leaking, discolored, expired or otherwise damaged vial.
- Handle the glass vial carefully. Wear suitable gloves and eye protection when handling breakage or leakage.
- Do not ingest. Avoid contact of vial contents with skin and eyes.
- Do not use for non-ultrasonic cleaning cycles or as a direct test of instrument cleanliness.

13. Storage and shelf life

Storage	2-25 °C in the original packaging
Protection	Protect from direct light and heat
Freezing	Do not freeze
Shelf life	24 months from the date of manufacture when stored under the specified conditions
Packaging	MZS-5635: 25 vials/box; MZS-5635-30: 30 vials/box

14. Disposal and breakage

Dispose of intact used vials according to facility policy and applicable local regulations for glass items used in decontamination areas. Do not discharge the indicator solution to drains.

If breakage or leakage occurs, restrict access, wear appropriate gloves and eye protection, collect glass mechanically, absorb liquid with inert material, and follow the facility spill and waste procedures.

15. Documentation and traceability

MEDIWISH TRACEABILITY LABEL	
REF	MZS-5635
LOT	20260701
EXP	2028-07-01
VIAL / POSITION	___ / ___

Each vial is supplied with lot traceability. A removable self-adhesive label carries REF, LOT, EXP and Vial/Position No. A 25-test record sheet is included with the standard box and downloadable routine and mapping records are available from MEDIWISH.

Color reference warning: Screen calibration, ambient lighting and printing conditions can affect perceived colors. Use the current printed MEDIWISH color reference under neutral white light whenever possible.

16. Manufacturer and quality management

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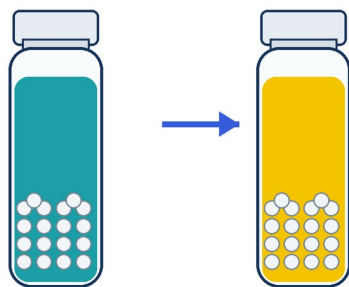


Product page and current documents

Manufactured under a quality management system certified to ISO 13485:2016 by NQA, Certificate No. 131860, valid through 30 November 2028.

MZS-5635 Vial Construction

Not to scale



Before use **Acceptable endpoint**

2 mL clear glass vial | 31 mm high x 11 mm OD | 1.5 mL solution
 16-20 glass beads | bead diameter 3.0 +/- 0.2 mm

Product overview: Ready-to-use, single-use colorimetric vial for routine monitoring, comparative trending and mapping of cavitation activity in ultrasonic cleaning baths.

Scope limitation: Visual qualitative/comparative endpoint only. Not a calibrated dB or W/cm² meter and not a direct cleanliness, disinfection or sterilization test.

Physical specification

Product codes: MZS-5635 (25/box); MZS-5635-30 (30/box)

Format: Sealed clear-glass colorimetric vial

Nominal vial capacity: 2 mL

Vial dimensions: 31 mm high x 11 mm outside diameter

Indicator solution: 1.5 mL; blue-green initial color

Cavitation elements: 16-20 glass beads

Bead diameter: 3.0 +/- 0.2 mm

Endpoint: Transparent yellow

Readout: Visual colorimetric

Reusability: Single use

Traceability

- Removable label: REF, LOT, EXP and Vial/Position No.
- Multi-test record sheet included in the standard box.
- Routine and mapping records downloadable from MEDIWISH.

Test and interpretation

Minimum interpretable exposure: 3 minutes

Standard MEDIWISH cycle: 5 minutes, uninterrupted

Diagnostic extension: Up to 7 minutes after an unsatisfactory 5-minute endpoint

Typical onset: Color transition may begin within the first minute

Read time: Immediately; preferably within 1 minute; no later than 5 minutes

Acceptable: Transparent yellow by 5 minutes

Unsatisfactory: Green/light green at 5 minutes

Fail: No visible change / blue-green at 5 minutes

Delayed: Yellow only after >5 to 7 minutes; investigate and repeat

Relative timing

Under otherwise identical conditions, a shorter time to yellow generally indicates a stronger relative response at the tested location.

Do not compare endpoint times when equipment, liquid, detergent concentration, temperature, degassing, load, position or test duration differ.

Minimum layouts

Periodic mapping: <=5 L: 4; 5-20 L: 6; >20 L: 12 positions

Routine function: <=5 L: 1; 5-20 L: 2; >20 L: 3 positions

Multi-level: At least one vial per basket per level for routine testing

Multi-bay: Treat each bay as an independent tank

Intended use and applications

- Routine Cavitation Function Test (daily or weekly according to facility policy)
- Periodic Cavitation Mapping Test at setup, planned intervals or after repair
- Post-service checks and investigation of uneven cavitation response
- Tabletop, single-chamber, multi-level and multi-bay ultrasonic systems
- Automated washers only during a separately accessible ultrasonic stage

>= 35 kHz | 18-70 °C | 5 min standard cycle

Read within 5 min | 25 / 30 vials per box | 24-month shelf life

Storage and packaging

Storage: 2-25 °C in original packaging

Protection: Protect from direct light and heat

Freezing: Do not freeze

Shelf life: 24 months from date of manufacture under specified conditions

Standard pack: MZS-5635: 25 vials/box

Pack variation: MZS-5635-30: 30 vials/box

Automated washer limitation

Use only during a separately accessible ultrasonic stage. Remove before thermal disinfection, high-temperature rinsing or drying. Do not process through a complete washer-disinfect cycle unless specifically validated by MEDIWISH.

Manufacturer / QMS

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Quality management system certified to ISO 13485:2016 by NQA, Certificate No. 131860, valid through 30 November 2028.

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Product page and current documents

Read and record the result immediately after the 5-minute cycle - preferably within 1 minute and no later than 5 minutes after cycle completion.

UNPROCESSED Blue-green before exposure Initial state. Do not use if the vial is not blue-green before processing.	ACCEPTABLE Transparent yellow by 5 minutes Specified indicator endpoint achieved at the tested location.
UNSATISFACTORY Green or light green at 5 minutes Incomplete or delayed response. Investigate conditions and repeat.	FAIL Blue-green / no visible change at 5 minutes No visible response under the applied test conditions.
Delayed response: Yellow reached only after 5 minutes but within 7 minutes = DELAYED RESPONSE. This is not a standard acceptable result. Investigate and repeat. No yellow by 7 minutes = FAIL.	
Important timing rule: Do not interpret an exposure shorter than 3 minutes. Any later color drift, fading or reversal must not be used to change the result recorded at the prescribed read time.	
Color-display warning: Screen calibration, ambient lighting and printing conditions may affect the apparent color. Use the current printed MEDIWISH reference under neutral white light whenever possible.	
Relative timing: under otherwise identical test conditions, a shorter time to yellow generally indicates a stronger relative response. Do not compare different machines or different bath conditions as if this were a calibrated physical measurement.	

Facility	Department	Cleaner ID	Make / Model	Tank volume	Frequency	Detergent / conc.	Reference position

Defined routine method: empty basket/tray; bath prepared and degassed; 5-minute uninterrupted cycle; read immediately (preferably within 1 minute, no later than 5 minutes).

No.	Date	Cleaner ID	REF / LOT / EXP	Vial / Pos.	Temp °C	Cycle	Time to yellow	Result	Operator	Corrective action / sign-off
1								A / U / F		
2								A / U / F		
3								A / U / F		
4								A / U / F		
5								A / U / F		
6								A / U / F		
7								A / U / F		
8								A / U / F		
9								A / U / F		
10								A / U / F		
11								A / U / F		
12								A / U / F		
13								A / U / F		
14								A / U / F		
15								A / U / F		
16								A / U / F		
17								A / U / F		
18								A / U / F		
19								A / U / F		
20								A / U / F		
21								A / U / F		
22								A / U / F		
23								A / U / F		
24								A / U / F		
25								A / U / F		

Result codes: A = Acceptable yellow by 5 min; U = Unsatisfactory green/light green at 5 min; F = Fail / no visible change.

Yellow only after >5 to 7 min: record DELAYED in corrective-action field; investigate and repeat.

Any later color drift does not replace the result recorded at the prescribed read time.

Facility	Department	Cleaner ID	Make / Model	Tank volume	Frequency	Detergent / conc.	Mapping reason
							Initial setup ☐ Periodic ☐ Post-service ☐ Deviation investigation ☐

Minimum Recommended Test Layouts

Positions are distributed across the working basket area at the same operating depth.

A. Periodic Cavitation Mapping Test

Small tank

<= 5 L: 4 points



Medium tank

5-20 L: 6 points



Large tank

> 20 L: 12 points



B. Routine Cavitation Function Test

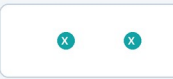
Small tank

<= 5 L: 1 reference point



Medium tank

5-20 L: 2 separated points



Large tank

> 20 L: inlet / centre / outlet



Layout selection: Use 4 positions for <=5 L, 6 for 5-20 L and 12 for >20 L. Treat each bay independently. For multi-level systems, map every level as a separate test plane.

Controlled conditions

Bath temperature (°C)	
Liquid fill level	
Degassing method/time	
Basket / holder configuration	
Standard test time	5 minutes
Read time after cycle	
Reference solution / detergent	

Comparability rule: Do not compare endpoint times if the equipment, liquid, detergent concentration, temperature, degassing, load, position or cycle differ.

Pos.	Level / Bay	Location	Temp °C	Time to yellow	Result	Retest
P1					A / U / F	☐
P2					A / U / F	☐
P3					A / U / F	☐
P4					A / U / F	☐
P5					A / U / F	☐
P6					A / U / F	☐
P7					A / U / F	☐
P8					A / U / F	☐
P9					A / U / F	☐
P10					A / U / F	☐
P11					A / U / F	☐
P12					A / U / F	☐

Mapping conclusion

Overall result	Acceptable ☐ Unsatisfactory ☐ Fail ☐
Action	Return to service ☐ Repeat after correction ☐ Service required ☐
Reviewed by	Name / signature: _____ Date: _____