

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

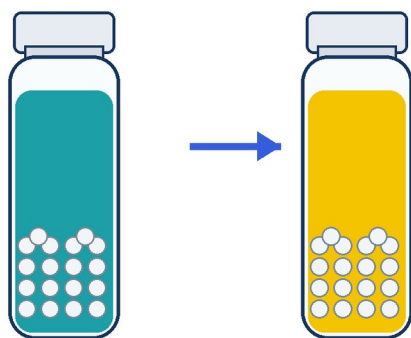
MZS-5635 is a single-use, sealed colorimetric vial for qualitative and comparative monitoring of cavitation activity in ultrasonic cleaning baths. It supports routine functional checks, periodic cavitation mapping and post-service checks in healthcare, laboratory and industrial ultrasonic cleaning systems.

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.

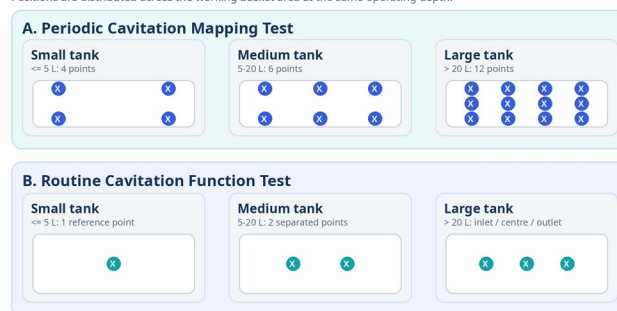
4. Preparation

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.

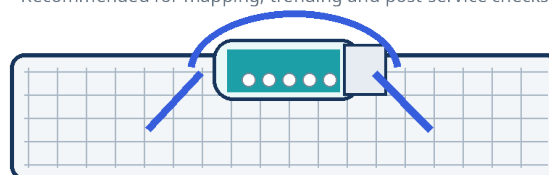


- Multi-level systems: for routine testing, use at least one vial in each basket on every level. For mapping, treat each level as a separate test plane.
- Multi-bay systems: treat each bay as an independent tank and apply the selected layout to each bay.
- Irregular geometry, independent transducer zones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