

**Ultrasonic washers
in medical device
reprocessing:**
Performance verification
& cavitation energy
monitoring

1. Introduction: Why cleaning comes first

In medical device reprocessing, cleaning is not a preliminary step – It is the most critical step. Any failure at this stage directly compromises the effectiveness of all subsequent disinfection and sterilization processes, ultimately putting patient safety at risk. This principle, well established in infection control science and reinforced by international guidelines, has driven growing interest in ultrasonic cleaning technologies over the past two decades.

Ultrasonic washers represent a specialized and indispensable cleaning modality designed for instruments with complex geometries: blind holes, fine crevices, internal lumens, jointed mechanisms, and optic or robotic components – areas where manual brushing or standard water pressure cannot reliably reach.

Core principle: If cleaning fails, sterilization fails
Residual organic soil on instrument surfaces acts as a physical barrier that prevents sterilizing agents – whether steam, chemical, or radiation – from reaching and inactivating all microbial contamination. A soiled instrument that appears “sterilized” may still carry viable pathogens. This is why ultrasonic cleaning is not optional for complex medical devices: it is a patient safety requirement.

2. The science of ultrasonic cleaning: cavitation

The unique cleaning efficacy of ultrasonic washers relies on a physical phenomenon called acoustic

cavitation. Understanding this mechanism is essential for appreciating why performance verification is both necessary and complex.

2.1 How cavitation works

Transducers bonded to the tank walls convert electrical energy into high-frequency sound waves (typically 35–45 kHz for medical device applications). These waves propagate through the cleaning solution, generating rapid alternating cycles of high and low pressure:

- **Formation:** Low-pressure phases cause water molecules to pull apart, generating microscopic vapor bubbles (cavities).
- **Inversion:** The bubbles grow and begin to collapse inward as pressure increases.
- **Compression:** High-pressure phases force the bubbles to implode violently.
- **Implosion:** Each collapsing bubble releases a high-energy microjet of liquid directed at adjacent surfaces – the mechanical force that dislodges soil from crevices, lumens, and joints.

Although invisible to the naked eye, the localized temperatures and pressures generated within each imploding cavitation bubble are extraordinarily intense. This is what gives ultrasonic cleaners their unique ability to penetrate and clean areas inaccessible to any other method.

2.2 Critical parameters that govern cavitation energy

Cavitation is not an on/off phenomenon. Its energy, intensity, and distribution within the tank are continuously modulated by multiple interacting variables:

Parameter	Technical significance
Frequency	Medical devices require 35–45 kHz. Too low = destructive cavitation; too high = reduced bubble formation.
Temperature	Optimal 60°C. Excessive heat creates vapor bubbles that cushion implosion, reducing energy transfer.
Water quality	Dissolved gases, ions, and impurities all alter cavitation efficiency. Pre-treated water is recommended (ANSI/AAMI ST108:2023 guidance).
Detergent	Low-foaming enzymatic formulations are required. High-foam detergents generate air bubbles that suppress cavitation.
Degassing	Mandatory before each use. Dissolved air in fresh solution absorbs ultrasonic energy, dramatically reducing cavitation intensity.
Basket & load	Overloading or using dense mesh baskets attenuates the ultrasonic wave before it reaches instruments.
Transducer condition	Individual transducer failure is silent and invisible – a malfunctioning transducer produces no sound, no error, and no visible sign.

3. The invisible risk: Why verification cannot be assumed

The single most important – and most frequently underestimated – characteristic of ultrasonic cavitation is that it is entirely invisible to the human eye. A machine that appears to be operating normally – with water, detergent, correct temperature, and audible hum – may be delivering severely insufficient, non-uniform, or zero cavitation energy.

3.1 Sources of silent process failure

- Transducer degradation or failure: Individual transducers can fail without triggering any alarm. In large-volume tanks with 15–50+ transducers, one or more may be non-functional, creating cold spots where instruments receive no ultrasonic energy – yet the machine continues to run.
- Solution contamination: Accumulated soil bioburden from previous cycles suppresses cavitation capacity, especially when solution is not changed frequently.
- Dissolved gas accumulation: Without proper degassing, dissolved air forms a damping layer that absorbs ultrasonic energy before cavitation can form.
- Chemical imbalance: Incorrect detergent concentration or the use of high-foaming products can reduce cavitation energy by 30–60%.
- Temperature drift: Even small deviations from optimal temperature ranges significantly alter bubble formation dynamics.

⚠ *The soaking tank risk*

Without verified cavitation, an ultrasonic washer functions as nothing more than an expensive soaking tank. Instruments emerge wet, apparently clean, but potentially contaminated in blind holes and lumens where passive soaking has no mechanical cleaning effect. These are precisely the areas ultrasonic cleaning is chosen to address – and the areas most likely to harbor residual viable pathogens.

3.2 The energy optimization challenge: Too little vs. too much

Cavitation energy must be calibrated within an optimal range. This is a critical concept often

overlooked in routine practice:

- Insufficient energy: Soil remains on instruments in crevices, lumens, and blind holes. Sterilization is compromised. Patient infection risk increases.
- Excessive energy: Prolonged or excessive cavitation causes permanent mechanical damage to delicate surgical instruments, optics, fiber optics, and microsurgical tools – representing significant financial and clinical risk.

Finding and maintaining this optimal window requires quantifiable, objective, and reproducible measurement – not visual estimation.

4. Regulatory landscape & best practices: What standards actually say

This section addresses a question that frequently arises in clinical practice: Are there specific mandatory regulations for ultrasonic washer performance verification? The answer requires careful nuance – and understanding it is essential for correctly positioning cavitation monitoring as a professional obligation, not an optional add-on.

4.1 The current regulatory reality

No single dedicated international ISO standard exists that specifically mandates cavitation energy quantification for ultrasonic washers in CSSD settings. However, this absence of a specific standard does not imply absence of obligation – and multiple authoritative frameworks address the requirement directly or indirectly.

Key regulatory principle

The complexity of the cavitation process – with its multiple interacting variables, invisible failure modes, and potential for both under- and over-performance – is itself the scientific rationale for mandatory verification. The regulatory frameworks below recognize this complexity and respond to it with explicit verification requirements.

4.2 International and regional regulatory frameworks

Framework	Scope / Region	Relevant provision on ultrasonic verification
ANSI/AAMI ST79:2017/(R)2022 w/ Amds A1–A4:2020 §7.6.4.3.3 & Annex D3	USA (widely adopted internationally)	Explicitly requires daily cavitation testing whenever the equipment is in use. Specifies routine tests (per solution change) and periodic functional tests (commissioning, repair, relocation). Annex D3 defines indicator placement protocols. Base standard 2017; reaffirmed 2022 with four amendments. Major revision in progress (initiated Sept. 2025).

Framework	Scope / Region	Relevant provision on ultrasonic verification
The Joint Commission (TJC)	USA hospital accreditation (global influence)	Requires healthcare facilities to identify, maintain, inspect, and test all inventoried medical equipment. Ultrasonic cleaners are explicitly included. Non-compliant cavitation verification can result in accreditation findings.
AORN Perioperative Standards	USA / International perioperative practice	Recommends daily testing of the cleaning process for all ultrasonic cleaners in use. Specifically supports cavitation performance verification as a best practice for safe instrument reprocessing.
HTM 01-01 Part D (NHS England, 2016)	United Kingdom	Mandates validation and periodic cavitation activity testing. Defines critical variables: frequency 35 kHz \pm 5 kHz, energy input 5-20 W/L. Requires commissioning tests and periodic revalidation after repairs or relocation.
WHTM 01-01 Part D (NHS Wales, 2019)	Wales / UK	Defines frequency, amplitude, and power as critical variables for ultrasonic cleaners. Specifies that cycle time and process parameters must be validated and documented. Periodic functional verification required.
HTM 01-05:2013 (NHS England)	UK Dental Settings	HTM 01-05 (England, 2013): requires quarterly foil ablation tests and weekly protein residue tests; mandates degassing before each use; cavitation monitoring logbook required.
ISO 15883-1:2024 / ISO 15883-2:2024 (EN ISO 15883-1:2025 / EN ISO 15883-2:2025)	International	Major revision published 2024 (adopted as European standard in 2025). Part 1 establishes general requirements, validation, routine control, and requalification for all washer-disinfectors. Part 2 covers thermal disinfection for critical and semi-critical devices. Referenced in national HTMs globally.
KRINKO/BfArM Recommendation (2012)	Germany	KRINKO recommendation has regulatory force via §23.1 of the German Infection Protection Act (IfSG) and was incorporated into §8 of the Medical Devices Operator Ordinance (MPBetreibV). Mandates validated, automated cleaning procedures including ultrasonic cleaning as a recognized pre-cleaning step.
AS 2773:2019 - Ultrasonic Cleaners for Health Service Organisations	Australia	The only national standard in the world dedicated exclusively to ultrasonic cleaners in healthcare settings. Specifies equipment requirements for ultrasonic cleaners used to clean reusable medical and surgical devices. Mandates daily performance (cavitation) testing. Referenced normatively in AS 5369:2023.
AS 5369:2023 - Reprocessing of Reusable Medical Devices	Australia / New Zealand	Replaced AS/NZS 4187:2014 in 2023. Comprehensive reprocessing standard that explicitly lists applicable standards for ultrasonic cleaners (referencing AS 2773:2019) alongside washer-disinfectors and sterilizers. Requires routine performance qualification of automated cleaning processes. Aligned with ISO 15883.

4.3 Why process complexity is itself the regulatory justification

The question of whether a specific standard mandates cavitation verification may miss the more fundamental point: the scientific and clinical logic for verification is overwhelming, and multiple frameworks reflect this through explicit recommendations.

Consider the following reasoning chain recognized across regulatory frameworks:

- Ultrasonic cleaners are selected specifically to clean areas unreachable by other methods.
- Those areas (lumens, blind holes, crevices) are also the areas most likely to harbor viable pathogens post-sterilization.
- Cavitation is the only mechanism that cleans those areas – and it is invisible and subject to silent failure.
- Therefore, verifying cavitation energy is not optional monitoring – It is the only way to confirm the process that the washer was specifically selected to perform is actually occurring.

Regulatory bottom line for healthcare facilities

AAMI ST79:2017/(R)2022, the most widely adopted comprehensive guide internationally, is unambiguous: perform cavitation testing daily whenever the equipment is in use. The Joint Commission's equipment inspection requirements create additional accountability. Australia's AS 2773:2019 is the only national standard worldwide dedicated exclusively to ultrasonic cleaners, and also mandates daily testing. Germany's KRINKO/MPBetreibV framework adds regulatory force in the European context. For facilities seeking international accreditation (JCI, ISO 9001 for healthcare, ACHS), documented cavitation verification is increasingly expected as evidence of process control in medical device reprocessing.

5. Chemdye® CDWU – CDWU-Z: Making the invisible visible

The Chemdye® CDWU and CDWU-Z Ultrasonic Cavitation Performance Test is an indicator system specifically designed to detect and signal the presence of adequate cavitation energy at a given location within an ultrasonic washer bath (see Figure 1).

Figure 1. A. Chemdye® CDWU-Z composition and intended use. Color change range upon exposure to cavitation. CDWU-Z contains the blue-reactive solution and zirconium cylinders. **B.** Chemdye® CDWU photograph to see the similarity with CDWU-Z (composition and intended use is the

same, except that CDWU contains glass beads instead of zirconium cylinders). For more information about these products, refer to www.terragence.com and search for the specific SKUs.

Figure 1.A



Figure 1.B



5.1 Mechanism of action

The Chemdye® CDWU and CDWU-Z consist of a sealed glass ampoule containing a reactive blue solution with glass beads / zirconium cylinders immersed in it (Figure 1). When placed in an ultrasonic bath with active cavitation:

- The cavitation energy causes mechanical vibration of the glass beads / zirconium cylinders within the reactive solution.
- This triggers a chemical reaction that produces a progressive color change from blue through shades of green toward yellow.
- A fully yellow result (accepted color) indicates that sufficient cavitation energy was delivered at that location.

- Any result remaining blue or green indicates insufficient cavitation energy – a process failure requiring investigation before instruments can be processed.

5.2 Usage protocol

Routine test

(Daily / per solution change)

- Perform after degassing, before instrument load
- Place 1–3 indicators (size/tank dependent)
- Rotate position between changes to map full tank

- Read result within 30 minutes of exposure
- Document and retain record before disposal

Periodic functional test

(Commissioning, repair, relocation)

- Map all transducer positions using manufacturer layout
- Place indicator in each transducer zone
- Identify cold spots and non-functional transducers
- Document all results as part of equipment qualification record
- Repeat after any repair or significant relocation

5.3 Technical specifications

Temperature Range	Room temperature up to 70°C (covers full clinical range of ultrasonic washer operation)
Frequency Range	Optimized for ~35 kHz (±5 kHz) – the internationally recommended range for medical device cleaning
Color Reversion	Reactive solution reverts post-exposure. Read and record immediately for better results (tolerance: 30 minutes).
Disposal	Sharp waste (glass ampoule). Contents are not classified as biohazardous, but glass requires appropriate disposal.
Holder System	Dedicated holders position the ampoule securely in the bath, preventing displacement by tank vibration. See CDWU-H.

6. Bionova® CaviTest: Objective quantification of cavitation energy

Bionova® CaviTest (Figure 2) is the first automated reading system designed to standardize and digitize the interpretation of Chemdye® CDWU / CDWU-Z indicators, transforming a subjective visual judgment into an objective, quantifiable, and traceable result.

6.1 The problem with visual interpretation

Traditional visual reading of cavitation indicators presents three systemic challenges in clinical practice:

- Subjectivity: Color perception varies between individuals, under different lighting conditions, and with borderline shades. A "near-yellow" result may be passed by one operator and failed by another.
- Operational uncertainty: Without standardized numerical criteria, staff may hesitate in borderline situations, leading to inconsistent corrective action.

- Traceability gap: Visual readings leave no permanent record. Once the indicator is discarded, no audit trail exists – limiting trend analysis, equipment performance monitoring, and regulatory compliance documentation.

6.2 System components and workflow

Bionova® CaviTest (Figure 2) is designed for simplicity and speed in a CSSD environment:

- Three independent reading positions with individual activation buttons.
- Instant result – no incubation, no waiting. The reader is an optical colorimeter, not an incubator.
- Dual result indication: Green LED (PASS) or Red LED (FAIL) for immediate visual feedback.
- Integrated thermal printer: Automatically prints a dated, timestamped ticket with device ID, serial number, position used, program, date/time, cavitation index, and PASS/FAIL result.
- USB connectivity: Integration with Bionova® software platforms for electronic data management and audit trail maintenance.
- Reprint function: Last 3 readings can be reprinted in case of label loss or verification need.



Figure 2. Bionova® CaviTest design and components. For more information please visit our website: www.terrigen.com.

6.3 Bionova® CaviTest technology: RGB to cavitation index

Bionova® CaviTest eliminates subjectivity through precise optical measurement:

- The reader measures light transmittance of the indicator solution using RGB (Red, Green, Blue)

color sensing.

- RGB values are mathematically converted to HSV parameters (Hue, Saturation, Value/Brightness) – a color space optimized for precise shade discrimination.
- These parameters are converted into a numerical Cavitation Index (CI) on a scale of 0 to 130:

CI value	Indicator color	Result	Interpretation
≥ 100	Yellow	PASS	Cavitation acceptance criteria met. Equipment may proceed to normal use.
70 – 99	Greenish yellow – Green	FAIL	Marginal cavitation energy. Approaching but not meeting acceptance criteria. Follow departmental corrective action protocol before processing instruments.
1 – 69	Green – Blueish green	FAIL	Partial cavitation energy delivered. Insufficient for reliable cleaning. Follow departmental corrective action protocol before processing instruments.
0	Blue	FAIL	No significant cavitation energy detected. Indicator classified as unprocessed. Follow departmental corrective action protocol before processing instruments.

6.4 Why the cavitation index matters beyond pass/fail

The numerical cavitation index provides value beyond the binary result:

- Trend monitoring: Declining CI values over time signal gradual transducer degradation before outright failure – enabling predictive maintenance.

- Spatial mapping: CI values across different tank positions reveal distribution uniformity or emerging cold spots.
- Documentation compliance: Printed records with timestamps satisfy audit and accreditation requirements that visual readings cannot provide.
- Decision clarity: Staff are freed from subjective color judgment – the instrument makes the determination, removing hesitation and error.

7. Comparison: visual approach vs. Bionova® CaviTest system

Feature	Visual reading	Bionova® CaviTest automated reader
Interpretation	Subjective (operator-dependent)	Objective (instrument-based, calibrated, numerical)
Quantification	Binary / qualitative (green or yellow)	Cavitation Index 0-130 (quantitative)
Traceability	None (record lost when indicator is discarded)	Printed ticket + USB/software record
Color reversion risk	High (result may change before reading)	Mitigated by instant, auto-recorded reading
Trend analysis	Not possible	Full numerical trend tracking over time
Audit support	Limited / manual logbook	Complete digital audit trail

8. Clinical and institutional implications

8.1 Patient safety

Inadequate cleaning of complex instruments – particularly those with lumens, blind holes, or articulating joints – has been directly linked to healthcare-associated infection outbreaks in the literature. Ultrasonic cleaning is specifically selected to address these high-risk areas. Verifying that it actually works is therefore a direct patient safety obligation.

8.2 Instrument lifecycle protection

Excessive cavitation energy causes permanent damage to delicate microsurgical instruments, endoscopes, robotic arms, and optic components. Bionova® CaviTest's quantitative CI enables facilities to document not only that cavitation is sufficient, but that it remains within the safe upper range – protecting a significant capital investment.

8.3 Regulatory and accreditation readiness

For facilities seeking or maintaining JCI, TJC, ISO 9001, or national health authority accreditation, documented cavitation verification is increasingly a standard expectation. Bionova® CaviTest provides the documented, timestamped, operator-attributed records that satisfy audit requirements – records that visual reading cannot produce.

8.4 Adapting to evolving medical devices

Robotic surgical systems, single-use/reusable

hybrid instruments, and next-generation minimally invasive devices create increasingly complex reprocessing requirements. Monitoring technologies must evolve in parallel. Quantitative cavitation measurement represents the necessary next step in CSSD process maturity.

9. Practical recommendations for healthcare facilities

Recommended practice protocol for ultrasonic washers

The following steps represent current best practice aligned with AAMI ST79:2017, TJC requirements, and NHS HTM guidance. They should be incorporated into CSSD standard operating procedures (SOPs) and staff training programs.

- Degas before every use: Run the full degassing cycle with fresh solution before each session. Never skip this step.
- Test daily (minimum): Perform a routine cavitation test with Chemdye® CDWU/CDWU-Z + Bionova® CaviTest reader before processing the first instrument load, and after every solution change.
- Rotate indicator positions: Systematically vary placement across the tank between tests to progressively map the full cavitation distribution over time.
- Perform periodic functional qualification: At commissioning, after any repair, and after relocation – test all transducer positions and document results

in the equipment qualification file.

- Record every result: Use Bionova® CaviTest's printed output for the immediate log and connect to digital management software for long-term trend analysis and audit readiness.
- Establish corrective action procedures: Define clear departmental protocols for what to do when a FAIL result is obtained - Including instrument quarantine, maintenance contact, and re-test requirements.
- Review trends periodically: Declining CI values are an early warning of transducer degradation. Act before failure, not after.
- Train all CSSD staff: Ensure that all operators understand why cavitation verification is required - not just how to perform it. Process understanding drives compliance.

10. Conclusion

Ultrasonic washers are indispensable tools for the safe reprocessing of complex medical devices. Their cleaning mechanism - acoustic cavitation - is powerful, precise, and entirely invisible. This invisibility is not a minor inconvenience; it is a fundamental process control challenge that defines the need for systematic, objective, and documented performance verification.

While no single ISO standard currently mandates a specific cavitation quantification method for CSSD ultrasonic washers, the combined weight of AAMI ST79:2017/(R)2022, The Joint Commission standards, AORN recommendations, NHS HTM guidance, the German KRINKO/BfArM/MPBetreibV framework, and the Australian AS 2773:2019 and AS 5369:2023 standards leaves no ambiguity: daily cavitation verification is a professional and institutional obligation. The scientific rationale - the complexity of the process, the invisibility of failure, and the direct link to patient safety - provides the strongest possible justification even in the absence of a single dedicated prescriptive standard.

The Chemdye® CDWU/CDWU-Z + Bionova® CaviTest system by Terragene S.A. represents the current state of the art in ultrasonic washer performance monitoring: moving from subjective visual estimation to objective, quantified, traceable, and actionable data. In an era of increasing regulatory scrutiny and evolving instrument complexity, this represents not just good practice, but the responsible standard of care.

Chemdye® CDWU/CDWU-Z make cavitation visible. Bionova® CaviTest makes it unquestionable.

Validate your cavitation. Control your process. Protect your instruments. Safeguard your patients.

Key references & standards

- ANSI/AAMI ST79:2017/(R)2022 w/ Amendments A1-A4:2020 - Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities (§7.6.4.3.3, Annex D3)
- ANSI/AAMI ST108:2023 - Water for the Reprocessing of Medical Devices
- The Joint Commission (TJC) - Medical Equipment Management Standards (EC.02.04.01)
- AORN Perioperative Standards and Recommended Practices - Cleaning and Processing of Surgical Instruments
- NHS Health Technical Memorandum HTM 01-01 Part D - Management and Decontamination of Surgical Instruments: Washer-Disinfectors (NHS England, July 2016)
- Welsh Health Technical Memorandum WHTM 01-01 Part D - Decontamination of Surgical Instruments: Washer-Disinfectors (NHS Wales, 2019)
- NHS Health Technical Memorandum HTM 01-05:2013 - Decontamination in Primary Care Dental Practices (NHS England)
- Scottish Health Technical Memorandum SHTM 01-05:2024 - Management, Equipment, and Process of Decontamination of Dental Instruments in an LDU (NHS Scotland, April 2024)
- ISO 15883-1:2024 / ISO 15883-2:2024 (adopted as EN ISO 15883-1:2025 / EN ISO 15883-2:2025) - Washer-Disinfectors: General Requirements, Terms, Definitions, and Tests [supersedes 2006 edition]
- KRINKO/BfArM - Hygiene Requirements for the Reprocessing of Medical Devices. Bundesgesundheitsblatt 2012, 55:1244-1310. Incorporated into German MPBetreibV (§8), last updated February 14, 2025
- AS 2773:2019 - Ultrasonic Cleaners for Health Service Organisations (Standards Australia, December 2019)
- AS 5369:2023 - Reprocessing of Reusable Medical Devices and Other Devices in Health and Non-Health Related Facilities (Standards Australia, 2023) [supersedes AS/NZS 4187:2014]
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