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# AS 5369:2023 RMD steriliser sampling information

Reusable Medical Devices (RMDs) used in dental, medical and surgical procedures are required to be cleaned, disinfected and sterilized according to AS 5369:2023. As part of compliance with the standard, feed waters and final rinse waters of washer disinfectors, thermal disinfectors, and chemical disinfectors (both automated and manual) are required to be tested. Monitoring the water on a regular basis ensures water is not too hard that it impairs the activity of detergents or cause deposits, scaling or corrosion of items processed, or that the water is not re-contaminating disinfected items with microorganisms or toxins.

AST is able to provide NATA accredited analytical results that meet the requirements of AS 5369:2023. Testing against other standards or other analytical suites is also available (eg EN 285; HTM 01-01).

## AS 5369:2023 compliance testing

Required analysis and maximum concentration levels of final rinse water quality for **manual cleaning, manual disinfection and washer-disinfectors** are specified in section 7.2.3.1, table 7.2 and table 8.1 of the standard:

| Analyte | Maximum Concentration Levels | | AST Limit of reporting |
|---|---|---|---|
| | Pre-cleaning, cleaning and rinses | Final Rinse | |
| pH | | 5.5-8 | 0.1 pH units |
| Conductivity 20°C | | 30 µS/cm | 5 µS/cm |
| Total Hardness (CaCO3) | 150 mg/L | 10 mg/L | 1 mg/L CaCO3 |
| Chloride (Cl) | 120 mg/L | 10 mg/L | 0.05 mg/L |
| Iron (Fe) | | 0.2 mg/L | 20 µg/L |
| Phosphates | | 0.2 mg/L | 0.003 mg/L |
| Silica ($SiO_2$) | | 1.0 mg/L | 0.1mg/L |
| Total Viable Count (cfu/100 mL)* | | 100 cfu/100mL | 1 cfu/mL |
| Endotoxin EU/mL | | 0.25 EU/mL | 0.1 EU/mL |

Required analysis and maximum concentration levels of final rinse water quality for **washer-disinfectors for thermolabile endoscopes** are specified in section 7.2.3.1, table 7.3 and table 8.1 of the standard:

| Analyte | Maximum Concentration Levels | | AST Limit of reporting |
|---|---|---|---|
| | Supply water | Final Rinse | |
| Total Hardness (CaCO3) | 150 mg/L | | 1 mg/L CaCO3 |
| Chloride (Cl) | 120 mg/L | | 0.05 mg/L |
| Conductivity 20°C | | As recommended by system manufacturer | 1 µS/cm |
| Total Viable Count (cfu/100 mL)* | | 10 cfu/100mL | 1 cfu/mL |
| Pseudomonas aeruginosa | | Not detected/100mL | N/A |
| (Atypical) Mycobacterium sp. | | Not detected/100mL | N/A |
| Chemical purity^ | | In accordance with WD manufacturer's recommendations | 1 µS/cm |
| Endotoxin EU/mL | | 30 EU/mL | 0.1 EU/mL |

* Total Viable Count is also known as Heterotrophic Plate Count, it is outsourced to the Public Health Laboratory.

^Water conductivity is an indicator of Chemical purity.

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Testing is required prior to equipment installation or relocation, or repair or modification, or change of type of RMD, then monthly. Endotoxin testing required annually. Test non-conformity requires corrective action and re-testing.
AST has NATA accreditation for the Bacterial Endotoxins test. The test is a limulus amoebocyte lysate (LAL) gel formation method of assessing endotoxin concentration by kinetic turbidimetric reaction time. It is currently the analytical method of choice in Australia for quantitative endotoxin analysis.
AST is co-located with a microbiological testing laboratory in New Town, Hobart. This lends itself to the convenience of a simultaneous sample drop off for both chemistry and microbiological testing. Please contact AST for further details if a single drop-off service for your chemistry and microbiology testing may be of use to you.

Required analysis and maximum concentration levels for feed water to a **dedicated steam generator for steam sterilizers** are specified in section 7.2.3.1, table 7.4 and table 8.1 of the standard:

| Analyte | Maximum Concentration Levels | AST Limit of reporting |
|---|---|---|
| | Feed water | |
| Evaporative residue# | 10 mg/L | 10 mg/L# |
| Silicates (molybdate reactive) | 1 mg/L | 0.1 mg/L |
| Iron (Fe) | 0.2 mg/L | 20 µg/L |
| Cadmium (Cd) | 0.005 mg/L | 0.1 µg/L |
| Lead (Pb) | 0.05 mg/L | 0.5 µg/L |
| Heavy Metals excluding Fe, Cd, Pb† | 0.1 mg/L | † |
| Chloride | 0.5 mg/L | 0.05 mg/L |
| Phosphates | 0.5 mg/L | 0.003 mg/L |
| Conductivity 20°C | 5 µS/cm | 1 µS/cm |
| pH | 5 - 7.5 | 0.1 pH units |
| Appearance | Colourless, clear without sediment | |
| Hardness | 2 mg $CaCO_3$/L | 1 mg/L |

# Evaporative residue is equivalent to Total Solids. Limit of reporting achieved with 500mL of sample.
† AST will test individual Heavy Metals from our accredited metals suite.
Sample water "Appearance" should be noted when sampling occurs. E.g. clear or cloudy; coloured or colourless; particulate matter present or absent. If you would like this information to appear on the analytical test report, please note Appearance Observations on the laboratory submission form and a request to include the information on the laboratory report.

It is advised that you contact AST for a quote and advice before starting any sampling program.
As part of AST's testing service, sample bottles are provided specific to individual suites of analysis. This is included in the quoted analysis cost along with return postage costs. AST's sample bottles are prepared and assessed for appropriateness for each test according to our NATA accredited quality system, and every batch of bottles is tested to ensure it is contamination-free.

**References and further information**

- AS 5369:2023 – Reprocessing of reusable medical devices and other devices in health and non-health related facilities.
- Australian Commission on Safety and Quality in Health Care – Advisory no: A16/03
- HTM 01-01: Management and decontamination of surgical instruments

When taking samples, prevent cross-contamination. Wear disposable gloves, do not touch inside surfaces of bottles or lids, and do not touch syringe tips or filter tips.

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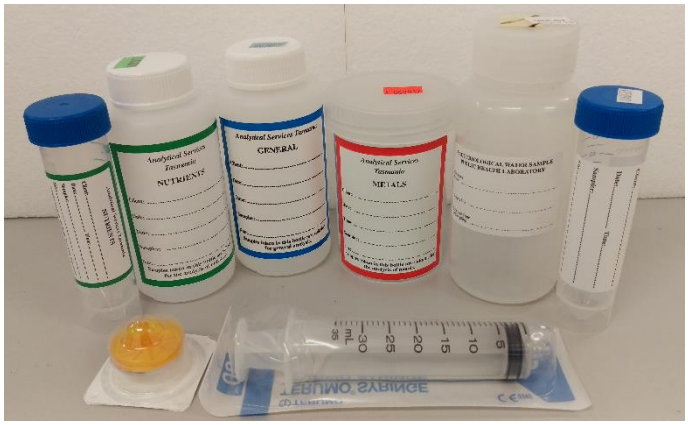
The following sample bottles should be filled when testing against table 7.2 final rinse or table 7.4 of the standard:




- Blue labelled plastic 250 mL
- Red labelled plastic 250 mL
- Green labelled plastic 250 mL
- Green labelled plastic 50 mL (filtered)
- White labelled sterile plastic 125 mL
- White labelled plastic 50 mL (when endotoxin testing is required)

And for pre-cleaning, cleaning or rinse testing against table 7.2; or supply water testing against table 7.3:

- Blue labelled plastic 250 mL
- Red labelled plastic 250 mL

Taking the water samples required for testing purposes is a relatively straight forward process. Water samples from steam sterilisers should be obtained from draw-off points installed at convenient locations within the system, as close to the washer-disinfector as possible. The first 50mL of sample taken at each sampling point should be run to waste. Samples for the chemistry tests (blue, red (and green if required) labelled bottles) can then be taken.

If a green labelled bottle is required (phosphate testing), filter a sub-sample from the green labelled 250mL bottle into a green labelled 50mL tube. Remove the syringe from its packet and draw up a full syringe of sample by dipping the tip into the full green labelled 250mL bottle. Remove the filter from its packet and screw it on to the filled syringe. Allow the first 2 – 5 mL of filtrate to go to waste. Collect the remainder of the filtered water in a green labelled 50mL tube labelled "Filtered for Dissolved Nutrients". One pass through the syringe will deliver ~ 30mL of sample. This is sufficient for analysis of soluble nutrients. Discard the used filter and syringe.

When sampling for the Total Viable Count and Endotoxin tests (white labelled bottles), all apparatus used for collecting samples should be sterile and pyrogen-free. The sampling point discharge surfaces should be wiped with alcohol and allowed to evaporate to dryness before sampling (**this evaporation step is very important**). Allow 200mL of water from the sampling point to run to waste. Using aseptic handling techniques collect the sample in the white labelled sterile/pyrogen-free sample bottles provided. Appearance of the sample should be noted (e.g. clear or cloudy, coloured or colourless).

Labels and submission forms should be filled out at the time of sampling. Samples should be kept cool and delivered to the laboratory on the same day as they are sampled.