

ASSE/IAPMO IGC 376-2022



PUBLIC REVIEW DRAFT

Industry Standard for

**UltraPure and Sterile Water – Water
Treatment Devices**



IAPMO Standard

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Published by

International Association of Plumbing and Mechanical Officials (IAPMO)

4755 East Philadelphia Street, Ontario, California, 91761, USA

1-800-854-2766 • 1-909-472-4100

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Printed in the United States of America

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Preface

This is the first edition of ASSE/IAPMO IGC 376, UltraPure and Sterile Water – Water Treatment Devices.

This Standard was developed by the IAPMO Standards Review Committee (SRC) in accordance with the policies and procedures regulating IAPMO industry standards development, Policy S-001, Standards Development Process. This Standard was approved as an IAPMO Industry Standard on **Month DD, YYYY**.

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- (4) *During its development, this Standard was made available for public review, thus providing an opportunity for additional input from stakeholders from industry, academia, regulatory agencies, and the public at large. Upon closing of public review, all comments received were duly considered and resolved by the IAPMO Standards Review Committee.*
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 - (a) *standard designation (number);*
 - (b) *relevant section, table, or figure number, as applicable;*
 - (c) *wording of the proposed change, tracking the changes between the original and the proposed wording; and*
 - (d) *rationale for the change.*
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 - (a) *the edition of the standard for which the interpretation is being requested;*
 - (b) *the definition of the problem, making reference to the specific section and, when appropriate, an illustrative sketch explaining the question;*
 - (c) *an explanation of circumstances surrounding the actual field conditions; and*
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ASSE/IAPMO IGC 376-2022

UltraPure and Sterile Water – Water Treatment Devices

1 Scope

1.1 Scope

This Standard covers performance testing for producing sterile or ultrapure water using tap water as a source. Ultrapure water parameters covered in this standard include conductivity, TDS, pH, TOC, Sodium, Chloride, Silica, Heterotrophic Plate Count (HPC) bacteria, Virus (MS-2; ATCC 15597-B1), and Endotoxin (from *Escherichia coli* ATCC 33780).

1.2 Alternative Materials

The requirements of this Standard are not intended to prevent the use of alternative materials or methods of construction provided such alternatives meet the intent and requirements of this Standard.

1.3 Terminology

In this Standard,

- (a) “shall” is used to express a requirement, i.e., a provision that the user is obliged to satisfy to comply with the Standard;
- (b) “should” is used to express a recommendation, but not a requirement;
- (c) “may” is used to express an option or something permissible within the scope of the Standard; and
- (d) “can” is used to express a possibility or a capability.

Notes accompanying sections of the Standard do not specify requirements or alternative requirements; their purpose is to separate explanatory or informative material from the text. Notes to tables and figures are considered part of the table or figure and can be written as requirements.

1.4 Units of Measurement

SI units are the primary units of record in global commerce. In this Standard, the inch/pound units are shown in parentheses. The values stated in each measurement system are equivalent in application, but each unit system is to be used independently. All references to gallons are to U.S. gallons.

2 Reference Publications

This Standard refers to the following publications and, where such reference is made, it shall be to the current edition of those publications, including all amendments published thereto.

APHA

Standard Methods for the Examination of Water and Wastewater, twentieth edition; American Public Health Association. 800 I Street, NW, Washington, DC 20001. <www.apha.org>

ASSE International

ASSE 1087

Title

ASTM International

ASTM D1193

Standard Specification for Reagent Water

ASTM D1125

Test Methods for Electrical Conductivity and Resistivity of Water

ASTM D1293

Test Methods for pH of Water

ASTM D4453

Practice for Handling of High Purity Water Samples

ASTM D4517

Standard Test Method for Low-Level Total Silica in High-Purity Water by Flameless Atomic Absorption Spectroscopy

ASTM D5128

Test Method for On-Line pH Measurement of Water of Low Conductivity

ASTM D5173

Standard Guide for On-Line Monitoring of Total Organic Carbon in Water by Oxidation and Detection of Resulting Carbon Dioxide

JIS (Japanese Industry Standard)

JIS K3824

NSF International

NSF/ANSI 244

Supplemental Microbiological Water Treatment Systems – Filtration

US Pharmacopeia 85

Bacteria Endotoxin Test; Photometric Methods

3 Definitions

The following definitions shall apply in this Standard:

Ultrapure Water — water that has been purified to uncommonly stringent specifications. It is virtually free of all contaminants including organic and inorganic compounds.

Sterile Water — water free of all viable (living) microorganisms.

Water for injection— water of extra high quality without significant contamination.

Reprocessing Medical Equipment—the process of cleaning, disinfection, and sterilization of reusable medical equipment/devices. There are two sub-categories: critical water and non-critical.

4 General Requirements

4.1 Electrical Requirements

4.1.1 Electrical Components

Water treatment devices incorporating electrical components or features shall comply with the applicable CSA and UL standards.

4.1.2 Button or Coin Cell Lithium Batteries

Water treatment devices incorporating button or coin cell lithium batteries shall comply with the applicable requirements of UL 4200A.

4.2 Operating Temperatures

Water treatment devices shall operate at temperatures between 2 and 38°C (35 and 100°F).

4.3 Operating Pressure

Water treatment devices shall operate at pressure between 207 and 552 kPa (30 and 80 psi)

4.4 Production Rate

Water treatment devices shall specify the ultrapure/sterile water product rate obtained during testing and recorded in gallon or liters per minute (Lpm, or gpm).

4.5 Resistivity Monitor

Water treatment device shall include a monitor that continuously displays resistivity to the user. Lab or testing facility will need a calibrated inline resistivity meter to compare to test unit's meter

4.6 Exclusive Endotoxin Treatment Devices

Exclusive endotoxin treatment devices shall comply with the requirements of JIS K3824. Analysis shall be performed using assays based on methodology described in USP 85 -Bacterial Endotoxin Test; Photometric methods.

5 Testing Requirements

5.1 Test Specimen, Test Apparatus, and Conditioning

5.1.1 Test Specimen

The test specimen shall consist of a complete water system device include all pre and post filters.

5.1.2 Test Apparatus

The test apparatus shall consist of a potable water supply set to dynamic pressure of 45 +/- 10 psi or the manufacturer's rated pressure with the inlet line size equal to or greater than the inlet connection of the water filtration device. Product water flow rate shall comply with the requirements of Section 5.6 (+/- 10%) The water temperate shall be 75 degrees F +/- 10 degrees. The potable water shall comply with the US EPA's primary and secondary drinking water requirements prior to spiking the water with the specified chemicals listed in Table 1.

5.1.3 Water Type Claim

The water treatment device shall be tested to section 5.2 or 5.3 or 5.4 or 5.5 depending on the performance claim being made. The device shall also be tested to section 5.6 and 5.7.

5.2 Type 1 Water including grades A, B and C

5.2.1 Type 1A Test Procedure

5.2.1.1 The potable water shall include the following parameters (testing can be performed using batch tanks or inline chemical adjustments):

- (a) TDS: 300 – 500 mg/L (NaCl shall be used to increase the TDS)
- (b) TOC: 2 – 3 mg/L (Tannic Acid shall be used to increase the TOC)
- (c) Sodium: 75 – 125 mg/L
- (d) Chloride: 50 – 125 mg/L
- (e) Silica: 20 – 30 mg/L
- (f) HPC: 1000 – 10000 cfu/mL; may be added to challenge water as E. coli
- (g) Endotoxin (from Escherichia coli ATCC 33780): 10 – 30 EU
- (h) Virus (Coliphage MS-2; ATCC 15597-B1): 1000 – 10000 pfu/mL

5.2.1.2 The water treatment device shall be installed and conditioned per the manufacturer's instructions using the potable water supply. After conditioning the system shall be operated continuously for 6 – 8 hours (Day 1), followed by a 16 – 18 hour idle period, then a final 6 – 8 hour continuous operation cycle (Day 2). The system shall be operated per the manufacturer's instructions. The initial sample shall be collected when the outlet water reaches the resistivity recommend by the manufacturer. One sample shall be collected during each hour of operation for a minimum of 6 samples on Day 1 and 6 samples on Day 2.

5.2.2 Performance Requirements

Effluent samples shall be analyzed for conductivity, Resistivity, TOC, Sodium, Chloride and Silica with the following maximum allowable levels:

- (a) Conductivity – 0.0555 $\mu\text{S}/\text{cm}$
- (b) Resistivity – 18 $\text{M}\Omega\cdot\text{cm}$
- (c) TOC – 50 $\mu\text{g}/\text{L}$
- (d) Sodium – 1 $\mu\text{g}/\text{L}$
- (e) Chloride – 1 $\mu\text{g}/\text{L}$
- (f) Total Silica 3 $\mu\text{g}/\text{L}$
- (g) HPC – 0.01 cfu/mL
- (h) Endotoxin – 0.03 EU/mL
- (i) Virus (Coliphage MS-2; ATCC 15597-B1): 0.1 pfu/mL

Sampling shall comply with ASTM D4453. Analysis shall comply with ASTM Standard Methods, ASTM D1125, ASTM D4517, ASTM D5128, and ASTM D5173. Bacteria, endotoxin, and virus (Coliphage MS-2; ATCC 15597-B1) shall be analyzed in accordance with Standard Methods 9215, USP 85- photometric method, and NSF/ANSI 244, respectively.

5.2.3 Type 1B Test Procedure

5.2.3.1 The potable water shall include the following parameters (testing can be performed using batch tanks or inline chemical adjustments):

- (a) TDS: 300 – 500 mg/L (NaCl shall be used to increase the TDS)
- (b) TOC: 2 – 3 mg/L (Tannic Acid shall be used to increase the TOC)
- (c) Sodium: 75 – 125 mg/L
- (d) Chloride: 50 – 125 mg/L
- (e) Silica: 20 – 30 mg/L
- (f) HPC: 1000 – 10000 cfu/mL; may be added to challenge water as E. coli
- (g) Endotoxin (from Escherichia coli ATCC 33780): 10 – 30 EU
- (h) Virus (Coliphage MS-2; ATCC 15597-B1): 1000 – 10000pfu/mL

5.2.3.2 The water treatment device shall be installed and conditioned per the manufacturer's instructions using the potable water supply. After conditioning the system shall be operated continuously for 6 – 8 hours (Day 1), followed by a 16 – 18 hour idle period, then a final 6 – 8 hour continuous operation cycle (Day 2). The system shall be operated per the manufacturer's instructions. The initial sample shall be collected when the outlet water reaches the resistivity recommend by the manufacturer. One sample shall be collected during each hour of operation for a minimum of 6 samples on Day 1 and 6 samples on Day 2.

5.2.4 Performance Requirements

Effluent samples shall be analyzed for conductivity, Resistivity, TOC, Sodium, Chloride and Silica with the following maximum allowable levels:

- (a) Conductivity – 0.0555 $\mu\text{S}/\text{cm}$
- (b) Resistivity – 18 $\text{M}\Omega\cdot\text{cm}$
- (c) TOC – 50 $\mu\text{g}/\text{L}$
- (d) Sodium – 1 $\mu\text{g}/\text{L}$
- (e) Chloride – 1 $\mu\text{g}/\text{L}$
- (f) Total Silica 3 $\mu\text{g}/\text{L}$
- (g) HPC – 0.1 cfu/mL
- (h) Endotoxin – 0.25 EU/mL
- (i) Virus: 1 pfu/mL

Sampling shall comply with ASTM D4453. Analysis shall comply with ASTM Standard Methods, ASTM D1125, ASTM D4517, ASTM D5128, and ASTM D5173. Bacteria, endotoxin, and virus (Coliphage MS-2; ATCC 15597-B1) shall be analyzed in accordance with Standard Methods 9215, USP 85- photometric method, and NSF/ANSI 244, respectively.

5.2.5 Type 1C Test Procedure

5.2.5.1 The potable water shall include the following parameters (testing can be performed using batch tanks or inline chemical adjustments):

- (a) TDS: 300 – 500 mg/L (NaCl shall be used to increase the TDS)
- (b) TOC: 2 – 3 mg/L (Tannic Acid shall be used to increase the TOC)
- (c) Sodium: 75 – 125 mg/L
- (d) Chloride: 50 – 125 mg/L
- (e) Silica: 20 – 30 mg/L
- (f) HPC: 1000 – 10000 cfu/mL; may be added to challenge water as E. coli

5.2.5.2 The water treatment device shall be installed and conditioned per the manufacturer's instructions using the potable water supply. After conditioning the system shall be operated continuously for 6 – 8 hours (Day 1), followed by a 16 – 18 hour idle period, then a final 6 – 8 hour continuous operation cycle (Day 2). The system shall be operated per the manufacturer's instructions. The initial sample shall be collected when the outlet water reaches the resistivity recommend by the manufacturer. One sample shall be collected during each hour of operation for a minimum of 6 samples on Day 1 and 6 samples on Day 2.

5.2.6 Performance Requirements

Effluent samples shall be analyzed for conductivity, Resistivity, TOC, Sodium, Chloride and Silica with the following maximum allowable levels:

- (a) Conductivity – 0.0555 $\mu\text{S}/\text{cm}$
- (b) Resistivity – 18 $\text{M}\Omega\cdot\text{cm}$
- (c) TOC – 50 $\mu\text{g}/\text{L}$
- (d) Sodium – 1 $\mu\text{g}/\text{L}$
- (e) Chloride – 1 $\mu\text{g}/\text{L}$
- (f) Total Silica 3 $\mu\text{g}/\text{L}$
- (g) HPC – 1 cfu/mL

Sampling shall comply with ASTM D4453. Analysis shall comply with ASTM Standard Methods, ASTM D1125, ASTM D4517, ASTM D5128, and ASTM D5173. Bacteria, endotoxin, and virus (Coliphage MS-2; ATCC 15597-B1) shall be analyzed in accordance with Standard Methods 9215, USP 85-Photometric method, and NSF/ANSI 244 , respectively.

5.3 Type 2 Water including grades A, B and C

5.3.1 Type 2A Test Procedure

5.3.1.1 The potable water shall include the following parameters (testing can be performed using batch tanks or inline chemical adjustments):

- (a) TDS: 300 – 500 mg/L (NaCl shall be used in increase the TDS)
- (b) TOC: 2 – 3 mg/L (Tannic Acid shall be used to increase the TOC)
- (c) Sodium: 75 – 125 mg/L
- (d) Chloride: 50 – 125 mg/L
- (e) Silica: 20 – 30 mg/L
- (f) HPC: 1000 – 10000 cfu/mL; may be added to challenge water as E. coli
- (g) Endotoxin (from Escherichia coli ATCC 33780): 10 – 30 EU
- (h) Virus (Coliphage MS-2; ATCC 15597-B1): 1000 – 10000 pfu/mL

5.3.1.2 The water treatment device shall be installed and conditioned per the manufacturer's instructions using the potable water supply. After conditioning the system shall be operated continuously for 6 – 8 hours (Day 1), followed by a 16 – 18 hour idle period, then a final 6 – 8 hour continuous operation cycle (Day 2). The system shall be operated per the manufacturer's instructions. The initial sample shall be collected when the outlet water reaches the resistivity recommend by the manufacturer. One sample shall be collected during each hour of operation for a minimum of 6 samples on Day 1 and 6 samples on Day 2.

5.3.2 Performance Requirements

Effluent samples shall be analyzed for conductivity, Resistivity, TOC, Sodium, Chloride and Silica with the following maximum allowable levels:

- (a) Conductivity – 1 $\mu\text{S}/\text{cm}$
- (b) Resistivity – 1 $\text{M}\Omega\cdot\text{cm}$
- (c) TOC – 50 $\mu\text{g}/\text{L}$
- (d) Sodium – 5 $\mu\text{g}/\text{L}$
- (e) Chloride – 5 $\mu\text{g}/\text{L}$
- (f) Total Silica 3 $\mu\text{g}/\text{L}$
- (g) HPC – 0.01 cfu/mL
- (h) Endotoxin – 0.03 EU/mL
- (i) Virus (Coliphage MS-2; ATCC 15597-B1): 0.1 pfu/mL

Sampling shall comply with ASTM D4453. Analysis shall comply with ASTM Standard Methods, ASTM D1125, ASTM D4517, ASTM D5128, and ASTM D5173. Bacteria, endotoxin, and virus (Coliphage MS-2; ATCC 15597-B1) shall be analyzed in accordance with Standard Methods 9215, USP 85-Photometric method, and NSF/ANSI 244 , respectively.

5.3.3 Type 2B Test Procedure

5.3.3.1 The potable water shall include the following parameters (testing can be performed using batch tanks or inline chemical adjustments):

- (a) TDS: 300 – 500 mg/L (NaCl shall be used to increase the TDS)
- (b) TOC: 2 – 3 mg/L (Tannic Acid shall be used to increase the TOC)
- (c) Sodium: 75 – 125 mg/L
- (d) Chloride: 50 – 125 mg/L
- (e) Silica: 20 – 30 mg/L
- (f) HPC: 1000 – 10000 cfu/mL; may be added to challenge water as E. coli
- (g) Endotoxin (from Escherichia coli ATCC 33780): 10 – 30 EU
- (h) Virus (Coliphage MS-2; ATCC 15597-B1): 1000 – 10000 pfu/mL

5.3.3.2 The water treatment device shall be installed and conditioned per the manufacturer's instructions using the potable water supply. After conditioning the system shall be operated continuously for 6 – 8 hours (Day 1), followed by a 16 – 18 hour idle period, then a final 6 – 8 hour continuous operation cycle (Day 2). The system shall be operated per the manufacturer's instructions. The initial sample shall be collected when the outlet water reaches the resistivity recommend by the manufacturer. One sample shall be collected during each hour of operation for a minimum of 6 samples on Day 1 and 6 samples on Day 2.

5.3.4 Performance Requirements

Effluent samples shall be analyzed for conductivity, Resistivity, TOC, Sodium, Chloride and Silica with the following maximum allowable levels:

- (a) Conductivity – 1 $\mu\text{S}/\text{cm}$
- (b) Resistivity – 1 $\text{M}\Omega\cdot\text{cm}$
- (c) TOC – 50 $\mu\text{g}/\text{L}$
- (d) Sodium – 5 $\mu\text{g}/\text{L}$
- (e) Chloride – 5 $\mu\text{g}/\text{L}$
- (f) Total Silica 3 $\mu\text{g}/\text{L}$
- (g) HPC – 0.1 cfu/mL
- (h) Endotoxin – 0.25 EU/mL
- (i) Virus (Coliphage MS-2; ATCC 15597-B1): 1 pfu/mL

Sampling shall comply with ASTM D4453. Analysis shall comply with ASTM Standard Methods, ASTM D1125, ASTM D4517, ASTM D5128, and ASTM D5173. Bacteria, endotoxin, and virus (Coliphage MS-2; ATCC 15597-B1) shall be analyzed in accordance with Standard Methods 9215, US P85-Photometric method, and NSF/ANSI 244 , respectively.

5.3.5 Type 2C Test Procedure

5.3.5.1 The potable water shall include the following parameters (testing can be performed using batch tanks or inline chemical adjustments):

- (a) TDS: 300 – 500 mg/L (NaCl shall be used to increase the TDS)
- (b) TOC: 2 – 3 mg/L (Tannic Acid shall be used to increase the TOC)
- (c) Sodium: 75 – 125 mg/L
- (d) Chloride: 50 – 125 mg/L
- (e) Silica: 20 – 30 mg/L
- (f) HPC: 1000 – 10000 cfu/mL; may be added to challenge water as E. coli

5.3.5.2 The water treatment device shall be installed and conditioned per the manufacturer's instructions using the potable water supply. After conditioning the system shall be operated continuously for 6 – 8 hours (Day 1), followed by a 16 – 18 hour idle period, then a final 6 – 8 hour continuous operation cycle (Day 2). The system shall be operated per the manufacturer's instructions. The initial sample shall be collected when the outlet water reaches the resistivity recommend by the manufacturer. One sample shall be collected during each hour of operation for a minimum of 6 samples on Day 1 and 6 samples on Day 2.

5.3.6 Performance Requirements

Effluent samples shall be analyzed for conductivity, Resistivity, TOC, Sodium, Chloride and Silica with the following maximum allowable levels:

- (a) Conductivity – 1 $\mu\text{S}/\text{cm}$
- (b) Resistivity – 1 $\text{M}\Omega\cdot\text{cm}$
- (c) TOC – 50 $\mu\text{g}/\text{L}$
- (d) Sodium – 5 $\mu\text{g}/\text{L}$
- (e) Chloride – 5 $\mu\text{g}/\text{L}$
- (f) Total Silica 3 $\mu\text{g}/\text{L}$
- (g) HPC – 1 cfu/mL

Sampling shall comply with ASTM D4453. Analysis shall comply with ASTM Standard Methods, ASTM D1125, ASTM D4517, ASTM D5128, and ASTM D5173. Bacteria shall be analyzed in accordance with Standard Methods 9215.

5.4 Type 3 Water including grades A, B and C

5.4.1 Type 3A Test Procedure

5.4.1.1 The potable water shall include the following parameters (testing can be performed using batch tanks or inline chemical adjustments):

- (a) TDS: 300 – 500 mg/L (NaCl shall be used to increase the TDS)
- (b) TOC: 2 – 3 mg/L (Tannic Acid shall be used to increase the TOC)
- (c) Sodium: 75 – 125 mg/L
- (d) Chloride: 50 – 125 mg/L
- (e) Silica: 20 – 30 mg/L
- (f) HPC: 1000 – 10000 cfu/mL; may be added to challenge water as *E. coli*
- (g) Endotoxin (from *Escherichia coli* ATCC 33780): 10 – 30 EU
- (h) Virus (Coliphage MS-2; ATCC 15597-B1): 1000 – 10000 pfu/mL

5.4.1.2 The water treatment device shall be installed and conditioned per the manufacturer's instructions using the potable water supply. After conditioning the system shall be operated continuously for 6 – 8 hours (Day 1), followed by a 16 – 18 hour idle period, then a final 6 – 8 hour continuous operation cycle (Day 2). The system shall be operated per the manufacturer's instructions. The initial sample shall be collected when the outlet water reaches the resistivity recommend by the manufacturer. One sample shall be collected during each hour of operation for a minimum of 6 samples on Day 1 and 6 samples on Day 2.

5.4.2 Performance Requirements

Effluent samples shall be analyzed for conductivity, Resistivity, TOC, Sodium, Chloride and Silica with the following maximum allowable levels:

- (a) Conductivity – 0.25 $\mu\text{S}/\text{cm}$
- (b) Resistivity – 4 $\text{M}\Omega\cdot\text{cm}$
- (c) TOC – 200 $\mu\text{g}/\text{L}$
- (d) Sodium – 10 $\mu\text{g}/\text{L}$
- (e) Chloride – 10 $\mu\text{g}/\text{L}$
- (f) Total Silica 500 $\mu\text{g}/\text{L}$
- (g) HPC – 0.01 cfu/mL
- (h) Endotoxin – 0.03 EU/mL
- (i) Virus (Coliphage MS-2; ATCC 15597-B1): 0.1 pfu/mL

Sampling shall comply with ASTM D4453. Analysis shall comply with ASTM Standard Methods, ASTM D1125, ASTM D4517, ASTM D5128, and ASTM D5173. Bacteria, endotoxin, and virus (Coliphage MS-2; ATCC 15597-B1) shall be analyzed in accordance with Standard Methods 9215, USP 85-Photometric method, and NSF/ANSI 244, respectively.

5.4.3 Type 3B Test Procedure

5.4.3.1 The potable water shall include the following parameters (testing can be performed using batch tanks or inline chemical adjustments):

- (a) TDS: 300 – 500 mg/L (NaCl shall be used to increase the TDS)
- (b) TOC: 2 – 3 mg/L (Tannic Acid shall be used to increase the TOC)
- (c) Sodium: 75 – 125 mg/L
- (d) Chloride: 50 – 125 mg/L
- (e) Silica: 20 – 30 mg/L
- (f) HPC: 1000 – 10000cfu/mL; may be added to challenge water as E. coli
- (g) Endotoxin (from Escherichia coli ATCC 33780): 10 – 30 EU
- (h) Virus (Coliphage MS-2; ATCC 15597-B1): 1000 – 10000 pfu/mL

5.4.3.2 The water treatment device shall be installed and conditioned per the manufacturer's instructions using the potable water supply. After conditioning the system shall be operated continuously for 6 – 8 hours (Day 1), followed by a 16 – 18 hour idle period, then a final 6 – 8 hour continuous operation cycle (Day 2). The system shall be operated per the manufacturer's instructions. The initial sample shall be collected when the outlet water reaches the resistivity recommend by the manufacturer. One sample shall be collected during each hour of operation for a minimum of 6 samples on Day 1 and 6 samples on Day 2.

5.4.4 Performance Requirements

Effluent samples shall be analyzed for conductivity, Resistivity, TOC, Sodium, Chloride and Silica with the following maximum allowable levels:

- (a) Conductivity – 0.25 $\mu\text{S}/\text{cm}$
- (b) Resistivity – 4 $\text{M}\Omega\cdot\text{cm}$
- (c) TOC – 200 $\mu\text{g}/\text{L}$
- (d) Sodium – 10 $\mu\text{g}/\text{L}$
- (e) Chloride – 10 $\mu\text{g}/\text{L}$
- (f) Total Silica 500 $\mu\text{g}/\text{L}$
- (g) HPC – 0.1 cfu/mL
- (h) Endotoxin – 0.25 EU/mL
- (i) Virus (Coliphage MS-2; ATCC 15597-B1): 1 pfu/mL

Sampling shall comply with ASTM D4453. Analysis shall comply with ASTM Standard Methods, ASTM D1125, ASTM D4517, ASTM D5128, and ASTM D5173. Bacteria, endotoxin, and virus (Coliphage MS-2; ATCC 15597-B1) shall be analyzed in accordance with Standard Methods 9215, USP 85-Photometric method, and NSF/ANSI 244, respectively.

5.4.5 Type 3C Test Procedure

5.4.5.1 The potable water shall include the following parameters (testing can be performed using batch tanks or inline chemical adjustments):

- (a) TDS: 300 – 500 mg/L (NaCl shall be used to increase the TDS)
- (b) TOC: 2 – 3 mg/L (Tannic Acid shall be used to increase the TOC)
- (c) Sodium: 75 – 125 mg/L
- (d) Chloride: 50 – 125 mg/L
- (e) Silica: 20 – 30 mg/L
- (f) HPC: 100 – 1000 cfu/mL; may be added to challenge water as E. coli

5.4.5.2 The water treatment device shall be installed and conditioned per the manufacturer's instructions using the potable water supply. After conditioning the system shall be operated continuously for 6 – 8 hours (Day 1), followed by a 16 – 18 hour idle period, then a final 6 – 8 hour continuous operation cycle (Day 2). The system shall be operated per the manufacturer's instructions. The initial sample shall be collected when the outlet water reaches the resistivity recommend by the manufacturer. One sample shall be collected during each hour of operation for a minimum of 6 samples on Day 1 and 6 samples on Day 2.

5.4.6 Performance Requirements

Effluent samples shall be analyzed for conductivity, Resistivity, TOC, Sodium, Chloride and Silica with the following maximum allowable levels:

- (a) Conductivity – 0.25 $\mu\text{S}/\text{cm}$
- (b) Resistivity – 4 $\text{M}\Omega\cdot\text{cm}$
- (c) TOC – 200 $\mu\text{g}/\text{L}$
- (d) Sodium – 10 $\mu\text{g}/\text{L}$
- (e) Chloride – 10 $\mu\text{g}/\text{L}$
- (f) Total Silica 500 $\mu\text{g}/\text{L}$
- (g) HPC – 1 cfu/mL

Sampling shall comply with ASTM D4453. Analysis shall comply with ASTM Standard Methods, ASTM D1125, ASTM D4517, ASTM D5128, and ASTM D5173. Bacteria shall be analyzed in accordance with Standard Methods 9215.

5.5 Type 4 Water including grades A, B and C

5.5.1 Type 4A Test Procedure

5.5.1.1 The potable water shall include the following parameters (testing can be performed using batch tanks or inline chemical adjustments):

- (a) TDS: 300 – 500 mg/L (NaCl shall be used to increase the TDS)
- (b) TOC: 2 – 3 mg/L (Tannic Acid shall be used to increase the TOC)
- (c) Sodium: 75 – 125 mg/L
- (d) Chloride: 50 – 125 mg/L
- (e) Silica: 20 – 30 mg/L
- (f) HPC: 1000 – 10000 cfu/mL; may be added to challenge water as E. coli
- (g) Endotoxin (from Escherichia coli ATCC 33780): 10 – 30 EU
- (h) Virus (Coliphage MS-2; ATCC 15597-B1): 1000 – 10000 pfu/mL

5.5.1.2 The water treatment device shall be installed and conditioned per the manufacturer's instructions using the potable water supply. After conditioning the system shall be operated continuously for 6 – 8 hours (Day 1), followed by a 16 – 18 hour idle period, then a final 6 – 8 hour continuous operation cycle (Day 2). The system shall be operated per the manufacturer's instructions. The initial sample shall be collected when the outlet water reaches the resistivity recommend by the manufacturer. One sample shall be collected during each hour of operation for a minimum of 6 samples on Day 1 and 6 samples on Day 2.

5.5.2 Performance Requirements

Effluent samples shall be analyzed for conductivity, Resistivity, TOC, Sodium, Chloride and Silica with the following maximum allowable levels:

- (a) Conductivity – 5 $\mu\text{S}/\text{cm}$
- (b) Resistivity – 0.2 $\text{M}\Omega\cdot\text{cm}$
- (c) Sodium – 50 $\mu\text{g}/\text{L}$
- (d) Chloride – 50 $\mu\text{g}/\text{L}$
- (e) HPC – 0.01 cfu/mL
- (f) Endotoxin – 0.03 EU/mL
- (g) Virus (Coliphage MS-2; ATCC 15597-B1): 0.1 pfu/mL

Sampling shall comply with ASTM D4453. Analysis shall comply with ASTM Standard Methods, ASTM D1125, ASTM D4517, ASTM D5128, and ASTM D5173. Bacteria, endotoxin, and virus (Coliphage MS-2; ATCC 15597-B1) shall be analyzed in accordance with Standard Methods 9215, USP85-Photometric method, and NSF/ANSI 244, respectively.

5.5.3 Type 4B Test Procedure

5.5.3.1 The potable water shall include the following parameters (testing can be performed using batch tanks or inline chemical adjustments):

- (a) TDS: 300 – 500 mg/L (NaCl shall be used to increase the TDS)
- (b) TOC: 2 – 3 mg/L (Tannic Acid shall be used to increase the TOC)
- (c) Sodium: 75 – 125 mg/L
- (d) Chloride: 50 – 125 mg/L
- (e) Silica: 20 – 30 mg/L
- (f) HPC: 1000 – 10000 cfu/mL; may be added to challenge water as E. coli
- (g) Endotoxin (from Escherichia coli ATCC 33780): 10 – 30 EU
- (h) Virus (Coliphage MS-2; ATCC 15597-B1): 1000 – 10000 pfu/mL

5.5.3.2 The water treatment device shall be installed and conditioned per the manufacturer's instructions using the potable water supply. After conditioning the system shall be operated continuously for 6 – 8 hours (Day 1), followed by a 16 – 18 hour idle period, then a final 6 – 8 hour continuous operation cycle (Day 2). The system shall be operated per the manufacturer's instructions. The initial sample shall be collected when the outlet water reaches the resistivity recommend by the manufacturer. One sample shall be collected during each hour of operation for a minimum of 6 samples on Day 1 and 6 samples on Day 2.

5.5.4 Performance Requirements

Effluent samples shall be analyzed for conductivity, Resistivity, TOC, Sodium, Chloride and Silica with the following maximum allowable levels:

- (a) Conductivity – 5 $\mu\text{S}/\text{cm}$
- (b) Resistivity – 0.2 $\text{M}\Omega\cdot\text{cm}$
- (c) Sodium – 50 $\mu\text{g}/\text{L}$
- (d) Chloride – 50 $\mu\text{g}/\text{L}$
- (e) HPC – 0.1 cfu/mL
- (f) Endotoxin – 0.25 EU/mL
- (g) Virus (Coliphage MS-2; ATCC 15597-B1: 1 pfu/mL)

Sampling shall comply with ASTM D4453. Analysis shall comply with ASTM Standard Methods, ASTM D1125, ASTM D4517, ASTM D5128, and ASTM D5173. Bacteria, endotoxin, and virus (Coliphage MS-2; ATCC 15597-B1) shall be analyzed in accordance with Standard Methods 9215, USP 85-Photometric method, and NSF/ANSI 244, respectively.

5.5.5 Type 4C Test Procedure

5.5.5.1 The potable water shall include the following parameters (testing can be performed using batch tanks or inline chemical adjustments):

- (a) TDS: 300 – 500 mg/L (NaCl shall be used to increase the TDS)
- (b) TOC: 2 – 3 mg/L (Tannic Acid shall be used to increase the TOC)
- (c) Sodium: 75 – 125 mg/L
- (d) Chloride: 50 – 125 mg/L
- (e) Silica: 20 – 30 mg/L
- (f) HPC: 100 – 1000 cfu/mL; may be added to challenge water as *E. coli*

5.5.5.2 The water treatment device shall be installed and conditioned per the manufacturer's instructions using the potable water supply. After conditioning the system shall be operated continuously for 6 – 8 hours (Day 1), followed by a 16 – 18 hour idle period, then a final 6 – 8 hour continuous operation cycle (Day 2). The system shall be operated per the manufacturer's instructions. The initial sample shall be collected when the outlet water reaches the resistivity recommend by the manufacturer. One sample shall be collected during each hour of operation for a minimum of 6 samples on Day 1 and 6 samples on Day 2.

5.5.6 Performance Requirements

Effluent samples shall be analyzed for conductivity, Resistivity, TOC, Sodium, Chloride and Silica with the following maximum allowable levels:

- (a) Conductivity – 5 $\mu\text{S}/\text{cm}$
- (b) Resistivity – 0.2 $\text{M}\Omega\cdot\text{cm}$
- (c) Sodium – 50 $\mu\text{g}/\text{L}$
- (d) Chloride – 50 $\mu\text{g}/\text{L}$
- (e) HPC – 1 cfu/mL

Sampling shall comply with ASTM D4453. Analysis shall comply with ASTM Standard Methods, ASTM D1125, ASTM D4517, ASTM D5128, and ASTM D5173. Bacteria shall be analyzed in accordance with Standard Methods 9215.

5.6 Water Production Rate

5.6.1 Test Procedure

The product rate test shall be conducted as follows:

- (a) The system shall be installed and conditioned per the manufacturer's instructions and conditioned using a potable water source that complies with the US EPA's primary and secondary drinking water regulations.
- (b) The system shall be operated per the manufacturer's instructions and run for 10 min. The flow rate shall be determined during the 10 min test by collecting the volume over 10 min or by using a calibrated flow meter.

5.6.2 Performance Requirement

The flow rate specified by the manufacturer shall be no greater than the flow rate determined during testing to section 5.6.1.

5.7 Structural Integrity

Structural integrity testing shall be conducted in accordance with ASSE 1087.

5.8 Water for Injection Test

5.8.1.1 The potable water shall include the following parameters (testing can be performed using batch tanks or inline chemical adjustments):

- (a) TDS: 300 – 500 mg/L (NaCl shall be used to increase the TDS)
- (b) TOC: 2 – 3 mg/L (Tannic Acid shall be used to increase the TOC)
- (c) Sodium: 75 – 125 mg/L
- (d) Chloride: 50 – 125 mg/L
- (e) Silica: 20 – 30 mg/L
- (f) HPC: 1000 – 10000 cfu/mL; may be added to challenge water as E. coli
- (g) Endotoxin (from Escherichia coli ATCC 33780): 10 – 30 EU

5.8.1.2 The water treatment device shall be installed and conditioned per the manufacturer's instructions using the potable water supply. After conditioning the system shall be operated continuously for 6 – 8 hours (Day 1), followed by a 16 – 18 hour idle period, then a final 6 – 8 hour continuous operation cycle (Day 2). The system shall be operated per the manufacturer's instructions. The initial sample shall be collected when the outlet water reaches the resistivity recommended by the manufacturer. One sample shall be collected during each hour of operation for a minimum of 6 samples on Day 1 and 6 samples on Day 2.

5.8.2 Performance Requirements

Effluent samples shall be analyzed for conductivity, Resistivity, TOC, Sodium, Chloride and Silica with the following maximum allowable levels:

- (a) Conductivity: < 1.3 uS/cm
- (b) Resistivity: > 0.8 MΩ·cm
- (c) TOC : < 500 µg/L
- (d) HPC: 0.1 cfu/mL
- (e) Endotoxin: 0.25 EU/mL

Sampling shall comply with ASTM D4453. Analysis shall comply with ASTM Standard Methods, ASTM D1125, ASTM D4517, ASTM D5128, and ASTM D5173. Bacteria and endotoxin shall be analyzed in accordance with Standard Methods 9215 and USP 85-Photometric method, respectively.

5.9 Purified Water Test

5.9.1 Test Procedure

5.9.1.1 The potable water shall include the following parameters (testing can be performed using batch tanks or inline chemical adjustments):

- (a) TDS: 300 – 500 mg/L (NaCl shall be used to increase the TDS)
- (b) TOC: 2 – 3 mg/L (Tannic Acid shall be used to increase the TOC)
- (c) Sodium: 75 – 125 mg/L
- (d) Chloride: 50 – 125 mg/L
- (e) Silica: 20 – 30 mg/L

5.9.1.2 The water treatment device shall be installed and conditioned per the manufacturer's instructions using the potable water supply. After conditioning the system shall be operated continuously for 6 – 8 hours (Day 1), followed by a 16 – 18 hour idle period, then a final 6 – 8 hour continuous operation cycle (Day 2). The system shall be operated per the manufacturer's instructions. The initial sample shall be collected when the outlet water reaches the resistivity recommend by the manufacturer. One sample shall be collected during each hour of operation for a minimum of 6 samples on Day 1 and 6 samples on Day 2.

5.9.2 Performance Requirements

Effluent samples shall be analyzed for conductivity, Resistivity, TOC, Sodium, Chloride and Silica with the following maximum allowable levels:

- (a) Conductivity: < 1.3 uS/cm
- (b) Resistivity: > 0.8 MΩ·cm
- (c) TOC: < 500 µg/L

Sampling shall comply with ASTM D4453. Analysis shall comply with ASTM Standard Methods, ASTM D1125, ASTM D4517, ASTM D5128, and ASTM D5173.

5.10 Reprocessing Medical Equipment Test

5.10.1 Test Procedure

5.10.1.1 The potable water shall include the following parameters (testing can be performed using batch tanks or inline chemical adjustments):

- (a) TDS: 300 – 500 mg/L (NaCl shall be used to increase the TDS)
- (b) TOC: 2 – 3 mg/L (Tannic Acid shall be used to increase the TOC)
- (c) Sodium: 75 – 125 mg/L
- (d) Chloride: 50 – 125 mg/L
- (e) Silica: 20 – 30 mg/L
- (f) HPC: 1000 – 10000 cfu/mL; may be added to challenge water as E. coli
- (g) Endotoxin (from Escherichia coli ATCC 33780): 10 – 30 EU

5.10.1.2 The water treatment device shall be installed and conditioned per the manufacturer's instructions using the potable water supply. After conditioning the system shall be operated continuously for 6 – 8 hours (Day 1), followed by a 16 – 18 hour idle period, then a final 6 – 8 hour continuous operation cycle (Day 2). The system shall be operated per the manufacturer's instructions. The initial sample shall be collected when the outlet water reaches the resistivity recommend by the manufacturer. One sample shall be collected during each hour of operation for a minimum of 6 samples on Day 1 and 6 samples on Day 2.

5.10.2 Performance Requirements

Effluent samples shall be analyzed for conductivity, Resistivity, TOC, Sodium, Chloride and Silica with the following maximum allowable levels:

Non – Critical

- (a) Conductivity: < 500 μ S/cm
- (b) TOC: < 1mg/ml (1000 ppm)
- (c) Chloride: < 250 μ g/L
- (d) pH: 6.0 – 9.0
- (e) Hardness: < 150 mg/L
- (f) HPC: < 10 cfu/mL
- (g) Endotoxin: < 20 EU/mL

Critical

- (a) Conductivity: <1 μ S/cm
- (b) TOC: < 1mg/ml (1000 ppm)
- (c) Chloride: <1 μ g/L
- (d) pH: 5.0 – 7.0
- (e) Hardness: <1 mg/L
- (f) HPC: < 10 cfu/mL
- (g) Endotoxin: < 10 EU/mL

Sampling shall comply with ASTM D4453. Analysis shall comply with ASTM Standard Methods, ASTM D1125, ASTM D4517, ASTM D5128, and ASTM D5173. Bacteria and endotoxin shall be analyzed in accordance with Standard Methods 9215 and USP 85-Photometric method, respectively.

6 Markings and Accompanying Literature

6.1 Markings

Ultrapure and sterile water treatment devices complying with this Standard shall be marked with the:

- (a) manufacturer's name or trademark;
- (b) model number;
- (c) IAPMO standard designation (i.e., "ASSE/IAPMO IGC 376");
- (d) intended service, where applicable (e.g., "potable water" or "non-potable applications only");
- (e) maximum working pressure or pressure rating; and
- (f) maximum operating temperature.

6.2 Visibility

Markings shall be permanent, legible, and visible after installation.

6.3 Installation Instructions

Ultrapure and sterile water treatment devices shall be accompanied by instructions for their installation, care and maintenance, and repair.



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