

3-A Sanitary Standard for Sensors and Sensor Fittings and Connections, Number 74-07

Standards Developing Organizations

3-A Sanitary Standards, Inc. (3-A SSI)

In collaboration with

United States Public Health Service (USPHS)/

United States Food and Drug Administration (USFDA)

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Disclaimers

3-A Sanitary Standards and 3-A Accepted Practices are developed through the efforts of experts, working on a volunteer basis, using science-based information and their professional experiences to reach consensus decisions on the sanitary (hygienic) criteria in these 3-A documents.

3-A Sanitary Standards Inc. (SSI), its employees and its volunteer committees/working groups shall not incur any obligation or liability for damages, including consequential damages, arising from or in connection with the development, use, interpretation, or reliance upon this 3-A Sanitary Standard.

3-A Sanitary Standards and 3-A Accepted Practices do not include provisions for mechanical, electrical, or personnel safety. Such safety criteria are established by government regulations and other standards development organizations (SDOs). Other SDO standards may be referenced.

Drawings and illustrations contained herein are examples to assist in understanding the criteria in this 3-A Sanitary Standard. Appendix drawings and illustrations are not intended to show all variations of the equipment or system nor are they exclusive of alternate approved methods. Appendix drawings and illustrations are non-normative.

Metric conversions are provided for convenience and are not intended to be mandatory.

The Appendix is an advisory or informative section unless specifically cited in the Materials or Fabrication Section as requiring conformance.

Foreword

This 3-A Sanitary Standard establishes minimum sanitary (hygienic) requirements for design, materials, fabrication, and/or installation of Sensors and Sensor Fittings and Connections

This 3-A Sanitary Standard is for use on a voluntary basis by directly and materially affected organizations such as equipment and machinery fabricators, processors, regulatory agencies, and by other SDOs to assure adequate public health protections exist for the equipment or systems and covered products. 3-A SSI uses these documents as its source of sanitary criteria for 3-A Symbol authorization.

This 3-A Sanitary Standard was developed jointly by 3-A SSI, the United States Public Health Service (USPHS), United States Food and Drug Administration (USFDA), the United States Department of Agriculture – Dairy Programs (USDA), and the European Hygienic Engineering & Design Group (EHEDG).

It is our intent to encourage inventive genius and provide a forum to discuss new developments. Suggestions for improvement and new technology are welcome at any time for consideration by 3-A SSI. Please forward comments to: 3-A SSI, 6888 Elm Street, Suite 2D, McLean, VA 22101-3829, USA or by fax: 703-761-6284, or by e-mail to: 3-ainfo@3-a.org.

A SCOPE

- A1 This 3-A Sanitary Standard applies to the sanitary aspects of sensors and sensor fittings and connections. The sensor begins at the instrument connection(s) and fitting(s) if required, process contact component(s) and all external component(s) necessary for operation.
- A1.1 This 3-A Sanitary Standard does not apply to 3-A Sanitary Standard for Flow Meters, 28-; 3-A Sanitary Standard for Refractometers and Energy-Absorbing Optical Sensors, 46-; or 3-A Sanitary Standard for Level Sensing Devices for Dry Products, 50-.
- A2 To conform to this 3-A Sanitary Standard, sensors and sensor fittings and connections shall conform to the following criteria for design, materials of construction, fabrication techniques and installation, as applicable, and the current revisions or editions of all referenced documents cited herein, and in the case of field-installed adaptors or spuds and their associated sensors, installation criteria.

B NORMATIVE REFERENCES

- B1 The following listed 3-A Sanitary Standards, 3-A Accepted Practices and other documents shall be considered as Normative References and the provisions of the referenced documents shall apply to this Standard without further reference in this document unless necessary to describe special considerations.

B2 3-A Sanitary Standards**Doc. No. Title (3-A Sanitary Standard for:)**

00-	General Requirements
33-	Metal Tubing
63-	Sanitary Fittings

C DEFINITIONS

The most current approved version of the *3-A Sanitary Standard for General Requirements, 00-* shall apply, unless otherwise noted herein with additions, clarifications, exceptions, modifications, or exclusions.

- C1 **Surfaces** (Refer to *3-A Sanitary Standard for General Requirements, 00-*)
- C2 *Sensor Fittings and Connections* (hereinafter referred to as “fittings”): Fittings and/or connections for instruments or their sensing elements that will be installed in product equipment and in sanitary pipelines for the measurement of fluid parameters and/or properties. These may include temperature, pressure, liquid level, pH, oxidation-reduction potential (ORP), viscosity, density, conductivity, or composition.

C3 Sensors

- C3.1 *Composition Sensor:* A device capable of measuring the chemical constituents of the product or solution.
- C3.2 *Conductivity Sensor:* A device sensitive to resistance changes in the product or solution as a function of ionic concentration.
- C3.3 *Density Sensor:* A sensor designed to measure the relative mass per unit volume (also referred to as “specific gravity”) of a liquid as compared to that of water.
- C3.4 *Liquid Level Sensor:* A device capable of measuring liquid product or solution height either directly or indirectly, or as a function of pressure.
- C3.5 *Microwave Level Sensor:* A sensor that uses microwave energy to detect the presence or absence of liquid or a sensor that uses microwave energy for continuous level measuring of liquid product.
- C3.6 *Oxidation-Reduction Potential (ORP) Electrode:* A noble metal electrode sensitive to electrochemical potential of the product or solution and a reference electrode providing electrolytic contact with the product or solution.
- C3.7 *pH Sensor:* A device which is sensitive to hydrogen ion activity requiring a hydrogen ion-sensitive electrode and a reference electrode providing electrolytic contact with the product or solution.
- C3.8 *Pressure Sensor:* A device sensitive to changes in force per unit area as exerted by the product or solution.
- C3.9 *Temperature Sensor:* A device sensitive to the degree of hotness or coldness of a product or solution.
- C3.10 *Ultrasonic Level Sensor:* A device capable of measuring liquid product or solution height using high frequency sound energy.
- C3.11 *Vibrating Element Sensor:* A device capable of measuring product or solution properties using the change in resistance to movement of a vibrating element.
- C3.12 *Viscosity Sensor:* A device sensitive to the flow resistance of product or solution.
- C4 *Noble Metal(s):* Metals, such as gold, silver, platinum, and iridium which have a relatively positive electrode potential, and which do not enter readily into chemical combination with non-metals. These materials have a high resistance to corrosive attack by acids and corrosive agents and resist atmospheric oxidation.
- C5 **Cleaning** (Refer to 3-A Sanitary Standard for General Requirements, 00-)
- C6 **Surface Modification** (Refer to 3-A Sanitary Standard for General Requirements, 00-)

D MATERIALS

The most current approved version of the *3-A Sanitary Standard for General Requirements, 00-* shall apply, unless otherwise noted herein with additions, clarifications, exceptions, modifications, or exclusions.

D1 Product Contact Surfaces (Refer to *3-A Sanitary Standard for General Requirements, 00-*)

D1.1 Metals (Refer to *3-A Sanitary Standard for General Requirements, 00-*), except that (AIST) 300 Series Types 301, 302, 303 shall not be used.

D1.1.1 Noble metals or their oxides may be used for pH or ORP electrodes and parts having the same functional purposes and shall be non-toxic.

D1.1.2 Solder may be used for attaching fiber optic sensors (Refer to *3-A Sanitary Standard for General Requirements, 00-*)

D1.2 Non-Metals (Refer to *3-A Sanitary Standard for General Requirements, 00-*)

D1.2.1 Glass may be used in pH or ORP electrodes and, when used, shall be heat and chemical resistant and non-toxic. (See Section G2.)

D1.2.2 Internal fluids, when used, shall be non-toxic and shall meet the requirements of the Federal Food, Drug and Cosmetic Act, as amended.

D1.2.3 Carbon and ceramic materials (including tungsten carbide) may be used for ion-permeable materials on pH electrodes or reference junctions in pH or ORP sensors, level sensors, or pressure sensors.

D1.2.4 Rubber and rubber-like materials may be used for sensor insulators, sensor holders, gaskets, diaphragms, bonded coatings and coverings, and parts having the same functional purposes, and when used for the specified application(s).

D1.2.5 Plastic materials may be used for sensors, sensor insulators, sensor holders, gaskets, diaphragms, bonded coatings and coverings, and parts having the same functional purposes and when used for the above-specified application(s).

D1.2.6 Ion-permeable plastic materials may be used on pH electrodes or reference junctions in pH or ORP sensors. Plastic materials shall be non-permeable to microorganisms and shall have an average pore size less than 0.20 µm.

D1.2.7 Adhesives used for bonding rubber and rubber like materials, bonding plastic materials, and bonding of carbon or ceramic components shall be non-toxic.

D1.2.8 Rubber and rubber-like materials, and plastic materials, and carbon or ceramic seal component materials may be bonded.

D2 Non-Product Contact Surfaces (Refer to *3-A Sanitary Standard for General Requirements, 00-*)

E FABRICATION OF PRODUCT AND SOLUTION CONTACT SURFACES

The most current approved version of the *3-A Sanitary Standard for General Requirements, 00-* shall apply, unless otherwise noted herein with additions, clarifications, exceptions, modifications, or exclusions.

Note: The illustrations shown in this Fabrication Clause are not to be interpreted as engineering drawings to be followed precisely. The illustrations are presented only to visually represent an example of the criterion described in the associated paragraph.

E1 Surface Texture (Refer to *3-A Sanitary Standard for General Requirements, 00-*)

E2 Joints (Refer to *3-A Sanitary Standard for General Requirements, 00-*)

E2.1 Permanent Joints (Refer to *3-A Sanitary Standard for General Requirements, 00-*), except that:

E2.1.1 Where neither welding nor soldering is practical, interference fits may be used to produce crevice-free permanent joints. Joints of this type may only be used to assemble metal-to-plastic parts having circular cross sections, free of shoulders or relieved areas.

E2.1.2 Bonded joints may be used (Refer to *3-A Sanitary Standard for General Requirements, 00-*).

E2.1.3 Gold- or silver-bearing solder may be used for attaching fiber optic sensors into fittings.

E2.1.4 Thermoplastics may be welded to permanently join plastic components (Refer to *3-A Sanitary Standard for General Requirements, 00-*).

E3 Coatings (Refer to *3-A Sanitary Standard for General Requirements, 00-*)

E4 Cleaning and Inspectability (Refer to *3-A Sanitary Standard for General Requirements, 00-*), except that:

E4.1 Surfaces that are a continuous tube of the same size shall have representative surfaces available for inspection.

E5 Draining (Refer to *3-A Sanitary Standard for General Requirements, 00-*)

E6 Gaskets, Gasket Retaining Grooves, O-rings and Seals (Refer to *3-A Sanitary Standard for General Requirements, 00-*), except that:

E6.1 When a gasket or similar seal is used to prevent product entry into a cavity behind the seal, the assembly shall be provided with a means for leak detection. The instrument or sensor shall either be equipped with an internal capability to detect the leak with a signal upon seal failure or a leak detection port to drain product that may leak past the seal upon seal failure. This latter provision for leak detection shall be at the lowest possible point in the assembly and, when provided, shall be at least 3/32 in. (2.38 mm) in diameter.