TSI® TOOLS FOR MEASURING SUBMICRON PARTICLE FILTRATION OF MEDICAL MASKS AND RESPIRATORS TO ASTM F2100

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APPLICATION NOTE AFT-007 (A4)

What are Medical Masks?

Medical masks are designed to be worn by health professionals during healthcare procedures. They are used with the intent of protecting both the wearer and the patient from infections spread by inhalable droplets and aerosols; see Figure 1. The category of "medical masks" includes procedure masks (also called "isolation masks") and surgical masks.

A distinct but closely-related category of medical protection devices is surgical respirators. Surgical respirators—also called medical respirators—are a type of respirator designed for use in medical settings. While surgical respirators do not fall into the "medical mask" family, they are also required to be tested to ASTM F2100.[1,2]

Figure 1: Examples of respiratory protection and barrier devices subject to ASTM F2100. Left: a procedure mask, also called an isolation mask. Center: surgical mask. Both of these device types fall into the category of "medical masks." At right is a surgical respirator, also called a medical respirator. While those devices are first and foremost considered to be respirators, they are designed for use in medical settings.

[1] ASTM International, formerly the American Society for Testing and Materials

[2] In the United States, respirators must meet the particle filtration requirements set forth in Title 42 of the Code of Federal Regulations, Part 84 (42 CFR 84). This standard is used for N95 and similar respirators. Other types of medical masks – procedure masks and surgical masks – are not subject to any additional requirements beyond ASTM F2100, unless specific instructions are given by national or regulatory bodies otherwise.

Surgical masks are typically worn by operating room personnel during surgeries and frequently have ties. Surgical respirators are similar to surgical masks but also must meet the more stringent filtration performance requirements of a respirator (e.g., N95). Procedure masks may have elastic ear loops and are often used for medical procedures outside of the operating theater.

The COVID-19 global pandemic has resulted in a more widespread use of these masks. Consequently, requirements for quality control and performance verification of these masks have increased as well.

How are Medical Masks Certified?

Medical mask certification around the world is governed by national and international standards. ASTM F2100 is one of the more widely-used international standards and hence is the focus of this document. This standard requires the material used to construct medical face masks to demonstrate certain levels of performance in five key characteristics: bacterial filtration, breathability (differential pressure), particulate filtration, blood resistance, and flammability.[3]

Rather than providing detailed test methods for each of these areas, ASTM F2100 is a "parent" method that calls upon several other published methods. Results from tests according to those five published methods can result in a medical mask falling into one of three categories. See Table 1 for more details.

Table 1: Medical Face Mask Material Requirements, with Test Methods and Criteria. See Table 1 in the text of ASTM F2100.

	Characteristic	Test Method Used to Measure Mask Performance	Medical Face Mask Material Requirements by Mask Performance (Barrier) Level, and Units of Measure			
			Level 1	Level 2	Level 3	Units
1	Bacterial Filtration efficiency (BFE)[4]	ASTM F2101	≥ 95	≥ 98	≥ 98	%
2	Differential Pressure	EN 14683:2019, Annex C	< 5.0	< 6.0	< 6.0	mm H_2O/cm^2
3	**Sub-Micron Particulate filtration efficiency (PFE) at 0.1 micron[5]**	**ASTM F2299**	**≥ 95**	**≥ 98**	**≥ 98**	**%**
4	Resistance to Penetration by Synthetic Blood	ASTM F1862	80	120	160	mm Hg; minimum pressure for "Pass" result
5	Flammability	16 CFR Part 1610	Class 1	Class 1	Class 1	*N/A*

Of these five diverse requirements, TSI® Incorporated offers tools pertinent to the particulate filtration efficiency (PFE) test.

Note the following about the differential pressure requirement (Characteristic #2):

- Differential pressure can be measured with the same setup as used for PFE (See Figures 2 and 3 below), provided the apparatus is equipped with pressure sensors and the aerosol generator is switched off.
- Surgical (medical) respirators are exempt from the differential pressure requirement of ASTM F2100, as that characteristic is already tested for those devices during the respirator testing they are required to undergo.

[3] Note that F2100 applies to medical mask materials, whereas 42 CFR 84 applies to completed devices.

[4] The bacterial filtration efficiency test (BFE) requires a very specialized apparatus that TSI currently does not support.

[5] In the United States, surgical respirators must also comply with the filtration performance standards set forth in 42 CFR 84 (e.g., N95). See footnote on first page.

TSI® Tools for Measuring the Submicron Particulate Filtration Efficiency (PFE) of Medical Masks and Respirators

PFE Testing According to ASTM F2299: General Requirements

Test Method ASTM F2299 is relied upon by ASTM F2100 for determining the submicron particulate filtration capabilities of medical mask media. F2299 is a general method designed for different uses, and it allows a wide range of potential sizes of challenge particles, 0.1 to 5 µm. Compliance with F2100 can be achieved when using nominally 0.1 µm polystyrene latex spheres (PSL) as the challenge aerosol.[6] The F2299 method requires the use of Optical Particle Counters (OPCs), and permits a wide range of media sample sizes and flow rates. The TSI Model 3160 Automated Filter Tester is an alternative approach permitting the user to conduct monodisperse testing from 15 to 800 nm. The Model 3160 is capable of generating submicron PSL aerosol and is an automated solution.

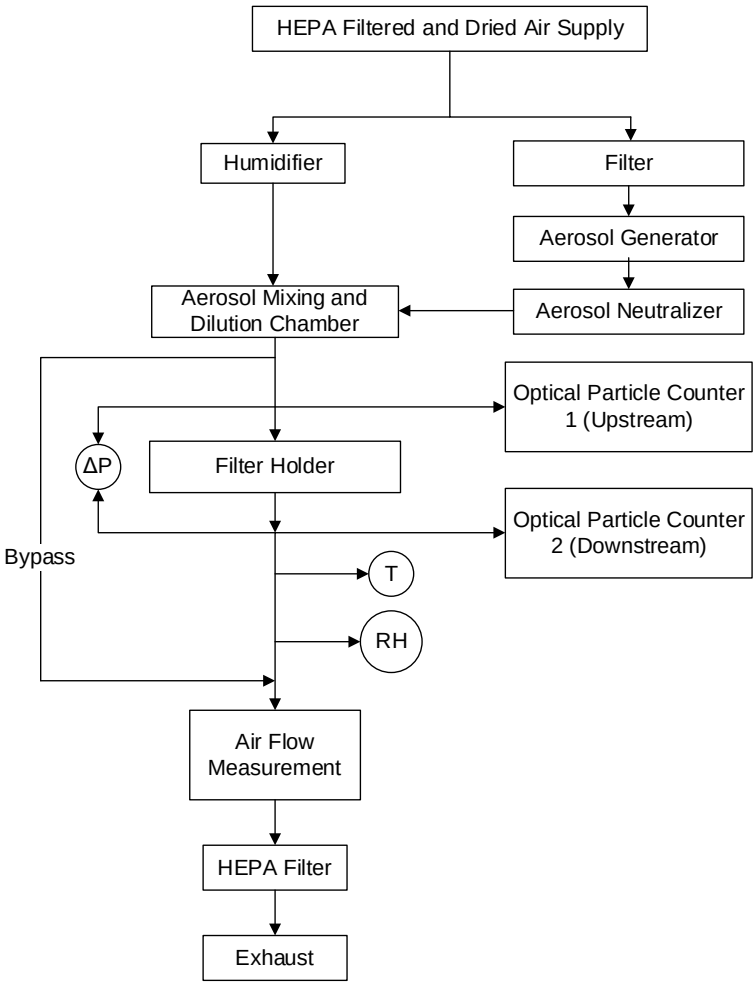


Figure 2: Generalized Apparatus for ASTM F2299 Testing. Figure reproduced from ASTM F2299 standard document.

[6] Strictly speaking, the aerosol generated in a component-based F2299 setup is not monodisperse: it contains the PSL (which are relatively monodisperse), but also polydisperse residue composed of additives and impurities. Much of the residue is smaller than 0.1 micron, but the OPC lower detection limit still overlaps the residue range somewhat. Hence, the OPCs are actually detecting a mixture of PSL and residue.

TSI® Solutions for ASTM F2299 Medical Mask Testing

Users have several options when choosing how to conduct F2299-associated medical mask testing. These options may be component-based solutions, or a user may opt for an automated solution.

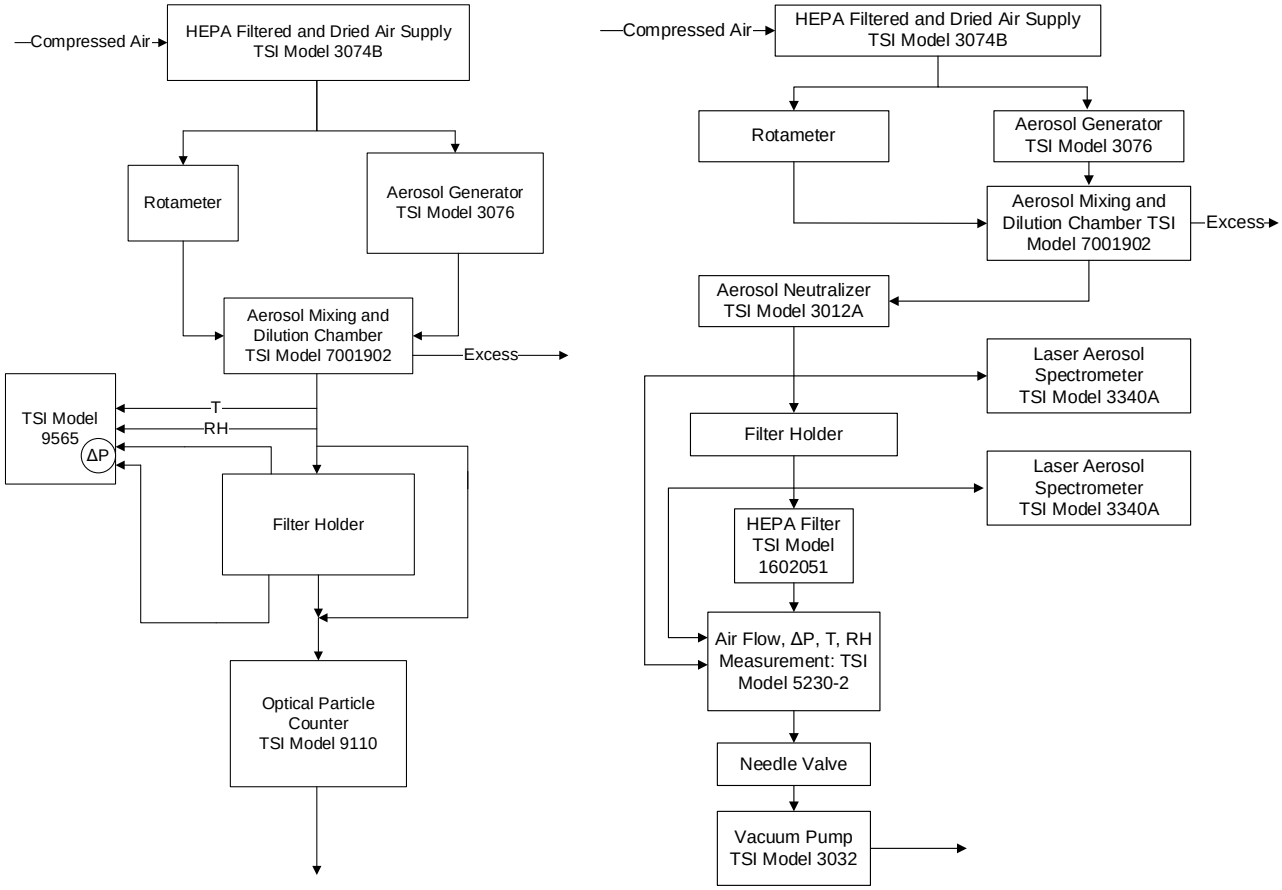
Component-Based Solutions

Within the category of "component-based solutions," users are creating test setups that vary slightly from one another. Two examples are shown in Figure 3 and Table 2: a variant with a system flow of one cubic foot per minute, and a variant that permits lower (and/or variable) system flows.

Table 2: TSI® Test System Components for F2299 Mask Testing

Function of Component	Component as Depicted in F2299 Text	Desired System Flow Rate	
		1 ft³/min	Variable / Lower
Air flow preparation and handling	Incoming air filter	Model 3074B	Model 3074B
	Incoming air humidifier	*(user's responsibility)*[A]	*(user's responsibility)*[A]
	Air flow measurement	*N/A*[B]	Model 5230-2
	Pressure, temperature, and humidity sensors	Model 9565	
	HEPA final filter	*N/A*	TSI PN 1602051
	Exhaust	*N/A*	Model 3032
Aerosol generation, conditioning, and preparation	Aerosol generator	Model 3076	Model 3076
	Aerosol neutralizer	*N/A* [C]	Model 3012A
	Mixing & dilution chamber	TSI PN 7001902	TSI PN 7001902
	Bypass branch	*(user's responsibility)*	*(user's responsibility)*
	Filter holder		
Detection	Upstream and downstream optical particle counter(s)	Model 9110[B]	Model 3340A[D]

[A] An external humidifier may not be required if the final challenge aerosol humidity meets the requirements with the addition of dry dilution air to the wet aerosol produced by the atomizer.
[B] The Model 9110's built-in pump regulates to 1 ft³/min.
[C] No neutralizer is used per the US FDA.
[D] The Model 3340A is a high-resolution laser spectrometer that requires low sample flow (typically 50 – 100 cc/min).



1 ft³/min System Flow **Lower/Variable System Flow**

Figure 3: Two examples of F2299 test setups. At left, the 1 ft³/min system is similar to that used by several contract testing laboratories in the United States. It only uses one detector. Note that this testing setup does not make use of a neutralizer, per US FDA requirements. It also differs from the requirements of F2299, if interpreted strictly, in that the OPC also is the flow source. The system at right can operate at different flow rates (below 1 ft³/min), uses two detectors, and includes a neutralizer. The components for each are described in Table 2.

Automated Solution

The TSI® Model 3160 Fractional Efficiency Automated Filter Tester is a turnkey solution that can provide data very similar to that required by ASTM F2299. The Model 3160 is designed to challenge filter media (and in some cases, finished filters) with monodisperse aerosol in the range of 15 to 800 nm. It generates a true monodisperse aerosol with an electrostatic classifier (EC) and counts particles with dual Condensation Particle Counters (CPCs). This enables the user to determine the fractional efficiency curve of the filter media under test, which includes determining the most penetrating particle size (MPPS). This is valuable information during the filter media development process, and can also be very useful in quality control efforts. HEPA and ULPA filters can be characterized using the Model 3160, which is capable of measuring 99.999999%+ of fractional efficiency. The Model 3160 can test filters with up to 100 L/min of flow.

The Model 3160 has the following technical differences with the requirements of ASTM F2299:

- CPCs are used instead of OPCs.
- DMA-classified (i.e. monodisperse[7]) oil and/or salt particles are typically used, but using PSL is possible.[8]
- While the 3160 and ASTM F2299 both require a neutralized aerosol, the US FDA requires use of a non-neutralized aerosol. Refer to Guidance for Industry and FDA Staff: Surgical Masks—Premarket Notification [510(k)] Submissions.

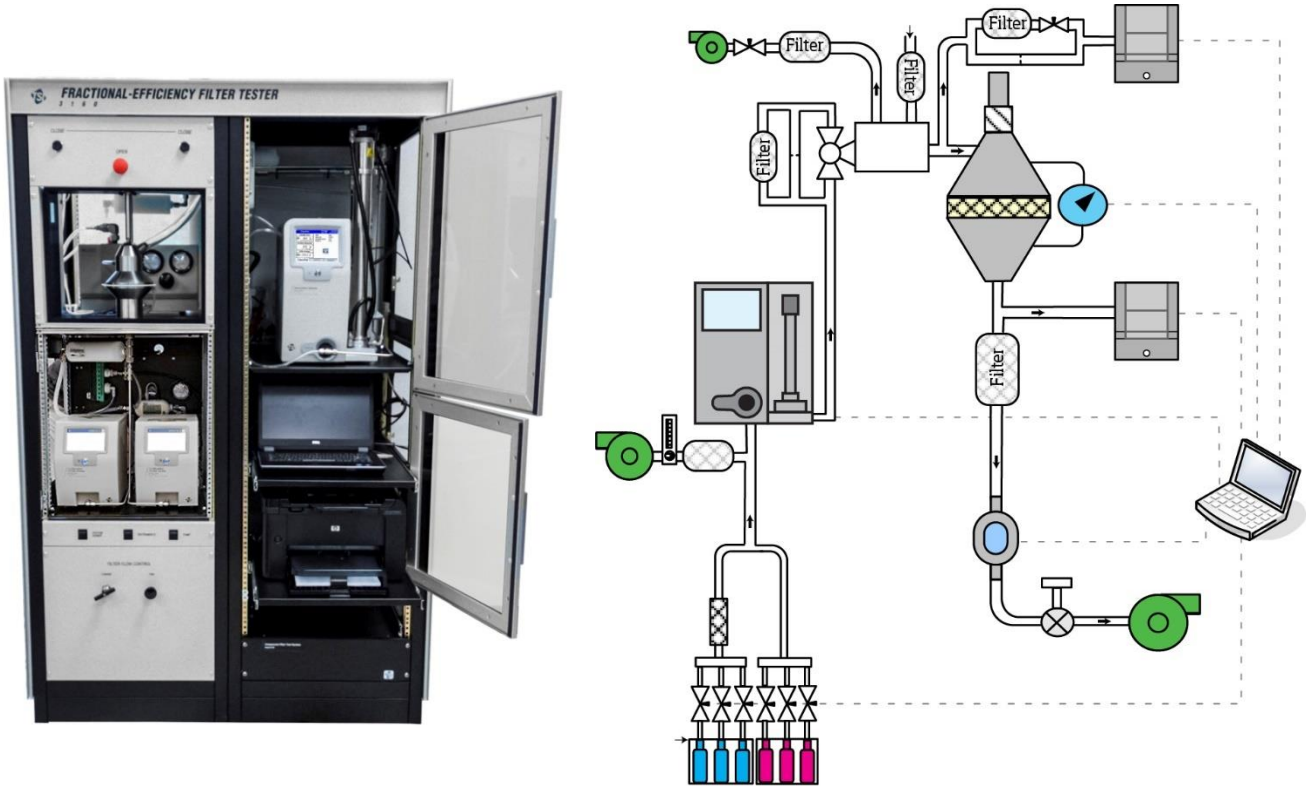


Figure 4: The Model 3160 Fractional Efficiency Automated Filter Tester. Left: the system as viewed from the front. Right: a schematic of the components of the tester.

[7] The Model 3160 uses the EC to remove the residue and impurities by size classification. As a result, the mask is challenged with truly only one particle size at a time, unlike the component-based F2299 method.
[8] The Model 3160 can generate PSL by placing it in the salt generators instead of NaCl.

Filtration Efficiency Testing for Surgical Respirators

As surgical respirators must meet the same filtration requirements as standard respirators (according to 42 CFR 84 in the United States), they are tested the same way. The TSI® CertiTest® Automated Filter Tester Model 8130A is a widely trusted and used automated filter tester solution for respirator testing. Figure 5 shows a picture and schematic of the Model 8130A.

The Model 8130A generates a polydisperse NaCl or oil challenge aerosol that is detected with two solid-state photometers. Photometers are used for their excellent sensitivity and dynamic range, as well as their ability to measure the large mass concentrations required for the loading testing of respirators. The 8130A can support flow rates of 10 to 110 L/min and can measure total filtration efficiencies up to 99.9999% during initial penetration and loading tests.

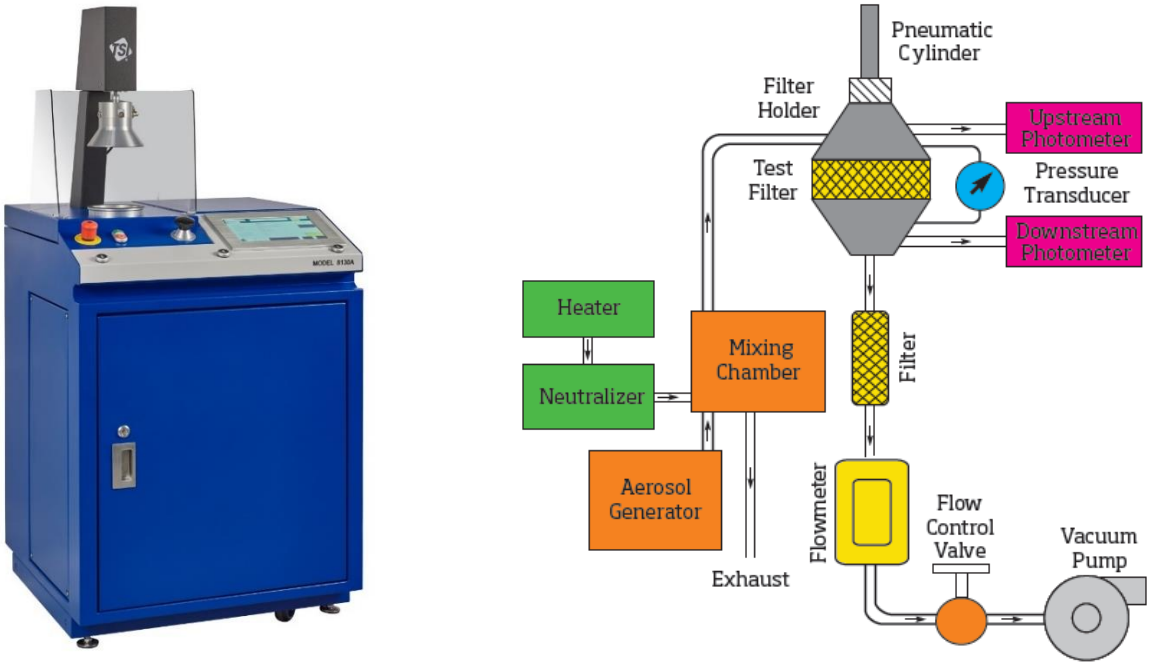


Figure 5: The Model 8130A Automated Filter Tester
Left: An isometric view of the tester from the front. Right: A schematic of the internal components of the tester.

An Anticipated Upcoming Change to ASTM F2100

As of December 2020, ASTM F2100 is being revised with respect to its PFE requirement. To date, ASTM F2100 has relied upon ASTM F2299 as a test method for measuring a medical masks PFE. It is anticipated that likely in the first half of 2021, ASTM F2100 will shift away from requiring ASTM F2299, and will instead require use of a method similar (but not identical to) to that described in 42 CFR part 84. This is being done to more closely align the filtration test method with the much more common and challenging test required for respirators.

For surgical and procedure masks, this newly-required test method will use the mask's initial filtration efficiency (when measured with NaCl aerosol, without a loading test).[9] Once this change is made, compliance with ASTM F2100 will call for much the same test equipment than what is currently used for 42 CFR part 84 compliant testing. It is anticipated that the TSI Model 8130A will meet these requirements, as it is already widely used for 42 CFR 84 testing in the United States. Note that individual jurisdictions and regulatory agencies may still impose additional (or different) requirements, so you must verify with the applicable regulatory agencies before proceeding with testing.

[9] For surgical respirators, since they are respirators first and foremost, the filtration test requirement will not change from the current 42 CFR 84. The revised F2100 PFE method is similar to 42 CFR 84, but requires just initial efficiency testing instead of loading testing.

References

1. ASTM F2100: Standard specification for performance of materials used in medical face masks. https://www.astm.org/Standards/F2100.htm
2. ASTM F2101: Standard test method for evaluating the bacterial filtration efficiency (BFE) of medical face mask materials, using a biological aerosol of *Staphylococcus aureus*. https://www.astm.org/Standards/F2101.htm
3. ASTM F2299: Standard test method for determining the initial efficiency of materials used in medical face masks to penetration by particulates using latex spheres. https://www.astm.org/Standards/F2299.htm
4. 42 CFR part 84: Approval of respiratory protective devices. https://www.ecfr.gov/cgi-bin/text-idx?SID=6b0b69703a73ccc1c57f3084ae6a29b7&mc=true&node=pt42.1.84&rgn=div5
5. EN 14683: Medical face masks – Requirements and test methods. https://standards.cen.eu/dyn/www/f?p=204:110:0::::FSP_PROJECT:69675&cs=1956C06A1BAF887FF462DD56057D34F29
6. Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submissions. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/surgical-masks-premarket-notification-510k-submissions
7. CertiTest® Automated Filter Tester Model 8130A specification sheet. A4 and US.
8. Automated Filter Tester Model 3160 specification sheet. A4 and US.
9. "42 CFR part 84 Standard." Application note AFT-001, US.
10. "42 CFR part 84 Testing Modes." Application note AFT-002, US.

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