

## **3M™ E-A-Rfit™ Dual-Ear Validation System Compliance with ANSI/ASA S12.71-2018**

**Q: What is ANSI/ASA S12.71-2018?**

A: This new standard is titled ANSI/ASA S12.71-2018, American National Standard Performance Criteria for Systems that Estimate the Attenuation of Passive Hearing Protectors for Individual Users. The standard contains criteria that equipment manufacturers should apply to their hearing protection fit-test systems to ensure accurate measurements and transparent reporting of results. In addition, a main requirement of this standard is that fit-test systems be evaluated by comparing their attenuation estimates to attenuation measured using the laboratory “gold standard,” real ear attenuation at threshold (REAT) method. The generic term used in the standard for a hearing protection fit-test system is Field Attenuation Estimation System or FAES. The standard recognizes various technologies and methods for conducting hearing protection fit testing and differentiates minimum requirements for a FAES based on the fit-test method it uses. This standard is the first of its kind worldwide.

**Q: Is compliance with ANSI/ASA S12.71-2018 mandatory?**

A: No. ANSI/ASA S12.71-2018 is a voluntary consensus standard. 3M™ has chosen to make the necessary minor modifications to the software and user instructions of our 3M™ E-A-Rfit™ Dual-Ear Validation System in order to fully comply with the standard.

**Q: Does compliance with ANSI/ASA S12.71-2018 mean that the Personal Attenuation Ratings (PARs) will be equal, regardless of which FAES I use?**

A: No. While it is possible that two different systems could produce the same PAR for a given fit test, it is not likely that every compliant system will produce exactly the same results. The commercially available systems use different technologies and approaches toward measuring and reporting results. For example, some FAESs report a pass/fail result while others calculate a single numerical PAR. Some systems are objective, meaning that a fit test consists of using microphones to measure sound pressure levels, while other systems are subjective, meaning that the listener must make a judgment about some type of acoustical signal.

Some FAESs use the actual hearing protection device (HPD) during the fit test and others use a modified HPD, or “surrogate” HPD. There are also differences among the systems like how many frequencies are tested. By setting minimum performance criteria for a variety of different technologies, the standard allows manufacturers to comply without strictly limiting the marketplace to one measurement method. Therefore, different FAES types can conform to the standard without generating the same PAR value for the same fit of an HPD. The 3M E-A-Rfit Dual-Ear Validation System is an objective measurement system that measures sound pressure levels outside and underneath the hearing protector simultaneously, using a surrogate hearing protector for the test. It calculates a PAR with the uncertainty value deducted automatically as an extra precaution.

### **About 3M™ E-A-Rfit™ Dual-Ear Validation System**

<b>System Type</b>	<b>Physical (Objective)</b>
Measurement Method	Field-Microphone in Real Ear (F-MIRE) using a surrogate hearing protector device
Result Output	Personal Attenuation Rating (PAR) calculated from attenuation measured at seven frequencies per ear simultaneously

**Q: How do I update my software?**

A: If an outdated version of the 3M E-A-Rfit Dual-Ear Validation System software is opened after the release date and the computer has an active internet connection, a banner will appear on the opening screen notifying you that an update is available. You will need to accept the update to initiate the program update. ANSI compliance begins with version number 5.9.1

**Q: Do I need to upgrade my hardware in order to be in compliance with ANSI/ASA S12.71-2018?**

A: No. There are no changes to hardware required.

**Q: I live and work outside the US. Why is ANSI/ASA compliance important to me?**

A: Many countries recognize the significance of standardization and currently use ANSI standards in guidance documents or as referenced by regulatory bodies. Although no government currently mandates compliance with this standard, it is possible that future policies could require use of a fit-test system that is compliant.

Being compliant with ANSI/ASA S12.71-2018 does not conflict with any other standard or regulation because this is the first and only standard in the world that provides guidance to manufacturers about hearing protection fit-test systems. Complying with the ANSI/ASA S12.71-2018 standard indicates that 3M has voluntarily chosen to align with the specifications it contains.

**Q: Does ANSI/ASA S12.71-2018 compliance require a major change to how the 3M E-A-Rfit Dual-Ear Validation System calculates PAR?**

A: No. ANSI/ASA S12.71-2018 defines PAR as a single number to be subtracted from an A-weighted noise exposure. The standard guides manufacturers to compute PAR in a manner similar to the Noise Level Reduction Statistic for use with A-weighting (NRSA) as defined in ANSI/ASA S12.68-2007 (R2017). The 3M E-A-Rfit Dual-Ear Validation System has always calculated PAR in this manner.

**Q: Does ANSI/ASA S12.71-2018 compliance require a major change to how the 3M E-A-Rfit Dual-Ear Validation System handles uncertainty?**

A: No. ANSI/ASA S12.71-2018 defines three components to combined uncertainty. These are measurement uncertainty, fitting uncertainty, and spectrum uncertainty. The 3M E-A-Rfit Dual-Ear Validation System has always included these three components and reported a combined uncertainty along with the PAR (Example: Binaural PAR =  $24 \pm 6$  dB).

To comply with ANSI/ASA S12.71-2018, a slight modification was made to the 3M E-A-Rfit Dual-Ear Validation System software: the uncertainty components are now applied to the PAR, instead of to each individual frequency prior to calculating the PAR.

**Q: How does the 3M E-A-Rfit Dual-Ear Validation System determine and minimize uncertainty?**

A: In preparation for making a hearing protector product 3M E-A-Rfit Dual-Ear Validation System compatible, the product undergoes rigorous testing in the 3M Indianapolis Acoustical Laboratories to determine the three uncertainty components. The testing procedure that 3M has always followed is closely aligned with the one in ANSI/ASA S12.71-2018.

The measurement uncertainty component summarizes any differences between the FAES attenuation estimate and the laboratory REAT measurement. ANSI/ASA S12.71-2018 requires that this measurement uncertainty be assessed and reported as a component of the total FAES uncertainty.

To minimize the measurement uncertainty component, the 3M E-A-Rfit Dual-Ear Validation System applies compensation factors at each frequency so that the attenuation estimates agree with REAT as closely as possible.

**Q: When did the 3M E-A-Rfit Dual-Ear Validation System become compliant with ANSI/ASA S12.71-2018?**  
A: The release date for the software upgrade is October 21, 2019. Installing version 5.9.1 brings the 3M E-A-Rfit Dual-Ear Validation System into compliance with ANSI /ASA S12.71-2018.

**Q: Will the changes that were made to the 3M E-A-Rfit Dual-Ear Validation Systems software affect my previous/existing fit test results?**

A: No. Changes to the 3M E-A-Rfit Dual-Ear Validation System software will not apply to existing results nor will any changes be applied retroactively to an existing database.

**Q: How will the changes made to the 3M E-A-Rfit Dual-Ear Validation System software affect the future fit test results?**

A: No significant changes to future fit test results are expected. The new standardized approach applies to how the uncertainty value is handled. By default, the 3M E-A-Rfit Dual-Ear Validation System has always taken a conservative approach by displaying the PAR minus uncertainty value as the overall PAR result. Any change to the uncertainty will automatically be incorporated in the PAR reported by the 3M E-A-Rfit Dual-Ear Validation System. The resulting PAR value is not expected to differ more than the typical test variability.

**Q: Will I need to retest everyone that I have previously tested because of ANSI/ASA S12.71-2018 compliance?**

A: No. There are no changes being made to existing data or data obtained prior to this software release. The PAR results obtained prior to this update are considered valid estimations of attenuation.

**Q: Are there any other changes that were made to the 3M E-A-Rfit Dual-Ear Validation System in order to be in compliance with ANSI/ASA S12.71-2018?**

A: No. There were no other changes to the software. However, the standard requires that specific information about a compliant FAES be made available to the user in the operating manual. The table below gives a summary of how the 3M E-A-Rfit Dual-Ear Validation System meets the performance criteria. The complete Table A-1, required by the standard, is located in Appendix A of the the 3M E-A-Rfit Dual-Ear Validation System *User Guide*.

ANSI/ASA S12.71-2018 Performance Factor	Description	Criteria for Manufacturer	How 3M E-A-Rfit Complies
Calibration/verification	FAESs shall have a defined procedure for calibrating the equipment and/or verifying the function and accuracy of measurements.	The interval for a physical calibration shall be defined, recommended not to exceed 2 years. Objective FAESs shall have a procedure to check the sensitivity of the microphones on a daily basis.	Factory calibration should be conducted at least every 2 years. A “daily” microphone verification is required upon launch of the software and automatically repeated every 4 hours of use or 50 tests.
Maximum allowable ambient sound level	This refers to the maximum amount of background noise that can be present during a fit test without interfering with the accuracy of the measurements	The maximum allowable ambient noise level limit must be specified in user instructions.	The maximum allowable ambient noise level limit is 85 dBA or 91 dBC.
Maximum sound exposure caused by the test signal	For some FAESs, the operator or a bystander to a fit-test system may be exposed to sound generated by the FAES during the measurement process. The purpose of this criteria is to assure that the operator is not overexposed to noise.	The FAES test signals must not exceed an exposure of 80 dB $L_{A8hn}$ or level of 105 dB $L_{Amax}$ over the course of a work shift to the unprotected bystander. If the FAES output exceeds these limits, the manufacturer must specify suitable protective methods.	The bystander noise exposure is estimated to be less than 80 dBA when normalized to an 8-hour shift.
Bias or nonlinearity of fit test results	Bias or nonlinearity is evaluated by comparing the FAES measurement results to reference REAT values.	The manufacturer must assess and minimize any bias or nonlinearity to decrease the measurement uncertainty.	Uncertainty measurements have been reevaluated and incorporated into the software.
Range of valid attenuation measurements	Users need to know minimum and maximum PAR values the FAES can measure to know what is an unreasonably low or high PAR for a given fitting.	The full range of measurable attenuation values must be assessed and reported. For psychophysical FAESs, this applies for those with hearing thresholds up to 25 dBHL at all frequencies.	PAR results may range from 1 to 43 dB
PAR uncertainty	The combined variability of the attenuation estimate consisting of three primary components: measurement, fit, and spectral.	The components of uncertainty must be evaluated, documented, and made available to the user.	The PAR uncertainty values are visible on the measurement screen.

**If you have any questions, please contact 3M PSD Technical Services at 1 (800) 243-4630.**

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