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DETERMINATION OF LOW FLOW WARNING DEVICE ACTIVATION FOR BREATH ASSIST TYPE TIGHT-FITTING POWERED AIR-PURIFYING RESPIRATORS STANDARD TESTING PROCEDURE (STP)

1. PURPOSE

This test establishes the procedure for ensuring that the level of protection provided by the low flow warning device requirement for breath assist type tight-fitting powered air-purifying respirators, series PAPR100, meet the requirements set forth in 42 CFR Part 84, Subpart K, 84.171(j).

2. GENERAL

This procedure describes the Determination of Low Flow Warning Device Activation for Breath Assist Type Tight-Fitting Powered Air-Purifying Respirators test procedure in sufficient detail that a person knowledgeable in the appropriate technical field can select equipment with the necessary resolution, conduct the test, and determine whether or not the product passes the test.

3. EQUIPMENT/MATERIAL

3.1. The list of necessary test equipment and materials follows:

3.1.1. National Instruments NI USB-9215A Portable USB-Based DAQ with Simultaneous Sampling; LabVIEW 2013; test software.

3.1.2. Mechanical Breather with 622 Kg.m/min. Cam as per U.S. BOM Drawings C-1748 (3/17/69) Breathing Machine and B-1198 (3/6/69) Breathing Cam. Or equivalent.

3.1.3. Anthropometric Headform, in accordance with ISO 16900, size medium, or equivalent.

3.1.4. Validyne Engineering model DP45-20 transducer used with Validyne Engineering model CD-19A carrier demodulator mounted in the Validyne MC1-333 module case. Accuracy: ± 0.5% F.S., pressure range up to 3.5 inches of water. Or equivalent.

3.1.5. 3-Liter lung in bottle with plastic tubing, Hans Rudolph Co. part number CM 1435, or equivalent.

3.1.6. Electronic Timer calibrated to hundredths of a second.

4. TESTING REQUIREMENTS AND CONDITIONS

4.1. Prior to beginning any testing, confirm that all measuring equipment employed has been calibrated in accordance with the testing laboratory's calibration procedure and schedule. All measuring equipment utilized for this testing must have been calibrated using a method traceable to recognized international standards when available.

4.2. Testing shall be conducted on as-received respirators at 25 ± 2.5 degrees Celsius (°C) and adhere to User's Instructions.

4.3. Three complete respirator systems will be evaluated for low flow warning device activation.

4.4. Determination of Low Flow Warning Device Visibility will be completed for any respirator with a visual warning device. The standard testing procedure is described in CVB-APR-STP-0087.

4.5. Determination of Low Flow Warning Device Sound Level on Series PAPR100 will be completed for any respirator with an audible warning device, where the warning provided is audible only, or other warnings are not readily apparent. The standard testing procedure is described in CVB-APR-STP-0085.

5. PROCEDURE

5.1. Follow individual instruction manuals for set up, calibration, and maintenance of equipment used in this procedure prior to beginning any testing. Malfunctioning equipment must be repaired or replaced and properly set up and calibrated before starting all tests.

5.2. Prior to any testing, the respirator shall be evaluated per the user check instructions in the User's Manual to ensure that the low flow warning(s) activate as designed.

5.3. Perform pre-test balancing of transducer and recording system.

5.3.1. Connect the transducer to be used during testing to a pressure regulated air supply. A pinch clamp, used for slight pressure changes, is placed in-line. An alternate method to generate low pressures for calibration is to use the Dwyer model A-396A calibration pump or equivalent.

5.3.2. Connect the transducer cable to the CD-19A demodulator in the MC1-333 module case, and then connect the demodulator system to the National Instruments DAQ. The DAQ is then connected to the PC via USB port. Turn the system on and press the Calibration button. After the calibration screen appears, with no load applied to the transducer, press the Zero button to set the zero-pressure point.

5.3.3. Apply a pressure of 0.5 inches of water to the transducer system. Check that the demodulator display reads 0.5 inches and adjust pressure if necessary. Then check that the waveform displayed is at 0.5 inches and adjust the LabVIEW readout if necessary.

5.3.4. Repeat step 5.1.3 with the pressures of 1.0, 1.5, and 2.0 inches of water until each pressure point reads correctly on the waveform. No adjustments should be necessary at this point.

5.3.5. Verify that the pressures are correct, by applying pressure at 1.5, 0.5, and 0.0 inches of water in descending order ensuring each pressure point reads correctly on the waveform. If adjustments are necessary, then repeat the calibration process for all pressures.

5.3.6. After the calibration sequence is complete, remove the pressure source from the system.

5.4. Low flow warning device activation for breath assist type tight-fitting powered air purifying respirators.

5.4.1. Take precautions to mount the pressure transducer in a manner that isolates it from shock and vibration, in particular, that which is induced by the breathing machine and the operation of the PAPR100.

5.4.2. Mount the respirator to the headform in the as-worn configuration following all pertinent User's Instructions. Do not connect headform to breathing machine.

5.4.3. Turn on breathing machine and use a timer or the built-in tachometer to verify that the cam is operating at 24 rpm (24 rpms yields a 40 lpm volume). Stop the breathing machine when the pistons are at the end of the upstroke and reset counter to zero.

5.4.4. Check that the waveform reads zero, then hit the Data Entry button and enter the task number, date, make and model of the unit being tested. (While this is being done the transducer should be connected to the recorder, but the transducer should not have any pressure load on it).

5.4.5. Connect the headform with the PAPR100 mounted to the lung-in-bottle assembly, using the tubing side that is connected to the breathing bag inside the bottle, and then connect the other tube from the lung in bottle to the breathing machine. Connect pressure transducer of the PC-based recording system to resistance port of the headform with a short length of tubing. Pressure is measured at a pitot ring positioned 25 mm inside of the trachea inlet.

5.4.6. Turn on the PAPR100 and the breathing machine. Ensure that no air flow warnings are present on the respirator.

5.4.7. Hit the Start button on the PC test software to begin data collection.

5.4.8. Restrict the flow to the respirator. This is done by incrementally adding restriction to the inlet of the respirator, such as attaching small pieces of adhesive tape or a similar flow restricting item.

5.4.9. Add increased flow restriction to the respirator inlet until the low flow warning device activates. Carefully adjust the flow restriction to determine the point at which the minimum restriction activates the low flow warning device. Save the pressure tracings for the breaths both immediately before and after warning activation.

5.4.10. Turn off the PAPR100 and breathing machine.

5.4.11. Retrieve the tracings for data analysis from the PC –based system which uses a custom LabView test software operating code to display the results.

5.5. Data Analysis

5.5.1. The PC-based system produces a trace showing the inhalation (negative) and exhalation (positive) breathing resistance. For this test the inhalation phase for the breaths both immediately before and after low flow warning device activation is the component for analysis. The PC-based system can be adjusted for sizing, i.e. how many peaks will appear on the screen. The spread of the waveform on the PC display will not affect the results.

5.5.2. For a breath assist type tight-fitting PAPR100, a greater than 115 LPM air flow is indicated by positive the peak values of the inhalation tracings with respect to the base-line (zero) established at the time the system is calibrated. A less than 115 LPM air flow is indicated by negative peak values of the inhalation tracings with respect to the base-line. The PC-based system will automatically log and display any negative peaks with sufficient area to qualify as conditions that are less than the minimum required air flow.

6. PASS/FAIL CRITERIA

6.1. The criterion for passing this test is set forth in 42 CFR Part 84, Subpart K, Section 81.171(j).

6.1.1. The low flow warning must actively and readily indicate when flow inside the respiratory inlet covering falls below the minimum required air flow. The minimum air flow shall be 115 LPM for tight-fitting PAPR100.

6.1.1.1. For a breath-assist type tight-fitting PAPR100, conditions below the minimum allowable flow of 115 LPM are indicated by a negative pressure measured inside the facepiece in relation to the immediate environment, during both inhalation and exhalation.

6.1.2. Any warning must be detectable by the wearer without any intervention by the wearer.

6.1.3. Warning devices must be configured so that they may not be de-energized while the blower is energized.

6.1.4. Any warnings which require different reactions by the wearer must be distinguishable from one another.

7. RECORDS/TEST SHEETS

7.1. Record the test data in a format that shall be stored and retrievable.

Revision History

Revision	Date	Reason for Revision
0.0	23 March 2020	Original Release