Technical standards for respiratory oscillometry: test loads for calibration and verification

To the Editor:

It has been brought to our attention that there is ambiguity in the ERS technical standards for respiratory oscillometry [1], specifically regarding the use of test loads for calibration and verification.

It is stated that (page 9): "The magnitude of that load impedance should be above the absolute value of Z_{rs} that is expected for any given patient or subject population in which the oscillometric device is to be used, including impedances encountered in children and adults during bronchial challenge testing. Therefore, it is recommended that test loads for adult testing be ~15 hPa·s·L^{-1} and for children ~40 hPa·s·L^{-1}." Similarly, in table 1: "The test loads should cover the range of Z_{rs} encountered in normal oscillometry use: adults ~15 hPa·s·L^{-1}; children ~40 hPa·s·L^{-1}."

The intent of these recommendations is to ensure that calibration of an oscillometric device is accurate over the appropriate range of Z_{rs} values encountered across patients and research participants. Note, typically the user does not perform calibration, only verification. In current practice, verifications are usually performed at the lower range of expected Z_{rs} values only (*i.e.* ~2 hPa·s·L^{-1} for adults and ~15 hPa·s·L^{-1} for children). This wording was intended to improve on this, including better definition of the Z_{rs} range of the population being tested.

Thus, our wording is clarified as follows: "Therefore, manufacturers should ensure calibration is accurate over the range of the expected impedances. To this end, we recommend that user verification be performed using a test load near the higher end of the expected testing range. This would depend on the population being tested: for school-aged children ~4.5 years old and above to adults we recommend approximately 15 hPa·s·L^{-1}, for pre-school ages 2.5 to ~4.5 years approximately 25 hPa·s·L^{-1}, and for infants approximately 40 hPa·s·L^{-1} [2]; if bronchial challenge is to be conducted, this increases the expected testing range. A second verification can be done at an intermediate or zero load (*i.e.* no load, or no load after accounting for the model of antimicrobial filter used, which can help verify the filter impedance). In any case, verification should be done at all oscillation frequencies to be used in testing."

Manufacturers must provide users with the appropriate physical test loads to facilitate regular verification. The frequency with which verifications are done is subject to local practice and should reflect typical patient testing rates; it should be done at least once on every testing day. The current recommended tolerance for verification is within the range ±10%, or ±0.1 hPa·s·L^{-1}, whichever is the greater. Should verification reveal that accuracy has deviated from this tolerance, then recalibration or maintenance by the manufacturer should be performed. To account for possible changes over time in test load characteristics, either an independent evaluation of the test load or verification of the device with a different test load should be performed at regular intervals, at least annually.

The standards also state that "Ideally, test loads should also include the elastic and inertial components of impedance." This reflects the importance of reactance as an outcome for oscillometry, and also underscores that impedance is a multi-dimensional variable, encompassing frequency-dependent resistance and reactance. This means that test loads whose characteristics change with frequencies would be superior to single or even two-point verification using resistive loads alone, as they would enable simultaneous

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User verification of device accuracy using test loads should encompass the expected range of Z_{rs} to be tested; this letter clarifies the definition of Z_{rs} ranges of the population being tested. Manufacturers should report accuracy of both R_{rs} and X_{rs}. https://bit.ly/2ZrnOCD

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testing of static calibration and frequency-dependent behaviour of the flow and pressure sensors. Here it is worth making a distinction between recommendations for manufacturers *versus* users. We recognise that a standardised reactive test load has not been established for calibration or verification. This is an active research area, driven by the poor comparability in reactance which remains across devices [3–7]. Until clarity is achieved, manufacturers should calibrate and provide accuracy reports for resistance and reactive impedance compared against the recommended tolerance limits. At present no specific recommendations for reactance test loads can be made for user verification, though this should be pursued by manufacturers.

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