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White Paper

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Calibration vs. Accuracy Check

All spirometers placed onto the market since 2009 must conform to ISO 26782[1]. It is also widely recognised by multiple guidelines and international respiratory societies that there should be quality control in spirometry[2]. Confusion can be raised over the definition and use of the terms used for these quality controls, which this short article aims to clear up.

The word calibration and its meaning with regards to spirometry in practice can cause controversy, especially when looking to purchase a new spirometry device. The term 'calibration' indicates that the device has an in-date certificate of accuracy traceable to international standards. This is carried out by the manufacturer and should be re-certified on annual service visits by a qualified service technician or at the interval specified by the manufacturer if more frequent. Once this is set, ALL commercially available diagnostic spirometry devices must have the ability to be checked by the user performing an 'accuracy check' or as sometimes confusingly referred to, a 'calibration check'. This is carried out with a certified calibration syringe of precise volume, typically 3-L. By performing an accuracy check, this verifies that the spirometer is reading correctly, i.e. that it is accurate. It is recommended that an accuracy check is to be performed prior to testing subjects each day that a spirometry session is set to take place[3]. This will ensure that the spirometer is giving the most accurate and reliable results possible to assist with diagnosis and monitoring of respiratory conditions.

The standard for spirometers ISO 26782:2009 states in the section on performance requirement: 7.1 that the maximum permissible error for the volume reading in the MEASUREMENT RANGE shall be ± 3,0 % of reading or 0,05 L (whichever is greater). This applies under the following environmental conditions: ambient temperature from 17 °C to 35 °C; relative humidity from 30 % RH to 75 % RH; ambient pressure from 850 hPa to 1060 hPa. In the section 8.2 Calibration it states: The spirometer, including its accessories, shall be provided with a means of checking the calibration of the spirometer using a 3-L calibration syringe with an accuracy of 0,5 % or better.

The ISO standard for spirometers is a legal requirement for CE Marked devices and thus supersedes the guidelines on spirometry published in 2005 by the ATS/ERS Task Force in respect of all technical aspects, but not regarding user guidelines which the ISO standard does not touch on, being a technical standard. ATS/ERS:2005 spirometry guidelines state:

'A calibration check is different from calibration and is the procedure used to validate that the device is within calibration limits, e.g. ± 3% of true. If a device fails its calibration check then a new calibration procedure or equipment maintenance is required. Calibration checks must be undertaken daily, or more frequently, if specified by the manufacturer.'

Note that a spirometer, as with any other measuring device, should have an accuracy check procedure performed after dismantling for cleaning or any other purpose, or if dropped or damage is suspected for any other reason. ISO 26782:2009 states that in this case the device shall be tested and the spirometer shall meet the requirements of Clause 7.

References:

1. ISO 26782:2009 Anaesthetic and respiratory equipment - spirometers intended for the measurement of time forced expired volumes in humans. This standard was last reviewed in 2014. ISO standards are reviewed every five years. ISO 26782:2009 specifies requirements for spirometers intended for the assessment of pulmonary function in humans weighing more than 10 kg and applies to spirometers that measure timed forced expired volumes, either as part of an integrated lung function device or as a stand-alone device, irrespective of the measuring method employed.

2. Miller M.R., Hankinson J, Brusasco V, Burgos F, Casaburi R, Coates A, Crapo R, Enright P, van der Grinten C.P. M, Gustafsson P, Jensen R, Johnson DC, MacIntyre N, McKay R, Navajas D, Pedersen OF, Pellegrino R, Viegi G and Wanger J. Standardisation of Spirometry. Eur Respir J 2005; 26:319-338

3. Levy M.L, Quanjer P.H, Brooker R, Cooper B.G, Holmes S, and Small I.R. Diagnostic Spirometry in Primary Care Proposed standards for general practice compliant with American Thoracic Society and European Respiratory Society recommendations. Primary Care Respiratory Journal 2009; 18(3):130-147