ATS/ERS 2019 SPIROMETRY STANDARDS EXPLAINED

How Vitalograph's New Product Range Bring These To Life

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It has been just over a year since the American Thoracic Society (ATS) and the European Respiratory Society (ERS) published an update to the standards on spirometry. The previous spirometry standards were published more than 15 years ago and in their own words 'Improvements in instrumentation and computational capabilities, together with new research studies and enhanced quality assurance approaches, have led to the need to update the 2005 technical standards for spirometry to take full advantage of current technical capabilities.'

Here, I will summarise some of the major changes in the latest guidelines and demonstrate where we have implemented these recommendations into our new PC based spirometer software (Spirotrac 6), desktop spirometer and handheld spirometer.

What Has Changed?

The ATS/ERS have highlighted 11 key updates, which are listed below. I will not address all of these but instead focus on the most interesting.

1. A new list of relative contraindications was added.
2. Spirometers are now required to meet International Organization for Standardization (ISO) 26782 standards, but with a maximum permissible accuracy error of ± 2.5%.
3. Device quality assurance procedures were updated.
4. Operator training as well as attainment and maintenance of competency were addressed.
5. The list of activities that patients should avoid before testing was updated.
6. There is a focus on the use of devices that measure both expiration and inspiration.
7. Maneuver acceptability and repeatability criteria were updated. The end of forced expiration (EOFE) was redefined.
8. Requirements for spirometry systems to provide uniform cues and feedback to the operator were added.
9. New withholding times for bronchodilators before bronchodilator responsiveness testing were developed.

A new grading system for assessment of spirometry quality was developed.

Standardised operator feedback options that promote synoptic reporting were developed.

Relative Contraindications

You may be surprised to learn that the 2005 ATS/ERS Standardisation of spirometry publication did not include any contraindications at all. In fact, the only contraindication to performing lung function testing that can be found in the 2005 series of 'ATS/ERS Task Force: Standardisation of Lung Function Testing' publications is that it is 'recommended that patients should not be tested within 1 month of a myocardial infarction'. The new standards include a list of relative (not absolute) contraindications, based on a review of the available evidence, including a change to the previous contraindication of spirometry testing within 1 month of a myocardial infarction to 1 week. Their recommendation is that operators should consider this new list of relative contraindications when electing to perform spirometry on a subject. It is up to you to decide whether the risks outweigh the benefits of spirometry for the particular subject.

Spirometer Accuracy And Quality Assurance

Possibly one of the most important and major changes has been to tighten the accuracy requirement for spirometers. Everyone is familiar with the previous standard of ± 3% for the spirometer (plus ± 0.5 % for the calibration syringe). This has been tightened to ± 2.5% for the spirometer (plus ± 0.5 % for the calibration syringe).

Standards published by the International Organisation for Standardisation (ISO) are endorsed worldwide. ISO 26782 (Anaesthetic and respiratory equipment — Spirometers intended for the measurement of time forced expired volumes in humans) covers the essential technical operating characteristics of spirometers. This standard includes new specifications for validation testing spirometers which replaces the ATS/ERS standard waveforms used previously, which are have been deemed to not be suitable for high tech modern spirometers. All spirometers must have a maximum permissible error of less than or equal to ± 2.5% when tested with a 3-litre calibration syringe using the thirteen test profiles of ISO 26782 Section 7, Annex C. In addition, 'Calibration verifications must be undertaken at least daily using a 3-litre syringe' regardless of flow sensor type. The effects of these will be to increase the accuracy, precision and quality of spirometry. Older devices and certain flow sensor technology may struggle to meet these new accuracy standards.

Vitalograph continues to use the Fleisch pneumotrachograph across all our new spirometers for both healthcare and clinical trials. This tried and testing technology has proven to be very accurate, well within the new ± 2.5% accuracy requirement, as well as being linear, reliable and robust – all important features for busy workloads.

ERS recommendations for performing spirometry during the COVID-19 pandemic and beyond is that 'Test should always be carried out with a high specification disposable in-line bacterial and viral filter in place (We recommend filters with minimum proven efficiency for high expiratory flow of 600 to 700 L/min). Use of disposable combined mouthpieces/sensors is not recommended at this time.'

The Fleisch has an extremely low flow impedance (resistance) even when used with one of our Bacterial-Viral Filters (BVF), meaning that neither expiratory nor inspiratory measurements are affected when used with a BVF. Testing of the Eco BVF with our flow head by Professor Colum Dunne at the University of Limerick concluded that the Vitalograph BVF is very effective in the prevention of microbial transfer to the flowhead, with no bioburden being detected using flowrates below 960 L/min. This means that frequency disassembly and cleaning isn't required as when a new BVF is used for every patient, the interior of the flowhead is protected meaning that only exterior surfaces require cleaning using 70% isopropyl alcohol.

Devices are required to allow the user to perform a calibration verification using a 3-L syringe, plus the ability to perform a new calibration should it fail the verification. It is a requirement that a calibration verification is undertaken at least daily regardless of the flow sensor used (even if it is disposable). If a BVF is used during testing, then it must also be used during verification/ recalibration.

Inspiration As Well As Expiration

Whereas previous guidelines were more focused on volume measurement devices using the expiration-only technique, this update focused more on modern spirometers which measure inspiratory and expiratory flow. The guidelines include a detailed step by step procedure on how to perform FVC manoeuvres from the preparation of the patient right through to checking for repeatability. The new standards see the FVC manoeuvre to be comprised of four distinct phases:

1. Maximal inspiration,
2. a 'blast' of expiration,
3. continued complete expiration for a maximum of 15 seconds, and
4. inspiration at maximal flow back to maximum lung volume

This does not mean that you can't choose to perform a FVC manoeuvre without the inspiration to total lung capacity at the end. In that case you would perform the first three phases of the manoeuvre, with the aim of the operator being satisfied that the subject is 'empty' before ending the test.

It is worth noting that there is no longer a minimum forced expiratory time (FET), so subjects can still have an acceptable FVC which is less than 6 seconds if it met the other criteria. At the other end of the scale, there is no need for subjects to continue to blow out beyond 15 seconds as it has been shown that FETs > 15 seconds do not provide meaning full data and rarely change clinical decisions.

Acceptability, Repeatability And Redefined End of Test

FEV1 and FVC are now to be individually evaluated for acceptability rather than a manoeuvre as a whole. An acceptable FEV1 from a manoeuvre can now be reported regardless of the quality of the FVC and vice versa. Also introduced is the concept of 'usable' whereby a technically unacceptable measurement can still be clinically useful. This is where the subject has performed the best they are able on this occasion but the manoeuvres do not meet all the criteria.

Previous standards used the term "end of test" (EOT) to mark end of forced expiration. There is a new stress on the importance of a maximal inspiration after the forced expiration. As such, the end of forced expiration is no longer the end of the recommended test procedure, and the term end of forced expiration (EOFE) has been introduced.

Recognising a satisfactory EOFE is important to ensure that a true FVC has been achieved. Achieving one of the following three recommended indicators of EOFE is required (Figure 1):`

1. The most reliable indicator is less than 0.025-L change in volume for at least 1 second (plateau).

2. Forced Expiratory Time (FET) reaches 15 seconds.

3. Subject unable to expire long enough to achieve 1 or 2, however is able to repeatedly achieve the same FVC and meets repeatability criteria.

The criteria for repeatability are, thankfully, quite straightforward. The aim is still to achieve a minimum of three acceptable FEV1 and FVC measurements. Repeatability is based on the difference between the two largest, acceptable FEV1 and FVC, regardless of whether they were from the same or different manoeuvres. For subjects over 6 years old the difference must be less than or equal to 150 ml. For subjects ages 6 years or less the difference must be less than or equal to 100 ml or 10% of the highest value, whichever is greater.

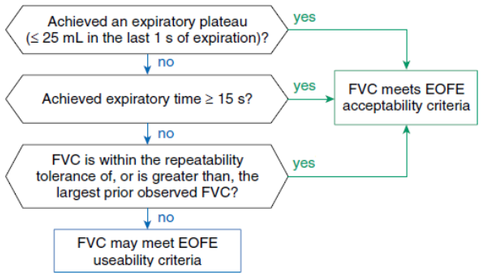

Figure 1: *Flowchart outlining EOFE acceptability for FVC.*

In order to save you the time and effort of having to calculate whether your subject has met the criteria for repeatability, our software automatically calculates the difference and displays it on the live testing screen. Figure 2 shows how Spirotrac6 displays the repeatability of FEV1 and FVC in both absolute values and percentage. The orange traffic light in this example denotes that only two acceptable tests have been performed.

Another new feature of Spirotrac 6 is the revamped Analysis tab, which provides more detailed feedback during testing. The traffic light classification scheme is used to highlight when you have achieved the minimum of three acceptable FEV1 and FVC measurements which are within the age-related criteria (figure 3). Other useful information on this tab is the pictogram which shows where the measured values lie compared to predicted for that subject, and system interpretation based on the GOLD and ATS/ERS guidelines.

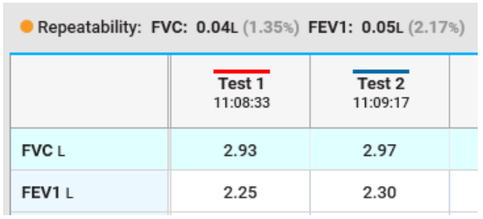

Figure 2: *Repeatability feedback in Spirotrac6.*

Operator Feedback

The guidelines recognise that spirometer manufacturers should provide feedback to the operator on the quality of the test data. We have implemented in-test prompts and post-test analysis for both individual manoeuvres and entire test sessions to help you identify that your subject has achieved an acceptable and repeatable FEV1 and FVC as well as achieving this new EOFE.

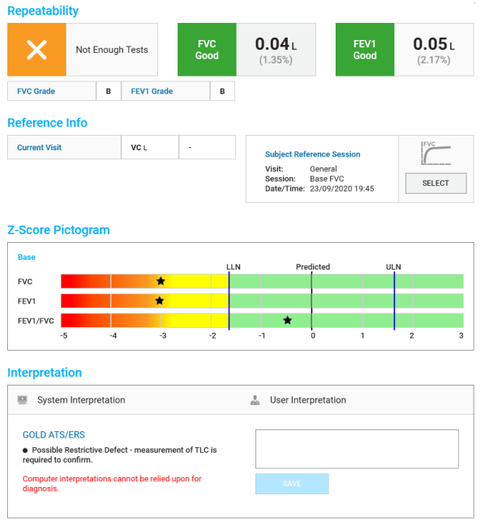

Figure 3: *Spirotrac 6 analysis tab.*

Firstly, during testing a green notification bar will appear when a plateau and/or fifteen seconds have been achieved, so that you can concentrate on your patient.

At the end of the test the software analyses that effort against each new criterion, such as start of test, cough free, EOFE, etc. A summary quality message using a clear and simple Accept/Usable/ Rejected scheme is then displayed where you can choose to accept or reject that test based on the feedback provided. Figure 4 is an example of the post-test feedback screen in Spirotrac 6, showing the seven criteria each manoeuvre is measured against.

Figure 5 shows an example of the further information provided under the 'Guidance' button. This offers explanations of why a criteria wasn't met and, where relevant, suggestions on what to tell the subject about how to improve their technique.

In addition to being able to accept or reject an entire manoeuvre, our new range of spirometers allow you to override the acceptability designation for the individual FEV1 and FVC as

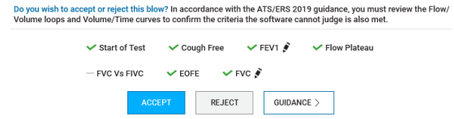

Figure 4: *Post manoeuvre test quality feedback.*

well as for the test as whole. This gives you full control over which FEV1 and FVC you want to report.

Bronchodilator Responsiveness Testing

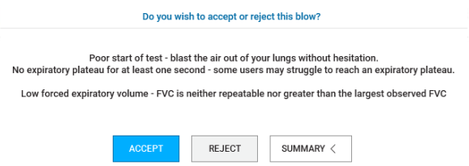

Figure 5: *Sample guidance regarding test quality.*

'Reversibility testing' has been replaced by the term 'Bronchodilator Responsiveness Testing' to avoid any implication that airway obstruction can be completely eliminated or reversed.

Both the percentage change and the absolute change in FEV1 and FVC compared with pre-bronchodilator values should be reported.

Grading

Spirometry results are very dependent upon subject cooperation and the ATS/ERS have recommended that a grading system is used for FEV1 and FVC (separately) which refers to the consistency of the blows. The aim is to inform

the interpreter about the level of confidence that the results represent the best that the subject was able to do at the time. The criteria used is the repeatability between the two largest FEV1 values and the two largest FVC values. The grades are A, B, C, D, E, U and F. Grade 'U' denotes 'Usable'. Figures 6 & 7 show the grading system for ages 6 and below, and for ages above 6.

Standardised Operator Comments And Reporting

Grade	Number of Measurements	Repeatability: Age ≤ 6 yrs
A	≥ 3 acceptable	Within 0.100 L *
B	2 acceptable	Within 0.100 L *
C	≥ 2 acceptable	Within 0.150 L *
D	≥ 2 acceptable	Within 0.200 L *
E	≥ 2 acceptable OR 1 acceptable	> 0.200 L * n/a
U	0 acceptable AND ≥ 1 usable	n/a
F	0 acceptable AND ≥ 0 usable	n/a

* Or 10% of the highest value, whichever is greater

Figure 6: *Grading system for FEV_1 and FVC for ages 6 and below.*

Grade	No. of measurements	Repeatability: Age > 6 yrs
A	≥ 3 acceptable	Within 0.150 L
B	2 acceptable	Within 0.150 L
C	≥ 2 acceptable	Within 0.200 L
D	≥ 2 acceptable	Within 0.250 L
E	≥ 2 acceptable OR 1 acceptable	> 0.250 L n/a
U	0 acceptable AND ≥ 1 usable	n/a
F	0 acceptable AND ≥ 0 usable	n/a

Figure 7: *Grading system for FEV_1 and FVC for > 6 years.*

Operator comments are a key part of the report, providing the interpreter important information about the subject's performance. Synoptic reporting is a clinical documentation method that uses structured checklists to help clinicians produce more complete, consistent and valuable medical reports. The aim of having standardised operator comments is to provide a more rapid and thorough means of generating meaningful operator comments to guide interpretation regardless of the operator.

Another recommendation is that the ATS Standardised Report form should be used and the default set of reference values for all ages should be the Global Lung Initiative (GLI) reference equations. We have implemented both recommendations and expanded our reporting capabilities to allow users to configure their own reports depending upon their preferences.

Connectivity is more important than ever, and the standards require that spirometers are able to export data to electronic medical records (EMR). All of our new spirometers will be supplied with Vitalograph Connect as standard. This new middleware software eliminates the need to scan reports by providing the bidirectional ability to interface directly with major EMRs.

Summary

- ATS/ERS Standardisation of Spirometry 2019 Update has introduced some key changes to how spirometry should be performed and reported.
- Spirometers must meet the ISO 26782:2009 standards and meet an accuracy of ± 2.5%.
- The default set of reference values for all ages should be the Global Lung Initiative (GLI) reference equations.
- FEV1 and FVC should be assessed for acceptability and repeatability separately and can be reported from separate manoeuvres.
- EOT has been replaced by EOFE to define the end of the forced manoeuvre.
- Subjects are no longer required to blow out for at least 6 seconds and no need to blow out beyond 15 seconds.
- A grading system for FEV1 and FVC has been introduced to quantify the quality of the measurements.
- Spirometers should provide enhanced feedback to the operator.
- Reversibility testing has been renamed Bronchodilator responsiveness testing.
- Vitalograph new spirometers have implemented the suggested changes to aid operators get the best results for their subjects.

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