



# Vitalink

VOLUME THREE

THE GOLD STANDARD IN RESPIRATORY TECHNOLOGY

## Overreading – The Quality Game

Unfortunately, it is a sad fact that we don't have enough hours in a day to become an expert at everything. Something has to give. And so, some people performing spirometry testing in a clinical setting, may not be as



JACK WANGER, AMERICAN THORACIC SOCIETY

'comfortable' as they could be because they often have other priorities and need to wear several hats. And, after all, spirometry can be fairly complicated, especially if bronchoprovocation testing is involved. Then it becomes very complicated, actually.

So it's a good idea to have the services of an 'overreader' available – or maybe we should call him or her an 'expert assistant.' Someone who can help ensure that the tests are being performed correctly and that the patient is giving their best. Then the doctor can be confident, when making decisions regarding treatment plans, that he is seeing accurate test results.

Test results are transmitted electronically from the clinic to the overreader.

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## Quality Spirometry for Clinical Trials

The success or failure of a clinical trial can have a huge financial implication for a pharmaceutical company. But it is one thing if the failure is due to lack of efficacy, quite another if the data collected is of poor quality so that no clear determination can be made.

Respiratory clinical trials are performed at clinical sites located around the country and even around the globe. Most of these sites already have spirometry equipment of some kind. Most of them have trained personnel to perform the testing on the patient. Most of them have at least heard of the word 'calibration'! But not all of them have much experience in spirometry or the resources to guarantee good results every time.

Vitalograph has recently released the latest version of their fully customizable 'Centralized Spirometry system' designed specifically to guarantee accurate, reliable results for spirometry testing, performed at multiple sites. It revolves around an 'Overreader', someone who is a real, live, spirometry expert. All results from the sites are forwarded electronically to the overreader for quality control purposes before being added to the main database. In this way, the testing can be graded and sites that are having problems maintaining the required level of quality can be notified and retrained if necessary.

This PC based system consists of two main software components, 'Spirotrac for Overread' (SpoR) and 'Overread'. The SpoR component is used at the clinic in conjunction with the Vitalograph 6800 Spirotrac hardware, which consists of a Fleisch

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# Monitor and Manage Asthma at Home

Experts agree that the best way to manage asthma is at home, allowing more effective control, improving quality of life and the need for less medical intervention.

Vitalograph asmaplan+ peak flow meters offer patients an inexpensive and convenient way to monitor and manage their asthma in the comfort of their own home.

Once the physician has established the patients target peak expiratory flow (PEF), a personalized action plan can be developed. The Vitalograph asmaplan+ has colored sliding indicators on the front and a color-coded label on the back-side providing space for this action plan, simplifying self-monitoring and self-management for asthma patients.

Vitalograph offers a variety of peak flow meters available in standard and low range versions. The SafeTway® disposable mouthpieces prevent cross-contamination making them ideal for multi-patient use of peak flow meters in clinics and other settings.

Vitalograph peak flow meters meet all peak flow meter standards, including the latest American Thoracic Society (ATS) 2005 recommendations. For more information about Vitalograph peak flow meters or to place an order, please contact the customer service team at (800) 255-6626. ✦



Color	Results	Sample Action Plan:
Green	Good readings, no asthma signs present	Continue regular treatment
Yellow	Caution, an episode of asthma may be present	Take additional medicines
Red	Signals a medical alert	Use bronchodilator and contact doctor immediately

## Proper Spirometry Testing Preparation and Coaching Ensure Quality Results

Spirometry can be one of the most beneficial and accurate ways of determining lung health, but only if the test is performed properly. Poorly performed tests, whether the result of lack of patient preparation, technician coaching or patient technique can result in misleading values and incorrect patient diagnosis.

A well-trained and competent technician will ensure that the patient is properly briefed and understands what is expected of them. The patient should first be properly prepared. They should not eat a heavy meal within two hours and not smoke within four to six hours of the test.

Cooperation from the patient during the test is the key to getting accurate results. Follow these testing steps:

- 1 The patient should be seated and sitting up straight.
- 2 Instruct the patient to breathe in as deeply as they can.
- 3 Make sure the subject's lips are sealed around the SafeTway mouthpiece or Bacterial Viral Filter.
- 4 Have patient blow out as hard and fast as they can.
- 5 Keep encouraging the patient to keep blowing for at least six seconds.

Often the patient will think they cannot blow out any longer, when they actually can. Coaching the subject before



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## A Chip Off the Old Block

Anyone who has ever called Vitalograph customer service has probably heard the voice of Reta Locke, the friendly voice that has helped many customers buy what they needed or solved a problem. She has been the anchor in that role for over 10 years.

But all good things come to an end and Reta has decided to retire so she can spend more time traveling with her husband Danny and taking time to smell the roses. Her colleagues and the hundreds of customers that she spoke to on a regular basis will miss her.



NICKOLE BENSON

The good news is before Reta left, she made sure that no one would be left in the lurch by hiring and training her replacement in all areas, from product knowledge to order progress, computer programs to trade shows.

And who is this new face in Vitalograph charged with carrying on Reta's good work? Her name is Nickole Benson.

Nickole has similar experience in customer service and management roles so she already had great communication skills before Reta started working with her. By the time they had finished their time together Reta said "she is going to work out just fine, I feel happy leaving my friends and customers in her hands now. But I hope everyone appreciates she still has a lot to learn which can only be done by experience and to please go easy on her in the early days, when she may not have all the answers to hand."

Nickole is married and lives in Lenexa, Kan. Outside of work she is working on furthering her education and in her free time, like Reta, enjoys working in the yard and tending to her roses bushes. Nickole looks forward to talking to you soon. ✧

## Quality Spirometry for Clinical Trials

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pneumotachometer based spirometer connected via a PC USB port. When new tests have been performed the PC connects to the Vitalograph server, either via a normal telephone line or via the Internet, and transmits the results. These results are encrypted, for security purposes and labeled with trial, site and patient identifiers.

The overreader checks for new data, usually on a daily basis, and using the sophisticated 'Overread' software tools, that Vitalograph have produced to assist him or her, grades the test results. They can also choose to exclude bad tests and record appropriate comments, which are attached to the data, regarding their decisions. Then, and only then, are the new results added to the main database and data integrity maintained.

Remember the golden rule, bad data in = bad data out. ✧

## Tech Corner

### Is Your Spirometer Clean?

Are the dirty spirometer gremlins giving you nightmares? Are you afraid your results will be wrong or your patients will become infected? Keeping your spirometer clean is very easy. Simply wipe any outer surfaces with a 70 percent Isopropyl alcohol solution on a weekly basis. To keep the inner workings of the breathing circuit clean, wash the assorted parts in warm soapy water, rinse thoroughly and make sure that all components are completely dry before reassembling. Be sure to check the calibration after every cleaning.

Don't have a lot of time to disassemble, clean and reassemble your spirometer? I recommend using the bacterial viral filters for all of your testing. This not only keeps the breathing circuit clean and your patients safe, but also basically eliminates cleaning altogether. For a few cents more you can chase the gremlins out of your dreams and get on with taking care of the patients. ✧

### Proper Spirometry Testing Preparation ...

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and during testing can make the difference between acceptable, accurate tests and ones that are unacceptable. Testing should be performed until at least three good tests are performed and good reproducibility is achieved.

For more information on spirometry procedures, a manual titled "Pulmonary Function Laboratory Management and Procedure Manual" is available from the American Thoracic Society. Contact the National Institute for Occupational Safety and Health (NIOSH) for a list of approved spirometry training courses. ✧

## Exhibitions

June 28-30

**COPD5 International Conference**  
Birmingham, England

July 13-17

**AARC – American Association  
for Respiratory Care**  
Phoenix, Ariz.

Sept. 2-6

**ERS – European Respiratory Society**  
Munich, Germany

Oct. 21-26

**CHEST 2006**  
Salt Lake City, Utah

Nov. 10-15

**ACAAI – American College of Asthma,  
Allergy & Immunology**  
Philadelphia, Pa.

Nov. 15-18

**Medica 2006**  
Messegelände Düsseldorf

## Overreading – The Quality Game

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Then, using special software, it is possible for overreaders to analyze all test results and make adjustments to their quality score. Individual tests and even whole test series can be rejected if the quality is not high enough, sometimes resulting in the need for repeat testing. Summary reports can then be sent back to the clinic to help identify quality issues.

Jack Wanger, American Thoracic Society (ATS) committee member and long-time overreader sums up his experience: "Since I started overreading data from clinical trials I have noticed a dramatic improvement in the quality of testing generally and therefore the quality of the test results being used to determine the outcome of the study."

Overreaders, in fact, have many strings to their bows. For example, they can get involved in site training and retraining. This can be done in person or remotely using the modern computer tools which are available. The training can be on the use of the equipment or often times it is assisting patient coaching methods. They can also check to see that the spirometer has been calibrated at the correct times and can be helpful in equipment diagnostic issues.

Vitalograph have been continuously developing their 'Overread' software for many years and have now released their latest version which can be fully customized to accommodate customers special needs. ♦

"So it's a good idea to have the services of an 'overreader' available – or maybe we should call him or her an 'expert assistant.' Someone who can help ensure that the tests are being performed correctly and that the patient is giving their best."



*Vitalink* is a publication  
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Your questions and comments  
regarding this newsletter are welcome.

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