



Protocol and procedure for undertaking Spirometry in a Community Setting

Document Version Control

Version Number	Details	Date	Author of Change	Description of Changes and reason for Change
1	First full review	October 2012	Katy Beckford	New Document
2	Change to Classification	April 2013	Katy Beckford	Updated with all classifications

Contents

Section	Content	Page No
1.0	Background	3
2.0	Definition	3
3.0	Who can undertake Spirometry?	4
4.0	Training for community staff undertaking spirometry	5
5.0	Who can have Spirometry?	5
6.0	Preparing the Patient	6
7.0	Spirometry Procedure	6
8.0	Common Errors	7
9.0	Interpretation of Results	8
10.0	Quality Control and Calibration	8
10.1	Biological Control	9
11.0	Infection Control	9
12.0	Audit	9
13.0	Reference List	10-11
14.0	Appendices	12-24

Protocol and procedure for undertaking Spirometry in a Community Setting.

1.0 Background

Chronic Lung disease, such as Chronic Obstructive Pulmonary Disease (COPD) and Asthma, is a major cause of mortality and morbidity in the UK. The prevalence of lung disease is predicted to increase during the next 20 years with more people dying from respiratory disease than coronary heart disease or cancer (Booker R 2005, Price D 2006). As a result of this there is now a need to increase access to Spirometry in a Primary Care Setting as this is a vital tool to help with the diagnosis of airflow obstruction in those presenting with breathlessness.

As well as being able to confirm airflow obstruction, spirometry can also assist in the diagnosis of restrictive lung diseases and lung cancers and can monitor a variety of respiratory disorders, assessing their response to treatment. The National Institute of Clinical Excellence (NICE) also recommends the use of spirometry to confirm the diagnosis and to assess the level of severity in COPD. (NICE 2010)

There are many Spirometers available on the market but the Community Respiratory service currently uses the MicroMedical Carefusion Microlab spirometer. Whilst there are other spirometers available this protocol is designed specifically for this model.

This protocol is intended to support Chronic Obstructive Pulmonary Disease (COPD) management and patient care and treatment in line with the current national guidelines, British Thoracic Society (BTS) and NICE and also follows the Guidelines for the Measurement of Respiratory Function (ARTP 1994).

The protocol must be kept up to date and is designed to follow the local trust guidelines on Infection Control, Clinical Record Keeping and Audit.

It is now seen as the gold standard for the diagnosis, assessment and monitoring of COPD and is the preferred method in adults (better than PEFr which is effort dependant) for demonstrating airways obstruction in the diagnosis of asthma (GP Update Handbook 2010).

2.0 Definition

Spirometry is the measurement of volumes and flows during forced expiratory manoeuvres in order to detect mechanical abnormalities associated with respiratory disorders (BTS 2010).

Spirometry is done by measuring the volume of air that the patient is able to expel from the lungs after maximal inspiration.

The measurements that are obtained are:

- a) **FVC** – Forced Vital Capacity. This is the maximum volume of air that can be forcefully expired after maximal inspiration
- b) **FEV₁** – Forced Expiratory Volume in 1 second. This is the maximum volume of air that can be forcefully expired in the first second of the FVC.
- c) **FEV₁/FVC** – This is the ratio of Forced Expiratory Volume in 1 second and Forced Vital Capacity.
- d) **VC** – Vital Capacity. This is a non-forced measurement and may be greater than the FVC in COPD. It gives an accurate measure of lung volume when the airways are floppy as in emphysema.

The difference between VC and FVC can indicate air trapping and if the VC is higher than the FVC then the VC is used in calculating the ratio.

By using spirometry to assess lung function it is possible to diagnose COPD and asthma with greater confidence and accuracy and spirometry is vital for assessing the severity of COPD.

The Community Respiratory Team mainly undertake routine spirometry for monitoring purposes but it is during these procedures that errors in diagnosis can be identified so some understanding of the results is important as this can help to ensure that the patients are optimally managed.

Spirometry is however only one way of interpreting COPD disease severity. Other measures, such as the MRC dyspnoea scale for measuring breathlessness, exacerbation frequency, body mass index, quality of life assessment, and exercise capacity all help to build a more complete picture (NCCCC 2010).

COPD is classified into 4 categories of severity depending on the spirometry results.

		NICE Clinical guideline 12 (2004)	ATS/ERS 2004	GOLD 2008	NICE Clinical guideline 101 (2010)
Post-bronchodilator FEV ₁ /FVC	FEV ₁ % predicted	Severity of airflow obstruction			
			Post-Bronchodilator	Post-Bronchodilator	Post-Bronchodilator
< 0.7	≥ 80%		Mild	Stage 1 – Mild	Stage 1 – Mild*
< 0.7	50-79%	Mild	Moderate	Stage 2 – Moderate	Stage 2 – Moderate
< 0.7	30-49%	Moderate	Severe	Stage 3 – Severe	Stage 3 – Severe
< 0.7	< 30%	Severe	Very Severe	Stage 4 – Very Severe**	Stage 4 – Very Severe**

* Symptoms should be present to diagnose COPD in people with mild airflow obstruction

** Or FEV₁ <50% with respiratory failure

A brief explanation of the interpretation of the results can be found in section 9.

3.0 Who can undertake Spirometry?

All staff who undertake spirometry must be able to recognise a technically acceptable and reproducible test. They must also be able to carry out the procedure and know how to encourage the patient to ensure that reproducible spirometry has been obtained.

Staff must be competent in the interpretation of spirometry and if the staff member is not competent or trained to do so then the interpretation must be carried out by a staff member who is.

There is no restriction on which staff member can undertake spirometry but all staff that perform spirometry testing must ensure that they are competent to do so. This includes Health Care Assistants being accountable for their own action and working within their framework of their personal scope of skill. It is the responsibility of the Respiratory Team Leader who will have undertaken the Spirometry Degree course to ensure staff maintain competency levels.

The competency levels of all staff who undertake Spirometry will be assessed on an annual basis.

4.0 Training for community staff undertaking Spirometry

To ensure that the spirometry has been performed effectively it is important that the personnel who carry out the test do so within the ARTP/BTS guidelines and are aware of how to prepare the patient.

In the UK, the Association for Respiratory Technology and Physiology (ARTP), in conjunction with the BTS through the BTS/ARTP Liaison Committee, have established a qualification to assess the competence of staff to perform spirometry.

Poorly performed spirometry can lead to inability to obtain an accurate result which can therefore lead to a misinterpretation of the results and a patient being given an incorrect diagnosis of their condition (Levy et al 2009)

It is important that all staff carrying out spirometry are educated to a particular level and for the Community Respiratory Team it has been decided that all staff who perform spirometry but who do not interpret spirometry results need to undertake a certificate in spirometry and all staff who interpret spirometry results need to undertake a degree level course.

This qualification requires on-going validation of competency which has to be renewed every two years.

As previously stated the competency of the staff who perform spirometry will be carried out by a member of staff who has undertaken the degree course.

In order for those staff involved in carrying out spirometry testing and interpretation of results to maintain competency levels they should undertake a minimum of 5 spirometry tests a week or 20 a month.

There are a variety of courses available for staff members who wish to undertake spirometry but the Community Respiratory Team recommends the Education for Health courses.

Currently there is no requirement for accreditation of primary care practitioners performing spirometry but this is currently under review at time of print and this protocol will be updated when the decision has been publicised.

5.0 Who can have Spirometry?

The Community Respiratory Service mainly perform spirometry on those patients who have a confirmed diagnosis of COPD and use it to monitor the disease trajectory.

The service can, however, also assist GPs in:

- Diagnosing a lung condition
- Reversibility testing using short acting bronchodilators. This however is not currently done and as the patients will require Salbutamol inhalers then it will be essential to obtain a PGD to be able to give the medication to the patient.
- Ruling out a lung condition

Although there are no absolute contraindications to performing spirometry and it is generally a safe procedure the service will NOT undertake spirometry on patients who:

- Are currently experiencing and exacerbation of their condition
- Had an exacerbation <4 weeks ago

- Have had an MI, CVA, Pulmonary embolism, Pneumothorax or lung, eye or abdominal surgery in the last 3 months
- Have unstable hypertension or angina
- Have Haemoptysis of unknown origin

(Increases Intraocular, Intrathoracic, Intra-abd and Intracranial pressure)

6.0 Preparing the Patient.

Spirometry can be undertaken 'opportunistically' but it is very helpful for the patients if there are aware of what to expect and can therefore come prepared.

It is important that the patient is aware of the procedure and what will happen during the procedure. The patient also needs to know what to do in order for the results to be as accurate as possible.

If possible ask patients:

- To avoid eating a large meal within 2 hours of the start of the test
- Not to smoke within 1 hour of the test
- Not to consume alcohol within 4 hours of the start of the test
- To wear loose and comfortable clothing that does not restrict their breathing
- To avoid vigorous exercise within 30 minutes of the start of the test
- To arrive for their appointment in plenty of time so that they are relaxed, and have time to visit the toilet.

If diagnostic bronchodilator reversibility testing is needed then the patients will also be required to

- Withhold their short-acting inhaled β_2 agonists for 2-4 hours
- Withhold their short-acting anticholinergics for 4-6 hours.
- Withhold their long-acting inhaled and oral sustained release β_2 agonists for 12-24 hours
- Withhold their long-acting inhaled anticholinergics for 24-36 hours
- Withhold their theophyllines for 12 hours and sustained release theophyllines for 24 hours

(Booker 2008)

A patient leaflet has been designed for the service to help to prepare the patient for their spirometry. The information for this leaflet has been taken from the Primary Care Respiratory Society (previously GPIAG) information leaflet (2007). (Appendix 1)

7.0 Spirometry Procedure

PROCEDURE	RATIONALE
1. Check calibration of the spirometer using a 3 litre syringe (for all Micro Medical Spirometers)	To ensure that the spirometer is accurate and no variance in the parameters in the machine have occurred
2. Wash hands before testing.	To ensure no cross contamination can occur
3. Go through the patient information leaflet with the patient. DO NOT proceed if the patient has any contraindications.	To ensure that they have followed the necessary requirements prior to testing
4. Explain the test fully to the patient and what is expected of them.	To be able to obtain the patients full informed consent
5. Obtain the patients Age, Sex, Ethnicity, Weight and measure height without shoes. If the patient has spinal deformities then obtain height by measuring their arm span.	To accurately calculate reference values
6. Ask the patient to sit down in a chair with arms, remove any tight clothing and if they have	Patients may feel dizzy or light headed and may faint during testing.

loose dentures then remove these.	If the patient has a great deal of central obesity then they may stand but have a chair behind them
7. Ensure that the patient is comfortable and does not have a full bladder	This will influence how hard they are able to blow
8. Check all the patients details are correct (age, gender, name, hospital number etc) and enter these details on to the spirometer	To ensure you have the correct patient and these details are correct on the printed results
9. Demonstrate clearly to the patient how to perform the Relaxed Vital Capacity (RVC) by putting the disposable mouthpiece to your mouth, between your teeth and sealing your lips around it. Perform the breath yourself.	To enable to patient to fully understand what is required with the aim of reducing the need for repeat blows
10. Apply the nose clip	To prevent air leaking from the nose and producing a reduced reading
11. Ask the patient to perform the RVC and repeat the manoeuvre to get 3 reproducible readings +/- 5% or 100mls	This measures the potential capacity of the lungs at rest and is compared against the forced blow It may take more than 3 attempts to ensure within the 5% so allow the patient to rest between blows.
12. Remove the nose clip	It is no longer needed
13. Demonstrate clearly to the patient how to perform the Forced Vital Capacity (FVC) by putting the disposable mouthpiece to your mouth, between your teeth and sealing your lips. Perform the breath yourself.	To enable to patient to fully understand what is required with the aim of reducing the need for repeat blows
14. Ask the patient to perform the FVC and repeat the manoeuvre to get 3 reproducible readings +/- 5% or 100mls	This measures the potential capacity of the lungs at rest and is compared against the forced blow It may take more than 3 attempts to ensure within the 5% so allow the patient to rest between blows.
15. For each FVC blow encourage the patient loudly saying "Blow hard, blow, blow blow..."	To ensure that maximal effort has been obtained as this is essential to demonstrate any abnormality.
16. Examine if the BTS criterion has been achieved	To ensure that the best of 2 readings are acceptable for interpretation
17. Print off a copy of the results for interpretation and write any issues with technique	This will help the clinician gage the reliability of the results
18. Scan the results in to the computer and save on the shared drive	Printed paper from the spirometer does not withstand age and will deteriorate over time.

8.0 Common Errors

It is not always easy to see if a patient is performing effective breaths for the accurate interpretation of spirometry and sometimes these are clearly seen on the summary printout.

There are a number of errors that can occur during the testing. All of these errors will mean that the test should be repeated.

These are:

- A leak at the mouth
- An obstructed mouthpiece due to tongue or false teeth

- A poorly coordinated start to the manoeuvre
- A cough within the first second of the manoeuvre, or a later cough if it is deemed to have interfered with the blow
- Early termination of the blow
- If the patient did not inspire to Total Lung Capacity (TLC)
- The expiratory effort was sub-maximal

(ARTP 1994)

9.0 Interpretation of Results

There are 3 basic patterns to recognise:

Normal: FEV₁ and FVC above 80% predicted
FEV₁/FVC ratio above 0.7

Obstructive: FEV₁ below 80% predicted – in Mild COPD this may be $\geq 80\%$
FVC can be normal or reduced – usually to a lesser degree than FEV₁
FEV₁/FVC ratio below 0.7

Restrictive: FEV₁ normal or mildly reduced
FVC below 80% predicted
FEV₁/FVC ratio normal – above 0.7 (GOLD 2007)

(Both volumes are reduced in proportion which is why the Ratio is normal or high)

Features of ventilator abnormality in spirometry			
	Obstructive	Restrictive	Mixed
FEV ₁	Reduced	Reduced	Reduced
FVC	Reduced or Normal	Reduced	Reduced
FEV ₁ /FVC	Reduced	Normal or increased	Reduced

(GOLD 2007)

It is also important to look at the flow-volume curves as this provides a quick and simple check on whether or not obstruction is present in the results.

10.0 Quality Control and Calibration

As a service we do not perform spirometry on a daily basis so the quality control must be performed before seeing the patient for a spirometry test. If the staff member is undertaking more than once test in a day in a clinical environment then the spirometer will only need to be calibrated once.

The patients that are reviewed by the Community Respiratory Team are usually seen in their own homes which will require the spirometer to be transported in the staff members' car to the patients' home. Spirometers do not respond well to movement or changes in temperature and as a result the spirometer will need to be calibrated in the patients' home prior to testing.

This is to be performed using a 3 litre calibration syringe and the measured value should be within 3% of the syringe value.

How to calibrate the MicroMedical spirometer can be found in Appendix 2.

Once the calibration has been performed this will need to be logged onto the calibration log which includes the temperature to enable the results to be reported at BTPS (Body Temperature Pressure Standard). (Appendix 3).

10.1 Biological Control

It is not always possible to have access to a calibration syringe due to the relative cost implications. If this is the case then it is important that Biological control is undertaken. To ensure that the Spirometer has been properly calibrated it is important to perform a biological control on a weekly basis (ARTP 1994)

To do this a member of staff is required to determine their normal physiological range and this is done by recording their spirometry daily, at the same time of day for 2 weeks. At least 10 recordings are required.

It is then necessary to calculate the mean (average) value for each lung function parameter and then to calculate the normal range. This will be plus or minus 5% of the mean of each parameter.

Once this range has been established then they can be used to verify the accuracy of the spirometer.

It needs to be the same member of staff each time so if that member of staff leaves then the biological control will need to be obtained again for another staff member.

If the spirometer measures outside the normal range for that person then it will need to be recalibrated.

The biological control log can be found in Appendix 4.

11.0 Infection Control

Hands should be washed between patients and gloves should be worn when handling potentially contaminated equipment.

It is not necessary to always use a bacterial viral filter for every spirometry test but if you have a patient who you suspect has an infection or has TB then it is essential that this is used.

Daily Cleaning – after each patient the mouthpiece holder should be cleaned using an alcohol wipe. Single patient use mouthpieces should be used for every patient.

Weekly Cleaning – The turbine should be removed and washed in Cidex OPA for 10 minutes, rinsed and left to air dry.

Please see Appendix 5 for comprehensive infection control instructions.

12.0 Audit

There will be a regular Audit of the spirometry protocol and procedure.

This will include:

- Log of spirometry calibration records
- Records of disinfection of spirometer
- Records of service and electrical check of spirometer
- Any clinical incidences will be recorded and investigated
- A database of all patients will be kept for clinical follow up and reassessment as appropriate.

REFERENCES

- American Thoracic Society. (1991) Lung Function testing: Selection of reference values and interpretive strategies. *American Review Respiratory Disease*;144(5):1202-18
- Bellamy, D. Bouchard, H. Henrichsen, S. et al. (2006) International Primary Care Respiratory group (IPCRG) Guidelines: Management of Chronic Obstructive Pulmonary Disease (COPD) *Primary Care Respiratory Journal*: 15, 48-57.
- Bellia, V. et al. Quality Control of spirometry in the elderly. (2000). The S.A.R.A study (SALute Respiration nell'Anziano: Respiratory Health in the Elderly) *American Journal of Respiratory Critical Care Medicine*; 161 (4 Pt 1): 1094-100
- BTS/ARTP Guidelines for the Measurement of Respiratory Function.(1994) *Respiratory Medicine*; 88: 165-194
- BTS/SIGN. British Thoracic Society, Scottish Intercollegiate Guidelines network. British Guideline on the Management of Asthma. Available from <http://www.brit-thoracic.org.uk>. Accessed on 03/02/2012.
- Enright, P. (2008) The use and abuse of office spirometry. *Primary Care Respiratory Journal* 2008;**63**(5): 387-8
- Ferguson, GT. Enright, PL. Buist, SA et al.(2000) Office Spirometry for Lung Health Assessment in Adults: A Consensus Statement from the National Lung Health Education Program. *Chest* 2000;117:1146-1161
- Gardner, RM, Clausen, JL, Crapo, RO. et al. (1986) American Thoracic Society Committee on Proficiency Standards for Clinical Pulmonary Laboratories. Quality assurance in pulmonary function laboratories. *Am Rev Respir Dis* 1986;**134**(3): 625-627.
- Kendrick, A. et al (2003). Infection Control of lung function equipment: A practical approach. *Respiratory Medicine*; 97(11):1163-79.
- Levy, ML et al. (2006) International Primary Care Respiratory Group (IPCRG) Guidelines: Diagnosis of respiratory diseases in primary care. *Primary Care Respiratory Journal* ;**15** (1): 20-34
- Levy ML, Quanjer PH, Booker R, et al. (2009) Diagnostic spirometry in primary care: Proposed standards for general practice compliant with American Thoracic and European Respiratory Society recommendations: a General Practice Airways Group (GPIAG) document, in association with the Association for Respiratory Technology and Physiology (ARTP) and Education for Health. *Primary Care Respiratory Journal*;**18**(3): 130-147
- Miller MR et al. (2005) Standardization of Spirometry. ATS/ERS Taskforce Standardization of Lung Function Testing. *European Respiratory Journal* ;**26**:319-338
- Miller, M.R. et al (2005a) ATS/ERS task force: standardisation of lung function testing: standardisation of spirometry. *European Respiratory Journal*; 26: 2, 319–338.
- Price, D et al. (2006). Symptom-based questionnaire for identifying COPD in smokers. *Respiration*: 73 (3) 285-95

Yawn BP, Enright PL, Lemanske J et al.(2007) Spirometry can be done in family physicians' offices and alters clinical decisions in management of asthma and COPD. *Chest*;132(4): 1162-8

White P, Wong W et al. (2007) Primary care spirometry: test quality and the feasibility and usefulness of specialist reporting. *British Journal of General Practice*;57: 701-705.

What is Spirometry?

Spirometry is a test used to accurately measure the amount of air you can breathe in and out of your lungs and how fast you can breathe that air out.

It is a painless procedure but it will require you to breathe as hard as you can which can make you breathless.

You will be able to rest in between the tests in order for you to get your breath back.

This leaflet has been designed for you to be well prepared for your test so that it is as easy and as useful as possible.

Can I take my medication?

If you have never had spirometry before and it is being undertaken to diagnose a lung condition then you may be asked to stop your respiratory medication prior to testing.

Please see the information within this leaflet to know which medication to stop and when you are required to do so.

Other medications can affect the test so you may be asked not to take them. You will be fully informed on which medication to stop prior to testing.

The following list of 'dos and don'ts' will help us to ensure we are obtaining the most accurate information from your lung test.

DO

- Wear loose and comfortable clothing that does not restrict or interfere with your breathing
- Arrive in plenty of time for your appointment so that you are relaxed and have time to visit the toilet before your test
- Ensure you remove any loose fitting dentures

DON'T

- Eat a big meal within 2 hours of the start of your appointment.
- Smoke within at least an hour before the start of the test
- Drink alcohol within 4 hours of the appointment
- Take any vigorous exercise within 30 minutes of the start of the test
- Take your medication if you have been asked not to prior to testing

What will I be asked to do?

For us to get the most out of your test you will be asked to:

- Breathe in and out until you have filled your lungs with air and cannot take any more in
- Put the mouthpiece into your mouth – far enough to avoid blocking it with your tongue or your teeth
- Make a good seal with your lips around the mouthpiece so that air does not escape around the edges
- Wear a nose clip on your nose to prevent air escaping down your nose during some of the tests. These nose clips are not uncomfortable
- Breathe in and out into the spirometer, completely emptying your lungs and squeezing out every last drop of air
- You will be asked to do this several times. You will be asked to breathe out slowly and completely in a relaxed way and you will also be asked to blow out as hard as you can and as fast as you can

- When you are asked to blow out as hard as you can it is essential that you put as much effort in to this as possible
- Whatever tests you are asked to do you will be instructed fully and given encouragement. You will also be able to rest between tests

If you have been asked to stop certain medication prior to testing please see below:

4-6hrs before do not use:

Salbutamol (Ventolin, Salamol, Aerolin)
Ipratropium Bromide (Atrovent)
Terbutaline (Bricanyl)

12hrs before do not use:

Salmeterol and Fluticasone (Seretide)
Formoterol and Budesonide (Symbicort)
Salmeterol (Serevent)
Formoterol Fumerate (Oxis, Foradil)

24hrs before do not use:

Theophylline (Uniphyllin, Nuelin)
Montelukast, Zafirkulast (Singulair, Accolate)
Tiotropium Bromide (Spiriva)

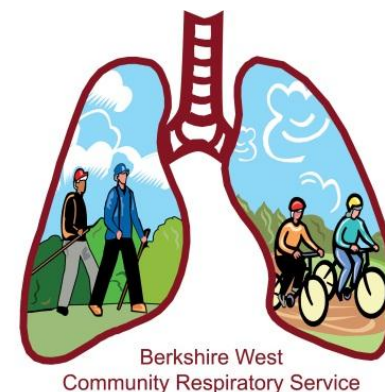
If you have any questions please do not hesitate to contact your Doctor or Nurse

Please inform the nurse at your appointment

if you have had any of the following:

- Recent chest infection requiring antibiotics or steroids
- Heart attack in the last 3 months
- Recent eye or abdominal surgery
- Unstable angina
- Perforated ear drum or ear infection
- Coughing up blood
- Thoracic, abdominal or aortic aneurism
- Recent CVA/Stroke
- Currently experiencing pain
- Possibility of being pregnant

SPIROMETRY TESTING



What do I need to know?

Information leaflet for Patients and their carers

Calibration Protocol (Accuracy Check)

Spirometers are precision instruments, calibrated to record the true volume of air exhaled into them. If accuracy is not checked, errors will go undetected. Calibration checks must be carried out with all types of spirometer as a daily routine and a log should be kept for medico-legal purposes (Miller et al, 2005a). Additional calibration checks are needed if the ambient temperature changes during the day or the equipment is moved.

A calibration syringe injects a known volume of air through the spirometer. The spirometer should record within 3% of this known volume:

- ± 30 ml for a 1-litre syringe;
- ± 90 ml for a 3-litre syringe.

The calibration of some spirometers can be updated if it is outside these limits. Others must be returned to the manufacturer for recalibrating.

The spirometer should also be verified using a biological control – usually a member of staff without lung disease. The lung function values of the control are determined by daily spirometry, at the same time of day over a two-week period (at least 10 recordings) and calculation of:

- The mean value for each spirometry parameter;
- The normal range ($\pm 5\%$ of the mean).

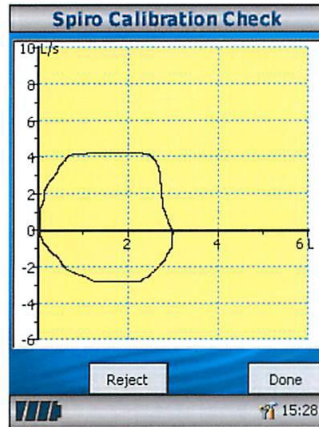
If the spirometer measures outside the normal range for that individual, it may need recalibrating. The spirometer and calibration syringe need regular servicing to ensure continued accuracy. Although the biological control is helpful in the absence of a calibration syringe it is a less reliable method of checking long term stability of spirometers (Levy M 2009).

The spirometer should be checked carefully once the spirometer has been cleaned as this is when water penetration or faulty re-assembly can mean that errors will occur.

If the calibration fails on a number of occasions prior to testing then the patients will need to be rescheduled and the spirometer sent for re-calibrating.

A recording of test conditions is important for accurate and repeatable spirometry. Errors should be corrected to body temperature and humidity. (Miller 2005).

Calibration Check

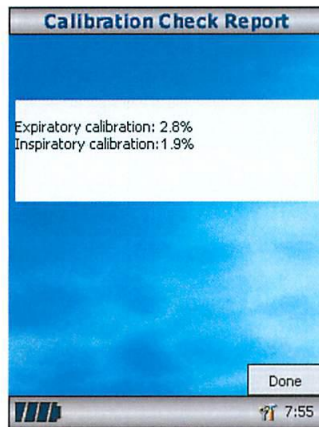


Select 'Calibration Check' from the main menu and then select 'check Calibration'.

Connect a 3 litre syringe to the transducer with the adapter supplied and empty by pushing the handle fully in.

Fill the syringe by pulling the handle at a constant rate until the end stop is reached and then immediately empty the syringe completely.

Press 'Done' to view the calibration check results.



The calibration error for expiration and inspiration are displayed. The calibration error should be less than 3% in each direction. If a greater error is shown, repeat the procedure ensuring that the syringe is emptied and filled in a smooth manner without jerking the handle. If an error greater than 3% is still shown, inspect the turbine transducer and clean if necessary.

Biological Control Calibration

**Spirometer Serial
Number.....**

<i>Parameters</i>	<i>Acceptable Range</i>	<i>Measured Results - Normal LF Day 1</i>	<i>Measured Results - Normal LF Day 2</i>	<i>Measured Results - Normal LF Day 3</i>	<i>Measured Results - Normal LF Day 4</i>	<i>Measured Results - Normal LF Day 5</i>	<i>Measured Results - Normal LF Day 6</i>	<i>Measured Results - Normal LF Day 7</i>	<i>Measured Results - Normal LF Day 8</i>	<i>Measured Results - Normal LF Day 9</i>	<i>Measured Results - Normal LF Day 10</i>
RVC											
FVC											
FEV ₁											
FEV ₁ / FVC											
PEF											

Cleaning Protocol for the
MicroMedical MicroLab
Spirometer.

Contents

Section	Content	Page No
1	Introduction	3
2	Objective	3
3	Definitions	4
4	Decision on which to use	4
5	Procedure	5
6	Performing Spirometry in Patients Homes	5
7	Cleaning the turbine	5
8	What to do if you have a patient with a known infection	6
	Appendix 1	8
	Appendix 2	9
	Appendix 3	10

Spirometer Cleaning Protocol

1.0 Introduction

This protocol is designed to guide staff members on the correct procedure for reducing the risk of cross infection when carrying out spirometry.

This is also used in conjunction with the local NHS Trusts policy on infection control.

2.0 Objective

Ensuring that spirometers are cleaned following up to date guidelines and procedures means that the risk of cross contamination is limited. It will also enable the Community Respiratory Team and other people associated with performing spirometry to ensure they are competent and confident with how to clean the spirometer effectively.

All healthcare personnel must comply with this protocol to make this effective.

This protocol adheres to the specific manufacturers' guidelines for the cleaning of the MicroLab spirometer as this is not currently covered in the Local Trust Infection Control Guidelines.

A decision has been made to include this protocol in the Local Trust Infection Control Policies and Procedures following a meeting with the Trust Infection Control Team and will be altered accordingly.

All Trust policy guidelines and rationales have been adhered to.

3.0 Definitions

This is taken from the Local Trust Infection Control Guidelines.

Decontamination: A process which removes or destroys contamination and thereby prevents infectious agents or other contaminants reaching a susceptible site in sufficient quantities to initiate infection or any other harmful response. Differing levels of decontamination are available. They are: cleaning followed by high level disinfection; or cleaning followed by sterilisation.

Cleaning: Is a process which physically removes contamination but does not necessarily destroy micro-organisms. The reduction of microbial contamination cannot be defined and will depend upon many factors including the efficiency of the cleaning process and the initial bio-burden.

Disinfection: Is a process used to reduce the number of viable organisms, which may not necessarily inactivate some viruses and bacterial spores. Disinfection will not achieve the same reduction in microbial contamination levels as sterilisation.

Sterilisation: Is a process used to render the object free from viable micro-organisms, including spores and viruses.

4.0 Decisions on which to use

According to the local trust policy and guideline the spirometer is classed as medium risk for medical device decontamination and therefore requires it to be cleaned using Disinfection and will be done so according to Micro Medical protocol (Appendix 1).

5.0 Procedure

Prior to performing spirometry it is important to establish whether the patient has a known infection such as a chest infection or MRSA.

If the patient has a known infection and the spirometry must be performed, then the Bacterial Viral Filters (BVF) must be used. (See page 5)

6.0 Performing Spirometry in Patients' homes

1. Wash your hands
2. Ask the patients to wash their hands
3. If the patient is infection free then use the cardboard one-way mouthpieces
4. If the patient has a known infection then use the BVF
5. Perform Spirometry
6. Wipe the housing of the transducer with a hard surface cleaner after each patient use
7. Do not use alcohol wipes on the screen of the spirometer as it can damage it
8. If you have used a BVF this must be removed with a gloved hand and put in the patient's own bin

7.0 Cleaning the Turbine

This information has been collated from the Carefusion website and is specifically designed for the MicroLab

1. This needs to be performed once a week and preferably at the end of the day to ensure that it is dry enough to use the following day
2. Prepare a solution of Cidex OPA (Carefusion guidelines state to use Perasafe but this cannot be purchased within the trust. Advice was sought and Cidex OPA was approved for use (Appendix 2) as per manufacturers guidelines (Alcohol and chlorine solutions should be avoided)
3. Remove the transducer from the housing
4. Immerse in the Cidex OPA for no longer than 10 minutes

5. Remove and rinse in distilled water
6. Leave to air dry, preferably overnight
7. Do not dry with any objects inserted into the transducer as this will result in damage
8. Reassemble spirometer according to manufacturer's guidelines
9. Check calibration/verification (see calibration guidelines)
10. Complete cleaning log (Appendix 3) and ensure that the following is entered
 - Date and Time of cleaning
 - Batch Number
 - Number of minutes soaked in the solution
 - Name
 - Signature

8.0 What to do if your patient has an infection.

If you have a patient who is known to be immuno suppressed then ensure that this patient has their spirometry performed at the beginning of the day, i.e. the first one of the day and a BVF must be used. This must be performed on a spirometer that has been thoroughly cleaned.

If you have a patient who is known to have TB then this patient group should not have their spirometry performed until they have been given the all clear by a consultant in writing.

If you have a patient who has a known chest infection then wherever possible these should be delayed for 6 weeks post exacerbation.

In exceptional cases, and if the spirometry has to be performed on this patient group then the necessary precautions must be followed.

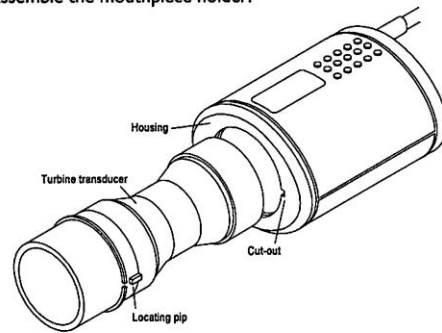
1. Glove and aprons should be worn
2. BVF must be used.
3. Thoroughly clean the transducer as per the guidelines. All external parts of the Spirometer must be cleaned using a wipe that has been fully immersed in Cidex OPA.

If you have a patient who had Bronchiectasis then they should always have their Spirometry performed using the BVM.

Cleaning the Transducer

The transducer requires no routine maintenance or servicing. However, if you wish to sterilise or clean the transducer it may be removed by means of the following procedure:

- 1 Rotating the turbine transducer anti-clockwise until the locating pip lines up with the small rectangular cut-out in the housing as shown below.
- 2 Gently pull the transducer away from the housing.
- 3 The transducer may now be immersed in warm soapy water for routine cleaning or immersed in cold sterilising solutions e.g. Perasafe for a maximum of 10 minutes (Alcohol and chloride solutions should be avoided). After cleaning/sterilising, the transducer should be rinsed briefly in distilled water and dried.
Perasafe is available from Micro Medical in convenient 81g containers, Cat No. SSC5000.
- 4 Re-assemble the mouthpiece holder.



Appendix 2

Re: Cleaning Spirometers

From: Carefusion

Date: 6th Jan 2012

Time: 09.57

Hi,

Thank you for your email. As an alternative to Presept you are able to use Cidex OPA. It needs to be the milder OPA solution that the standard Cidex. The manufacturers advise against using any chlorine based solutions as these can discolour the plastic surrounding the vane. Again, they advise distilled water but in practice a large majority of practices do use tap water and this is fine.

I hope this helps. Just let me know if you have any further queries

Kind Regards

References

ARTP/BTS. Guidelines for the Measurement of Respiratory Function. *Resp Med* 1994; 88, 165-194

Booker, R. (2008) *Vital Lung Function*. Your essential reference for the management and assessment of lung function. London. Class Publishing.

Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. (Updated 2007). <http://www.goldcopd.org>.

<http://www.gp-handbook.co.uk/>

GPIAG. Protocols Spirometry in COPD. Protocol Number 1. Issue 1. August 2007.

Levy, M. Quanjer, P. et al. Diagnostic Spirometry in Primary Care. Proposed standards for general practice compliant with American Thoracic Society and European Respiratory Society recommendations. *Prim Care Resp J* (2009); 18(3): 130-147.

National Collaborating Centre for Chronic Conditions. Chronic obstructive pulmonary disease: national clinical guideline on management of chronic obstructive pulmonary disease in adults in primary and secondary care. *Thorax* 2003, 59 (Suppl 1); 1-232.

NICE. Chronic Obstructive Pulmonary Disease: Management of chronic obstructive pulmonary disease in adults in primary and secondary care. June 2010.

Price, D et al. Spirometry in primary care case-identification, diagnosis and management of COPD. *Prim care Resp J* (2009); 18(3) 216-223.