

For personal use only

Not to be reproduced without the permission of the *Primary Care Respiratory Journal*

Peak flow meters - single patient use - a solution to the problem

Vitalograph Limited

Bernard R Garb

There is a current debate on the use or misuse of Peak Flow Meters in clinics - should they be used for different patients? In recent communication with the PCRJ Editor I was surprised that a UK Primary Care Trust was no longer intending to use Peak Flow Meters because of fears of cross contamination, based on the misconception that all Peak Flow Meters are only intended for Single Subject Use; this has come about due to the labelling requirements for NHS use

This also highlighted the wider debate on the value of Peak Flow Meters in the diagnosis and management of asthma. A Spirometer is always regarded as the 'proper' tool for measuring pulmonary function, but does the simple, inexpensive Peak Flow Meter have a place in the clinic

It is difficult for healthcare professionals to keep up to date as the healthcare environment and legislation becomes increasingly regulated. A reputable manufacturer is under obligation to provide clear and

concise instructions to the users of their medical devices. As a consequence, these User Instructions are continually being updated and improved, so the latest instructions are a good source to interpret current legislation, guidelines and good practice. I make no apologies for quoting extracts, in italics, from relevant current User Instructions below, which will I hope help to clarify the debate. A sample of a current Peak Flow Meter User Instruction Leaflet is available free of charge. Vitalograph also has a range of educational materials on spirometry and Peak Flow

It is clear that these instructions anticipate either home use or use in clinic. I think the root of the misunderstanding is the Drug Tariff Specification 5 which stipulates that NHS Prescribable PFMs must be labelled 'Single Use'. Some healthcare professionals are obviously unaware that there are other types of Peak Flow Meter available in the UK. The normal types have a proper (linear measuring) scale as well as instructions for cleaning and use with multiple subjects

Bernard R Garb

Correspondence to
Bernard Garb
Managing Director
Vitalograph Ltd
Maids Moreton
Buckingham
MK18 1S

Tel: +44 (0)1280 827110
Fax: +44 (0)1280 823302

sales@vitalograph.co.uk

www.vitalograph.co.uk

Date submitted: 07/08/0

Date Accepted: 22/08/0

Primary Care Respiratory Journal
2002
11(3) 493-9

Asthma Care in Partnership with your Physician

Your doctor will take the time to educate you in self-management of your asthma. This will start upon diagnosis and continue with all members of the healthcare team. Your Management Plan will be tailored to your needs, but will include: basic facts about asthma; roles of medications; risk factors; your own inhaler; when and how to take rescue actions

How do I get an Action Plan

Only your doctor can determine the best action plan for you. This is likely to be preceded by an initial assessment followed by a diagnostic phase. During the diagnostic phase you will need to record your peak flow scores. Your Action Plan is then assessed against your peak flow scores over several days. Your treatment and/or the action plan may be changed following the diagnostic phase. This procedure may be repeated until your optimum Management Plan is proven

Q. What is my Normal Value

Your 'Normal Value' is the best Peak Flow value that you can achieve. This is your '100%' or 'reference' value. Population normative standards are not clinically useful in ongoing serial monitoring of your asthma

Important Note: Only your doctor or specialist nurse should complete or change your Action Plan, so it is important to take your meter with you whenever you visit the doctor. If you are starting a new management plan your doctor will need to see your Peak Expiratory Flow Record Chart as well

The clinic must educate, show the asthmatic how to use a Peak Flow Meter and determine the patient's own 'Normal' (Best) value in order to make the Management Plan. If the subject has not yet been prescribed with a Peak Flow Meter the clinic must provide one. If the subject remembers to bring in his Peak Flow Meter what if it is over three years old or if, on testing against a calibrated spirometer, it proves out of tolerance? It must be disposed of in either case.

So, the Clinic should have Peak Flow Meters, but since they are a measuring device in a clinical setting they must be subject to the same controls and traceable calibration as any other measuring device. This is a simple procedure that the clinic must set up, or get a competent service provide

Care and Cleaning of your Peak Flow Meter

Your Peak Flow Meter should continue to give reliable measurements for up to two years, after which time you should ask your doctor for a new unit. Avoid crushing the unit and keep it clean and dust free. If you suspect the unit is damaged or is measuring incorrectly, contact your doctor immediately. The outer surfaces should be thoroughly cleaned and disinfected at least every month, more often if necessary. We recommend the use of an alcohol wipe, paying special attention to the mouthpiece area. Material: Recyclable medical grade ABS plastic.

In Clinic: Use disposable SafeTway mouthpieces to prevent cross-infection risks; Certify calibration at least annually.

For personal use only

Not to be reproduced without the permission of the *Primary Care Respiratory Journal*

Hospitals and surgeries normally purchase direct from Vitalograph and we sell many meters of the NHS type to such clinics for multiple subject use. Our standard Peak Flow Meter (Cat Nr 43201) would be an example. But the use of disposable mouthpieces with an integral one-way valve, is essential.

The SafeTway mouthpiece protects against cross contamination between patients due to its unique patented valve which stops inhalation from the Pea

Flow Meter. Due to the low cost compared to Bacterial Viral Filters and their simple yet effective patented design, the SafeTway mouthpieces are increasingly popular in Clinics. They also have special coating certified to 90/128/EEC to prevent leakage and an inner lining to guard against cardboard dust inhalation. ■

Vitalograph donates £1 to Lung Research for every SafeTway mouthpiece box sold

Peak flow meter manufacturers comment - single patient use Ferraris Medical Limited

Graham Peck

Intended use

The now common, low cost, plastic, peak-flow indicators, available by prescription, intended for personal use in asthma management programmes, are single patient use devices. 'Single patient' means that only one subject, due to the risks of cross contamination, should use the device. Single use devices are available for the masses, in low cost form but by design will often have some of the following properties

- No inbuilt cross-contamination counter-measures
- Poor resilience to disinfection
- Limited service life
- Lowest absolute accuracy amongst peak-flow measurement devices

For these reasons, any question of use of such device in multi patient applications must be dispelled

The provision of such a device to the 'single patient' is consistent with these properties. The issue of self contamination is mute, the service life is consistent with the duration of use, and the relative measurements soon become more important than the absolutes, (regardless of Wright or ATS scale differences)

Where multi-patient use is necessary for a peak-flow device, a suitable multi-patient device should be chosen, the chief differences being the improved disinfection properties of this type of device, longer service life and better durability of measurement accuracy

What contamination

When a sick person visits the doctor's office with symptoms that require peak-flow measurement, is there a chance the person has a respiratory infection

If this person blows with all their might into a peak flow device, will any aerosol be deposited in or about the peak-flow device

If another person uses the device with no intermediate disinfection, could that person contract a cross infection

It would seem unlikely that the answers to all the above questions are negative in all cases, but we need

to cater for all cases

Mitigating circumstance

Some devices are specified to have non-return valves and with disposable cardboard mouthpieces, they might seem safe

Some devices may be specified as being usable with microbial filter

There is a wealth of anecdotal evidence among experienced workers in the field of respiratory measurement that cross contamination is a non-issue none of them ever having cultivated a significant bug from a breath hose or the innards of a spirometer bell

Responsibility

For a few years now the European directives, to which manufacturers are increasingly bound, have unambiguously stated that where a device is able to be disinfected between multi-patient uses, the instructions should be supplied by the manufacturer and invariably a validation on such instruction will be required. (The American FDA deals particularly strictly on this issue) As responsible manufacturers, we have to put patient safety first, and be sure every application of our devices is beyond question

Cost

Being manufactured for prescription, the low cost plastic peak-flow devices are easily obtained for next to nothing. A proper multi-patient device, on the other hand, may cost several hundred pounds. However, the significance of intended purpose must not be overlooked, and the top-drawer, plastic device with cardboard attachments should be seen as something between at best a cheap solution, and at worst an unacceptable risk

Trend

The use of disposables on a disposable device is something of a paradox, but in the extreme, the cost of the throw away part is all-important

Some manufacturers appear to be addressing this by the use of filters, plain mouthpieces or valve mouthpieces.

The absence of reported cross infection is surely not enough to substantiate this practice, and cost may be compromising good practice.

Graham Peck
Head of Product
Development

Correspondence to
Graham Peck
Ferraris Medical Ltd
4 Harford Court
John Tate Road
Northford SG13 7N
Tel: +44 (0)1992 526300
Fax: +44 (0)1992 52632

info@ferrarismedical.co

<http://www.ferrarismedical.co>

Date submitted: 14/08/0
Date Accepted: 22/08/0

Prim Care Resp 2002
11(3) 94-9