Innocor®

SPIROMETRY METHOD

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1 SPIROMETRY METHOD

1.1 SCOPE

The purpose of this document is to give an introduction to the Spirometry Method used in Innocor. This section applies to users of Innocor with only limited experience in spirometry measurements. This document will enable the reader to understand the spirometry parameters measured by Innocor and the way they are determined.

For more detailed information about the spirometry method, please contact Innovision A/S or consult the "Standardisation of lung function testing" in:

Eur Respir J 2005; 26: 319-338 Series "ATS/ERS task force: Standardisation of lung function testing"
Edited by V. Brusasco, R. Crapo and G. Viegi.
Number 2 in this series: Standardisation of spirometry

1.2 INTRODUCTION

Spirometry is a physiological test that measures how an individual inhales or exhales volumes of air as a function of time. Spirometry is invaluable as a screening test of general respiratory health. The Innocor spirometry measures only a sub-set of the many spirometric variables during a forced expiration manoeuvre. The measured variables are used together with an exercise test in diagnosing the subject. Is the patient's exercise intolerance caused by ventilatory limitation or is the abnormality caused by a limitation in the cardiovascular system?

The spirometry manoeuvre starts with normal tidal breathing followed by a rapid and complete inspiration. Then immediately after the subjects makes a maximal / forced expiration until no more air can be expelled. Finally the subject performs a fast inspiration.

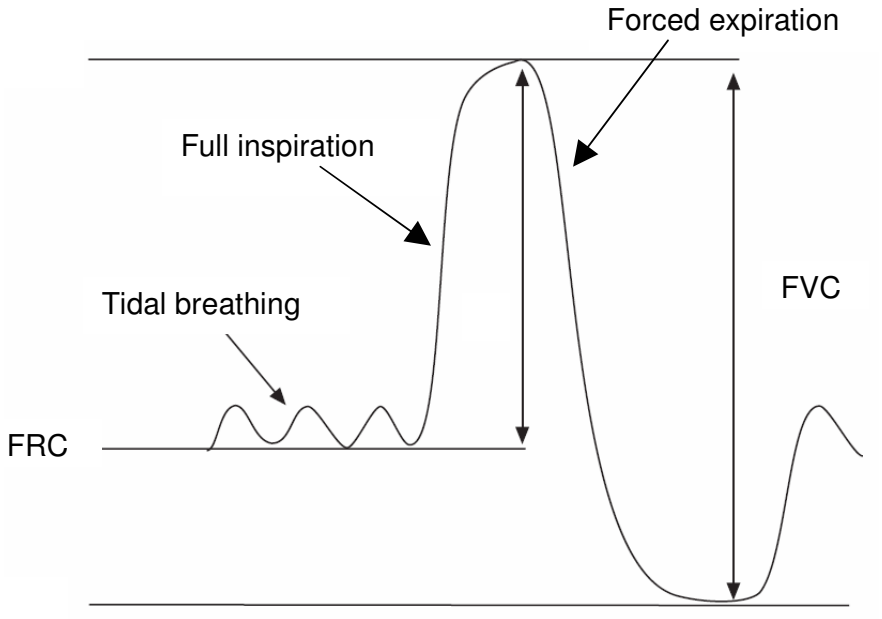

Figure 1.2–1 Spirometry manoeuvre (Modified from Standardisation of spirometry)

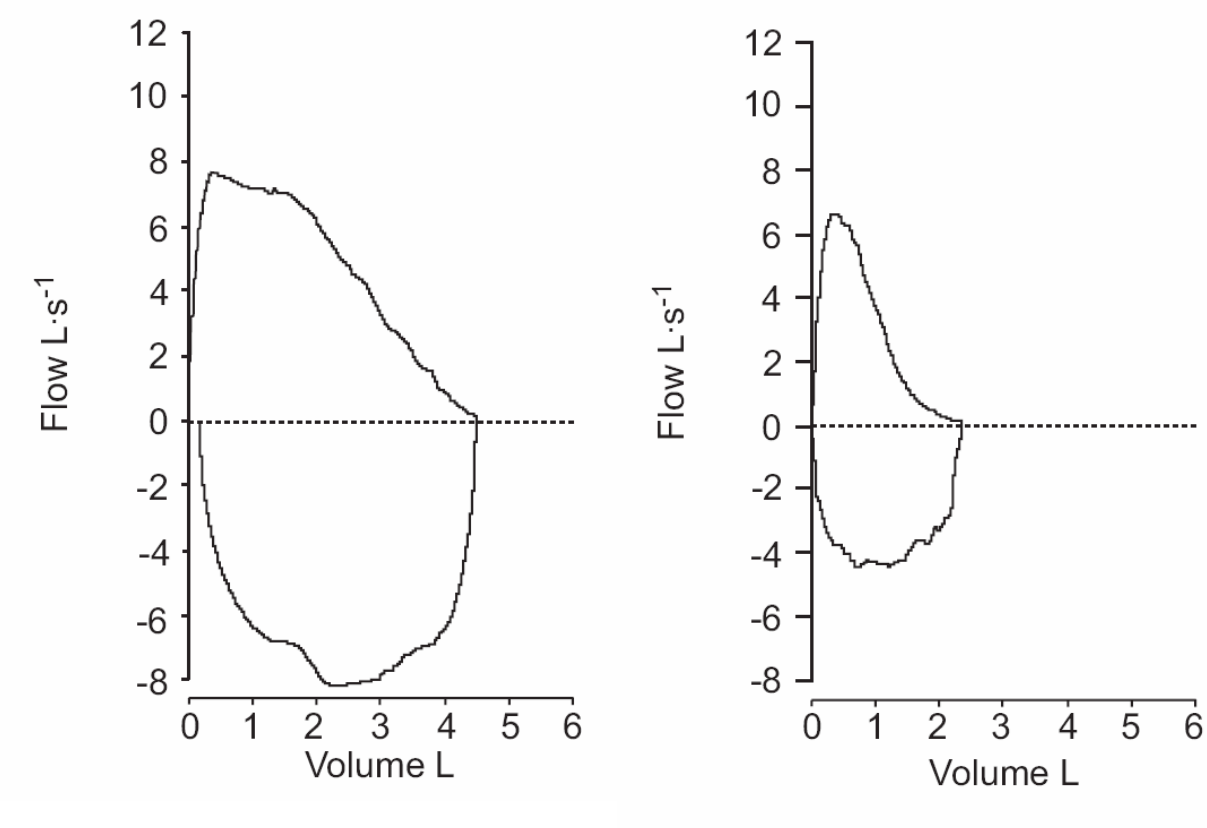

Figure 1.2–2 Flow-volume loop of a normal subject (left) & a normal elderly subject (right). (From Standardisation of spirometry)

1.3 SPIROMETRY PARAMETERS

The spirometry parameters measured by the Innocor are:

Abbreviation	Name	Unit
FVC	Forced vital capacity	L [BTPS]
FEV_1	Forced expiratory volume in one second	L [BTPS]
FEV_1%	FEV_1 / FVC	%
PEF	Peak expiratory flow	l/sec [BTPS]
MEF 75*	Maximal instantaneous forced expiratory flow where 75% of the FVC remains to be expired	l/sec [BTPS]
MEF 50*	Maximal instantaneous forced expiratory flow where 50% of the FVC remains to be expired	l/sec [BTPS]
MEF 25*	Maximal instantaneous forced expiratory flow where 25% of the FVC remains to be expired	l/sec [BTPS]
FET	Forced expiratory time	Sec
MVV	Maximum voluntary ventilation	L/min [BTPS]

**see 1.3.5*

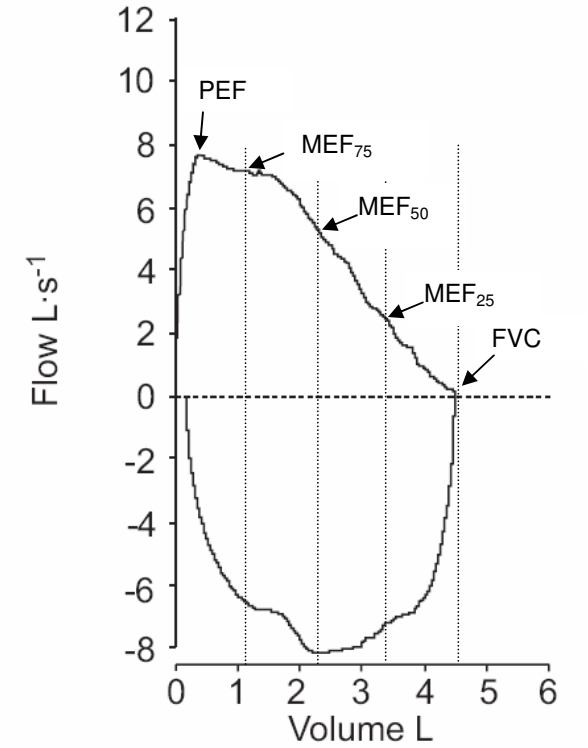

Figure 1.3–1 Flow volume curve (Modified from Standardisation of spirometry)

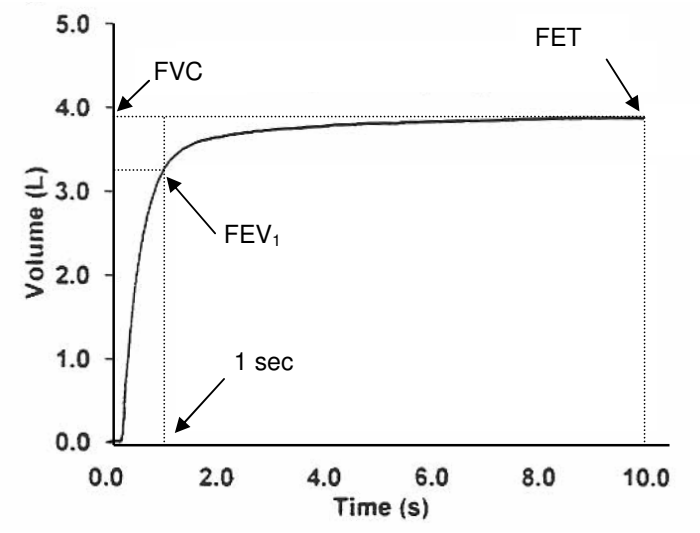

Figure 1.3–2 Volume time curve

1.3.1 Forced Vital capacity (FVC)

FVC, the forced vital capacity, is the volume delivered during an expiration made as forcefully and completely as possible starting from full inspiration. The FVC is illustrated in figure 1.3–2.

1.3.2 Forced expiratory volume in one second (FEV_1)

FEV_1, the forced expiratory volume in one second, is the volume delivered in the first second of an FVC manoeuvre. The FEV_1 is illustrated in figure 1.3–2 as the volume after 1 second.

1.3.3 FEV_1%

FEV_1% is the ratio: FEV_1 / FVC in %.

1.3.4 Peak expiratory flow (PEF)

PEF, the peak expiratory flow, is the maximum expiratory flow delivered in an FVC manoeuvre. The PEF is illustrated in figure 1.3–1 as the maximum flow.

1.3.5 Maximal instantaneous forced expiratory flow (MEF)

MEF 75 is the maximal instantaneous forced expiratory flow where 75% of the FVC remains to be expired. MEF 75 is identical to FEF 25, which is maximal instantaneous forced expiratory flow where 25% of the FVC has been expired.

MEF 50 is the maximal instantaneous forced expiratory flow where 50% of the FVC remains to be expired. MEF 50 is identical to FEF 50.

MEF 25 is the maximal instantaneous forced expiratory flow where 25% of the FVC remains to be expired. MEF 25 is identical to FEF 75.

The MEF 75, MEF 50 & MEF 25 are illustrated in figure 1.3–1.

1.3.6 Force expiratory time (FET)

FET, the forced expiratory time, is the time of the spirometry manoeuvre from start of expiration to the end of the expiration. The FET is illustrated in figure 1.3–2 as the maximum time.

1.3.7 Maximum voluntary ventilation (MVV)

MVV, the maximum voluntary ventilation, is the maximum volume of air a subject can breathe over a specified period of time (12 seconds for normal subjects). The MVV is highly correlated to the FEV_1 and in the Innocor spirometry the MVV is estimated as:

$MVV = 40 \bullet FEV_1$

1.4 SPIROMETRY EVALUATION

1.4.1 Start of manoeuvre criteria

The start of the manoeuvre must be fast in order to be sure that the FEV_1 comes from a maximal effort curve. This is checked by the following ATS definition/requirement:
The start of manoeuvre, for the purpose of timing, is determined by a back extrapolation method. The method is finding the largest slope on the volume-time curve and back extrapolates to zero volume based on an 80 ms averaged volume curve. The new “time zero” is defining the start for all timed measurements. The volume at time zero (EV) shall be less than 5% of FVC or 0.150 l, whichever is greatest, in order to have a satisfactory start of manoeuvre, see figure below.

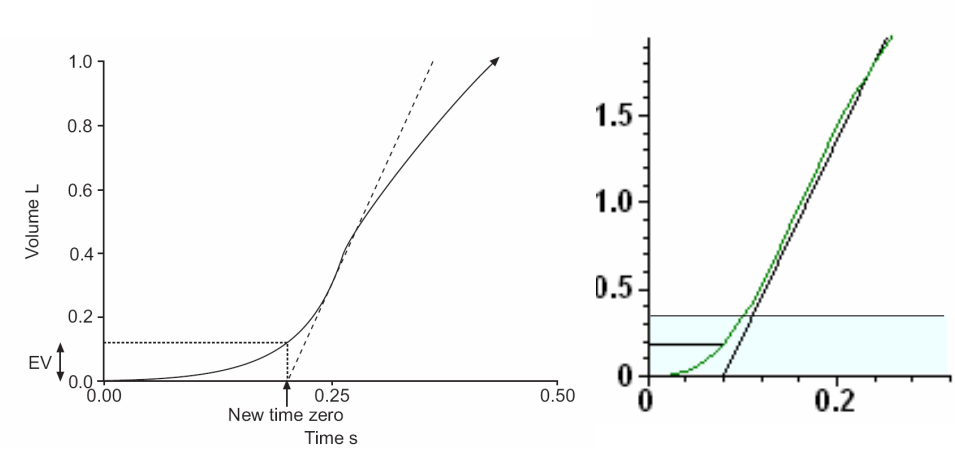

Figure 1.4–1 Start of volume time curve (Left: from Standardisation of spirometry, Right: from Innocor)

1.4.2 End of manoeuvre criteria

A satisfactory end of a manoeuvre is by ATS defined as a no change in volume (<0.025L) for 1 second after the subject has exhaled more than 6 seconds (3 seconds for children under 10 years). See example below, where the requirement is met for the left manoeuvre, but not for the right.

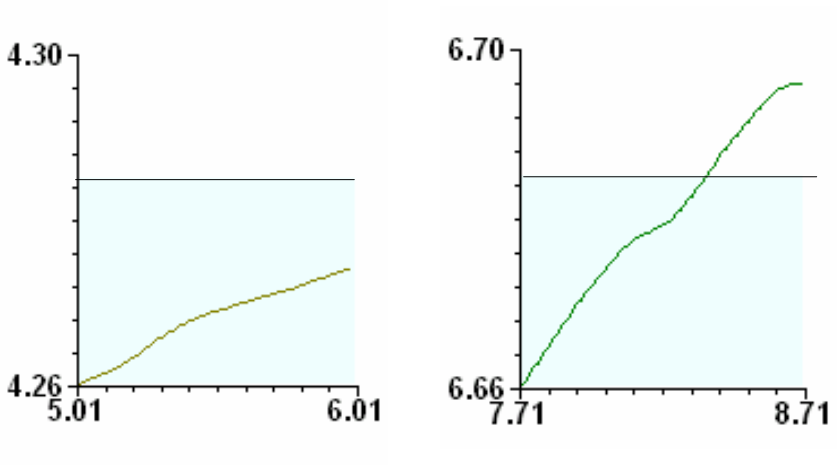

Figure 1.4–2 End of volume time curve (from Innocor)

1.4.3 Spirometry test acceptance

Based on minimum 3 acceptable manoeuvres, an acceptable repeatability is achieved when the difference between the 2 largest FVC is less than 0.150 L and the difference between the 2 largest FEV_1 is less than 0.150 L. (If the FVC is less than 1.0 L the criteria is 0.100 L).

1.4.4 Selecting best performed manoeuvre

The criteria for selecting the best performed manoeuvre are according to the ATS requirements:

- The largest FEV_1 found in the accepted manoeuvres is recorded.
- The largest FVC found in the accepted manoeuvres is recorded.
- FEV_1% is calculated as FEV_1 / FVC, even if they do not come from the same manoeuvre.
- The manoeuvre with the largest sum of FVC + FEV_1 is selected as the best performed manoeuvre, and the rest of the parameters are based on this manoeuvre.