

ABOUT MIR™ SPIROMETRY INTERPRETATION AND QUALITY CONTROL GRADE

Spirometry is a test which requires active cooperation from the patient. To assist the healthcare professional in performing a correct Spirometry test, MIR™ developed a proprietary algorithm based on ATS/ERS latest recommendations. The results of this algorithm are the Automatic Interpretation of the Spirometry Session and the definition of the Quality grade of the Spirometry Session. Interpretation and Quality grade are available on all MIR™ spirometers and softwares.

About the Interpretation

Automatic Interpretation refers to Forced Vital Capacity (FVC), and is represented by a colored traffic light indicator associated to a specific message. The messages can include the following:

- a) Normal spirometry
- b) Slight obstruction/restriction
- c) Moderate obstruction/restriction
- d) Moderately severe obstruction/restriction
- e) Severe obstruction/restriction
- f) Very severe obstruction/restriction
- g) The final interpretation level is "restriction + obstruction", where the indicator light indicates the worst parameter between restriction and obstruction.

Severity Classification of an Obstruction is based on FEV1 value, compared to predicted.

Severity Classification of a Restriction is based on the highest value between FVC/EVC/IVC, compared to predicted.

About the Quality Control Grade

After each FVC or VC test, the Quality Control Grade of the Session is also calculated, based on a scale from A to F grades. For each spirometry session, a minimum of 3 to a maximum of 8 attempts shall be performed. The quality control system uses letters as described below:

1st case: PRE test

A = at the end of two acceptable attempts, the variation of the two highest FEV1 values and the two highest FEV6 values are less than or equal to 100 mL.

B = at the end of two acceptable attempts, the variation of the two highest FEV1 values is between 101 and 150 mL

C = at the end of two acceptable attempts, the variation of the two highest FEV1 values is between 151 and 200 mL

D = only one attempts was acceptable or there is more than one acceptable attempts but the variation of the two highest FEV1 values is greater than 200 mL

F = no acceptable attempts.

2nd case: POST bronchodilator test

A = two acceptable tests, the variation of the two highest FEV1 values is less than or equal to 100 mL.

B = two acceptable tests, the variation of the two highest FEV1 values is between 100 and 200 mL. C = two acceptable tests, the variation of the two highest FEV1 values is greater than 200 mL.

D = one acceptable test

F = no acceptable test

So as you can see, the grading system is based primarily on the reproducibility of acceptable tests. "**Acceptable**" is also an ATS/ERS medical term and acceptable test in general are:

- A good start of exhalation
- Free from artifacts
- No cough during first second of exhalation (for FEV 1)
- No glottis closure or abrupt termination (for FVC)
- No early termination or cutoff (for FVC)
- Maximal effort provided throughout the maneuver
- No obstructed mouthpiece

While using MIR™ equipment, basically you can consider a test “acceptable” when there are no error messages in winspiroPRO™ for a specific attempt, such as:

- blow out longer
- do not hesitate
- expire all the air
- etc.

Acceptability Criteria is calculated by the MIR™ Spirometer when used in stand-alone mode, or by winspiroPRO™ when the spirometer is connected to the software for real time test.

Acceptability Criteria will change from time to time according to the latest spirometry guidelines.

So to avoid any discrepancy when a test is performed on the Spirometer in stand-alone mode first and then imported in winspiroPRO™, the rule is that winspiroPRO™ will always import also the same Acceptability Criteria used by the Spirometer in stand-alone mode, prevent using its own in this specific situations.