MIR
MEDICAL INTERNATIONAL RESEARCH

Declaration concerning MIR Spirobank Smart spirometers

October 2020

To Whom it may concern

MIR s.r.l. Medical International Research manufacturer of Spirobank Smart medical devices declares as follow:

Taking in consideration that:

1. One of the most important factors to guarantee the accuracy of the turbine of a spirometer are the algorithm of the software for the measurement of the flow and volume. The algorithm which we use on our device have been validated on a significant quantity of turbines which represent the "population" of the turbines produced. These turbines represent the min/max limit and the algorithm guarantee that the turbines pass all ATS test for the diagnostic device which are even more severe than for home-care.

   Spirobank Smart complies with the most important change introduced by the "ATS 2019 update" standard: the volume accuracy of **+-2.5%.**

   According to "ATS 2019 update" the Volume accuracy is expected to be +/- 2.5%, to be evaluated using the test profiles ISO 26782.

   With reference to the repeatability of the PEF and FEF2575, according to ATS new guidelines authors:

   "The 2019 spirometry standards specify the use of ISO 26782 and do not require the use of PW24 or FT26 to evaluate spirometry performance. However, if PW24 or F26 are used, the volume accuracy is expected to be +/- 2.5.
   Due to the word count limitation for the 2019 Spirometry standards update compared to the 2005 standards, there was not sufficient space to include a separate update for peak flow meters or peak flow measurement standards. When considering the revised accuracy requirements, the consensus was that if the spirometer meets the prescribed +/- 2.5% accuracy requirements for the ISO test profiles, then the peak flow measured from the maximal expiratory maneuver would be adequate. Similarly, there were no further accuracy verification requirements for the measurement of FEF25-75"

2. During the production every single MIR turbine is tested with a computerized flow controller; turbines which have PASS result (ie within the tolerance allowed) are mounted on the devices

3. During the production there is an automatic test made on each single main board of the spirometer that measures several relevant data to verify the correct functioning of all electronic components. The results of each test are memorized in a log file including the serial number

The complete process described in points 1 to 3 guarantees the accuracy of the turbine and the correct functioning of the device

Therefore, based on the information provided all devices and turbines mounted on the spirometer purchased have been singularly tested and PASS all tests.

Sincerely

Paolo Boschetti Sacco
MIR Chairman