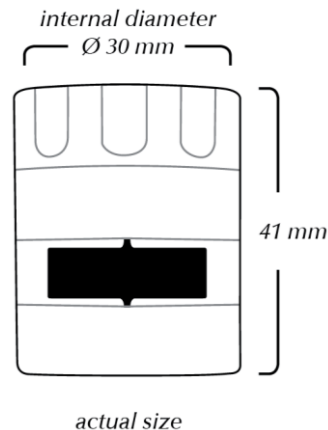


Introduction

MIR - Medical International Research, has been designing and producing spirometry turbines since 1994 and has developed models which are tested for their accuracy and calibrated using sophisticated instruments. During 2007 MIR began selling the world's first Disposable Turbine, for which it has an international patent which has already been released in some countries. The product is identified by its commercial logo **FlowMir**.



Standards and control systems

Due to its accurate design – dimensions, materials used and automatic production process the product has been able to pass all the tests foreseen by the ATS (American Thoracic Society). After a long planning and equally long testing phase, MIR defined a test and created an automatic pump instrument called Digital Flow Tester.

The test is carried out immediately after the assembly and immediately before the packaging of every single turbine. The Digital Flow Tester is able to generate and measure flow with a resolution of 10 microlitri/sec equivalent to that of the special computerised Pulmonary Waveform Generator used to verify the well known ATS standard.

This choice guarantees a rigid standard for the repeatability and accuracy of every single turbine produced.

Production Process

The Disposable Turbine is made up of 3 components using automatic moulding machines:

- ✓ Turbine body
- ✓ pallet
- ✓ deflector

The innovation of the disposable turbine with respect to the traditional Reusable is that it has automatic production which guarantees the following advantages:

- ✓ the characteristics of the components remain maintained over time
- ✓ an elevated repeatability and accuracy of measurement is maintained.

After assembling the components in a clean room the Disposable Turbine is tested and if this test is passed it is packaged and sealed up to guarantee hygiene and to protect it from eventual external contamination up until it will be used.

Test in Production

The international ATS standard foresees hundreds of repeated tests after which the structure of the device and accessories remain unchanged.

These tests are applicable to devices which guarantee a long duration or which are of unlimited duration such as the reusable turbine.

In the case of the Disposable Turbine for the obvious motive that the product is of limited duration the test would be destructive and therefore the same criteria would not be applicable on every unit produced. In this case the tests followed are based on repeatability and accuracy. In particular the production of the Disposable Turbine foresees the execution of the tests detailed below:

Every single product is tested using a Digital Flow Tester before being packed. Every turbine must give a flow measurement which come in precise intervals of acceptability, if it is not acceptable the turbine is discarded. The criteria of acceptability is computerised. This guarantees the repeatability of the measurement.

For every production lot a significant number of samples are tested with a special computerised Pulmonary Waveform Generator, to perform the ATS standard. The results of these tests are documented and archived and can be used to provide evidence of repeatability and accuracy of measurements for the spirometry parameters.

Only in the case in which the tests described above are passed will the production lot be suitable for commercialisation.

The identification of each lot always appears on each pack of turbines (pack of 100 pieces).

Conclusion

The Disposable Turbine proves to be an accurate product for the following data:

- ✓ results obtained in the design and development phase
- ✓ controls on the production process adopted
- ✓ tests carried out on each single piece

The above therefore guarantees the repeatability and accuracy of every single unit produced.

MIR - Medical International Research, declares that every single Disposable Turbine model "FlowMir" is individually tested with controlled and calibrated instruments.

Only products which pass these tests during the production phase are declared compliant and therefore suitable to be put on the market.