

FORSCHUNGSINSTITUT FÜR KLINISCHE MEDIZINTECHNIK

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Certification

Nebulizer Performance Test Result

Type: NB60

Manufacturer: Rossmax Int. Ltd., Taipei, Taiwan.

It is hereby certified, that the above given compact piston-type nebulizer, NB60, has been tested by Rossmax Int. Ltd under the subsequent review of the FIMT (Asperg, Germany) regarding

- (1) the aerosol particle size distribution
- (2) nebulization output rate (including medication delivery)
- (3) effective residual volume
- (4) Reliability in long-time operation.

Tests have been provided according to the standards and regulations given with EN13544 – 2009 (Respiratory Therapy Equipment-Part 1: Nebulizing Systems and their Components) and the FDA Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators-1993.

The aerosol particle size was tested by two methods, the Malvern Spraytec Reflectometry Technique (A), as well as the Marble 298 Cascade Impactor Method (B).

In both (A) and (B), The NB60 complied with the medically requested mass median aerodynamic diameter MMAD < 5 [µm] as well as with the Rossmax specification of MMAD < 3 [µm]: In (B) MMAD (2.5% NaF) is found as being 2.34 [µm] with a fine particle dose FPD of 80.11 %.

The nebulization rate, including the application of ipratropium bromide, flixotide, terbutaline sulphate and salbutamol resulted in a flow > 0.249 [ml/min] in open valve condition and a flow of > 0.108 [ml/min] in closed valve condition.

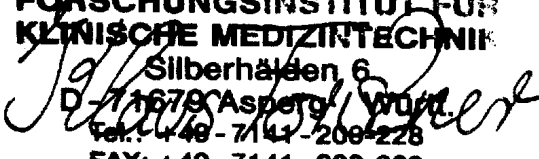
The residual volume has been < 0.63 [ml] in both closed and open valve status.

The reliability test disclosed no parameter degradation: A MMAD of < 2.78 [µm] and a nebulization rate > 0.25 [ml/min] was found within all of the 400 [h] operation period.

The Rossmax test results are listed in the document attached.

Asperg, April 24, 2014

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