



Improved Aerosol Therapy

FAVORITE Inhalation



**AKITA<sup>®</sup> JET**



## FAVORITE Inhalation

# Flow And Volume Regulated Inhalation Technology

For optimized aerosolized drug inhalation, Activaero has developed a unique therapy concept called FAVORITE. The FAVORITE concept provides optimized inhalation flow and volume for patients with lung disease. The electronically controlled inhalation is based on therapeutic and dosing requirements and can be adjusted to the patient's individual condition. With FAVORITE, the AKITA® JET system offers a quality improvement for inhalation therapy.

## What makes FAVORITE special compared to conventional nebulizers:

- ▶ Consistently higher and reproducible lung dosing
- ▶ 50% higher drug use efficiency for drug cost savings
- ▶ “Drug Targeting”– targeted drug deposition into predefined areas of the lung where the drug is most effective
- ▶ Electronic patient data and full compliance control



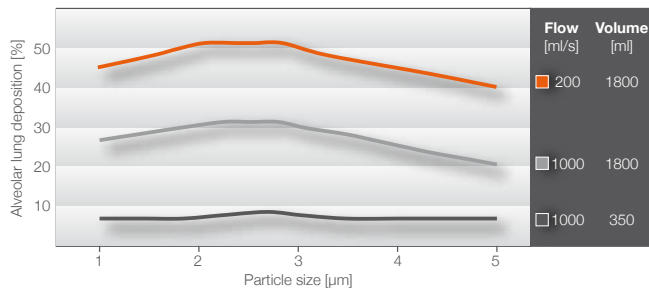
## The key to successful inhalation therapy

# Slow Inspiration and High Inhalation Volume

Every inhalation system can generate an optimal aerosol, but only AKITA® JET can control the optimized inhalation maneuvers.

Particle size is not the only crucial factor with regard to inhaled drugs. Additionally, optimized breathing patterns combined with slow inspiration and a high inhalation volume is needed in order to sufficiently deliver the drug to a specific site of action within the lung.

## AKITA® JET guarantees optimal, patient-specific inhalation and volume.



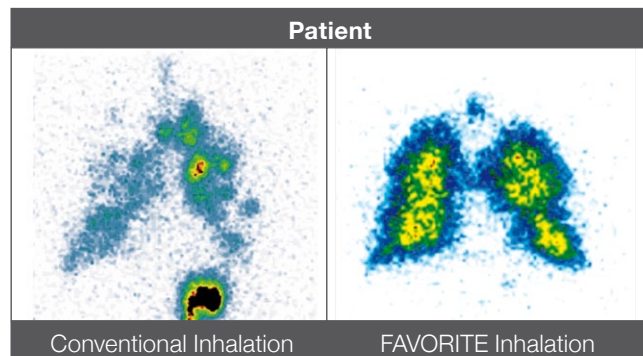
Alveolar lung deposition of 1 to 5 µm particles following inhalation using different inspiration patterns and inhalation volumes. <sup>1</sup>



## Intelligent solutions for enhanced lung deposition Controlled Respiration with Over Pressure

The concept of FAVORITE inhalation is based on flow and volume controlled respiration utilizing a slight over pressure to guide the patient. The slight increase in pressure is often required in order to efficiently deliver the drug to less ventilated areas in the lungs, especially with regard to patients with pulmonary obstructions.

AKITA® JET effectively delivers the drug into all areas of the lung

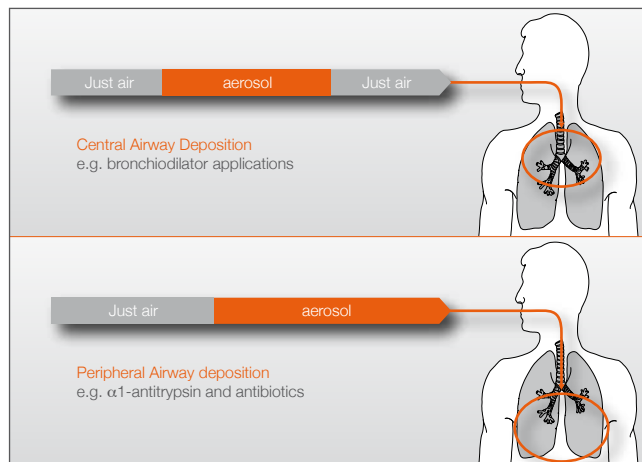


Scintigraphic depiction of lung deposition in a healthy subject and in a patient with pulmonary obstructions following drug inhalation (Black area is the swallowed drug in the stomach due to high deposition in the throat).<sup>2</sup>

## “Drug Targeting” Therapy for Predefined Areas of the Lung

FAVORITE allows continuous control of both aerosolized drugs and air during the inhalation process. Pre-defined variation in the pattern of the drug and air bolus means that drug deposition can be navigated into a certain region of the lung (e.g. either the lower or central airways). Depending on the drug and therapeutic goal, a drug can be deposited directly at the place of action, an easily adjusted process called “Drug Targeting”.

For the very first time in inhaled treatment, AKITA® JET allows for precise “Drug Targeting”



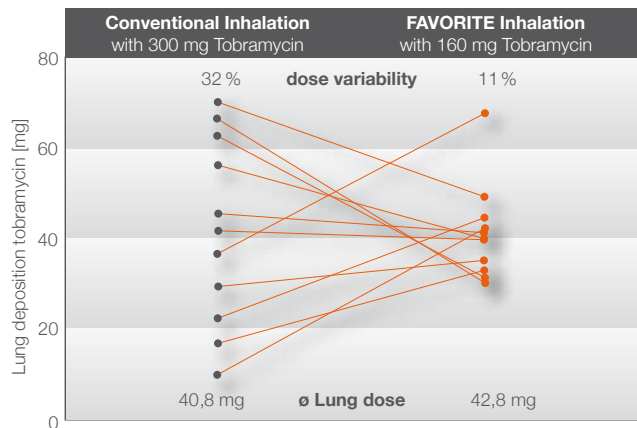
Possible inhalation patterns using AKITA® JET for targeted drug deposition in the central or peripheral airways.



## Accurate and cost-effective therapy Enhanced Dosing and Inhalation of Expensive Drugs

With FAVORITE, nebulization occurs only during inspiration. When combined with AKITA® JET and controlled breathing techniques, FAVORITE inhalation provides equivalent lung dosing with a significantly reduced input dose in comparison to conventional inhalation systems. Additionally, variability of the inhaled drug dosage is reduced dramatically as seen in clinical studies (e.g. for the inhalation of Tobramycin).

### A special task for AKITA® JET: Efficient and safe use of antibiotics

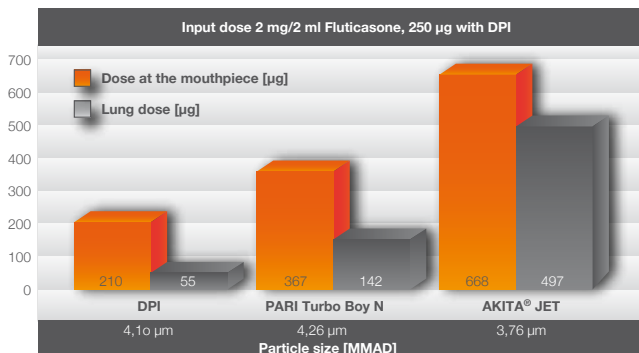


*Inhalation of Tobramycin (TOBI®) in a homogeneous collective of 12 healthy volunteers, detected szinitigraphic means and cross-over investigation. <sup>3</sup>*

## New treatment options Greater Lung Dosing with FAVORITE

Compared to conventional inhalation systems, AKITA® JET allows for a significantly higher drug deposition in the lungs even with average dosing. AKITA® JET deposits 75% of the dose measured at the mouthpiece into the lungs, which allows for new treatment options, such as high-dosed inhalation therapy. With regard to severe asthma, inhaling a higher dose of Fluticasone using AKITA® JET could reduce the need for systemic therapy and prevent related side effects.

### AKITA® JET allows for a significantly higher drug deposition in the lungs



*In vitro study with Fluticasone: Drug concentration at the mouthpiece and lung deposition measured using different inhalation systems <sup>4</sup>*

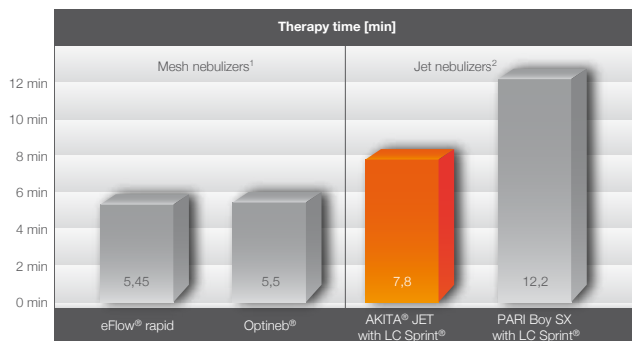


## Increasing therapeutic quality

# Effective Inhalation and Shorter Treatment Time

The AKITA® JET inhalation system uses a reliable and robust jet nebulizer technology for aerosol generation. In comparison with a jet nebulizer using a normal compressor, a jet nebulizer combined with AKITA® JET significantly decreases inhalation time. Each inspiration with AKITA® JET is highly efficient with regard to the amount of drug deposited in the lungs per breath, meaning that fewer breaths are needed in order to reach the required dosage. Even a high dose of drugs, such as 300 mg of Tobramycin, can be inhaled in less than 10 minutes using AKITA® JET.

AKITA® JET provides high quality therapy within a short treatment period



Inhalation time for Tobramycin 300 mg/4 ml, AKITA® JET vs. mesh nebulizer and conventional jet nebulizer<sup>5, 6</sup>

## The SMART CARD

# Specific Therapy Control

AKITA® JET's improved SMART CARD CONCEPT – simple and flexible.

The SMART CARD is an electronic chip card that provides and controls all relevant therapy parameters for the inhalation of a specific drug. The AKITA® JET display allows the patient to quickly and effectively adapt inhalation time per breath to his or her own inhalation capabilities. At the same time, the SMART CARD stores all treatment data which allows physicians and patients to easily optimize and analyze the therapy.

Precise drug dosage with the SMART CARD Concept – simple, flexible and patient-focused

Smart Card ID	Inhalation time per breath	Total number of breaths
000991		
<b>Language</b>	1,5 sec (0,3 l)	84
English	2,0 sec (0,4 l)	56
<b>Inhalation units</b>	2,5 sec (0,5 l)	46
600	3,0 sec (0,6 l)	36
<b>Drug</b>	3,5 sec (0,7 l)	33
Colistin	4,0 sec (0,8 l)	28
<b>Dosage</b>	5,0 sec (1,0 l)	21
1 Mio IE Colistin/3,0 ml	6,0 sec (1,2 l)	17
<b>Deposition</b>	7,0 sec (1,4 l)	14
Peripheral-alveolar	8,0 sec (1,6 l)	12

The patient gets one SMART CARD per drug and dosage, e.g. for the antibiotic, Colistin.



AKITA® JET Control Unit	
<b>Inhalation flow</b>	12 l/min
<b>Weight</b>	2,85 kg
<b>Size (L x H x B)</b>	206 x 180 x 130 mm (including nebulizer)
<b>Electric protection</b>	category II Type B
AKITA® JET Power Supply	
<b>Manufacturer</b>	FRIWO
<b>Model</b>	DT50 Medical
<b>Type</b>	FW7405M/24
<b>Input voltage</b>	100 – 240 V / 50 -60 Hz / 1,1 A
<b>Output voltage</b>	24 VDC 2,2 A
AKITA® JET Nebulizer Set	
<b>Manufacturer</b>	PARI
<b>Model</b>	LC Sprint®
<b>Min. input volume</b>	2 ml
<b>Max. input volume</b>	8 ml
<b>Flow rate</b>	12 l/min
<b>Aerosol release</b>	0,23 ml/min
<b>MMAD Mass Median Aerodynamic Diameter</b>	3,8 µm (sodium fluoride solution 1,0 %)
Additional Information	
<b>Germany</b>	HMZ 14.24.01.3002
<b>Europe</b>	in accordance with 93/43/EWG
<b>USA</b>	cleared in the USA (K090730)
<b>Commercial launch</b>	2008
<b>Manufactured in</b>	Germany
<b>Producer</b>	ACTIVAERO
<b>Distribution, technical service, reimbursement</b>	National medical technology partner

## Literature list

1.) ICRP 1994; *Human Respiratory Tract Model for Radiological Protection. A Report of a Task Group of the International Commission on Radiological Protection. Ann. ICRP 24, 1-482 (1994).*

2.) Meyer et al. 2001; *Deposition von therapeutischen Aerosolen in der Lungenperipherie. Aerosole in der Inhalationstherapie, ed. G. Scheuch. Vol. 5. 2001, Dustri-Verlag Dr Karl Feistle: München. 93-100.*

3.) Brandt et al. 2006; *Reduction of Drug-Dose and Therapy-Costs in High-Dose Tobramycin-Inhalation, Journal of Cystic Fibrosis 2006; 5: Suppl 1: 86 June 2006.*

4.) Müllinger et al. 2008; *Drug Output of Inhalers is not a Predictor of Lung Dose. Abstracts of the RDD Conference, Respiratory Drug Delivery 2008; Arizona, USA.*

5.) Schneiders et al 2008; *In-vitro Characterization of Bramitob® with Next Generation Nebulisers, Journal of Cystic Fibrosis 2006 CF - Volume 7, Supplement 3, Page S26, July 2008.*

6.) Kroneberg et al 2009; *The Choice of Nebulizers Effects Treatment Time and the Delivered Dose of Tobramycin. Abstract of DDL, Drug Delivery to the Lungs Conference; Dec. 2009, Edinburgh; UK.*

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**ACTIVAERO®**

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