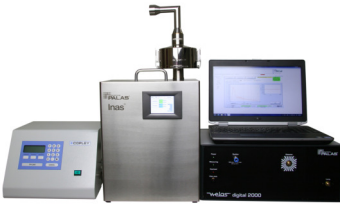


Real-time particle size and particle quantitative determination of spray bursts for MDIs (Metered Dose Inhaler), nebulizers and DPIs



## Description

Inas® is the only measurement system in the world that also reliably and reproducibly determines the particle size and particle quantity of individual spray bursts from inhalers with a temporal resolution of 10 ms and in concentrations up to  $10^7$  particles/cm<sup>3</sup>. It is based on the counting measurement method, the welas® digital white light aerosol spectrometer and therefore guarantees very good particle size resolution and very good particle size classification accuracy (ISO 21501-1). The Inas® 100 is equipped with the welas® 2070 sensor and a dilution unit and can be operated with variable suction volume flows of up to 100 l/min. The volume flow is set using a mass flow (measurement of MDIs and nebulizers). With dynamic suction controlled by the differential pressure (measurement of DPIs), the suction is controlled using a critical nozzle. The established Copley breathing simulator (TPK 2000 with Copley Suction Pump HCP 5) is used for this purpose. This is a long established method in pharmaceutical research used in combination with cascade impactors (e.g. NGIs). The so-called "Throat" is used as the aerosol inlet in accordance with the Pharmacopoeia. This simulates the separation of particles in the throat. The inhaler (DPI) is inserted in the Throat and the measurement is performed automatically. The Copley Preseparator is used between the throat and the aerosol spectrometer. This separates out the large particles ( $> 50 \mu\text{m}$ ) that serve as the carrier for the active substance. The Copley TDK 2000 is connected before the HCP5 Copley Suction Pump to simulate different breaths. In addition, the Inas® 100 system has a powerful processor that allows the course of a measurement to be determined with regard to concentration and other distribution parameters, such as the Sauter diameter, in the particle size range 0.2 - 40  $\mu\text{m}$ . The evaluation of the measured data for the determination of particle size distributions is exclusively based on unambiguous, mathematically reproducible algorithms. Several spray bursts can be displayed and compared in a graph. The schematic structure of Inas® 100 is presented in Figure 1:

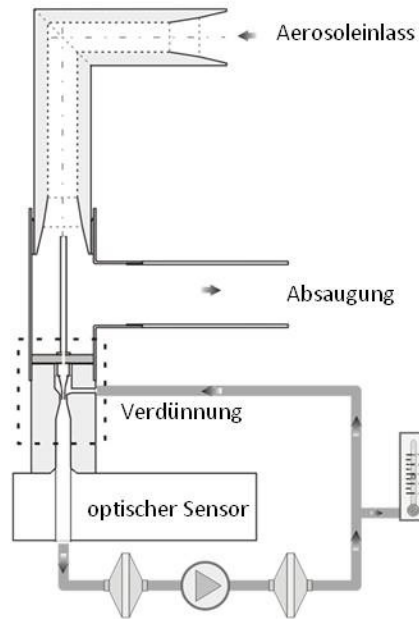
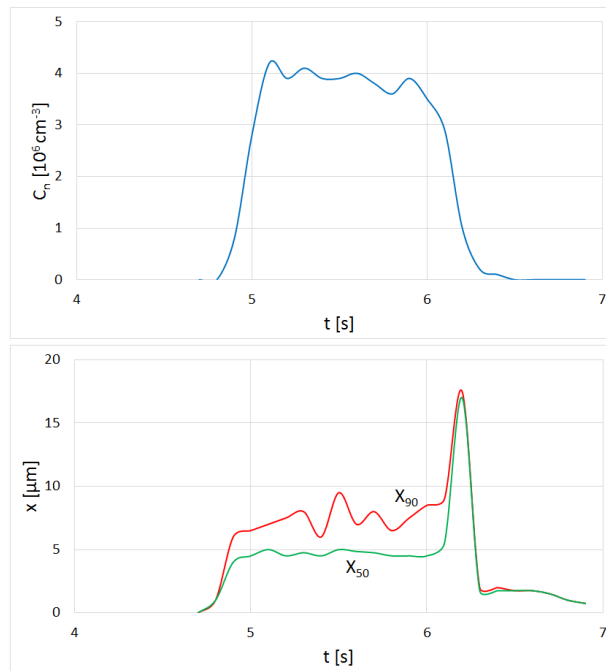
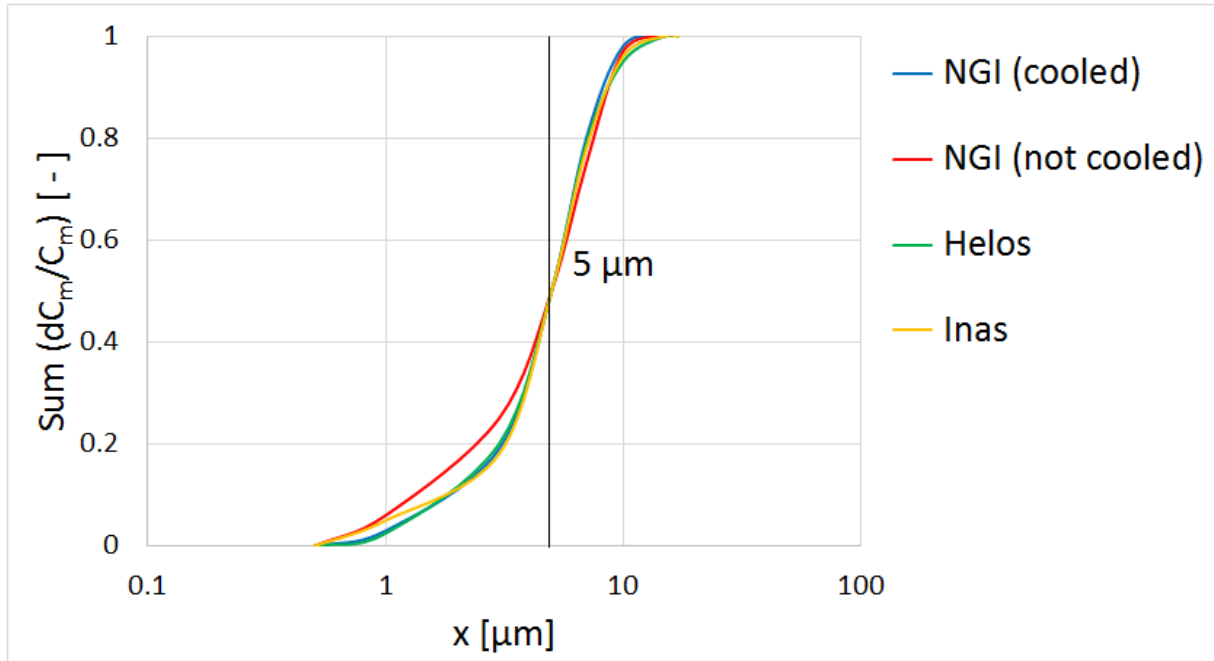


Figure 1: The schematic structure of Inas<sup>®</sup> 100



Graph 1\*: The time course measured with Inas<sup>®</sup> of the number concentration and the mass-related  $X_{50}$  and  $X_{90}$  value Inas of a single MDI spray burst (Respimat<sup>®</sup> Soft Inhaler, Boehringer Ingelheim) in 100 ms resolution. In contrast with a cascade impactor, with Inas<sup>®</sup> 100 a measurement can be performed in seconds and this can be immediately evaluated with a resolution down to 10 ms (see Graph 1). Compared with the laser diffractor, the Inas<sup>®</sup> 100 also measures the concentration of the aerosol and smallest particles with the highest accuracy. The good agreement of the particle size determination with other measurement

methods has been determined by the Pharmaceutical Institute of the Christian Albrecht University in Kiel (Germany). Graph 2 shows the size distributions measured with the Inas<sup>®</sup> 100 as compared with measurement using a cascade impactor (NGI) and laser diffractor.



Graph 2\*: Comparison of mass-related sum distributions measured with the NGI impactor (MSP Corp., USA), the Helos laser diffractor (Sympatec GmbH, Germany) and the Inas<sup>®</sup> light-scattering spectrometer (Palas<sup>®</sup> GmbH, Germany) of a nano suspension nebulized with the Pari LC Plus (Pari GmbH, Germany). On the basis of these special properties of the Inas<sup>®</sup> 100, the quality assurance of inhalers or the development of nozzle systems for various active substances can be carried out economically, reproducibly and convincingly. The particle sizes and quantities of MDIs, DPIs and nebulizers can be determined in minutes at different temperatures, e.g. when stored in the car in summer or winter as compared with room temperature or with different breaths.

[\*Source: "Entwicklung von Aufgabesystemen zur Charakterisierung pharmazeutischer Aerosole mit einem optischen Partikelzähler" (translation: "Development of sampling systems for characterization of pharmaceutical aerosols with an optical particle counter", Maren Kuhli, doctoral theses at the Faculty of Mathematics and Natural Sciences Christian Albrecht University, Kiel (Germany))]

## Benefits

- Measuring range 0.2 - 40  $\mu\text{m}$  (3 measuring ranges selectable in one device)
- Very high temporally resolved particle size and particle quantity determination down to 10 ms
- Concentration range up to  $10^7$  particles/cm<sup>3</sup>
- Characterization of a single spray burst in a few seconds
- Rapid determination of size distributions and concentrations
- Calibration, cleaning and lamp replacement can all be performed independently by the customer
- Extensive, practically-oriented and user-friendly software
- Low maintenance
- Simple operation
- Reliable function
- Reduces your operating expenses

## Datasheet

<i>Parameter</i>	<i>Description</i>
<b>Interfaces</b>	USB
<b>Measurement range (size)</b>	0.2 - 40 µm (3 measurement ranges)
<b>Size channels</b>	up to 128 (64/decade)
<b>Measuring principle</b>	Optical light-scattering
<b>Measurement range (number C<sub>N</sub>)</b>	0 - 1 • 10 <sup>7</sup> particles/cm <sup>3</sup>
<b>Volume flow</b>	15 l/min (nebulizer), 30 l/min (MDI), variable flow rate up to 100 l/min (DPI) controlled by differential pressure according to the European Pharmacopoeia
<b>Data acquisition</b>	20 MHz processor, 256 raw data channels, digital
<b>Light source</b>	Xenon arc lamp 35 W
<b>User interface</b>	Laptop or pc
<b>Dimensions</b>	Top part: 600 • 260 • 170 mm, desktop case: 190 • 450 • 370 mm
<b>Support options</b>	Direct remote access, Palas <sup>®</sup> webserver service
<b>Weight</b>	approx. 25 kg

## Applications

- Characterization of spray and nebulizer nozzles
- Characterization of inhalation aerosols in accordance with the European Pharmacopoeia with 15 l/min, 30 l/min or variable flow rates
- Characterization of inhalation aerosols in accordance with the European Pharmacopoeia with variable flow rates up to 100 l/min controlled by the differential pressure
- Measurement of MDIs, nebulizers and PDIs

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