



Droplet / Particle Size Distribution (APSD)

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Andersen Cascade Impactor without Pre-separator for Inhalation Aerosols, Inhalation Sprays, and Nasal Aerosols.

MDIs

Metered dose inhalers (MDIs) represent a combination of drug and device, utilizing energy stored in a pressurized liquefied gas propellant to produce aerosols suitable for delivering drugs to the lungs. These products are fundamental in managing conditions like asthma, COPD, and various respiratory diseases.

The dimensions of droplets and particles released by metered dose inhalers (MDIs) as they traverse the mouth-throat area significantly influence the deposition of inhaled particles within the respiratory tract. For suspension or solution nasal aerosols and nasal sprays, it's essential to analyze the droplet/particle size distribution of the emitted plume following delivery under particular experimental conditions. For these specific purposes different types of impactors (basically, ACI 8 Stage and NGI) are used.

Cut-Off Diameters (μm) for Andersen Cascade Impactor with and without Pre-Separator at 28.3 L/min Compared with Use at 60 and 90 L/min:

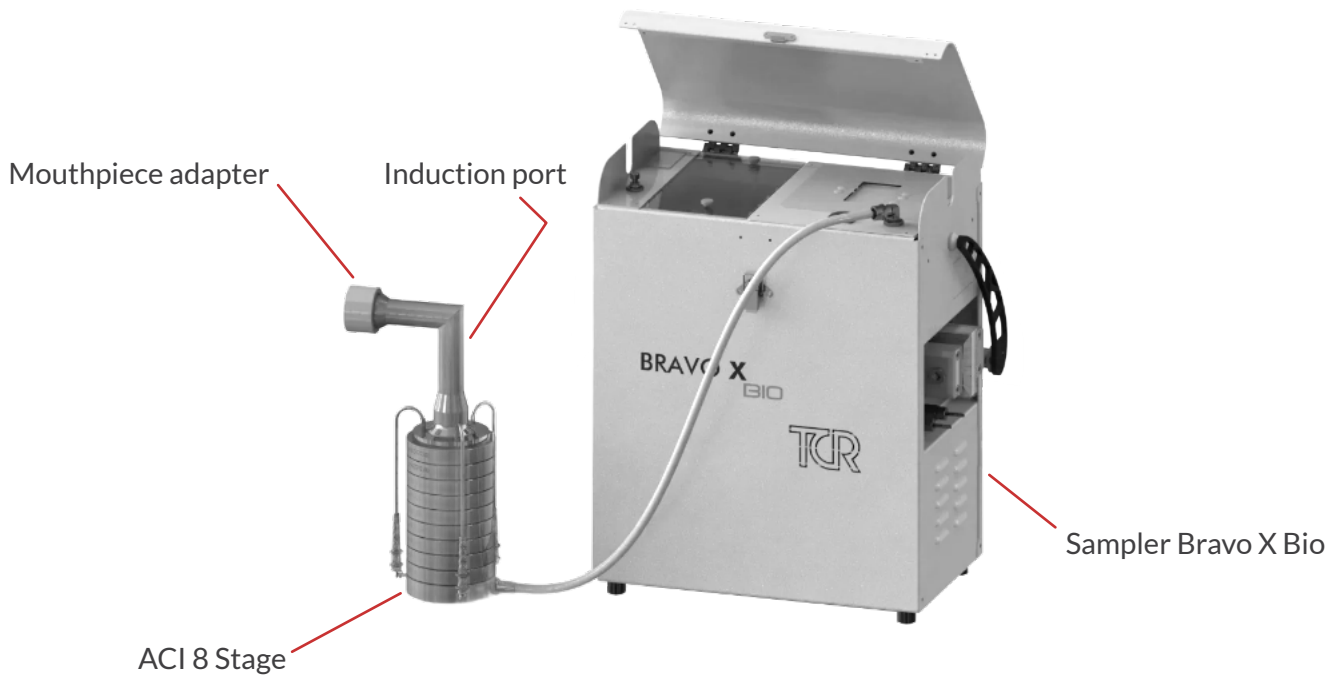
The device is a Cascade Impactor with eight stages and an after filter. The material can be aluminum or stainless steel. Use this apparatus at a flow rate of 28.3 L/min ($\pm 5\%$) for MDIs and 28.3-90 L/min for DPIs unless otherwise prescribed in the individual monograph.

Stage	28.3 L/min	60 L/min	90 L/min
-2	-	-	8.0
-1	-	8.6	6.5
-0	9.0	6.5	5.2
1	5.8	4.4	3.5
2	4.7	3.2	2.6
3	3.3	1.9	1.7
4	2.1	1.2	1.0
5	1.1	0.55	0.22
6	0.7	0.26	-
7	0.4	-	-





Andersen Cascade Impactor 8 Stage without Pre-separator:



Cut-off diameters (μm) for Next Generation Impactor with and without Pre-separator at 30, 60, and 100 L/min:

Use this apparatus at a flow rate of 30 L/min ($\pm 5\%$) for MDIs and 30-100 L/min for DPIs unless otherwise prescribed in the individual monograph.

Stage	30 L/min	60 L/min	100 L/min
1	11.72	8.06	6.12
2	6.40	4.46	3.42
3	3.99	2.82	2.18
4	2.30	1.66	1.31
5	1.36	0.94	0.72
6	0.83	0.55	0.40
7	0.54	0.34	0.24
MOC	0.36	0.14	0.07

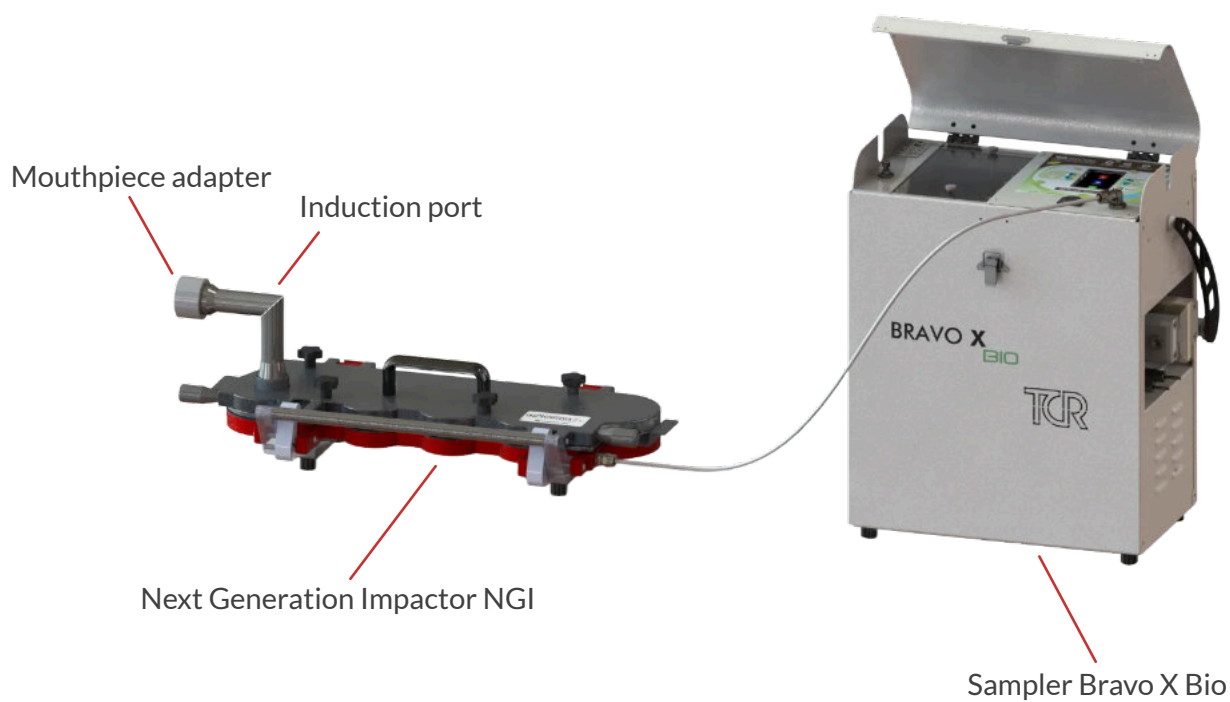


Droplet / Particle Size Distribution (APSD)

NEXT GENERATION IMPACTOR



Next Generation Impactor without Pre-separator:



Andersen Cascade Impactor with Pre-separator for Inhalation Powders and Nasal Powders

DPIs

Marketed dry powder inhaler (DPIs) products employ diverse formulation and device technologies to ensure consistent delivery of the active pharmaceutical ingredient (APIs) to patients. Regardless of the specific drug delivery platform, it is imperative that the dose maintains a suitable quality and aerodynamic particle size distribution (APSD) to deposit effectively in the target region of the lungs, thus achieving the desired therapeutic outcome. While the general notion that the APSD of the API should be $< 5 \mu\text{m}$ for deep lung penetration serves as a helpful guideline for both innovator and generic inhaled products, it is important to recognize the complexity of this process and the various factors that can influence particle deposition.

For these specific purposes different types of impactors (basically, ACI 8 Stage and NGI) are used. There are several differences in the testing of DPIs and MDIs, including variations in working airflows, flow resistance, volume setting, sampling and the presence of a Pre-separator for DPIs.

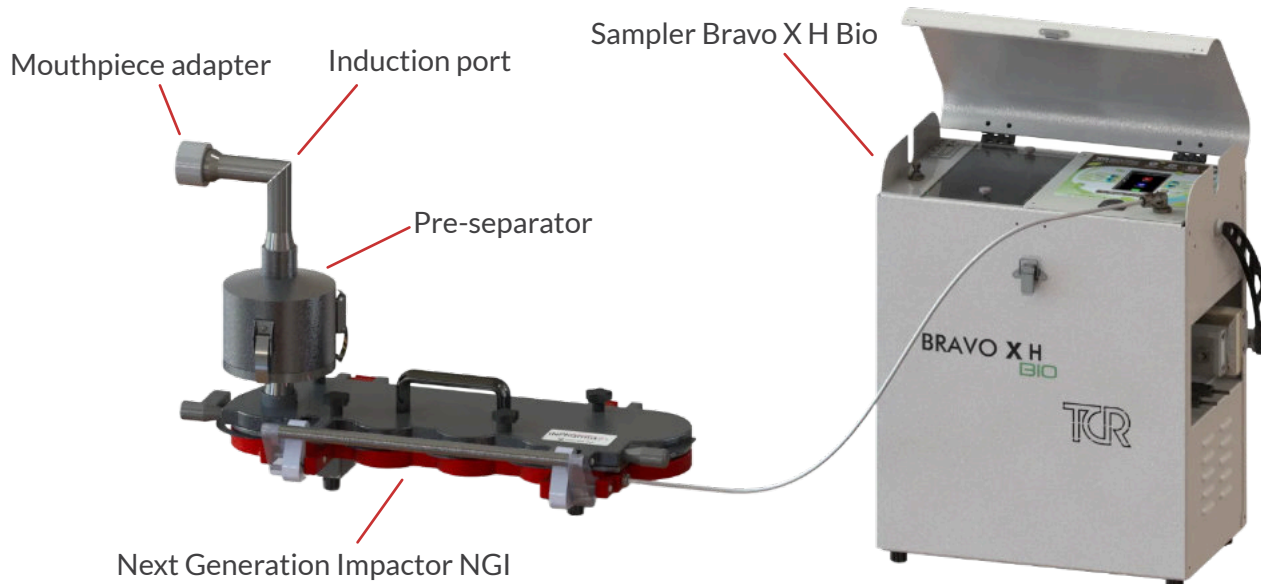


Andersen Cascade Impactor 8 Stage with Pre-separator:





Next Generation Impactor with Pre-separator:



Product Codes

Product	Code
Andersen Cascade Impactor 8 Stage	AC99-120-0020SP
Conversion KIT 28.3 L/min to 60 L/min	AC99-120-0027SP
Conversion KIT 28.3 L/min to 90 L/min	AC99-120-0029SP
Next Generation Impactor NGI	AC99-122-0900SP
Induction Port for ACI 8 Stage	AC99-120-0023SP
Induction Port NGI	AC99-122-0901SP
Pre-separator for ACI 8 Stage - 28,3 L/min	AC99-120-0026SP
Pre-separator for ACI 8 Stage - 60 L/min	AC99-120-0075SP
Pre-separator for ACI 8 Stage - 90 L/min	AC99-120-0076SP
NGI Pre-separator	AC99-122-0902SP
Bravo X Bio Pump	AA99-000-0740SP
Bravo X H Bio Pump	AA99-000-0744SP

We offer a distinctive mouthpiece adapter that seamlessly connects to the Induction port. Upon request, we can customize the membranes where inhalers will be positioned, ensuring tailored solutions to meet specific needs:

Cyclohaler membrane	AC99-120-0093SP
Handihaler membrane	AC99-120-0092SP

The introduction of an integrated system by InPharmaTEC streamlines the testing process for inhalation products, such as MDIs and DPIs. By combining critical components—flowmeter, solenoid valve, timer, vacuum pump, differential pressure transducer, critical flow controller (for both, MDIs and DPIs), into one unit, the workflow is indeed simplified, reducing potential sources of error and enhancing efficiency.

