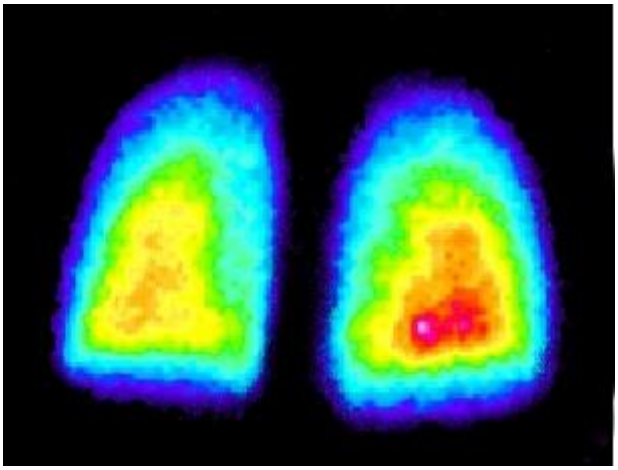
SmartVent™

the next generation of lung ventilation imaging



Diagnostic Imaging Limited

Elkington Lodge
Welford
Northamptonshire
NN6 6HE
England

Tel: +44 (0)845 226 0520
Fax: +44 (0)845 226 0521
e-mail: info@diagimaging.com
www.diagimaging.com

ISO 13485 Medical Devices Quality Management Certification

ISO 9001 Quality Management Certification

OHIM – OFFICE FOR HARMONIZATION IN THE INTERNAL MARKET
TRADE MARKS AND DESIGNS
Registration No. 000210596-0001

Benefits

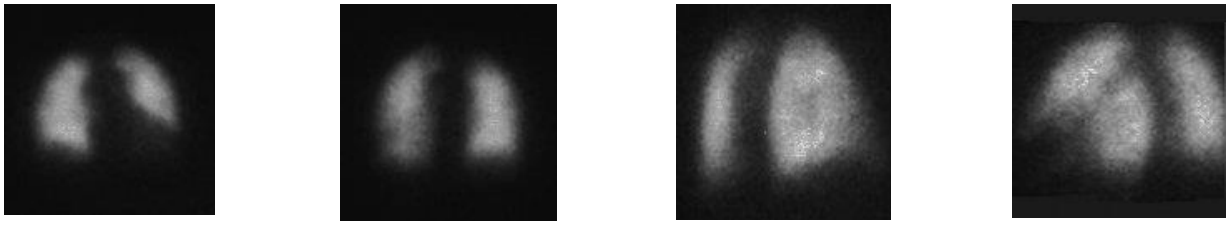
- Excellent, consistent, image quality
- Electronic radioaerosol generation – gas cylinders not required
- Silent operation
- Low activity requirements – approx. 600 MBq per patient
- Rapid uptake – 1 to 2 minutes per patient
- Low resistance – easier for the patient
- Efficient shielding – low radiation dose
- Breath activated, on demand delivery of aerosol. No leakage from the system from non-compliant patients.
- Total mobility – can be moved between imaging rooms
- Cost effective and competitively priced

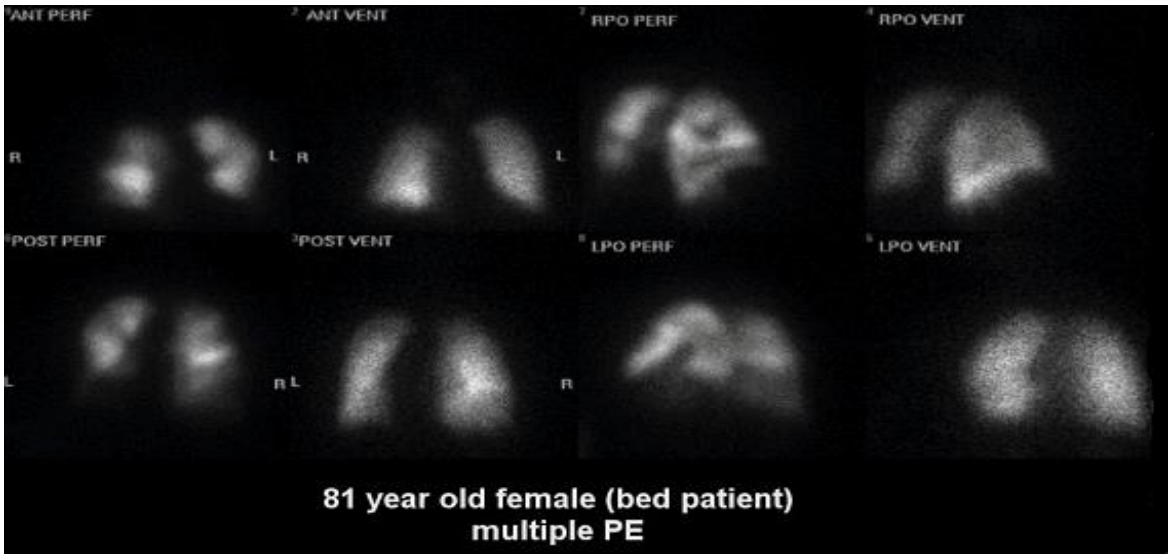
Example images (courtesy of Norfolk & Norwich University Hospital)

Patient: 77 year old female with chest pain

Good quality images, no central deposition or GI uptake

400 MBq Tc-99m DTPA, 1min 30 secs. breathing time

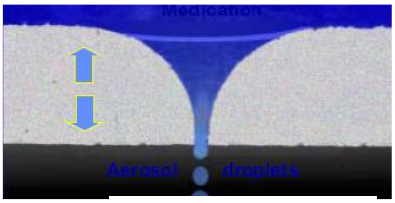


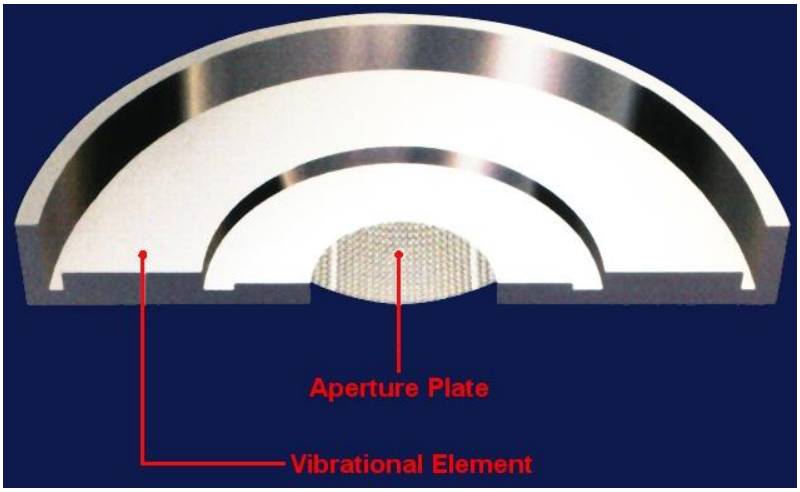


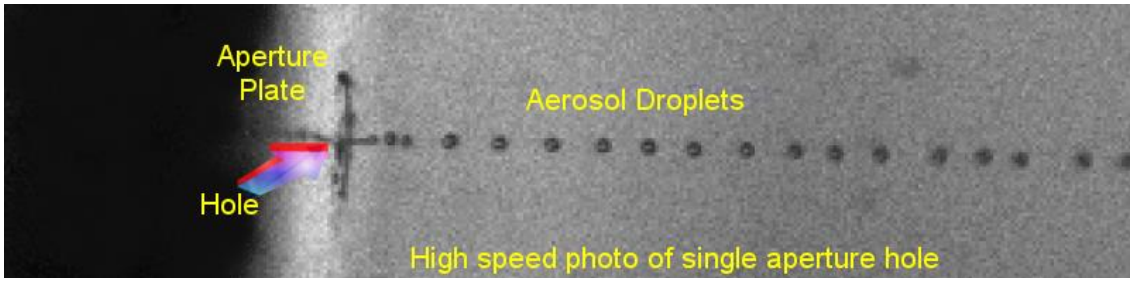
SmartVent™ - How does it Work?

SmartVent™ uses an electronic micropump to produce liquid aerosol in a manner unlike any other technology currently available.

At the heart of the **SmartVent™** aerosol generator is a unique dome-shaped aperture plate containing over 1,000 precision-formed tapered holes, surrounded by a vibrational element. When energy is applied, the aperture plate vibrates at over 125,000 times per second. This rapid vibration causes each aperture to act as a micropump, drawing liquid through the holes to form consistently sized droplets**.**







Shielded canister and circuit

Performance Characteristics

Dose required (per patient): approx. 600 MBq of ^{99m}Tc DTPA

Volume required: 0.5 -1ml (per patient)

Patient uptake time: typically less than 90 seconds

Count rate using above parameters:

HR collimator: 1-1.5 kcps

GP collimator: 1.5-2 kcps

HS collimator: 3-4 kcps

Particle size, delivery rate and efficiency

Conventional radioaerosol delivery systems utilise venturi nebulizers that deliver a broad spectrum of particles sizes at high pressure to the patient. In order to achieve satisfactory alveolar deposition, systems based on the venturi principle require the large particles to be removed before the patient breathes in the aerosol. Incorporating baffles, settling bags or subjecting the airflow within the nebulizer to a swirling pattern may achieve this.

These systems suffer from inefficient use of the Tc-99m DTPA, as the 'dead volume' is typically 50% or more of the added dose. Moreover, due to the relatively high particle size variation of these systems, a significant proportion of the generated aerosol is unusable, as the circuit will baffle it out.

Systems with inadequate baffling will result in poorer image quality with relatively high uptake in the throat, oesophagus, stomach and central airways.

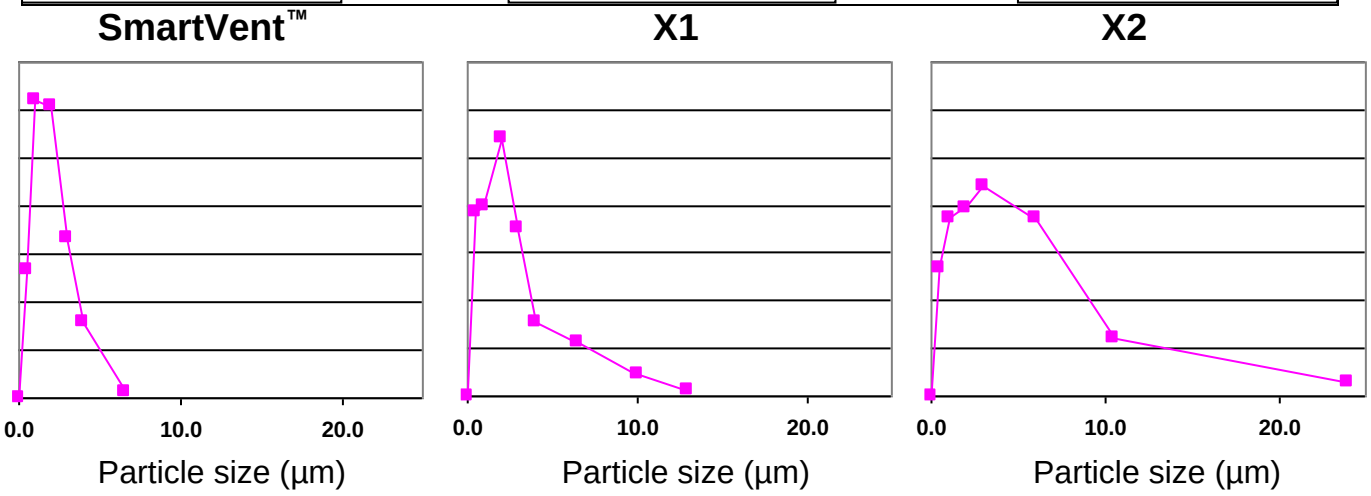
SmartVent™ does not suffer from these inefficiencies. The volumetric median diameter (VMD) of the aerosol particles has been measured at 1.32 microns with a low proportion of particles outside the respirable range. Systems based on the venturi principle tend to produce larger particles with a significantly higher proportion outside the desired size range.

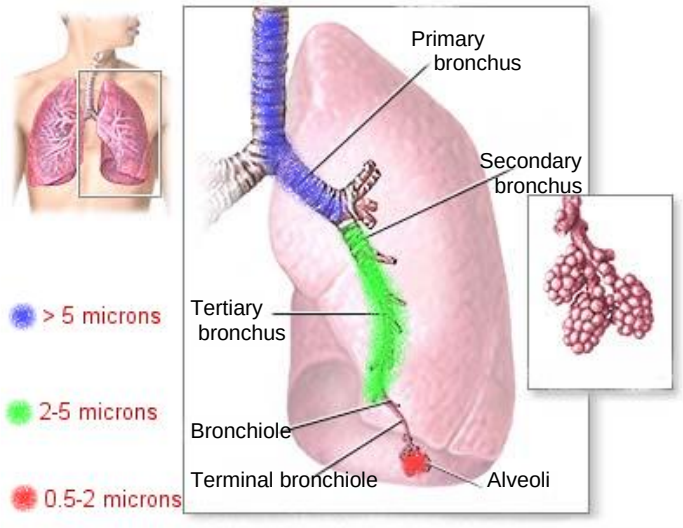
Particle size measurements were performed with a Malvern Spraytech Laser Particle sizer connected to a Heims Rudolph Breathing Simulator.

Particle size measurement results

Particle size measurements were performed on the **SmartVent™** system and compared to two other commercially available aerosol systems that are based on the venturi principle:

SmartVent™		**X1**		**X2**	
Size(µm)	%Volume	Size(µm)	%Volume	Size(µm)	%Volume
0.0	0.0	0.0	0.0	0.0	0.0
0.5	13.3	0.5	19.3	0.5	13.5
1.0	31.0	1.0	19.8	1.0	18.6
2.0	30.4	2.0	27.1	2.0	19.7
3.0	16.6	3.0	17.6	3.0	22.0
4.0	8.0	4.0	7.7	6.0	18.7
6.5	0.7	6.5	5.6	10.5	6.0
		10.0	2.2	24.0	1.4
		13.0	0.6		
VMD	**1.32µm**	**VMD**	**1.56µm**	**VMD**	**2.12µm**
%Volume > 3µm 8.70%		**%Volume > 3µm 16.10%**		**%Volume > 3µm 26.10%**	





Evaluation of aerosol escape due to non-co-operative patients

SmartVent™ was compared to two other radioaerosol delivery systems for potential aerosol escape if patients were to remove the mouthpiece during administration.

SmartVent™ and other systems (X1 and X2) were set up in accordance to the operating instructions and loaded with the recommended activity and volume of Tc-99m DTPA.

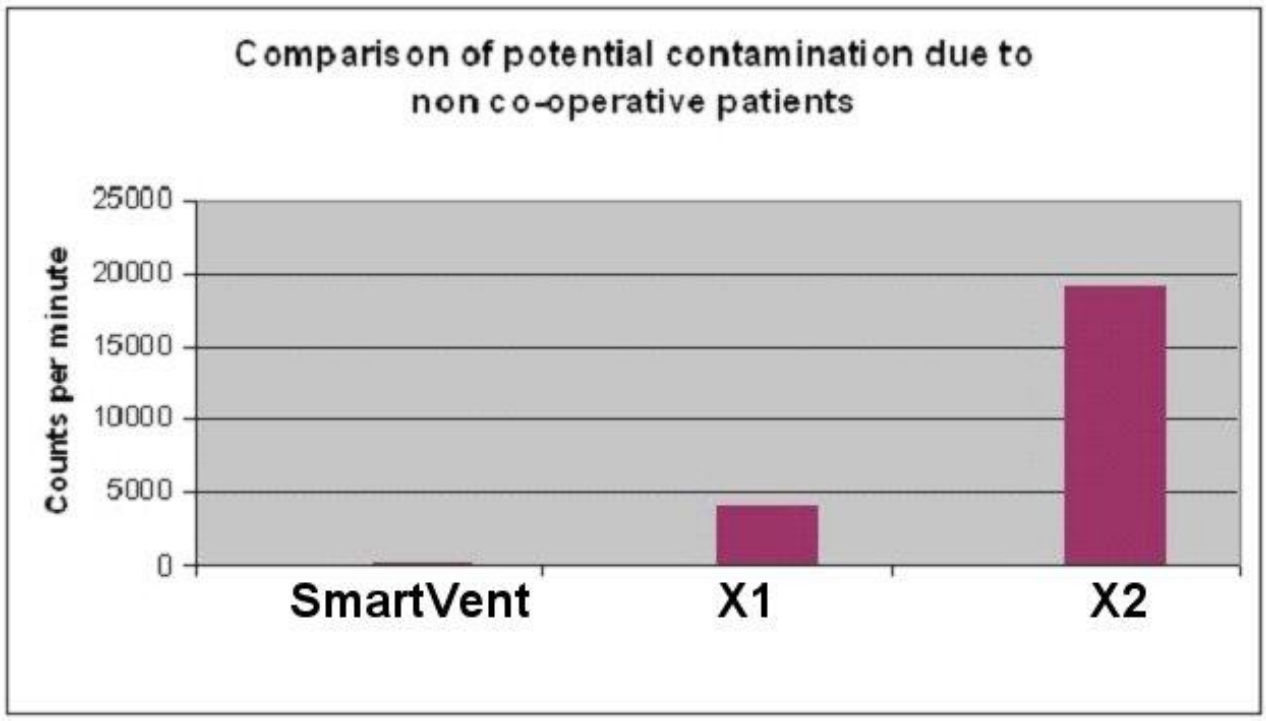
The mouthpiece was replaced by a high efficiency filter, Intersurgical Clear Guard 2.

The systems were then turned on for 15 seconds.

The filters were removed from each system, placed in a sealed bag and counted for radiation on a single head gamma camera.

Results

	SmartVent™	X1	X2
Background corrected counts in filter 15 seconds run time with recommended activity level	ND	4,132	19,057



These results show that **SmartVent™** will not 'leak' radioaerosol into the atmosphere if a patient removes the mouthpiece during administration. Two other systems, X1 and X2, will release significant levels of radioaerosol if the patient removes the mouthpiece.

SmartVent™ Relative Efficiency

SmartVent™ was compared to two other radioaerosol delivery systems for relative delivery efficiency.

All three systems were set up in accordance with the operating instructions and loaded with 800 MBq in 2.5 ml Tc-99m DTPA.

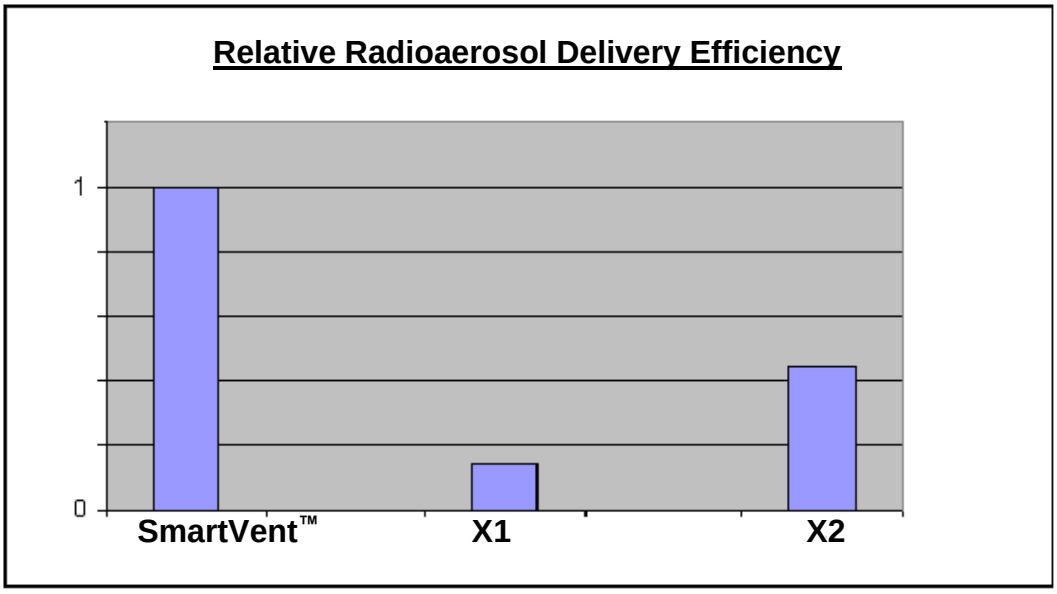
A high efficiency filter was placed between the mouthpiece and system outlet.

A volunteer then breathed through the mouthpiece for 1 minute with the system turned on.

Filters were then removed, placed in a sealed bag and counted for radiation on a single head gamma camera.

Results

	SmartVent™	X1	X2
Average Counts/min	97,821	14,424	45,302
Background subtracted	96,391	12,994	43,872
Relative delivery efficiency	1	0.14	0.45



These results show that the delivery rate of **SmartVent™** is significantly higher than for systems X1 and X2

Dead Volume and Flow Rate measurements

SmartVent™ was compared to two other commercially available radioaerosol delivery systems, (X1and X2), for dead volume and flow rate.

Varying volumes of normal saline were injected into each product. The aerosol flow was started in accordance with the manufacturers operating instructions. For the systems requiring air flow to produce the aerosol, (X1 & X2), the time was recorded when the uniform, constant plume of vapour changed into an erratic flow. After this point, the aerosol generation continues, due to the vaporisation of condensed droplets in nebulizer, but at a greatly reduced rate.

SmartVent™ shows a constant generation rate without aerosol generation of condensed solution.

Results:

SmartVent™ Generator Serial No.	Emptying time(s) (1.0 ml saline)	Emptying time(s) (1.5 ml saline)	Emptying time(s) (2.5 ml saline)	'Dead Volume' (µl)	Flow rate (ml/min)
045934-137	146	220	366	<5	0.41
045935-077	147	220	364	<5	0.41
045944-055	137	206	341	<5	0.44
045944-139	139	209	347	<5	0.43
X1	34	80	350	875	0.22
X2	86	265	560	710	0.20

These results confirm that **SmartVent™** has a significantly higher efficiency compared to other radioaerosol nebulizer systems that require a propellant gas, such as air or oxygen, to generate the flow of aerosol. **SmartVent™** has an effective 'dead volume' of less than 5ul. This means that the vast majority of the volume added to the generator is converted to aerosol.

Products X1 and X2 both have a significant dead volume. This means that these systems require a higher volume and activity in order to achieve satisfactory radioaerosol deposition.

The system flow rate is an indicator of the aerosol uptake rate. The output of the **SmartVent™** system is significantly higher than for the other nebulizer systems, indicating that the uptake rate in patient's lungs is more rapid compared to standard nebulizer systems.

Typical ventilation times

Due to the high efficiency of **SmartVent™** total activity, volume and concentration levels of Tc-99m DTPA can be customised to suit local requirements. The following chart indicates some of the possibilities:

Tc-DTPA MBq	Volume mls	Maximum Vent time	Typical Vent time
500	0.5	1min 10secs	<1min
500	1.0	2mins 25secs	2mins
500	1.5	3mins 45secs	3mins
400	1.0	2mins 25secs	2mins 15secs
400	1.5	3mins 45secs	3mins 30secs

The delivery times have been verified over a large number of patients of different ages and conditions, and represent a delivered count rate of approximately 20-30% of a typical perfusion dose.

For patients that are experiencing respiratory distress, a higher initial concentration with an activity level of 800 MBq, will result in an even more rapid uptake time. It is possible to achieve an acceptable count-rate in a few breaths, if necessary.

Patient acceptability

SmartVent™ has been designed to be patient and user friendly. The low resistance circuit design allows patients to breathe more easily than through conventional aerosol systems that are pressurised. Also, as the system is very easy to turn off and on, patients that need to take a rest during aerosol administration can easily be accommodated without loss of image quality or uptake efficiency.

Ease of use and safety

SmartVent™ is very easy to use. As the system is CE marked for single session use, and the delivery tubing is single use, the generator can be loaded with sufficient activity for a number of patients. Between patients the delivery tubing is replaced without the necessity of opening the radiation shield. This will help to minimise radiation dose to the operator.

To start and stop the aerosol generation, the only requirement is to press the on/off button on the power supply. This results in better control of the aerosol administration compared to venturi systems.

As the generation is totally passive, if a patient removes the mouthpiece during the study, Tc-99m DTPA aerosol will not escape from the circuit. This removes a major cause of contamination resulting from radioaerosol studies and allows the patient to be ventilated in front of the gamma camera if required.