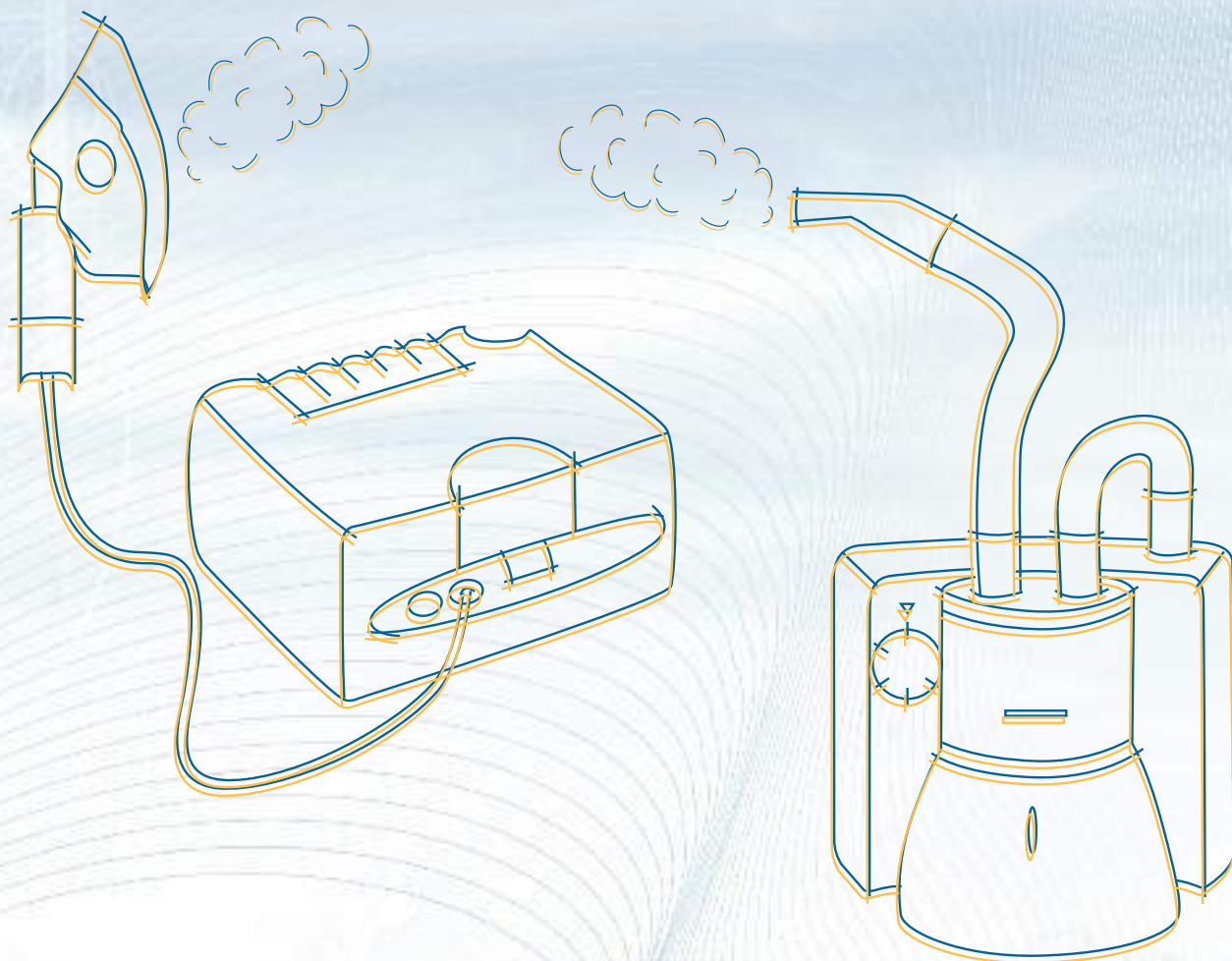




SYSTEM'AM[®]

SYSTEM ASSISTANCE MEDICAL

Aerosol Generators Home Care Range



What is Aerosol Therapy ?

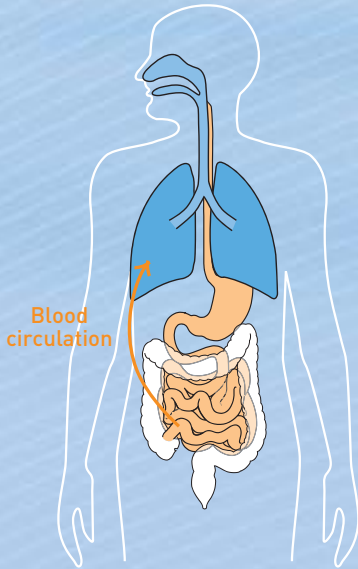
DEFINITION

An aerosol is a suspension of solid or liquid particles in a gas or a gaseous mixture (e.g. : air). In the field of medical aerosol therapy the aerosol is a drug mist to be inhaled by the patient.

INDICATIONS

- asthma
- cystic fibrosis
- COPD
- bronchitis
- winter ailments (bronchitis...)
- ENT pathologies
- sinusitis
- rhinitis...

AVANTAGES ADVANTAGES OF AEROSOL THERAPY AGAINST MEDICATION BY MOUTH



RAPID and DIRECT access to the targeted organ

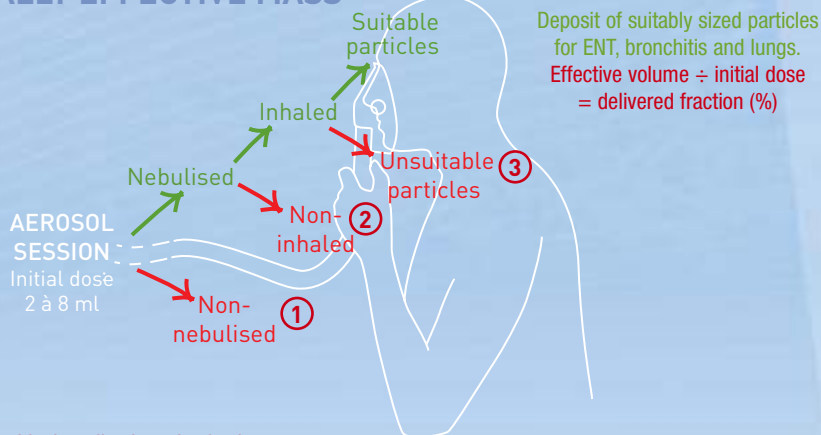
- Increased efficiency
- Smaller dose of the necessary medication
- Low systemic route
- Lower side effects



INDIRECT and SLOWER

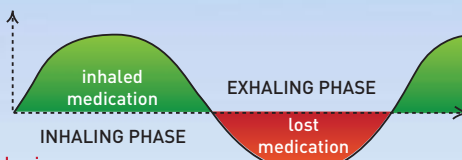
- Medication distributed to all areas whether or not required thus the effects are systemically present

FROM THE REALLY PRESCRIBED DOSE TO THE REALLY EFFECTIVE MASS



① Residual medication «dead volume» : A part of the initial dose is not nebulised. It is located in the tubing and in the equipment. It constitutes the residual or dead volume.

② Nebulised medication lost : Mist produced during the exhaling phase.



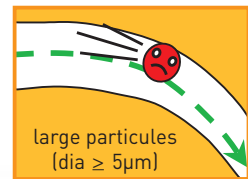
③ Inhaled particles but of unsuitable size : Too large particles do not reach the bronchia and the lower tract. And too small particles remain in suspension and are evacuated on exhaling.

1 THE GRANULOMETRIC QU

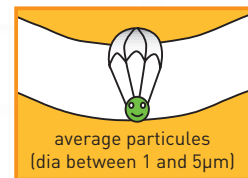
• Particle size and the deposi

The effect of the medication in the airwa particularly on the size of the particles. To gu measure globally between 1µm and 5µm. penetrate the respiratory system and those evacuated on exhalation.

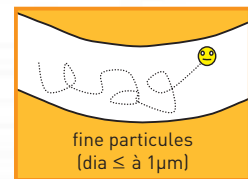
Deposition of inhaled particu the size of th



➤ **Impaction**
The large parti gaseous flow co largely trapped rapid breathing.



➤ **Sedimenta**
The average siz the effect of the where the gase the respiratory method to follow

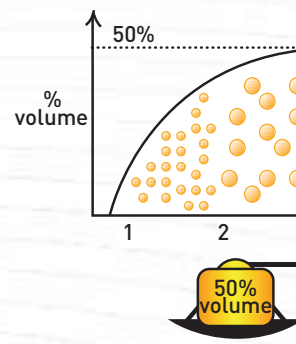


➤ **Diffusion**
The small parti with the gas mo in the area of th is of no signific in the air and ar

• MMAD

MMAD is a unit of measure expressed in µm generator. It concerns Mass Median Aerody such that half of the mass produced by the a is of particles greater than this diameter.

Graph example of dist



2 DURATION OF NEBULISA

Nebulisation speed of a generator is variable It is equal to the volume substance to be neb required for the nebulisation of 4ml of medic than 30 minutes according to the model use

- **Briefly** : High output = Shorter session = More effective treat

at you should know...

5 keys to efficient treatment

QUALITY OF THE PARTICLES

Deposition mechanism

Deposition responds to various mechanisms and depends on the particle size. To guarantee effective treatment medication particles must be of a size that in fact particles of greater size will be too large to reach their target and will be rejected on exhalation.

Factors: 3 things which depend in part on the size of the produced particles

Large particles [$\text{dia} \geq 5\mu\text{m}$] propelled by their volume in the airway will collide with the walls and turnings. They are therefore rejected in the upper parts of the airways. Impact is helped by the turbulence of the air flow.

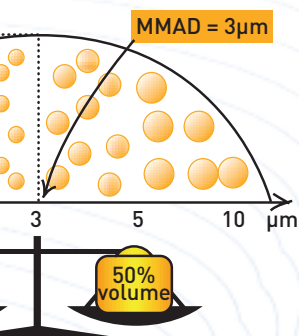
Deposition

Medium-sized particles [dia between $1\mu\text{m}$ and $5\mu\text{m}$] fall under their own weight into the trachea-bronchial area, an area where the air flow speed is almost zero, notably at the time of pause between inhaling and exhaling. This is the most efficient in treatment for broncho-pulmonary ailments.

Small particles [$\text{dia} \leq 1\mu\text{m}$] move in a disordered way colliding with the molecules. This is the Brownian movement. They remain in the terminal bronchioles and the cells but this method is not efficient as 80% of these particles remain in suspension and are rejected on exhalation.

The MMAD (Mass Median Aerodynamic Diameter) provides for granulometric quality in an aerosol. It is the dynamic diameter relating to the diameter of particles. The MMAD consists of smaller particles and the other half of larger particles.

Distribution from an aerosol



Duration

Duration depends according to the aerosol used.

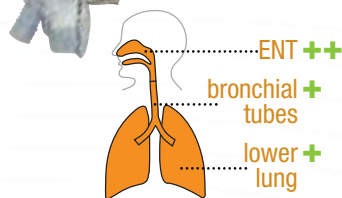
The duration of the session is calculated by dividing the aerosol's output speed by the aerosol's output speed. The time required for the initial solution may vary between 5 minutes and more.

atment

3 INTERFACES CHOICE



Mask



Indications :

Treatment of the «upper» respiratory pathologies (pharyngitis, laryngitis).

Advantages :

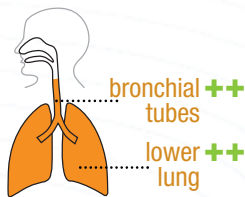
Multi-purpose and suitable for children.

Disadvantages :

Less effective for ENT treatments or lungs than a dedicated nasal or oral mask.



Mouth piece



Indications :

Treatment of the lower respiratory pathologies, asthma, cystic fibrosis, pneumocystosis).

Advantages :

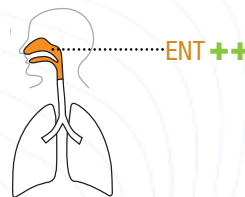
This is the most efficient piece for the treatment of the lungs area.

Disadvantages :

Not really suitable for children < 5 years of age for ENT treatment.



Nasal piece



Indications :

Treatment of ENT diseases (rhinitis, sinusitis, otitis).

Advantages :

This is the most efficient piece for the treatment of the ENT area.

Disadvantages :

Not really suitable for children < 5 years of age for treatment aimed at the lungs.

4 RESIDUAL OR DEAD VOLUME

At the end of the session when the unit produces no more aerosol some solution remains in the tubing, the walls and the base of the nebuliser. This medication, trapped in the unit and not inhaled, is known as dead or residual volume.

The dead volume is a constant property to each unit shown in the notice. It can vary in accordance with the model used between 0.6 ml and 2 ml.

It is accepted that in order to obtain a satisfactory percentage of inhaled medication, the initial volume to be nebulised must be equal to at least 4 times the dead volume. The dilution of the medication will therefore take into account the dead volume of the unit used.

Briefly : A nebulizer providing a lower dead volume will require a lower dilution and will allow to reduce session time.

	Medication volume PRIOR to dilution	Medication volume AFTER to dilution	Dead volume	Duration of the session
SMALL dilution volume			With a weak dilution medication waste will be greater because the quantity of the main ingredient in the dead volume is greater (more concentrated solution).	The session time will be shorter if the solution is weak.
LARGE dilution volume			With a stronger solution medication waste will be smaller because the quantity of the main ingredient in the dead volume is smaller (less concentrated solution).	The session time will be longer if the solution is strong.

Briefly : A good dilution is a compromise.

5 OPERATING NOISE

Often forgotten, this is quite a significant matter in carrying out treatment. Particularly with children and chronic patients a session of several minutes will be more easily tolerated and therefore more effective if the equipment does not make too much noise.

ST 23 & ST 24

(Pneumatic aerosol generator ST23)



ENT +
bronchial tubes ++
lower lungs ++

(Pneumatic aerosol generator with sonic effect ST24)



ENT ++
bronchial tubes ++
lower lungs ++

THE "PLUS" OF ST 23 AND ST 24

A rotary compressor

- No need for maintenance or checking as both output and pressure are stable.
- Powerful motor providing fast nebulisation.

Simple use and maintenance

- Device available with shulder bag (accessory).



SPECIFICS ST 24

Sonic effect

- Useful for sinus penetration of the medication particles (ENT treatments)



Without sonic effects

- Low particle deposition in the sinuses.



With sonic effect

- Good particle deposition in the sinuses.

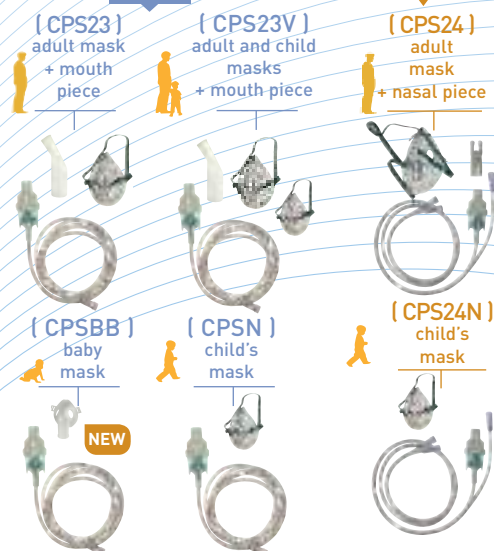


Electronically controlled sonic effect

- No action required effect from the patient
- Improves the comfort of the patient
- Makes for more effective treatment

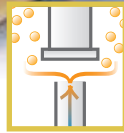
STANDARD SETS

SONIC SETS



RECOMMENDED NEBULISATION SETS

		Patients < 1 year of age	Patients from 1 to 10 years of age	Patients > 10 years of age
Treatment of the lower respiratory tracks	ST 23		CPSBB	CPSN or CPS23V with child mask
	ST 24			CPS23 with mouth piece or CPS23V with mouth piece
Treatment of upper respiratory tracks	ST 23		CPSBB	CPSN or CPS23V with child mask
	ST 24			CPS23 with mask or CPS23V with adult mask
			CPS24N	CPS24



PNEUMATIC TECHNOLOGY

Operating principles

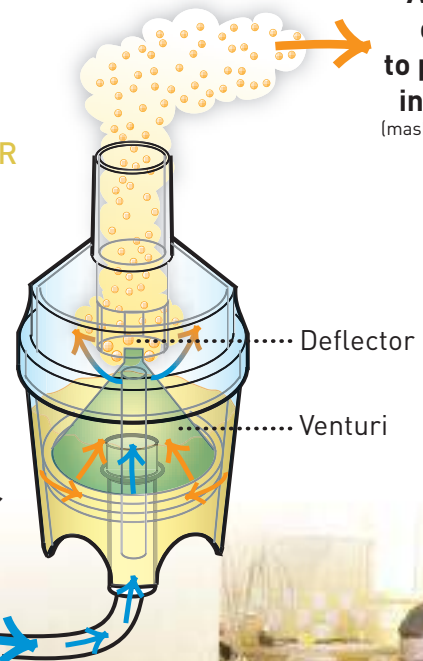
- Compressed air is pumped into the pneumatic unit to the nebuliser via a fine tube.
- Inside the nebuliser the compressed air causes a lowering of pressure and sets up a venturi effect which takes up the medication solution and projects it against the deflector (or impactor).
- The effect of this function is to produce micrometric particles which form the aerosol.
- The size of the obtained particles is proportional to the gas output.
- In hospitals the nebuliser is frequently connected directly to the medical air or oxygen socket on the wall.



NEBULISER

Aerosol outlet to patient's interface
(mask either mouth or nasal)

Compressed air supplied by the compressor



TECHNICAL CHARACTERISTICS

Motor characteristics

- Maximum pressure : 2 bars
- operating pressure : 0,8 bars
- Maximum output : 16l/min
- operating output : 8 l/min

Characteristics of the particles produced in accordance with norm NF-EN 13544-1 [NaF 1% - filled volume 4ml

- MMAD = 5,4µm (measured by Malvern® optical laser diffraction)
- MMAD = 3,9 µm (measured by cascade impaction)
- Output of produced aerosol liquid : 0,08ml/min
- Quantity of produced aerosol (inhalable volume) : 0,76ml
- Inhaled delivered fraction : 19%
- 58% of particles < 5 µm

Capacity

- Nebulisation capacity : 2 to 8 ml
- Dead/residual volume : ± 1ml

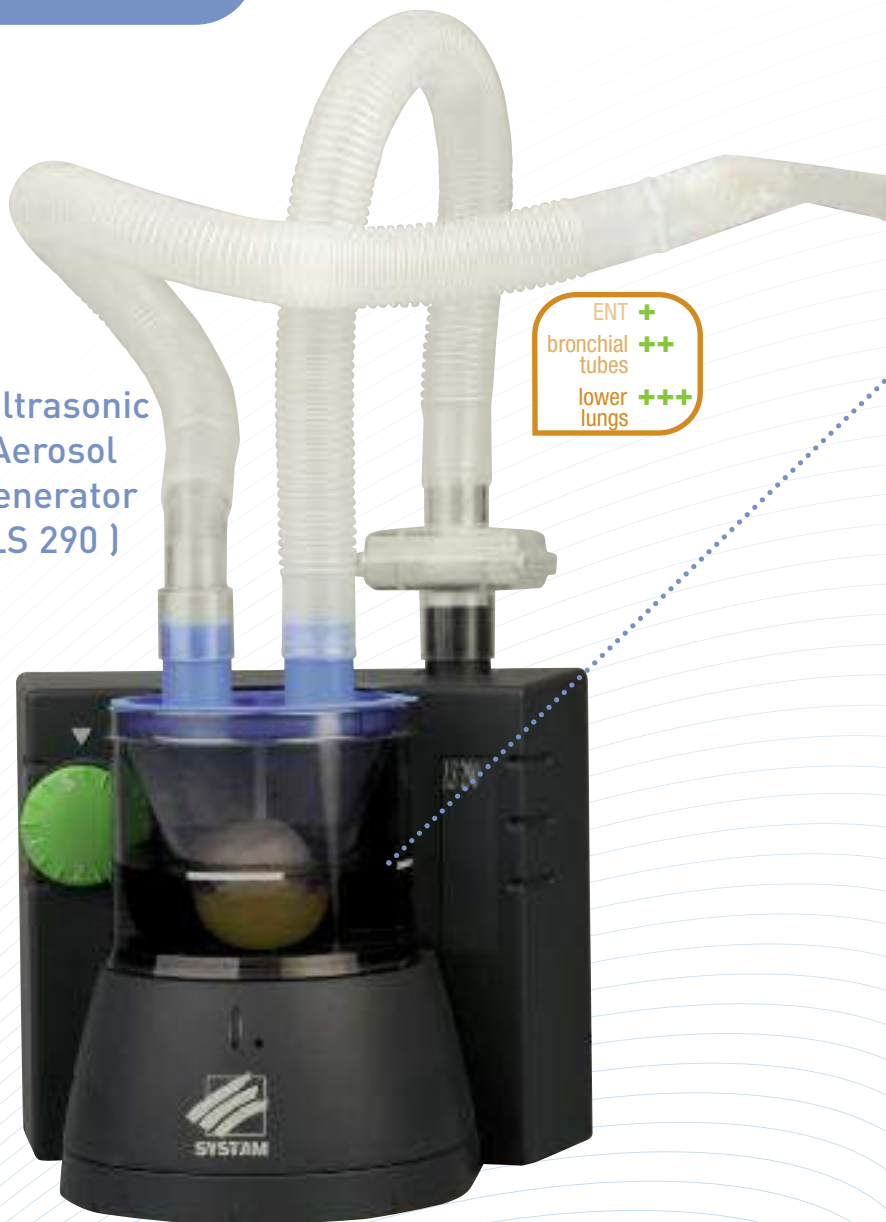
Other

- Dust filter
- Thermal cut-out (in accordance with electrical security norms and CEM NF EN 60601-1 and 60601-2)



LS 290

(Ultrasonic
Aerosol
Generator
LS 290)



ENT +
bronchial tubes ++
lower lungs +++

THE "PLUS" OF THE LS 290

The efficiency of ultrasonic technology

- Optimal sized particles : MMAD = 4.7 μm (measured by Malvern2 laser optical diffraction).
- Great homogeneity in the aerosol particles (71% of particles < 5 μm), for a greater portion of molecules of suitable size and therefore greater treatment efficiency.

Double container units

- The system of double container ultrasonic units avoids all risk of heating the molecules and the deterioration of the main ingredient (type RH Dnase fragile and thermolabile molecules).
- Possibility to nebulise suspensions such as budesonide.
- Closed inhaling circuit (no contact with the unit) = device suitable for multi-patients-use.
- Prevents wear of the quartz.

Particularly suitable for paediatric use

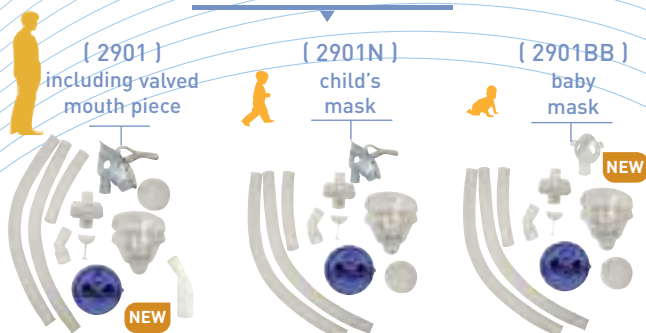
- Low noise
- Very short sessions



Devis available with shulder bag.



ULTRASONIC AEROSOLTHERAPY KITS



RECOMMENDED NEBULISATION SETS

Patients < 1 year of age	Patients from 1 to 10 years of age	Patients > 10 years of age
LS 290	2901BB	2901N
	2901	

PATENTED CONTROL'DOSE® SYSTEM : A SYST'AM® INNOVATION

- Reduces the dead volume thus limiting the dilution of the medication
- Shorter sessions
- Maximum proportion of inhaled medication

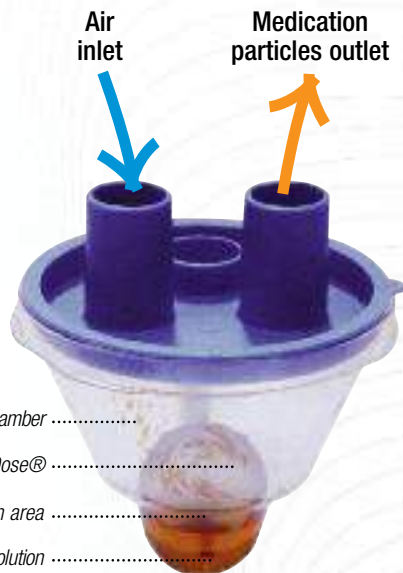


Controlled dosage...

- Permits the nebulisation of very small quantities of medication (from 2 to 8 ml) without dilution.
- Permits the nebulisation of a dose with a residual volume of 0.6 ml. The medicinal solution is contained in the volume created under the Control'Dose® and the medication particles are transmitted to the patient.

...Controlled time !

- Reduces the duration of the aerosol session.
- Reduces therefore the patient participation (particularly for children of young age).
- Therefore guarantees more effective treatment.



ULTRASONIC TECHNOLOGY

Principles of operation

- Under the influence of an oscillator the quartz located at the bottom of the container is subjected to very high frequency vibration which produces ultrasound (waves).
- These waves pass through the liquid right up to the surface of the solution generating a liquid film consisting of very fine droplets (cavitation principle).
- The size of the particles so produced is proportional to the length of the quartz wave (fixed for each unit) but the density of nebulisation (= the quantity of particles emitted or output) can be modulated by varying the amplitude of the quartz.

TECHNICAL CHARACTERISTICS

Generator characteristics

- Quartz frequency : 2,4 Mhz
- Ventilation for both active and passive patients

Characteristics of particles produced in accordance with

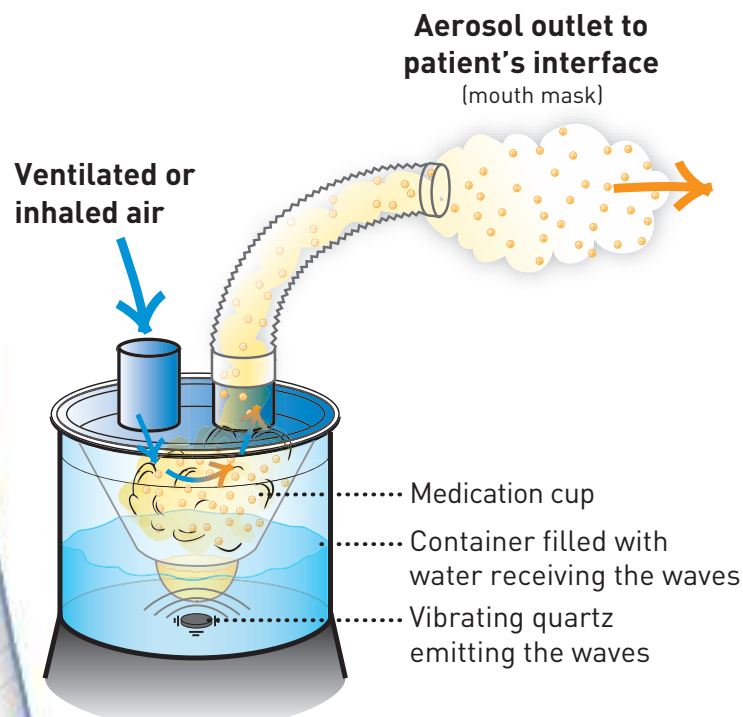
- norm NF-EN 13544-1 (NaF 1% - [Filled Volume 4ml])
- MMAD (measured by Malvern® laser optical diffraction) = 4,7 µm
- Aerosol liquid product output : 0,10 ml/min
- Produced aerosol quantity (inhalable volume) : 1,28 ml
- Delivered fraction (inhaled) : 32%
- 71% of particles < 5 µm

Capacity

- Nebulisation capacity : - 2 to 8 ml with Control'Dose®
- 8 to 39 ml without Control'Dose®
- Dead volume : ± 0,6 ml

Other

- In conformity with electrical security norms and CEM NF EN 60601-1 and 60601-2





The most frequently nebulised medication

Bronchodilators : they treat bronchial hyperactivity thus keeping the bronchia open (relaxed). With fast action their effect lasts several hours. Several studies show the benefit of the association of the β_2 mimetics (Salbutamol, Terbutaline) and the anticholinergics (ipratropium bromide) in the area of acute chronic asthma and bouts of COPD.

Antibiotics : Aerosols allow to deliver drugs directly on the targeted area. They provide relief directly to the affected area and thereby a sharp reduction in systemic toxicity.

Fluidisers : these are used to fluidise secretions and to avoid bronchial obstruction particularly sometimes in the area of COPD.

Anti-inflammatories : these are used to fight inflammation, particularly steroids are prescribed for the treatment of asthma.

Mucolytics : mainly in the area of cystic fibrosis, they provide quality changes in bronchial secretions (elasticity, rigidity and viscosity) and their quantity to improve mucociliary purifying.

Medication not recommended with nebulisers

Oily products should be avoided since they risk lipid pneumonia (pneumonia connected to the inhalation of non-soluble lipids in the organism). Thus the essential oils with full market approval for the administration of inhalation by fumigation should not be prescribed by nebuliser. As in the case of the nebuliser the whole product is nebulised (lipids + volatile elements) while with fumigation only the volatile element is inhaled by the patient.

However it is not advisable to nebulise hypotonic or hypertonic preparations. Therefore avoid those preparations as they have potentially dangerous additives (sulphites).

Medicinal Mixtures

Principle

Whichever kind of nebuliser used (pneumatic or ultrasonic) certain medications must not be used together to avoid the risk of :

- reduced granulometric quality,
- reduced efficiency,
- formation of precipitates.

The nebulisation of a mixture of incompatible medications can therefore result in :

- no aerosol at the jet of the nebuliser
- the production of wrongly sized particles unlikely to guarantee effective treatment.

When prescribing a mixture of two or more medications it is essential to check that the mixture prescribed is truly nebulisable.

If there is any doubt it is preferable to provide the medications one after the other rinsing the nebuliser after each use.

The main mixtures to avoid

As a general rule the following mixtures will be problematic (list not exhaustive)

- antibiotics + steroids
- antibiotics of the aminoglycoside group (framicetine, gentaline, nebcine, netromicine, amikacin, ...) + any other medication
- acetylcysteine + antibiotics
- acetylcysteine + steroids

Preparation of aerosol sessions

Start by washing the hands thoroughly.

Prepare the nebuliser in accordance with the user manual supplied (connection of the tubes, interface, etc...)

For the ultrasonic versions fill the water container up to the mark before positioning the medication cup (the medication must not come into contact with the quartz).

Pour the medicinal solution into the nebuliser container (or into the medication cup in the case of the ultrasonic version) scrupulously observing the prescribed quantity. If necessary dilute the medication in line with the prescription.

Do not mix different medications in the container or in the cup unless it is specifically stated in the prescription.

Any mixing must always be done with sterile equipment. Do not re-use an open ampoule for a different session.

Procedure for an aerosol therapy session

Adopt a comfortable seated position, back straight is such a way as to keep the windpipe as straight as possible in order to prevent impact.

The efficiency of an aerosol therapy session depends largely on the breathing rhythm of the patient. This is why breathing should be slow and deep with a pause of 5 – 10 seconds before exhaling in order to maximise the effect of the sedimentation in the airways.

Finishing the aerosol therapy session

Unless otherwise indicated the aerosol therapy session finishes when the aerosol ceases. There will always be some medication in the aerosol. This is normal. It is called "dead" or "residual" volume (see page 3 "aerosol therapy – what you should know").

Then the various parts must be cleaned (mask, nebuliser, tubing, cup, container ...etc) in warm water with a little detergent. NB : Take care to avoid friction to the quartz at the base of the container in the ultrasonic versions in order to avoid damage.

Rinse in plenty of water and meticulously dry all the parts with a clean cloth in order to avoid contamination or deterioration of the equipment.

Then disinfect the equipment with diluted bleach or any other disinfectant, then again meticulously dry it and store in a dry place.

Take care always to renew the water in the container of the ultrasonic version.

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