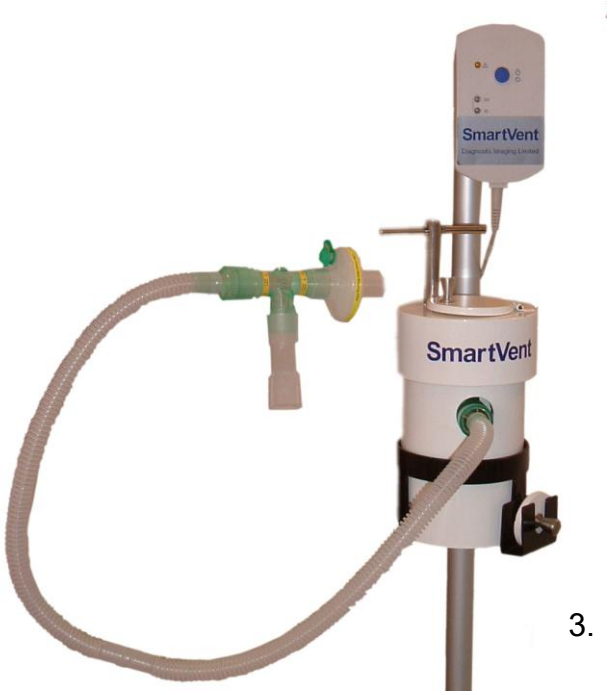
SmartVent™

Instructions for Use

Version 4 – (Dec 2009)



3.

1. SmartVent™ is a radioaerosol delivery system that has been developed to give unrivalled performance for lung ventilation scintigraphy. Consistent, excellent image quality is combined with low activity requirement and rapid uptake.

Please read the whole of this document before using SmartVent™

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INTRODUCTION

The SmartVent™ system is a portable medical device for multiple patient use that is intended to aerosolize DTPA to assist physicians in diagnosing certain lung diseases.

The control module operates from the AC/DC adaptor and can be operated on its internal rechargeable battery for up to 30 minutes. The product operates without compressed gas, making it suitable for portable applications.

Specifications

Physical

3.1.	Canister dimensions:	26 cm H x 12 cm Diameter
	Canister shielding:	3 mm lead
	Control module dimensions:	33 mm H x 75 mm W x 131 mm D
	AC/DC adapter cable:	2.1 m long.
5.	Canister weight (with generator):	5 kg
	Control module weight:	230 g, including battery and cable.
	Generator capacity:	maximum 10 ml

Environmental

Operating:

Temperature range:	10°C up to 45°C.
Atmospheric pressure:	450 to 1,100 hPa.
Humidity:	15 to 95% relative humidity.
Noise level:	35 dBA measured at 0.3 m distance.

Storage and transport:

Temperature range:	-20 to +60°C (-4 to +140°F).
Atmospheric pressure:	450 to 1,100 hPa.
Humidity:	15 to 95% relative humidity.

Performance

Flow rate:	0.2 to 0.6 mL/minute
Droplet size:	VMD = 1.32 µm with >91% of droplets <3 µm
Residual volume:	<0.3 ml

Power

Power source:	can operate from the supplied AC/DC adapter (input 100 to 240 VCA 50 – 60 Hz, output 9V) or internal rechargeable battery (4.8 V nominal output)
Power consumption:	< 6.6 Watts (charging), ≤ 2.0 Watts (operating)
Patient isolation:	control module circuitry provides 4 kilovolt patient isolation and complies with IEC 60601-1, UL2601-1 and AAMI ESI standards

WARNINGS

Read and study all instructions before using SmartVent™

To avoid damage to the generator, do not use a syringe with needle to add solution

Do not use de-ionised water to test or clean the generator

1. Only use Tc-99m DTPA solution for ventilation studies with SmartVent. Colloidal preparations must be avoided

Patient circuits are for single use only

Only qualified personnel should operate the device

Do not leave patients unattended during operation

Do not use in the presence of a flammable anesthetic mixture combined with air or with oxygen or nitrous oxide

Do not use to aerosolize alcohol-based medications, which can ignite in oxygen-enriched air under high pressure

To avoid the risk of fire, do not use in the presence of flammable substances

Staff administering the aerosol should wear protective gloves and coats at all times

The system should be assembled as described on page 7

To avoid mechanical or electrical damage, do not drop the canister, nebulizer unit or the control module

Do not use in the presence of devices generating high electromagnetic fields such as magnetic resonance imaging (MRI) equipment

Remove the generator from the canister before cleaning

Do not immerse or autoclave the control module or AC/DC adapter

Disassemble all parts before cleaning

Use only with components specified by Diagnostic Imaging Ltd. Inspect all parts before use, and do not use if any parts are missing, cracked or damaged. In case of missing parts, malfunction or damage, contact your Diagnostic Imaging Ltd. sales representative

Do not use or store outside of specified environmental conditions

The SmartVent™ control module contains a nickel metal hydride (NiMH) rechargeable battery, which should be disposed of in accordance with local governing restrictions at the end of its useful life

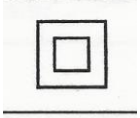
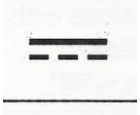
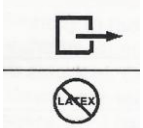
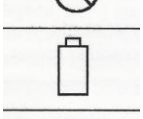
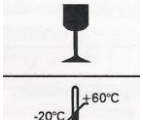
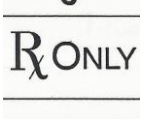
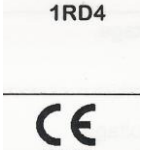
Do not use with any other AC/DC adapter as damage to the controller may result.

Electromagnetic susceptibility

This device meets the requirements of the Electromagnetic Compatibility (EMC), pursuant to the Collateral Standard, EN60601-1-2 (second edition), which addresses EMC in North America, Europe and other global communities. This includes immunity to radio frequency electric fields and electrostatic discharge, in addition to the other applicable requirements of the standard. Compliance with EMC standards does not mean a device has total immunity; certain devices (mobile phones, pagers, etc.) can interrupt operation if they are used near medical equipment. Follow institutional protocol regarding the use and location of devices that could interfere with medical equipment operation.

Note: This device is classified as Class II Type BF medical electrical equipment and the device complies with specified safety levels for electrical isolation and leakage current. The SmartVent™ AC/DC adapter has no connection to earth ground because the necessary level of protection is achieved through the use of double insulation.

SYMBOLS

	Attention, consult accompanying documents.
	Degree of protection against dripping water
	Class II equipment per IEC60601-1
	Class BF equipment per IEC60601-1
	On/Off power button (standby)
	Timer selection (to select the 15 minute or 30 minute nebulization time).
	Control Module Input – DC voltage
	Control Module Output – AC voltage
	Output
	Components are latex free
	Battery status indicator
	Fragile, handle with care
	Storage temperature limitations -20°C to +60°C
	Keep dry
	Federal (US) law restricts this device to sale by or on order of a physician
	Classified by Underwriters Laboratories Inc. with respect to electric shock, fire and mechanical hazards only in accordance with UL 2601-1 (1RD4) and with respect to electric shock, fore, mechanical and other specified hazards only in accordance with CAN/CSA C22.2 No 601.1, Medical equipment certified for Canada (1RD4).
	This device complies with the requirements of the Medical Devices Directive (93/42/EEC).

PROCEDURE

- Ensure that the controller battery has sufficient charge to complete the procedure, typically 1min – 1min 30 Secs. An overnight charge will allow more than thirty minutes of aerosol generation. If the controller green indicator light begins to flash during the procedure connect the charger to the controller. The system can be used and the internal battery charged at the same time.

- Load the generator chamber with approx. 600 MBq of ^{99m}TC DTPA in 0.7 – 0.8 mL per patient. The system can be loaded with this dose as each patient arrives or, can be loaded with sufficient DTPA to administer the aerosol to the number of patients expected. i.e. if 4 patients are expected then approx. 2,400 MBq in 3 mL. The generator chamber will hold 10 mL.
  Note: this activity level may be reduced or increased depending on local requirements.

- Remove the output port shield and store on the tray attached to the cradle. Connect a patient circuit to the output tube projecting through the output port. Align patient circuit with patient before connecting to avoid any kinks in the circuit. Patient may be erect or supine.

- Explain the procedure to the patient. Position the patient so that the patient circuit tubing is as straight as possible and insert the mouthpiece in the patient's mouth.

- Instruct the patient to breathe through mouthpiece as if 'sucking and blowing through a straw'. Ensure a good seal between patient's lips and mouthpiece. Apply a nose clip. If the patient has a problem with the mouthpiece and nose clip then a facemask may be used instead.

- When patient is breathing comfortably through the system, press controller blue start/stop button once. Aerosol will be seen entering the patient circuit.

- When sufficient aerosol is administered, press controller blue start/stop button once, and ask the patient to continue breathing through the mouthpiece/facemask for a few more seconds to clear the patient circuit.

- Remove nose clip, if used, and patient circuit from patient and commence imaging as soon as possible.

- Remove the used patient circuit from the canister and leave in a suitable shielded container to decay before disposal. Replace the output port shield onto the output tube.

- When the last patient of the session has been completed, ensure that the output port shield is plugged onto the output tube. Press the controller blue start/stop button and leave running to ensure the contents of the generator are "boiled off". When the controller has finished this cycle disconnect the canister cable from the controller and move the canister, with cable, to a safe place to allow the contents to decay.

- When suitably decayed the canister contents can be cleaned as described on page 9.

- For QA testing check the function of the generator by performing the following procedure on a monthly basis:

  Connect the Generator to the controller cable without using a Generator Connector and position so that the Generator is horizontal. Load the Generator with 1mL of saline (or clean tap water) ensuring the fluid is over the aperture plate. Start the Controller and stop when the Generator has run to dryness. Make a note of the time taken in seconds. Apply the formula (1/seconds)*60 to give the flow rate. (i.e. 2min 40 secs = 160 secs:=(1/160)*60 = 0.375 mL per minute. The flow rate should be between 0.2 and 0.6 mL/min. If not contact Diagnostic Imaging Ltd.

SmartVent™

Assembly Instructions

The system comprises:

Generator	Multiple Use
Generator Filler Cap	Multiple Use
Generator Connector	Single Session (per day)
Canister (pot)	Multiple Use
Controller	Multiple Use
Controller Charger	Multiple Use
Cradle	Multiple Use
Shield	Multiple Use
Steam Cleaner	Multiple Use
Patient Circuits	Single Use (per patient)

1

Connect a clean generator, with filler cap, to the cable connector inside the canister. The connector can be connected any way round.

2

With generator connected to the cable and hanging over side of canister, insert generator connector into the retaining tube at bottom of canister ensuring output tube is facing output port.

3

When generator connector is in place position vertically and align output tube with output port by holding in place with finger.

4

Connect generator to generator connector inside canister keeping output tube protruding through output port using finger.

5

Attach canister lid. Align centre of generator with centre of loading port and keep output tube protruding through output port using finger.

6

Tighten lid down (do not over tighten) with T bar handle, ensure the T bar handle does not prevent the loading port cover opening or closing. Open generator filler cap.

7

Connect generator cable to controller. Press blue button to check connection (no yellow fault light) then press blue button again to switch off controller.

8

Fix output tube shield, load isotope through loading port using a SYRINGE WITH NO NEEDLE. Hold syringe vertically and press plunger slowly. Close loading port cover. System is now ready for use.

SmartVent™
Controls and indicators

Power On/Off

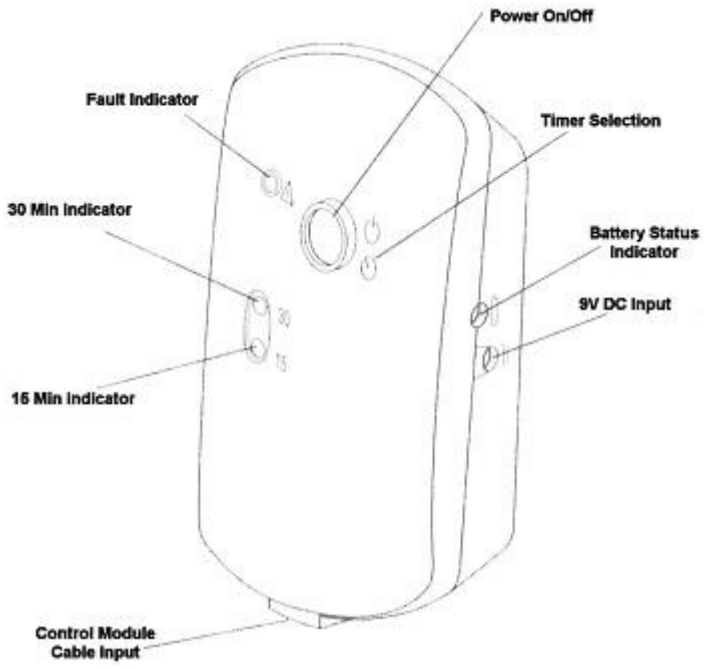
- Pressing and immediately releasing selects the 15 minute nebulization cycle
- Pressing and holding more than 3 seconds selects the 30 minute nebulization cycle
- Press during nebulization turns off power to the nebulizer

4.2. **15 Min indicator**

- Green (steadily lit) = 15 minute nebulization cycle
- Green (flashing) = Low battery power
- Nebulizer automatically powers off after 15 minutes have elapsed

4.2. **30 Min indicator**

- Green (steadily lit) = 30 minute nebulization cycle
- Green (flashing) = Low battery power
- Nebulizer automatically powers off after 30 minutes have elapsed



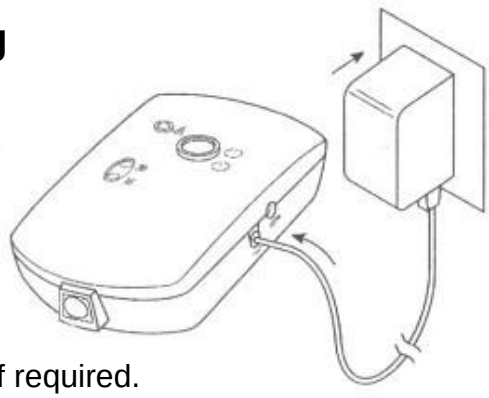
4.3. **Battery status indicator**

- Green = Battery fully charged
- Amber = Battery charging
- No light = Battery in operation

4.1. **Fault indicator**

- Prior to loading Tc-DTPA, press the ON/OFF button to test the circuit. If the fault indicator light comes on (amber), check all connections and test again. If the fault still exists contact Diagnostic Imaging Ltd

Battery Charging



To recharge the battery, connect the AC/DC adapter to the control module and AC power (see figure). The battery status indicator is amber while charging and green when fully charged. For the first charging allow a minimum of four hours for the internal battery to fully charge. The battery should be recharged every night during normal use.
The system can be used and charged at the same time if required.
The batteries last typically 2-3 years before needing replacing. If the Controller battery does not keep its charge after charging contact Diagnostic Imaging Ltd.

Note: If the control module is placed in long-term storage, it is recommended that the battery be recharged every 3 months.

SmartVent™
Cleaning Procedures

1. Single use circuit:

After each patient, disconnect and leave to decay in a suitable shielded waste container. Dispose of when decayed.

2. Generator Connector:

This is classified as a 'Single Session' component.

At the end of each session with SmartVent™, allow 36-72 hours for the contents of the canister to decay before removing the components from the canister. Disconnect the Generator Connector from the Generator and discard. The Generator can now be cleaned.

Decay table for 500GBq of ^{99m}Tc

After 6 hours	250 MBq
After 12 hours	125 MBq
After 18 hours	63 MBq
After 24 hours	32 MBq
After 30 hours	16 MBq
After 36 hours	8 MBq
After 42 hours	4 MBq

e.g. if 500 MBq of ^{99m}Tc is left in the canister at 4pm on Monday, by Wednesday morning there will be 4 MBq left.

3. Aerosol Generator

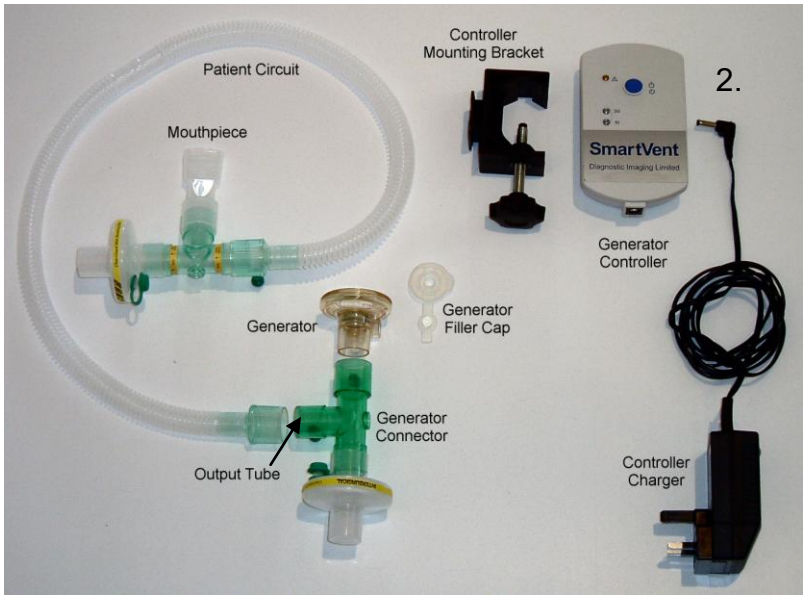
The generator does not come into contact with the patient and is classified as low risk of contamination. Therefore, cleaning is all that is required. Instructions for SmartVent™ Aerosol Generator cleaning are provided separately.

4. Control module, cable and AC/DC adaptor

Wipe clean with a damp cloth.

SmartVent™
Component Identification

2.



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