Ultravent™
Radioaerosol Delivery System

For Single Patient Use

Caution:

Rx ONLY Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

Ventilation Kit and Shield Instructions For Use

Warning:

Single use This ventilation kit is FOR SINGLE PATIENT USE ONLY. Reuse can cause cross-infection. After using this ventilation kit once, it should be disposed of using appropriate techniques for the disposal of biohazardous materials.

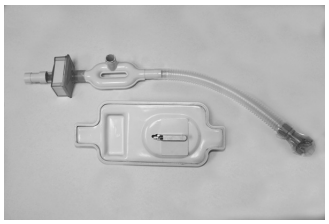
PHT DEHP This product contains DEHP. The intended use limits exposure to transient contact, minimizing the risk of DEHP release from the device. In order to avoid undue risk of DEHP exposure in children and nursing or pregnant women, product should only be used as directed.

Assembly Instructions:

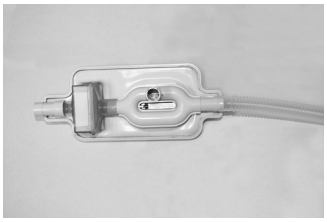
1. Remove the Ultravent Ventilation Kit from its packaging. Components include:

   a. Radioaerosol generator
   b. Manifold fitted with aerosol trap (bacterial filter)
   c. Plastic tubing
   d. Noseclip
   e. Air/O_2 Interconnector
   f. Mouthpiece
   g. Plastic disposal bag

2. Secure plastic tubing/mouthpiece assembly to the end of the manifold **opposite** the aerosol trap.



3. Open the Ultravent Shield (Catalog No. N685A0) by rotating the handles down and lifting the cover. Remove the inner lid (with handle).



4. Attach the manifold/trap assembly to the retaining mechanism on the bottom side of the inner lid. Rotate the black locking knob on the release lever on the upper side of the lid.

   • Confirm that the assembly is firmly attached.

5. Firmly attach the cut-end of the Air/O_2 Interconnector to the air/oxygen inlet nozzle at the base of the radioaerosol generator.

6. Attach the other end of the Air/O_2 Interconnector to the oxygen supply. Note: Compressed air may also be used with the Ultravent.

   • Check oxygen source and tubing for obstructions, leaks and secure connections.

7. Place the radioaerosol generator, with Air/O_2 Interconnector attached, into the well in the base of the shield. Align the generator's air/oxygen inlet nozzle with the corresponding slot in the plastic base, and press the generator down until it seats snugly in the base.

   • Assure that the generator is level.

8. Route the Air/O_2 Interconnector tubing out the patient end of the shield by means of the channel provided. Secure the tubing by pushing it into the narrow channel at the patient end of the shield.

   • Confirm that the tubing will not crimp, nor impede the reinstallation of the inner lid and manifold.

9. Check for proper oxygen flow by **slowly** turning on the oxygen to a flow rate of 9 to 12 liters/minute. Place hand over the top of the radioaerosol generator to ensure a steady oxygen flow.

   Note: If a water bottle or humidifier is attached to the oxygen source, it must be detached for system to operate properly.

10. Turn off oxygen.

11. Prepare the Tc 99m DTPA according to manufacturer's instructions. **See Radioaerosol Administration Protocol for concentration to be used.**

12. Using a shielded syringe inject a minimum of 2 mL Tc 99m DTPA solution into the radioaerosol generator through the top opening.

13. Immediately reinstall the inner lid such that the manifold assembly engages the radioaerosol generator and the tubing mouthpiece assembly exits from the patient end of the shield. Press the inner lid down **firmly** until the manifold/radioaerosol generator locking engagement is heard and felt.

   Note: Once the radioaerosol generator is locked to the manifold they cannot be separated.

14. Close the cover and rotate the handle opposite the patient to the locked position.

Radioaerosol Administration Protocol:

Oxygen flow rate, radioactivity concentration, and radioaerosol inhalation period may be varied to accommodate the protocol desired.

Increasing oxygen flow rate, concentration of radioactivity, and/or radioaerosol inhalation time will increase deposition of radioactivity in the lung allowing faster imaging, efficient collection of more counts per image, and use of the system for post-perfusion or SPECT studies.

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SUGGESTED PROTOCOLS:

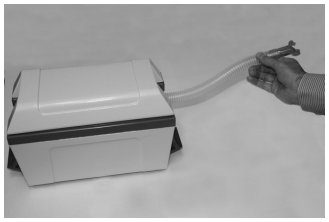
Pre-perfusion:

1. Oxygen flow rate – 10 to 12 liters/minute.
2. Volume of solution added to radioaerosol generator – 2 to 3 mL.
3. Technetium-99m concentration of solution added to radioaerosol generator – 15 to 20 mCi/mL.
4. Radioaerosol inhalation, period – 3 to 5 minutes.

Post-perfusion:

1. Use Tc 99m MAA dose of 1 or 2 mCi for perfusion study.
2. Post-perfusion ventilation.
   a. Oxygen flow rate – 11 to 12 liters/minute.
   b. Volume of solution added to radioaerosol generator – 2 to 3 mL.
   c. Technetium-99m concentration of solution added to radioaerosol generator – 25 to 30 mCi/mL.
   d. Radioaerosol inhalation period – 4 to 10 minutes.

Operating Instructions:



1. Place the mouthpiece in the patient's mouth, making sure the tongue is under the mouthpiece and not occluding the opening.
2. Apply the noseclip.
3. Instruct the patient to take five or six test breaths (normal tidal breathing) from the system before the oxygen is turned on. This assures that oxygen flow is unimpeded and the patient is familiar with the breathing techniques.
4. Gradually turn on oxygen [taking 2 to 4 seconds (max.) to attain a flow rate of 9 liters/minute]. Then adjust flow rate to desired setting.

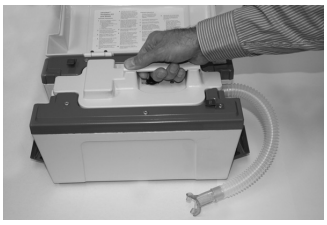
   Caution: Abruptly turning the flow rate to final setting may detach tubing from radioaerosol generator.
5. Instruct the patient to breathe normally through the system until the desired amount of radioactivity is delivered to the lungs. No holding of breath is necessary.

   Caution: In order to reduce the risk of radiation leakage into the environment, ensure that the mouthpiece is held securely in the patient's mouth before initiating airflow. **Be prepared throughout the inhalation period to shut off oxygen flow immediately if the patient releases the mouthpiece.**
6. After inhalation, turn off the oxygen and instruct the patient to continue breathing through the mouthpiece taking five tidal breaths before coming off the system.
7. Remove the noseclip.
8. Imaging may be performed immediately, or the patient may be moved to another location for imaging.

   Note: A large field-of-view gamma camera with a low-energy, all-purpose collimator is recommended.

DISPOSAL INSTRUCTIONS:

Caution: The ventilation kit should be disposed of using standard techniques for the disposal of biohazardous and radioactive materials.



1. To remove the Ultravent device, lower handles, open cover.
2. Disconnect Air/O_2 Interconnector from oxygen supply fitting.
3. Lift the inner lid straight up, removing the entire radioaerosol generator/manifold assembly from the shield, making sure to pull the oxygen supply tubing out of its retaining channel.
4. To remove the radioaerosol generator/manifold assembly from the inner lid, position the unit over a shielded disposal container, and rotate the locking knob to the open position. Push the release latch forward while tilting the lid upward.

   Note: The unit should drop off easily into the shielded disposal container.
5. Alternatively, the contaminated unit may be stored in the shield until it can be appropriately disposed of.

   a. At the conclusion of the procedure, lower the shield handles, open the cover and wrap the used oxygen tubing around the inner lid handle. Disconnect the mouthpiece tubing assembly and attach it to the inside of the shield using the clips provided.

   b. Close the cover and rotate both handles to their locked position for storage of the unit until disposal.

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CURIUM™

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