Xenotron™ I Xenon (Xe 133) Gas Dispenser

For Use with Xenon Xe 133 Gas In Curium Unit Dose Vials

CAUTION

To provide adequate radiation protection, use Catalog No. 048 Xe 133 Vial Shield when transferring Xenon Xe 133 gas.

Prior to each use of the Xenotron, perform the following Pre-Use Inspection.

- 1. Bulb Valve Check (closed position): Remove bulb from the handle luer port of the Xenotron I Xenon Xe 133 Gas Dispenser by turning counterclockwise. Squeeze bulb until the sides touch then place finger over bottom opening and release squeeze. Bulb should refill with air through valve on top of bulb.
- 2. Bulb Valve Check (open position): With finger still over bottom opening, squeeze bulb. A small amount of air will exit from top opening before valve will shut. Air should no longer escape from valve and there should be resistance to the squeeze.
- 3. Needle Patency Check (side luer port): Securely install the bulb onto the Xenotron side luer port by engaging and turning clockwise. Squeeze bulb 3-5 times. It should easily squeeze and refill with air when on the side luer port. This is an indicator of acceptable needle flow and patency.
- 4. Needle Patency Check (handle luer port): Remove bulb and securely install on handle luer port by engaging and turning clockwise. Squeeze bulb 3-5 times. It should easily squeeze and refill with air when on the handle luer port. This is an indicator of acceptable needle flow and patency.
- 5. Vial Shield Inspection: Remove vial shield from Xenotron. Verify that the vial shield cavity is free of debris. Remove debris if applicable.
- 6. Needle Inspection: Visually confirm that the needle is clear of debris, is straight and not bent. Remove debris if applicable.
- 7. Latch Inspection: With empty vial shield inserted, verify latch opens and closes freely.

NOTE: If the results of the above Pre-Use Inspection steps are not able to be rectified by the user, contact Curium for further instructions.

Directions For Use

- 1. Remove Xe 133 gas unit dose vial from shipping shield and assay in dose calibrator.
- 2. Attach stopcock end of Catalog No. 047 Xenotron I Stopcock and Interconnector Assembly to Xenotron I side luer port. Close stopcock.
- 3. Remove vial shield from Xenotron I Xenon (Xe 133) Gas Dispenser, resting on flat surface, by pulling out latch all the way and lifting dispenser straight
- 4. Place Xenon gas vial into vial shield with septum up.
- 5. Lower dispenser straight down onto vial shield until it rests on vial shield.
- 6. Close latch by pushing into dispenser

NOTE: Latch handle must be pushed all the way into the dispenser body.

- 7. Connect end of Interconnector Assembly to Xenon gas delivery system (spirometer or other breathing device). Do not over tighten. If entry to delivery system is made by hypodermic needle, use 18 gauge or larger needle.
- 8. Open stopcock fully and with hand wrapped around handle, immediately squeeze the rubber bulb quickly and completely into the handle with all four fingers and hold for three seconds. Maintain compression of the bulb and close stopcock prior to releasing compression.
- 9. Disconnect dispenser and place back on flat surface.
- 10. Pull out latch and lift the dispenser straight up to remove the vial shield.
- 11. Remove exhausted vial from the Xenotron needle and discard in compliance with established requirements for disposal of radioactive waste.
- 12. Lower dispenser straight down onto vial shield. Close latch until flush with dispenser.

Manufactured for: Curium US LLC Maryland Heights, MO 63043 USA

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Xenon (Xe 133) **Gas Dispenser** 046

Xenotron™ I

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Symbol Glossary

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Symbol	Symbol Title	Definition	Standard Title/Reference Number
SN	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices – Symbols to be used with medical device labels – General requirements (Reference Number of Symbol: 5.1.7).
REF	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices – Symbols to be used with medical device labels – General requirements (Reference