



INHALATION ANESTHESIA SYSTEMS

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Remanufactured Isoflurane Vaporizers

There is a difference and it is not just the price.

Don't be misled concerning Isoflurane vaporizers. Some companies are "converting" or "remanufacturing" old inexpensive Enflurane (Ethrane®) vaporizers, then reselling them as freshly serviced Isoflurane vaporizers. However, it is important for you to know there are profound differences between genuine Isoflurane vaporizers and these Enflurane imposters.

Independent Evaluation

Working with Ohmeda, the original manufacturer of these vaporizers and another independent vaporizer service center, it has been determined that some of these "remanufactured" or "converted" vaporizers are still comprised primarily of Enflurane components. Based on the evidence Ohmeda presented, there are added risks to your anesthetic procedure using these counterfeit vaporizers. We cannot quantify these risks to your patients. However, an excerpt from a previous Ohmeda report on one of these "remanufactured" vaporizers states,

"The results of the calibration tests...clearly show that the vaporizer neither performs correctly as in Isoflurane or Enflurane vaporizer having failed both 5 LPM room air tests. In fact, as an Isoflurane vaporizer the readings taken at the 5% dial setting are marginally reportable to the FDA as an MDR (Medical Device Report), if used in the human market."

Documented Problems

- The output percentage concentrations of Isoflurane using these vaporizers can be high to specification. Some delivered concentrations in excess of 10%.
- None of the "converted" or "remanufactured" vaporizers inspected were serviced to manufacturers' specifications for any anesthetic agent.
- No manufacturer authorized service center will service these vaporizers.

The only three options available to the owners of these "remanufactured" vaporizers are:



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1. Truly convert the vaporizer to Isoflurane by replacing all the Enflurane components.
2. Remove the Isoflurane labels, install Enflurane labels and service the vaporizer as Enflurane.
3. Return the vaporizer unserviced with a warning sticker that reads: "Dangerous - Do Not Use".

Always ask:

"Am I getting a vaporizer that was originally manufactured for use with Isoflurane?"

"Can proof of this be documented?"

Indicators

If you doubt the status of your vaporizer, here are some things to look for:

- If the number scale on the dial goes past 5%, or if the dial itself can be turned past 5% after depressing the dial stop button a second time, you may have an Enflurane vaporizer.
- On the Ohio 100 series vaporizer, if the nomenclature "% Forane ® (Isoflurane) / volume of mixture" is missing on the dial label, you may have an Enflurane vaporizer.
- If the word "remanufactured" or "converted" is present on any label of the vaporizer, you may have an Enflurane vaporizer.

The only way to know for certain if you have a "remanufactured" vaporizer is to send it to an independent service center for evaluation. We are happy to help you get your vaporizer evaluated and have genuine Isoflurane loaner vaporizers available for you.

We believe it is important that you have full disclosure of the facts.

For additional information, please contact us.

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