

12 August 2003

Dear Customer

### **The use of substitute components with Fisher & Paykel Healthcare Humidification Systems**

Fisher & Paykel Healthcare, design, manufacture and distribute heated humidification systems for patients undergoing ventilatory, pressure or supplemental oxygen support. Fisher & Paykel Healthcare humidification systems are comprised of three main components, an electronic controller, a humidification chamber and a breathing circuit.

Fisher & Paykel Healthcare humidification systems incorporate a sophisticated electronic controller that makes specific assumptions about other components of the system. This requires the other components of the system to have very specific and exacting characteristics for optimal performance, safety and functionality.

Because of these very specific component requirements, Fisher & Paykel Healthcare electronic controllers and their supporting documentation contain warnings that clearly state that the use of other than Fisher & Paykel Healthcare components may impair performance or compromise safety.

Particular issues regarding certain substitute components that may affect patient safety and Fisher & Paykel Healthcare humidification system performance include:

- 1) Safety
  - (a) Absence of a secondary backup float and valve assembly in auto feed chambers
  - (b) Absence of a self closing clamp on water feed sets for manual feed chambers
  - (c) Potential thermal hazards
  - (d) Alarm accuracy
  
- 2) Performance
  - (a) Temperature sensing accuracy
  - (b) Flow measurement accuracy
  - (c) Humidity delivery requirements as per ISO 8185 humidifier standard

Fisher & Paykel Healthcare ensure that its own humidification systems meet precise internal and international standards and comply with regulatory requirements of individual countries. This is achieved by subjecting the entire system rather than individual components to these standards and requirements.

For these reasons we advise that only Fisher & Paykel Healthcare components should be used in conjunction with Fisher & Paykel Healthcare humidifier controllers.

If safety and performance issues occur as a result of the use of substitute components Fisher & Paykel Healthcare will be obliged to disclaim all liability.

Yours sincerely



Brigid Glass  
Quality & Regulatory Affairs Manager