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After inspection and safety testing of the Capnograph, model VM-2500-S, together with the associated Nomo adapter accessory we declare that:

When used in combination with the disposable PE-sampling line and under consideration that the Nomo Adapter may be reused, then the risk of cross infection can be considered negligible.

Rationale:

The operation of the VM-2500-S is based on the active suction of patients' breath gas samples into the monitor, so the positive direction of any potential infectious samples is towards the monitor and contained within the Nomo line's integrated filter. If the disposable PE-sampling line including the airway adapter is removed between each patient, the risk of cross contamination between patients is very low. In addition the Nomo adapter is manufactured with a female Luer lock connector, the design of which does not have any exposed internal surfaces. Additionally the sampling line cannot be by-passed, since the Nomo adapter cannot be connected directly to the patient airway adapter due to the connector on the airway adapter also being a female Luer lock.

Restrictions:

This statement is valid only if the user operates the VM-2500-S in accordance with the operating instructions and attaches a new PE-sampling line when monitoring the next patient. The product labelling requests the operator to read the instructions for use. Cross contamination safety is not assured if the disposable 200 cm PE-sampling line is not used. Other microbiological issues (other than mentioned here) are not affected.

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