

Bazara, Michael G.

From: Bazara, Michael G.
Sent: Monday, June 25, 2001 12:47 PM
To: 'AlexSMCCC@aol.com'
Subject: RE: Cuff Deflation Data

Mr. Stenzler:

We have the following requests with respect to your PMA submission P890057s14, and will send a copy of these requests to the panel as part of the FDA review. We would be happy to receive your response to these requests as an amendment to S14, and to include your response in our mailing to the panel anticipated for approximately July 2, 2001.

1) As we have discussed previously, deflation of the tracheal tube cuff is part of your HFOV treatment strategy if the PCO₂ is high (Page 39 of the panel mailing; page 13 of amendment 4 of s14). Because your ventilator maintains a continuous positive pressure, cuff deflation will be a form of tracheal gas insufflation and will reduce the system deadspace. Please describe how this strategy was used in the clinical trial.

2) Please describe the training program that will be provided by Sensormedics when an institution purchases your 3100B ventilator.

Please let us know if you intend to provide a response that can be sent to the panel. As you know, the information that is sent to the panel will be made public by the FDA, except for the material that is redacted for specific reasons. Material to be sent to the panel must be received by July 2. Because of the brief time that is allotted, we will accept the information for the panel as an e-mail, if your e-mail contains the statement that a copy will be sent to the FDA document mail center as an amendment to this supplement.

Thanks,

Michael Bazara