

From: [Bob Marsh](#)

Sent: Mon, 23 Apr 2018 08:02:19

To:

Cc:

Subject: FW: PAFS Deterioration - Philips RI

Sensitivity: High

Lee,

You have tried to help us with this before (around August of 2016), and it is back again. The customer is finding degradation of the ester foam and the urethane film in their device, such that particles are breaking off and flowing in the airstream. The customer states (below) what the composite is exposed to. I suspect the temperature is above ambient because of the blower, but I don't think it can be too high since the air goes to a patient's airway (CPAP machine).

We did not receive any feedback from the samples we sent last time, so we do not know if switching to an ether foam would help.

Any thoughts? Does exposure to pure oxygen accelerate ester degradation? Would it do the same for ether? Or for that matter, the urethane film?

Thanks,
BobM

From: Testa, Vincent

Sent: Friday, April 20, 2018 3:06 PM

To: Bonnie Peterson <bonnie@polytechinc.com>

Subject: PAFS Deterioration

Importance: High

Hello Bonnie,

Over the past few years you've helped me with technical questions regarding your foam. Now I have an issue that I'm hoping you can help me resolve. We use the PAFS foam in the air path of our Trilogy family of ventilators as a means for noise reduction (drawings attached). Recently we've received a few complaints from our customers that the foam is disintegrating (images attached, these are separate parts). To me it appears as if the open cell foam is disintegrating. The material sheds and is pulled into the ventilator air path. As you can imagine, this is not a good situation for our users.

I'm wondering what could cause this material to break down. The specification sheet says it has excellent resistance to heat, moisture and chemicals. We do not recommend or specify any means to clean or disinfect this foam. In fact, our device is designed such that these components can be replaced by the customer. Other than room air the only other elements this foam is exposed to normally are isopropyl alcohol and pure oxygen.

- Isopropyl alcohol – To ease the insertion of the 1044528 into the 1035281 assembly, the vertical walls of the plastic are swiped with alcohol to keep the L4 adhesive from sticking. This is done at our supplier. Note, no alcohol is used in the presence of the 1044529 foam, and these two pieces of foam do not come into contact with each other until final assembly at our facility (well long after the alcohol would have evaporated).
- Oxygen – Pure oxygen can be ported into the device. It comes into direct contact with both pieces of foam.

Any guidance would be appreciated. We should be able to provide samples if desired. I flagged this message with high importance since we are addressing a potential safety concern.

Thank you,

Vince Testa
Project Mechanical Engineer
Philips Home Healthcare Solutions
1740 Golden Mile Hwy
Monroeville, PA 15146

**EXHIBIT
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WTB 000054

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