

Making the Connection – Benefits of Hybernite Heated Tubing for CPAP Therapy

When heated humidification alone did not do the job, survey respondents verified what Plastiflex engineers suspected: heated tubes provide added comfort.

Many clinicians and sleep lab directors agree that heated tubes enhance the benefit of heated humidification. Do patients feel the same way?

Rik Langerock, vice president of Sales and Marketing for Plastiflex Healthcare, sought to answer this question with detailed post-market surveillance data. He and officials at Plastiflex decided to test the Belgium-based company's Hybernite Rainout Control (ROC) System, which includes the proprietary Heated Breathing Tube (HBT) and Power Supply Unit (PSU), on 34 CPAP users.

Survey organizers drafted a questionnaire filled with responses that ranged from 1 to 4 (see graphs) to correspond with various criteria. The all-adult group had been using heated humidification, but not all had necessarily experienced rainout. "Our belief is that every patient who has a heated humidifier ought to have the benefit of a heated tube," emphasizes Langerock.

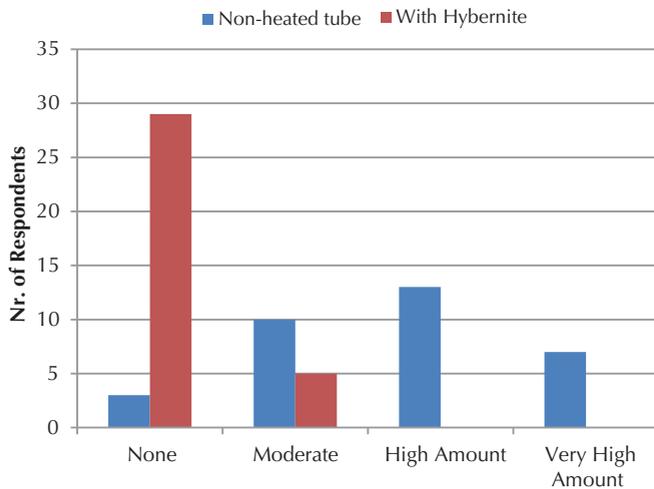


Fig. 1. Condensation in the Tube

Prior to using Hybernite, 31 of 34 respondents (see Fig. 1.) reported moderate to very high condensation. After Hybernite heated tubes were installed, Langerock largely got the results he expected, with a whopping 29 reporting all condensation gone, and five ratcheting it down to moderate. No one reported high or very high amounts after Hybernite installation.

"Those moderate patients were probably having huge amounts of condensation before," adds Langerock. "Did we solve the problem? Absolutely. Did we solve it for all patients at all conditions? Not necessarily, because conditions such as humidifier settings and ambient conditions can vary."

Condensation in the mask is also significantly reduced by using the Hybernite Heated Hose (See Fig. 2.). Since the temperature of the air arriving at the mask is warmer, there

is less chance for condensation. Condensation in the mask is also caused by the air exhaled by the patient. This air is fully saturated –100% humidified – so condensation is more likely to happen.

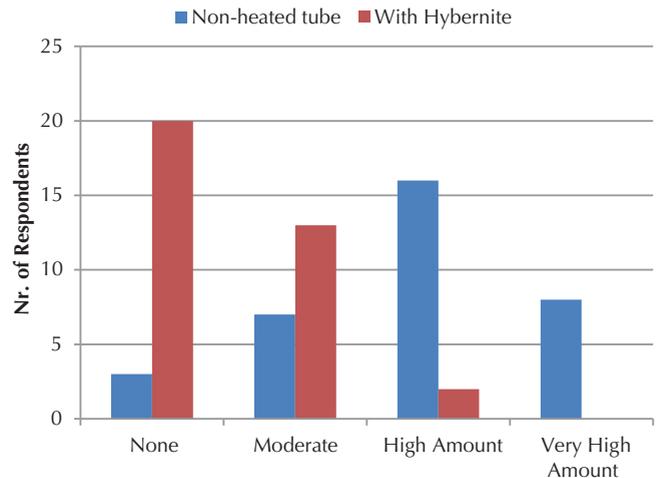


Fig. 2. Condensation in the Mask

Cold Comfort

CPAP machines blow at fairly high air speeds, and Langerock wanted to gauge the perception of cold air with a standard tube vs the Hybernite heated hose. The graph reveals a shift in the perception of cold air from very high to high with standard tubes down to none or moderate with heated (see Fig. 3.).

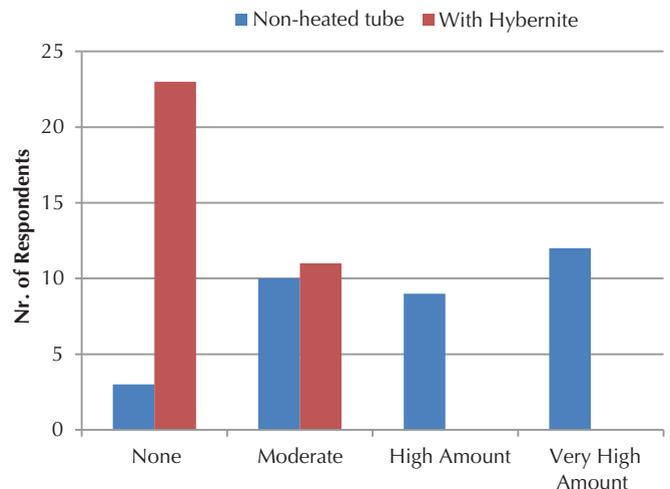


Fig. 3. Cold Air

Under the overall banner of comfort (see Fig. 4.), Langerock went to a 5-point scale for ratings that ranged between very bad to very good. Rating "overall comfort" and "user friendliness," Hybernite scored a vast majority of respondents rating both aspects neutral to very high.

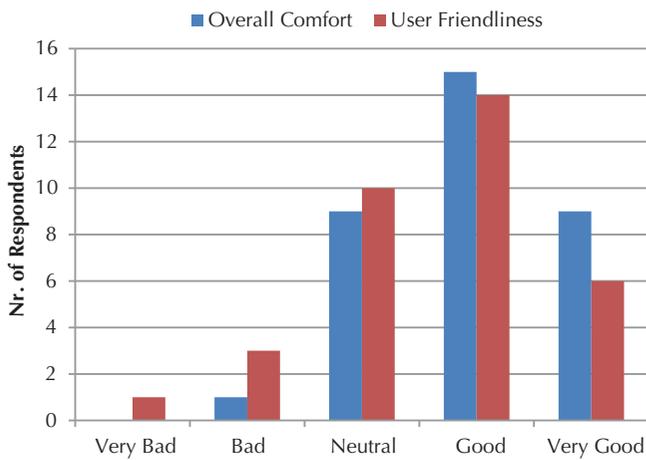


Fig. 4. Therapy with Hybernite

Just one person accounted for a less than user friendly rating, but far from discounting the statistical outlier, officials searched for reasons. With a background in chemical engineering, Langerock used his meticulous nature to ask and receive reasons for all answers, whether positive or negative.

In some cases, seemingly small components added up to some frustration for a small minority of users. “The on/off switch was one of the things that surfaced,” says Langerock. “We didn’t want to make it too bulky, but some wanted a larger and easier mechanism to turn the device on and off. We respect these responses, and we are using the feedback to improve the next generation models. If it’s not a user-friendly feature, we will take it to heart and make a design change. That is extremely important.”

Noise in the Tube

Countless manufacturers have worked hard to make CPAP units slick and suitable for night stands, but the problem of noise is usually bound to strict physical limitations found in tubes. Specifically, condensation collects in the siphon and reduces the bore of the tube, leading to pressure fluctuations. “When you normally have 19 mm of internal diameter, it gets further reduced due to water droplets collecting in the tube,” explains Langerock. “The CPAP machine will try to generate the proper pressure to push the water out, and you get the gurgling sound going back and forth in that tube. Because it’s a tube, it’s like shouting in a tunnel, and it carries the noise all the way to the mask, and patients wake up because of that.”

Hybernite largely solves the problem for those with high noise levels in the mask because moisture droplets generating condensation are reduced. Hard numbers (see Fig. 5.) show that 30 out of 32 gauged noise at zero to moderate with Hybernite in place.

Dry Mouth, Dry Nose

Dry nose and mouth, together with nasal congestion (see Fig. 6 and Fig. 7.), are symptoms of suboptimal humidification, and Langerock is convinced those problems are at least partly influenced by inferior tubes. From the beginning, he says, heated humidification was designed to eliminate nose bleeds, head aches, and dry nose/mouth. “We are not necessarily solving

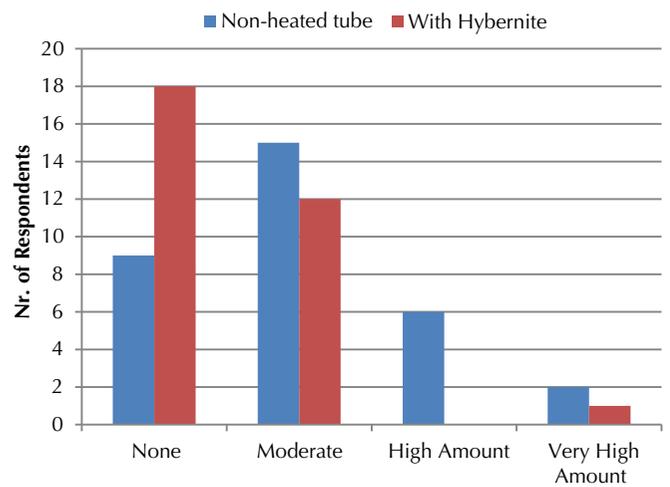


Fig. 5. Noise in Tube

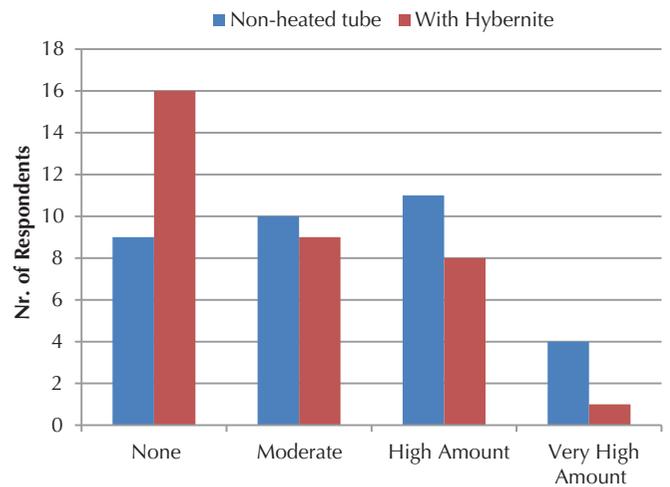


Fig. 6. Dry Mouth

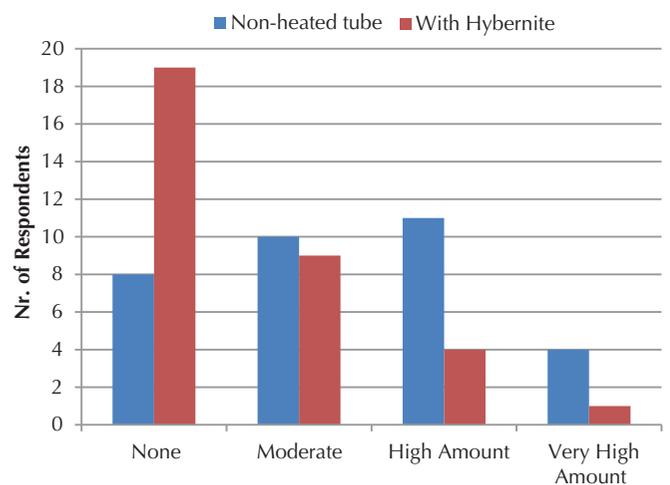


Fig. 7. Dry Nose

those problems with Hybernite alone,” says Langerock. “However, when patients are using their humidifier in combination with Hybernite, the humidity created at the humidifier end is conveyed to the mask where it matters.”

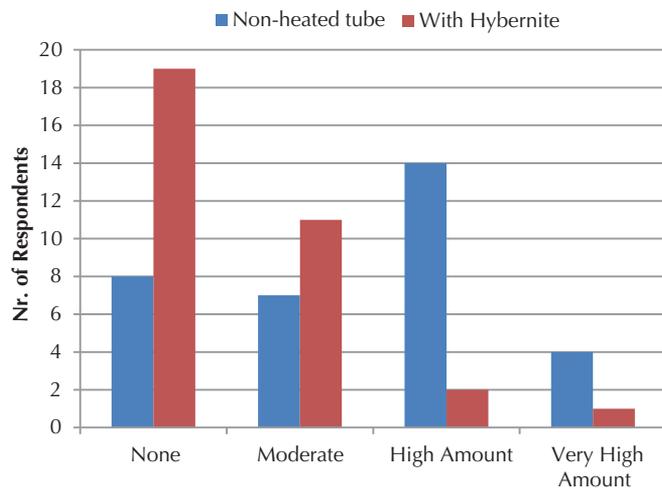


Fig. 8. Nasal Congestion

Hybernite keeps water in the vapor phase, and any humidification that remains in this phase is, by definition, not condensing. “You see from these graphs that Hybernite is a valuable tool to improve humidification, because what you generate at the humidifier, Hybernite brings to the patient more effectively,” says Langerock. “The same rationale is true for dry mouth, dry nose, and nasal congestion [see Fig. 8]. Ideally, patients should have the chance to increase the setting on their humidifier to create the optimal humidification. Without

heated tubes, you would increase the chance for condensation. With Hybernite, you can absolutely increase humidity without the extra condensation. Again, everyone who has a heated humidifier should have a heated tube, just like in critical care ventilation.”

Unappreciated No More

A handsome bathroom fixture may work perfectly, but adequate pipes and a trusty hot water heater must perform flawlessly behind the scenes. For flashy new CPAP units, proper tubing often serves the same unappreciated function.

In the world of critical care ventilation, however, heated tubing is far from unappreciated. Instead, the technology is standard operating procedure because it dramatically reduces pesky condensation. Langerock, for one, believes the same standards of comfort should apply to CPAP patients.

One way to bring this convenience to sufferers of sleep disordered breathing is to make the tubes as user friendly as possible. In addition to the 22 mm standard tube connection that fits virtually all machines, the Hybernite does not draw power from the CPAP or the humidifier. “We have a separate power supply that only powers the tube,” explains Langerock. “We do not interact with any of the features of the CPAP machine or the humidifier. Whatever the manufacturer of the CPAP and humidifier desires for output, Hybernite does not change that.”

Why don’t competitors do the same thing? “Not a lot of companies have hoses as their number one focus,” muses Langerock. “Tubing is our passion, and we want to be the tubing system manufacturer of choice providing benefits to the user in terms of comfort, convenience, compliance, and cost.”

Two Years Later: Tube Makers Building Their Market

Two years ago, Plastiflex decided to expand its respected tube and hose manufacturing to other industries. After an exhaustive fact-finding period that took company officials to numerous health-related trade shows, designers narrowed their focus to CPAP tubing, a niche where complaints about condensation and comfort abounded.

According to Rik Langerock, vice president of Sales and Marketing for Belgium-based Plastiflex Healthcare, condensation in the breathing circuits was a persistent problem, and a key area where his company could make a difference. “We spoke to all kinds of people in the supply and value chain and it was condensation in the respiratory tubes that we found to be significant,” says Langerock. “A second related need was more comfortable air to the patient.”

Comfort usually means warmer and/or more humid air, and this is where Plastiflex was able to use its considerable expertise. Other factors such as mask materials and proper fit play a role, but Langerock and his team were determined to only tackle what they knew best. “You must understand what matches with your core competency as a company,” says Langerock. “Our core competence is in the design and manufacturing of hose systems solutions.”

Plastiflex engineers ultimately came up with the Hybernite Rainout Control (ROC) System, which includes the proprietary Heated Breathing Tube (HBT) and Power Supply Unit (PSU). The Hybernite HBT connects to the PSU via a plug-and-play connector, with copper wires embedded in the tubing wall. These wires generate heat that maintains air temperature inside the tube, ultimately warding off problematic condensation. The wires are positioned for uniform heating along the tube’s entire length, a system that avoids water droplets on the wall of the tube and the resulting accumulation of moisture.

Targeting America and Europe was no small endeavor, but Langerock says the relative simplicity of the message has resonated on both continents. The Hybernite ROC is essentially two main parts; one is a heated breathing tube and the other is a power supply.

With standard conical connectors, the Hybernite ROC has taken the role of a universal solution that can be fully used onto any flow generator or humidifier—including all types of masks that use standard tubes. “We worked on this for a long time obtaining all the proper approvals,” says Langerock. “Plastiflex Healthcare is ISO 13485 certified and QSR compliant, as are our manufacturing locations. That’s why we are able to sell the Hybernite directly to DME and sleep labs under our own name and brand.”