

MEDICAL DEVICE BREATHING GAS PATHWAY OUTPUT TESTING

Medical devices such as ventilators, CPAP machines, nebulizers, etc. require the use of internal compressors, fans, external compressed gases for the delivery of gases to patients. Other medical devices are used in place for delivery of gases to patients such as tracheostomy tubes, cannulas, respiratory therapy devices, etc. The air output of these devices may contain contaminants that can unknowingly cause physical harm to patients. The FDA requires the air output of these devices be tested to ensure contaminants are not being delivered to patients.

The International Organization for Standardization (ISO) has published ISO Standard 18562:2017; *Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications*, Parts 1-4, which addresses the risk of potentially hazardous substances delivered to the patient through the gas pathway. These parts include:

- Part-1—Evaluation and testing within a risk management process
- Part-2—Tests for emissions of particulate matter
- Part-3—Tests for emissions of volatile organic compounds (VOCs)
- Part-4—Tests for leachables in condensate

LEGEND provides customized air output capture systems to fit your specific device allowing for real-time monitoring along with sample collection/analysis for these harmful contaminants following ISO 18562 Part-2, Test for Emissions of Particulate Matter and 18562 Part-3, Test for Emissions of Volatile Organic Compounds (VOCs). In addition, LEGEND offers testing for leachables in condensate following ISO 18562-4.

Testing/Analytical Capabilities

- Volatile Organic Compounds (EPA TO-15)
- PM2.5/PM10 Particulates (Real Time Monitoring)
- Leachables in Condensate
- Ozone, Carbon Dioxide, Carbon Monoxide

LEGEND is ISO 9001-2008 registered and an ISO 17025-2005 accredited laboratory

About LEGEND

Our primary goal is to combine extensive laboratory and regulatory experience to deliver a diverse range of services to our clients, while supplying the best analytical and consulting services value. We are committed to the continuous improvement in the quality and scope of the services we provide.



Contacts:

Corey Campbell, CHMM
651.221.4064
ccampbell@legend-group.com

Tom Barrett
651.221.4060
tbarrett@legend-group.com