HEPA Filters, Extra Oral/ Intra Oral Suction, UV Air Purifiers

Questions to consider before purchasing a dental air purifying and aerosol-reducing device for your clinic.

1. **Where are you planning to use the device?** Are you putting the device in the waiting area, in an office space or in a treatment area? You will need different specification and regulations depending on where you are using the device.

2. **Does the device need to be FDA approved?** All medical devices used in the United States are subject to FDA Regulations. If you are using the air purifying or aerosol-reducing device to prevent a disease, then it is subject to FDA regulations. You can find out if the medical device manufacturer is registered with the FDA and if the medical device is listed with the FDA by searching the Establishment Registration & Device Listing.

   For Extra/Intra oral suction devices: If intended for dental suction, these would be classified as suction operatory units, product code EBR, Class I exempt, under 21 CFR 872.6640. If, however, indicated for removing pathogens, such as related to COVID-19, this would likely be classified as a medical recirculating air cleaner, which is not exempt but is subject to premarket clearance (510(k)) under 21 CFR 880.5045, Class II, product code FRF.

   Facilities should work with local Office of Environmental Health and Engineering staff to ensure air filtering devices align with facility HVAC components and to assess potential impact to required air pressurization relationships and nitrous oxide exhaust systems. In addition, local Clinical Engineering staff may be able to provide medical device technical expertise and ensure appropriate maintenance schedules.

3. **How much air exchanges per hour or CFM does the device provide?** You will want to determine if the device purchased is adequate for the space in which you plan to use the device. Air changes per hour (ACH): ACH = CADR (cfm) x60 (min/hr) ÷ room volume (ft^3)

4. **Is the device safe?** Only use devices for which evidence of effectiveness and safety is clear. Manufacturer data should be carefully considered. Some systems may emit ozone, hydroxyl radicals and superoxide anions at unsafe levels.

5. **Does the device have proper filtration?** True Hepa Filters are at least 99.97% efficient at filtering 0.3 µm mass median diameter (MMD) particles in standard tests. Watch for filters that may say “HEPA TYPE” or “HEPA LIKE”, these are not true HEPA filters. Medical Grade HEPA filters are H13 and H14 and filter 0.1 micron at 99.95%, 99.995% respectively.

6. **Is the device too loud?** Consider the noise level of the device at the desired ACH. Average decibel level of human speech is 50-65 decibels. Hearing loss can start at 85 decibels or higher.

7. **Is the device cost effective?** Air purification devices can range from $150 to $50,000. It is important to evaluate the safety benefit the devices provides versus the cost of the device.

8. **Is the device practical for your practice?** Look at size of device and how it will affect provider and dental assistant working space.

Dental Clinics should engage with local institutional environmental health and/or engineering to discuss potential impact on current HVAC systems, particularly nitrous exhaust and required negative/positive air pressurization required. Dental clinics should engage with infection prevention or ICP committees to ensure appropriate purchase.

Please note that the air purification system may be tested and evaluated by the following organizations:

IEST- Institute of Environmental Sciences and Technology http://www.iest.org
NAFA - National Air Filtration Association - http://www.nafahq.org
UL – UL-Underwriters Laboratory - www.ul.com
Interteks ETL- Intertek ETL Certification program-.intertek.com/
CARB- California Air Resources Board-/ww2.arb.ca.gov/e-cert
AHAM-Association of Home Appliance Manufacturers-www.aham.org