



## **NEWS FOR IMMEDIATE RELEASE – December 5, 2020**

### **FDA Releases Guidance Approving FFR Dry Heat Mask Reprocessing**

The FDA recently issued an Enforcement Policy Guideline allowing dry heat to be used in decontaminating N95 masks – <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-bioburden-reduction-systems-using-dry-heat-support-single-user-reuse-certain>.

The RH-N95 Mask Decontamination System manufactured by CPAC Equipment, Inc. ([www.cpac.com](http://www.cpac.com)), meets all of the FDA guidance requirements for reprocessing FDA acceptable N95 respirator masks. Through the convenience of on-site reprocessing using the RH-N95 tabletop decontamination system, healthcare providers can decontaminate their N95 respirators for single-user reuse up to 20 cycles while maintaining mask performance and integrity.

CPAC uses their FDA-Cleared RapidHeat™ sterilization technology in their manufacture of the RH-N95 Mask Decontamination System. The principal safety advantage in using RapidHeat technology to decontaminate N95 masks is that there are no chemicals or steam used, which would require complete aeration or drying before mask reuse.

Another unique feature of the RH-N95 is that it comes with a dual USB flash drive allowing the practitioner to switch back and forth from a mask decontamination system to a sterilizer that can process wrapped or unwrapped instruments in minutes. The easy software download takes less than 5 minutes. For example, a practitioner could start the day with a mask decontamination cycle and then using the conversion flash drive switch to the higher-temperature RapidHeat sterilization of instruments for the rest of the day.

For immediate additional information: Call Toll Free 800-828-6011, ext. 1372 or E-mail [dbaker@cpac.com](mailto:dbaker@cpac.com).