Decontamination of Compatible N95 Respirators: Training and Setup Verification Form

IMPORTANT NOTE ON COMPATIBLE N95 RESPIRATORS: The Bioquell Technology System can only be used with 3M respirator models 1860, 8210, 1804, and 1870+ ("compatible N95 respirators"). These are the only compatible N95 respirators authorized for decontamination under the Emergency Use Authorization (EUA).

Respirators that are NIOSH-approved before decontamination (https://wwwn.cdc.gov/niosh-cel/) only retain their NIOSH approval status post-decontamination if the respirator manufacturer permits the use of the decontamination method with the specific system and cycle parameters. To determine the NIOSH approval status of a specific decontaminated, NIOSH-approved respirator, please check with the respirator manufacturer and/or check the respirator labeling. If a respirator is no longer NIOSH-approved after use of the particular decontamination method, its performance (i.e., fit, filtration, and breathability) might not consistently meet NIOSH-approved N95 standards.

The Bioquell Technology System has neither been cleared nor approved by FDA, but has been authorized for emergency use by FDA under an EUA for the decontamination of compatible N95 respirators for single-user reuse by healthcare personnel to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates. The emergency use of the Bioquell Technology System is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices during the COVID-19 outbreak, under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Instructions

Please complete and submit this form along with photographic evidence (3#) to solutions@bioquell.com. Please contact (215) 682-0225 if you have any questions.

Bioquell Inc. will work with your healthcare facility to ensure that the room is properly configured for the Bioquell Technology System to deliver a controlled and monitored decontamination process. Bioquell Inc. will train designated personnel at your healthcare facility during the setup verification on execution of the decontamination process. Completion of such training and setup is documented with this form "Decontamination of Compatible N95 Respirators: Training and Setup Verification Form (Setup Verification Form)," which your healthcare facility must complete and then sign and submit, along with photographic evidence, to solutions@bioquell.com.

Bioquell Inc. will review the Setup Verification Form completed and signed by your healthcare facility. If it is found to be acceptable, Bioquell Inc. will sign the Setup Verification Form and share it with Ecolab Inc., Bioquell Inc.'s parent company, for final review and approval.

Ecolab Inc. will review the Setup Verification Form that has been completed and signed by your healthcare facility and reviewed and signed by Bioquell Inc. If the Setup Verification Form is acceptable to Ecolab Inc., Ecolab Inc. will sign the Setup Verification Form and provide Bioquell Inc. and your healthcare facility with a final signed copy to indicate approval for your healthcare facility to start routine decontamination operations.

Routine decontamination operations can begin ONLY after the above setup verification activities have been completed.

Please note that if requested by FDA, Ecolab Inc. must also submit the Setup Verification Form to FDA.

Section A: Facility Information

Name of Healthcare Facility		Street Address Including City, State, and ZIP Code	
Contact Name		Contact Phone Number	

Section B: Decontamination Setup

Name of designated decontamination room		Room Size Number of Respirators	
Room setup. Circle location of biological indicators (BIs)	{Attach pictures of room}	Bioquell Vapor Generator Model Name	

Section C: Processing Parameters

Programmed Room Volume (BQ50); Injection Time (minutes) for other models		Injection rate (grams/minute)	
Dwell time (minutes)		Aeration time (minutes)	
Biological Indicator growth tubes at 24 hours	{Attach picture}		
Biological Indicator growth tubes at 7 days	{Attach picture}		

Please input results from the evaluation of Biological Indicators (BI)

Date of gassing cycle		
	Result post 24-hour incubation	Result post 7-day incubation
Date		
Readers Initials		
BI Position		
1		
2		
3		
4		
5		
Positive (+'ve) control		
Example	-	+
+ = Growth - = No growth NR = No reading		

Section D: Signatures

Healthcare Facility

I confirm that the information provided in this information is complete and accurate.

Signature _____ *Signature of the Person Submitting this Form*

Name _____ *Name of the Person Submitting this Form (print)*

Date of Signature ____ ____ ____ *MM* *DD* *YY*

Bioquell

I confirm that the room at the specified healthcare facility has been properly configured to decontaminate compatible N95 respirators.

Signature _____ *Signature of the Person Submitting this Form*

Name _____ *Name of the Person Submitting this Form (print)*

Date of Signature ____ ____ ____

Ecolab

I confirm that the setup verification activities at the specified healthcare facility have been properly conducted and the specified healthcare facility may begin decontamination cycles for the compatible N95 respirators.

Signature _____ *Signature of the Person Submitting this Form*

Name _____ *Name of the Person Submitting this Form (print)*

Date of Signature ____ ____ ____