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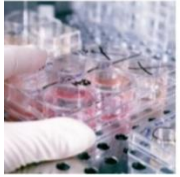

NIOH

Research day 2020

Validation of three decontamination methods for respirators used in South Africa to address stock shortages during the COVID-19 Pandemic

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INTRODUCTION

- Filtering facepiece respirators (FFRs) such as N95, FFP2, KN95 provide respiratory protection in a variety of workplaces, where other higher hierarchy controls are ineffective.

- With the global shortage of personal protective equipment (PPE) due to several reasons including supply chain constraints, the need for reuse of equipment is vitally important and lifesaving.

- Many facilities are already practising extended use and reuse (1 week), due to stock shortages to cope with the expected increase in demand.

INTRODUCTION

- CDC, WHO and NIOSH do not recommend that FFRs be routinely decontaminated and reused as it is inconsistent with their approved use.

- However, due to the unprecedented crisis and FFR shortages, it is explored as a capacity strategy to ensure continued availability without exposing workers to the SARS-CoV-2 which can survive on fomite surfaces for long periods (up to 9 days).

- Decontamination methods (e.g. bleach, ethylene oxide, chlorine gas, microwave, soap, **UVGI, VHP, heat sterilisation (moist, dry)**)

Aim

This study aims to investigate the impact of three decontamination methods on the performance criteria and determine the feasibility of applying the technology for decontamination of FFRs for reuse in South Africa.

N95 Mask Decontamination and Reuse

REBEL COVID-19

Objectives

- To evaluate the potential applicability of the three decontamination methods in the laboratory setting for commonly used FFRs in South Africa

- To determine the post decontamination and reuse performance of FFRs (filtration and fit)

- To assess post decontamination safety (visual inspection - safety and durability, off-gassing)

Methodology

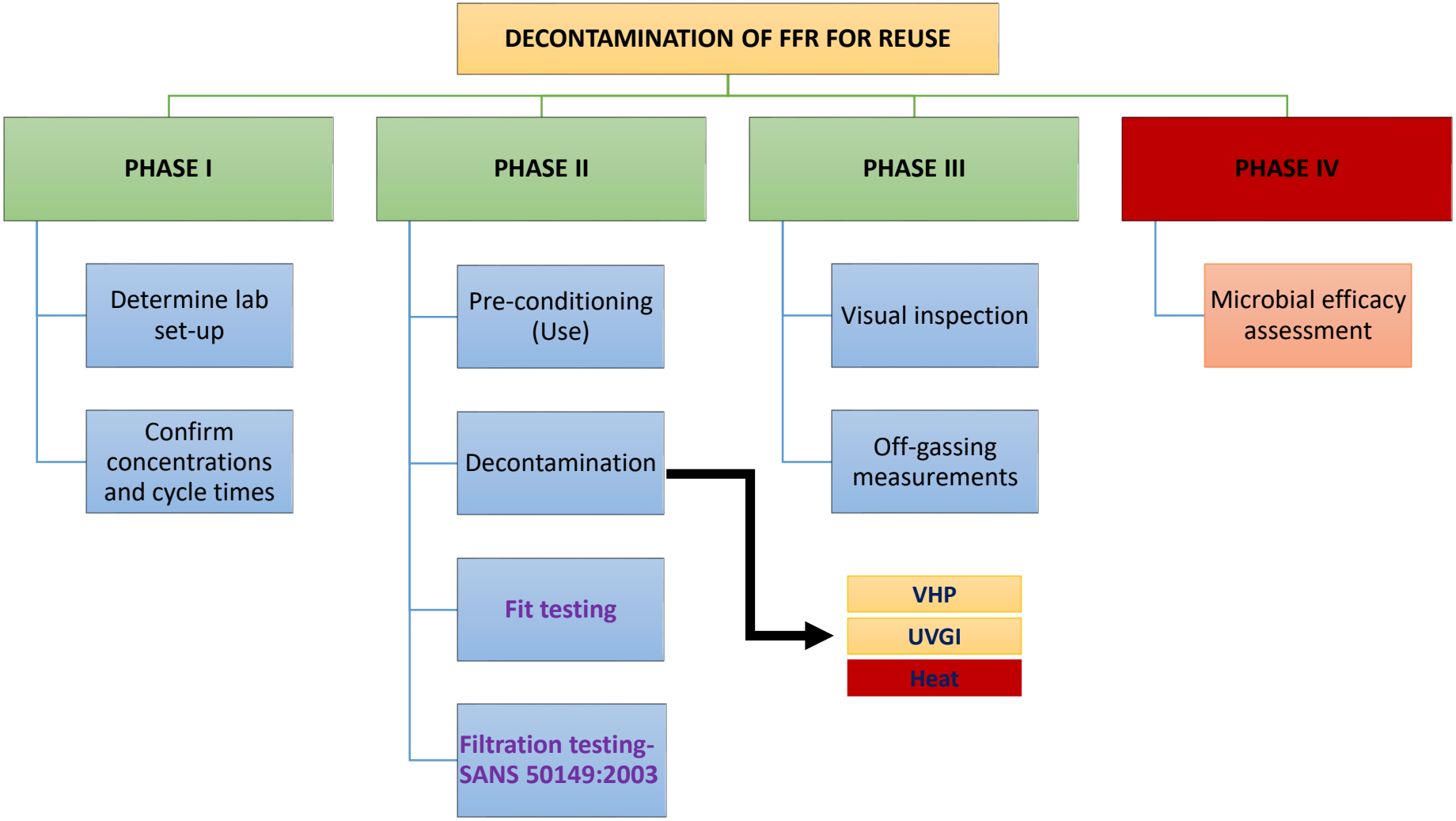


Figure 1 Illustration of the four phases of the study

Methodology

Study type: Experimental study design

	N95				FFP2		KN95
	(United States NIOSH-42CFR84)				(Europe EN 149-2001/SANS 50149-2003)		(China GB2626-2006)
	Cupped	Duck bill	Makrite	Vflex	Green line 5200	3M FFP2	KN95
	1860	PFR95	9500	9105S	5200	8810SSA	
UVGI	18	18	18	NT	18	18	18
VHP	19	19	19	19	19	19	19

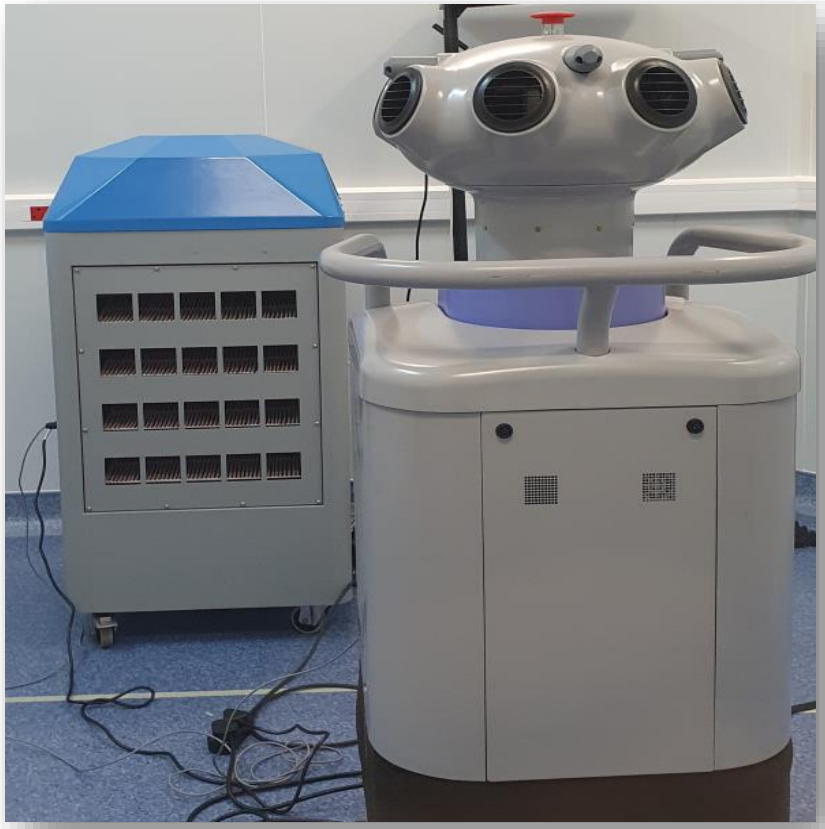
Mask Types

- The performance and integrity of the FFRs was determined by conducting standardized human FFR fit testing using the TSI PortaCount Model 8038 (OSHA protocol)
- Regular users were selected to eliminate the issue of poor donning

Methodology: VHP

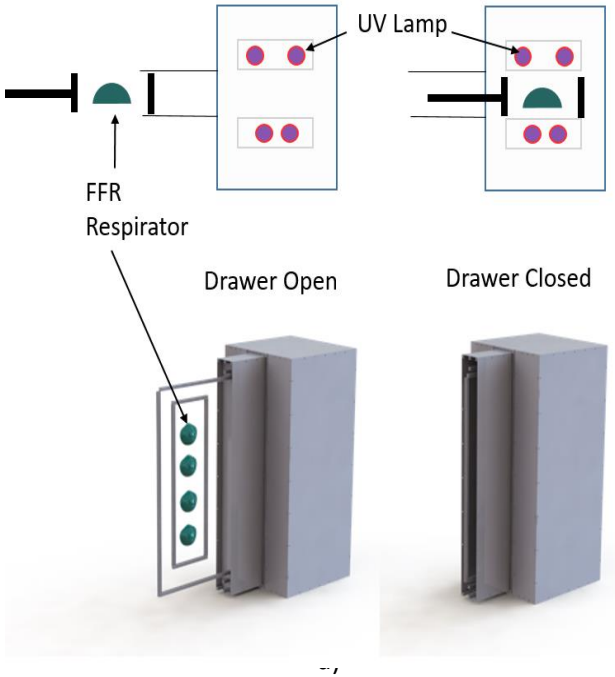
Test parameters

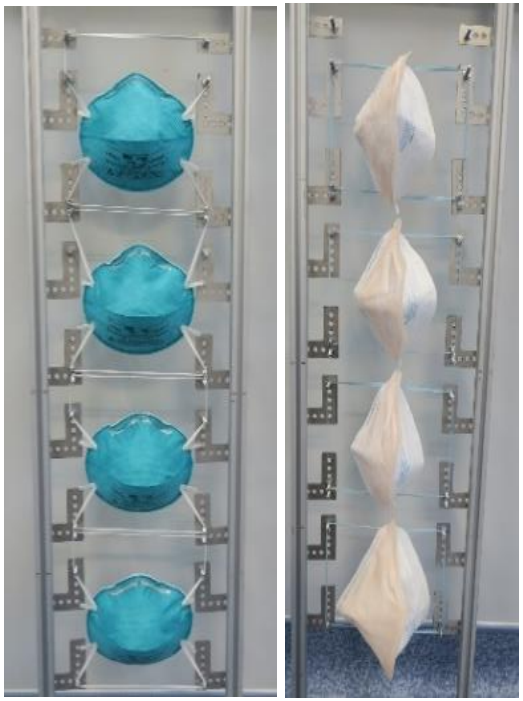
- 10 g/m^3 concentration (35% hydrogen peroxide solution)
- Gassing 21 minutes
- Dwelling at 5 minutes
- Aeration time: Overnight



Methodology: UVGI

Minimum of 1.2 J/cm^2 UV-C exposure on all areas of the mask





FFR Type	FFR Models	Measured Micro Watts per cm^2		Max-Min Ratio	Total correction	Final Dose Time (mins)
		Min	Max			
One	3M 1860 NIOSH, 3M1860 SABS, Markrite,	3231.1	8633	2.67	1.276	7.90
Two	Greenline, KN95	3922.8	8156	2.08	1.593	8.12
Three	Kimberly Clarke	3076.0	5964	1.94	1.404	9.13

Results: Fit testing for VHP

Participant ID	3M 1860 N95	Kimberly Clarke N95	3M 8810SSA FFP2	Makrite 9500 N95	Green line 5200 FFP2	KN95	V-flex
FFR001	30	1	5	0	0	0	21
FFR002	2	3	5	0	0	0	NT
FFR003	1	4	2	0	0	0	30
FFR004	30	3	0	2	0	0	NT
FFR005	9	5	30	NT	30	NT	30
FFR006	22	14	12	0	0	0	27
FFR007	2	1	1	0	1	0	21
FFR008	1	0	3	NT	0	0	23
FFR009	2	0	1	0	0	0	1
FFR010	15	4	0	0	0	0	NT
FFR011	5	0	0	0	0	0	NT
FFR014	13	0	13	0	0	0	NT
FFR017	7	0	0		0	0	5
FFR020	7	0	5	0	0	0	0
FFR023	0	0	0	0	0	0	0
FFR033	30	30	0	0	0	0	0
FFR034	7	1	1	0	7	NT	3
FFR035	0	4	3	0	0	0	30
FFR036	0	1	1	0	0	0	0

KEY: NT - NOT TESTED

Results: Fit testing for UVGI

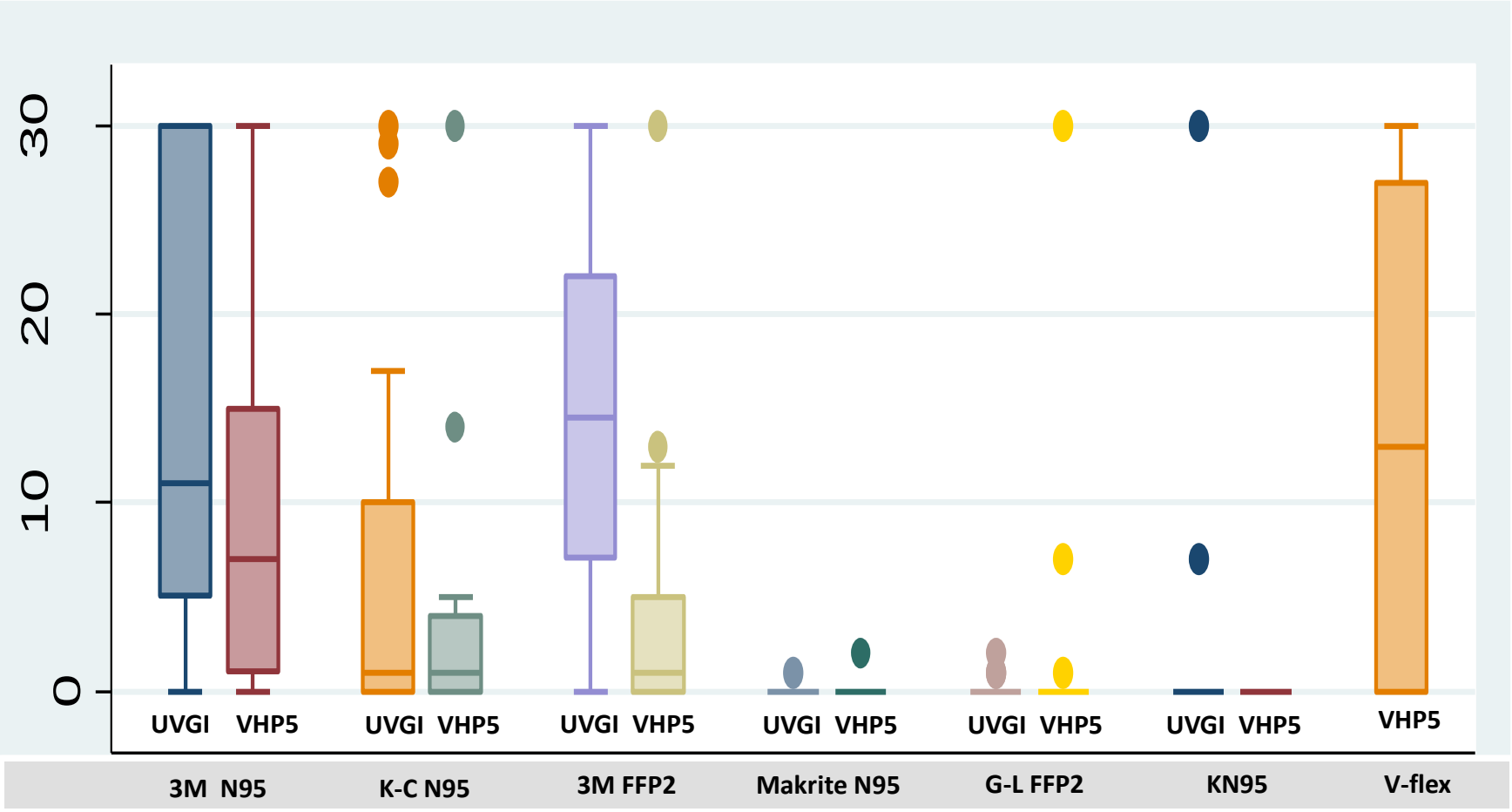
Participant ID	3M 1860 N95	Kimberly Clarke N95	3M 8810SSA FFP2	Makrite 9500 N95	Green line 5200 FFP2	KN95	V-flex
FFR001	30	0	14	0	0	0	NT
FFR003	30	8	30	0	0	0	NT
FFR004	30	30	19	1	0	30	NT
FFR005	30	27	11	0	2	0	NT
FFR006	12	17	16	0	0	0	NT
FFR007	1	0	6	0	1	0	NT
FFR008	7	4	15	0	0	0	NT
FFR012	0	0	1	0	0	0	NT
FFR013	5	0	0	0	0	0	NT
FFR017	10	0	9	0	0	0	NT
FFR026	30	1	7	0	0	7	NT
FFR028	30	1	0	0	0	0	NT
FFR029	5	0	22	0	0	0	NT
FFR030	3	2	15	0	0	0	NT
FFR031	7	1	12	0	1	0	NT
FFR032	17	10	26	0	0	0	NT
FFR033	30	NT	30	0	0	0	NT
FFR035	1	29	30	0	0	0	NT

KEY: NT - NOT TESTED

Fit testing Results: VHP vs UVGI

	FFR Type	UVGI Mean (SD)	VHP Mean (SD)	Kruskal-Wallis (P value)
1	3M 1860 N95	15.4 (12.6)	9.6 (10.8)	0.1447
2	Kimberly Clarke N95	7.6 (11.0)	3.7 (7.2)	0.5577
3	3M 8810SSA FFP2	14.6 (10.0)	4.3 (7.3)	**0.0014**
4	Makrite 9500 N95	0.1 (0.2)	0.1 (0.5)	0.9587
5	Green line 5200 FFP2	0.2 (0.5)	2 (7.0)	0.9757
6	KN95	2.1 (7.2)	0 (0)	0.5234
7	V-flex	Not tested	13.6 (13.2)	Not applicable

Results: VHP vs UVGI



Results: Filtration efficiency and Inspection

	Before decontamination (VPH)	Average after decontamination (VPH)	Effect	Filtration Maximum specification
Kimberly -Clarke	0.7	2.9	Increase	6
Greenline FFP2	1.7	2.2	Increase	6
3M FFP2 NRD	0.1	2.6	Increase	6
3M 1860 N95	0.5	0.6	Increase	6
KN95		25		6
Makrite 9500-N96	0.9	0.6	Decrease	6

Safety inspection of Respirators

Inspection		Odour	
VHP	UVGI	VHP	UVGI
One FFR -Straps broke	Four FFR -Straps broke	Two participants	All participants

Discussion

- The **decontamination methods did not appear to impact on the fit** as some participants failed fit testing before decontamination on the first day
- **Fit testing** appear to be **more affected by donning & doffing**, as some passed with adjustment and repeat
- Common brands – 3M & Halyard (Kimberly Clarke) performed better on fit testing for both pre and post decontamination
- Makrite 9500 N95 and Green line 5200 FFP2: very few (0.3 and 0.7% respectively) completed the cycles
- No participants passed fit testing for KN95 for VHP, however 2 passed for UVGI: one 30 cycles and another 7 cycles (different batch)

Discussion

- More people completed more cycles after UVGI decontamination compared to VHP
- The difference was significant for 3M 8810SSA FFP2, but was not significant for 3M 1860 N95 and Kimberly Clarke N95
- V-flex was only done with VHP with participants completing an average of 13 cycles
- Of the six FFR types tested for filtration only KN95 failed filtration after VHP decontamination and similar trend is observed with the fit testing

Limitations

- Limited number of FFRs in terms of size due to shortages of supply during COVID-19 outbreak
- V-flex not tested with UVGI due to design (folds)

Conclusion

- The decontamination methods did not appear to impact on the fit and filtration (except for KN 95) as some participants failed fit testing before decontamination on the first day and most FFR types passed filtration test.

- Instead, the donning and doffing of FFRs together with lack of variety of FFRs sizes may be a contributory factory to fit failure.

Acknowledgements

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THANK YOU

ANY QUESTIONS?

Reduce, Reuse, and Recycle N95 Respirators

REDUCE

Wear As Long as Possible

- Extend use by wearing the N95 as long as possible.
- Perform hand hygiene before donning.
- Put the N95 on correctly and perform a seal check.

RECYCLE

Decontaminate When Possible

Ensure the N95 is in good condition and meets all the criteria for reuse after decontamination.

For more information on decontamination and reuse, reference this link:

https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html

REUSE

Wear With Multiple Patients

- Perform hand hygiene before donning.
- Inspect the N95 and reuse only if it is not visibly soiled, damp, or damaged.
- Put the N95 on correctly. Do not touch the inside.
- Perform a seal check. If you are unable to obtain a seal, **discard the N95.**
- **Discard the N95** if it is:
  - Visibly wet, overly damp, or dirty.
  - Grossly contaminated with blood or other bodily fluids.
  - Used for a patient co-infected with another respiratory infection.

When reusing N95s, label according to your facility guidelines. This will typically include your name and date of first use.