



THE UNIVERSITY OF KANSAS HEALTH SYSTEM

Care Collaborative

Supply Chain Update

04-29-2020



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Opening Comments

Craig Rohleder, Senior Director of Supply Chain Mgmt & Admin



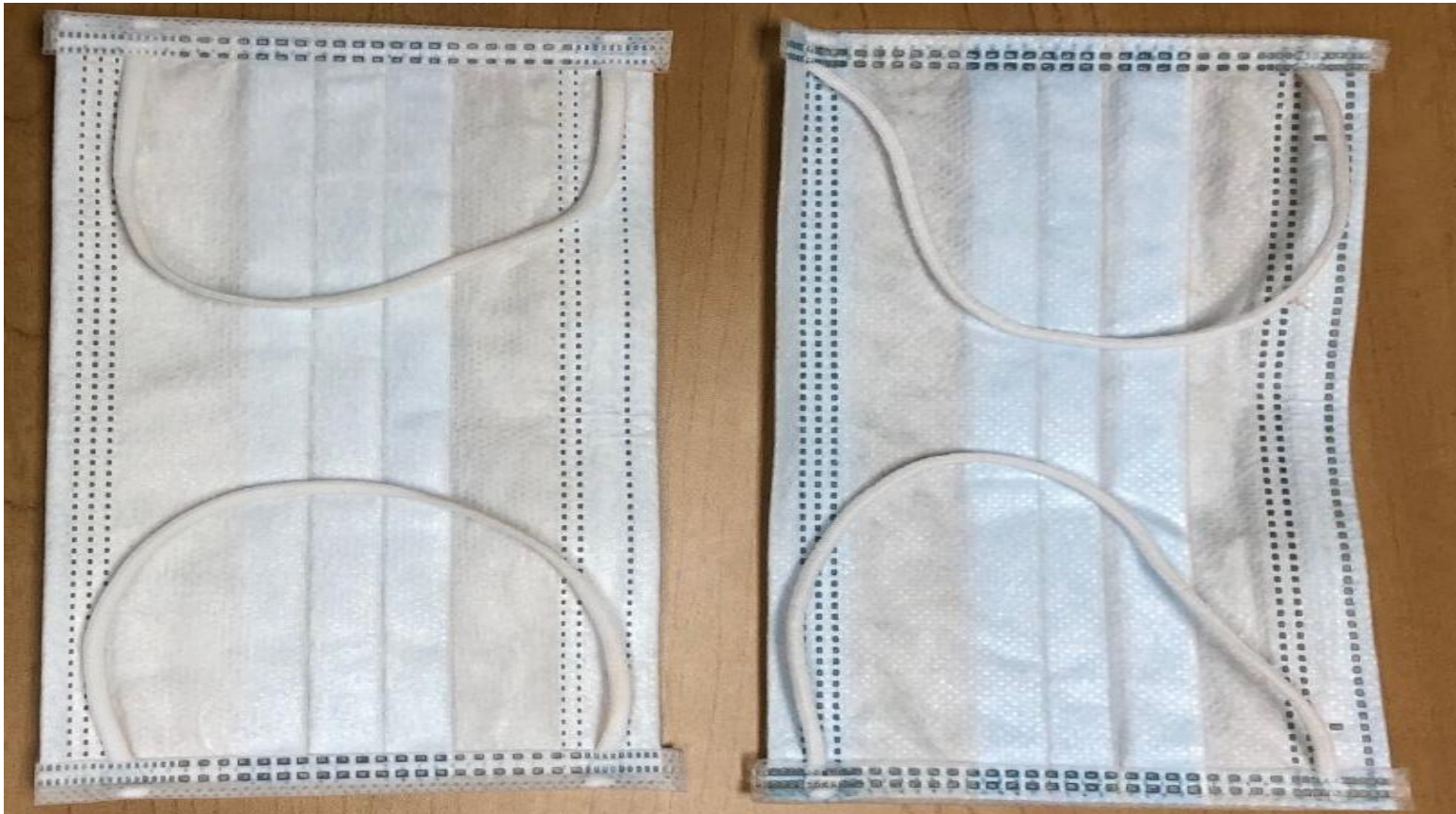
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Level 1 Masks Quality Issues

Craig Rohleder, Senior Director of Supply Chain Mgmt & Admin

Level 1 Masks Quality Issues

Passes Vetting Process



Level 1 Masks Quality Issues

Fails Vetting Process

Defective Level 1 Masks:

- Nose piece does not secure, loose around cheeks, tie falls off
- TUKHS has removed from circulation





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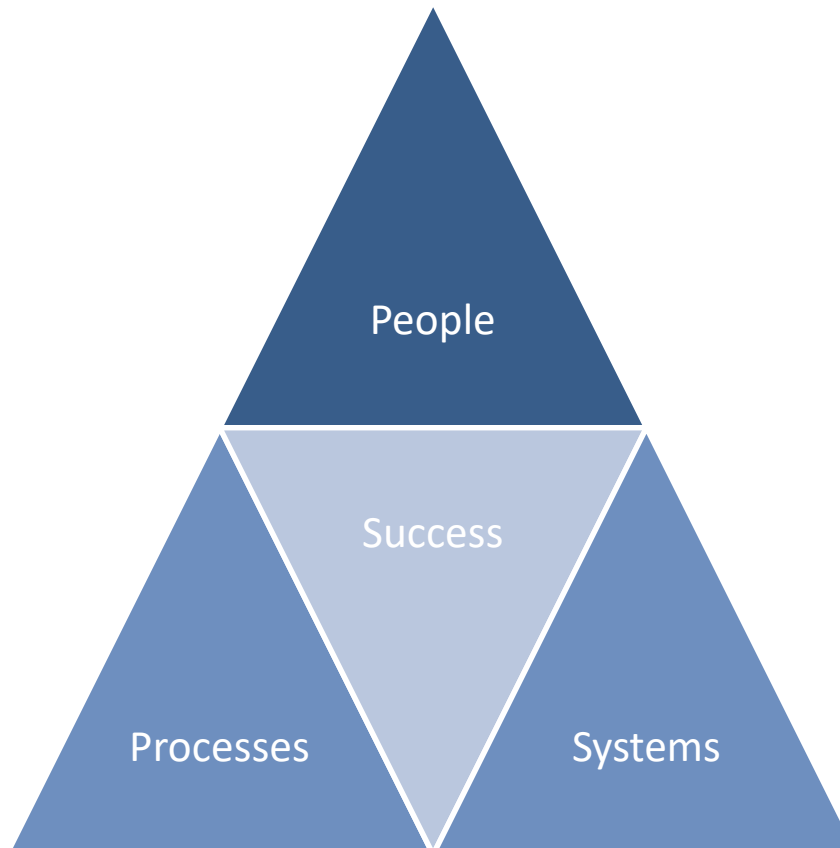
N95 Cross Walk

Angie Bruns, System Director, Value Analysis

Today's objective:

1. Why we built a cross walk
2. Review the crosswalk

People + Processes + Systems = Success



What we heard from our people...

“We are out of N95 Masks!!”

After discovery, what Supply Chain heard was...

“I received a different N95 mask than I had been fit-tested for previously” ...

Solution: we needed to go back to our people, process and systems mindset

Through collaboration and research

Healthcare Respirator and Surgical Masks (may be approved for this during this healthcare emergency)						
Size	3M (UK produces 1870/1870+, US produces other #s)	Moldex McKesson	Honeywell-construction rating	Pasture	TBD: Dust Mask	HealthPro
Small	1860s, 1805s, 1804s	2201N95			16-90081	
Standard/Medium / Universal	1870, 1870+, 8210Plus (not surgical mask), 1860	2300N95 (med/large)	H901	F550G and A502G (no size listed; universal)	16-90007	42CFR84
Large	8511				16-90004	
XL					16-90001	
**KEY: Green highlighted is product currently in stock as of Monday 4-6-20						

Crosswalk Review

	The University of Kansas Health System's ABC for N95	
	Small	Standard/Medium
A	3M 1860S	3M 1870/1870+/1860
B	Moldex 2201N95	Moldex 2300N95
C	16-90081	42CFR84
D		F550G and A502G
E		8210Plus
F		16-90007

ABC Model was determined based upon IFU criteria and quantities available of the products.

Additional resources

When to Utilize:

Links:

How and When to utilize N95 Respirators

https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhcp%2Frespirator-supply-strategies.html




Reuse protocol for N95s

<https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html>

3M Surgical mask v. N95 respirator



SurgicalN95vStandardN95TB.pdf

Manufacturer	Reference #	Size	
3M	1860s	SM	
3M	1805s	SM	
3M	1804s	SM	



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Trusted Suppliers

Kim Smith, System Director, Strategic Sourcing-Supply Chain

Supply Chain Vendor Vetting Process

April 2020

The recommendation is to always use a preferred/trusted vendor. If applicable, use resources available through your Group Purchasing Organization (GPO) and Regional Purchasing Coalition (RPC) as well as contracts with local vendors

When the above options are not available, use the following process in determining whether a vendor should or should not be trusted:

Situation: You receive notification from a source regarding a vendor who claims to be able to provide critical supplies needed.

1. Does the vendor specialize in healthcare sales?
 - a. If no, proceed with caution in the vetting process
 - b. If yes, proceed with vetting process
2. Contact the Vendor:
 - a. Communication with the vendor should include but not limited to, requests for the following information:
 - i. Product(s) list
 - ii. Product(s) certifications: Food and Drug Administration (FDA), Center for Disease Control (CDC) and the Environmental Protection Agency (EPA)
 - iii. What is the minimum order requirement with pricing?
 - iv. What are the terms and conditions for purchasing?
 - v. Ask for pictures of the product(s).
 - vi. Ask for product specifications, i.e. material used.
 - vii. Request IRS W-9 form for US-based companies (W-8 for international companies)
 1. If none, do not proceed
 2. If provided, proceed with vetting process
 - viii. What is the name and location of the manufacturer?
 - ix. Can the product(s) be compared with other, vetted products?
3. Review information sent:
 - a. Confirm certifications provided (FDA, CDC, EPA)
 - b. Review dates of certification, are they current?
 - c. Is product requiring certification listed on certificate and on website?
 - d. Review product manufacturer. Does manufacturer deal in medical supplies or other business venture? If manufacturer is not healthcare-related, proceed with caution.
 - e. Do the minimum requirements meet/exceed our current preferred product, i.e. material used, % of ingredients adequate, etc.?
 - f. Confirm Vendor/Manufacturer are legitimate through other sources:
 - i. Federal Bureau of Investigation (FBI): <https://www.fbi.gov/coronavirus>. Have there been complaints lodged against vendor/manufacturer?
 - ii. CDC: <https://www.cdc.gov/>
 - iii. Office of the Inspector General (OIG): <https://exclusions.oig.hhs.gov/>
 - iv. GPO/RPC:
 1. Trusted vendor links can be obtained through these organizations
 2. Peer organizations – Ask vendor for organizations in area they have worked with. Confirm with peers at the organization.

3. Member organizations, such as, AHRMM, Google searches, etc. can also provide feedback through their networks.
- g. Review required contract payment terms:
- i. A vendor Purchase Order (PO) or Invoice is always preferred
 - ii. What is the percentage required to put down on the product(s)?
 1. If 100% required in advance (pre-pay), proceed with caution. This is possibly a fraudulent situation.
 2. If terms include a percentage down before shipment, then a percentage when shipped, then balance on arrival, better scenario you are dealing with a legitimate vendor.
 3. Be careful of wiring money to a vendor unless they have met the vetting requirements
 4. Does the vendor allow for escrow, so that funds are released upon receipt? This allows for inspection and validation of product.
4. Shipping Cost/Time
- Air Freight/Ground Freight
- a. Verify price of shipment, it can sometimes be upwards of 100% of the total cost. Ensure it is an economical option before proceeding
 - b. For overseas shipments, air freight is preferred over cargo ships. Water freight can take 40-45 days.
 - c. Ground - More economical stateside
 - d. Shipping from/to
 - i. What is the country of origin and receiving customs challenges?
 - ii. What is the expected time of arrival?
 - iii. Is there a local option that would be more cost effective?

Product Validation Tracker

Vizient Sg2 Product validation tracker – Criteria used:

- Hyperlink to FDA or CDC (NIOSH) website if applicable for the registered or researched manufacturer
- The type of product(s) the original requestor submitted for review matches FDA Classification
- FDA Registered: Determine if manufacturer was confirmed to be registered on the FDA website
- FDA Device Listed: Determine whether the precise items requested for review are listed on the FDA website
- NIOSH Approved: Determine whether the precise items requested for review are approved by NIOSH as applicable



Product
Validation Tracker

3M Fraud Alert



April 8, 2020
Revision 2

Fraudulent Activity, Price Gouging, and Counterfeit Products

At 3M, we are committed to doing all we can to help combat the fraudulent, price gouging, and counterfeit activity that is unfortunately occurring in connection with COVID-19. Examples include people fraudulently representing themselves as being affiliated with 3M and having authentic 3M product to sell, selling (or offering to sell) 3M products at grossly inflated prices, selling counterfeit products falsely claimed to be from 3M, and falsely claiming to manufacture 3M products. In many cases, these scammers will try and secure funds in advance and then disappear once the money is received.

3M will not tolerate any such activity by 3M authorized channel partners and we will aggressively pursue third-parties that seek to take advantage of this crisis. We are working with law enforcement authorities around the world – including, in the U.S., the U.S. Attorney General, state Attorneys General, and local authorities.

We have also created a new **3M COVID-19 Fraud hotline** for the U.S. and Canada that end-users and purchasers of 3M products can call for information to help detect fraud and avoid counterfeit products. You can reach this hotline by calling: **1 (800) 426-8688**.

In addition to the hotline, you can report a concern in the U.S. at www.go.3m.com/covidfraud. You can report a concern in Canada at www.go.3m.com/covidfraud-en-ca (English) or www.go.3m.com/covidfraud-fr-ca (French).

3M recommends purchasing our products only from a 3M authorized distributor or dealer, as that offers the greatest assurance that you will receive authentic 3M products.

If you need help identifying 3M authorized distributors and dealers in your area, please contact **3M Help Center** at www.3m.com/3M/en_US/company-us/help-center or **1 (888) 364-3577** in the United States. In Canada, please contact **3M Canada Customer Service** at **1 (800) 364-3577**.

With regard to 3M respirators specifically, we are providing the following additional information to help stop price gouging and sales of counterfeit products:

- 3M has not changed the prices we charge for 3M respirators as a result of the COVID-19 outbreak.
- We are actively working to eliminate price gouging, including making referrals to law enforcement where appropriate.
- To help customers identify and avoid inflated prices, we are now publishing current single-case list prices for many of the most common 3M N95 respirator models sold in the U.S.
- List prices for these models sold in Canada are similar on a currency-adjusted basis.

	Model #	List Price (USD)
Surgical N95 Respirators	1804	\$0.68
	1804S	\$0.68
	1860	\$1.27
	1860S	\$1.27
	1870+	\$1.78
Standard N95 Respirators	8210	\$1.02 - \$1.31
	8210Plus	\$1.18 - \$1.50
	8210V	\$1.48 - \$1.88
	8110S	\$1.08 - \$1.37
	8200	\$0.63 - \$0.80
	8511	\$2.45 - \$3.11
	9105	\$0.64 - \$0.81
	9105S	\$0.64 - \$0.81
	9210+	\$1.40 - \$1.78
9211+	\$2.68 - \$3.40	

U.S. Department of Health & Human Services

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FDA U.S. FOOD & DRUG ADMINISTRATION

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Establishment Registration & Device Listing

FDA Home Medical Devices Databases

This database includes:

- medical device manufacturers registered with FDA and
- medical devices listed with FDA

Note: Registration of a device establishment, assignment of a registration number, or listing of a medical device does not in any way denote approval of the establishment or its products by FDA.

[Learn More...](#)

Other Databases

- 510(k)s
- De Novo
- Medical Device Reports (MAUDE)
- CDRH Export Certificate Validation (CECV)
- CDRH FOIA Electronic Reading Room
- CFR Title 21
- CLIA
- Device Classification
- FDA Guidance Documents
- Humanitarian Device Exemption
- Medsun Reports
- Premarket Approvals (PMAs)
- Post-Approval Studies
- Postmarket Surveillance Studies
- Radiation-Emitting Products
- Radiation-Emitting Electronic Products Corrective Actions
- Recalls
- Standards
- Total Product Life Cycle
- X-Ray Assembler

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Establishment or Trade Name	<input type="text"/>	Registration or FEI Number	<input type="text"/>
Owner/Operator Name	<input type="text"/>	Owner/Operator Number	<input type="text"/>
Proprietary Name	<input type="text"/>	Classification Device Name	<input type="text"/>
Product Code	<input type="text"/>	Establishment Type	<input type="text"/>
Establishment State (U.S.)	<input type="text"/>	Establishment Country *	<input type="text"/>

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Need to update your information? To modify, add, or delete information, [log onto your FURLS account](#).
The changes will appear in the public registration and listing database when it is updated. Please note: There is a delay between the time that the data is uploaded and the time that the data appears in the public registration and listing database. Existing device listings may also be effected by the update and may not be fully viewable until after the update has been completed. Updates are generally completed weekly by Monday evening.

* Category includes Countries, States and Regions

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FDA

Wrong Certification



CERTIFICATE OF FDA REGISTRATION
 Certification No.: CTCSD2019377131

Dear Official Correspondent:

This document provides notification of the registration number assigned to your establishment:

Establishment:

Address:

Owner/Operator Number:
 Registration Number:

Listing Number	Premarket Submission Number	Product Code	Device Name	Activities
D2350456	Exempt	L5A	Massager, therapeutic, electric	Manufacturer

Robert Van

General Manager
 CTC REGISTRATION/CDC
 Email: ctc-ams@ctc.com
 Web: <http://www.ctc-ams.com/>



Validity: Oct. 27, 2018 - Dec. 31, 2020

Conclusion:
 This certificate makes no other representations or warranties, nor does it make any representations and warranties to any person or entity other than the named certificate holder. CTC assumes no liability to any person or entity in connection with the foregoing. The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. CTC is not affiliated with the U.S. Food and Drug Administration.


Visit official website: <https://www.fda.gov/>



CERTIFICATE

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Right Certification



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Proprietary Name:	HEALCARE RESPIRATO; HEALTHCARE RESPIRAT
Classification Name:	RESPIRATOR, SURGICAL
Product Code:	MSH
Device Class:	2
Regulation Number:	878.4040
Medical Specialty:	General & Plastic Surgery
Registered Establishment Name:	SURE ON INDUSTRIES LTD.
Registered Establishment Number:	9614598
Premarket Submission Number:	K020474
Owner/Operator:	Makrite Industries, Inc.
Owner/Operator Number:	8043227
Establishment Operations:	Contract Manufacturer; Foreign Exporter; Manufacturer

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PDI Consolidation

Kim Smith, System Director, Strategic Sourcing-Supply Chain

PDI Consolidation

From:	Lawson #	Product Description	To:	Lawson #	Alternate Product Description
Q89072	98202309	Sani-Cloth Plus - Large Canister	P13872	445547	Sani-Cloth AF3 - Large Canister
Q85084		Sani-Cloth Plus - X-Large Canister	Q86984	418361	Super Sani-Cloth - X-Large Canister
P25372		Sani-Cloth Prime - Large Canister	Q55172	S11213496	Super Sani-Cloth - Large Canister
P24284		Sani-Cloth Prime - X-Large Canister	Q86984	418361	Super Sani-Cloth - X-Large Canister
H06182		Sani-Cloth Prime - Large Packets	H04082		Super Sani-Cloth - Large Packets
U13195		Sani-Cloth Prime - X-Large Packets	U87295		Super Sani-Cloth - X-Large Packets
Q08472		Sani-Cloth HB - Large Canister	P13872	445547	Sani-Cloth AF3 - Large Canister
Q85484	440713	Sani-Cloth HB - X-Large Canister	P63884	S441678	Sani-Cloth AF3 - X-Large Canister
P03672	S458225	Easy Screen® Medium Canister	N/A		No Alternate SKU
P13472	483455	Sani-Hands® Medium Canister	N/A		No Alternate SKU
P15984	S469839	Sani-Hands Large Canister	N/A		No Alternate SKU
A580FW		Sani Professional® Table Turners	N/A		No Alternate SKU
G125DA		Sani Professional Disinfecting Wipes 100 Ct	N/A		No Alternate SKU
P22884		Sani Professional Disinfecting Wipes 200 Ct	N/A		No Alternate SKU
P56784		Sani Professional No-Rinse 95 Ct	N/A		No Alternate SKU
P66784		Sani Professional No-Rinse 175 Ct	N/A		No Alternate SKU
M30472		Sani Professional No-Rinse Multi-Surface 72 Ct	N/A		No Alternate SKU
P92084		Sani Professional 300 Ct	N/A		No Alternate SKU
P97584		Sani Professional Sani-Hands Kids BZK	N/A		No Alternate SKU



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Introduction, David Gaston

Jeff Andersen, Vice President, Payor and Market Strategy

David Gaston

- David Gaston is the System Senior Director – State Network for Strategic Healthcare Solutions as part of The University of Kansas Health System. David joined in 2020.
- David grew up in the Kanas City area and got his bachelor’s degree in Business Marketing from Baker University in 2007.
- Prior to joining The University of Kansas Health System, David worked in insurance for Colonial Life providing benefits solutions to businesses. Prior to Colonial Life, David worked for Physician’s Business Network providing business solutions to physician practices and hospitals, with a focus on billing, coding, and revenue cycle management.
- With Strategic Healthcare Solutions, David will be helping to spearhead a new initiative as part of The University of Kansas Health System, and the state Governor’s continued long running objective for the hospital to better serve the health care organizations and providers across the entire state of Kansas.



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Strategic Healthcare Solutions

Jeff Andersen, Vice President, Payor and Market Strategy

Strategic Healthcare Solutions

Strategic Healthcare Solutions is a network across Kansas designed to improve the operational efficiencies of healthcare organizations by leveraging economies of scale and strategic partnerships. The University of Kansas Health System supply chain portfolio leverages more than 92 hospitals and a \$1 billion supply spend.

By joining Strategic Healthcare Solutions, your organization will have access to the highest purchasing tier possible and the best practices for supply chain clinical integration.

In the future, we will provide additional solutions based on your needs. Future solutions may include insurance, pharmacy, EICU, reference lab and other collaborative opportunities.

We look forward to partnering with you to explore value-driven solutions for your organization.

For more information or to join our network, please contact:

David Gaston

System Senior Director, State Network

913-484-7696 | dgaston4@kumc.edu

Jeff Andersen

Vice President, Payor and Market Strategy

913-208-4748 | jandersen3@kumc.edu





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Helpful Links

Helpful Links:

Health Data:

<https://covid19.healthdata.org/projections>

Burn Rate Calculator:

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/burn-calculator.html>

PPE References and sources of evidence:

<https://protect-us.mimecast.com/s/spWICNk25yu9AzDxiREC1a?domain=ahrmm.org>

<https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html>

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-supply-strategies.html>

https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsource3respreuse.html

http://www.apic.org/Resource_/TinyMceFileManager/Advocacy-PDFs/APIC_Position_Ext_the_Use_and_or_Reus_Resp_Prot_in_Hlthcare_Settings1209I.pdf

University of Washington COVID-19 Resource Site:

<https://protect-us.mimecast.com/s/YKVqCkRIONhrEDr2T2RTRq?domain=covid-19.uwmedicine.org>

US Food and Drug Website:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm>

National Institute for Occupational Safety and Health:

<https://www.cdc.gov/niosh/srchpage.html>

Sg2 COVID-19 Surge Demand Calculator:

<https://www.sg2.com/sg2-covid-19-surge-demand-calculator/>

https://www.vizientinc.com/covid-19?covid19_home_slider



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Questions and Closing

Thank you!