

THIS TEMPLATE IS TO BE USED AS A BASE FOR WRITING AN INSTRUCTIONS FOR USE (IFU) MANUAL FOR YOUR DEVICE. WHERE APPROPRIATE ADD MORE INFORMATION TO COVER ALL ASPECTS OF YOUR DEVICE FROM MANUFACTURING TO CLEANING AND USE.

THIS DOCUMENT IS TO SERVE AS A BEGINNING OF A DRAFT FOR SUBMISSION TO NIH DURING COVID19 RESPONSE.

ANY CLAIMS MADE REGARDING YOUR DEVICE IN THIS IFU NEED TO BE SUPPORTED BY SUBMISSION OF TESTING DATA WHEN APPROPRIATE.

(DEVICE NAME) - Instructions for Use

These instructions for use correspond to **Revision (#)** of the **(DEVICE NAME)**. **(IF DEVICE HAS LABEL ON IT INCLUDE WHERE SUCH LABEL CAN BE FOUND)**

Appropriate Use Criteria

This supplementary **(DEVICE DESCRIPTION)** was created as an emergency action in effort to provide protection as a backup Personal Protective Equipment (PPE) option if the traditional PPE devices have become unavailable. This device has not gone through the same regulatory approval process as traditional PPE, but has gone through a special verification process expedited strictly for the response to the COVID-19 pandemic.

This device is intended to be use only for the duration of the public health emergency related to COVID-19 declared by the Department of Health and Human Services (HHS), including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (PHS Act). The decision to implement this device should be made with careful consideration and under the consultation of the corresponding institution's occupational health and infection control departments.

(INSERT DEVICE DESCRIPTION AND APPROPRIATE REFERENCE FOR AN FDA GUIDANCE DOCUMENTS THAT CORRELATES TO DEVICE. IF APPROPRIATE INCLUDE DEFERENCE FOR USAGE PER CDC, OSHA, FDA OR NIOSH)

(INSERT ANY APPLICABLE NOTICE REGARDING WARNINGS FOR USAGE OF DEVICE)

The information included in this document provides device description and feature overview, recommended assembly steps, and cleaning instructions for reuse.

Device Overview

(OVERVIEW OF DEVICE, DESCRIPTION OF PARTS, AND FEATURES OF DEVICE).
INCLUDE IMAGE OF DEVICE AS FIG. 1.

(DESCRIBE ASSEMBLY, AND ANY ADDITIONAL PARTS WHICH MAY NEED TO BE
PURCHASED SEPARATE FROM DIVICE. INCLUDE EXACT SKU NUMBERS OR
REFERENCE LINKS FOR THOSE.)

(BRIEFLY DESCRIBE IF AND HOW DEVICE CAN BE DISINFECTED)

See Appendix A for recommended disinfecting solutions and sterilization methods for this
device. (INCLUDE ALL TESTED METHODS FOR DISINFECTION AND/OR STERLIZATION
OF DEVICE)

See Appendix B for guidelines on material selection. (INCLUDE ALL POTENTIAL MATERIALS
TO BE USED FOR DEVICE)

Components to be disposed of after every use or immediately after potential
contamination by bodily fluids: (INCLUDE IF APPLICABLE)

-
-
-
-

Components to be disinfected and reused: (INCLUDE IF APPLICABLE)

-
-

(INCLUDE LABELED IMAGE OF DEVICE)

Fig. 1

Point of Care Assembly and Cleaning Instructions

For instruction on how to properly assemble, clean, and reassemble for reuse of (DEVICE NAME), please refer to the steps outlined below.

Assembly Steps

(INCLUDE DETAILED STEP BY STEP INSTRUCTIONS FOR ASSEMBLY OF DEVICE. ATTACHING ADDITIONAL IMAGES FOR DESCRIPTION AND ASSEMBLY STEPS OF Y DEVICE WHERE APPROPRIATE. MAKE SURE TO INCORPORATE THE FOLLOWING STEPS AS PART OF ASSEMBLY INSTRUCTIONS:

- I. FINA A CLEAN DISINFECTION INVIRONMENT TO WORK IN
- II. DON A PAIR OF CLEAN GLOVES
- III. DO FINAL INSPECTION OF OUR DEVICE PRIOR TO DELIVERY

(INCLUDE CDC, FDA, OSHA OR NIOSH LINKS TO OFFICIAL WEBSITES WHICH DESCRIBE GUIDELINES FOR USAGE OF DEVICE WHEN APPROPRIATE, EXAMPLES OF SUCH DEVICES INCLUDE: FACE MASKS, FACE SHIELDS, GOWNS, GLOVES, FACE HOODS, ETC.)

Recommended Cleaning

The recommended materials selected for making the reusable components of this (DEVICE NAME) have a proven track record for remaining stable during and after the use of the list of disinfectants and sterilization process outlined in Appendix A. However, there has been no formal testing completed yet to support the claim that the use of disinfectants alone is a sufficient cleaning approach against the COVID19 virus specifically on the surface of this material.

Because of this, it is recommended that the following disinfection and sterilization steps are performed after each user is finished using (DEVICE NAME) and the user has followed the proper procedures for doffing the device.

(INCLUDE APPROPRIATE STEPS FOR CLEANING OF DEVICE. ONLY TESTED METHODS SHOULD BE INCLUDED)

MAKE SURE YOU ARE USING EPA REGISTERED DEVICES FOR COVID19. NOTE WHICH DISINFECTANTS WERE USED DURING TESTING.

[EPA guidelines in List N: Disinfectants for Use Against SARS-CoV-2.](#)

Preparing the Supplementary Mask for Reuse.

(INCLUDE STEPS FOR PROPER HANDLING AND ASSEMBLY OF DEVICE PRIOR TO REUSE. ADD IMAGES WHERE APPROPRIATE)

Appendix A: Recommended Disinfectants and Sterilization Methods

From FDA guidelines on [Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 \(COVID-19\) Public Health Emergency](#) released March 2020 it is recommended that “this policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Department of Health and Human Services (HHS), including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (PHS Act)”. The policy recommends to use an approved disinfection agent as it should “minimize the viability of SARS-CoV-2” on the surface of **(DEVICE NAME)**.

Recommended Disinfecting Agents:

From the [EPA guidelines in List N: Disinfectants for Use Against SARS-CoV-2](#), it is recommended to use the following solutions for the disinfecting procedures of this device.

(INCLUDED A LIST OF TESTED DISINFECTION AGENTS WHICH YOU HAVE EVALUATED)

Recommended Sterilization Method: **(WHEN APPLICABLE)**

Below is a table outlining the sterilization parameters that are recommended to be used for autoclave sterilization processing.

(INCLUDE APPROPRIATE PARAMETERS AND EQUIPMENT TO STERILIZE DEVICE. ONLY INCLUDE TESTED METHODS OF STERILIZATION)

(INCLUDE ANY ADDITIONAL NOTES FOR INSPECTION OR TESTING OF DEVICE AFTER STERILIZATION)

Appendix B: Recommended Materials

(INCLUDE ALL MATERIALS FOR CONSIDERATION IN MAKING OF DEVICE. INCLUDE AS MUCH DETAIL AS POSSIBLE (SUPPLIER, SKU NUMBERS, ETC) AND WHERE APPROPRIATE LIST ANY SUBSTITUTES AND ASTM STANDARDS THESE SUBSTITUTE MATERIALS NEED TO MEET IN ORDER TO QUALIFY FOR APPROPRIATE MATERIALS USED IN DEVICE MANUFACTURING.)

Appendix C: Materials in Direct Contact with Skin

(LIST ANY MATERIALS, AND DETAILS FOR SAID MATERIALS WHICH MAY COME IN CONTACT WITH SKIN OF A USER. INCLUDE DESCRIPTION OF THOSE PARTS AND MATERIALS.)