NANO HACK MAVERICK
A REUSABLE GENERAL USE FACE MASK
Specially designed to be manufactured using injection molding and additive manufacturing
By Copper3D

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https://www.3dprintlife.com/
NANOHACK MAVERICK - Instructions for Use

These instructions for use correspond to Revision (#1) of the NANOHACK MAVERICK. This mask design is open source and the digital files for injection molding and additive manufacturing are available at the NIH 3D Print Exchange: https://3dprint.nih.gov/collections/cov

Appropriate Use Criteria

This supplementary general use face mask 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.

NANOHACK MAVERICK is a general use face masks that protects the wearer from physically contaminating their mucous membranes (mouth and nose) with virus on their hands, and additionally decrease the risk of asymptomatic COVID positive wearers of the mask unintentionally transmitting the virus. These are not intended for use by health care professionals in a health care setting. These may or may not meet fluid barrier or filtration efficiency levels. The information included in this document provides device description and feature overview, recommended assembly steps, and cleaning instructions for reuse.
Device Overview

The purpose of the NANO HACK MAVERICK facemask is to offer the general population a degree of protection from airborne particles and prevent spreading liquid contaminating the airways. The NANO HACK MAVERICK facemask is not intended for use as a medical device.

The filtration system used in the NANO HACK MAVERICK consists of a triple layer of variable density non-woven polypropylene material, an antiviral net, and a locking system (Fig. 1). According to the manufacturer specifications the Bacterial Filtration Efficiency (BFE) ranges from 98.9% to 99.9%, blocking up to 99.9% of particulates. This filter system has been tested under the OSHA protocol with a filtration result equivalent to N99 (Protocol OSHA 29CFR1910.134, Test method: QNFT using TSI PortaCount; see testing report attached).

This mask design can be fabricated using additive manufacturing or using injection molding. We are providing two different types of files.

The injection molded or 3D printed version can be purchased from the 3D Print Life website: https://www.3dprintlife.com/

See Appendix A for recommended disinfecting solutions and sterilization methods for this device.

See Appendix B for guidelines on material selection.

Components to be disinfected and reused:
- All components described in figure 1, including mask structure, fasteners (with elastics), internal sealing ring, internal filtering ring, and external cap.
- We recommend changing the non-woven polypropylene every day or after 12 hours of use (Figure 1).

Figure 1. NANO HACK MAVERICK Structure (Injection molded version).
Point of Care Assembly and Cleaning Instructions

For instruction on how to properly assemble, clean, and reassemble for reuse of NANO HACK MAVERICK, please refer to the steps outlined below.

Assembly Steps (Injection molded version)

The injection molded version of nanohack maverick comes completely assembled with 5 extra disposable filters. The injection molded version can be purchased from the 3D print life website: https://www.3dprintlife.com/

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

Assembly Steps (3D printed version)

AFTER ALL THE PARTS ARE PRINTED AND POST-PROCEESED:
I. FINA A CLEAN DISINFECTION INVIRONMENT TO WORK IN
II. DON A PAIR OF CLEAN GLOVES
III. USE INTERNAL RING AS A TEMPLATE TO CUT SEVERAL CIRCLES FROM A STTDARD SURIGICAL MASK
IV. PLACE CIRCLE FROM SURICAL MASK INSIDE INTERNAL RING AND FILTER CAP
V. SCREW CAP ON THE 3D PRINTED MASK
VI. PLACE ELASTIC ON THE CHANNELS OF MASK
VII. DO FINAL INSPECTION OF OUR DEVICE PRIOR TO DELIVERY
Health and Safety Practices

https://www.cdc.gov/niosh/topics/healthcarehsp/respiratory.html

Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators

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

Considerations for Wearing Masks


How to Select, Wear, and Clean Your Mask

**Recommended Cleaning**

The recommended materials selected for making the reusable components of NANOHACK MAVERICK 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 NANOHACK MAVERICK and the user has followed the proper procedures for doffing the device.

See Appendix A for recommended disinfecting solutions and sterilization methods for this device.

**Preparing the Supplementary Mask for Reuse.**

**How to take off mask and reuse it**

1. Carefully, untie the strings behind your head or stretch the ear loops.
2. Handle only by the ear loops or ties.
3. Place the mask in disinfectant solution or spray it thoroughly.
4. Be careful not to touch your eyes, nose, and mouth when removing and wash hands immediately after removing.

After washing the mask, rinse it and dry it before using it again.
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 NANOHACK MAVERICK.

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: Formulations such as spray bottles and wipes containing bleach solutions contain 5% sodium hypochlorite or ethyl alcohol (70%) have shown to be effective.

Recommended Sterilization Method:

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

NANOHACK MAVERICK Steps for Cleaning and Disinfection (World Health Organization)

Personal protective equipment is required when cleaning or processing equipment and instruments, to protect against splashing, spraying or aerosols.

1. **Washing**: Wash the equipment with soap (e.g. liquid dish soap) and clean water.
2. **Rinsing**: Rinse the equipment completely with clean water.
3. **Disinfect**: Disinfect the equipment to inactivate any remaining pathogens. Use chemical disinfection if plastic part cannot tolerate 80°C. Different countries have different disinfection protocols. Here are the most accessible chemical germicides and methods:
   3.1. Method 1: Alcohol is effective against influenza virus. Ethyl alcohol (70%) is a powerful broad-spectrum germicide and is considered generally superior to isopropyl alcohol. Since alcohol is flammable, limit its use as a surface disinfectant to small surface-areas and use it in well-ventilated spaces only. Prolonged and repeated use of alcohol as a disinfectant can also cause discoloration, swelling, hardening and cracking of rubber and certain plastics.
   3.2. Method 2: Most household bleach solutions contain 5% sodium hypochlorite (50,000 parts per million available chlorine). Recommended dilution: 1:100 dilution of 5% sodium hypochlorite is the usual recommendation. Use 1-part bleach to 99 parts cold tap water (1:100 dilution) for disinfection of surfaces. Adjust ratio of bleach to water as needed to achieve appropriate concentration of sodium hypochlorite. For example, for bleach preparations containing 2.5% sodium hypochlorite, use twice as much bleach (i.e. 2 parts bleach to 98 parts water).

1. **Rinsing**: If using chemical disinfection, rinse with sterile or clean water (i.e. water boiled for 5 minutes and cooled). Sterile water is preferred for rinsing off residual liquid chemical disinfectant from a respiratory device that has been chemically disinfected for reuse, because tap or distilled water may harbour microorganisms that can cause pneumonia.
However, when rinsing with sterile water is not feasible, instead, rinse with tap water or filtered water (i.e. water passed through a 0.2 µ filter). Disinfection by immersion is recommended with a contact time of 30 minutes.

2. **Dry equipment**: Follow the previous step by an alcohol rinse and forced-air drying.

3. **Store**: Store equipment dry in closed packages.
Appendix B: Recommended Materials

Additive Manufacturing

Biocompatibility: The material used to manufacture this 3D printed face mask Polylactic Acid (PLActive) and Thermoplastic polyurethane (MDFlex), have been considered as “non-cytotoxic” and safe for skin contact under ISO 10993-5 Biological Evaluation of Medical Devices-Part 5 (Tests for in vitro cytotoxicity), ISO 10993-10 Biological evaluation of medical devices Part 10 (Tests for irritation and skin sensitization) and ISO 1093-12 Biological evaluation of medical devices Part 12 (Sample preparation and reference materials).

Injection Molding

Biocompatibility: Styrene-ethylene-butylene-styrene (SEBS). Injection molding is a manufacturing process for producing parts by injecting molten material into a mold. Injection molding will be performed using an SEBS polymer. has been considered as “non-cytotoxic” and safe for skin contact under ISO 10993-5 Biological Evaluation of Medical Devices-Part 5 (Tests for in vitro cytotoxicity), ISO 10993-10 Biological evaluation of medical devices Part 10 (Tests for irritation and skin sensitization) and ISO 1093-12 Biological evaluation of medical devices Part 12 (Sample preparation and reference materials).

See biocompatibility tests attached
Appendix C: Materials in Direct Contact with Skin

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