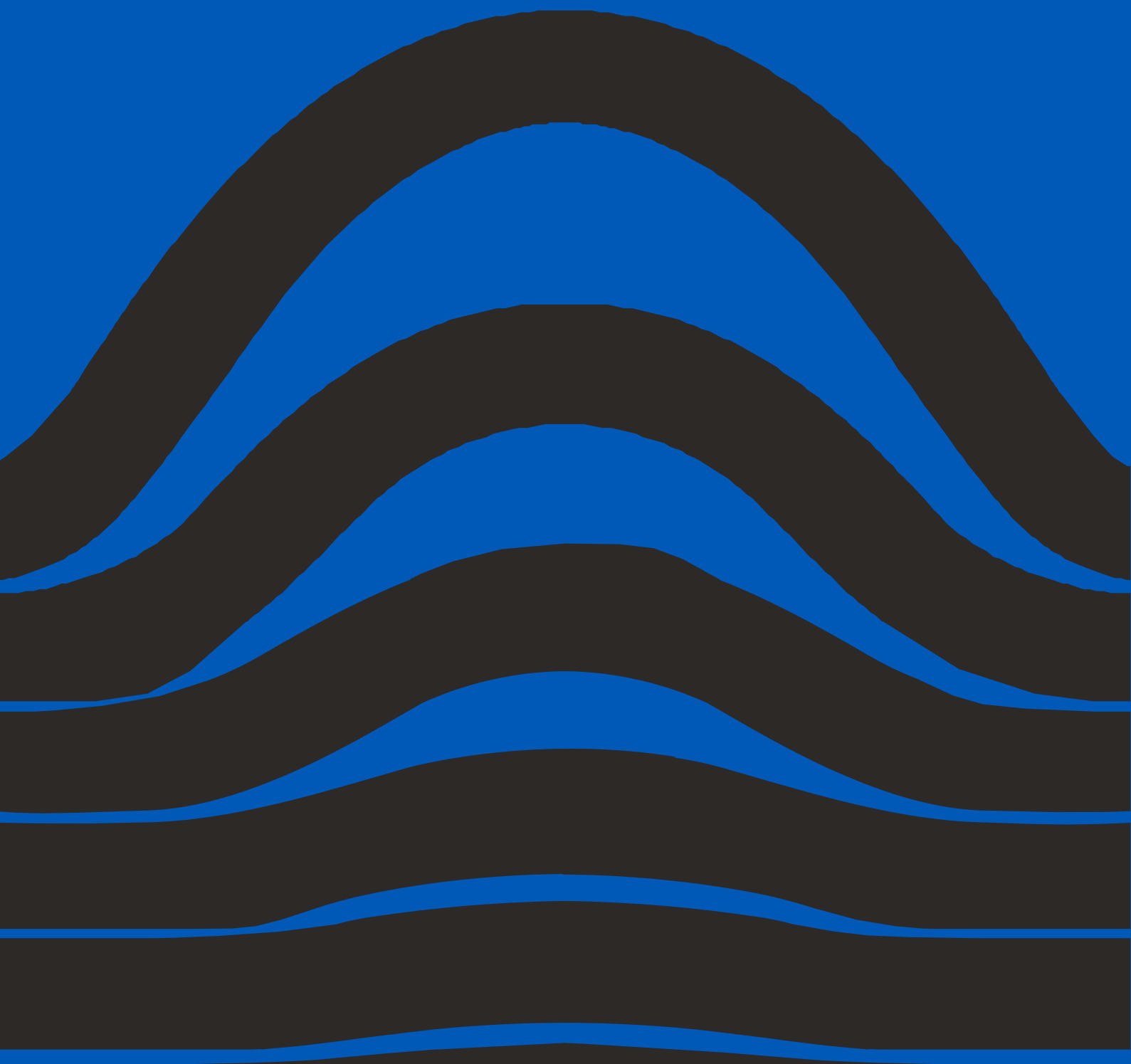




Safety protocol for optical centres



Legal advice

These protocols have been prepared to provide general information about applicable safety recommendations for global use. Please understand that the recommended practices may change over time and different localities may have additional safety and hygiene requirements applicable to its respective local businesses and residents.

Accordingly, these protocols should not be a substitute for your clinical judgement, and you should also check with your provincial government and public health authority to determine whether there are any additional local rules, orders or guidelines applicable to your business. Retailers and stores are strongly advised to follow all the guidelines issued from time to time by the local public health authority and government bodies on how to protect yourself and others from COVID 19.

These guidelines are being distributed without warranty of any kind, either express or implied. These guidelines are being issued for information purposes only. Hoya and its employees and agents shall not be liable for any reasons whatsoever to users of this document for any loss, damage, claim, compensation, fees, damages, cost (including attorney fees), fines, expense or consequential damages incurred or arising by reason of any person using or relying on the information, whether caused by reason of any error, negligent act, omission or misrepresentation in the Information or otherwise.

These guidelines and its recommendations provided a general overview of the present publicly available information at the time these guidelines were prepared and are not intended to provide or substitute for legal or regulatory advice or counsel.

The protocol has been reviewed and approved for this purpose and use only by Pentax Medical Europe Reprocessing and Infection Control Leader.

Introduction

As a result of the health risk that has emerged over the last the last several months, it is important to consider certain procedures and protections to limit contagion and preserve your health and your patients' health. *

The rules are based on the transmission of the virus which happens primarily with the release of droplets from the upper respiratory tract. Infection prevention must be focused on droplet prevention.

The purpose of all hygiene measures is to reduce the load of pathogens, considering the source of infection and transmission path, in order to not transmit infection to patient or vice versa.

This protocol therefore contains a collection of measures to be implemented in optical centres, in line with the health authorities' indications. The hygiene protocol has been developed following the three main phases of the patient journey, in addition to the general rules.

Protocol structure



Before the visit

Management of appointments and entrance in-store



Inside the shop

Visual check inside of the refraction room, eyewear selection inside the store and its video centration



After the visit

Preparation and delivery of the glasses to the patient and payment



General rules



Appendix



Before the visit: New needs requirements



Increase online enquiries



Limit attendance inside
the optical centre



Optimize time of each visitor
inside the Optical Centre





Before the visit: New practices

a. Appointment management

Appointments for visits, frame choice or eyewear delivery will have to be taken:

- By phone or message
- In store only in limited cases

Appointments should be managed in different time slots to avoid overlapping of waiting patients and crowding inside the store. It's also important to make a pre anamnesis in order to prepare the visit.

During the booking, request that patients visit the shop wearing a mask* and by themselves, or only with necessary people. If patients do not have a mask, the optical centre should provide it.

Ask the patient if in the last 14 days they have had contact with individuals who tested positive for COVID-19 or presented flu (cough, sneeze..) or fever symptoms (over 37.5°)
If one of the following points is positive, the appointment must be made at least 14 days later.

It is the patient's responsibility to inform the Optical Center if he or she manifests the symptoms again in the vicinity of the appointment so that it can be postponed.

*if requested by local rules





Before the visit: New practices

b. Entrance in the Optical Centre



Unless the store locks and unlocks the door to manage flow, a member of staff will need to be allocated to manage incoming patients.

It is necessary to define and communicate the maximum number of people allowed in store, to accommodate minimum interpersonal distance, and avoid crowding.

The maximum number of people depends on store layout and size (sq. ft.) guaranteeing from 1.5 to 2 meters, (approx. 6 ft.) distance or according to local rules.

All patients are asked to thoroughly sanitize their hands when entering the optical centre. Appropriate, approved disinfection services shall be made visible to patients in the entrance area.

It is suggested to have a people managing in/out in order to guarantee common safety.

c. Reception of patients inside

Avoid handshakes and unnecessary contact to ensure complete security and peace of mind.



*ACCORDING TO THE WORLD HEALTH ORGANIZATION (WHO), POINT OF CARE IS THE PLACE WHERE THREE ELEMENTS COME TOGETHER: THE PATIENT, THE HEALTH CARE WORKER AND CARE OR TREATMENT INVOLVING CONTACT WITH THE PATIENT OR THEIR SURROUNDINGS, WITHIN THE PATIENT ZONE. THE PATIENT ZONE IS DEFINED AS THE AREA WITHIN A RADIUS OF 6.5 FEET FROM THE POINT OF CARE.



Inside the shop: New needs requirements



Respect the distance
given by current regulations



Optimize timing of
"frame selection"

There should be a marker on the floor showing where patients stand or footprints to show where patients should go. If there is a waiting area, make sure chairs are an appropriate distance apart. Do not have reading materials in the waiting area.





Inside the shop: New practices

a. Refraction - visual check

Try not to get too close with patients and keep a safe distance during eye exam. Always sanitize hands and use a mask/visor before interacting with/ touching any patient.

Hygienically discard anything used to wipe the eye secretions or tears (such as a paper towel etc.,)

Allow only examiner and examinee in the examination room during eye exams.

The use of digital tools is strongly recommended as they allow a better sanitation than the paper tools.

- All instruments and equipment must be disinfected before and after use, especially forehead pads, cheek pads and mandibular pads.
- If it is necessary to work closely between examiner and examinee (e.g. using a slit lamp), use a special plexiglass sneeze shield on the instrument. *

In case of traditional instruments, it is important to check if the optotype in use is a disinfectable plasticised Optotype.

*PLEASE ACTIVELY CONSULT ALL YOUR EQUIPMENT SUPPLIERS FOR DETAILS REGARDING THE PROTECTION AND SAFE USAGE OF THE EQUIPMENT DURING THESE TIMES.



Inside the shop: New practices

b. Frame selection

The frame selection represents a strong point of contact with the patient and it requires a long time in the optical centre. As such, it is important to follow some basic rules for the sanitation of display glasses.

- Sanitize displayed glasses daily and communicate to the patients that daily cleaning is the policy of the clinic and if the patient requests, re-sanitize in front of him.
- Sanitize selected frames that the patient handles after use.

After the trial, place the glasses on a tray, for immediate cleaning after they've been worn.





Inside the shop: New practices

c. Video centration



The fitting phase requires close proximity to the patient's face.

This is why modern video centration systems can help considerably in hygienic safety.

When using standard or manual instruments, because of close distance between ECP's and patients' mouths, it is necessary:

- Thoroughly sanitize pupillometers, including the forehead bar and nose pads, and use a mask or special plexiglass sneeze shield with the instrument
- In case of manual centration, sanitize hands and use a visor with mask.
- Clean all devices after each patient regardless whether gloves are used.





After the visit: New needs requirements



Optimize time waiting in the
Optical Centre



Sanitized eyewear delivery





After the visit: New needs requirements

a. Glasses preparation or repair:



During mounting, all instruments used must be sanitized.

On delivery, sanitize the eyeglasses in front of the patient, using:

- UV lamp UV-C*
- Sanitize cloths or sprays

b. Delivery

- Sanitize your hands before delivery and adjust the glasses on the patient's face wearing a mask and visor.
- Release a leaflet certifying the glasses hygiene status and advise patient on how to keep glasses clean at home.
- Suggest the purchase of appropriate sanitizing cloths/sprays and any anti-fog cloths/spray to facilitate the use of the glasses with the mask.



*NOTE THAT THIS SHOULD BE DEVICES APPROVED FOR THE INTENDED USE OF SANITIZING/ DECONTAMINATION THESE OBJECTS (GLASSES, FRAMES).



General rules

- Everyone inside the store (familiar, staff) will need to be trained on the new rules.
- Hygiene guidance about distancing, cleaning, and protection should be sign posted around the store.



General hygiene rules and sanitizing the environment



SANITIZE HANDS, USE A DISPOSABLE MASK* AND VISOR

Always wear a mask and visor when entering the refraction room or approach the patient's face for eyeglass adjustment.

GLOVES

Penetration resistant, single use / disposable, non-sterile, hypoallergenic

- Change gloves if they become torn or heavily contaminated
- Remove and discard after each patient
- Immediately wash hands after each patient
- Gloves are not necessary if proper hand sanitizing is performed by the ECP.

MASK

Disposable, single use. High-risk recommendation: N95/FFP-2 without valve. Low risk: surgical mask

- Remove and discard after each patient. If masks are indicated for reuse, decontaminate them conforming to the manufacturer's instructions

GOWN

Due to the kind of tasks performed (examination) and the working area (risk assessment), it's not necessary to wear gowns.



*WHEN REQUESTED

**NOTE THAT THIS SHOULD BE DEVICES APPROVED FOR THE INTENDED USE OF SANITIZING/DECONTAMINATION THESE OBJECTS (GLASSES, FRAMES).



General hygiene rules and sanitizing the environment



- FREQUENTLY SANITIZE HANDS* prior to each patient visit, rub with hand sanitizer in front of the patient.
- MAKE SANITIZER DISPENSER* OR GLOVES AVAILABLE to patients within the store.
- SANITIZE ALL WORK TOOLS AND DIGITAL DEVICES before each use in front of the patient and/or after each patient (e.g. video camera systems, auto refractometer, reunion and armchair, phoropter, trial frame, tablet, etc.)
- SANITIZE ALL SURFACES TOUCHED BY PATIENTS, after each patient, e.g. bathroom fixtures, light switches, doorknobs, front desk counters and chair arms.
- USE DISPOSABLE MATERIAL e.g. tear substitutes, wipes, saline solution, etc.
- USE ULTRASOUND SYSTEMS for deep cleaning of the frame (without lenses).
- USE SPECIAL UV-C LAMPS that disinfect the glasses (without lenses).
- USE ANTI-FOG CLOTHS in case you're wearing glasses along with the mask.
- AIR THE PREMISES NATURALLY to encourage air recycling.
- TO ENFORCE THE SAFETY DISTANCE by indicating the safety distance on the ground and with appropriate signs to respect.
- CLEARLY MARK RULES AT THE ENTRANCE and inform each patient when they can go inside.

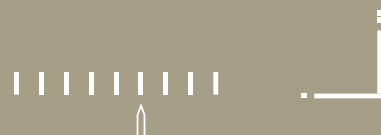


* AN INSTALLING WALL-MOUNTED AUTOMATIC HAND SANITIZER UNITS IS THE BEST OPTION, OR ONE ON A STANDARD. THESE NO-TOUCH DISPENSERS ARE MORE APPROPRIATE THAN THE ONES THAT REQUIRE YOUR HAND TO TOUCH THE PUMP.



Appendix

Details and original sources

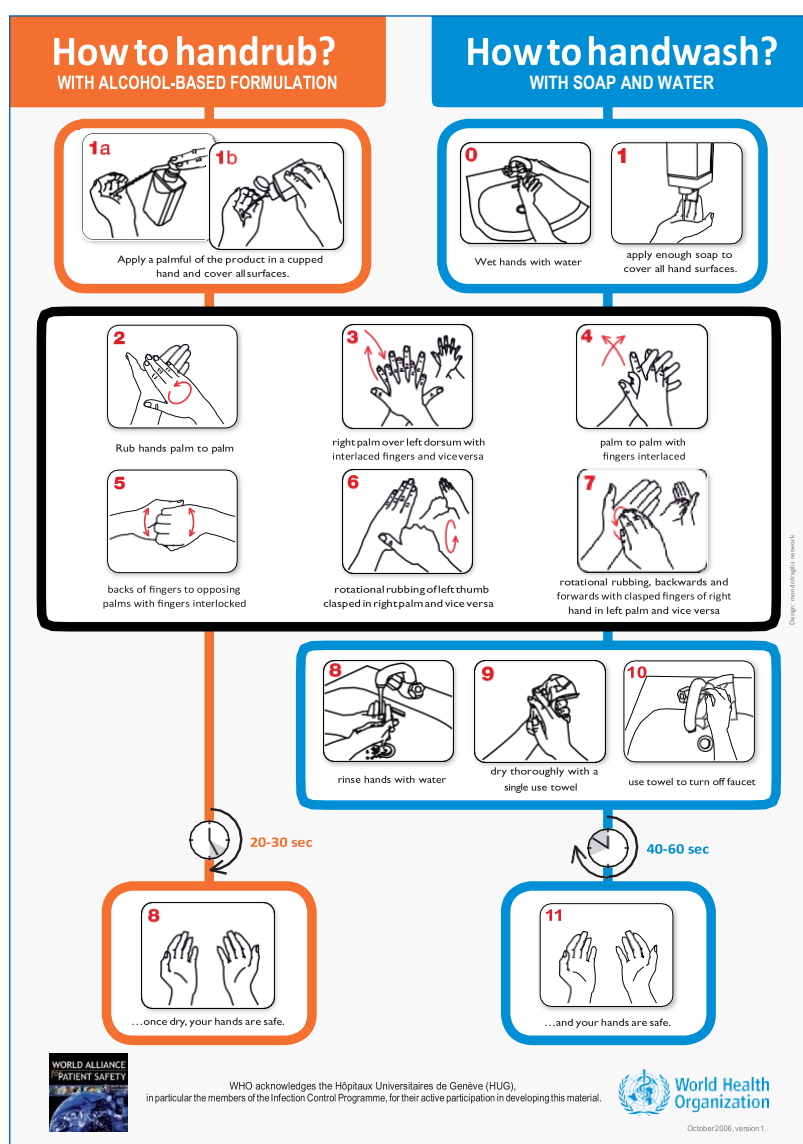




Appendix 1

To sanitize hands, use an alcohol-based hand sanitizer for at least 30 seconds. Wash hands with water and soap if visible soiled / contaminated or no hand sanitizer is available.

See the rules in the picture on how to wash and correctly rub your hands.



Video:

<https://www.youtube.com/watch?v=B3eq5fLzAOo>

Link World Health Organization:

<https://www.who.int/gpsc/tools/GPSC-HandRub-Wash.pdf>



Appendix 2

Video centration

The centration phase requires a close distance to the patient's face. As such, modern video centration systems can help considerably. Correct centration in complete hygienic safety can be carried out using:

- a) Video Measurement Tools: without support on the eyeglass; maintain correct distance with the patient.
- b) Portable Video Measurement Tools: one metre distance from the patient. However, if is necessary to place the support on the patient's glasses – always sanitize the centration support properly and use the visor mask.



Appendix 3

How to sanitize

- Instruments, digital devices*: To clean, use microfiber cloths. To sanitize, use a wipe with a minimum of 70% alcohol (ethanol, propanol, or a product based on this).
- General surfaces* – Use products based on:
 - more than 70% alcohol (ethanol, propanol)
 - a disinfectant based on Sodium Hypochlorite (0,1-0,5%).
- Frames: Ophthalmic frames are made with a variety of materials; be aware that different frame materials exhibit different chemical reactions to isopropyl alcohol and sanitizers with high alcohol content. Water and specific detergent or UV-C lamp can be a solution. In both cases we suggest you refer to manufacturer's product specs.
- Lenses: clean with gentle soap and water or alcohol-based sanitizer and denatured alcohol.

Cleaning And Disinfecting Your Facility

Everyday Steps, Steps When Someone is Sick, and Considerations for Employers

How to clean and disinfect

Wear disposable gloves to clean and disinfect.

Clean

- **Clean surfaces using soap and water.** Practice routine cleaning of frequently touched surfaces.

High touch surfaces include:

Tables, doorknobs, light switches, counters, handles, desks, phones, keyboards, rollers, faucets, sinks, etc.

Disinfect

- Clean the area or item with soap and water or another detergent if it is dirty. Then, use a household disinfectant.
- **Recommend use of EPA-registered household disinfectants.** Follow the instructions on the label to ensure safe and effective use of the product.

Many products recommend:

- Keeping surface wet for a period of time (see product label)
- Precautions such as wearing gloves and making sure you have good ventilation during use of the product.

Diluted household bleach solutions may also be used if appropriate for the surface. Check to ensure the product is not past its expiration date. Uncipent household bleach will be effective against coronaviruses when properly diluted.

Follow manufacturer's instructions for application and proper ventilation. Never mix household bleach with ammonia or any other cleanser.

Leave solution on the surface for at least 1 minute

To make a bleach solution, mix:

- 5 tablespoons (1/3rd cup) bleach per gallon of water

OR

- 4 teaspoons bleach per quart of water

Alcohol solutions with at least 70% alcohol.

Soft surfaces

For soft surfaces such as **carpeted floor, rugs, and drapes**

- **Clean the surface using soap and water** or with cleaners appropriate for use on these surfaces.

CDC

[cdc.gov/coronavirus](https://www.cdc.gov/coronavirus)

See the link to underline how to clean or disinfect your facilities
<https://www.cdc.gov/coronavirus/2019-ncov/community/disinfecting-building-facility-H.pdf>



Appendix 4

Personal protective equipment (PPE)

How to safely put on and remove PPE.

PDF:

<https://www.cdc.gov/hai/pdfs/ppe/ppe-sequence.pdf>

Video:

https://www.youtube.com/watch?v=iOnYD3A_XY4

SEQUENCE FOR PUTTING ON PERSONAL PROTECTIVE EQUIPMENT (PPE)

The type of PPE used will vary based on the level of precautions required, such as standard and contact, droplet or airborne infection isolation precautions. The procedure for putting on and removing PPE should be tailored to the specific type of PPE.

- 1. GOWN**
 - Fully cover torso from neck to knees, arms to end of wrists, and wrap around the back
 - Fasten in back of neck and waist
- 2. MASK OR RESPIRATOR**
 - Secure ties or elastic bands at middle of head and neck
 - Fit flexible band to nose bridge
 - Fit snug to face and below chin
 - Fit-check respirator
- 3. GOGGLES OR FACE SHIELD**
 - Place over face and eyes and adjust to fit
- 4. GLOVES**
 - Extend to cover wrist of isolation gown

USE SAFE WORK PRACTICES TO PROTECT YOURSELF AND LIMIT THE SPREAD OF CONTAMINATION

- Keep hands away from face
- Limit surfaces touched
- Change gloves when torn or heavily contaminated
- Perform hand hygiene




HOW TO SAFELY REMOVE PERSONAL PROTECTIVE EQUIPMENT (PPE) EXAMPLE 1

There are a variety of ways to safely remove PPE without contaminating your clothing, skin, or mucous membranes with potentially infectious materials. Here is one example. Remove all PPE before exiting the patient room except a respirator, if worn. Remove the respirator after leaving the patient room and closing the door. Remove PPE in the following sequence:

- 1. GLOVES**
 - Outside of gloves are contaminated!
 - If your hands get contaminated during glove removal, immediately wash your hands or use an alcohol-based hand sanitizer
 - Using a gloved hand, grasp the palm area of the other gloved hand and peel off first glove
 - Hold removed glove in gloved hand
 - Slide fingers of ungloved hand under remaining glove at wrist and peel off second glove over first glove
 - Discard gloves in a waste container
- 2. GOGGLES OR FACE SHIELD**
 - Outside of goggles or face shield are contaminated!
 - If your hands get contaminated during goggles or face shield removal, immediately wash your hands or use an alcohol-based hand sanitizer
 - Remove goggles or face shield from the back by lifting head band or ear pieces
 - If the lens is reusable, place in designated receptacle for reprocessing. Otherwise, discard in a waste container
- 3. GOWN**
 - Gown front and sleeves are contaminated!
 - If your hands get contaminated during gown removal, immediately wash your hands or use an alcohol-based hand sanitizer
 - Lift gown from back, taking care that sleeves don't contact your body when reaching for ties
 - Roll gown away from neck and shoulders, touching inside of gown only
 - Turn gown inside out
 - Fold and roll into a bundle and discard in a waste container
- 4. MASK OR RESPIRATOR**
 - Front of mask/respirator is contaminated — DO NOT TOUCH!
 - If your hands get contaminated during mask/respirator removal, immediately wash your hands or use an alcohol-based hand sanitizer
 - Grasp bottom tie or elastic of the mask/respirator, then the area at the top, and remove without touching the front
 - Discard in a waste container
- 5. WASH HANDS OR USE AN ALCOHOL-BASED HAND SANITIZER IMMEDIATELY AFTER REMOVING ALL PPE**

PERFORM HAND HYGIENE BETWEEN STEPS IF HANDS BECOME CONTAMINATED AND IMMEDIATELY AFTER REMOVING ALL PPE




HOW TO SAFELY REMOVE PERSONAL PROTECTIVE EQUIPMENT (PPE) EXAMPLE 2

Here is another way to safely remove PPE without contaminating your clothing, skin, or mucous membranes with potentially infectious materials. Remove all PPE before exiting the patient room except a respirator, if worn. Remove the respirator after leaving the patient room and closing the door. Remove PPE in the following sequence:

- 1. GOWN AND GLOVES**
 - Gown front and sleeves and the outside of gloves are contaminated!
 - If your hands get contaminated during gown or glove removal, immediately wash your hands or use an alcohol-based hand sanitizer
 - Grasp the gown in the front and pull away from your body so that the front belt, breaking outside of gown only with gloved hands
 - While removing the gown, fold or roll the gown inside-out into a bundle
 - As you are removing the gown, and off your gloves at the same time, only touching the inside of the gloves and gown with your bare hands. Place the gown and gloves into a waste container
- 2. GOGGLES OR FACE SHIELD**
 - Outside of goggles or face shield are contaminated!
 - If your hands get contaminated during goggles or face shield removal, immediately wash your hands or use an alcohol-based hand sanitizer
 - Remove goggles or face shield from the back by lifting head band and without touching the front of the goggles or face shield
 - If the lens is reusable, place in designated receptacle for reprocessing. Otherwise, discard in a waste container
- 3. MASK OR RESPIRATOR**
 - Front of mask/respirator is contaminated — DO NOT TOUCH!
 - If your hands get contaminated during mask/respirator removal, immediately wash your hands or use an alcohol-based hand sanitizer
 - Grasp bottom tie or elastic of the mask/respirator, then the area at the top, and remove without touching the front
 - Discard in a waste container
- 4. WASH HANDS OR USE AN ALCOHOL-BASED HAND SANITIZER IMMEDIATELY AFTER REMOVING ALL PPE**

PERFORM HAND HYGIENE BETWEEN STEPS IF HANDS BECOME CONTAMINATED AND IMMEDIATELY AFTER REMOVING ALL PPE



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