
Working With Contaminated or Suspected Contaminated Medical Devices SOP # ABCD-14-16-40007

WORKING WITH CONTAMINATED OR SUSPECTED CONTAMINATED MEDICAL DEVICES – BIOMEDICAL ENGINEERING

1. Purpose

As defined in [Policy #ABCD-14-11-40004](#), employees of the Lower Mainland Biomedical Engineering Department may need to work on contaminated devices or devices that they suspect are contaminated. This procedure outlines the best practices to be used when handling a medical device that is contaminated or is suspected to be contaminated.

2. Definitions

Acronym or Word	Definition
BMET	Biomedical Engineering Technologist
Donning	The act of putting on PPE
Doffing	The act of removing PPE
IPAC	Infection Prevention and Control Department
PPE	Personal protective equipment

3. Scope

This procedure will be used at all Fraser Health Authority (FHA), Providence Health Care (PHC), Provincial Health Services Authority (PHSA), and Vancouver Coastal Health (VCH) sites. It will be used by all employees of the Lower Mainland Biomedical Engineering Department as well as all students, engineers, vendors, or anyone else working under the direction of a Biomedical Engineering Department employee.

This procedure covers any contaminated or suspected contaminated medical devices that a Biomedical Engineering Technologist may work on in a Biomedical Engineering Department or clinical area.

3.1 Exceptions

This procedure will be used at all times at all sites. If there are any questions about appropriate practice when dealing with a contaminated device or a device that is suspected of being contaminated, seek direction from the site's Infection Prevention and Control Department (IPAC).

4. Procedure

4.1 Staff Training

All BMETs (new hires and existing) must complete the following training courses:

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- Infection Prevention and Control Practices for Health Care Personnel Not Involved in Direct Clinical Care
 - Covers basic principles of infection control within the healthcare system, including hand hygiene, sharps management, blood and body fluid exposure and clean-up, proper use of personal protective equipment, and additional precautions
 - [Learning Hub Course ID: 8301](#)
- S2S: Chemical Spill Response Training (Code Brown)
 - [Learning Hub Course ID: 5926](#)

For courses that expire, Learning Hub will send an automatic reminder to register for refresher training.

4.2 Cleaning and Decontaminating Medical Equipment Used with Persons under Investigation or Confirmed of Having a Rare or Emerging High Consequences Pathogen (e.g. Ebola)

If a site's IPAC has determined that a patient has a rare or emerging high consequence pathogen, there is a specific protocol from the Office of the Provincial Health Officer that **must** be followed. The site's Infection Control Practitioner will give direction to the Biomedical Engineering Department on how to enter/exit the contamination zone as well as how to clean/disinfect the contaminated devices.

[Module "Recommendations for Cleaning and Decontaminating Medical Equipment used with Persons under Investigation or Confirmed of Having a Rare or Emerging High Consequences Pathogen"](#), available within the Learning Hub course ["Biocontainment Cleaning of Medical Equipment for High Threat Pathogens"](#).

COVID-19 is not considered a rare or emerging high consequence pathogen.

4.3 Cleaning and Disinfecting Medical Devices Involved In a Spill Incident

If a medical device is involved in a spill incident, follow the site's Code Brown procedure.

- [FHA Code Brown](#)
- [PHSA Code Brown](#)
- [VCH & PHC Code Brown](#)

If an employee has been exposed to a hazardous substance, they must seek immediate medical attention.

- [FHA First Aid & Workplace Injury Procedure](#)
- [PHSA First Aid & Workplace Injury Procedure](#)
- [VCH First Aid & Workplace Injury Procedure](#)
- [PHC First Aid & Workplace Injury Procedure](#)

4.4 Cleaning and Disinfecting Medical Devices

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It is an expectation that all devices have been cleaned and disinfected before they arrive in the department, except for unique circumstances (e.g. device involved with incident). A BMET may choose to do an additional cleaning/disinfecting before working on a device.

- If the inspection/repair/cleaning process of a device could result in aerosolization, e.g. using compressed air to clean or dry a device, a designated dirty room should be used. If that is not possible, consult with the site's IPAC on how to mitigate the risks from the aerosolization.
- If the inspection/repair/cleaning process will not generate aerosolization, it is acceptable to designate one end of a work bench as the dirty area with the other end of the bench being a clean area. All clean items must be removed from the dirty area before any work is done on the device. There must be an obvious separation between the dirty and clean areas at all times. All work surfaces, tools, or other items in the dirty area must be cleaned and disinfected after you are finished working on the device.

If a BMET is removing a medical device from a clinical area, they are responsible for ensuring that the device is cleaned/disinfected before it leaves the area. The BMET can choose to clean/disinfect the medical device themselves or they can ask the clinical area staff to clean/disinfect the device.

4.4.1 Before Cleaning and Disinfecting Medical Devices

Prior to working on a medical device, visually inspect the device and determine the appropriate protocols to be followed:

- Hand hygiene protocol
- PPE protocol
- Sharps disposal protocol

4.4.2 Hand Hygiene

Always follow proper hand hygiene procedures before and after you work on any medical device. There are two acceptable methods of hand hygiene:

- Washing with soap and water (primary method if hands are visibly soiled)
 - Wet hands before dispensing soap.
 - Cover all surfaces of hands with soap.
 - Vigorously rub palms, fingers, thumbs, backs of hands, and wrists for 30 seconds.
 - Rinse hands.
 - Dry completely with disposable paper towel.
- Alcohol based hand rub (ABHR)
 - Apply ABHR to palms of dry hands.
 - Rub palms, fingers, thumbs, backs of hands, and wrists until hands are dry.

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Proper hand hygiene can be compromised by rings, watches, bracelets, etc. They should be removed before cleaning your hands.

Gloves are not a replacement for hand hygiene. Hands must be cleaned prior to putting gloves on (donning) and after removing gloves (doffing).

Training reference: [Hand Hygiene Module of Learning Hub Course 8301](#)

4.4.3 Personal Protective Equipment (PPE)

Proper PPE should always be used when working with contaminated or suspected contaminated devices.

Refer to Table 1 for the PPE requirements for different scenarios involving contaminated devices.

Table 1: PPE Requirements for Different Scenarios

Personal Protective Equipment (PPE)	When to Use
Gloves	Visibly soiled devices (includes blood/body fluid), risk of splash
Gown	Risk of splash
N95 respirator/surgical mask* and eye protection	Aerosols present When using a brush or compressed air

Follow your site's protocol for when to use an N95 respirator* or surgical mask:

- [FHA](#)
- [PHSA](#)
- [VCH & PHC](#)

*Fit testing is required for N95 respirators. Contact your OH&S Committee for additional information.

PPE may also be required depending on the disinfectant used. Refer to the disinfectant's safety data sheet (SDS) and product instructions.

When PPE is required, adhere to the steps in Table 2 for putting PPE on (donning) and taking PPE off (doffing).

Table 2: Donning and Doffing PPE

Donning (Putting PPE on)	Doffing (Taking PPE off)
<ol style="list-style-type: none"> 1. Perform hand hygiene 2. Put on gown if required 	<ol style="list-style-type: none"> 1. Remove gloves 2. Perform hand hygiene

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<ol style="list-style-type: none"> 3. Put on N95 respirator/surgical mask if required 4. Put on goggles or face shield if required 5. Put on hair cover if required 6. Put on gloves 	<ol style="list-style-type: none"> 3. Remove gown 4. Perform hand hygiene 5. Remove hair cover 6. Remove goggles or face shield 7. Perform hand hygiene 8. Remove N95 respirator/surgical mask 9. Perform hand hygiene
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Follow your site's protocol for donning and doffing PPE:

FHA: [Donning, Doffing](#)

PHSA: [Donning, Doffing](#)

VCH & PHC: [Donning, Doffing](#)

Training reference: [PPE Module of Learning Hub Course 8301](#)

4.4.4 Sharps Disposal

Remove any sharps from the device and dispose of them in a proper Sharps container.

If you are unfamiliar with how to safely remove a sharp component from a device, ask for guidance from another BMET or from a clinical user.

4.4.5 Procedure for Cleaning and Disinfecting Medical Devices

The device must be cleaned and disinfected with the appropriate cleaning and disinfecting product.

For detailed instructions on appropriate products and procedures for cleaning/disinfecting medical devices, refer to the Health Authority guidance documents below:

- FHA: [Cleaning and Disinfecting Medical Equipment Resources](#)
- PHSA: [BCCW Master Equipment Cleaning Guide](#)
- PHC & VCH: [VCH Master Equipment Cleaning & Disinfecting Manual](#)

Adhere to these general practices when cleaning/disinfecting devices:

- Wipe all surfaces with the appropriate cleaning and disinfecting product.
- Use wipes to remove any foreign matter (dust, soil, food, feces, blood, sputum) from the device using friction and a rub/scrub motion. Clean from the cleanest area to the dirtiest area. Use as many wipes as necessary to remove any visible contamination.
- When all visible contamination has been removed, use new wipes to disinfect the medical device. Allow product's stated "Wet Contact Time" (found on the label for the product) and let it air dry.

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- If you are disassembling a device, you will need to clean and disinfect interior surfaces if they have become contaminated.
- Circuit boards and other internal components may not be cleanable. Discuss options with a supervisor, engineer, and/or the site's IPAC.
- Use the same cleaning/disinfecting products on tools, carts, and work surfaces if these come in contact with contaminated devices.
- Follow your site's protocols when delivering medical devices back to clinical areas or to the Medical Device Reprocessing Department (MDRD) for reprocessing.

4.5 Transporting Contaminated Devices

If a device must be transported while it is contaminated, the BMET must reduce the cross-contamination risk:

- If the device is on wheels:
 - Clean the wheels of any contamination before you move the device from its original location.
 - Cover the rest of the device so that nothing comes into contact with the contaminated surfaces.
- If the device is not on wheels:
 - Place the device in a plastic bag, a box, a container, or cover/wrap it so that nothing comes into contact with the contaminated surfaces.
 - If you are using a cart to transport the device, the cart must be wiped down with the appropriate cleaning and disinfecting product.

4.6 Shipping Contaminated Devices to Vendors

- All devices should be cleaned and disinfected before being shipped to a vendor.
- When a device must be returned to a vendor in a contaminated state (e.g. endoscope with leak¹, device involved with incident investigation), contact the vendor and the site's Shipping Department and follow their protocols for shipping contaminated devices (could include steps such as bagging device in biohazard bag, use of biohazard shipping container).

¹Devices such as endoscopes have internal channels and are cleaned in specific scope washing machines. If an endoscope has a leak, it cannot be cleaned in the scope washing machine. Thus, an endoscope with leak is considered contaminated even if its external surfaces have been cleaned with approved cleaning and disinfecting products.

4.7 Incident Investigations

When a device is involved in an incident, it may be necessary to investigate the device while it is still contaminated.

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- Bring the contaminated device to the designated dirty area/room.
- Refer to sections 4.4.2 through 4.4.4 to determine the appropriate protocols to be followed for hand hygiene, PPE, and sharps disposal.
- If any contaminated components need to be removed from the device, keep them within the designated dirty area/room.
- Following the investigation of the contaminated device and/or disposable item, determine if they need to be returned to the vendor for further investigation:
 - Return of device/disposable item to vendor required: Refer to Section 4.4.5 if the device will be shipped as a clean/disinfected item or Section 4.6 if the device is going to be shipped as a contaminated item.
 - Return of device to vendor not required: Refer to Section 4.4.5 on how to clean and disinfect the device.
 - Return of disposable item to vendor not required: Dispose of in appropriate container/bin.
 - Drugs should be returned to the unit where the device was sent from.
 - If unsure of the appropriate waste stream for products, contact the unit where the device was sent from for direction.

5. Reference Documents

- Lower Mainland Health Authority guidance documents for cleaning/disinfecting devices:
 - FHA: [Cleaning and Disinfecting Medical Equipment Resources](#)
 - PHSA: [BCCW Master Equipment Cleaning Guide](#)
 - PHC & VCH: [VCH Master Equipment Cleaning & Disinfecting Manual](#)
- Lower Mainland Health Authority Infection Prevention And Control (IPAC) websites:
 - [FHA IPAC](#)
 - [PHC IPAC](#)
 - [PHSA BC Children's & Women's IPAC](#)
 - [VCH IPAC](#)
- Lower Mainland Health Authority Chemical Safety & Spill Response websites:
 - [FHA Code Brown](#)
 - [PHSA Code Brown](#)
 - [VCH & PHC Code Brown](#)
- Lower Mainland Health Authority First Aid & Workplace Injury procedures:
 - [FHA First Aid & Workplace Injury Procedure](#)
 - [PHSA First Aid & Workplace Injury Procedure](#)
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- [PHC First Aid & Workplace Injury Procedure](#)
- [“Recommendations for Cleaning and Decontaminating Medical Equipment used with Persons under Investigation or Confirmed of Having a Rare or Emerging High Consequences Pathogen”](#) – Available within the Learning Hub course
- [LMBME Policy # ABCD-14-11-40004](#)
- [LMBME SOP 012 Decommissioning of Medical Devices](#)

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