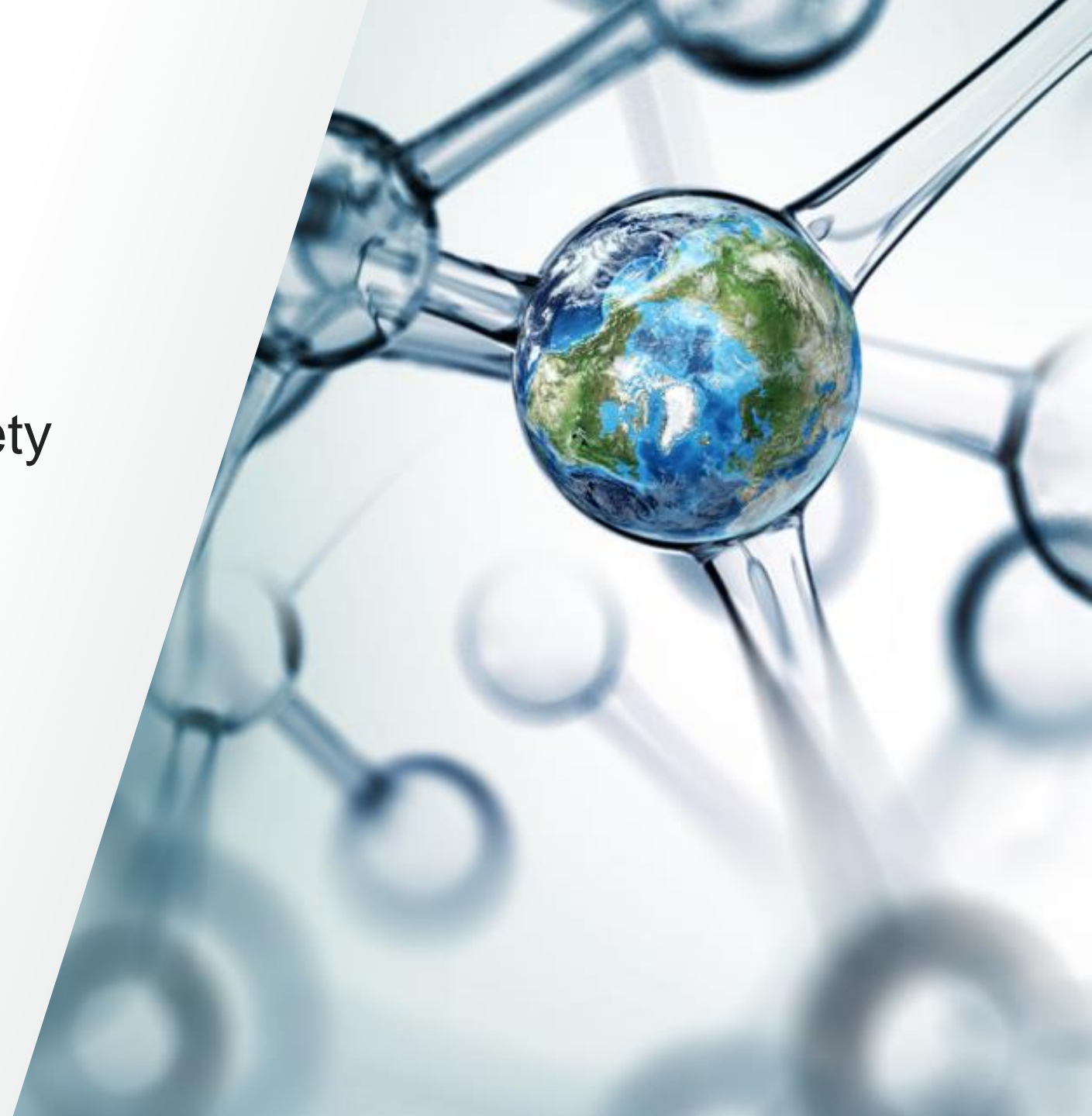


Theory of Operations

Bigfoot Decontamination for Safety
and Biosafety Testing, Decision
Matrix

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Revisions

Revision	Change Description	Changed By/Date
A	New Release	LG 6/6/2023
B	Added specific guidance for all biosafety procedures	LG 8/11/2023
C	Updated slide 7 to included the required tools and training for all procedures	LG 8/29/2023
D	Updated slide 6 to better explain purpose of the slide. Removed HEPA filter replacement to reduce confusion.	LG 9/26/2023
E	Added specific guidance for Loader, Sort Module, Streams Module, and Output replacement procedures, Pages 7 and 8.	LG 1/17/2024
F	Reduced the decontamination requirements for service activities that expose contaminated fluid lines from a full fluidic decontamination to no fluidic decontamination.	LG 3/29/2024

Purpose/Scope

<p>Purpose</p>	<p>This is an internal document. Do not distribute this document to users/customers.</p> <p>This document is supplemental information that is intended to more fully explain the documents DF00214 Certificate of Instrument Decontamination and FRM0005274_Certificate of Instrument Decontamination. These two documents are intended to be simple and easy to understand for customers, but not be comprehensive for all cases. This document is intended to be the comprehensive resource for when questions arise from the decontamination process or documentation.</p> <p>The purpose of these decontamination forms are to provide a record that the instruments have been properly decontaminated to minimize exposure to biohazardous agents. The form FRM0005274 is a generic Thermo Fisher form that does not contain Bigfoot-specific information. DF00214 is the required companion document that includes the Bigfoot-specific information.</p> <p>Although this document attempts to be comprehensive, there will be special circumstances that demand different action on a case-by-case basis.</p>
<p>Scope</p>	<p>This document is limited to providing information about the decontamination of Bigfoot for the purpose of user/employee safety in either of the two cases:</p> <ol style="list-style-type: none"> 1) Instrument Returns 2) Field Service Visits <p>This scope of this document does not include information about decontamination for the purpose of keeping the instrument fluidics clean for the purpose of improving instrument performance.</p>

Process – Field Service Activities

1	If decontamination is required, send the FRM0005274 and DF00214 to the customer. These can be found in the Bigfoot Knowledge Base.
2	Explain the required decontamination method based on the biosafety category of their lab.
3	Depending on the specific circumstance, the user, GSS, or Fort Collins will coordinate the VPHP decontamination of the instrument.
4	The user must sign the both forms above after the proper decontamination is performed based on the biosafety level.
5	Field service activity can proceed.

Process – Instrument Returns

1	Send the forms FRM0005274 and DF00214 to the customer. These can be found in the Bigfoot Knowledge Base.
2	Explain the required decontamination method based on the biosafety category of their lab.
3	Depending on the specific circumstance, the user, GSS, or Fort Collins will coordinate the VPHP decontamination of the instrument.
4	The user must sign the both forms above after the proper decontamination is performed based on the biosafety level.
5	Return can proceed.

Decision Matrix – Decontamination for Safety

Purpose: The tables on this page define when either biosafety enclosure or fluidic decontamination is required based on the type of service activity and the biosafety level of the lab. All biosafety systems procedures have specific requirements defined on the next page. This page should be used as guidance when the decontamination requirements are not defined for an existing procedure. For example, if a service activity required completely removing a waste catcher in a BSL2 lab, this would break biosafety enclosure containment, and would expose contaminated fluid lines. Therefore, this would require surface disinfection treatment, but no fluidic decontamination prior to removing the waste catcher.

Table 1: Biosafety Enclosure Decontamination Requirements

Service Activity	Biosafety Level 1	Biosafety Level 2	Biosafety Level 3
Return an instrument	Surface disinfection treatment required	VPHP Decon Required	Standard + Whole Instrument VPHP Decon Required
Service - Does break containment	Surface disinfection treatment required	Surface disinfection treatment required	VPHP Decon Required
Service, Inside Enclosure - Does not break containment	No treatment required	Surface disinfection treatment required	Surface disinfection treatment required
Service, Outside Enclosure - Does not break containment	No treatment required	No treatment required	No treatment required

Table 2: Fluidic Decontamination Requirements

Service Activity	Biosafety Level 1	Biosafety Level 2	Biosafety Level 3
Return an instrument	2 Load or NADCC Decon Required	2 Load or NADCC Decon Required	2 Load or NADCC Decon Required
Service - Does expose contaminated fluid lines	No Fluidic Decon	No Fluidic Decon	2 Load or NADCC Decon Required
Service - Does not expose contaminated fluid lines	No Fluidic Decon	No Fluidic Decon	No Fluidic Decon

Table 3: Parts Return or Disposal Requirements

Parts Category	Biosafety Level 1	Biosafety Level 2	Biosafety Level 3
Fluidic part that contacts sample	No Fluidic Decon	2 Load or NADCC Decon Required and surface disinfection required	No returns allowable Must be disposed according to lab SOP
Part inside biosafety enclosure	Surface disinfection treatment not required	Surface disinfection treatment required	No returns allowable Must be disposed according to lab SOP
Part outside biosafety enclosure	Surface disinfection treatment not required	Surface disinfection treatment required except for electronics and optical filters	No returns allowable Must be disposed according to lab SOP



Decision Matrix – Decontamination for Safety

Table 4: Guidance for select procedures		BSL1/2 (CL1/2)					BSL3 (CL3)				
		VPHP Decontamination Required?	VPHP Decontamination Financial Responsibility	FSE Testing	3rd Party Testing	3rd Party Testing Financial Responsibility	VPHP Decontamination Required?	VPHP Decontamination Financial Responsibility	FSE Testing	3rd Party Testing	3rd Party Testing Financial Responsibility
Procedure	Description										
DT00309	Installation, PMI (Biosafety Enclosure Calibration, Airflow Balancing)	No	N/A	N/A	At user discretion	User	Yes	User	N/A	At user discretion	User
DT00311	Aerosol Management System Fan Replacement	No	N/A	Yes, DT00309	At user discretion	User	Yes	User	Yes, DT00309	At user discretion	User
DT00313	Biosafety enclosure Fan Replacement	No	N/A	Yes, DT00309	At user discretion	User	Yes	User	Yes, DT00309	At user discretion	User
DT00308	Aerosol Management System HEPA Filter Replacement	Yes	User	Yes, DT00309 and DT00320	At user discretion	User	Yes	User	Yes, DT00309 and DT00320	At user discretion	User
DT00307	Biosafety enclosure HEPA Filter Replacement	Yes	User	Yes, DT00309 and DT00320	At user discretion	User	Yes	User	Yes, DT00309 and DT00320	At user discretion	User
DT00312	Aerosol Management System Module Replacement	Yes	User	Yes, DT00309 and DT00320	At user discretion	User	Yes	User	Yes, DT00309 and DT00320	At user discretion	User
DT00290	Loader Replacement OR any Loader service that requires breaking the loader right seal wall	No	N/A	Yes, DT00326	At user discretion	User	Yes	User	Yes, DT00326	At user discretion	User
DT00297	Sort Module Replacement (Original to Cooled) OR any service that requires removing the Sort Module	No	N/A	Yes, DT00326	At user discretion	User	Yes	User	Yes, DT00326	At user discretion	User
DT00349	Field Repair, Sort Plates Module OR any service that requires removing the Sort Module	No	N/A	Yes, DT00326	At user discretion	User	Yes	User	Yes, DT00326	At user discretion	User
N/A	Any streams module service that requires breaking the streams window seal	No	N/A	Yes, DT00326	At user discretion	User	Yes	User	Yes, DT00326	At user discretion	User
N/A	Output Replacement	No	N/A	No	At user discretion	User	Yes	User	Yes, DT00326	At user discretion	User

Decision Matrix – Decontamination for Safety

Procedure	Description	Spare Parts Kit	All Required Tool Kits	Bigfoot Biosafety Systems Basics Service Training Required	Bigfoot HEPA Filter Replacement and Verification Service Training Required	Bigfoot Containment Verification Service Training Required
DT00153	Canopy Connection Installation and Calibration	PL00329 or PL00384	PS00314	X		
DT00307	Biosafety enclosure HEPA Filter Replacement	PS00252	PS00320, PS00329, PS00330	X	X	
DT00308	Aerosol Management System HEPA Filter Replacement	PS00251	PS00320, PS00329, PS00330	X	X	
DT00309	Biosafety Enclosure Calibration, Airflow Balancing	N/A	PS00320	X		
DT00311	Aerosol Management System Fan Replacement	PS00243	PS00320	X		
DT00312	Aerosol Management System Module Replacement	PS00385	PS00320, PS00329, PS00330	X	X	
DT00313	Biosafety enclosure Fan Replacement	PS00244	PS00320	X		
DT00320	HEPA Filter Leak Tests, Field Service	N/A	PS00329, PS00330	X	X	
DT00326	Biosafety Enclosure, Containment Verification	N/A	PS00329, PS00330	X		X
DT00290	Loader Replacement OR any Loader service that requires breaking the loader right seal wall	PS00395	PS00329, PS00330			X
DT00297	Sort Module Replacement (Original to Cooled) OR any service that requires removing the Sort Module	PS00382 PS00221	PS00329, PS00330			X
DT00349	Field Repair, Sort Plates Module OR any service that requires removing the Sort Module	PS00381	PS00329, PS00330			X
N/A	Any streams module service that requires breaking the streams window seal	PS00295	PS00329, PS00330			X
N/A	Output Replacement	PS00350	PS00329, PS00330			X

Definitions

1	<p>Surface Disinfection. Use of a surface disinfectant to decontaminate easily accessible surfaces inside the Biosafety Enclosure. Spray and wipe down all interior surfaces of the Sort Chamber and Biosafety Enclosure work surfaces with 70% Ethanol alcohol and wipe clean. Do not directly spray the intersection chamber (due to sensitive optics) or the loader (due to seals).</p>
2	<p>Fluidics Decontamination, NADCC. The standard method found from the login screen when the instrument is shut down:</p> <div data-bbox="1251 425 1528 605" data-label="Image">  </div>
3	<p>Fluidics Decontamination, 2 Load Decon. Only use in cases where the NADCC method is inadequate such as when needing to fluidically decontaminated an instrument that is so contaminated that proper circulation of fluid or adequate contact due to thick bacterial growth is not possible. This method is only accessed by logging into SQS with the service login.</p> <div data-bbox="1217 796 1592 1006" data-label="Image">  </div>
4	<p>VPHP Decontamination. Vapor Phase Hydrogen Peroxide decontamination the Biosafety Enclosure. A method to decontaminate the interior of the biosafety enclosure so it is safe to work inside or ship. See DT00156. VHP is a trademark of Steris, therefore we must use the phrase and acronym VPHP. DT00187 is an alternative low-cost VPHP method that should only be used in regions where an existing local provider uses the equipment specified in this document. This is an internal procedure that TSS uses in the United States. This procedure is unlikely to be useful outside the United States.</p>
5	<p>Whole instrument VPHP Decontamination. In cases that a Bigfoot instrument that was present in a BSL3 lab needs to be removed from that lab, the entire instrument, rather than only the interior of the Biosafety Enclosure, needs to be decontaminated. There is no existing procedure for this. It will be the responsibility of the customer to perform this decontamination and validate their method with Chemical and Biological Indicators.</p>

Definitions

1	<p>Inside Biosafety Enclosure. Inside the carcass of the biosafety enclosure Primary Containment Device. Modules inside the biosafety enclosure include everything inside the Sort Chamber, Nozzle Mover Chamber including the Intersection Chamber, the greater Atrium including the Loader. This also includes all the ducts and plenums of the Biosafety systems including the Aerosol Management System, and HEPA filters and fans.</p>
2	<p>Outside Biosafety Enclosure. Everything on the instrument excluding the items inside the biosafety enclosure as listed above.</p>
3	<p>Breaking Biosafety Enclosure Containment. Removing a seal or otherwise allowing contaminated aerosols from inside the Biosafety Enclosure to escape from the interior of the Biosafety Enclosure. Examples include, but aren't limited to, removing a Sort Module, Output, Waste Catcher, Loader or a HEPA filter.</p> <p>Turning off the Biosafety Enclosure Fan for the purposes of calibration or testing also breaks Biosafety Enclosure Containment since the inward flow of air is disrupted by this action. This should be considered breaking containment in some circumstances.</p>
4	<p>Exposure to Contaminated Fluid Lines. Any fluid line that may contain user sample, examples include: Sample line, waste lines, some peristaltic pumps, waste bottles, waste catcher, the loader, etc.</p>
5	<p>3rd Party Testing. This is shorthand for all the testing required to verify the performance of the biosafety enclosure. The procedure for the 3rd party testing is DT00149. This testing verifies that the air velocities are correct, the HEPA filter performance meets specifications, and an optional functional containment test called a KI Discus test. This testing is typically performed by hiring a third-party service provider such as TSS or Unity Clean Air.</p>
6	<p>Containment Testing. The functional test of using the HEPA filter penetration test equipment (PS00329 and PS00330) to confirm that the seals of the biosafety enclosure are intact and not leaking. This required the shipment of the test equipment PS00329 and PS00330 to the customer location and training on how to use the tools.</p>

Additional Guidance

1	<p>The Biosafety Level is determined by the level that the instrument was used in, not the specific biology that was run.</p> <p>Even if the customer only ran fixed BSL1 or Hazard Group 1 material, but the instrument was located in a BSL2 lab, we still must consider the instrument as a BSL2 instrument. Since most of our customers are in BSL2 labs this means that most instrument require VPHP decon prior to returns.</p>
2	<p>The decontamination decision matrix defines the minimum required treatment. It is not an exhaustive list or appropriate in all cases. Field Service Engineers should take additional precautions to protect themselves from exposure to biohazardous agents in many circumstances.</p>