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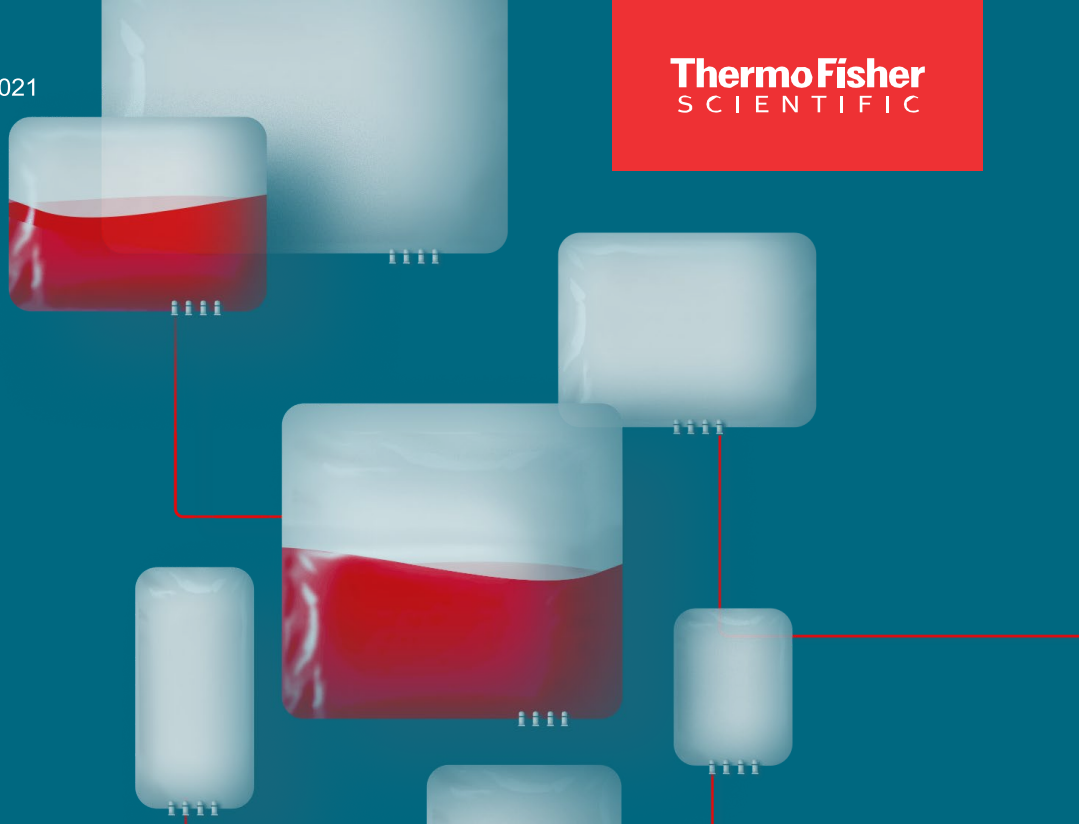


BioProcessing Systems

Single Use BioProcessing Systems Unpacking and Inspection Guide

Revision | **M**
March 2026

thermo scientific

Contents

Warnings and safety information

WARNING: Read and understand this user's guide before unpacking and using BioProcessing Systems.

Failure to follow the instructions contained in this document could result in damage to the product, failure to perform as expected, or personal injury.

CAUTION: Bioprocessing Systems are subject to damage if not handled with care. Special handling instructions are prescribed when using BPCs for transportation of large volumes of process liquids.

Using additional packaging materials is strongly recommended for BPCs used to transport process liquids. This additional packaging should include:

1. Flexible plastic liners positioned between the BioProcessing System and the outer, rigid support container to help avoid vibration-related abrasions to the system.
2. Dunnage or restriction plates to help reduce wave-action induced cyclic fatigue of the BioProcessing System, which can result in leaks or product loss.

CAUTION: Thermo Fisher does not apply pressure ratings to Single Use Systems. However, Thermo Fisher recommends operating pressures in the chamber of the Single Use System should not exceed 0.5psi during use. Operating above 0.5psi may damage the product and void the product warranty.

Please contact our technical support team at 1 435 792 8500, option 2, or at techsupport.bioprocessing@thermofisher.com for more information.

Use the following safety equipment while unpacking BPCs:

- Gloves
- Lab coat, where appropriate or required

How to use this guide

Scope of this publication

This document covers the unpacking and inspection of Thermo Scientific™ Bioprocessing Systems, including both 2D and 3D BPCs, manifolds, and tubing assemblies.

Document change information

A summary of the changes that have been made to this document are listed below.

Rev.	Date	Section	Description	Author
F	12/2021	--	Reformatted using new brand template	E. Hale
F	12/2021	Appendix C	Added Sample Initial Diagnosis Checklist	E. Hale
F	12/2021	3.3.1	Added BPC defect evaluation section, flowchart, and Tables 3.4–3.7	E. Hale
F	12/2021	1.1.3	Updated product label image	E. Hale
G	07/2022	1.1.1, 1.1.2, 2.2.3, 2.2.4,	Minor edits to text for greater clarity	C. Jones
G	07/2022	2.2.5	Added section on tamper evident covers	C. Jones
H	01/2023	1.2.5	Added unpacking steps for filters with valve covers	T. Golightly
I	05/2023	3.3.1	Figure 3.6 updated to improve method for checking integrity (Detail added retrospectively at Rev J)	J. Stahl
J	03/2024	Warnings and safety information	Pressure detail added	C. Hunter
J	03/2024	Related Publications	User Guides and TUPP documents added	C. Hunter
J	03/2024	1.2.1, 1.2.5, 2.1.2, 2.1.3, 2.2.1, 3.1, 3.3 & Table 3.4	Amended detail to reflect current guidance and addition of table 3.4	C. Hunter
J	03/2024	Table 3.5 – 3.17	Defect evaluation section reformatted to enlarge pictures, improve guidance & add detail for Striations/imPULSE issues	C. Hunter
J	03/2024	Appendix C	Amended to reflect current format	C. Hunter
K	03/2025	2.2.4 & 3.1	Amended to correct detail for pictures (2.2.4) and references (3.1).	C. Hunter
K	03/2025	Tables 3.13, 3.17 & 3.18	Additional information added to rationale in 3.13, Pleats and Perimeter Seal Anomalies in PL-01026/PL-01077 film defect added. Amendment to 3.18 to add unacceptable condition.	C. Hunter
L	02/2026	Table 3.1 – 3.3	Subvisible added to tables 3.1 & 3.2. Table 3.3 updated to show new Embedded specification. Foreign Objects detail merged into tables 3.1 & 3.2 as applicable.	C. Hunter
L	02/2026	All	Amended document title to replace BPC with BioProcessing Systems to reflect current content, minor amendments throughout to align with new title.	C. Hunter
L	02/2026	Related Publications	DOC0280 - Particle Evaluation in Single-Use Systems added.	C. Hunter
L	02/2026	2.2.3 & 2.2.5	OnePack restraint system detail added to 2.2.3 and information updated for Tamper Evident Covers.	C. Hunter
M	03/2026	Table 3.3	Correction to Embedded specification	C. Hunter

Questions about this publication

If you have any questions or concerns about the content of this publication, please contact your Thermo Fisher Scientific sales team.

Related publications

Please contact your local sales representative for information about the related publications listed below.

Publication	Document number
HyPerforma Single-Use Mixer (S.U.M) User's Guide	DOC0002
HyPerforma 2.1 Single-Use Bioreactor (S.U.B) User's Guide	DOC0014
Thermo Scientific Single-Use Bioreactor	DOC0015
Thermo Scientific BPC Validation Guide	DOC0017
HyPerforma 5.1 Single-Use Bioreactor (S.U.B) User's Guide	DOC0022
Harvestainer BPC User Guide	DOC0024
HyPerforma Single-Use Fermentor (S.U.F) User's Guide	DOC0031
Hyperforma Mixtainer System User's Guide	DOC0037
HyPerforma SUM with Touchscreen Console User's Guide	DOC0042
HyPerforma imPULSE Mixer User's Guide	DOC0043
HyPerforma Single Use Mixer (S.U.M) with Touchscreen Console	DOC0061
HyPerforma DynaDrive S.U.B User's Guide	DOC0090
imPULSE S.U.M with Touchscreen Console User's Guide	DOC0099
Thermo Scientific imPULSE MDS S.U.M User's Guide	DOC0203
Single Use Division TUPP (SUD Network sites)	DOC0253
HyPerforma Single-Use Mixer (S.U.M) with Touchscreen Console	DOC0254
imPULSE (S.U.M) with Touchscreen Console User's Guide	DOC0255
Particle Evaluation in Single-Use Systems	DOC0280

Abbreviations/acronyms

See the list below for definitions of abbreviations used in this publication.

BPC	BioProcess Container
cGMP	Current good manufacturing processes
COA	Certificate of Analysis
S.U.B.	Single-Use Bioreactor
S.U.F.	Single-Use Fermenter
S.U.M.	Single-Use Mixer
P.O. D	Proof of Delivery

1

Introduction to the BioProcessing System

1.1 BioProcessing System packaging

1.1.1 Outer packaging

The outer packaging consists of a cardboard box and bubble wrap. The bubble wrap is used to cushion products, and is found on the bottom, between, and on top of the product inside the box.

1.1.2 Inner packaging

BioProcessing System inner packaging varies by product type and size and may vary on custom products. These may include:

- A BPC restraint system with cardboard inserts
- At least two protective polybags that cover the entire BioProcessing System assembly.
- Tamper evident covers that encase the end fixtures of each of the line sets on a BPC or tubing assemblies
- Bubble wrap surrounding filters, connectors, clamps, and cable ties.
- A layer of bubble wrap placed between coils of tubing and the chamber.

1.1.3 Labeling

The product label (Figure 1.1) is found on each BPC chamber, or on the innermost polybag. It may also be found on the outside of the box.

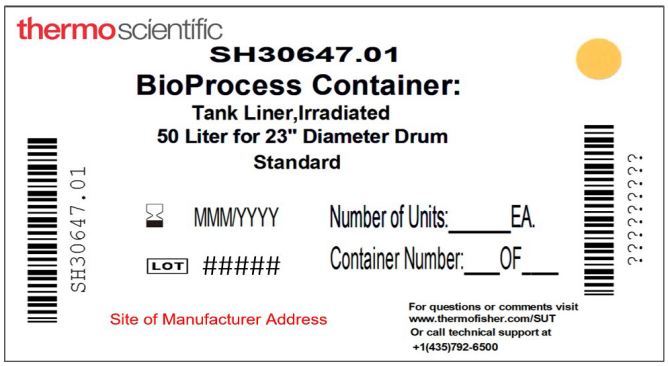


Figure 1.1. Example of a product label.

The product label includes the following information:

- Lot number
- Description
- Manufacturing date (custom products)
- Expiration date (standard products)

The innermost section of the first polybag surrounding the product contains the following:

- Component labels for filters with our serial number
- Inspection record label, which contains the inspector's initials, the employee reference number, and the unit number.
- May include the product label.

The outermost polybag may include the user handling instructions for the BPC label. The box labels also include:

- Product label
- User handling instructions for the BPC
- Filter labels
- Box inspection label.

1.2 BioProcessing System components

1.2.1 BPC chamber

All BPC chambers have an identification stamp. The lot number and a serial number (Figure 1.2) are printed with the identification stamp.

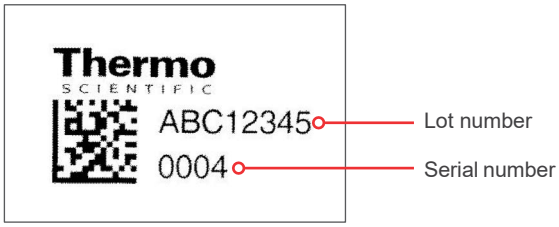


Figure 1.2. Example of identification stamp.

There are two chamber tests performed on BPCs. The chamber inflation test includes the following:

- A representative sample is subject to an inflation test for leaks.
- Each chamber is inflated, and then visually inspected for leaks

The chamber burst test includes the following:

- A representative sample is subject to burst testing, which slowly inflates a chamber until a total failure occurs.
- This test is carried out to evaluate the risk factor of the fault.

Thermo Scientific Single Use Technology products are maintained with an ongoing stability program where post gamma shelf-life data is maintained for all items within the component library. Components with the shortest shelf life on the assembly may limit the shelf life of the entire assembly.

Note: For BPC Validation information, refer to DOC0017 - Thermo Scientific BPC Validation Guide

Note: Please be aware that variations in color may be observed in the components of assembled single-use systems. Typically, these components appear yellow, but there may be a wide range of color changes. This variation is caused by Gamma radiation, which can cause cross-linking in the materials. Cross-linking can enhance the strength and rigidity of the components but may also make them more brittle and give them a yellow color hue in plastic and silicone polymers. It is important to note that discolored components are still considered acceptable.

1.2.2 Ports

Ports are the points where line sets connect to the main chamber. They are sealed into the film during the manufacturing of the chamber. The chamber lot number consists of the ports and the film used to create the chamber.

1.2.3 Tubing

Tubing is a flexible component that allows for the transfer of liquid from one location to another. Tubing materials and sizes vary greatly.

1.2.4 Fittings and connectors

Fittings are the T, Y, and X straight or elbow components that allow a line set to:

- Change tubing sizes.
- Allow for manifolding.
- Direct a flow path.

Connectors allow a line set to connect to another BPC, tubing assembly, vessel, or other equipment. Various types of connectors exist, including aseptic, steam-through, small volume, and sampling. Depending on design, many connectors can have liquid- tight terminations, such as caps and plugs. In other circumstances, only dust protection barriers are used in addition to polybags.

1.2.5 Filters

Filter flow direction is critical for processes. If the filter is fitted in the wrong direction, it will reduce the performance of the filter, and in some cases, will not provide the required filtration. The flow direction is indicated on the product drawing or schematic. Filters should be used in accordance with the current manufacturer's guidelines.

Unpacking filters packaged with valve cover

Removing the single valve cover.

1. Carefully lay the filter with the valves facing up.
2. Press the cable tie tab with a fingernail or tool (Figure 1.3). While the tab is being pressed, slide the head of the cable tie off of the cable tie end (Figure 1.4).

Figure 1.3. Pressing cable tie tab at the base of the filter.

Figure 1.4. Sliding cable tie head off of cable tie end.

3. Remove the single valve cover, if applicable.
4. Repeat for all single valve covers found on the filter.

Note: The valve cover should not be reused. Dispose of or properly recycle the cable tie and valve cover.

Removing the dual valve cover, if applicable

1. Carefully lay the filters with the valves facing up.
2. Hold the filters in place with one hand and grab the center of the dual valve cover with one hand (Figure 1.5).

Figure 1.5. Grabbing dual valve cover with one hand.

3. Pull up on the dual valve cover until it releases from both filter housings (Figure 1.6).

Figure 1.6. Removing dual valve cover from filter housing.

4. Repeat for all dual valve covers found on the filter housings.

Note: The dual valve cover should not be reused. Dispose of or properly recycle the dual valve cover.

2

Unpacking

2.1 Initial setup

A safety cutter or similar tool is required for unpacking BioProcessing Systems.

2.1.1 Document review

Review the following documents first in every shipment:

- Packing list
- Certificate of Analysis (COA) (**Note:** non-cGMP products will not include a COA)
- Product label

If the shipment is missing a COA, visit the Thermo Fisher Scientific website and search for the part number and the lot number. If no product label is found on the outside of the shipping box, standard and non-cGMP product labels are found on the product. If the shipment is missing the packing slip, check with the receiving department or contact your local sales representative to request a copy. If information does not match the documentation, or required documents cannot be obtained, contact your local sales representative.

2.1.2 Appropriate workspace conditions

Acceptable carriers and surfaces comfortably accommodate the footprint of the system, have smooth edges and rounded corners to prevent accidental damage to units.

(Figures 2.1 and 2.2). Unacceptable carriers and surfaces include carts and wire racks that have sharp edges (Figure 2.3).

Figure 2.1. Smooth edges on an acceptable surface.

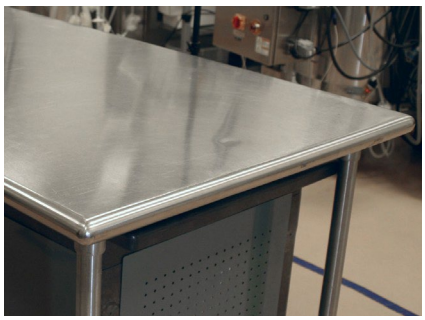


Figure 2.2. Rounded corners on an acceptable surface.

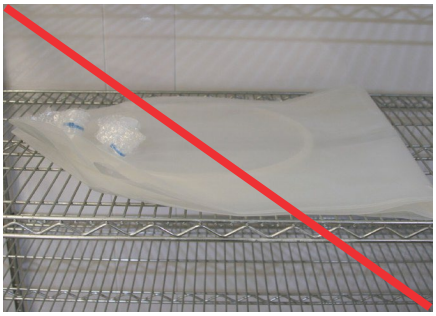


Figure 2.3. Wire rack as an unacceptable surface.

Use the following BioProcessing System handling guidelines:

- Ensure all workspaces are free of sharp objects.
- Do not drag any part of the product across the floor or surfaces.
- Use acceptable trays, carts, tables, or hold the product by hand.
- Handle the product carefully.
    - Do not lift using tubing lines.
    - Utilize two or more individuals when handling BioProcessing units 500L & larger.
    - Do not drop.
    - If possible, pad cart and table surfaces when staging the unit.
- Avoid leaving sharp objects (scissors, cutters, scalpels, etc.) in the vicinity of the BioProcessing System.

2.1.3 Storage requirements

- Store the BioProcessing System in its original packaging, until ready to use.

Note: If you are storing an unpacked product, avoid crushing, which can cause holes or other damage in the chamber film.

- Stack the product no higher than the quantity found in the original box.
- Visual management should be used for Operator awareness of stack height.
- Avoid tearing or puncturing the bag by eliminating the use of sharp objects near the product.

Note: Specific information on compatible support containers or freezing product in BioProcess Containers is available on request.

2.2 Unboxing the BioProcessing System

2.2.1 Acceptable and unacceptable box conditions

See Figures 2.4 and 2.5 for acceptable shipping box conditions. The product is still usable if the box arrives in these conditions.

Figure 2.4. Worn box corner.

Figure 2.5. Minor perforation on the box.

See Figures 2.6 and 2.7 for unacceptable shipping box conditions. If your package arrives in a similar condition, it is recommended to refuse the shipment or add comments to the Proof of Delivery (P.O.D) document to assist with any investigation. It is important for the customer's goods receiving procedure to include a detailed explanation of this process.

Figure 2.6. Crushed box.

Figure 2.7. Puncture mark through the box.

Boxes showing damage should be assessed to see if the damage has penetrated the box wall. If this is the case, it is necessary to inspect the poly packaging to determine if there is any damage that has affected the integrity of the unit.

2.2.2 Opening the box

Position the box with the top side facing up. Pull the sealed joint up and away from the box. Then, use a safety cutter or another similar tool along the taped seam (Figure 2.8).

CAUTION: Never use straight blades to open the BioProcessing Systems box. Never open from the bottom of the box or through any part of the cardboard.

Figure 2.8. Using a safety cutter to open the box.

2.2.3 Removing the BPC restraint system

A BPC restraint system is added to all Single-Use Bioreactor (S.U.B.), Single-Use Mixers (S.U.M.), and Single-Use Fermenters (S.U.F.) BPC assemblies (except imPULSE mixer BPCs) with the intention of keeping the BPC assembly flat and preventing damage.

CAUTION: Never use sharps or other tools to cut the restraint system from its top, as damage may occur to the polybag or BPC.

There are two different types of restraint system, Retention & OnePack . The Retention system uses a folded corrugate base with retention straps across the BPC. The OnePack system uses a corrugate mattress and stretch wrap across the entire BPC.

Determine which type of restraint system your product was packaged with and use the following appropriate steps to remove the BPC from the restraint system.**2.2.3.1 Retention System**

1. Remove the inner packaging with the restraint system and BPC attached. There are handles on the inner packaging to assist with removal (Figure 2.9).

Figure 2.9. Handles on inner packaging.

2. Turn the inner packaging on its side (Figure 2.10).

Figure 2.10. Inner packaging on its side.

3. Either cut the restraint on the bottom with a safety cutter or undo the cardboard inserts to remove the inner packaging (Figures 2.11 and 2.12).

Figure 2.11. Cutting the restraint on the bottom of the inner packaging.

Figure 2.12. Undoing and removing the cardboard inserts.

2.2.3.2 OnePack Wrap System

1. Remove the inner packaging with the Mattress and BPC attached. There are handle slots on the mattress to assist with removal (Figure 2.13).

Figure 2.13. Inner packaging removed from the box.

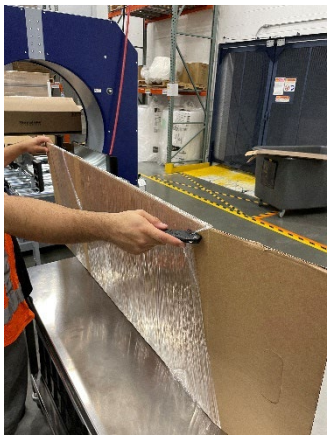


Figure 2.14. Cutting stretch wrap from the mattress.

2. Turn the mattress on its side.
3. Using a safety cutter, cut the stretch wrap along the bottom of the mattress (Figure 2.14)

2.2.4 Opening the protective polybags

After removing the BPC from the restraint system inside the box (if applicable), inspect the product for damage. If there is no damage, proceed to open each polybag, individually. Use a safety cutter or another similar tool along the edge of the polybag to carefully open (5). As a last resort, you may use a finger to punch a hole through the end of the polybag and carefully tear it open, using both hands (Figure 2.16).

Note: Polybags primarily act as dust covers and protection during transportation. Cosmetic damage to packaging does not change the form, fit or function of the BioProcessing System. Scratches, snags, pinholes, and other blemishes in the polybags do not compromise fluid path sterility.

Figure 2.15. Opening the outer polybag with a safety cutter.

Figure 2.16. Opening the outer polybag by hand.

2.2.5 Tamper evident covers

Tamper evident covers encase the end fixtures of each line set on the BPC or tubing assemblies. The covers are secured with a cable tie that will not have the tail snipped, this is to prevent the formation of sharp edges that could damage the product (Figure 2.17). They act as visual indicators that line set end fixtures are undisturbed. **You should only open these covers when you are ready to use the product.**

Figure 2.17. Tamper evident covers cable ties do not have tails snipped.

3

Inspection

3.1 Inspecting the chamber

Place the BPC on a proper workspace surface. Unfold the chamber either all the way open or in segments to inspect for damage or abnormalities.

CAUTION: It is important not to unfold imPULSE & DynaDrive BioProcess containers for pre-use inspection, as this may result in damage. Please refer to the Related Publications list for product specific user guides. These guides can be requested by contacting techsupport.bioprocessing@thermofisher.com

Normal folding marks, light surface wrinkles, and light stress marks are acceptable (see Figures 3.1 and 3.2).

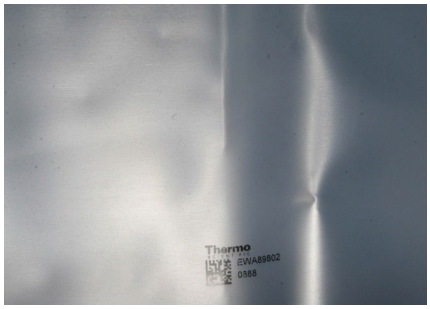


Figure 3.1. Folding marks on the BPC chamber.

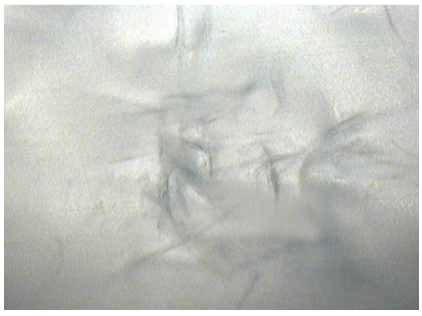


Figure 3.2. Light stress marks on the BPC chamber.

Cross-folding (Figure 3.3), however, involves folding the BPC in more than one direction, and is a main contributor to causing leaks in the chamber. Avoid cross-folding whenever possible.

Figure 3.3. Example of cross-folding.

Carbon or gel particulate on the surface (Figures 3.4 and 3.5) is also acceptable. See the film inspection criteria in section 3.3 for more information.

Figure 3.4. Gel particulate on BPC surface.

Figure 3.5. Carbon particulate on BPC surface

3.2 Optional inspections

3.2.1 Inspecting tubing

Inspect the tubing for signs of damage or abnormalities. **Note:** After irradiation, a tube may set in a slightly bent or kinked position as a result of the packaging operation. Packaging configurations are in place to reduce bent or kinked tubing. However, various tubing configurations can make bends or kinks difficult to eliminate. Most tubing kinks are cosmetic and may be opened manually by pinching the wall of the tubing to release the kink without impact to product integrity.

3.2.2 Inspecting connection points and connectors

Inspect the connection points for the presence of a retainer type (such as cable ties or BarbLock™ retainers), and proper fit.

Inspect connectors for missing caps or plugs on the ends. Connector inspection should also include the inspection of aseptic, steam-through, and steam-to connectors to ensure that they are in the correct position and have not been actuated. Connectors should be used in accordance with the manufacturer's current guidelines.

3.2.3 Inspecting filters

Verify the flow direction. Note that vents on filters are fragile and handle with care. Filters should be used in accordance with the manufacturer's current guidelines.

3.3 Product inspection criteria

Each chamber and finished good is inspected for gels/carbons and particulate, based on the criteria listed in Tables 3.1–3.4.

Particulate could be either a gel, carbon, or foreign material. Gel and carbon are formed during the resin-to-film conversion process. Carbons that are built up in the equipment can be released and embedded in BPC film. Gels are resin solids that pass through the extruder screens and can be extruded with the BPC chamber film and embedded within the layers.

NOTE: Operators and quality personnel should be aware that Hamilton OneFerm single-use pH sensors will inherently leach small amounts of KCl salt into the BPC. Originating from the reference electrode, this particulate is a non-toxic salt that may appear to be a foreign particulate.

Table 3.1. Particulate product contact (fluid path). No particle density for any size shall exceed 4 per ft².

Size	Criteria
< 0.02 mm²	Not counted (subvisible)
0.02–0.15 mm²	≤ 3 per ft²
0.20–2 mm²	≤ 1 per ft²
> 2 mm²	0
Fibers or Metallic Particulate	None allowed
Hair	None allowed

Table 3.2. Particulate non-product contact. No particle density for any size shall exceed 5 per ft².

Size	Criteria
< 0.02 mm²	Not counted (subvisible)
0.02–0.15 mm²	≤ 5 per ft²
0.20–2 mm²	≤ 3 per ft²
2.5–5 mm²	≤ 1 per ft²
> 5 mm²	0
Metallic Particulate	None allowed
Hair	None allowed

Table 3.3. Embedded carbons/gels.

Size	Criteria
< 0.02 mm²	Not counted (subvisible)
0.02-0.60 mm²	≤ 10 per ft²
0.60–2.5 mm²	≤ 3 per ft²
> 2.5 mm²	0

3.3.1 BioProcessing Systems defect evaluation

See Figure 3.6 for a flowchart depicting the process of evaluating defects.

Tables 3.5 – 3.18 provide a library of defects, their potential causes, acceptance criteria, and example photos.

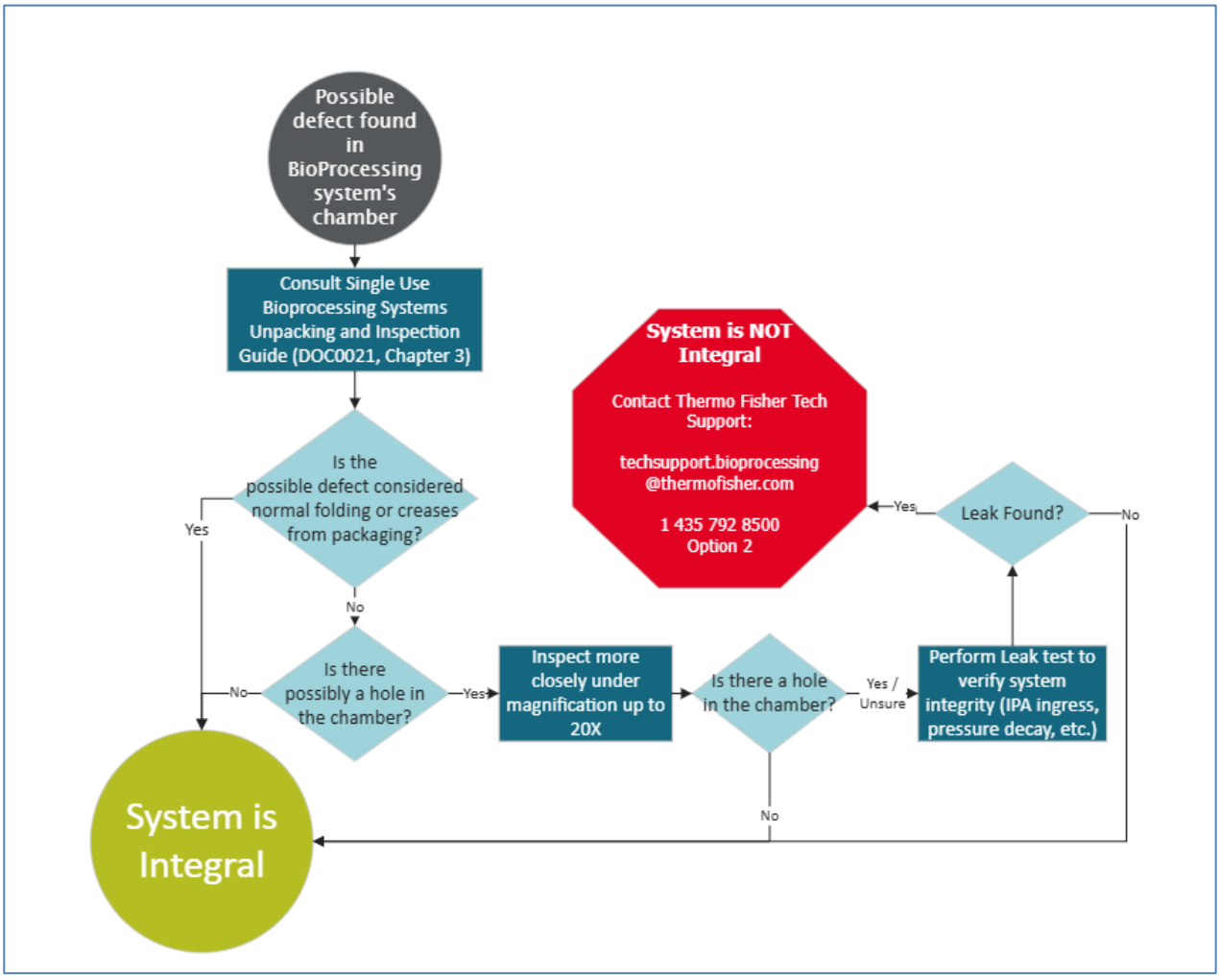


Figure 3.6. BioProcessing Sytems inspection flowchart.

Table 3.5. Defect library.

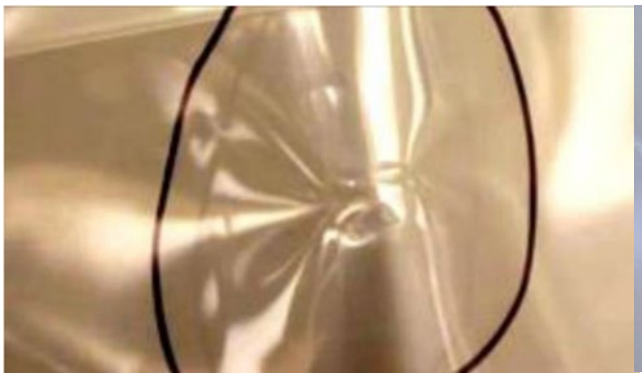
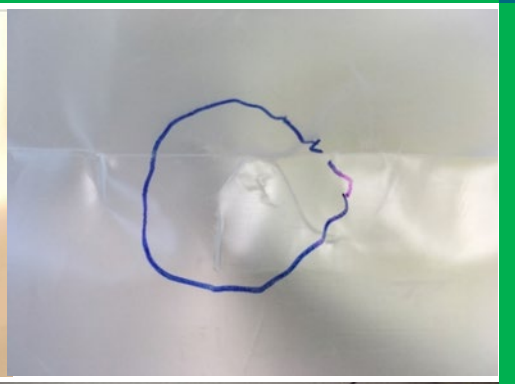
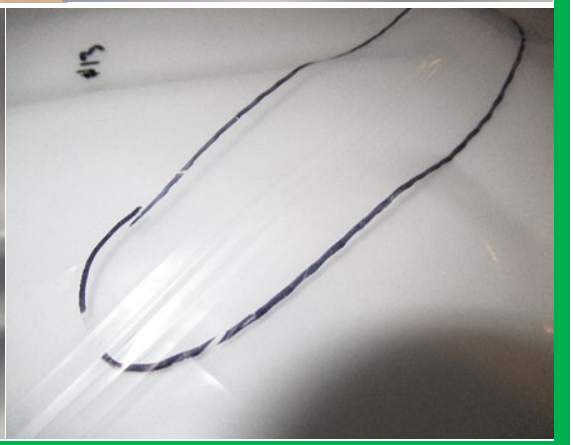
Defect	Crease/Wrinkle	
Description	Line or ridge that spans across the film.	
Observable Characteristics	Similar appearance to a wrinkle or fold in clothing.	
Potential Causes	• Folding of the film during extrusion, lamination. • Folding of the film once sealed into a BPC.	
Acceptance Criteria		
Acceptable: All creases are acceptable		**Unacceptable:** N/A
Example Image(s)		
		
		
Rationale	Creases are cosmetic in nature and do not impact product performance. Creases do not have an impact on the integrity of the film supported by Thermo Fisher pressure/leak testing.	

Table 3.6. Defect library (continued).

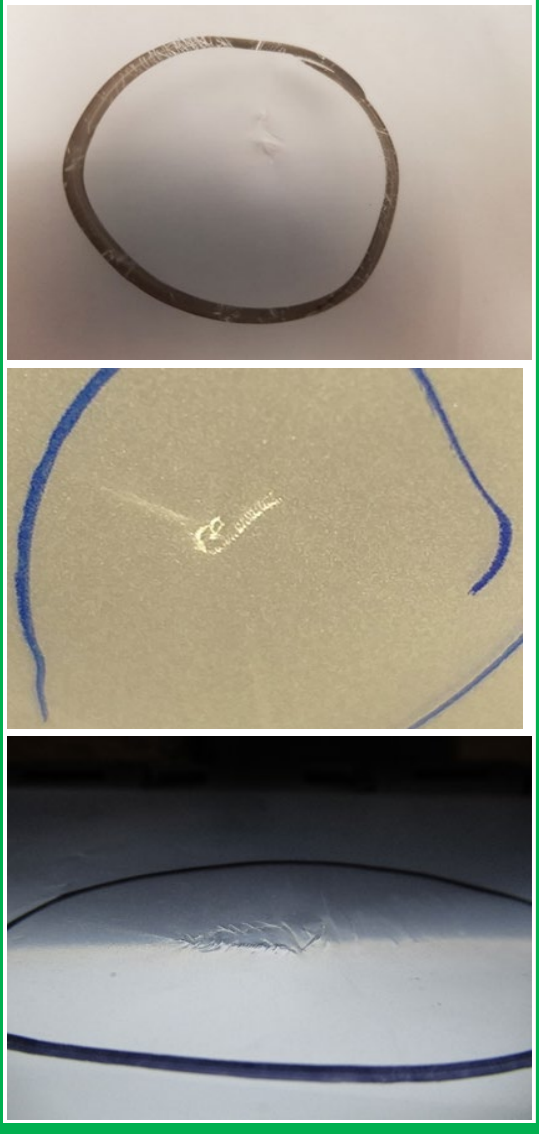
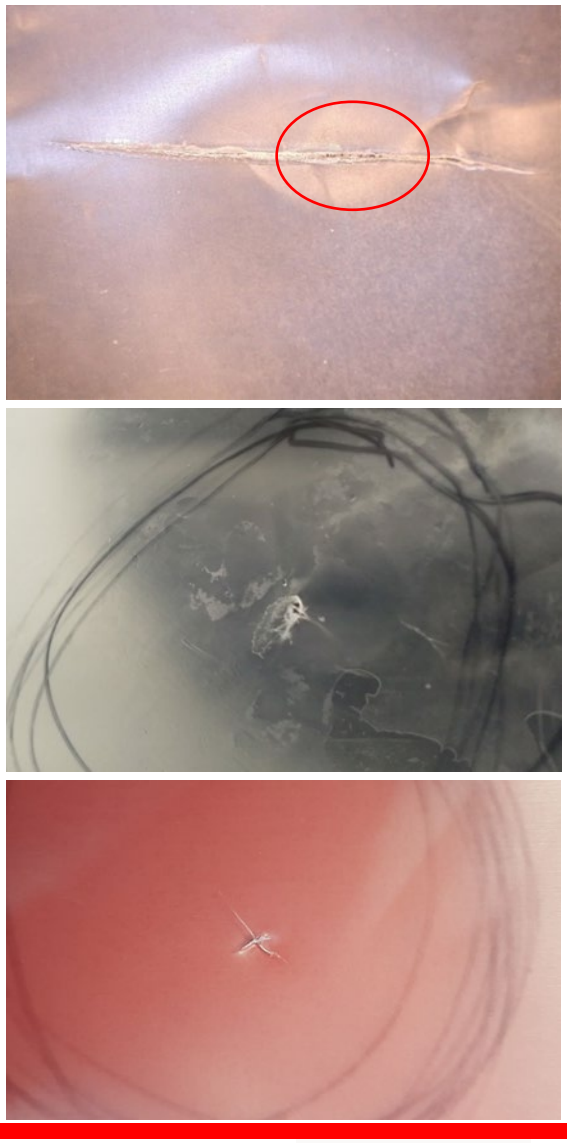
Defect	Film Imperfections – Also known as Scratch, Score, Scuff, Abrasion
Description	Scratch, score or mark on the film surface.
Observable Characteristics	Smooth or rough edges dependent on origin. May be tactile. Marking can appear as white smeared film and may have plastic, fiber-like protrusions; often with white cloudiness around the area.
Potential Causes	Rubbing, dragging or impact.
Acceptance Criteria	
Acceptable: Film imperfections are acceptable if there are no hole's present in the film.	**Unacceptable:** If a visible hole is present, magnification and light can be used for evaluation.
Example Image(s)	
	
Rationale	Acceptable examples were confirmed to be integral during pressure/leak testing.

Table 3.7. Defect library (continued).

Defect	Cut
Description	Thin, linear mechanical damage to the film.
Observable Characteristics	Clean and smooth edges, little or no adjacent whitening.
Potential Causes	• Sharp cutting instruments such as scissors or box cutters. Can be inadvertently caused during removal of packaging material. • Sharp surface in the workspace (e.g. table, support hardware).
Acceptance Criteria	
Acceptable: N/A	**Unacceptable:** All cuts are unacceptable
Example Image(s)	
	
Rationale	Cuts are as a result of improper handling by the end user and should be investigated by the customer when discovered.

Table 3.8. Defect library (continued).

Defect	Rupture/burst	
Description	Gross failure of bag – mechanical stress exceeds material strength	
Observable Characteristics	Stretching of film around the hole, sometimes with adjacent whitening; tending to protrude outwards.	
Potential Causes	• Improper deployment/filling of BPC (e.g. overfilling or over-pressurization of BPC, improper spider or hoist height). • A misalignment between the use conditions and supplier-qualified design space.	
Acceptance Criteria		
Acceptable: N/A		**Unacceptable:** All ruptures are unacceptable
Example Image(s)		
		
Rationale	Ruptures are as a result of improper handling by the end user and should be investigated by the customer when discovered. BioProcessing Systems are not pressure vessels.	

Table 3.9. Defect library (continued).

Defect	Kinked/bent tubing
Description	Tubing is no longer uniform around the inner axis; typically, within a confined area of the tubing
Observable Characteristics	A fold, sharp bend, or blockage of tubing that has taken the shape of the bend; tubing cannot be straightened without assistance.
Potential Causes	• The assembly is packaged such that the tubing is bent, kinked, or clamped. • The gamma irradiation process can cause cross-linking of the polymer, sealing tubing shut at the location where the tubing walls are in contact.
Acceptance Criteria	
Acceptable: If minor manipulation returns the tubing to an open flow path/useable state.	**Unacceptable:** If an open flow path cannot be achieved with minor manipulation.
Example Image(s)	
 	 
Rationale	Some tubing types are more susceptible to fusing if kinked then gamma irradiated and remain in a closed path state.

Table 3.10. Defect library (continued).

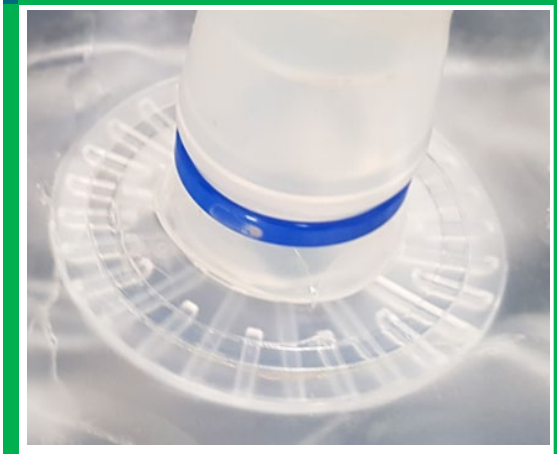
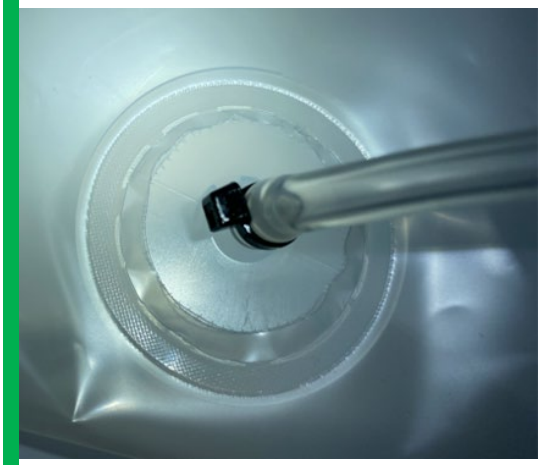
Defect	Incomplete port seam/damaged port seal
Description	A distinct separation or voids/gaps between a port or other rigid fitment and one or more individual pieces of film at a seal.
Observable Characteristics	Insufficient or incomplete seal on the BPC chamber; seal may have voids, bubbles, wrinkles, or channels spanning from the fluid path to the external non-fluid path side of the seal.
Potential Causes	• Incomplete or improper sealing (inadequate energy delivered during sealing process). • Misalignment during sealing. • Film wrinkled during sealing. • Excessive side load from attached stiff and/or heavy tubing.
Acceptance Criteria	
Acceptable: If seal is consistent around perimeter with respect to colour and width; no voids are present.	**Unacceptable:** Where a missing port seam (top red image) is identified, or a gap or void is present in the seam (bottom red image).
Example Image(s)	
 	 
Rationale	Port seams are applied using validated equipment and settings, so the product should be accepted if a full seal is present.

Table 3.11. Defect library (continued).

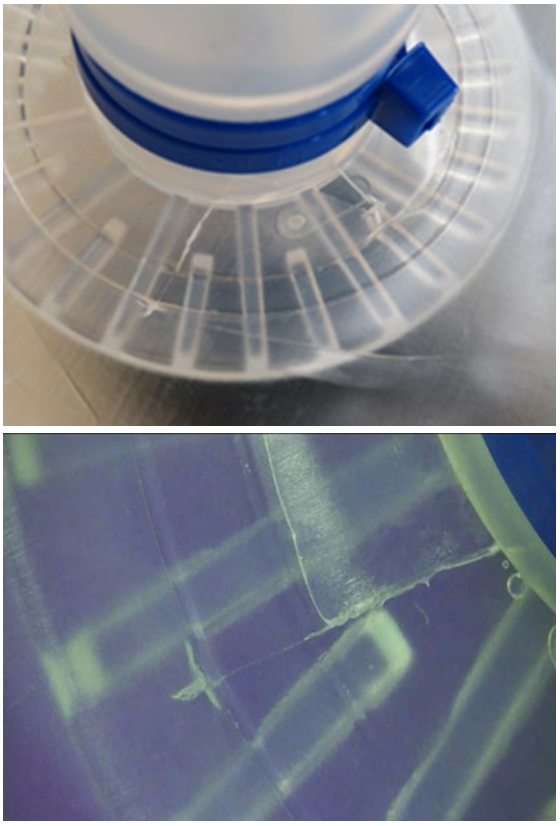
Defect	Film Outside of Sealed Area	
Description	• Chamber Port tabs - Visible cross-cut film tabs on chamber ports. • Port Cut Skirting – Film that appears to be unsealed around	
Observable Characteristics	• Chamber Port tabs -Triangular shaped tabs of film visible outside of the chamber port tube. • Port Cut Skirting – Film between the seam and the port cut.	
Potential Causes	Chamber Port tabs - Tabs caught outside of the port tube when the tube is manually fitted to the chamber port. Port Cut Skirting – Normal area of film that is between the port cut and the port seam (indicated with arrows in the picture bottom left).	
Acceptance Criteria		
Acceptable: Where Port Cut Skirting and Chamber Port Tabs are outside of the sealed area and a full seam is present, the crosscut does not extend through the port seam.		**Unacceptable:** If the port cut has torn and extends through the port seam.
Example Image(s)		
		
Rationale	Port tabs being visible outside of the port tube or Port Cut skirting if no tear is present/outside the sealed chamber area is a cosmetic issue. Tube securing devices and port seams provide unit integrity.	

Table 3.12. Defect library (continued).

Defect	Incomplete Film Seam	
Description	A distinct separation or voids/gaps between two or more individual pieces of film at a seal.	
Observable Characteristics	Insufficient or incomplete seal on the BPC chamber; seal may have voids, bubbles, wrinkles, or channels spanning from the fluid path to the external non-fluid path side of the seal.	
Potential Causes	• Incomplete or improper sealing (inadequate energy delivered during sealing process). • Misalignment during film sealing. • Film wrinkled during sealing.	
Acceptance Criteria		
Acceptable: All units with a complete seam.		**Unacceptable:** All units with a gap in the seam.
Example Image(s)		
		
Rationale	Film seams are applied using validated equipment, so the product should be accepted if a full seal is present.	

Table 3.13. Defect library (continued).

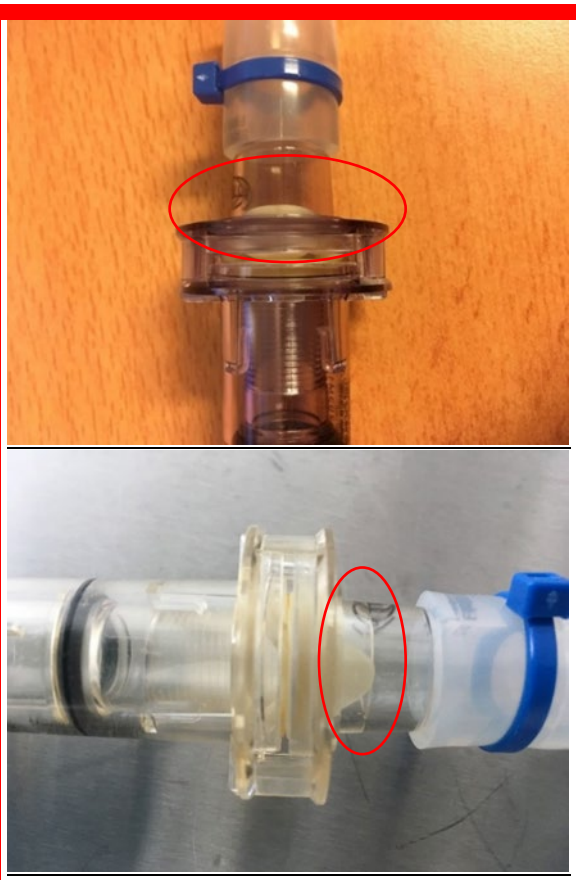
Defect	Kleenpak™ connector grommet rollover	
Description	One or both grommets are snagged by the male connector spike, causing it to jam before complete actuation.	
Observable Characteristics	Full actuation cannot be completed, Grommet is visible, having been displaced and pushed into the female connector.	
Potential Causes	• Asynchronous peel strip removal. • Not using the Kleenpak Assembly Aid	
Acceptance Criteria		
Acceptable: If no issues are detected during actuation and hard stop is reached.		**Unacceptable:** If peel strips are not removed simultaneously and during actuation the grommet obstructs and prevents a hard stop from being reached. In the red photos, the grommet is visibly snagged following actuation.
Example Image(s)		
		
Rationale	Per guidance from the Kleenpak Connector manufacturer. If grommet rollover is identified, this should be investigated by the customer when discovered for correct technique being used as this is not something controlled by Thermo Fisher and is only done at actuation by the end user during the connection process.	

Table 3.14. Defect library (continued).

Defect	Opta Connector	
Description	Torn OPTA membrane	
Observable Characteristics	• Tear in membrane. • Pieces of membrane are still attached to the connector body	
Potential Causes	Operator error during membrane removal while making a male to female OPTA connection.	
Acceptance Criteria		
Acceptable: If the OPTA pull tab is successfully detected without tears in the membrane.		**Unacceptable:** If the OPTA membrane contains a tear.
Example Image(s)		
		
Rationale	The membrane will tear when an operator insufficiently pulls the tab; the gasket within the joined male & female components can un-seat, which may result in a joint leak. If a tear is identified, this should be investigated by the customer when discovered for correct technique being used.	

Table 3.15. Defect library (continued).

Defect	Tubing damage
Description	Defect or damage in the tubing wall
Observable Characteristics	Cuts, tears, or imperfections identified in the outer wall of the tubing.
Potential Causes	• Tubing pulled tight/kinked against the connector/filter hose barb. • Damage caused by sharp tooling used to open packaging.
Acceptance Criteria	
Acceptable: If damage appears to be cosmetic and the tube wall has not been compromised.	**Unacceptable:** If a visible hole is present; magnification and light can be used for evaluation.
Example Image(s)	
	
Rationale	Visual imperfections where no hole is present, and an open flow path is achieved should not adversely affect product use.

Table 3.16. Defect Library (continued)

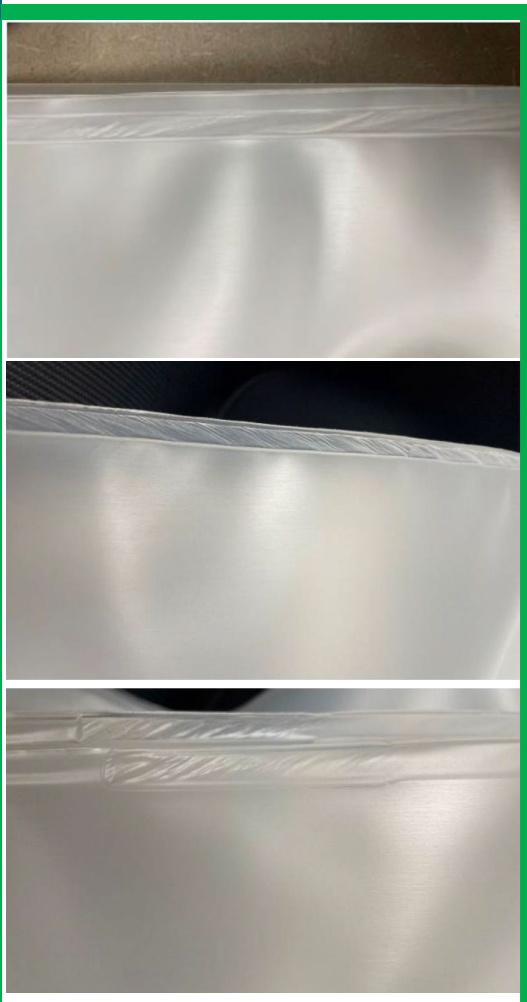
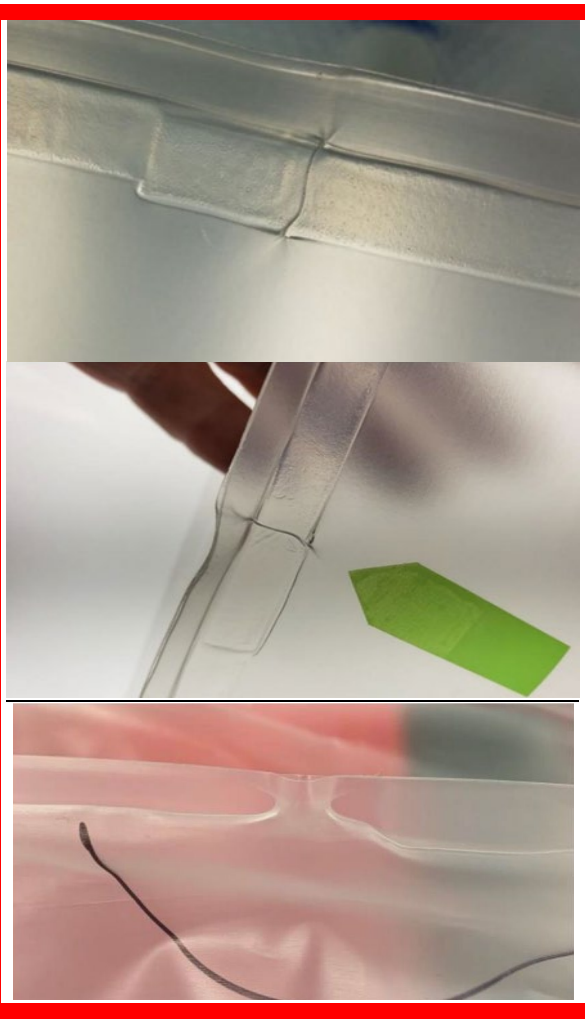
Defect	Striations on Seams (CX5-14 & Aegis Film only)
Description	Visual anomalies in the BPC chamber seam
Observable Characteristics	Wrinkles or wave like appearance in the chamber seams
Potential Causes	• Caused by tension in the machine while the seal is still hot and are especially prominent in areas of overlapping seams. • These striations are a result of the movement of the film within the equipment and the appropriate tension and speed that is required.
Acceptance Criteria	
Acceptable: No voids showing in the chamber seam and minimum seam width of 1/8”.	**Unacceptable:** Any fold or crease that can be seen inside the seal. Pleats pose a risk of a potential leak path. A void where the seal did not occur
Example Image(s)	
	
Rationale	Striations have been thoroughly tested and studied and found to pose no risk to the product's processing capabilities. Acceptable images shown are from chambers burst tested and the seams were not the weak point.

Table 3.17. Defect Library (continued)

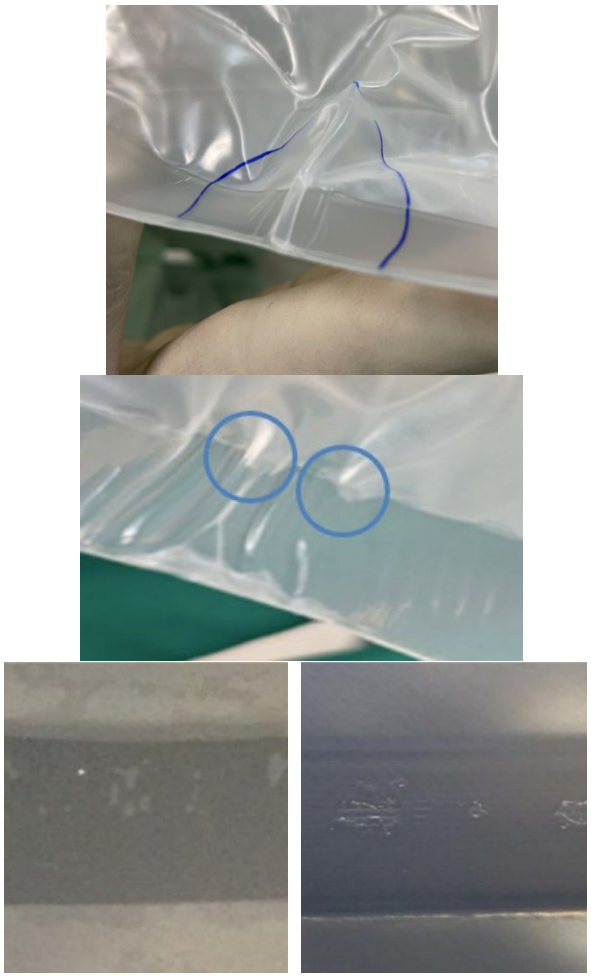
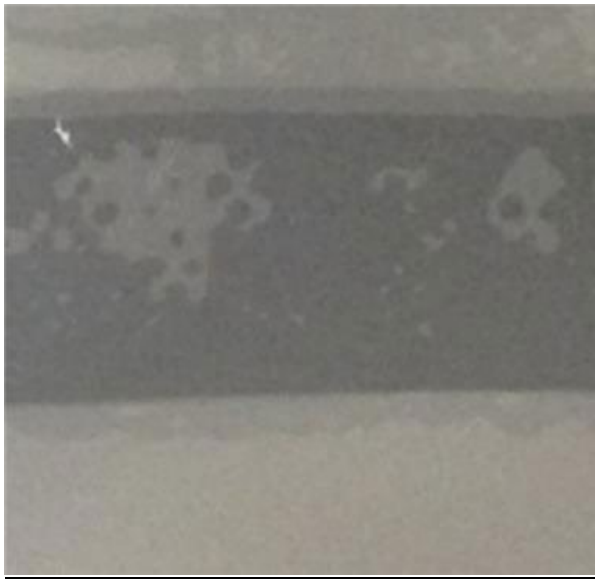
Defect	Pleats and Perimeter Seal Anomalies (PL-01026/PL-01077 Film Only)
Description	Visual anomalies in the BPC chamber seam
Observable Characteristics	Raised fold and/or discoloration of the film in the chamber seams
Potential Causes	• Pleats are the result of creases in the film that are present during the sealing cycle. They can occur on any seal but are most prevalent on V-seals. • Voids are the result of air pockets being trapped during the sealing cycle. Worn Teflon can produce a pattern that is visually similar and purely cosmetic. Voids will have a smooth surface texture whereas worn Teflon will create a rough surface texture.
Acceptance Criteria	
Acceptable: Voids showing in the chamber seam that do not exceed 1/8” as measured across the width of the seal. Any seal with a minimum of 1/4” as measured across the width of the seal. All Pleats are considered acceptable.	**Unacceptable:** Voids in the seal exceeding 1/8” as measured across the width of the seal. Any seal less than 1/4” as measured across the width of the seal.
Example Image(s)	
	
Rationale	The validated settings for the critical process parameters have proven to produce seal welds that are free from channel leaks and exceed the tensile strength of the film itself.

Table 3.18. Defect library (continued).

Defect	imPULSE Single Use Mixer – Bent Shaft / Offset Shaft / Twisted Diaphragm	
Description	Unnatural appearance of the mixer head shaft/diaphragm	
Observable Characteristics	• Bent/Offset Shaft – The shaft appears to be bent at an angle or offset that is not perpendicular to the surface of the mixing plate while in a packaged state. • Twisted Diaphragm – The diaphragm appears to be twisted around the axis of the shaft. • Deformed Diaphragm Lip – The lip of the diaphragm appears to be bent.	
Potential Causes	Due to the positioning of the mixer head during the folding process at the packaging step, the shaft/diaphragm appear to be deformed.	
Acceptance Criteria		
Acceptable: Units showing the appearance of Bent/Offset Shafts (Diaphragms) and Twisted Diaphragms.		**Unacceptable:** Diaphragms with a deformed lip.
Example Image(s)		
		
Rationale	Upon unfolding and unpackaging the twist/offset/bend will relieve, and the diaphragm will re-align with the shaft. Deformed Diaphragm Lips will not self-correct and chambers with this nonconformity have the potential to not seat correctly in the mixer vessel. This may result in damage to the chamber during agitation.	

4

Product support

4.1 Reporting an issue

If any issues are found during the inspection process, contact your Thermo Scientific product sales representative. You will be asked to describe the nature of the issue, and in some cases, the product will need to be sent to us for further inspection. Thermo Scientific sales and quality teams will reply to all product reports.

When reporting an issue, please include the following information:

- Product code
- Lot number
- Description of the issue
- Customer name
- Order name.
- Quantity under complaint
- Color photographs of the product, if possible

See Appendix C for a sample Initial Diagnosis Checklist for BioProcessing System issues. Contact your sales representative or our support team for more information.

4.2 Contact information

For general questions, contact our support team:

- bpp.technicalsupport@thermofisher.com
- 1 800 792 8500 (Option 2)

Appendix A—Manufacturing drawings and product specifications

Manufacturing drawings

The manufacturing drawing (Figure A.1) that accompanies a standard product is controlled by Thermo Fisher Scientific and is available by request. The drawing includes:

- Detailed visualization of the product
- Product parts list

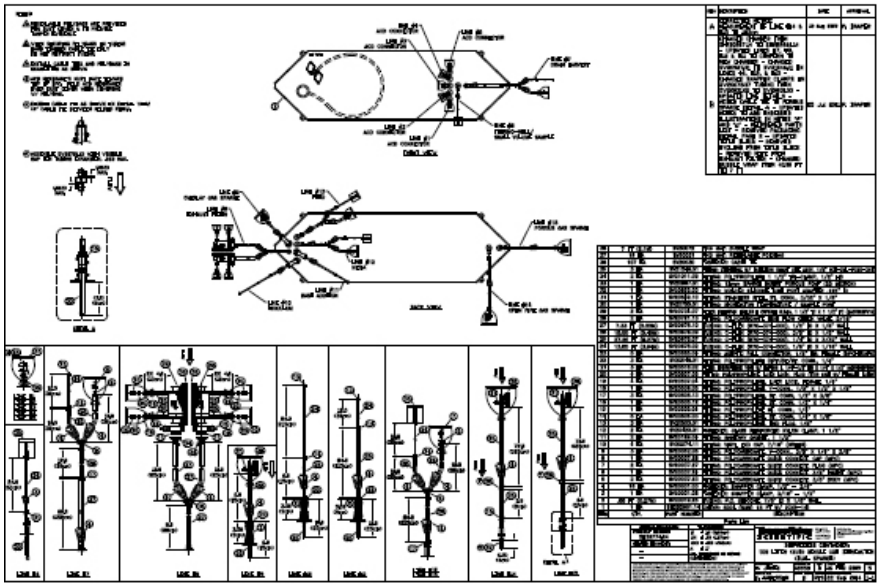


Figure A.1. Example of a manufacturing drawing for a standard product.

The manufacturing drawing accompanying a custom product is controlled by the customer and is part of the agreement with the customer. They include the same details as drawings for standard products. Customer approval is required for changes made to a manufacturing drawing for a custom product.

Product specifications

Product specifications may be used to cross-check customer specifications with vendor specifications. Product specification is not required for BioProcessing System inspection.

Appendix B—Certificates of Analysis

Certificates of Analysis (COAs) differ by product. They may include the following types of information:

- Lot number
- Description
- Expiration date
- Irradiation dosage
- Inspection
- Biological reactivity
- Cytotoxicity
- Physiochemical
- EP testing
- Endotoxin
- Particulate
- Certificate of Irradiation

Certificates of Processing for irradiated products provide the date of processing and dosage information. Filter certificates are available upon request. Non-cGMP products do not have a COA.

Appendix C—Sample Initial Diagnosis Checklist

The following pages show an example of an Initial Diagnosis Checklist used to describe the event surrounding an issue with your BioProcessing System. Contact our support team for more information on obtaining and using this form.

Thermo Fisher Scientific Initial Diagnosis Checklist

Please return to: techsupport.bioprocessing@thermofisher.com Phone: +1 435 792-8500 Option 2

Completed By (Customer Contact Information)	
Name:	
Title/Department:	
Email Address:	
Company:	
Company Address:	
Customer Reference #:	
Technical and Quality Contacts (May be contacted for further investigation, questions, and activity)	
Technical Contact	Quality Contact
Name:	
Title/Department:	
Email Address:	
Phone Number:	
Site of Occurrence	
Site Name:	
Address:	
City:	
State:	
Country:	
Impacted Assembly ID	
Thermo Fisher Part #:	
Thermo Fisher Lot #:	
Thermo Fisher Part Description:	
PO #:	
Finished good unit number (located on label on inner liner of product):	
Chamber unit number (located on chamber lot stamp on product):	
Quantity for Investigation:	
Quantity Originally Received:	
Sales Rep:	
Date and Time of Occurrence	
Date:	
Time:	

Single-Use Event Reporting Checklist

General Event Description

Record the full problem statement at the time of the event identification. Include all relevant details of where/when in process the event occurred and details of defect/leak, e.g. size/shape of leak (if it can be determined) and rate of leak.

Action Required

☐ Event requires an investigation

☐ Event reported for tracking only

When Observed

☐ Incoming Receipt

☐ Pre-Use Inspection *(Includes visual inspection after removal from packaging polybags)*

☐ Storage

☐ Use *(During and after installation, can include pre-use pressure decay test)*

☐ Post-Use

Defect/Damage Location

☐ Photos of Defect/Damage Location Attached *(If possible, take and label multiple photographs, including close-up and zoomed-out views)*

☐ Defect/Damage Location Marked on Assembly *(Use a felt-tipped lab marker)*

☐ Description of Defect Location:

Impacted Unit Operation

Specify what operation (e.g. media preparation, buffer preparation, cell culture, chromatography, integrity test) was impacted by the event.

Associated Equipment ID

Identify any equipment that corresponds to the event, e.g. stainless-steel carrier, S.U.B. support vessel, etc.

☐ N/A

Room

Specify room that corresponds to the department in the facility where the event occur.

Operators Involved

E.g. Who installed or discovered?

Single-Use Event Reporting Checklist

Defect/Damage Category

Leak From:	**Other Defect/Damage:**
☐ Chamber Film (Chamber Lot # if applicable):	☐ Foreign Material/Particles (For particulate size & count required):
☐ Tubing Engagement/Connection	☐ Sensor Issue
☐ Seal/Weld (Port, Perimeter Seal) (Chamber Lot # if applicable):	☐ Damaged Component
☐ Tubing	☐ Incorrect Assembly
☐ Could Not Be Determined	☐ Filter Issue
☐ Other:	☐ Other:

Record Defect Location

Confirm defect location and mark on technical drawing of assembly (if applicable) for better context of issue location.

☐ Issue Location Marked on Product Drawing
☐ N/A

Operating Conditions

☐ N/A (if pre-use)

Temperature/Pressure:

Flow Rate:

Fill Volume:

Agitation Rate:

Operation Duration:

Number of Users:

Historical Experience with Failure Mode

Summarize whether the failure mode has been observed before. Reference previously reported events, if applicable.

Summary of (CUSTOMER) Root Cause Analysis

Summarize outcome of root cause analysis performed, including causes that were ruled out and any testing performed.

Next Steps

Provide procedure reference or other documentation, if applicable.

☐ Assembly left in place for investigation

☐ Assembly uninstalled, labeled, and set aside for investigation

☐ Assembly decontaminated per:

☐ Assembly will not be returned or is not available for investigation (limited investigation requested).

Single-Use Event Reporting Checklist

List of Attachments Provided to Thermo Fisher
Check all that apply:
☐ Photos or Video of Defect Location
☐ Marked-up Assembly Drawing Indicating Defect Location
☐ Decontamination Summary
☐ Other:

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Learn more at **thermofisher.com/sut**

thermo scientific

For Research Use Only. Not for use in diagnostic procedures.

 DOC0021 Rev. M