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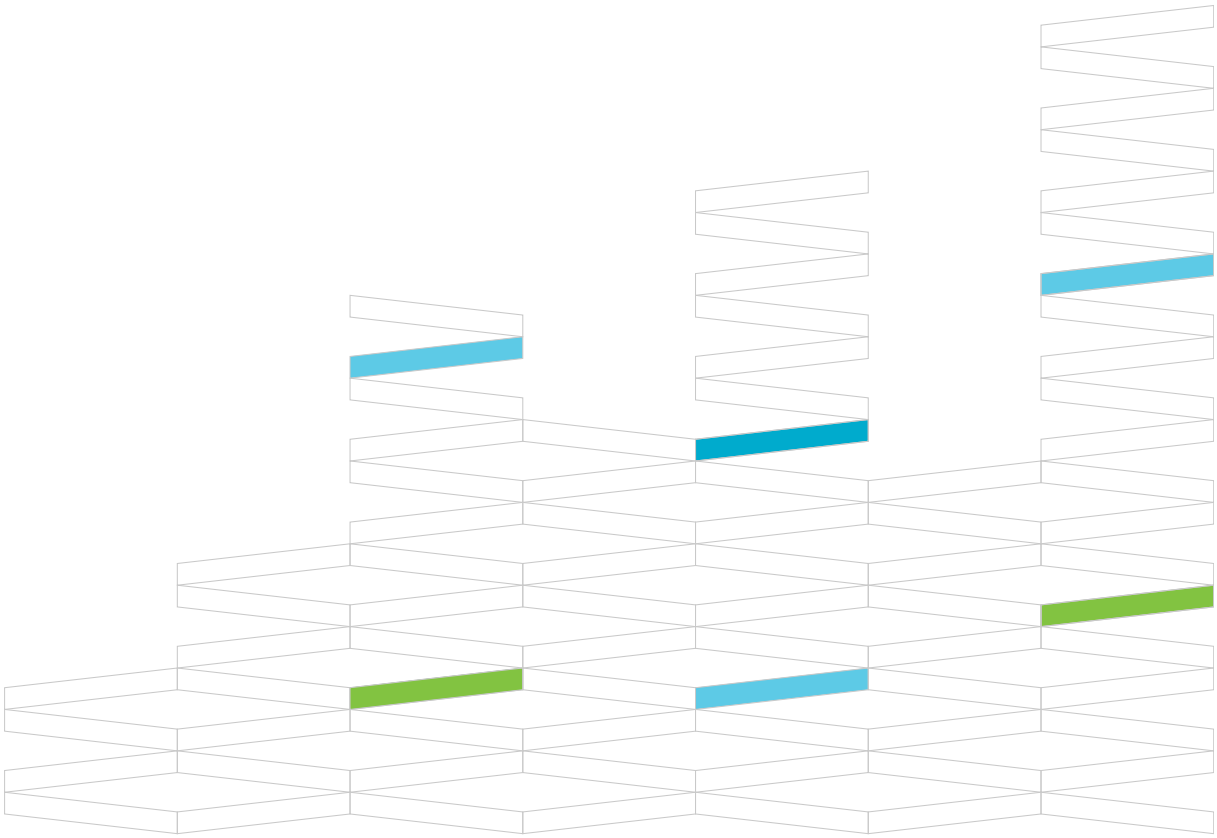
Magnetic Separation Platform (MSP)

Instructions for use



Revision History

Issue	Date	Author	Description
A1	18MARCH2020	CP	Initial DRAFT
A2	3JUNE2020	ZAZL	Revised all sections
A4	22JNE2020	SIH	Revisions
A5	23ZJUN2020	SIH	Revisions
A6	23JUN2020	ZNZC	Added Troubleshooting options

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Invetech

CONTENTS

1. REFERENCED DOCUMENTS

Doc #	Document Name	Document ID
1	MSP Service and Maintenance Manual	DEBM_1183

2. SAFETY NOTICE

Attention: The following are general safety precautions that may not be related to specific procedures and may not appear elsewhere in this manual. All personnel must read, understand and apply these precautions before operating the system. All personnel working with and around the machine must also be aware of the hazards and safe operating procedures. The hazards of individual procedures are included in the warning and cautions section of these instructions. Any staff not familiar with safe working procedures of the machine should not operate the machinery.

Always follow the product labels and recommendations from the manufacturer and follow the power requirement in the system specification. Instrument use in a manner not specified by Invetech may impair machine protection, deliver incorrect results or cause system failure. For more information, contact Invetech.

In addition to the general safety items in this manual, state and federal law of the country in which the machine is operated also applies. Furthermore, the operating company responsible for the machine may impose additional safety restrictions and procedures. It is the responsibility of the machine operator to ensure that all safety procedures are correctly followed.

2.1 Alerts for Warning, Caution, Notice in this document

Warning

Warning indicates a potential hazardous situation which, if not avoided, could cause death or serious injury.

Caution

Caution indicates a potential hazardous situation which, if not avoided, can cause minor or moderate injury. Caution can also alert against unsafe practices or indicate the possibility of system functions being impaired and poor-quality outcomes.

Notice

Notice draws attention to notable information.

2.2 Symbol Glossary Table

Symbol	Meaning
	**Title of symbol: Caution** Indicates caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences. Operators need to review instructions for use for important cautionary information.
	**Title of symbol: Warning Biological hazard** Take care to avoid exposure to a biological hazard ISO 7010-W009
	**Title of symbol: Warning Electricity** Take care to avoid coming into contact with electrical components behind this panel. ISO 7010-W012 IEC 60417-5036
	**Title of symbol: Warning; Crushing of hands** Take car to avoid injury to hands when in the vicinity of equipment with closing mechanical parts. ISO7010-W024
	**Title of symbol: Warning; Pinch** Take care to avoid injury to hands when in the vicinity of equipment with running mechanical parts like peristaltic pumps.
	**Title of symbol: Read operator's Manual** To indicate that the operator's manual or card should be read before continuing operations. This document 'Instructions for Use' should be considered the Operators manual. ISO7000-0790
	**Title of symbol: Manufacture** To identify the manufacturer of a product. The Name and location of manufacture will accompany this symbol. This is to Identify who the legal manufacturer of the product is.

2.3 Authorized Persons

Warning

The instrument shall only be operated by trained personnel or in the presence of trained personnel. Reasonable care must be taken to prevent unauthorized access to the instrument.

Warning

Maintenance of the instrument shall only be performed by qualified service technician/personnel.

Caution

Roles and responsibilities for operators should be clearly defined prior to operation.

Warning

Operators are responsible for the safety of third parties in the immediate vicinity of the instrument.

2.4 Personal Protective Equipment (PPE)

Warning

Wear Personal Protective Equipment (PPE) such as gloves, eye shields, and lab coats when performing any procedure. To avoid injury, observe and follow all the warnings and cautions throughout these instructions. Wash hands thoroughly after contact with sample media and all maintenance activities. Observe all laboratory policies and procedures related to the handling of biohazardous materials. Refer to the applicable sources (such as Material Safety Data Sheets) for specific hazard information.

Caution

Appropriate personal protective equipment must be correctly used whenever moving, cleaning or interacting with the instrument.

Caution

During cleaning ensure that the correct PPE is used for the type of cleaning agent used. If unsure always refer to the Material Safety Data Sheet (MSDS) provided with the cleaning agent.

2.5 Equipment Operation

Caution

Read all product manuals and consult with Invetech trained personnel before you operate the system. Do not perform any procedure before you carefully read all instructions. Always follow the product labels and the recommendation from the manufacturer. For more information, contact Invetech.

Warning

The disposable kits and bags supplied by Invetech for the MSP instrument are the only sets to be used. Alternate tubing or bags may risk damage to the instrument and could compromise the safety and proper functionality of the MSP instrument.

Warnings

Only use fluids compatible with the disposable sets. NEVER use Flammable or explosive materials

Warning

Do not deposit any potentially hazardous materials within the clearance envelope. See instrument specification section 10.3 for distances.

Warning

Unless prompted by the machine, an operator should not interact with hardware during an automated process. Users should not stay within the clearance envelope longer than necessary for operational reasons. See instrument specification section 10.3 for distances.

Warning

Always operate the system with all shields and doors in position. Secure them to avoid injury.

Warning

Risk of personal injury from electrical shock. Electronic components can cause shock or injury. To prevent possible injury or shock, do not modify the instrument and do not remove any components (such as covers, doors, or panels) unless otherwise instructed in this document. Enclosure shall be closed before power is restored.

Caution

Hair shall be restrained, and loose-fitting clothing or jewellery must not be worn when interacting with the equipment.

Caution

Do not lean against the instrument even when it is not in operation.

Caution

Shut down PC/HMI before powering off instrument. Allow at least 10 seconds between power down and reapplying power. Failure to do so may damage the equipment and/or corrupt files such that equipment will not operate.

Caution

Take care when closing the platen door as it may cause crush injuries.

2.6 Mechanical Hazards

Warning

Always ensure that mechanical components and moving equipment are stopped and de-energised before loading tubing or interacting with hardware.

Warning

Unless prompted by the instrument, always ensure the system is not performing an automated process before opening pump.

Warning

Never place fingers into the pump even when pump is stopped.

Caution

Never place fingers into a pinch hazard, even during loading.

Warning

Always ensure that all body parts are clear from crush hazards before operating hardware.

Notification that crush or pinch hazards are present which could cause minor to serious injury are highlighted by signage on the instrument.

Warning

Take care when interacting with the MSP as the magnetic platen uses a strong permanent magnetic field. Can be harmful to pacemaker wearers and others with medical implants. Keep tools and other metal objects away.

2.7 Electrical Hazards

Warning

Incorrect grounding can cause electric shock and damage the system. Never operate the system until the power cord is connected correctly to an electrical ground. Use a three-pronged (grounded) power cord to connect the system to a matching three-wire grounded outlet. Do not use an adapter to connect the power plug to a two-pronged outlet.

Warning

All electrical equipment must be electrically isolated from mains power prior to performing any electrical work or opening or removing doors or covers.

Warning

Work carried out on the electrical equipment must only be performed by qualified/competent technician/personnel.

Warning

Ensure that doors and covers are closed and in place prior to power being restored.

Hazardous voltage or presence of voltage which could cause serious injury are highlighted by signage on the instrument

Warning

Recommend plugging this system into a power circuit that has a residual-current device or ground fault circuit interrupt.

2.8 Chemical and Biological Hazards

Normal operations may involve the used of substances that are pathogenic or toxic. Such substances should only be used with the system when all safety precautions taken.

Warning

Handle body fluids with care as they can transmit disease. No known test can offer complete assurance that samples are free from micro-organisms. Some of the most virulent—Hepatitis (B and C) and HIV (I–V) viruses, atypical mycobacteria, and certain systemic fungi—further emphasize the need for aerosol protection. Handle all infectious samples according to good laboratory procedures and methods to prevent spread of disease. Because spills may generate aerosols, observe proper safety precautions for aerosol containment. Do not run toxic, pathogenic, or radioactive materials in this bag filler without taking appropriate safety precautions. Biosafe containment should be used when Risk Group II materials (as identified in the World Health Organization Laboratory Biosafety Manual) are handled; materials of a higher group require more than one level of protection.

Warning

Dispose of all waste solutions and biological contaminated disposable consumables according to appropriate environmental health and safety guidelines.

Notice

In the event that hazardous material is spilt, the user has responsibility for carrying out appropriate decontamination. See cleaning section of this manual.
It is the responsibility of the operator to decontaminate the instrument before requesting service by Invetech.

2.9 Safety Against risk of Fire

This instrument is not designed for use with materials capable of developing flammable or explosive vapours. Do not run such materials (such as chloroform or ethyl alcohol) in this instrument nor handle or store them with in the 30cm (1ft) area surrounding the Instrument.

Warning

In case of fire, the machine should immediately be isolated from mains power.

2.10 Additional Hazard Notifications

Warning

Use the safety features of the instrument. Do not compromise the integrity of safety interlocks and sensors.
Under normal operating conditions, the instrument protects the user from exposure to moving parts. The magnetic platen safety door has an interlock to secure the door. Never attempt to defeat these interlocks. Intentionally defeating these safety measures causes a risk of injury from moving parts. The back panel is designed to only be accessed by tools to prevent access to hazards therein.

Warning

There is a risk of personal injury if electronic equipment is used near fumes or flammable gases. Avoid this risk by never operating electronic equipment close to fumes or flammable gases.

Warning

Do not use running fluid, pressure hose or spray tools when cleaning this instrument. Cleaning is only to be conducted by wiping.

Warning

Only use specified cleaning and disinfecting products and chemicals. See Cleaning section for appropriate solutions.

Caution

Do not install software that is not approved by Invetech on the system. To prevent virus contamination, only use software that is an original copyrighted version.

3. INTRODUCTION

3.1 Purpose of this manual

This Instructions for Use describes the Invetech Magnetic Separation Platform (MSP) and its operating procedures.

3.2 Intended use

The system is a device for isolation of magnetic beads, that uses single use sterile disposables to maintain a functionally closed workflow. The system is designed to be used in a professional laboratory environment and should only be operated by trained personnel. This instrument is for laboratory use only.

3.3 Abbreviations

Term	Definition
MSP	Magnetic Separation Platform
CFC	Counter Flow Centrifuge
HMI	Human Machine Interface (touch display)

3.4 Scope of document

This document does not include specific instructions for the operation of modules not developed by Invetech, such as the offboard tube welder.

4. EQUIPMENT DESCRIPTION

4.1 Overview

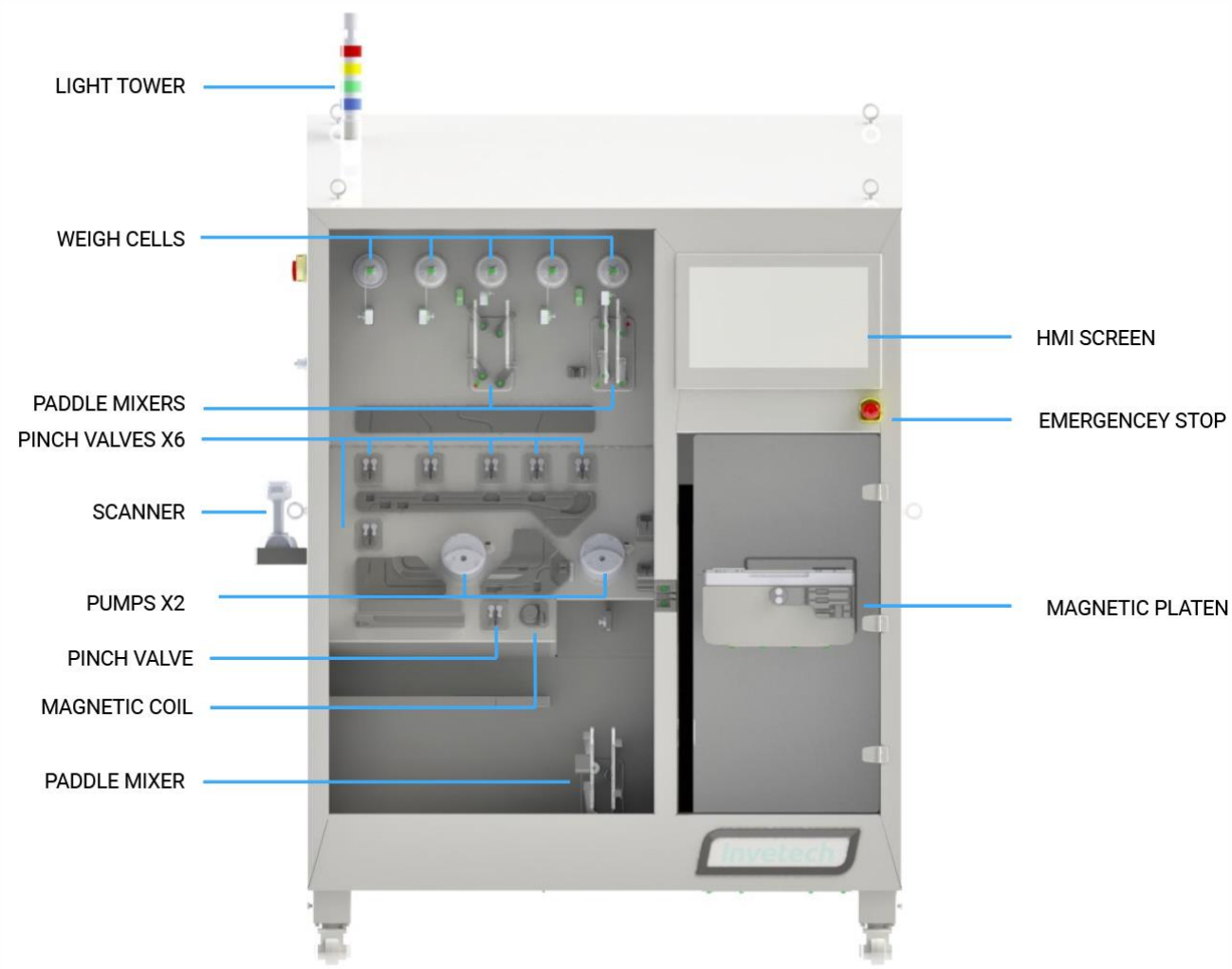
The MSP is a single platform for selection and separation of magnetic beads mixed with cells. It includes an integrated magnetic platen that performs the role of cell selection.

The entire process is completed in a closed manner using single-use tubes and bag sets. Each set is manually loaded into the MSP at the beginning of a process, with connections between tubing formed through external aseptic connections.

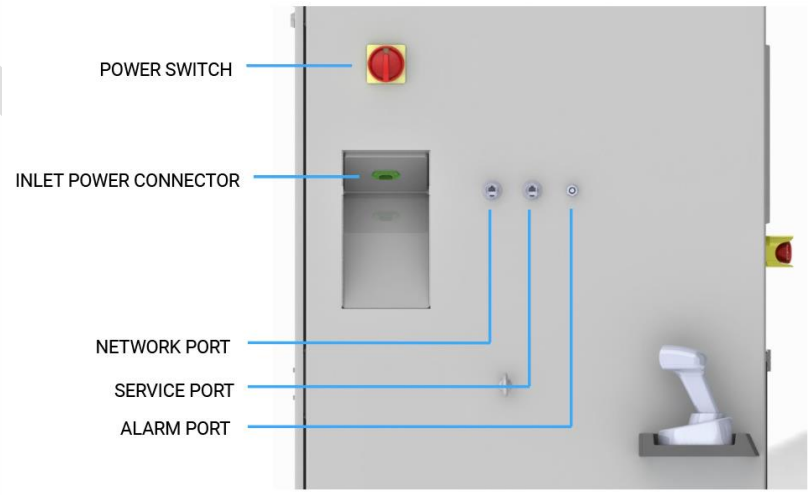
During processing, the operator should not interact with any component of the system, unless prompted to do so via the operator interface.

At completion of processing, the used tube-sets and bags are manually removed and stored or disposed of as biological waste.

Front View:



Left hand side view:



4.2 Safety Circuit

Due to the potential hazards that have been identified in this device a safety system has been incorporated to keep operators isolated from these hazard sources. The source of hazards are mains powered electricity and the magnetic platen module, that would cause harm if an operator interacted with these moving parts while energized.

The safety system prevents user exposure to hazards from the rotating platen module by restricting physical access. The chassis also provides the primary protection from access to mains voltage.

The instrument has an E-Stop button below the HMI, which will engage the safety circuit when pressed. This will de-energize the 3 paddle mixers, stop both peri pumps, stop the magnetic platen module, and engage the platen rotational brake.

The platen safety door also has an interlock. If the door is opened, this will stop the magnetic platen module, and engage the platen rotational brake.

Each Peri Pump has a safety function if the pump guard is opened, both pumps are de-energized.

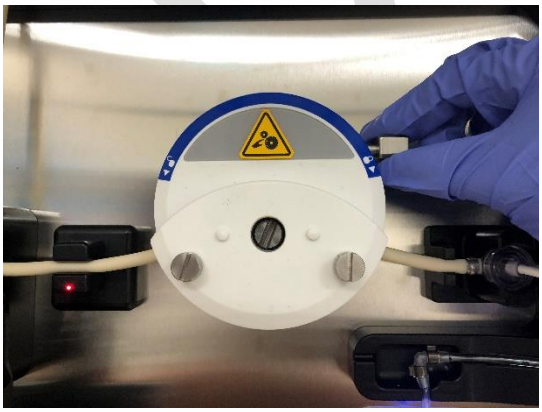
If a safety relay is triggered the cause must be removed (disengage E-Stop by twisting the button, and or close the safety door, and or close pump cover) and then press the “Reset Safety” button. This is performed either on the main home screen or on the P&ID screen.

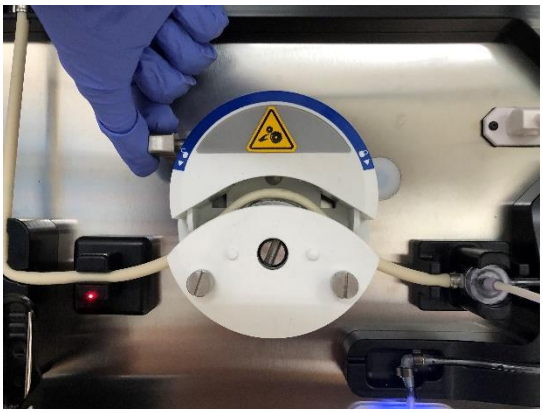
4.3 Peristaltic Pump

The peristaltic pump is used to pump fluid, with pinch valves providing the necessary control to route fluid to/from the desired bag.

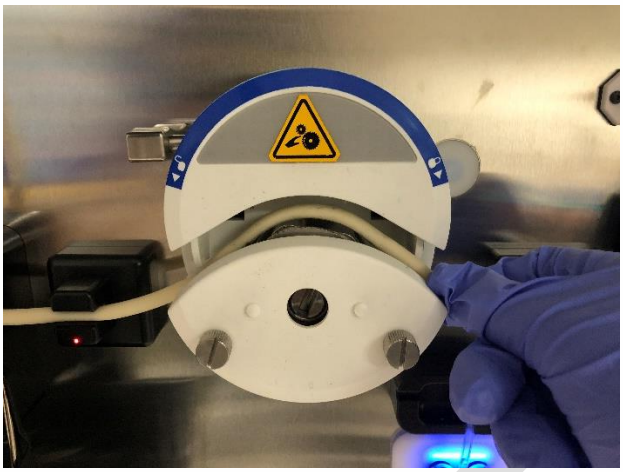
The pump has an integrated guard with an interlock that does not allow operation whilst open. However, **caution** should be exercised due to the **crush hazard**.

To unlock pump, use the lever and move it anticlockwise. To lock pump, use the lever and move it clockwise.





To load tubing into pump, guide tube on either side through the V channels in the guard. **DO NOT** place fingers into pump.

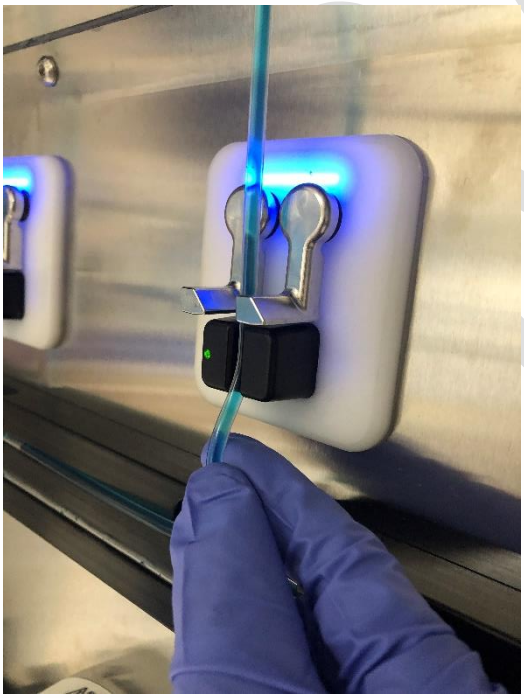


4.4 Pinch Valves

There are seven pinch valves located on the MSP to direct fluid flow. They are very simple to use and limited pinch force (spring to close). All pinch valves have an incorporated bubble sensor to detect the presence of air bubbles, and to keep the tube in the correct location.

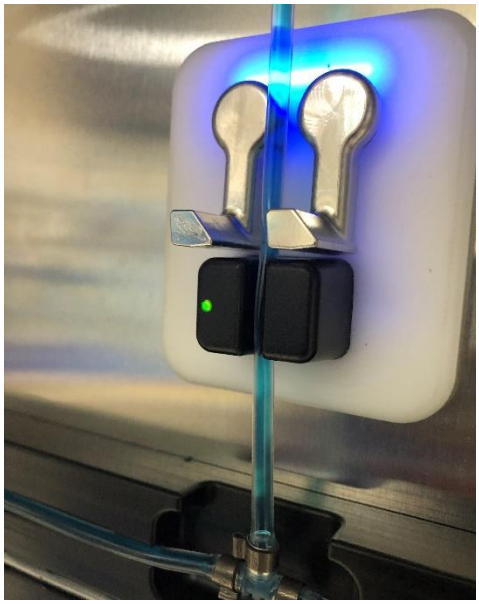
Hold the tubing on either side of the pinch valve and place between the arms. Firmly push the tube into the bubble sensor.

Lift the tube from above or below the pinch valve arms to remove.



4.5 Bubble detectors

There are nine bubble detectors on the MSP, signalling whether air or fluid is present at that location. The LED indicator will be red when no tube is loaded or when air is in the loaded tube. The LED will be green when there is liquid detected in the loaded tube.



4.6 Weigh module

There are five weigh modules located on the MSP. The weigh module monitors the mass of bags hanging on the weigh cells, to enable mass controlled transfer of fluid from bags.

Notice

The weigh cells are sensitive to any movement of the bags or tubing hanging from them, which could adversely impact fluid transfer accuracy. Do not interact with the bags or tubing unless instructed to via the HMI. Never hang anything, or lean anything against the load cells, other than the prescribed tube set components.

Notice

Weigh cells measure fluid mass. Fluid transfers are controlled by volume, with a density compensation applied to convert from mass to volume. Ensure the correct density compensation factor is entered for each weigh cell prior to processing, via the weigh cell faceplate.

4.7 Paddle mixer

There are three paddle mixers integrated into the platform. Its role is to gently agitate fluid within a bag, providing a homogenous mixture.

The paddle mixer utilises an array of constant force magnetic springs to apply limited squeeze force in the event of an inadvertent user interaction. In the opening direction a sprung breakaway mechanism is provided to limit force able to be applied between paddles and adjacent objects.

The paddle mixer speed is controlled on the faceplate by a '% speed' control. The table below shows the conversion between '% speed' and number of oscillations per minute, where a single oscillation is the paddles moving from open, to closed, to open again.

Speed %	Oscillations/min
20	4.5
40	14
60	23
80	32
100	41

For example, 60% speed will squeeze the bag 23 times in a minute.

4.8 Magnetic Platen module

Warning

Take care when interacting with the MSP as the magnetic platen uses a strong permanent magnetic field. Can be harmful to pacemaker wearers and others with medical implants. Keep tools and other metal objects away.

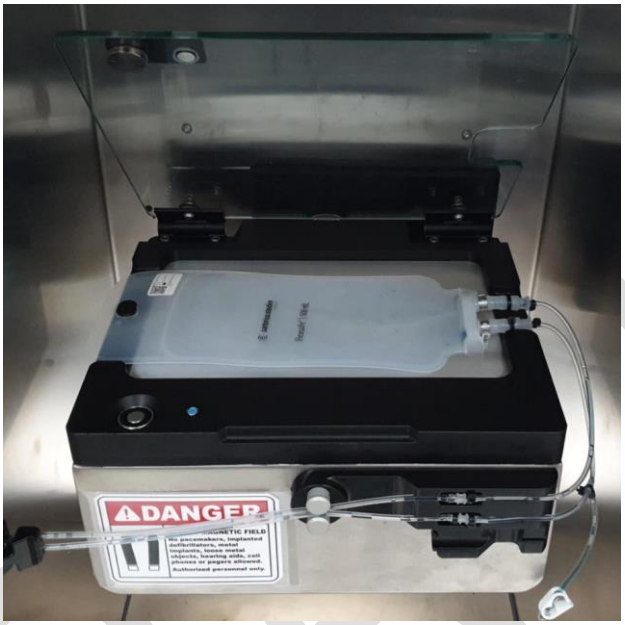
The rotating magnetic platen module uses permanent magnets to isolate magnetic beads (Dynabeads) within fluid media. In this way, cells bound to beads can be isolated from the remainder of the fluid. The platen module sits in a recessed cavity, behind a safety door.

The bag for isolation is loaded onto the platen surface, and a glass door is provided to limit the bag height ("pillowing") so that the magnetic field remains effective throughout the depth of the bag. The door has an electromagnet, which keeps the door closed during processing.

The platen can rotate to provide mixing and also pause at an angle to facilitate fluid loading or draining. The rotational axis is fitted with a friction brake, which is engaged when the safety door is opened, and the user interacts with the platen. This prevents the platen from rotating during interaction.

Notice

Do not attempt to manually rotate the platen module by hand at any time. This may damage the brake component.



4.9 Secondary Magnet

Warning

Take care when interacting with the Secondary Magnet as this uses a strong permanent magnetic field. Can be harmful to pacemaker wearers and others with medical implants. Keep tools and other metal objects away.

A secondary magnet is integrated with the platform to capture any beads failed to be captured by the magnet on the rotating platen when transferring cultured cells to the output bag, during the Bead Removal process. This is a magnetic cylinder, which the disposable kit tubing is wound around, and a cap is attached magnetically to facilitate tube loading and retention.

4.10 Pressure sensor

This device is unused. There is a dust cap provided that should be installed, take care to ensure that the tether does not interfere with tubeset loading.

4.11 Cell Selection Disposable Kit

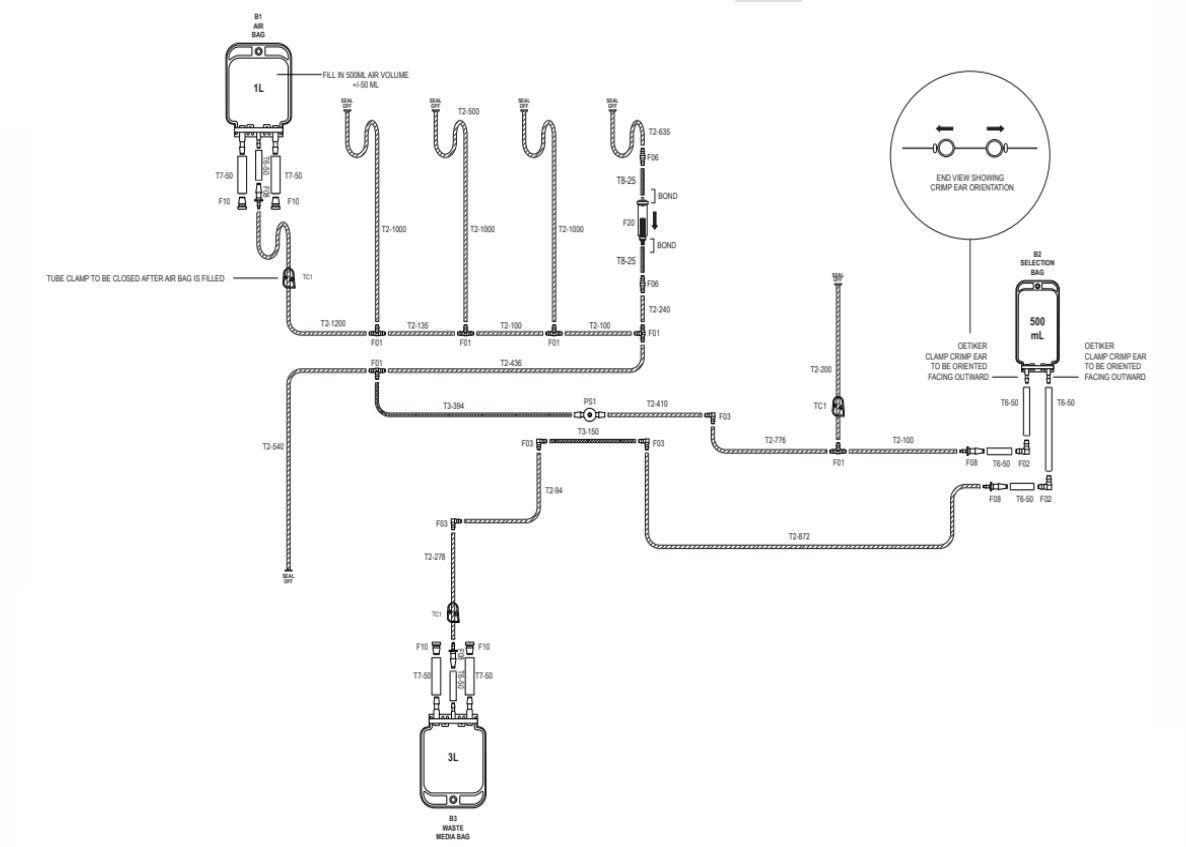
The MSP disposable kit for the cell selection method enables completion of procedure in a closed environment. The key components that makeup the disposable kit are:

Cell selection bag – 500ml bag for magnetic cell selection

Air bag – a 1L bag that chases air from tubing during running of method to ensure accurate dispensing of fluid into the intended output bag.

Waste bag –a 3L collection bag for all processing where the desire is to dispose of the output media.

Filter –capture cell clumps from the cell collection bag.



4.11.1 Selection Buffer Bag

Holds Selection buffer solution.

4.11.2 Dynabead Bag

Holds Dynabead solution.

4.11.3 Culture Media Bag

Holds Culture media solution.

4.11.4 Cell Collection Bag

Holds incoming Cells.

4.11.5 Permalife Bag

The output bag of the cell selection method. This will be transferred to another platform for further processing.

4.12 Bead Removal Disposable Kit

The kit for the bead removal method enables completion of procedure in a closed environment. The key components that makeup the disposable kit are:

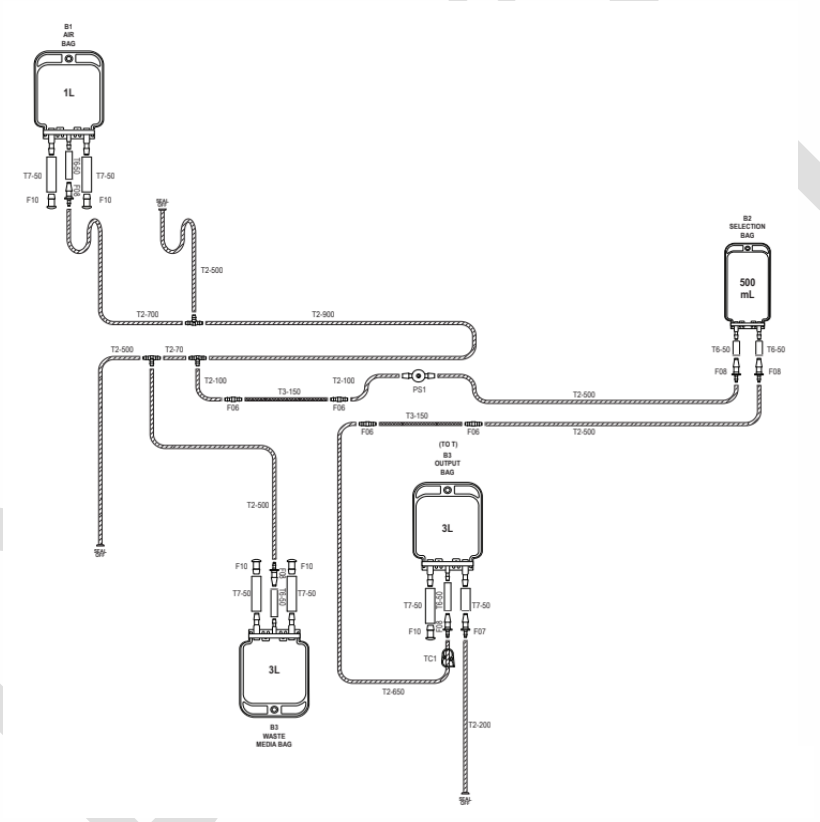
Primary bag – a 500mL bag that is placed on the magnetic platen to capture beads.

Air bag – a 1L bag that chases air from tubing during running of method to ensure accurate dispensing of fluid into the intended output bag.

Waste bag –a 3L collection bag for all processing where the desire is to dispose of the output media.

Debead cell collection bag – a 3L bag that holds the output from this method.

The disposable set consists of a 500mL primary bag, 1L air bag, one 3L waste bag and one 3L debead cell collection bag (output).



4.12.1 Debead Buffer Bag

This bag holds buffer solution that functions in maintaining a stable pH. It is the 2nd bag from the left and sits directly adjacent to the air bag from the disposable set.

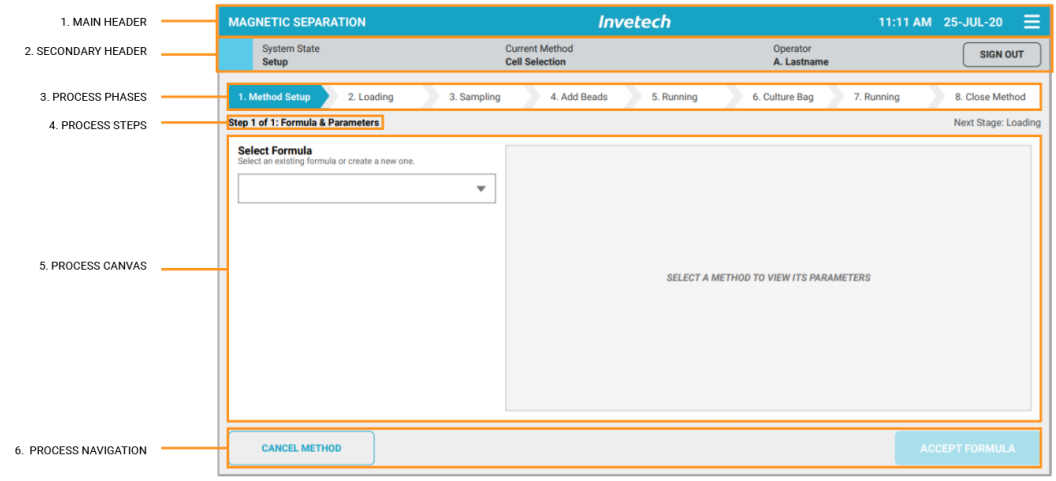
4.12.2 Dynamic Culture Bag

The input bag of the bead removal method.

4.13 Operator Interface Panel – HMI

A user can interface with device by interacting with the HMI. The following describes key elements of the digital user interface. Whenever imputing data to a field in the HMI enter should be used to confirm input into that field.

4.13.1 Primary Interface



1. **Main Header**

   Platform Name

   Time, Date

   Side Menu

2. **Secondary Header**

   System state

   Method

   Operator

   Login/Sign Out button

3. **Process Phases**

   Phases of operation indicator to call out current in process phase.

4. **Process Steps**

   Step indicator to inform user of current step, and number of existing steps required.

5. **Process Canvas**

   Process Title

   Direct Selection inputs

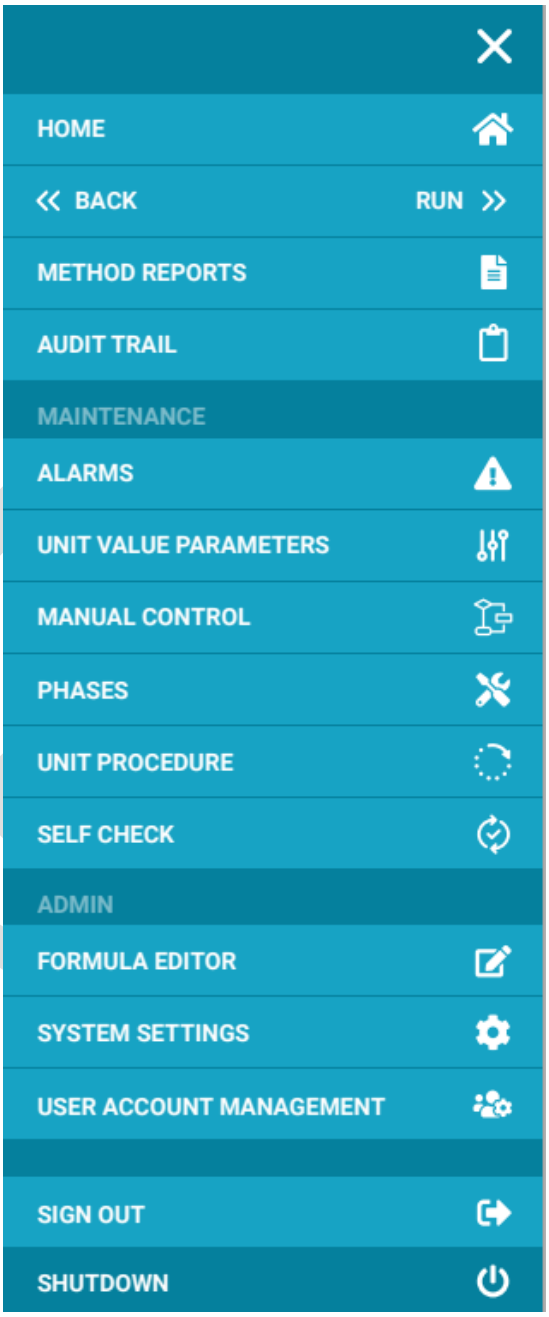
   Visual Diagram

6. **Process Navigation**

   Navigation Selections to move between processes

4.13.2 Side Menu

1. **Home**
   - Return to Home screen, If a method is in setup or running you will be returned to the step the method is curently at.



2. **Method Reports**
   - View PDF Batch Report (inlcuding audit trail)

3. **Audit Trail**
   - View PDF Batch Report (including audit trail)

4. **Alarms**
   - View Alarm History

5. **Unit Value Parameters**
   - View or edit parameters specific to device

6. **Manual Control**
   - View live status of various component, manual control for troubleshooting

7. **Phases**
   - For development purpose only

8. **Unit Procedure**
   - For development purpose only

9. **Self Check**
   - For development purpose only

10. **Formula Editor**
    - View and edit saved Formulas

11. **System Settings**
    - View softare version
    - Enable/Disable custom fields input fields
    - Exit software to access operating system

12. **User Account Management**
    - Manage User Profile

13. **Sign Out**

14. **Shutdown**
    Wait until the HMI turns off before using the Main Power Switch. A user with authorised permission is required to be logged in for shutdown of device to be successful.

⚠ Caution

Shut down PC/HMI before turning off power. This is done in the HMI software. And wait for the HMI screen to go blank before pressing the Main Power Switch or removing the electrical supply lead. Allow at least 10 seconds before turning power on again. Failure to do so may damage the device and/or corrupt files such that the device with not operate.

4.13.3 Understanding Transition Conditions

When preparing a Method, in some instances, the digital user interface will not allow a user to proceed to the next screen until a Transition Condition is satisfied. This is communicated when the 'NEXT' or 'ACCEPT' button is disabled.

The digital user interface does not inform the user why a Transition Condition is not satisfied. Transition Condition tips will be captured providing guidance how to enable next step progress.

4.14 Light tower states

The light tower is mounted on top of the MSP and provides indications of the systems status at a glance. The states are as follows:

Colour/Sound	Trigger Conditions
Red – Flashing	Emergency Stop Button Pressed
Red – Constant	Safety System Tripped
Yellow – Flashing	Equipment Alarms Equipment / Control Module Alarms (faulty devices / instrumentation)
Yellow – Constant	Process Alarms Process Execution / Phase Alarms (e.g. in Hold state)
Green – Flashing	*Not currently defined.*
Green – Constant	Process Running
Blue – Flashing	Operator Action Required • User prompt • Safety reset required
Blue – Constant	Pump Guard Open
Buzzer/Sounder	*Not currently defined.*

5. OPERATING PROCEDURES

5.1 Power Up, System Initialization

When power is connected to the platform, the user can turn on the system by rotating the power switch located on the left-hand side of the MSP. Wait for the platform to initialize and the HMI to display the home screen.

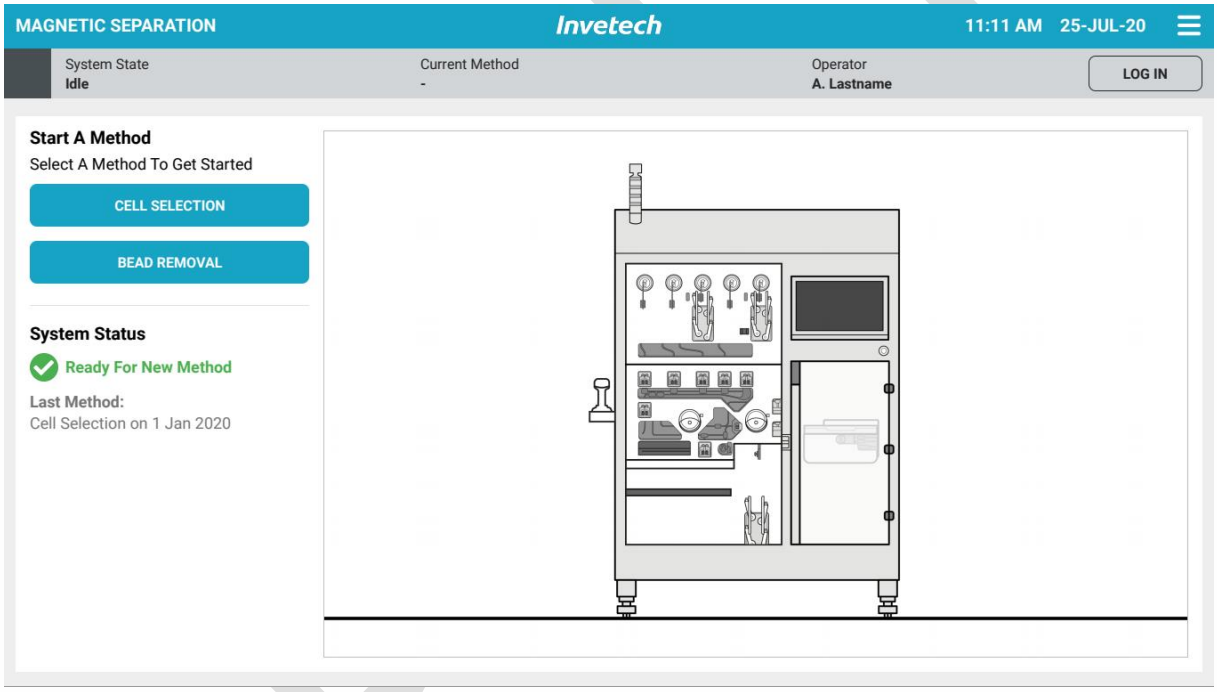
5.2 Running a Method (Cell Selection)

The following provides a combination instruction of:

I. How to remove disposable kit elements from the packaging

II. What to consider for each step communicated on the HMI

Once ‘Cell Selection’ is selected on the HMI home screen, the user will be led through the following sequence.

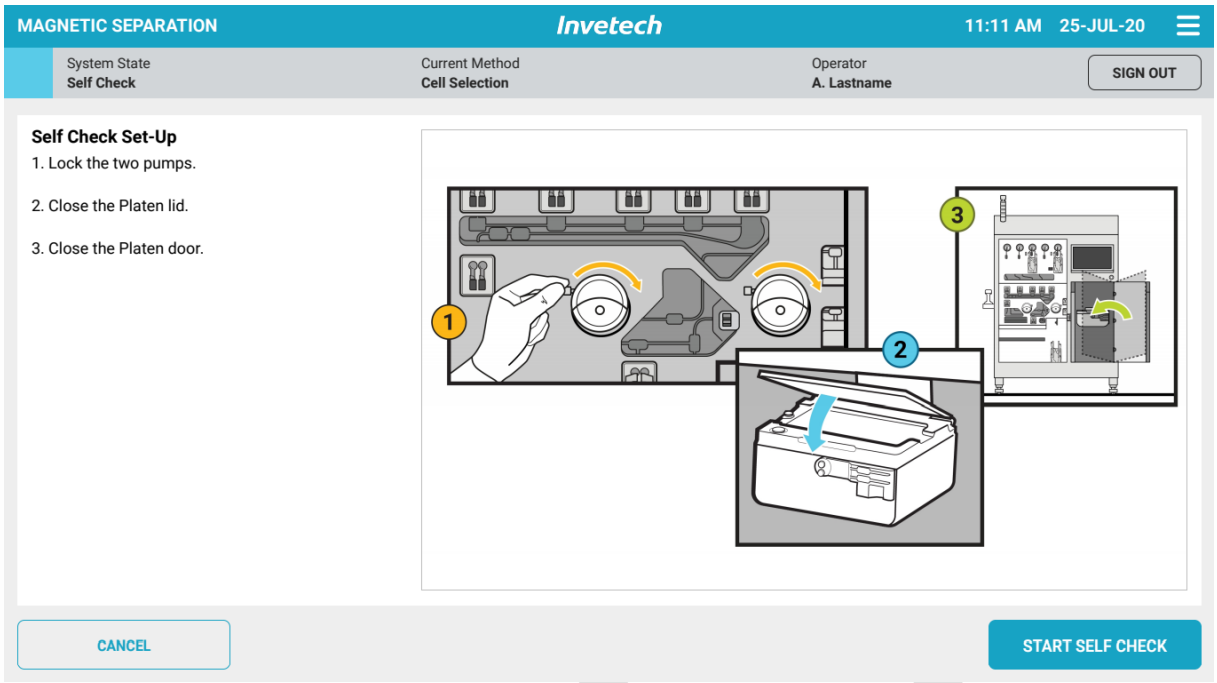


5.2.1 Self-Check

The user is requested to prepare the device for Self-Check. Follow the onscreen steps to prepare the device for Self-Check. An automated sequence will follow once ‘Start Self Check’ is selected, in which the device ensures all control modules are functional and prepared for the method.

⚠ Warning

Unless prompted by the machine, an operator should not interact with hardware during an automated process. Users should not stay within the clearance envelope longer than necessary for operational reasons. See instrument specification section of distances.



Notice

Transition Condition Tip

I. Ensure both **pumps are locked firmly**, done so by rotating their levers clockwise.

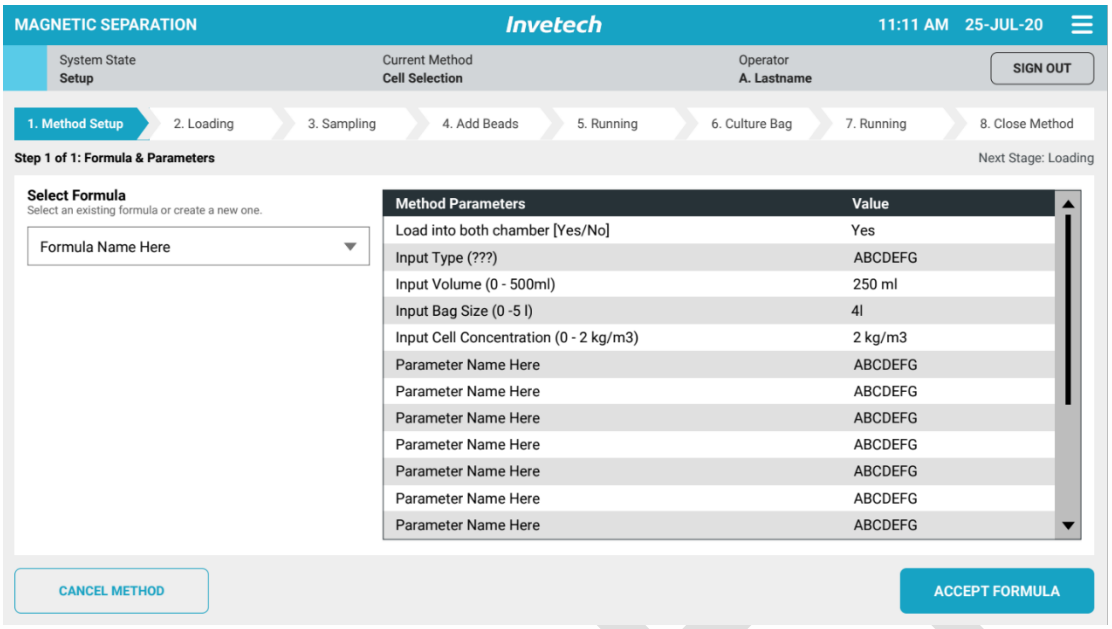
II. The **magnetic platen lid is closed.** Ensure there are no impediments to the magnetic latch.

III. The **platen door is closed.** Ensure there are no impediments to the front of the magnetic latch.

IV. If there are any **faults during the self-check**, tap **cancel**. Take note of the fault and resolve before reattempting check.

5.2.2 Method Set-up

Select method parameter from ‘Formula’ drop down.



Notice

Transition Condition Tip

I. A formula needs to be selected before the ‘Accept Formula’ button is enabled.

Notice

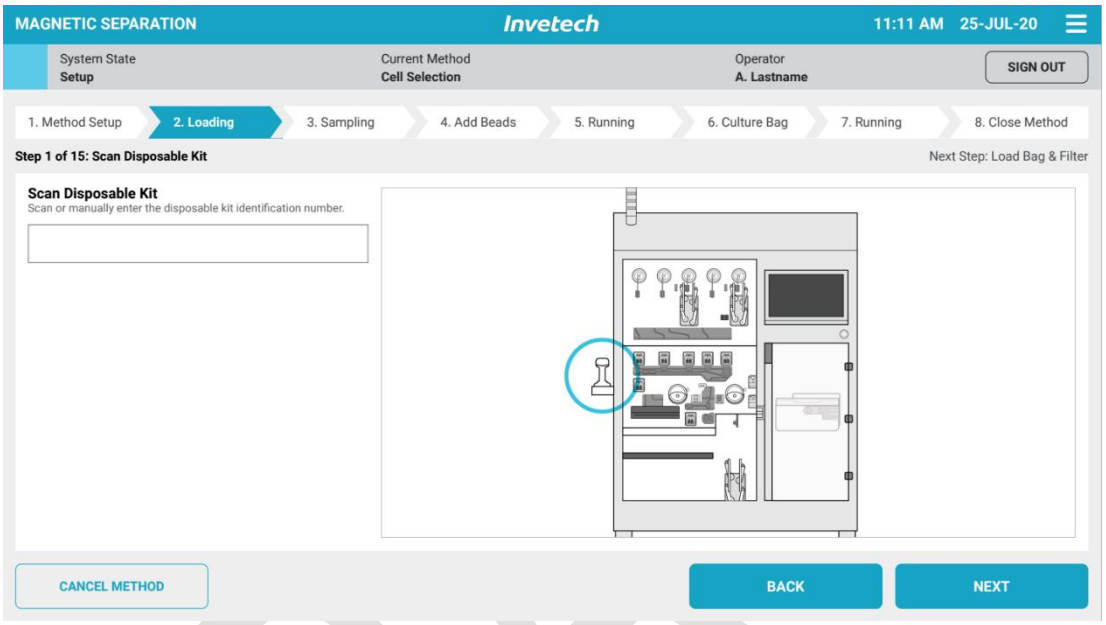
The suitability of parameters entered is not guaranteed. Care should be taken to ensure required parameters are entered correctly.

5.2.3 Loading

This phase of the procedure describes the loading of the disposable kit to platform and verification required prior to sampling phase.

5.2.3.1 Scan Disposable Kit

Scan the disposable set barcode using the MSP barcode scanner, located on the left-hand side of the platform. The barcode is located on the disposable set **packaging**.

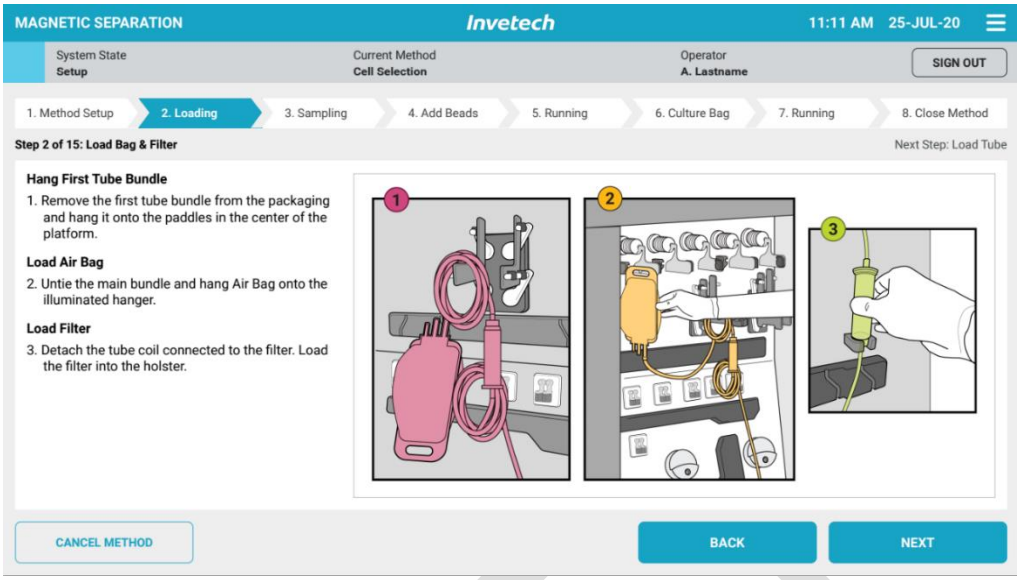


Notice

Transition Condition Tip

I. A value must be entered within the Scan Disposable Kit field to enable the ‘Next’ button.

5.2.3.2 Load Bag and Filter



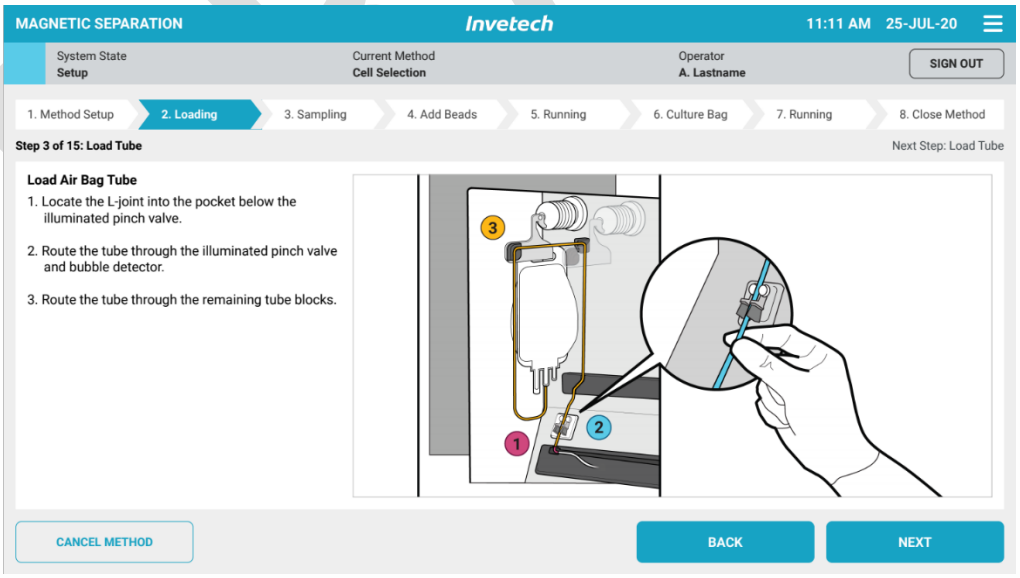
Notice

Transition Condition Tip

I. If the bag mass is not detected at the right time, an alarm will sound if the weigh module detects an out of range bag weight.

II. The Operator must acknowledge these alarms

5.2.3.3 Load Air Bag Tube



Notice

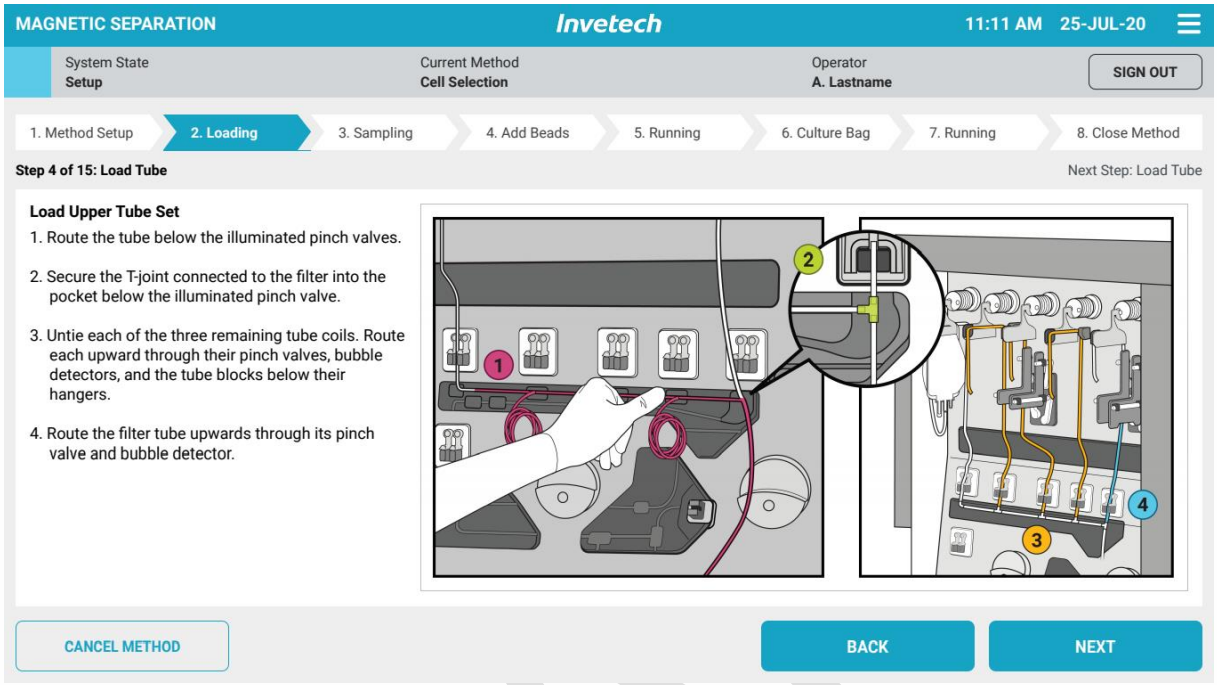
Check:

I. Tubing through pinch valve sits **between the clamping arms**.

II. Tubing is **pushed firmly into the bubble detector**.

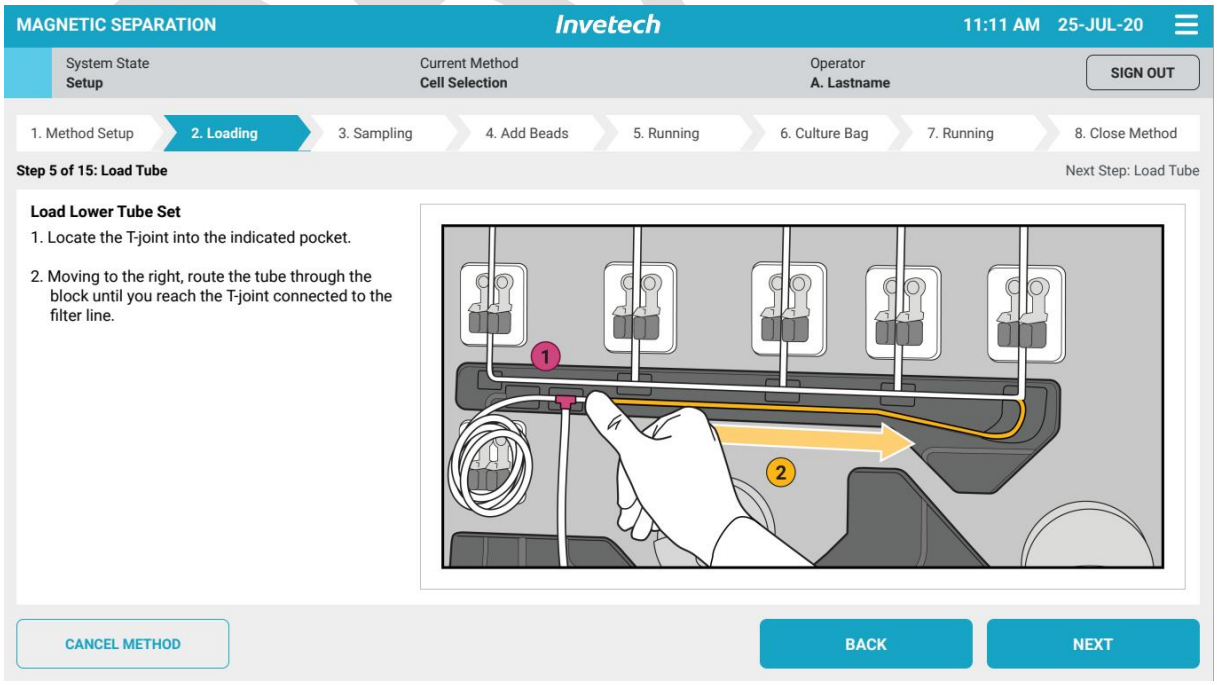
This check needs to be completed where tube routing through pinch valves are required.

5.2.3.4 Load Upper Tube Set

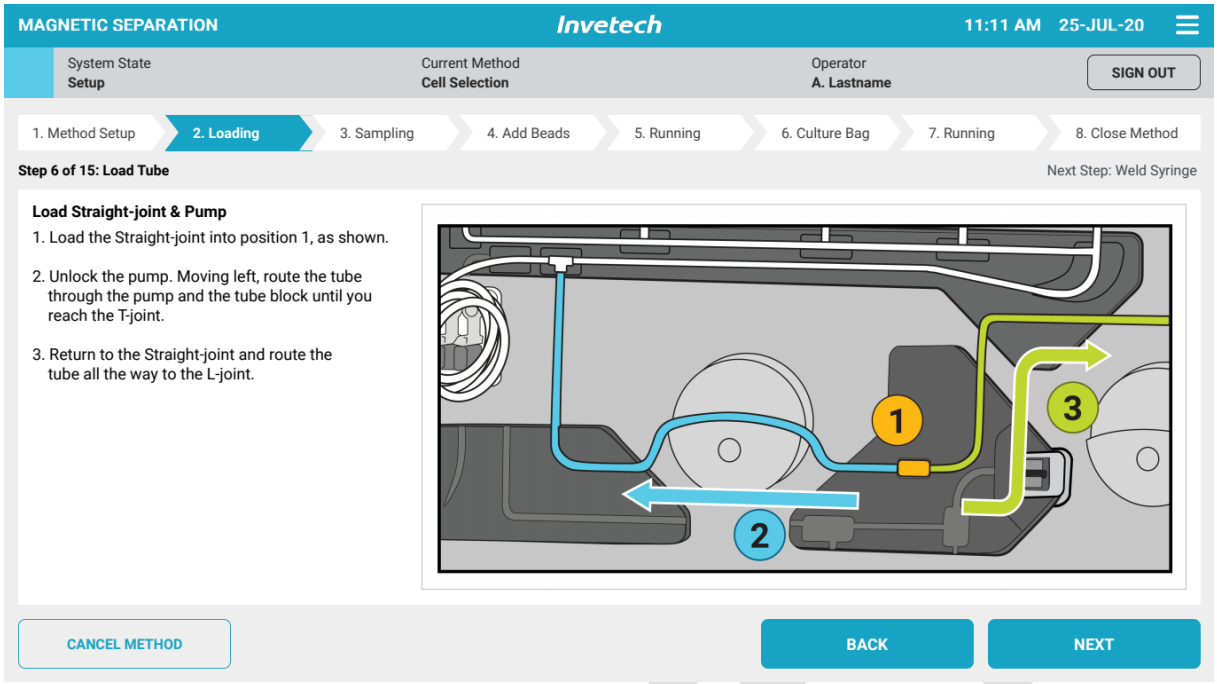


5.2.3.5 Load Lower Tube Set

The amount of excess underneath the rightmost pinch valve is undefined. Start at the T-junction and work towards the right.



5.2.3.6 Load Pressure Sensor and Pump



Notice

Check:

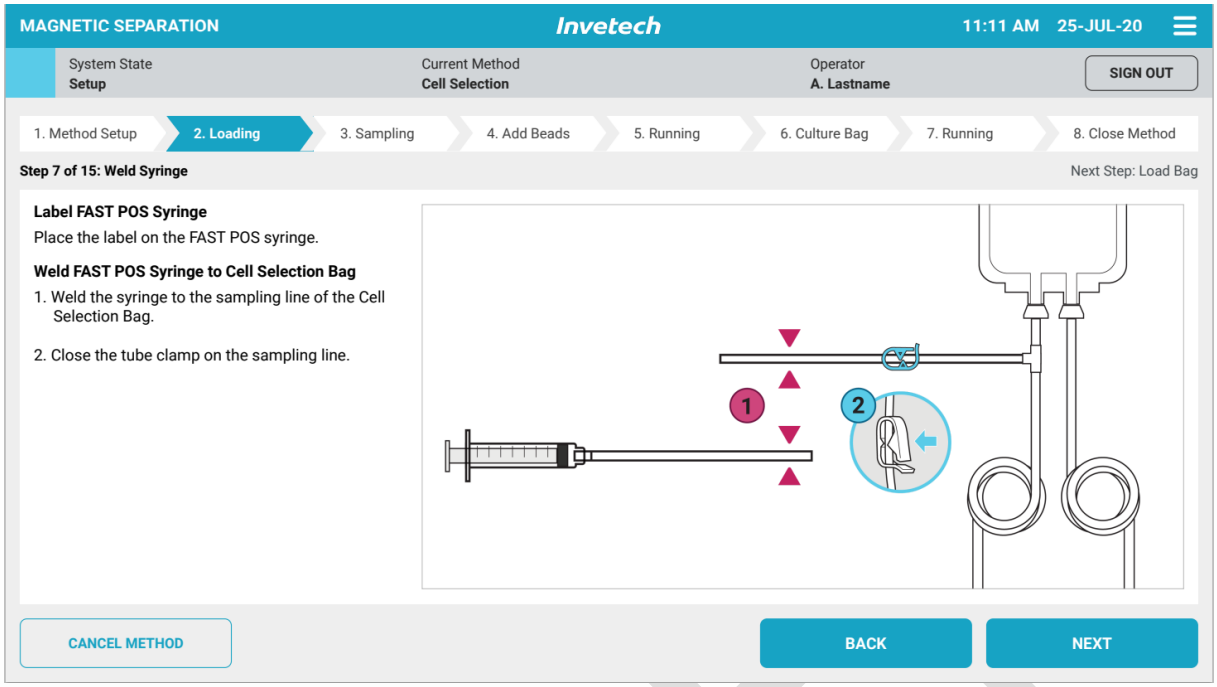
I. Tubing on either side of peristaltic **pump** sits **within the guide blocks**.

II. Tubing on either side of the **pressure sensor** sits **within the guides**.

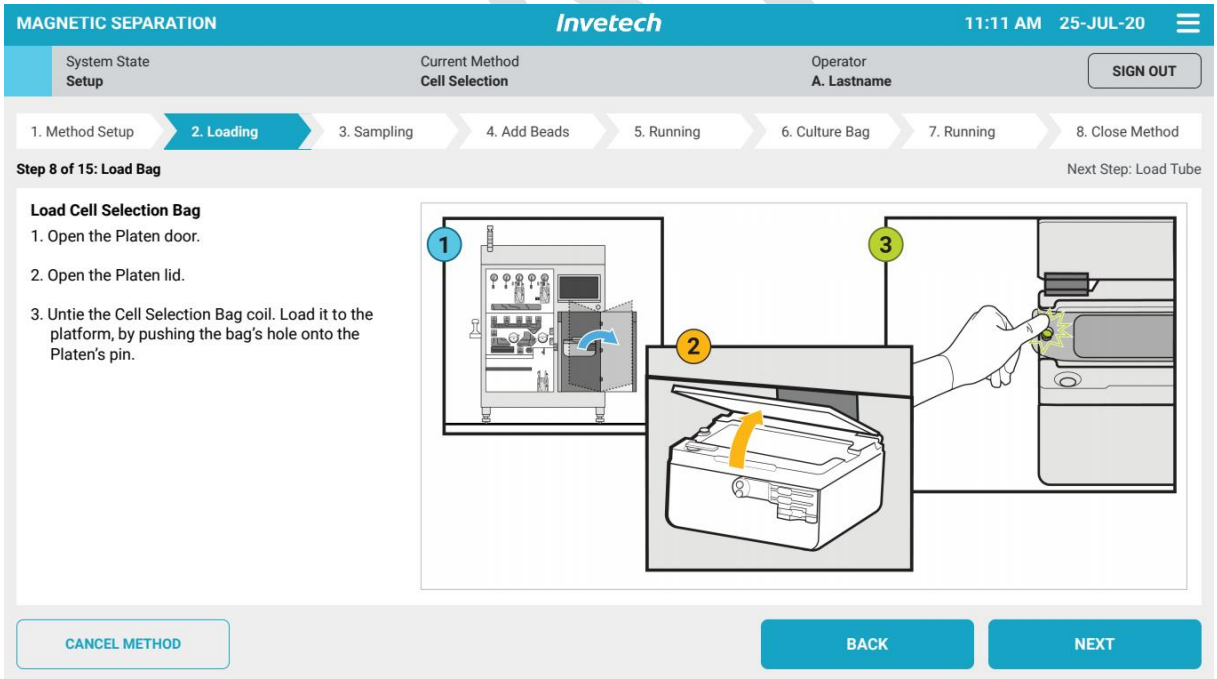
III. **Pressure sensor** connector is **pushed firmly** into the platform port.

This check needs to be completed where tube routing through peristaltic pumps are required.

5.2.3.7 Weld Syringe

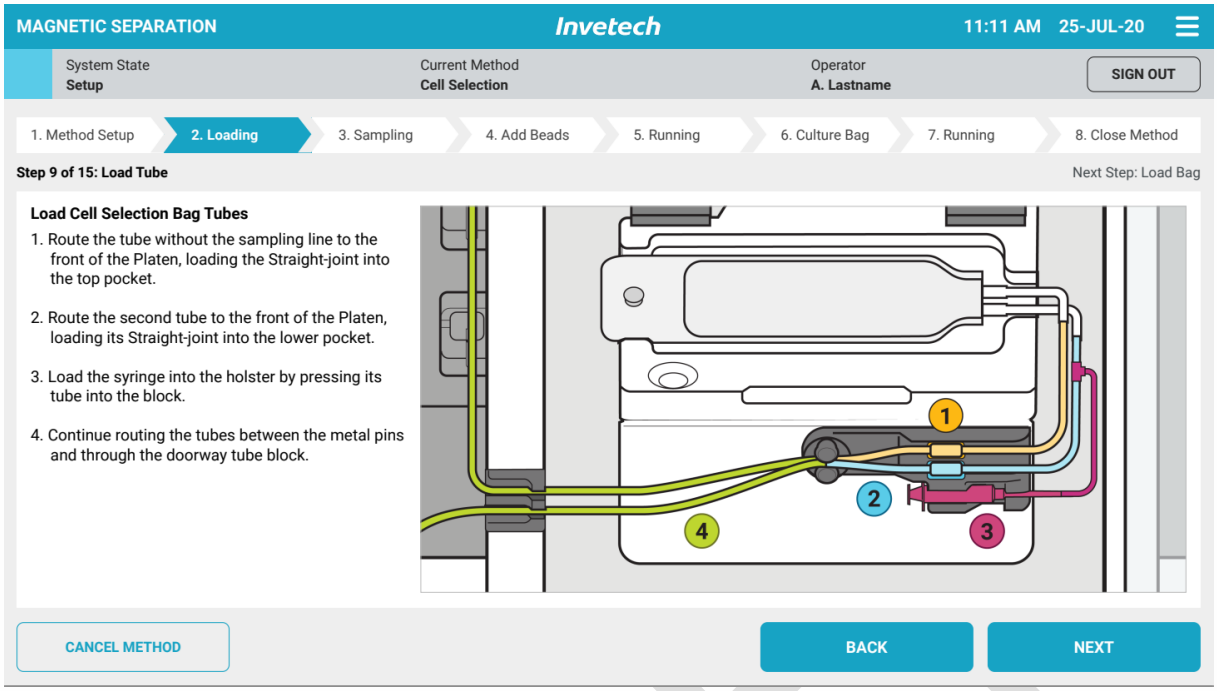


5.2.3.8 Load Cell Selection Bag



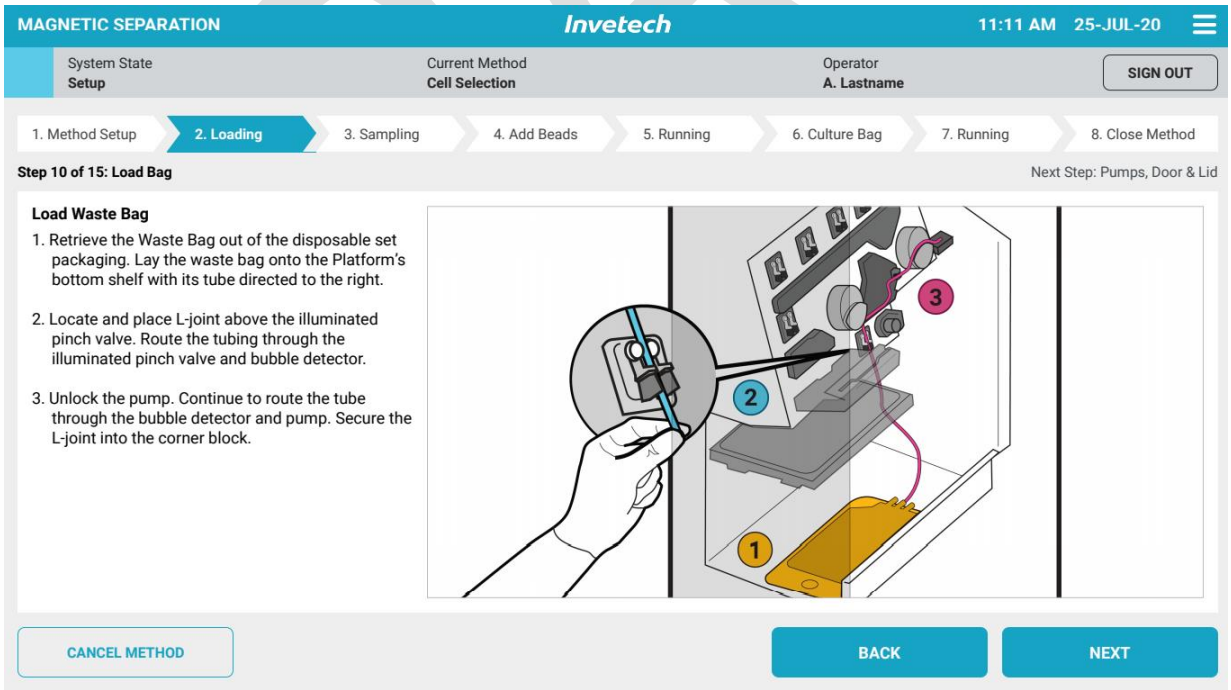
There are two tube lines emerging from the 500mL bag. The end with a T-junction should be oriented towards the user. For easier identification, this end has a tube clamp and is sealed.

5.2.3.9 Load Cell Selection Bag Tubes

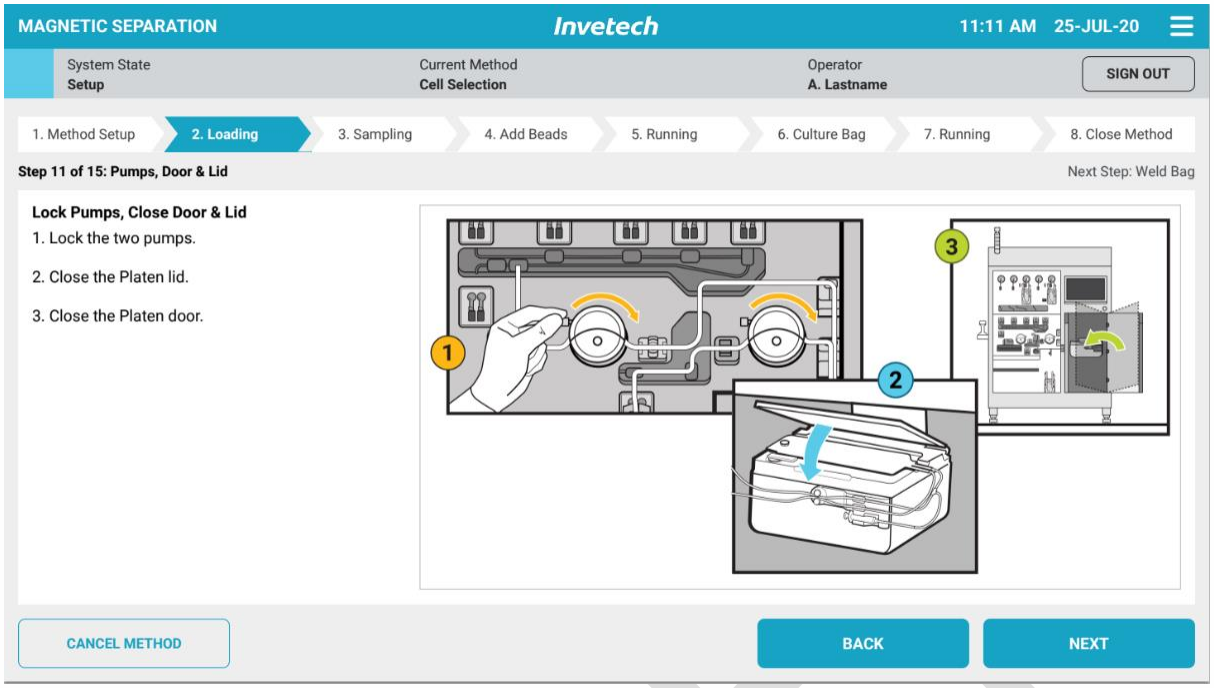


5.2.3.10 Load Waste Bag

The image below shows the GMP configuration. For CDP platform, the waste bag can be folded and sit in the tray directly below the pinch valve.



5.2.3.11 Lock Pumps, Close Door and Lid



Notice

Transition Condition Tip

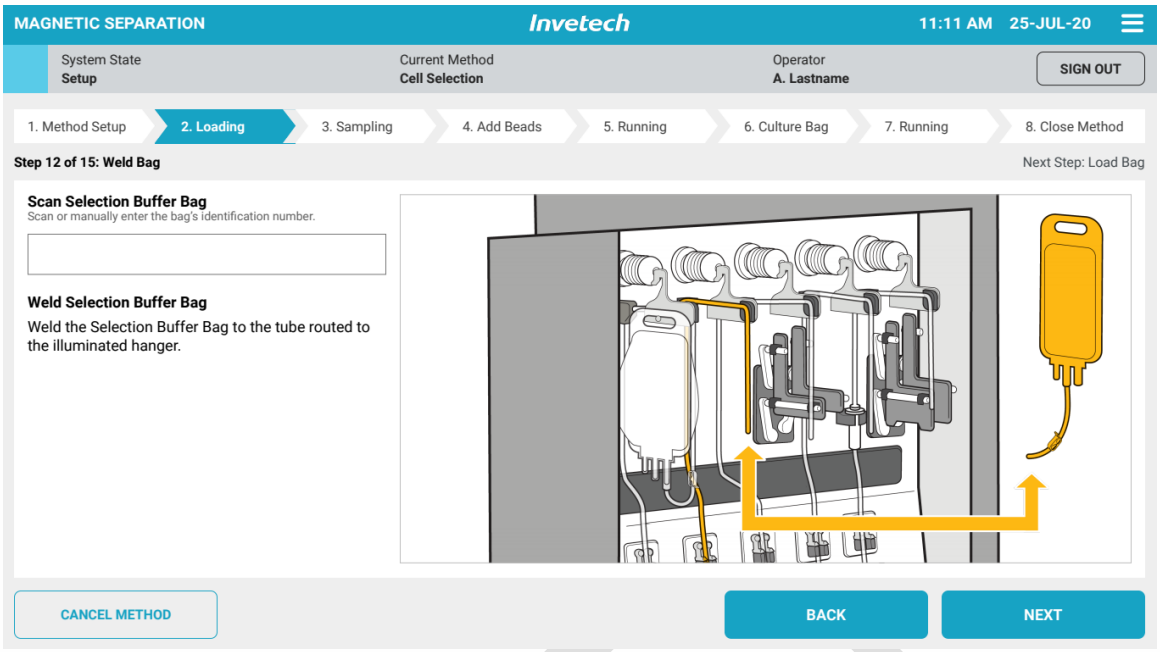
I. Ensure both **pumps are locked firmly**, done so by rotating their levers clockwise. Inspect tubing and confirm it is located appropriately between the pump guide blocks.

II. The **magnetic platen lid is closed.** Ensure there are no impediments to the magnetic latch. Inspect tubing and confirm it is located appropriately within tube blocks and does not interfere with lid closure.

III. The **platen door is closed.** Ensure there are no impediments to the front of the magnetic latch. Inspect tubing and confirm it is located appropriately within tube blocks and does not interfere with door closure.

5.2.3.12 Weld Selection Buffer Bag

Scan the selection buffer bag barcode using the MSP barcode scanner, located on the left-hand side of the platform.

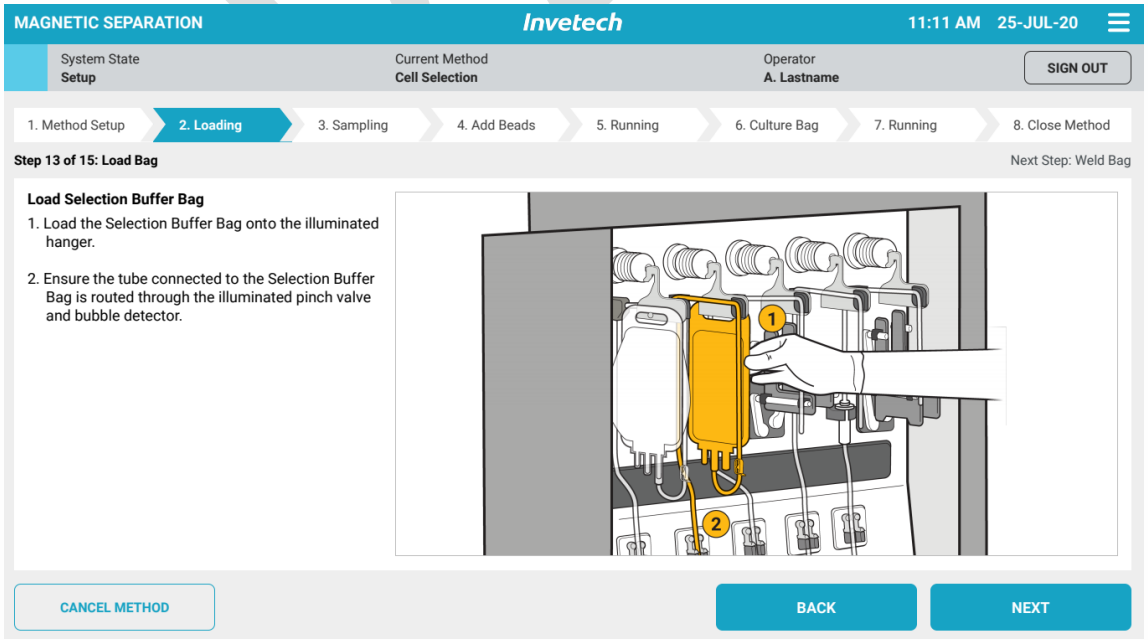


Notice

Transition Condition Tip

I. A value must be entered within the Scan Selection Buffer Bag field to enable the 'Next' button.

5.2.3.13 Load Selection Buffer Bag



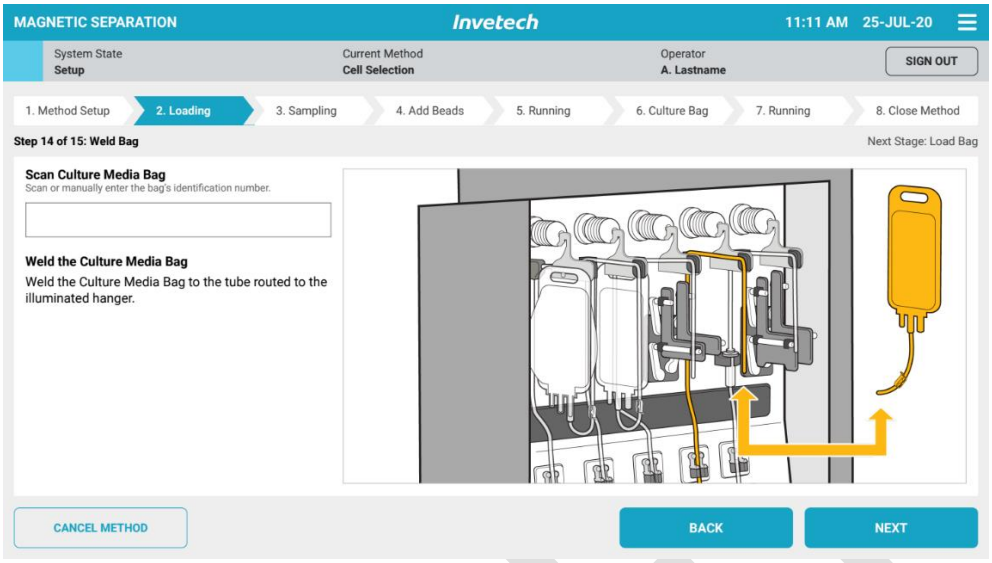
Notice

Transition Condition Tip

I. An alarm will sound if the weigh module detects an out of range buffer bag weight.

5.2.3.14 Scan Culture Media Bag

Scan the culture media bag barcode using the MSP barcode scanner, located on the left-hand side of the platform.

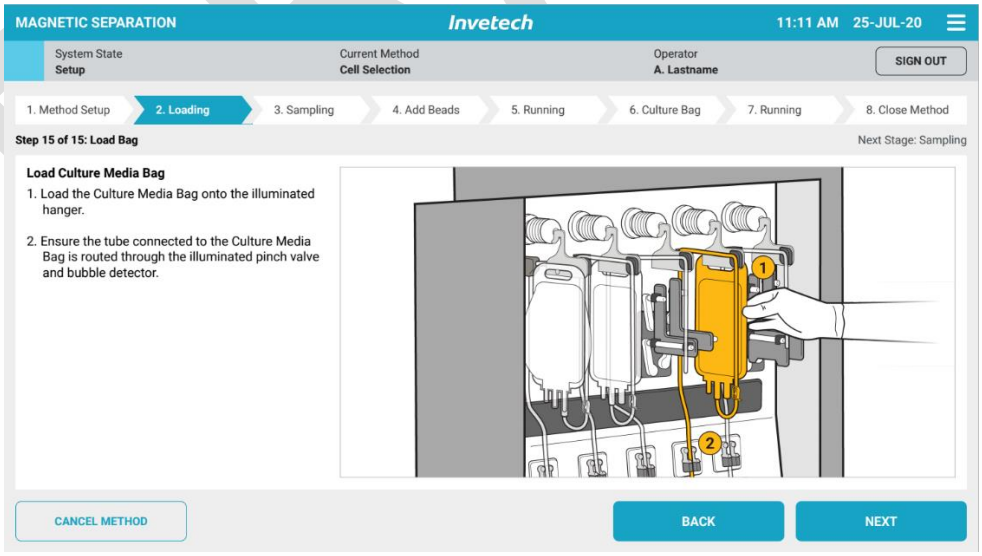


Notice

Transition Condition Tip

I. A value must be entered within the Scan Culture Media Bag field to enable the ‘Next’ button.

5.2.3.15 Load Culture Media Bag



Notice

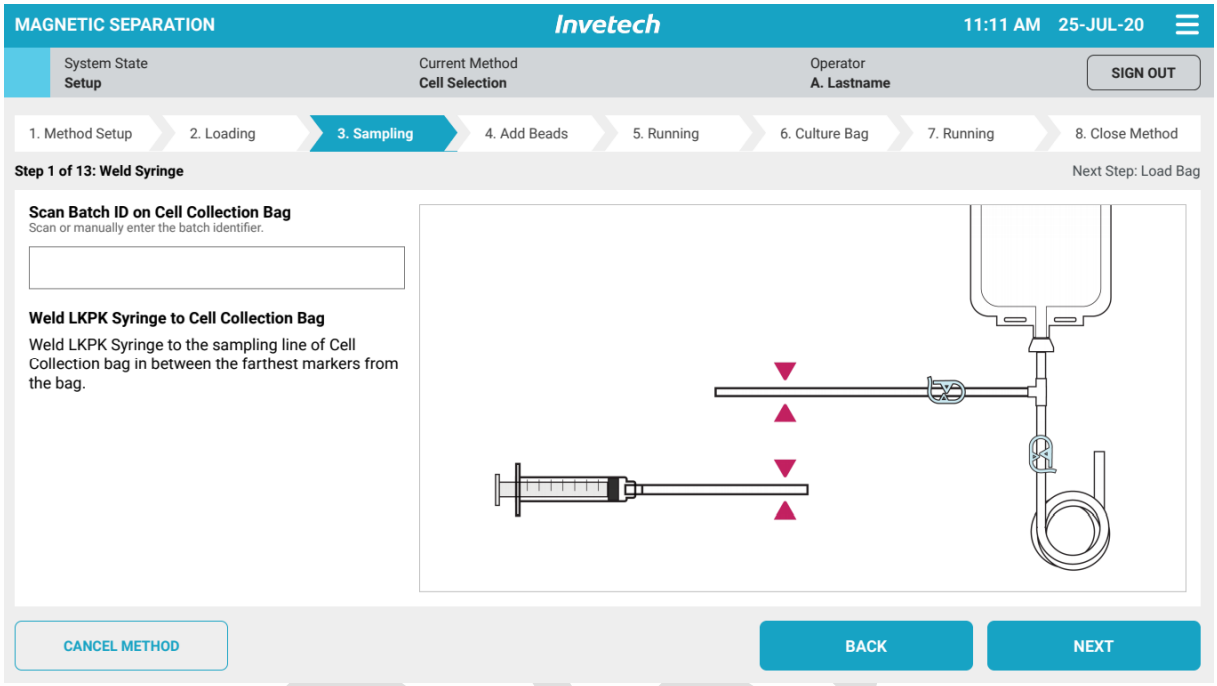
Transition Condition Tip

I. An alarm will sound if the weigh module detects an out of range culture media bag weight.

5.2.4 Sampling

5.2.4.1 Scan Batch ID on Cell Collection Bag

Scan the cell collection bag barcode using the MSP barcode scanner, located on the left-hand side of the platform.



Notice

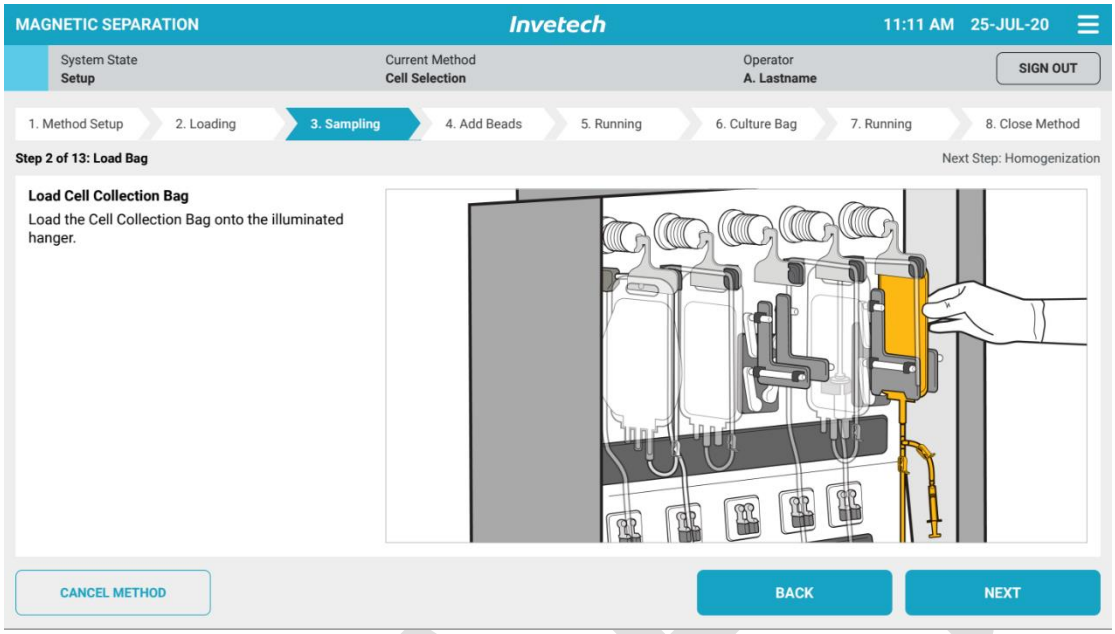
Transition Condition Tip

I. Cell collection bag must be scanned before the ‘Next’ button is enabled.

II. Batch ID will match the cell collection bag ID

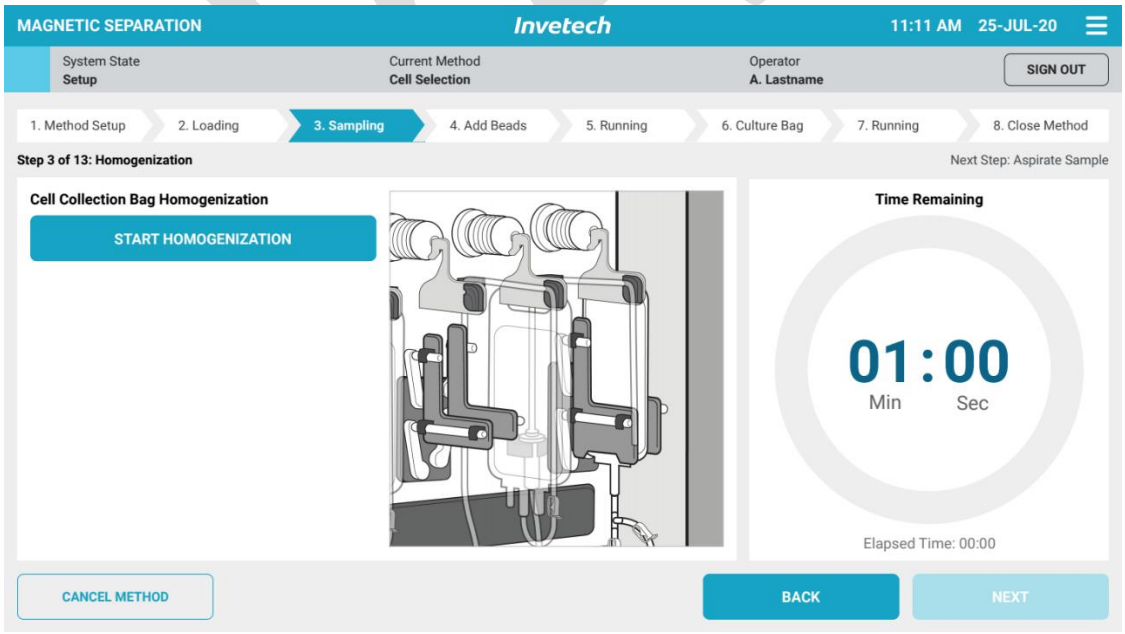
5.2.4.2 Load Cell Collection Bag

Ensure that the syringe tube end is facing the user as depicted below.



5.2.4.3 Cell Collection Bag Homogenization

Push the “start homogenization” button. The countdown will begin, displaying both time remaining and time elapsed. This process will take approximately 60 seconds and the paddle mixers will automatically cease agitation after the elapsed time.

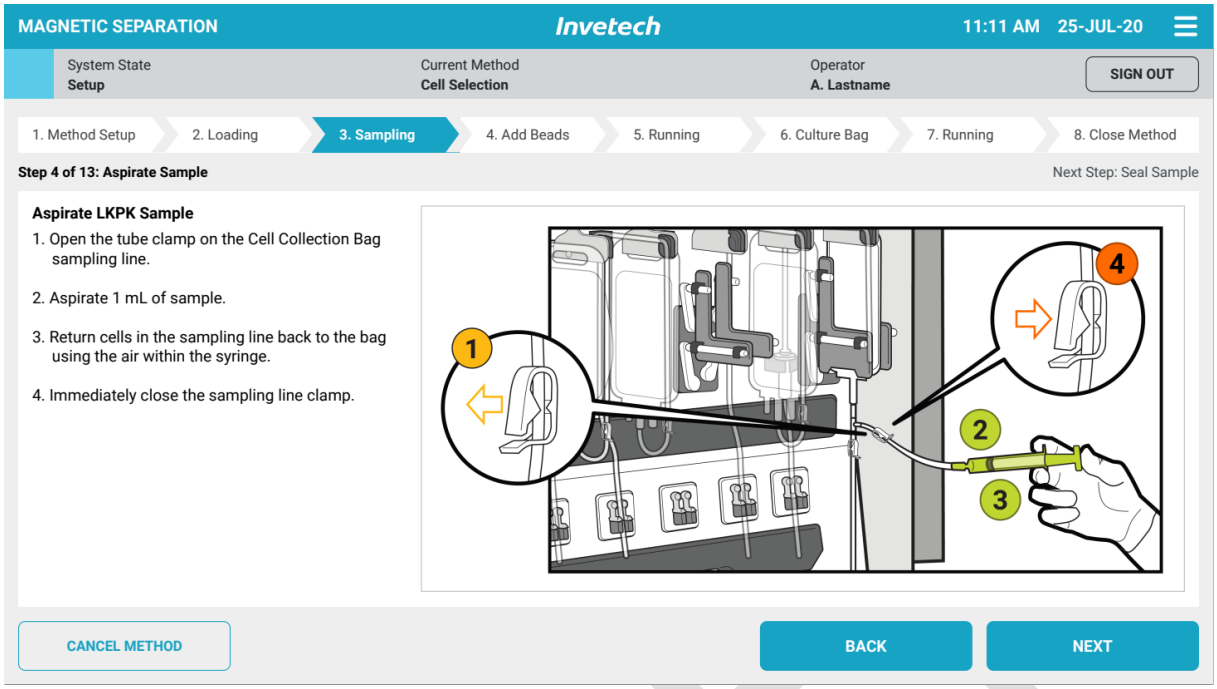


Notice

Transition Condition Tip

I. The next stage cannot begin until the full time has elapsed.

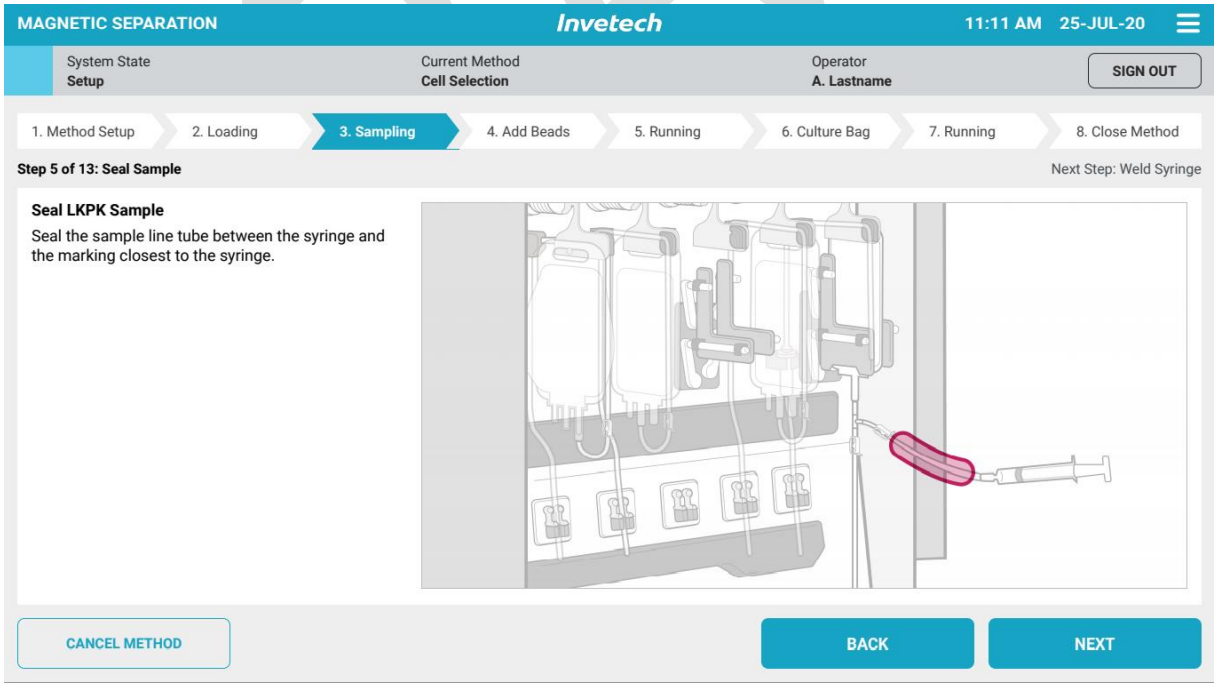
5.2.4.4 Aspirate LKPK Sample



5.2.4.5 Seal LKPK Sample

Confirm outside of tube is free from condensation before RF sealing.

Three seals are required along the IPC sample line.



5.2.4.6 Follow HMI instructions and repeat for LKPK RET and LKPK TRDRET sample:

1. Weld LKPK RET/ LKPK TRDRET syringe to sampling line

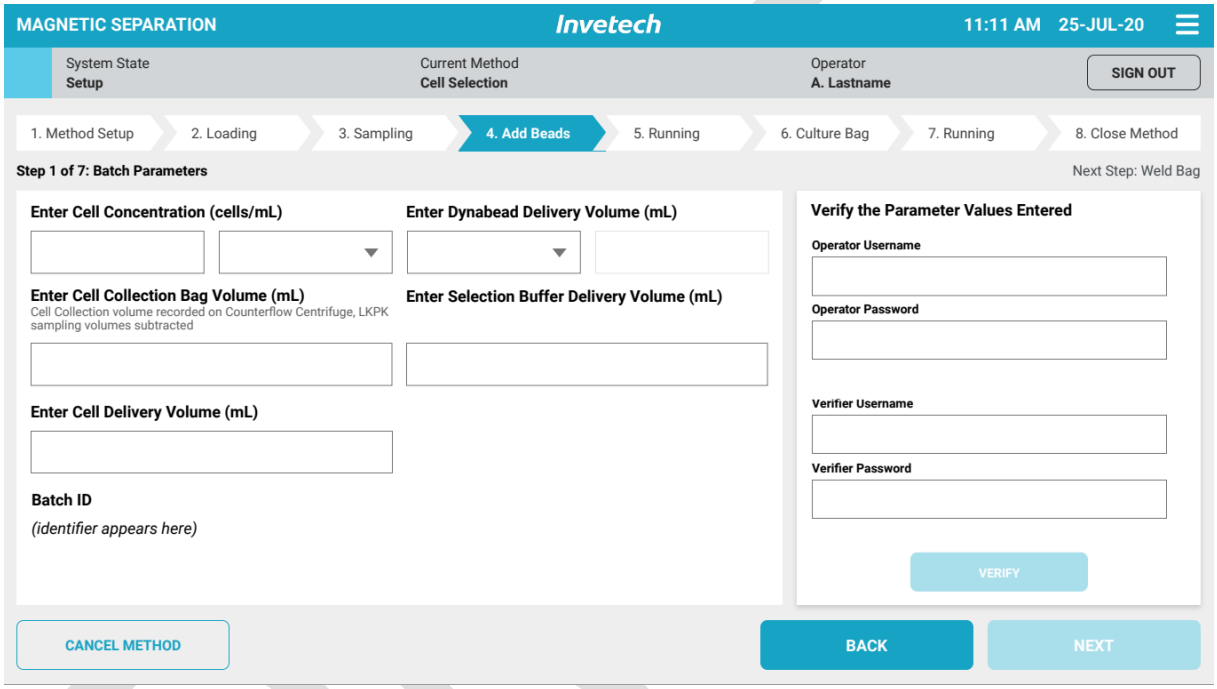
2. Load cell collection bag onto hanger
3. Homogenization of Cell Collection Bag
4. Aspirate sample
5. Seal sample

5.2.5 Add Beads

5.2.5.1 Batch Parameters

Enter information into the relevant fields and verify the parameter values entered.

- If cell concentration is greater than 1.33 billion cells, the cell delivery volume will be utilized to dose cells.
- If cell concentration is between 333 million and 1.33 billion cells, **DO NOT** enter a volume into the cell delivery volume field. The system will begin the transferring of cells.



Verification:

The system requires an independent verifier (separate to current operator) to confirm that the disposable kit is loaded correctly, and the selected parameters are correct before allowing to proceed. The start button is hidden until the verification process is complete.

Notice

Transition Condition Tip

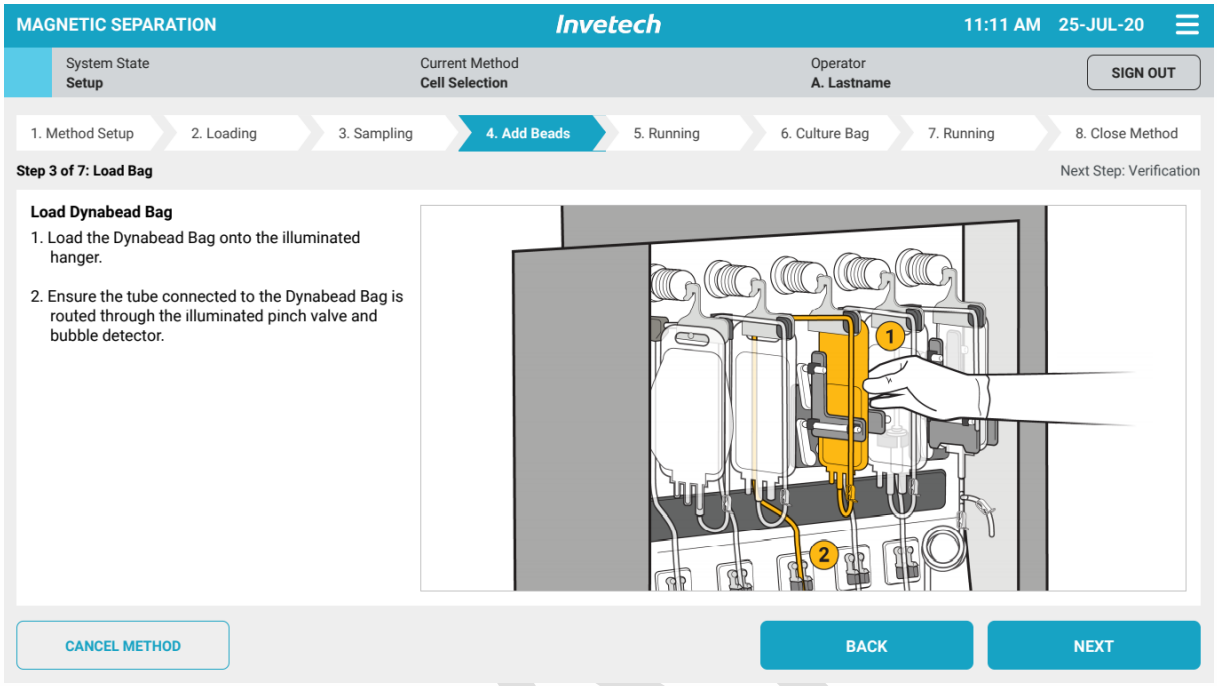
I. All fields must be filled before operator verification stage can begin.

II. Operator must sign off on disposable kit loading before verifier approval.

III. Verifier must sign off on disposable kit loading before operator resumes control.

5.2.5.2 Scan, Weld and Load Dynabead Bag

Scan the Dynabead bag barcode using the MSP barcode scanner, located on the left-hand side of the platform. Load onto the illuminated hanger and complete verification.



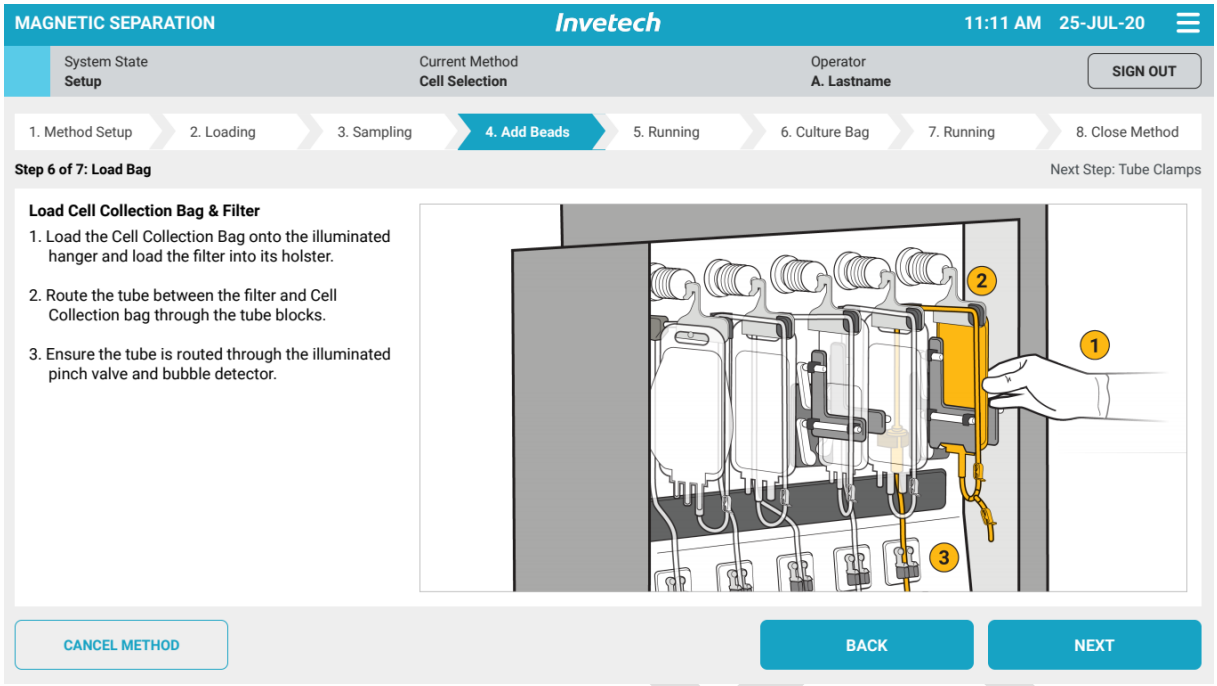
Notice

Transition Condition Tip

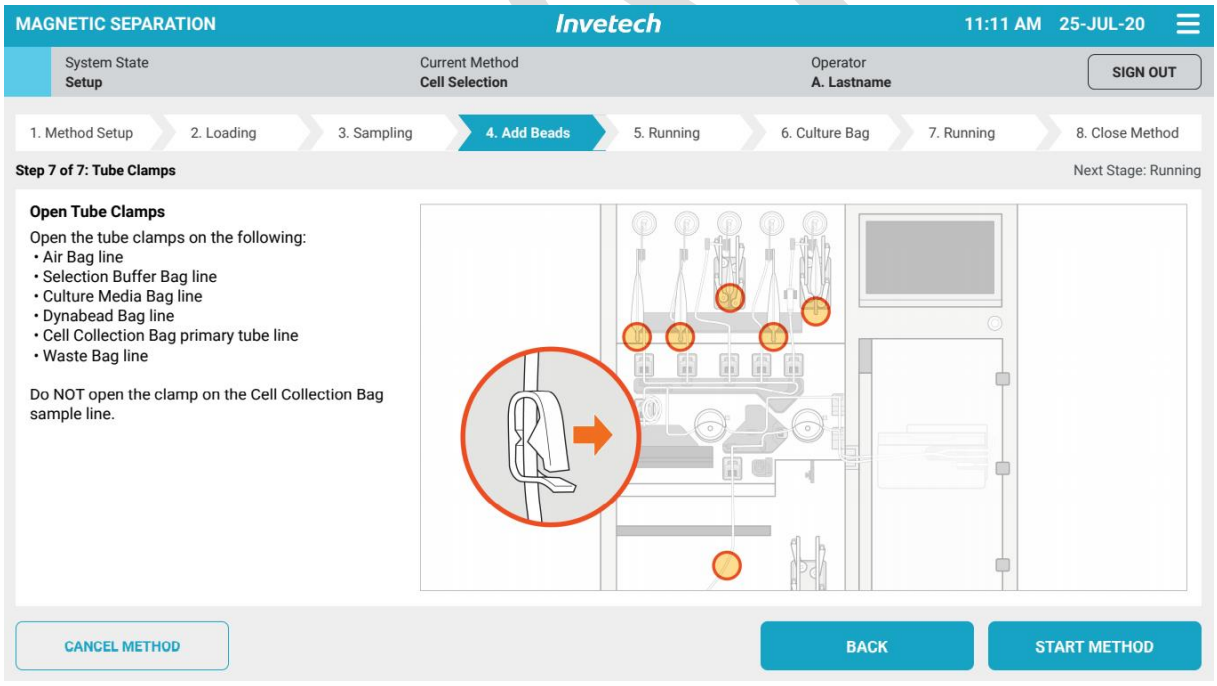
I. A value must be entered within the Scan Dynabead Bag field to enable the ‘Next’ button.

II. An alarm will sound if the weigh module detects an out of range Dynabead bag weight.

5.2.5.3 Weld and Load Cell Collection Bag



5.2.5.4 Open Tube Clamps



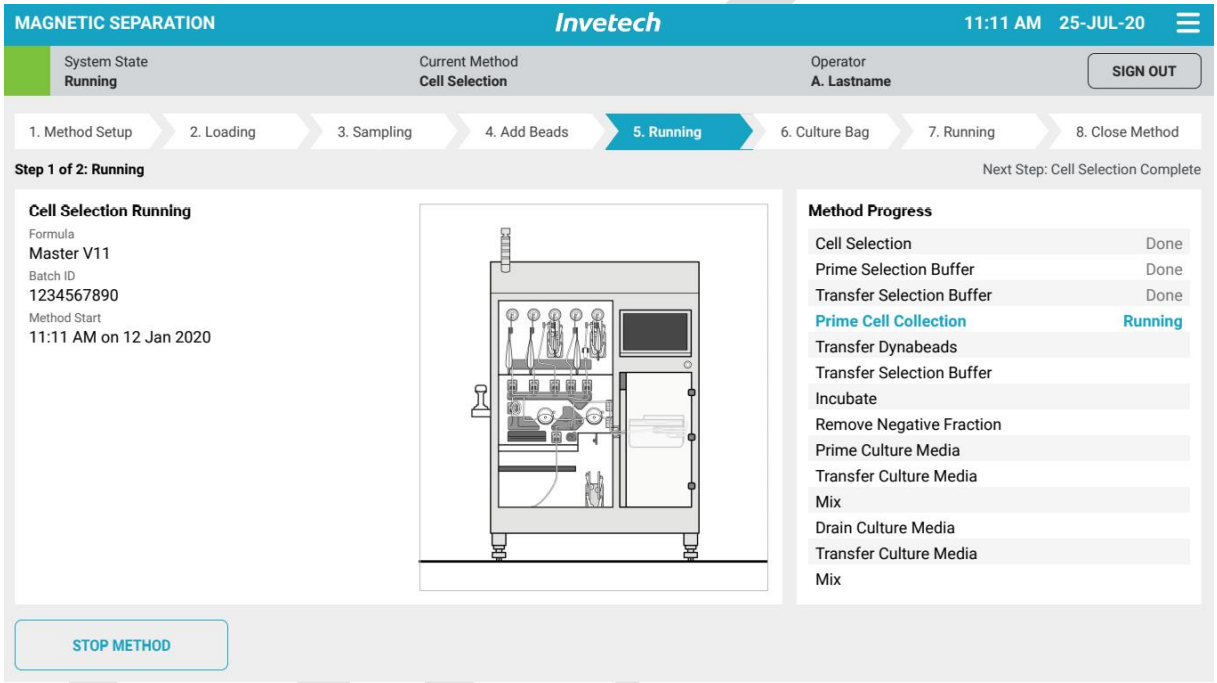
5.2.6 Running

5.2.6.1 Cell Selection Running

A user can stop the method whilst MSP is in operation through hold or abort. Refer to section 5.4 for more information. Whilst the Method is running, the digital user interface will provide ongoing visibility of Method Progress, communicated via key phases of the Method.

Warning

Unless prompted by the machine, an operator should not interact with hardware during an automated process. Users should not stay within the clearance envelope longer than necessary for operational reasons. See device specification section of distances.



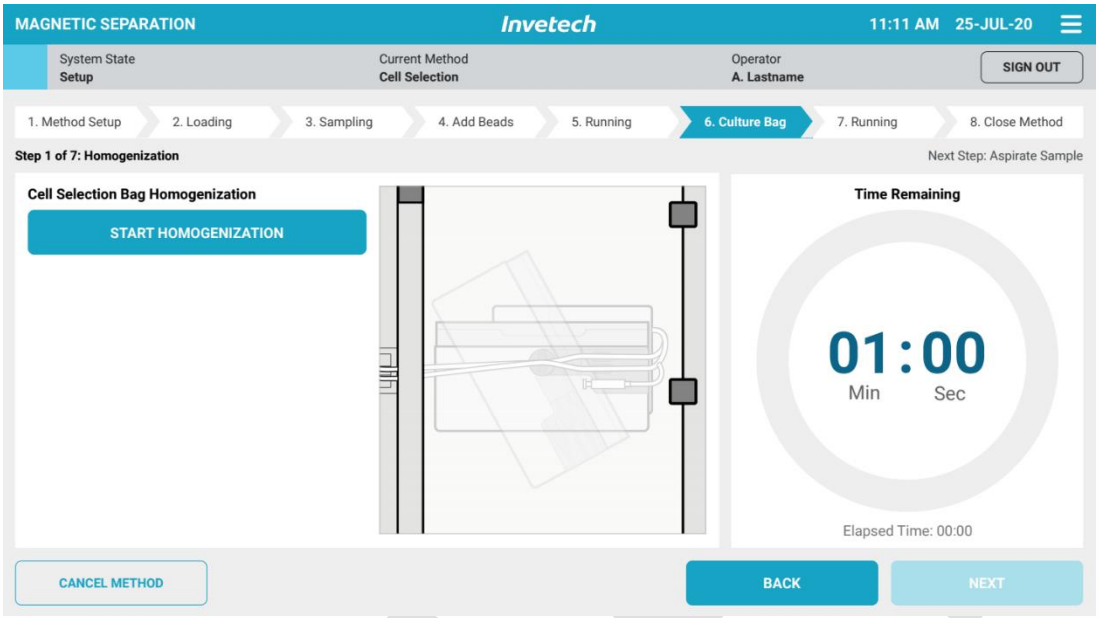
Notice

Transition Condition Tip

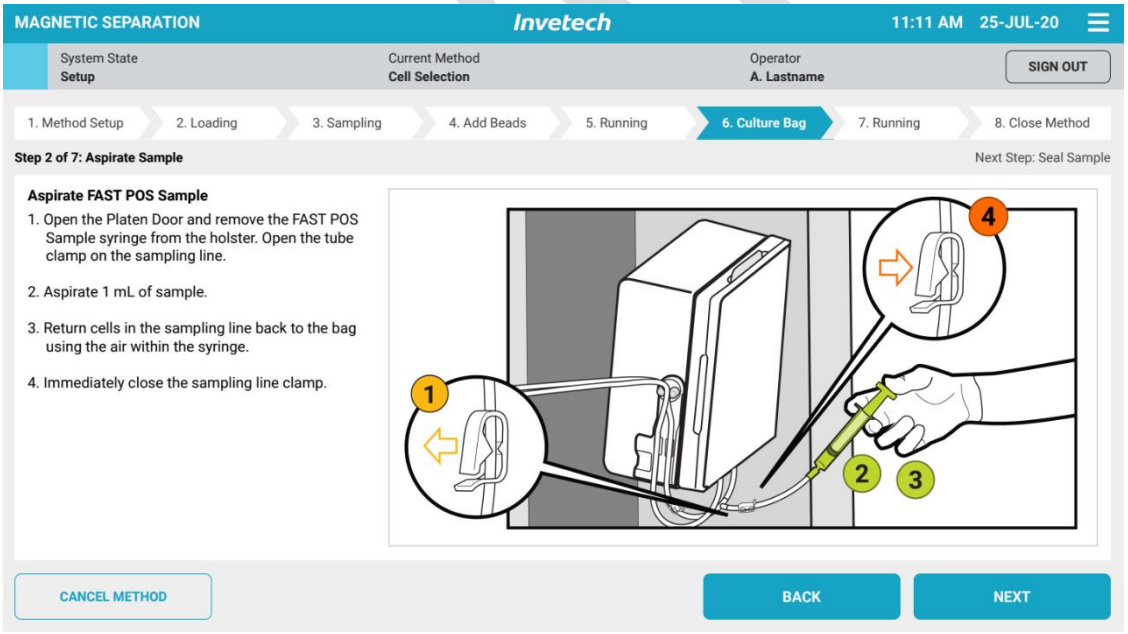
I. The Method must be complete before the ‘Next’ button is enabled.

5.2.7 Culture Bag

5.2.7.1 Cell Selection Bag Homogenization



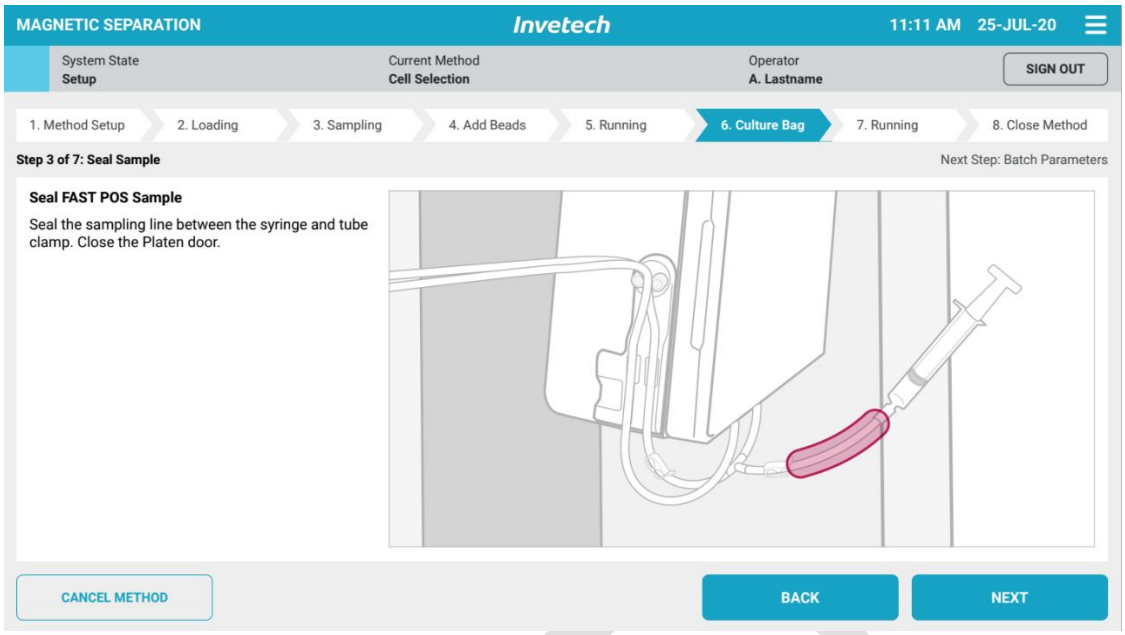
5.2.7.2 Aspirate FAST POS Sample



5.2.7.3 Seal FAST POS Sample

Confirm outside of tube is free from condensation before RF sealing.

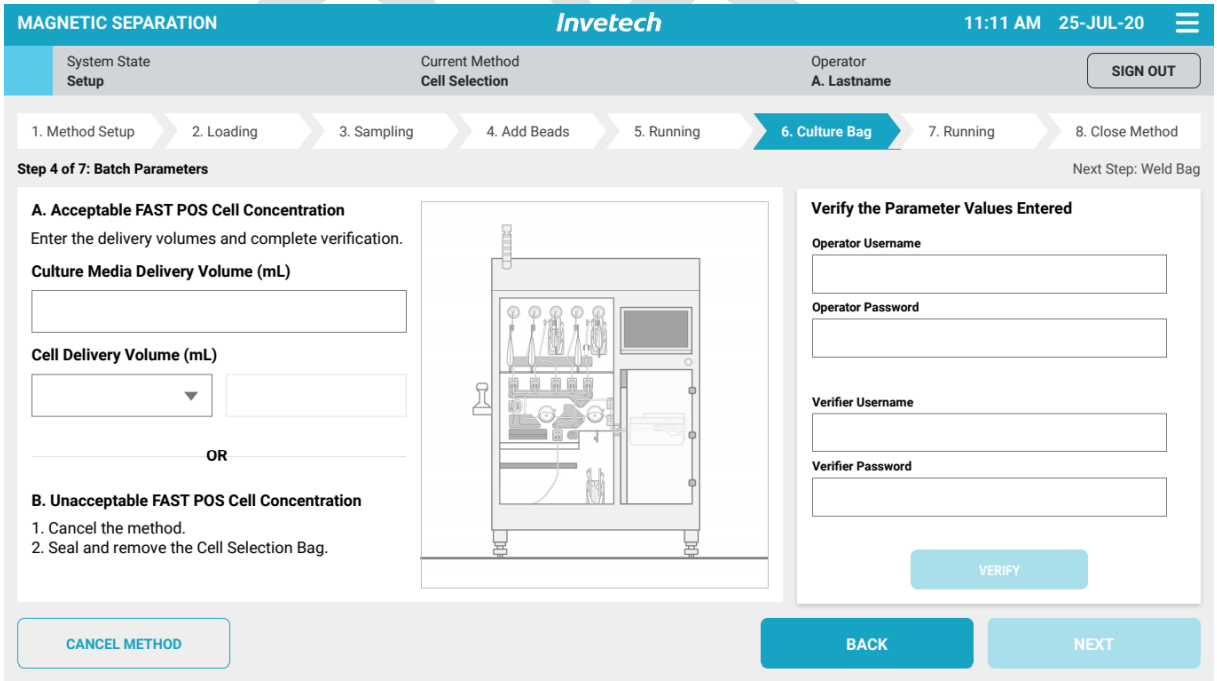
Three seals are required along the IPC sample line.



5.2.7.4 Acceptable FAST POS Cell Concentration

If FAST POS Cell Concentration is acceptable, fill in the required fields as indicated on the HMI. If it is found to be **unacceptable**, push the **'Cancel Method'** button. Refer to section 5.4 Cancelling or Stopping a Method for further instruction and information.

Complete verification process for parameter values entered.



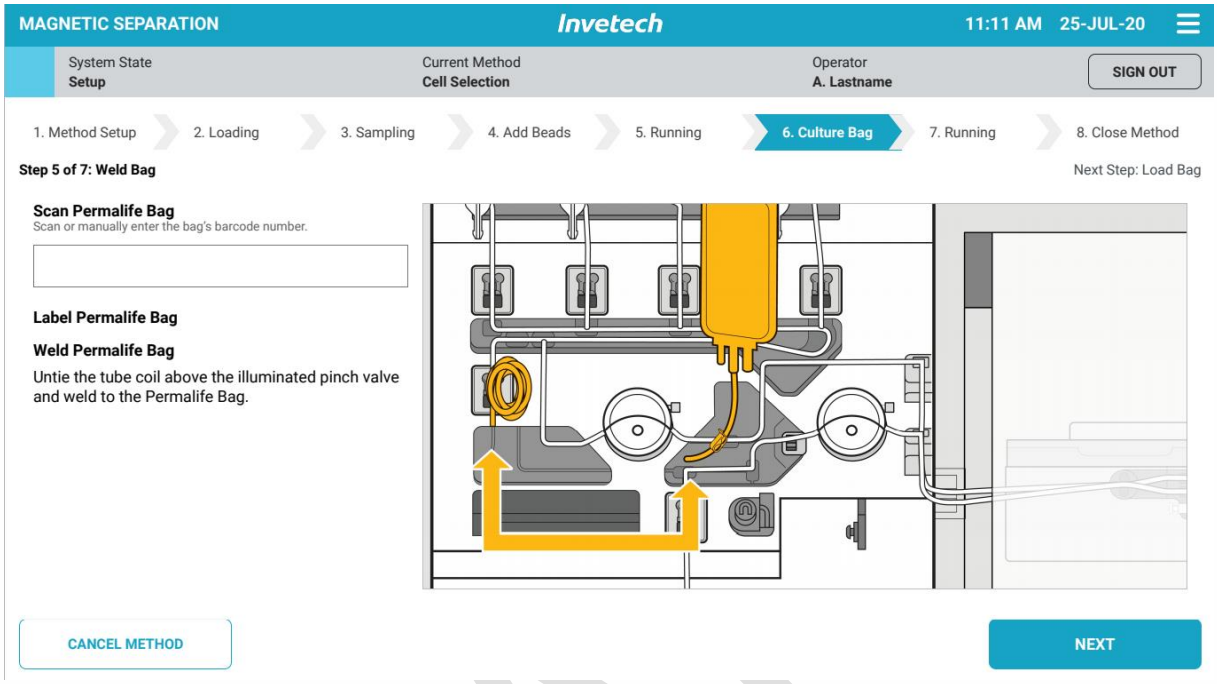
Notice

Transition Condition Tip

I. All fields must be filled before operator verification stage can begin.

5.2.7.5 Scan Permalife Bag

Scan the Permalife bag barcode using the MSP barcode scanner, located on the left-hand side of the platform.

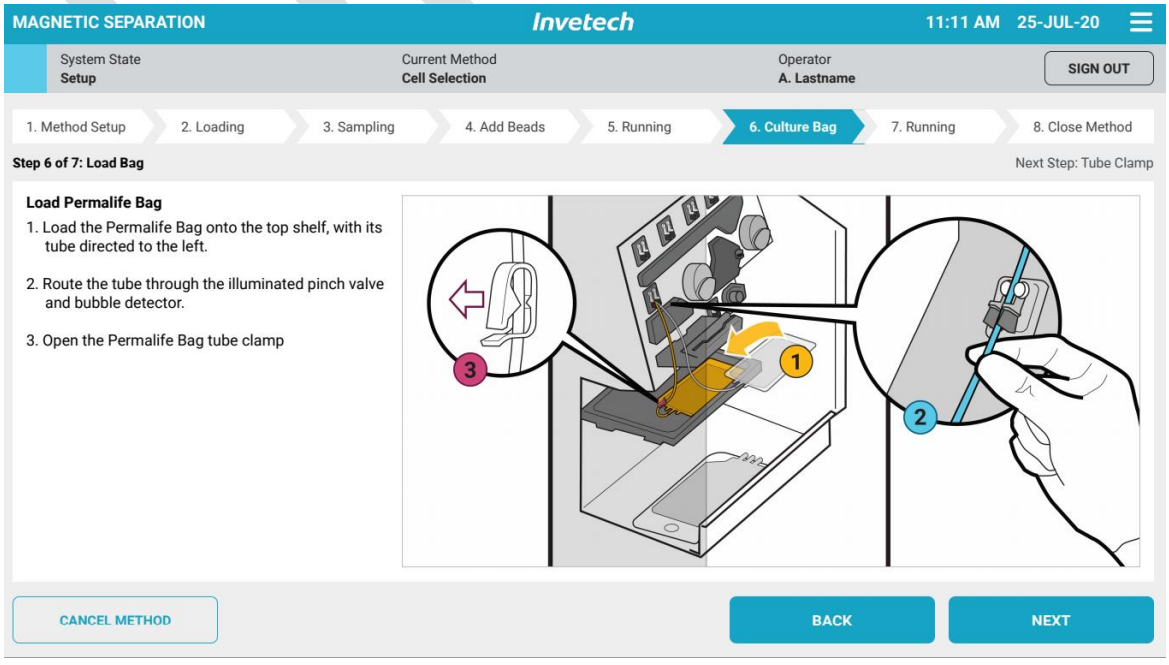


Notice

Transition Condition Tip

I. A value must be entered within the Scan Permalife Bag field to enable the 'Next' button.

5.2.7.6 Load Permalife Bag and Verify Disposable Kit Loading



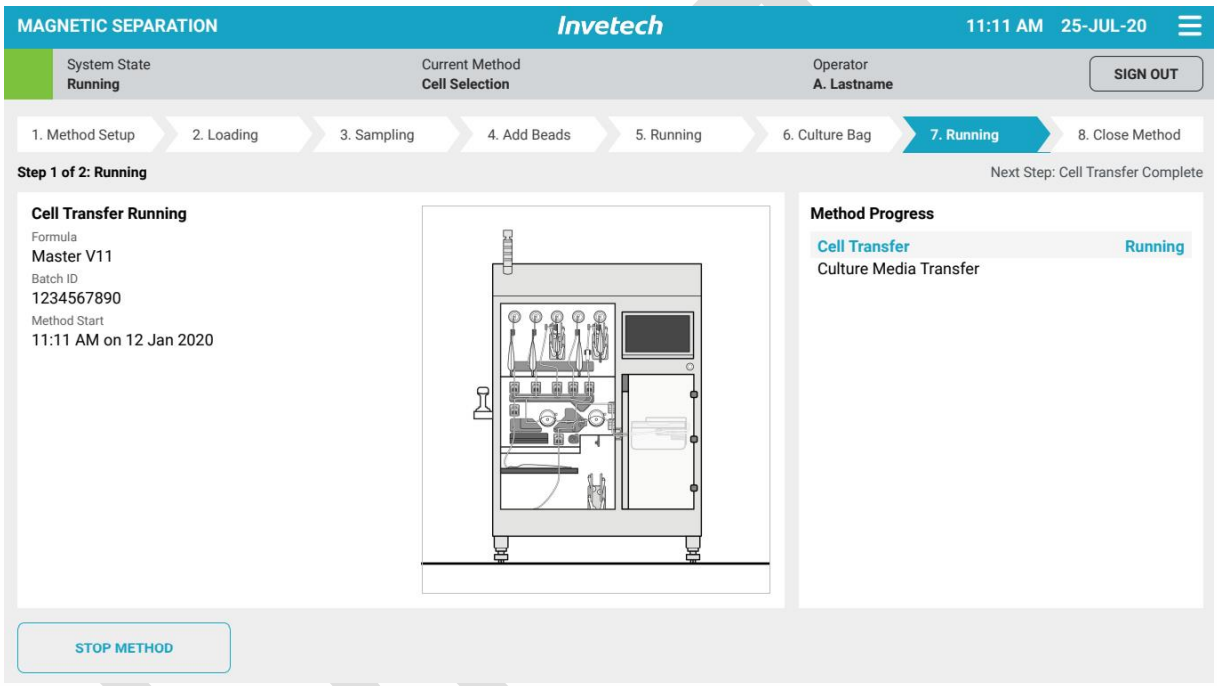
5.2.8 Running

5.2.8.1 Cell Transfer Running

A user can stop the method whilst MSP is in operation through hold or abort. Refer to section 5.4 for more information. Whilst the Method process is running, the digital user interface will provide ongoing visibility of Method Progress, communicated via key phases of the Method

Warning

Unless prompted by the machine, an operator should not interact with hardware during an automated process. Users should not stay within the clearance envelope longer than necessary for operational reasons. See instrument specification section of distances.



Notice

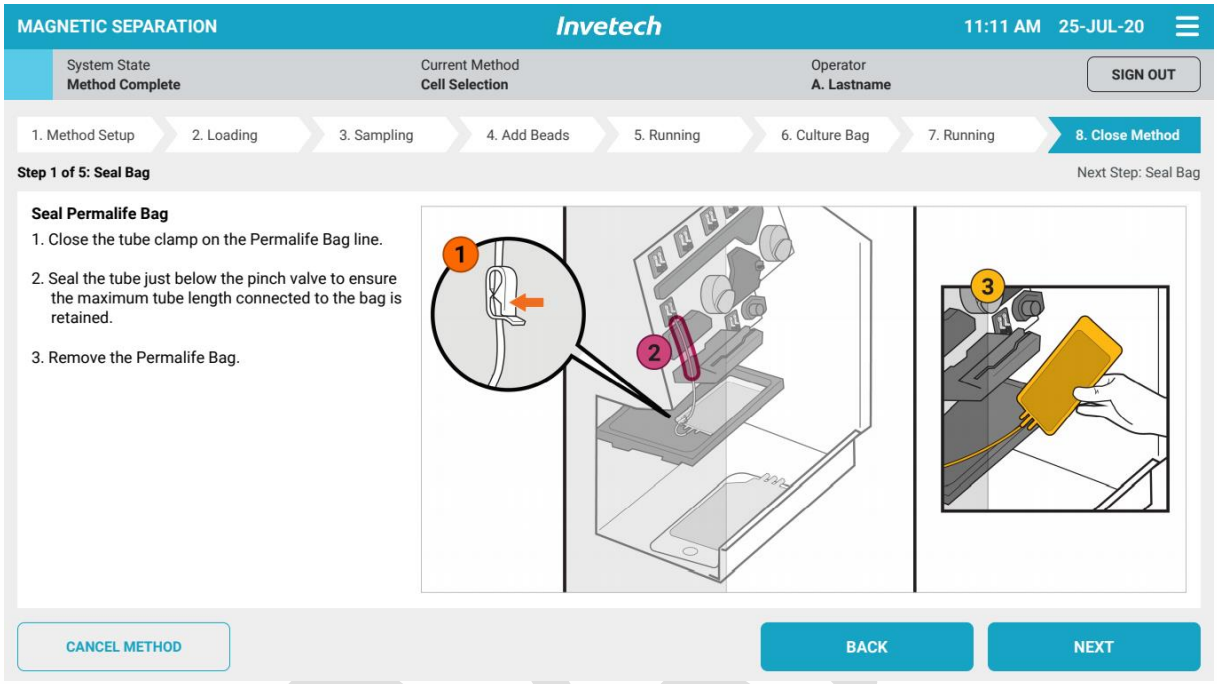
Transition Condition Tip

I. The Method must be complete before the ‘Next’ button is enabled.

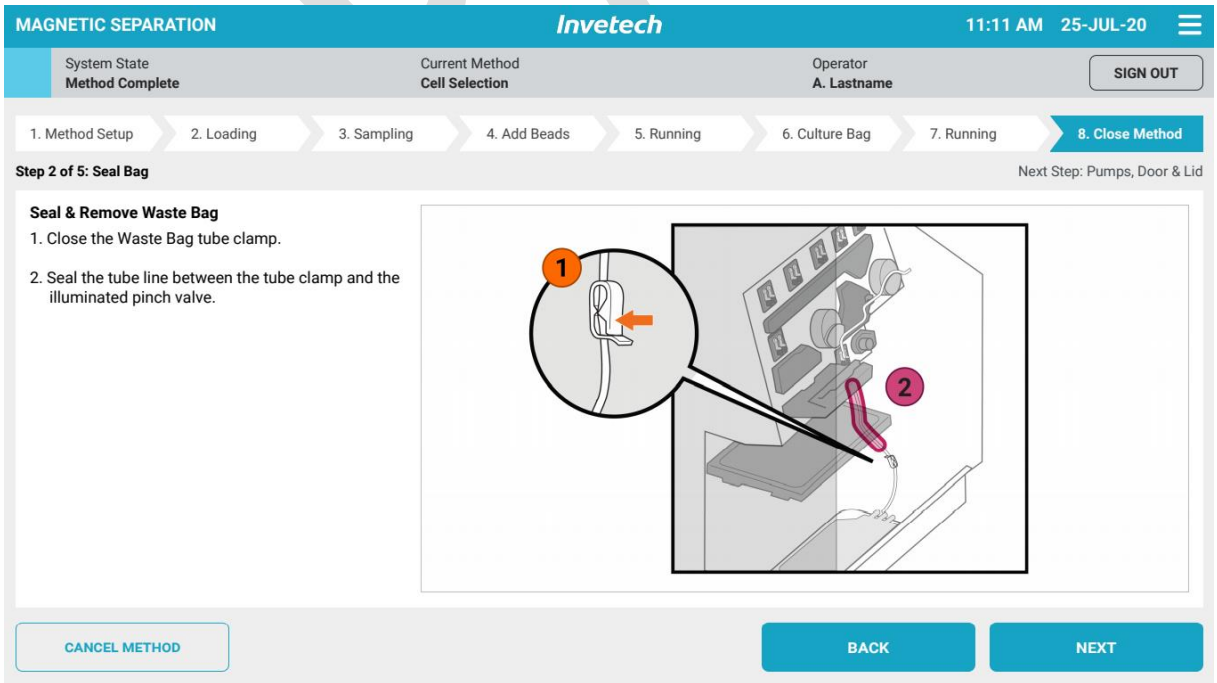
5.2.9 Close Method

This closure of the method constitutes the removal of the bags and disposal of the disposable kit.

5.2.9.1 Seal Permalife Bag



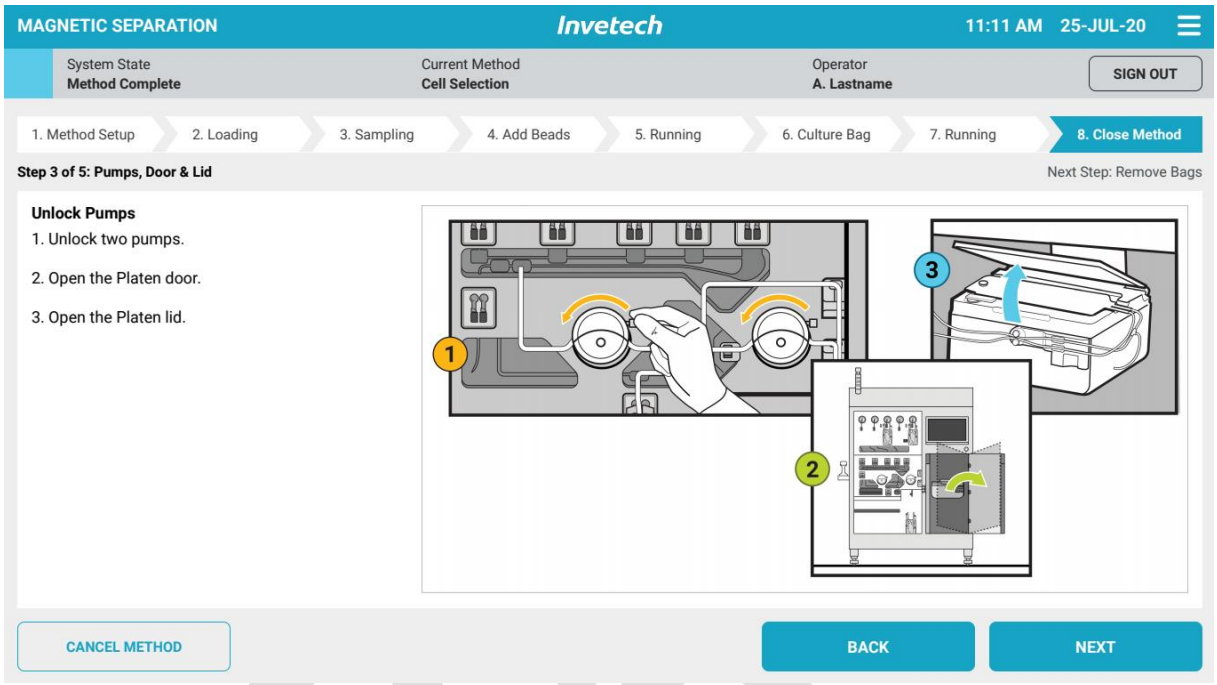
5.2.9.2 Seal and Remove Waste Bag



5.2.9.3 Unlock Pumps

Warning

Unless prompted by the machine, an operator should not interact with hardware during an automated process. Users should not stay within the clearance envelope longer than necessary for operational reasons. See instrument specification section of distances.



Notice

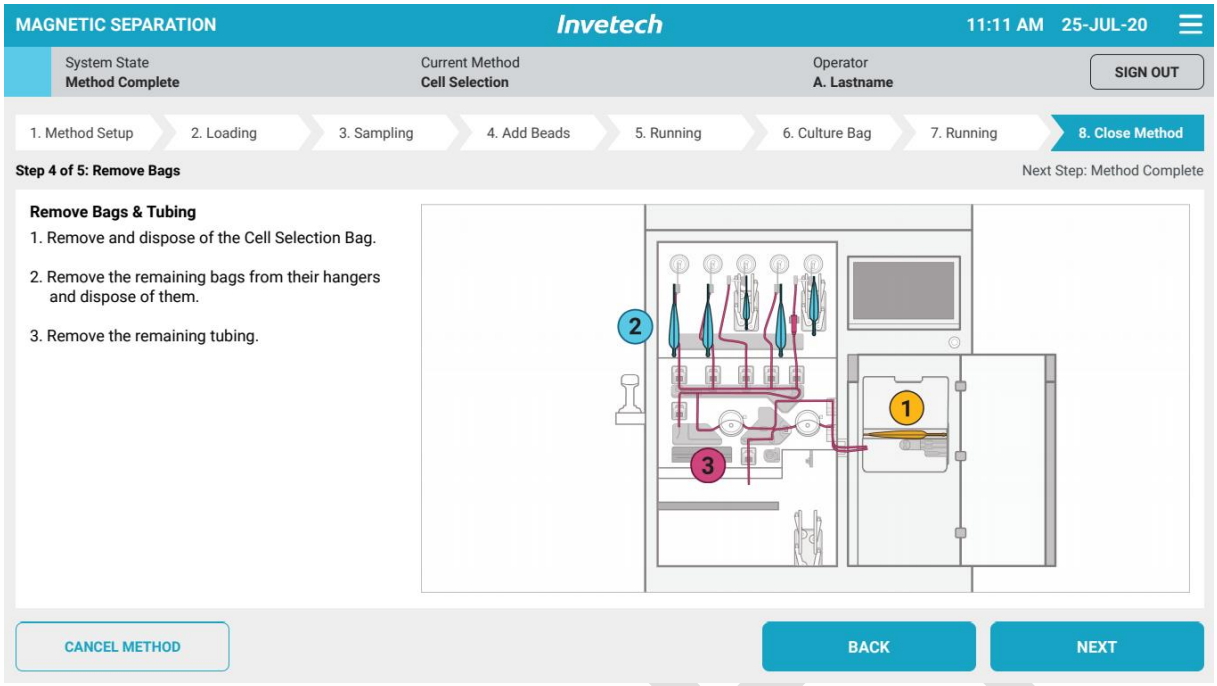
Transition Condition Tip

I. Ensure both **pumps are open**, done so by rotating their levers anticlockwise.

II. The **magnetic platen lid is open.** Ensure there are no impediments to the magnetic latch.

III. The **platen door is open.** Ensure there are no impediments to the front of the magnetic latch.

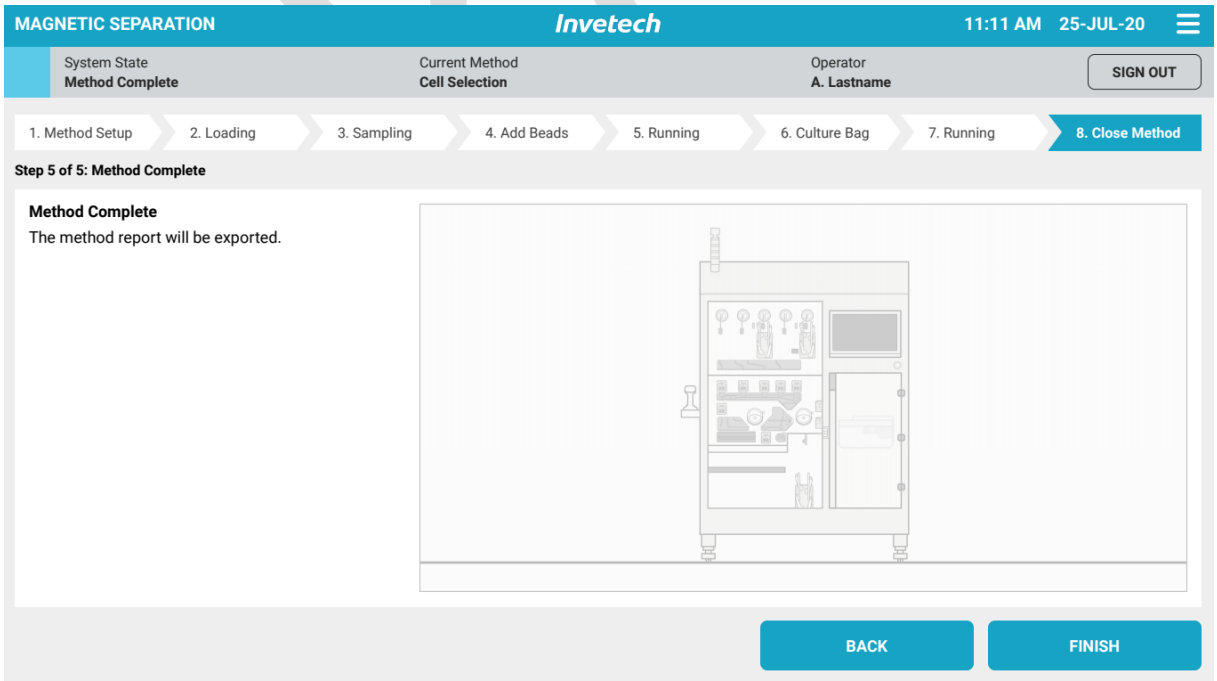
5.2.9.4 Remove Bags and Tubing



5.2.9.5 Method Complete

The batch report will be generated at the completion of the method.

Note that this report will include all events, alarms and warning since the last report was generated.



5.3 Running a Method (Bead Removal)

The following provides a combination instruction of:

I. How to remove disposable kit elements from packaging

II. What to consider for each step communicated on the HMI

Once ‘Bead Removal is selected on the HMI home screen, the user will be led through the following sequence.

5.3.1 Self-Check and Method Set-Up

The user is requested to prepare the device for Self-Check. An automated sequence will follow once ‘Start Self Check’ is selected, in which the device ensures all control modules are functional and prepared for the method. Selection of method parameter is achieved through the ‘Formula’ drop down box.

Warning

Unless prompted by the machine, an operator should not interact with hardware during an automated process. Users should not stay within the clearance envelope longer than necessary for operational reasons. See instrument specification section of distances.

Notice

Transition Condition Tip

I. Ensure both **pumps are locked firmly**, done so by rotating their levers clockwise.

II. The **magnetic platen lid is closed.** Ensure there are no impediments to the magnetic latch.

III. The **platen door is closed.** Ensure there are no impediments to the front of the magnetic latch.

IV. If there are any **faults during the self-check**, tap **cancel**. Take note of the fault and resolve before reattempting check.

5.3.2 *Method Set-Up and Loading Disposable Kit*

Check that the **correct disposable** has been selected. There is a difference between the cell selection and bead removal disposable kits. Refer to section 4 outlining the equipment for each method.

Follow HMI instructions to load disposable kit.

Notice

Check:

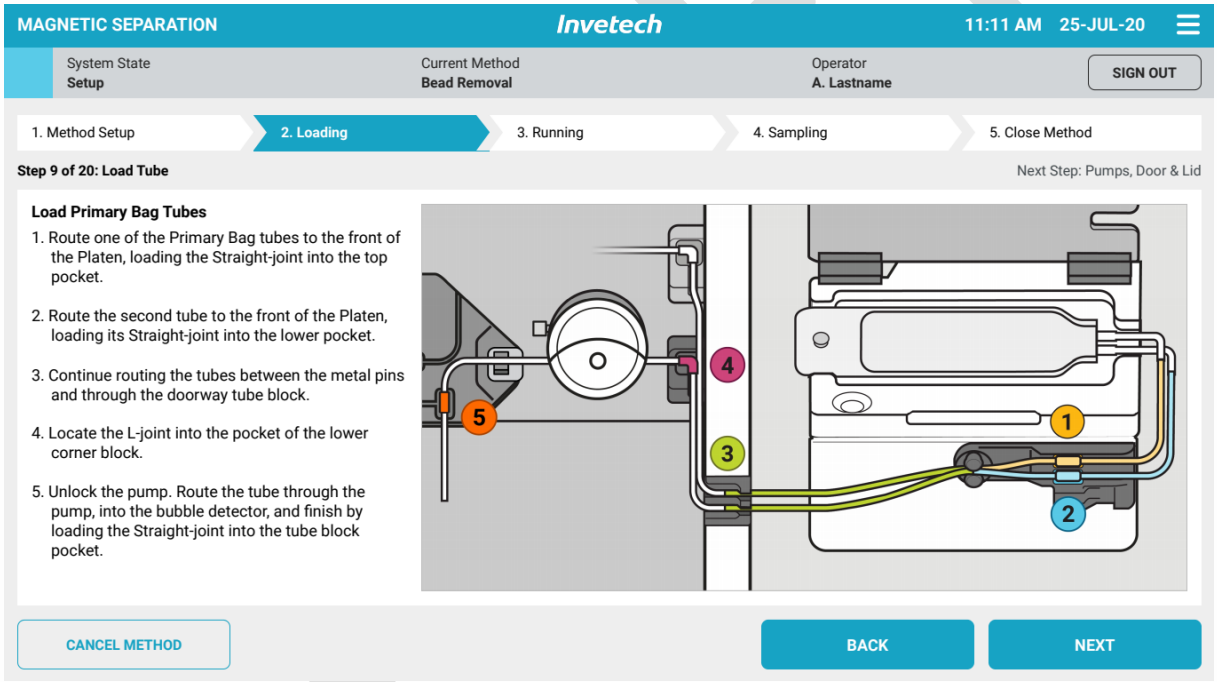
I. Tubing through pinch valve sits **between the clamping arms**.

II. Tubing is **pushed firmly into the bubble detector**.

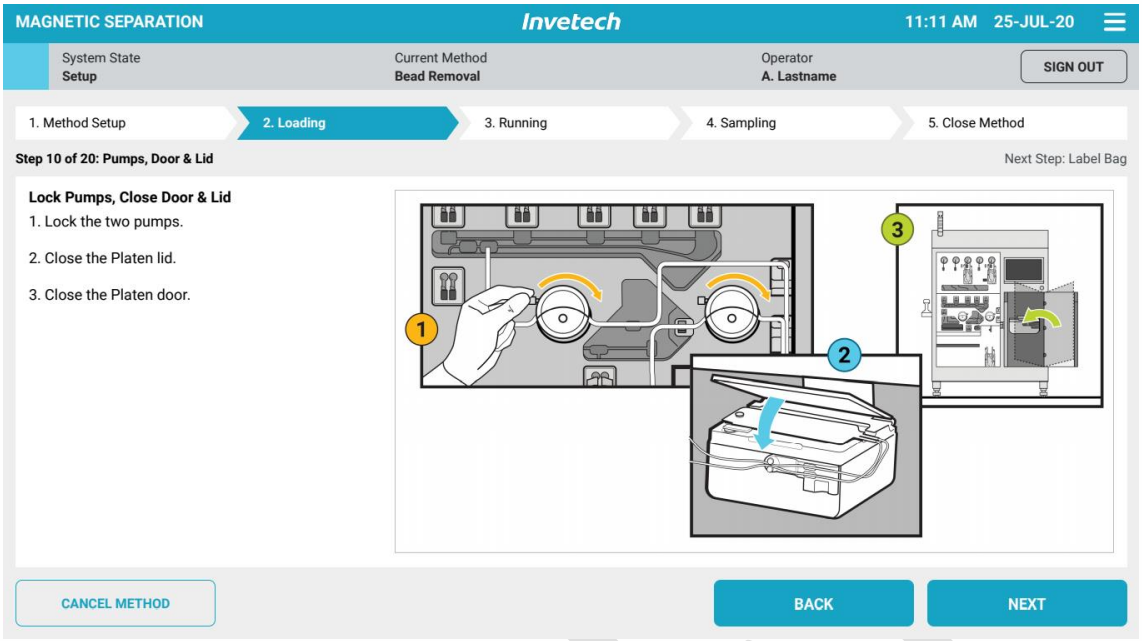
III. Tubing on either side of peristaltic **pump** sits **within the guide blocks**.

5.3.2.1 Load Tube

Primary bag on magnetic platen is not directional.



5.3.2.2 Lock Pumps, Close Door and Lid



Notice

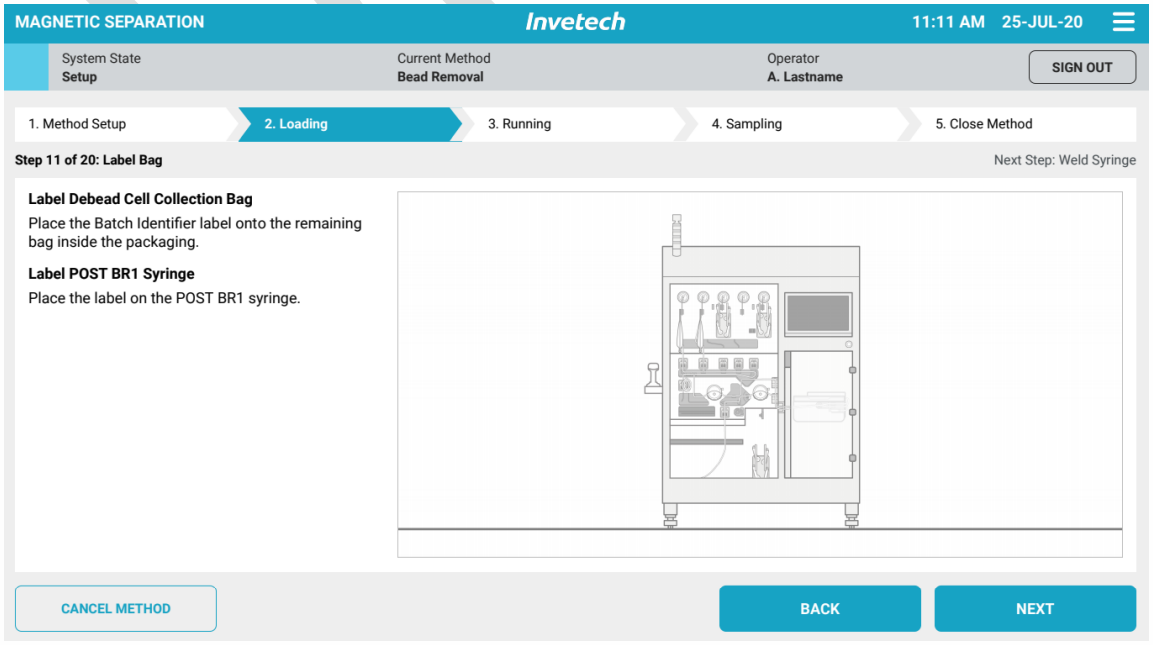
Transition Condition Tip

I. Ensure both **pumps are locked firmly**, done so by rotating their levers clockwise.

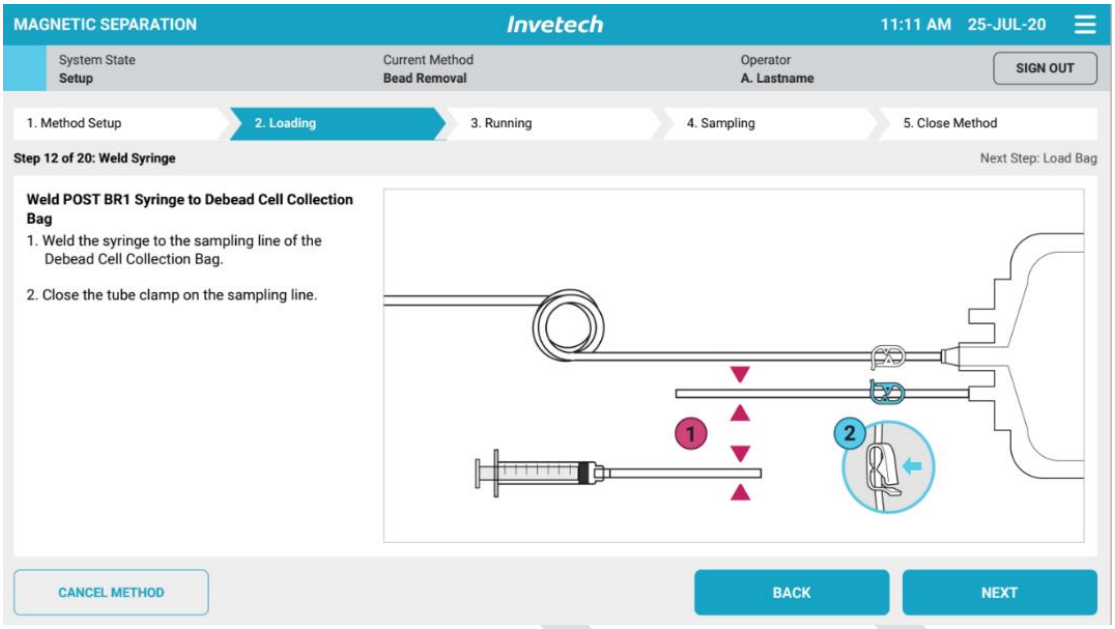
II. The **magnetic platen lid is closed.** Ensure there are no impediments to the magnetic latch.

III. The **platen door is closed.** Ensure there are no impediments to the front of the magnetic latch.

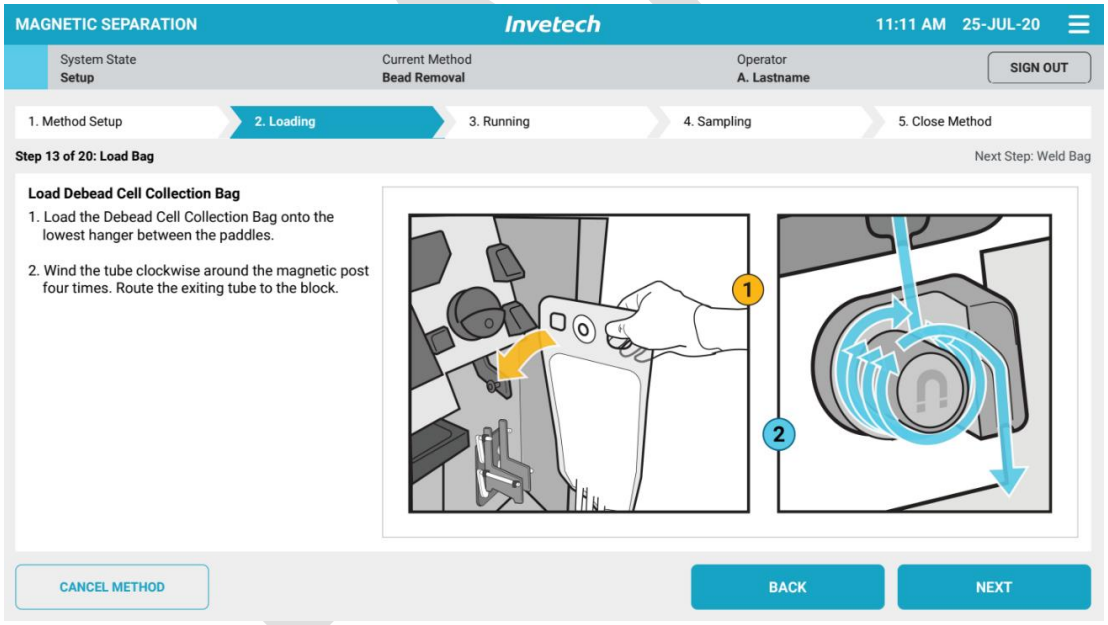
5.3.2.3 Label Bags



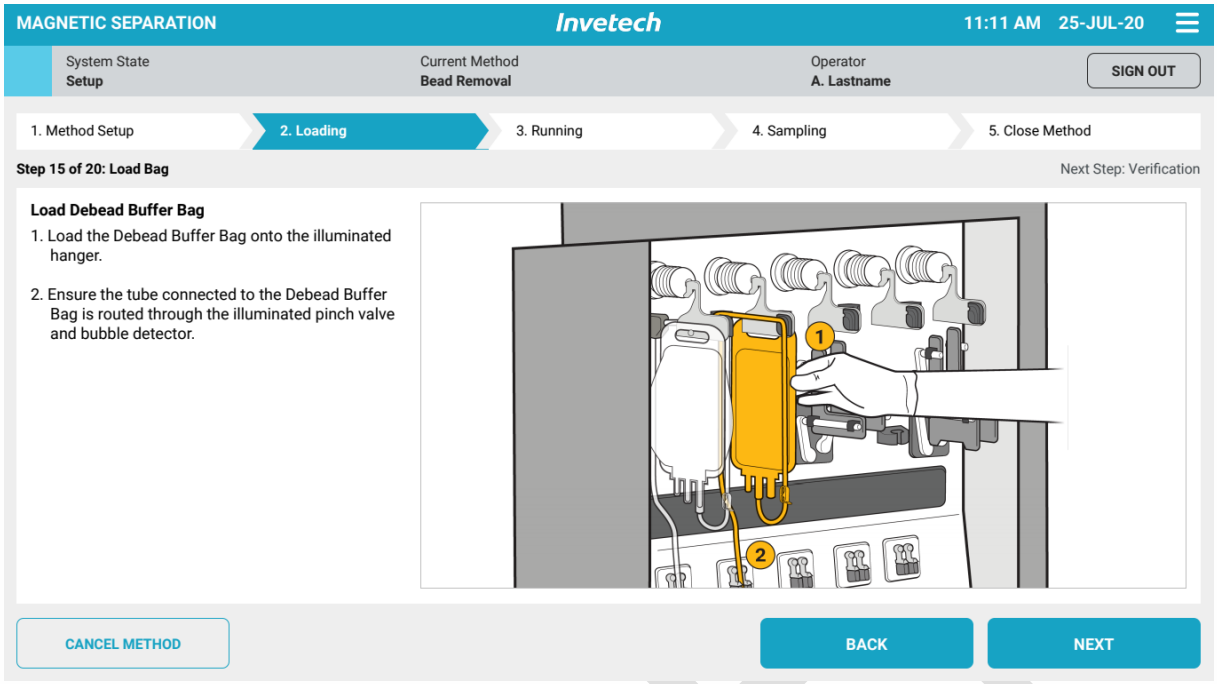
5.3.2.4 Weld Syringe



5.3.2.5 Load Debead Cell Collection Bag



5.3.2.6 Scan, Load and Verify Debead Buffer Bag



Verification:

The system requires an independent verifier (separate to current operator) to confirm that the disposable kit is loaded correctly, and the selected parameters are correct before allowing to proceed. The start button is hidden until the verification process is complete.

Notice

Transition Condition Tip

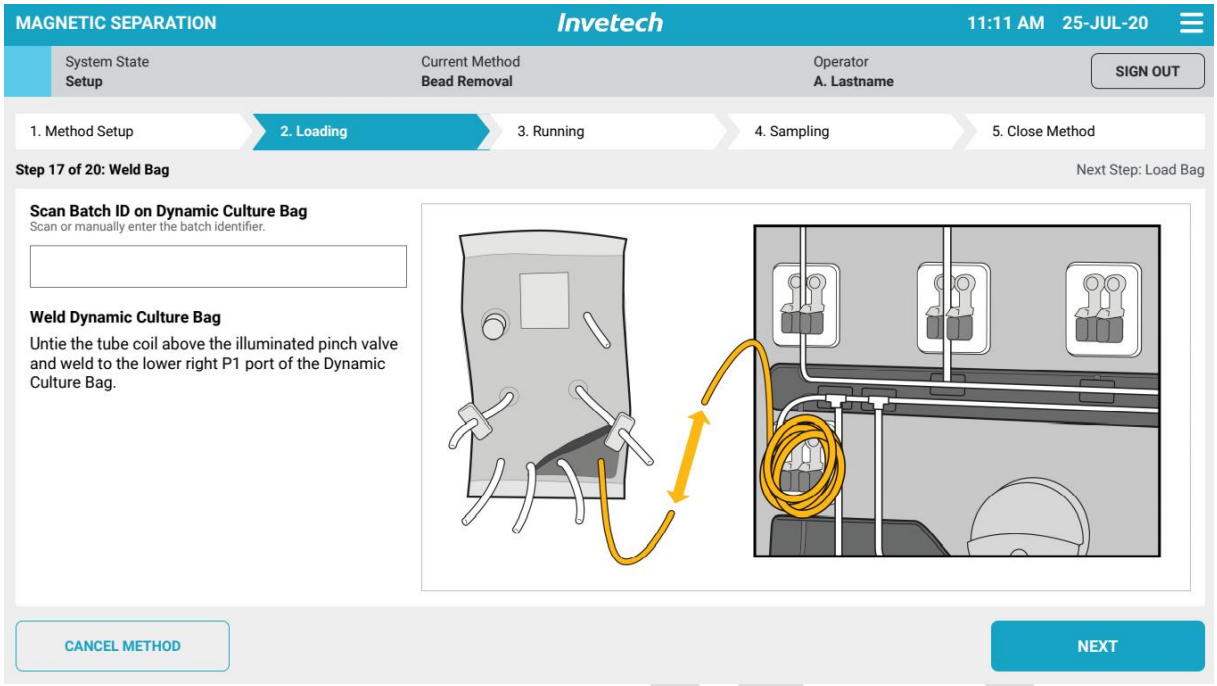
I. A value must be entered within the Scan Debead Buffer Bag field to enable the ‘Next’ button.

II. All fields must be filled before operator verification stage can begin.

III. Operator must sign off on disposable kit loading before verifier approval.

IV. Verifier must sign off on disposable kit loading before operator resumes control.

5.3.2.7 Scan Batch ID on Dynamic Culture Bag



Notice

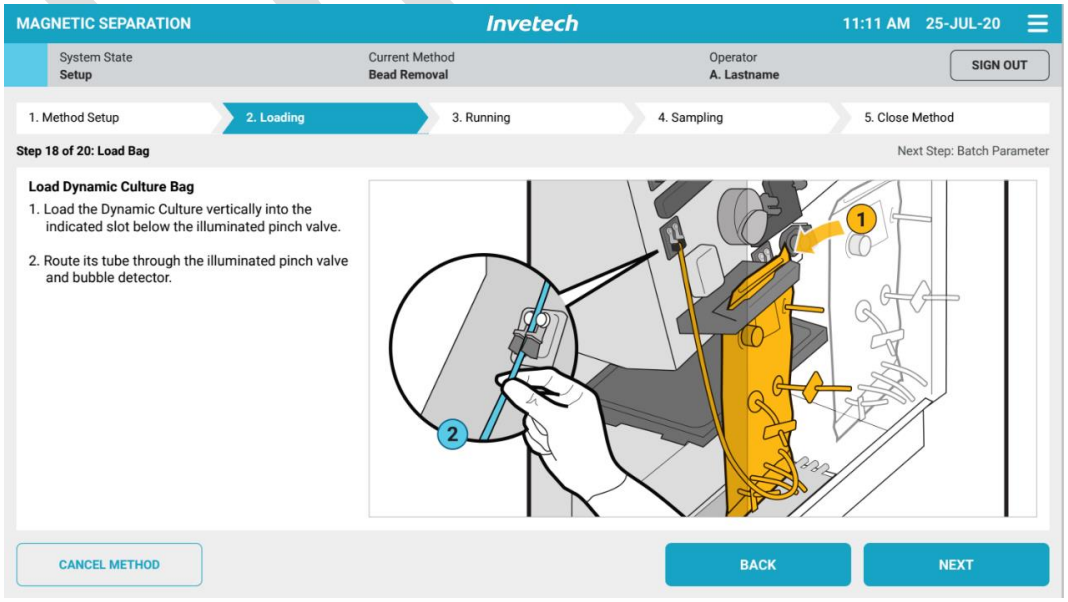
Transition Condition Tip

I. A value must be entered within the Scan Dynamic Culture Bag field to enable the 'Next' button.

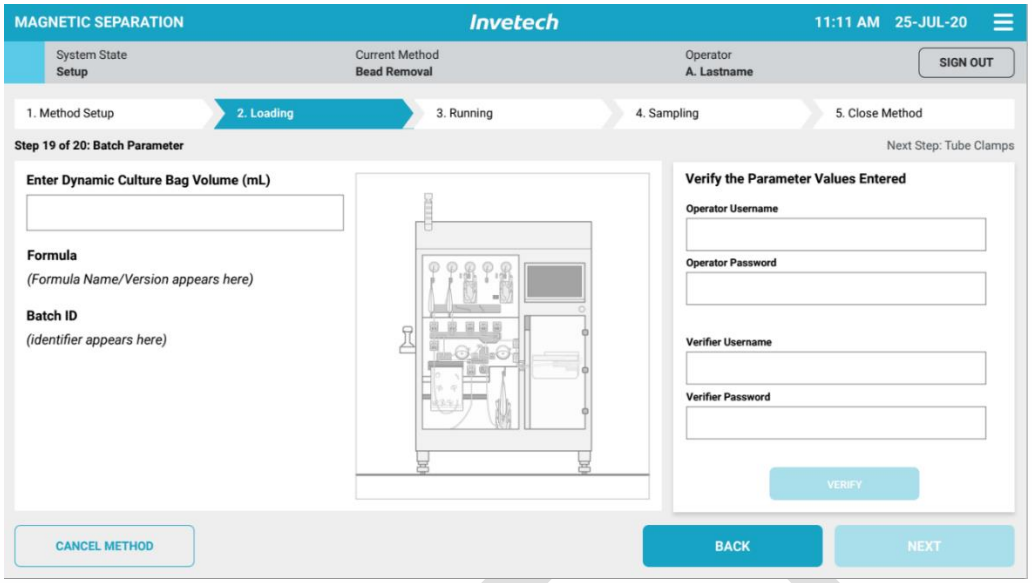
II. Check **correct tubing line** of dynamic culture bag is welded.

5.3.2.8 Load Dynamic Culture Bag

Ensure that tube lines from dynamic culture bag faces the user as shown below.



5.3.2.9 Enter Batch Parameters and Verify

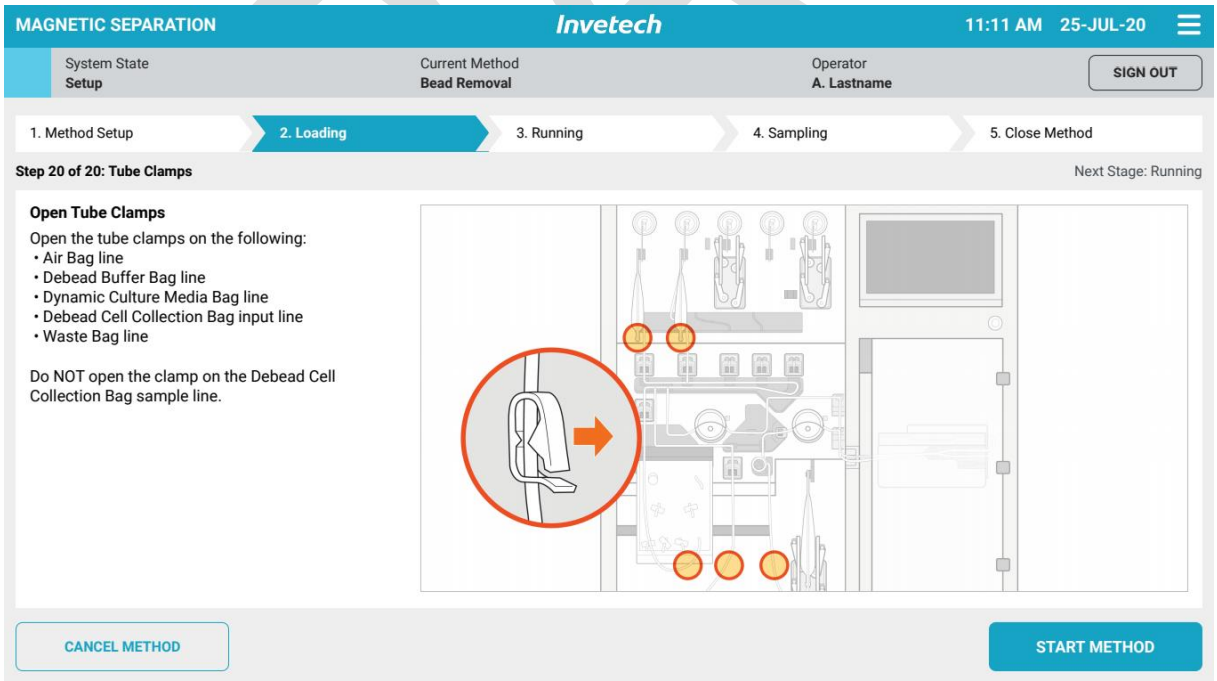


Notice

Transition Condition Tip

I. All fields must be filled before operator verification stage can begin.

5.3.2.10 Open Tube Clamps



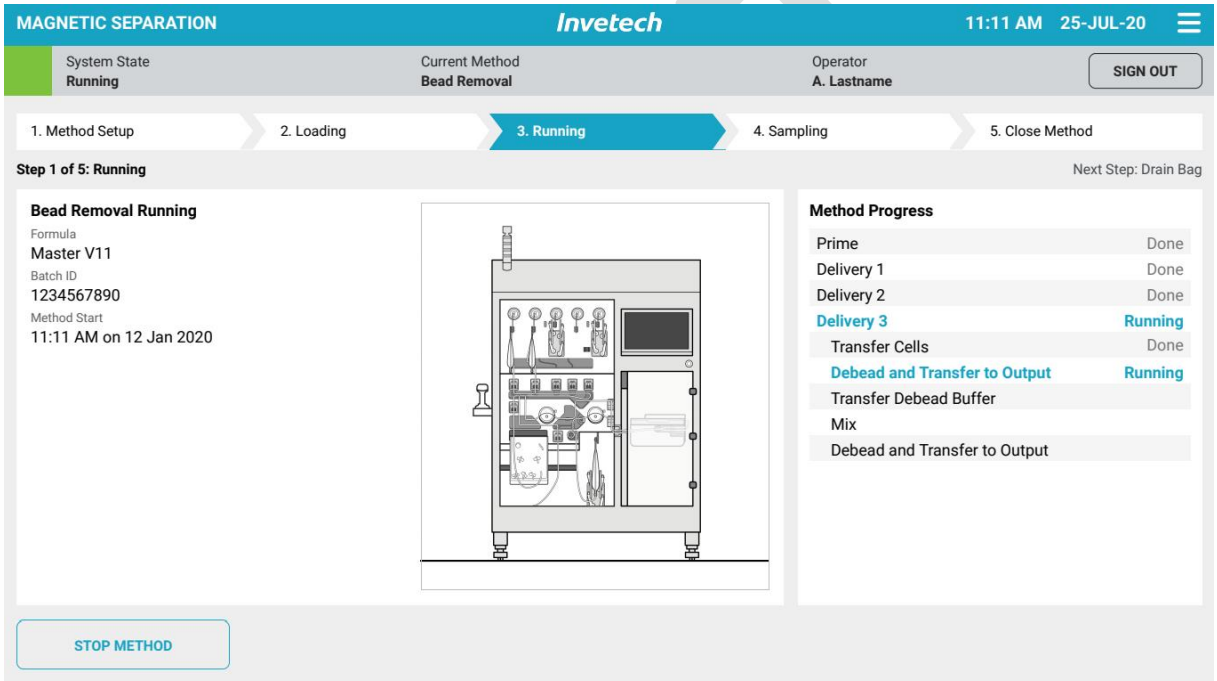
5.3.3 Running

5.3.3.1 Bead Removal Running

A user can stop the method whilst MSP is in operation through hold or abort. Refer to section 5.4 for more information. Whilst the Method process is running, the digital user interface will provide ongoing visibility of Method Progress, communicated via key phases of the Method.

Warning

Unless prompted by the machine, an operator should not interact with hardware during an automated process. Users should not stay within the clearance envelope longer than necessary for operational reasons. See instrument specification section of distances.

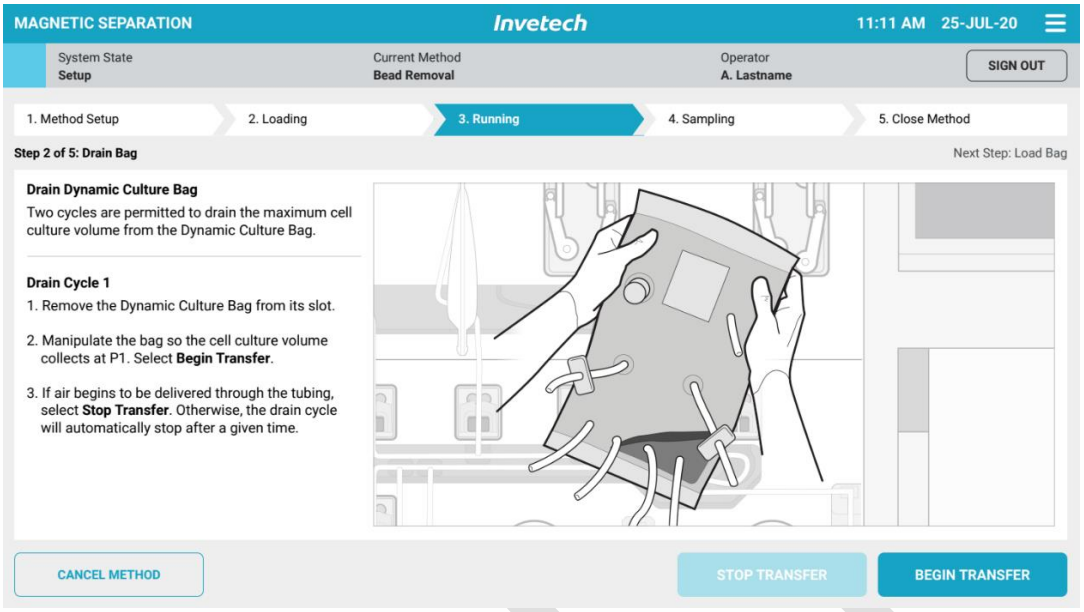


Notice

Transition Condition Tip

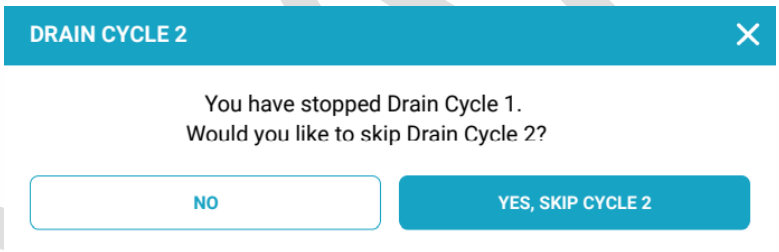
I. The Method must be complete before the ‘Next’ button is enabled.

5.3.3.2 First Drain Bag

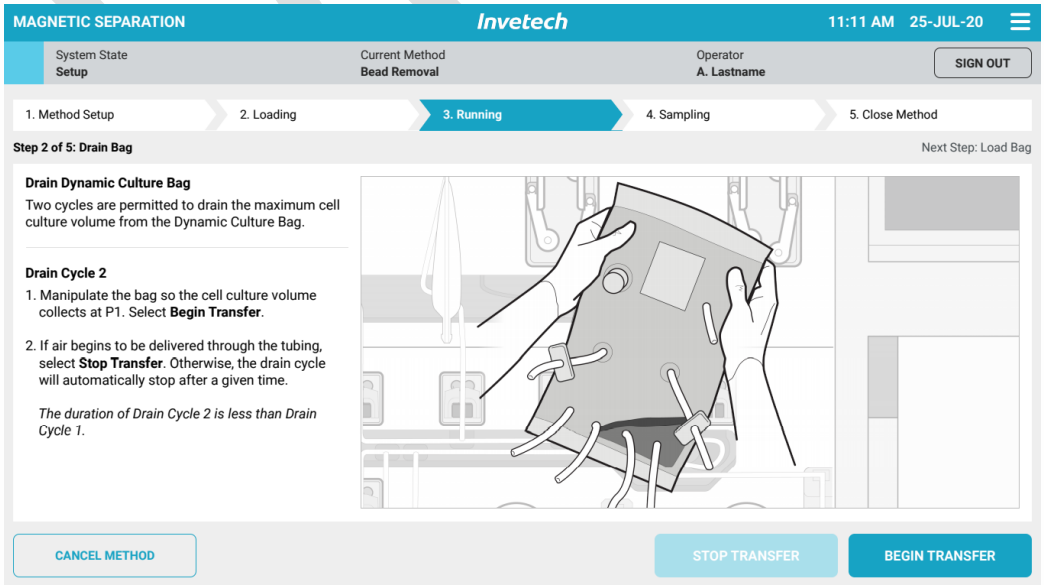


5.3.3.3 Stop Transfer

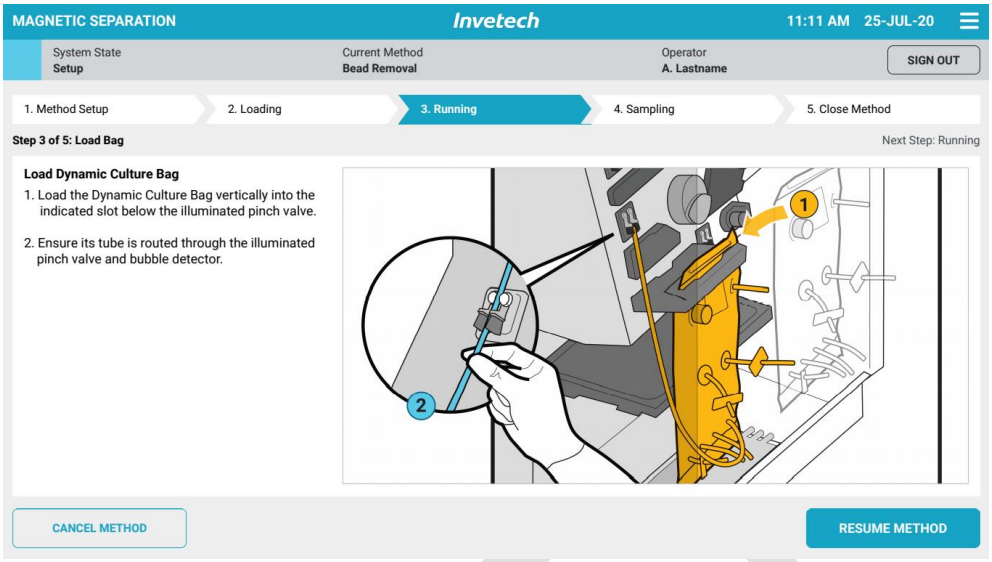
If user pushes ‘Stop Transfer’ HMI will trigger the following message. Accepting this condition will skip the second drain cycle.



5.3.3.4 Second Drain Cycle



5.3.3.5 Load Dynamic Culture Bag

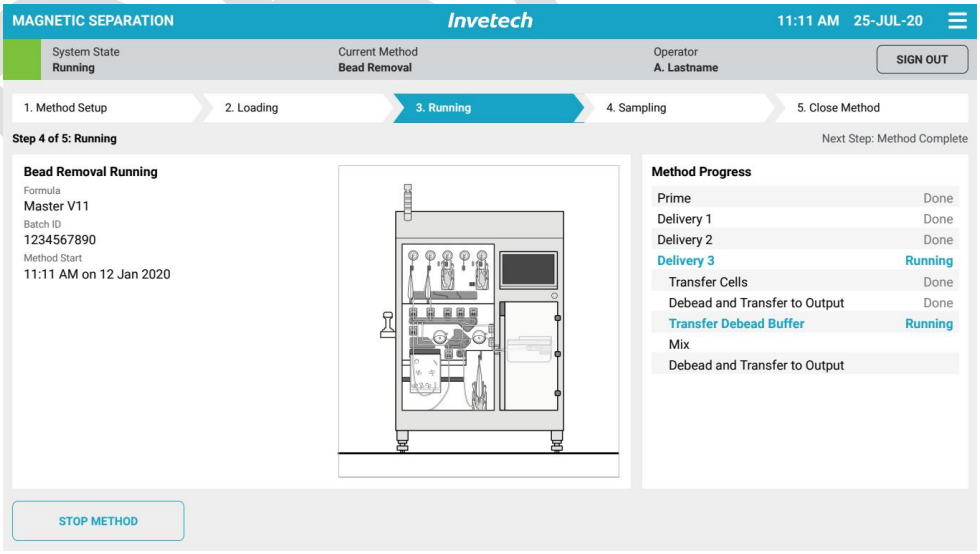


5.3.3.6 Bead Removal Running

A user can stop the method whilst MSP is in operation through hold or abort. Refer to section 5.4 for more information. Whilst the Method process is running, the digital user interface will provide ongoing visibility of Method Progress, communicated via key phases of the Method.

Warning

Unless prompted by the machine, an operator should not interact with hardware during an automated process. Users should not stay within the clearance envelope longer than necessary for operational reasons. See instrument specification section of distances.



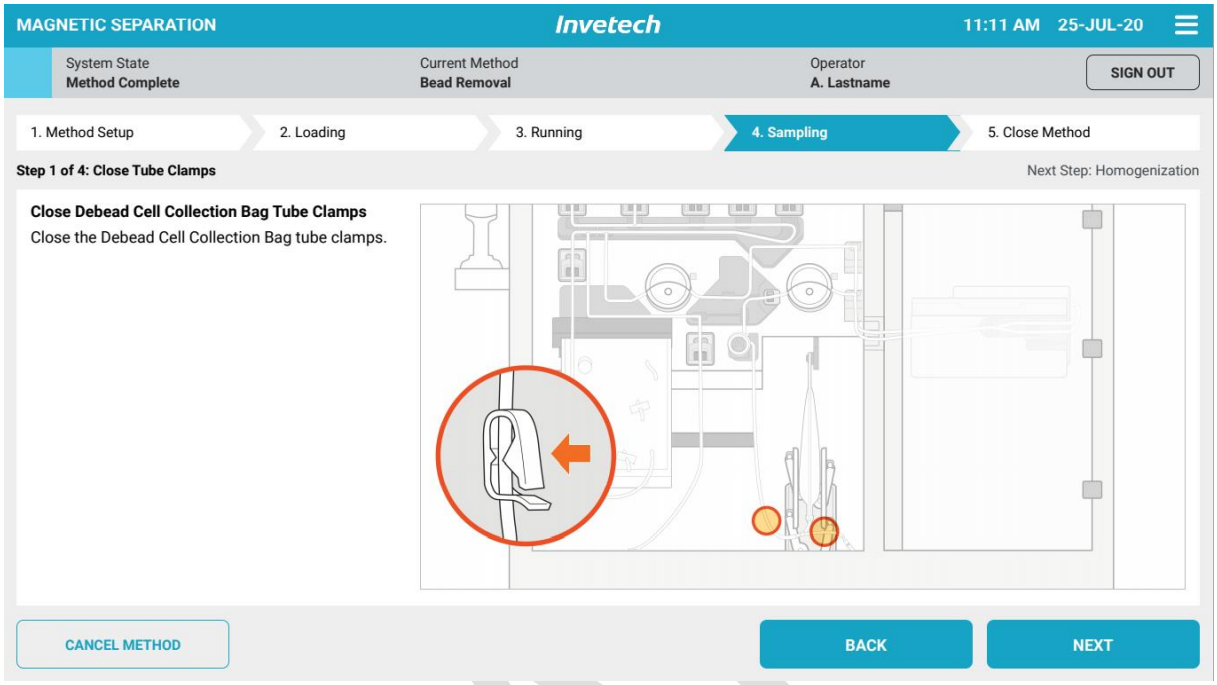
Notice

Transition Condition Tip

I. The Method must be complete before the ‘Next’ button is enabled.

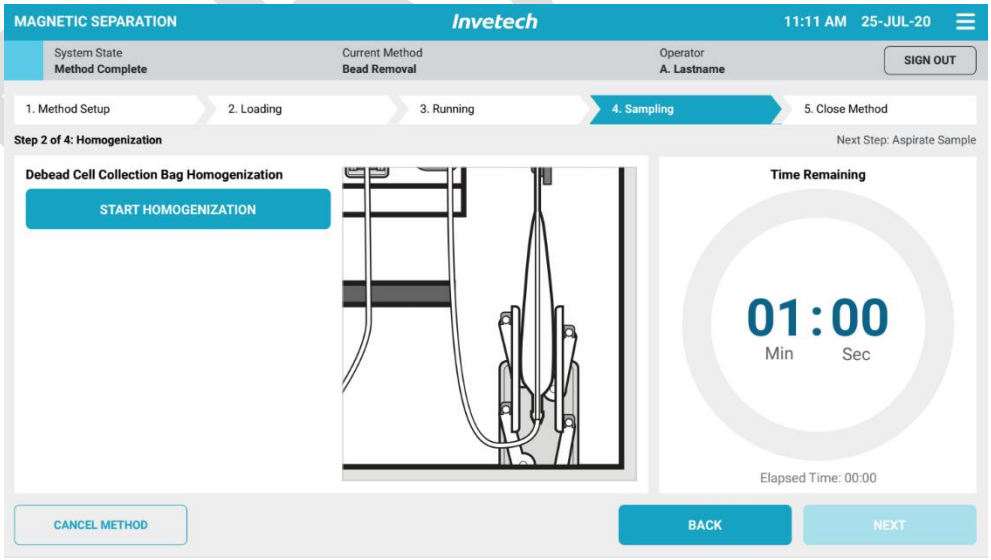
5.3.4 Sampling

5.3.4.1 Close Debead Cell Collection Bag Tube Clamps



5.3.4.2 Start Homogenization

Push the “start homogenization” button. The countdown will begin, displaying both time remaining and time elapsed. This process will take approximately 60 seconds and the paddle mixers will automatically cease agitation after the elapsed time.

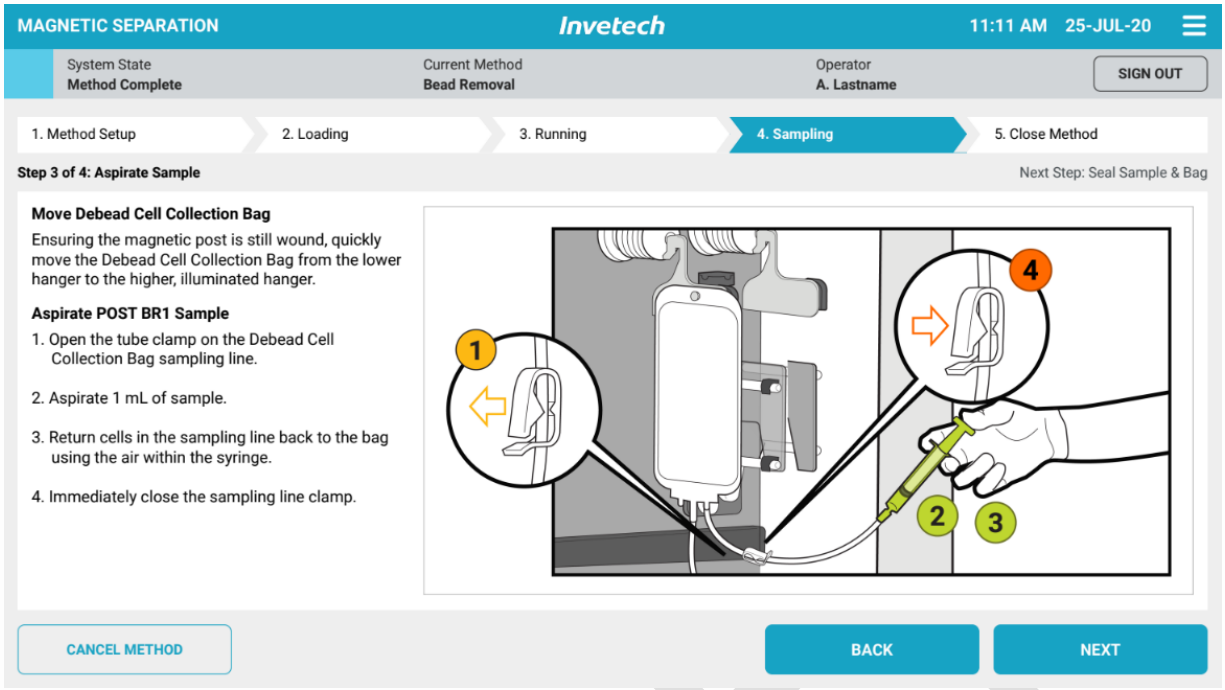


Notice

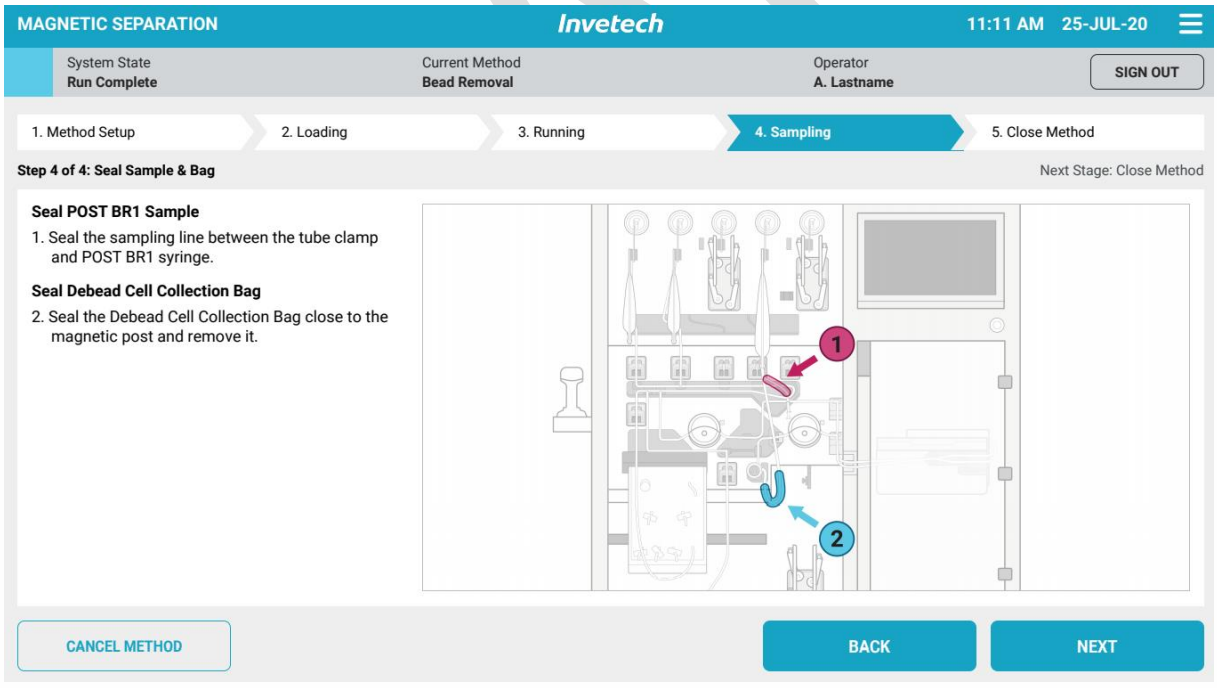
Transition Condition Tip

I. The next stage cannot begin until the full time has elapsed.

5.3.4.3 Aspirate Sample



5.3.4.4 Seal and Sample Bag



5.3.5 Close Method

Outline of Steps:

1. Seal and remove waste bags
2. Unlock pumps
3. Remove bags and tubing

Warning

Unless prompted by the machine, an operator should not interact with hardware during an automated process. Users should not stay within the clearance envelope longer than necessary for operational reasons. See instrument specification section of distances.

Notice

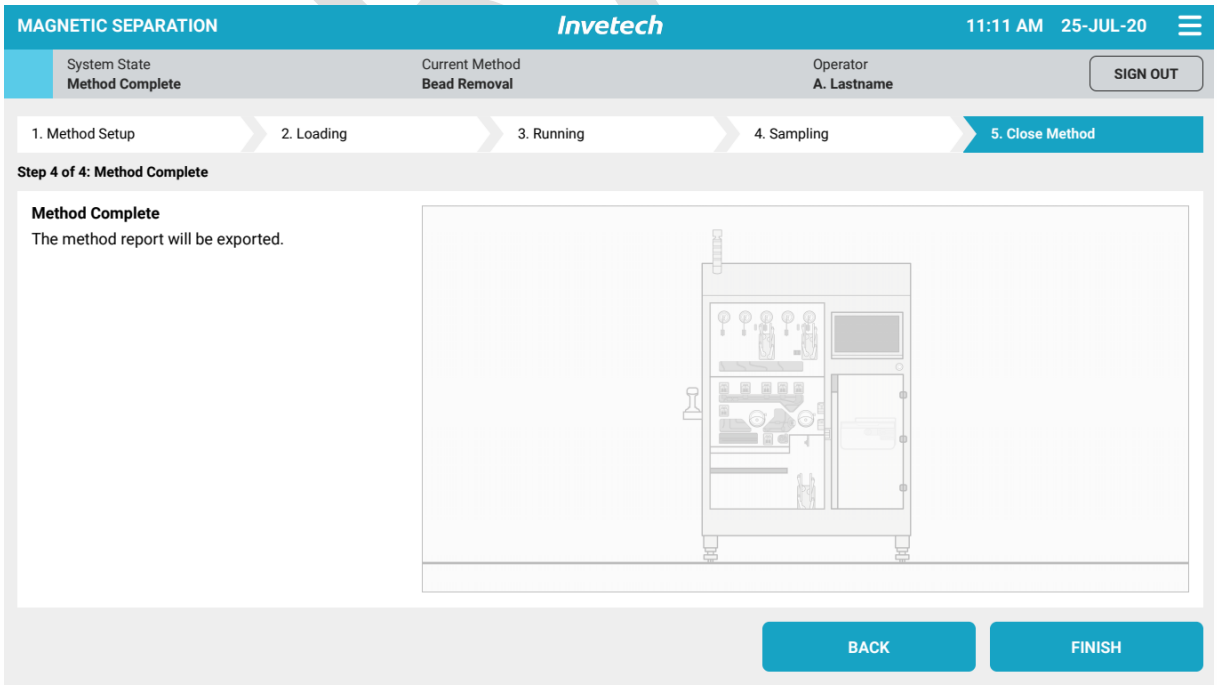
Transition Condition Tip

I. Ensure both **pumps are open**, done so by rotating their levers anticlockwise.

II. The **magnetic platen lid is open.** Ensure there are no impediments to the magnetic latch.

III. The **platen door is open.** Ensure there are no impediments to the front of the magnetic latch.

5.3.5.1 Method Complete



5.4 Cancelling or Stopping a Method

There are two ways in which a user can prematurely end a Method.

5.4.1 Cancel Method

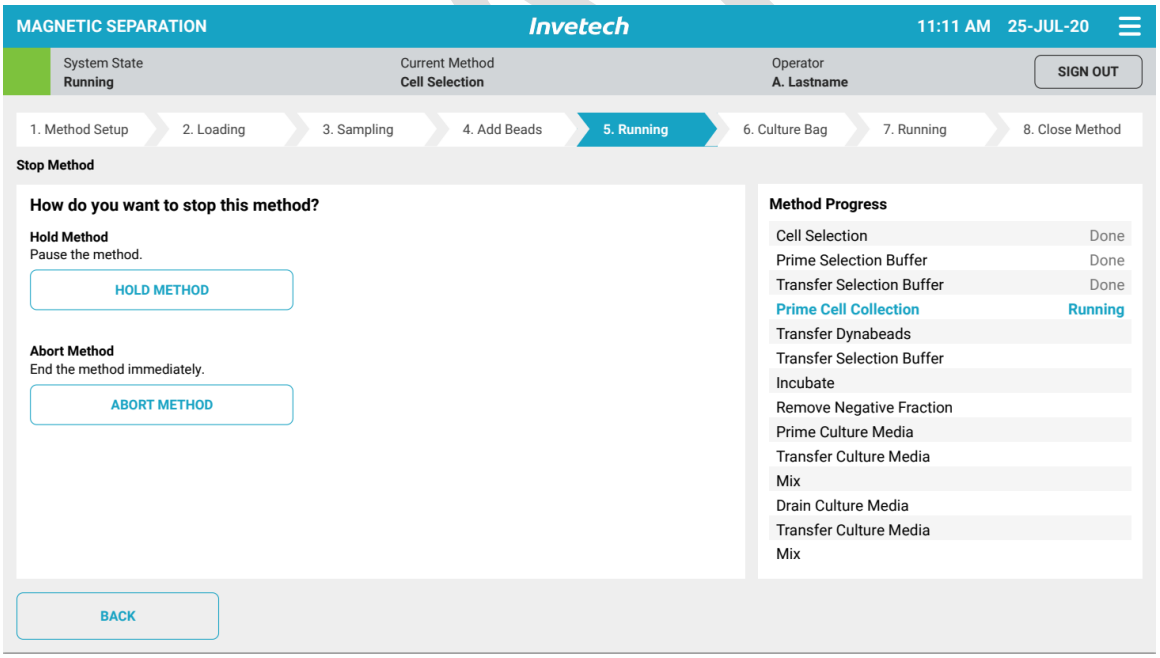
Cancelling Method is the user action of ending a Method during any stage of the process. This only requires an acknowledge to cancel the Method, at which point the user will be returned to the home screen.

5.4.2 Stop Method

Stopping Method is a user action during the running phase. Once indicating intent to stop a Method, the operator has the opportunity to stop the Method in two ways:

I. Hold Method – once selecting and acknowledging this option, the device temporarily stops the Method, returning the user to the running screen. State of phase will be shown as “Method on Hold” with an option to “Resume Method” or “Stop Method”. This allows the user to determine if the phase step can be reversed manually before resuming or fix any potential errors that have arisen without ruining a whole batch

II. Abort Method – once selecting and acknowledging this option, the device will immediately stop the Method, returning the user to the home screen. The user is expected to the remove the disposable kit with no instruction on the HMI.



6. USER ACCOUNT MANAGEMENT

7. TROUBLE SHOOTING

The table below gives some observed conditions with possible rectifications.

Observed condition	Possible fault	Possible rectification
Liquid volume not reducing in bags	Blocked tube .	Check all tube clips have been released Check tube set is loaded correctly with no kinks
Liquid has not primed correctly	caused by a premature bubble tripping the bubble sensor.	Premature bubble could be a result of the user handling the bag during processing.
Noisy peristaltic pump	Air bubble in rotor preventing fluid movement	Hold method to avoid rupture
Platen Lid has popped open	To much air has been pumped into cell bag	Check for leaks in tube set. Hold the method, manually pump excess air to waste and resume method
Safety door has been opened	Used has opened the door during method	Close door and reset safety switch
E-Stop button has been pressed	User has pressed the E-Stop for variety of reasons	Fix possible fault. Reset E-Stop and safety button. If viable to do so resume method

7.1 ALARMS

The unit records procedure states for phases (PH) and unit procedures (UP). These progress from IDLE, STARTING, RUNNING, COMPLETE and back to IDLE.

As the device moves through a method, items are recorded in the log. This is written out in the batch report at the end of a successful method. The batch report will contain all the items since the last batch report was created.

In the occurrence of an abnormal response the device will alert the user and record an Alarm, Warning or Event. There may be multiple alerts from a single root issue.

If there are any faults during the self check to proceed the user must tap cancel. Take note of the fault and resolve before trying again. Eg Door closures, weigh cell.

Error Description	Resolution
Air bag weigh module is out of range	Check correct bag has been loaded.
Selection buffer weigh module is out of range	Check correct bag has been loaded. There is insufficient volume in the bag.
Dynabeads weigh module is out of range	Check correct bag has been loaded. There is insufficient volume in the bag.
Culture media weigh module is out of range	Check correct bag has been loaded. There is insufficient volume in the bag.
Cells weigh module is out of range	Check correct bag has been loaded. There is insufficient volume in the bag.
Elapsed time is outside of range without seeing bubble sensor triggering (transition condition) during priming sequence.	Check tubing is firmly pushed into the bubble sensors.
Source weigh module value does not change when pump is running during close loop dispense	1. Check if bag is empty. 2. Check channels are not blocked a. Open appropriate tube clamps
Debead buffer weigh module is out of range after debead buffer bag loading.	Check correct bag has been loaded. There is insufficient volume in the bag.

8. CLEANING

The device should be cleaned when needed. This can be done with a cloth dampened with suitable detergent diluted with water to remove dust. See maintenance manual for details of suitable cleaning agents.

⚠ Caution

Before using any cleaning or decontamination methods except those recommended by Invetech above, users should check with Invetech that the proposed method will not damage the equipment

8.1 After a leak or spill

Use disposable wipes to remove bulk fluid. Then wipe device with disinfectant wipes or 70% Isopropyl alcohol with water.

9. ROUTINE MAINTENANCE & CHECKS

Included in these instructions for use are the daily routine maintenance and checks. For longer interval i.e. annual maintenance, consult the device maintenance manual.

9.1 Daily

- Wipe down and clean device according to SOP.

10. PRODUCT SPECIFICATIONS

This section summarizes the MSP information such as size, power requirements and environmental requirements. For additional information contact your Invetech representative.

The system does not come with Anti-Virus Software installed. This is in order to allow the end user to install the anti-virus software of their choice and leverage site licensing. Therefore, the anti-virus configuration and update management will be handled by external systems. This will include loading of virus definitions to the Anti-virus software on the system. Anti-virus software packages compatible with Siemens WinCC Runtime Advanced v16 include:

- Trend MICRO OfficeScan v12.0
- McAfee Endpoint Security v10.5
- Symantec Endpoint Protection V14.0
- Kaspersky Endpoint Security V11.1
- 360 Total Security Qihoo “360 Safe Guard” V11.5
- Microsoft Windows Defender (version of installed operation system)

⚠ Caution

While the above packages have been approved by Siemens, Invetech has not conducted any testing of these packages, or any assessment of the possibility of these packages having an adverse effect on the proper functioning of the equipment. It is the responsibility of the end user to ensure any package does not have an adverse impact on the equipment, including but not limited to issues resulting from popups on screen obstructing the HMI, automatic updating, or automatic system restart.

10.1 Environment requirements

The MSP instrument is for indoor use only.

Table 10.1 Environment requirements

Specification	Operating Range
Temperature	15℃ to 27℃, (59℉ to 81℉)
Humidity	20% to 75% Relative Humidity non-Condensing
Operating Altitude	Up to 2000m, (6500ft)

10.2 Dimensions and Weights

Table 10.2 Dimensions and Weights

Variable	Dimensions
Weight	740kg*, (1635lb)

Hight	2140mm, (84.25in)
Width	1470mm, (57.87in)
Depth	840mm, (33in)

*Dry weight, without disposable or fluids.

10.3 Device Clearances

There are no specific clearances required for equipment operation.

Personal and hazardous substances clearance envelope is 300mm(12in) from all sides when operating

10.4 Power requirements

	Requirements
Voltage	110-264VAC
Frequency	50-60Hz
Current	8A

Warning

It is highly recommendation to power the device from an outlet protected by a Ground Fault Circuit Interrupter (GFCI), Residual Current Detection (RCD), or similar Earth Leakage system.