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Magnetic Separation Platform (MSP)

Service and Maintenance Manual





Revision History

Issue	Date	Author	Description
A1	29SEP2020	ZNZC	Initial Release GMP
A2	04OCT2020	ZNZC	Clarification of weigh cell protocol
A3	20NOV2020	ZNZC	Added cleaning and control SW information

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1. REFERENCED DOCUMENTS

Doc #	Document Name	Document ID
1	MSP Critical spares list	DEBM_1186

2. SAFETY NOTICE

Read all product instructions and consult with Invetech trained personnel before operating the system. Do not perform any procedure before you have read and understand the instruction. Always follow the product labels and the recommendation for the manufacture. For more information contact Invetech.

All personnel working with and around the instrument must be aware of the hazards and safe operating procedures. The hazards of individual procedures are included in the warning and cautions of these instructions. Any staff not familiar with safe working procedures of the instrument should not operate it.

Follow the power requirements in the system specification. If you use the instrument in a manner not specified by Invetech, the protection provided by the instrument can be impaired and incorrect results or system failure can occur.

In addition to the general safety items in this manual, state and federal law of the country in which the instrument is operated also applies. Furthermore, the operating company responsible for the instrument may impose additional safety restrictions and procedures. It is the responsibility of the instrument 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 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 poor-quality outcomes.

1 Notice

Notice draws attention to notable information.

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2.2 Symbol Glossary Table

Symbol	Meaning
Λ	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
4	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 arts.
	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
	legal manufacturer of the product is.





2.3 Authorized Persons

\land 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.

Marning

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

\land Warning

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

2.4 Personal Protective Equipment (PPE)

\Lambda 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.





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



Figure 1 This caution label is included on the device

Marning

Unless prompted by the machine, an operator should not interact with hardware during an automated process.

\land Warning

Always operate the instrument with all shields and doors in position and secured to avoid injury.

Marning

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.

2.6 Mechanical Hazards

Marning

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

\land Warning

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





Marning

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

▲ Caution

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

Marning

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



Figure 2 Notification that pinch or crush hazards are present which could cause minor to serious injury are highlighted by labels on the device.





Take care when interacting with the MSP as the magnetic platen uses a strong magnetic field when in operation. Any users with implanted devices that may be affected are not advised to operate the machine.

Figure 3 Strong magnetic fields are highlighted by labels on the device.

2.7 Electrical

Marning

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.



Marning

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.

Marning

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



Figure 4 Hazardous voltage is highlighted by labels on the device.

2.8 Safety Against risk of Fire

This machine 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 device nor handle or store them with in the 30cm (1ft) area surrounding the device.

\Lambda Warning

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

2.9 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 platen 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.





Use the tools recommended by Invetech for troubleshooting and maintenance. Refer to maintenance, troubleshooting, and error recovery instructions for information about specific tools.



Do not use running fluid, pressure hose or powered spray tools when cleaning this device. Cleaning is only to be conducted by wiping and hand spray bottles.

Marning

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.



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.



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3. INTRODUCTION

3.1 **Purpose of this manual**

This Service and Maintenance Manual describes the Invetech Magnetic Separation Platform (MSP) and its required maintenance that must be conducted in order to keep the platform operated as designed. The manual is not all inclusive but includes the service requirement know to date. There may be elements that need additional service depending on usage. This manual is expected to be added to with service items in the future.

3.2 Intended use

The system is a selection and transduction instrument 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
MOP	Mechanical Overload Protection

 Table 1 Abbreviations used throughout this document

3.4 Scope of document

This document does not include specific instructions for the service of modules not developed by Invetech, such as the offboard tube welder or the barcode scanner. Please consult the relevant user instruction for these items.

4. EQUIPMENT DESCRIPTION

4.1 Overview

The MSP is a single platform for incubation, selection, separation and transduction of washed cells. It includes an integrated magnetic platen that performs the role of cell separation.

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 welds.

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:



Figure 5 - Key features of the MSP device



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 deenergized.

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 Disposable MSP Set

The Disposable set are single use only and not for reuse. They have no service or maintenance apart from appropriate storage before use and disposal after use.

4.4 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 doesn't allow operation whilst open. However, **caution** should be exercised due to the **pinch hazard**.

4.5 Pinch Valves

There are seven pinch valves located through the MSP to direct fluid flow. They are very simple to use and limited pinch force (spring to close).

4.6 Bubble detectors

There are nine bubble detectors integrated into the MSP signalling whether air or fluid is present in tubing 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 in the loaded tube.



4.7 Weigh modules

There are five weigh modules located on the platform. These weigh modules ensure accurate volume transfer between bags. 3kg capacity Weigh Modules are utilised.

4.8 Paddle mixers

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.

4.9 Magnetic Platen module

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 positively selected or cells unbound from beads can have the beads removed.

The platen can rotate to provide mixing and also pause at an angle to facilitate fluid loading or draining.

A lid is provided to limit the bag height ("pillowing") so that the magnetic field remains effective through the depth of the bag.

4.10 Secondary Magnet

A coil magnet is integrated with the platform to capture beads failed to be captured by the magnet on the rotating platen when transferring cultured cells to the output bag.

4.11 Operator Interface Panel – HMI

The main user interface on the MSP is the HMI. The elements of the HMI that are most relevant for service and maintenance are described below. For additional information and general instructions for loading a disposable kit and running a Method, refer to the MSP Instructions for Use.

4.11.1 Access levels

Certain features of the device can only be accessed by users with specific login permissions. As can be seen in the table below, a user with 'Maintenance' level authorization has the highest level of access to the device.

If access is attempted by a user that does not have the appropriate permissions the login window will appear. This is the prompt for a user with permission to login so the action can then be performed.

													Ve	et	'e	C	h
Groups		Normal Operation of Devices	Manual Device Operation	Equipment Maintenance	Configuration & Tuning Maintenance	Engineering Configuration	Acknowledge and Shelve Alarms	Supervisory Operations	Disable Alarms Bypass Permissives & Interlocks	Basic Navigation	Normal Production	Set-point and Parameter Override	Override/Force Sequences	Process Exception Handling, Adv. Production	Navigate Across Units/Applications	Shutdown Application, Windows OS Access	Admin: Security, Users, Passwords, System
LOCAL USER Group Names	DOMAIN USER Group Names	17	16	15	14	13	12	11	10	9	7	6	5	4	3	2	1
OPERATOR	P7300-16200- S1_MSP_OPER	х								Х	х	Х		Х			
SUPERVISOR	P7300-16200- S1_MSP_SUPERV	х	Х				Х	х	х	Х	х	х	Х	х	х		
ADMINISTRATOR	P7300-16200- S1_MSP_ADMIN									Х					Х	Х	Х
MAINTENANCE	P7300-16200- S1_MSP_MAINT	х	Х	Х	х	Х	Х	Х	х	Х	Х	Х	Х	Х	Х	Х	

Table 2 – Assigned authorisation for user groups (adapted from: DEBM_1213_B1_GMP SDS System Design)

4.11.2 Side Menu

The Side Menu appears when the button (three horizontal lines) in the top right corner of the primary HMI screen is selected.

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MAGNETIC SEPA	RATION			Invetech		16:30:	54	НОМЕ	*
System State	e	Curren Cell 1	nt Method Batch ID Selection			Operator 192.168.0.150/ms	p_maint		RUN>>
	SM-01	WE-02	WE-03	WE-04	WE-05		Bar	METHOD REPORTS	-
Phases			FZ-01	MEDIA		Z-02	Lot		
Unit	AIR	BUFF	BEAD	ULTURE	GELL			ALARMS	۸
Valves	T	Ţ	Ţ	Ţ	Ţ			UNIT VALUE PARAMETERS	۱۹۱
Safety	FV-01	FV-02	FV-03	FV-04	FV-05			P&ID DIAGRAM	ର୍ଶ୍ୱ ୪
								UNIT PROCEDURE	ੰ
	AE-01	AE-02	AE-03	AE-04	AE-05			ADMIN	
								FORMULA EDITOR	Ľ
	CULTURE		8			<u>O</u> P-01		SYSTEM SETTINGS	*
PS-01 PS-01 PS-02 PS-02		AE-06	FV-06			-		USER ACCOUNT MANAGEMENT	-10
UPS OK UPS OK	WASTE	0				<u> </u>		SIGN OUT	6
		AE-07	FV-07	Сошести	AE-0	09	-	SHUT DOWN	Ċ
				FZ-03					

Figure 6 Side Menu and the primary screen

This menu provides access to Method records, maintenance, administration, sign out and shutdown settings. These are detailed in the table below.

Button	Description
HOME	Returns to Home screen.
	If a Method is in 'set up' or 'running' the operator will be returned to the primary screen at the step the Method is currently at.
METHOD REPORTS	View PDF Batch Report (including Audit Trail)
ALARMS	View Alarm History
UNIT VALUE PARAMETERS	Contains parameters specific to the device/phase that do not vary from one Method to the next.
	Operators can view this page, however only those with Maintenance and Supervisor authorization can edit the values.
P&ID Diagram	Refer to section 4.11.3.
PHASES	For development purposes only.
	Can be accessed by users with Supervisor and Maintenance authorisation only.
	This allows access to run each phase of a Method individually.



UNIT PROCEDURE	For development purposes only.
	Can be accessed by users with Supervisor and Maintenance authorisation only.
FORMULA EDITOR	Can be accessed by users with Supervisor and Maintenance authorisation only.
	View, edit, and create formulas.
SYSTEM SETTINGS	View software version.
	Enable/Disable strobe lights.
	Enable/Disable custom fields input fields.
	Exit software to access operating system.
USER ACCOUNT MANAGEMENT	Manage user profiles.
SIGN OUT	Signs out the operator that is logged in.
SHUTDOWN	Shuts down the HMI. To do this, a user with authorised permissions needs to be logged in.
	▲ Caution
	For routine device shutdown: shut down the PC/HMI first, before removing power to the whole device.
	• Shutdown the HMI through the HMI screen.
	 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 the power on again. Failure to do so may damage the device and/or corrupt files such that the device will not operate.

Table 3 Side Menu descriptions

4.11.3 P&ID Diagram

Located within the Side Menu, the P&ID Diagram provides an overview of the main electromechanical components of the device. Figure 7 shows the P&ID as shown on the HMI and Table 4 provides a description of the component names and abreviations.



MAGNETIC SEP	ARATION			Invetech		16:23:57	14-Sep-2020	=
System Sta Idle	te	Curren Cell S	t Method Batch ID election		Operat	or	[LOGIN
Stack Lights Phases Unit Valves Safety PS-01 PS-01 PS-02 PS-02	SM-01	WE-02 WH-02 FV-02 AE-02	WE-03 FV-03 FV-03 FV-06	WE-04 VIGW 3NLTOC	WE-05 FZ-02 FV-05 AE-05	B Li D P-01	ar Code Scanner	HZS-01
UPS OK UPS OK	WASTE	AE-07	FV-07	COLLECTION FZ-03	AE-09	Q		

Figure 7 P&ID Diagram as seen on the HMI

When logged in, a user is able to perform the following actions through the P&ID:

- Toggle the strobes on and off.
- View the live status of each component (eg. pinch valve open).
- Reset the safety circuit.
- Access manual device operation for trouble shooting (Maintenance and Supervisor only).

To Put Components into Manual Mode for Troubleshooting

After logging in with Maintenance permissions:

- Press the component icon in the P&ID. The component control 'faceplate' will be shown.
- The component can be changed from 'Automatic' to 'Manual' mode by selecting the appropriate button.
- The grey banner above the buttons indicate which mode is active.

Returning the Components to Automatic Mode

▲ Caution

• Components must be set to AUTOMATIC for the component to operate as expected during a Method/other automated process.

▲ Caution

• The components will no longer work as intended in an automated process if they are left in Manual mode.





											٩	R	R	R			Ħ												μ	÷	
											ß	Ц	4	6	ч		А	U											h		
Į	ę	ę	ę	ų	ų		ę	ę		ņ	ņ	ę	ų	ę	ę	ę		ņ	ų		ę	ų	ų	ę	ę	ę	ę	ų			
																4															
															9																
		۸	u	г	п	O		и	А	п	1	С			8			Ν	л	А	n	ч	U	1	۱I						
															2																
	Ζ	×	×	2							×					7		×	x		×	x		×	×	×	×	2			

This **must** show as 'AUTOMATIC' on the component faceplate for the component to operate as expected during a Method/other automated process.

Figure 8 Component control mode: Automatic vs Manual

Instance	Description	P&ID Ref.
PU-01	JVL Stepper Motor Pump	P-01
PU-02	JVL Stepper Motor Pump	P-02
WE-01	Air bag Weigh Module	WE-01
WE-02	Buffer bag Weigh Module	WE-02
WE-03	Beads bag Weigh Module	WE-03
WE-04	Culture Media bag Weigh Module	WE-04
WE-05	Cells bag Weigh Module	WE-05
FV-01	Air bag Valve	FV-01
FV-02	Buffer bag Valve	FV-02
FV-03	Beads bag Valve	FV-03
FV-04	Culture Media bag Valve	FV-04
FV-05	Cells bag Valve	FV-05
FV-06	Culture bag Valve	FV-06
FV-07	Waste bag Valve	FV-07
AE-01	Air bag Bubble Detector	AE-01
AE-02	Buffer bag Bubble Detector	AE-02
AE-03	Beads bag Bubble Detector	AE-03
AE-04	Culture Media bag Bubble Detector	AE-04
AE-05	Cells bag Bubble Detector	AE-05
AE-06	Culture bag Bubble Detector	AE-06
AE-07	Waste bag Bubble Detector	AE-07
SR-Status	SafetyRelay Status	N.A.
HZS-01	Emergency Stop Push Button	HZS-01
GSS-01	Main Door Closed Safety Sensor	GSS-01
PS-01	Power Supply 1 Status	N.A.
PS-02	Power Supply 2 Status	N.A.
UPS-01	Uninterruptible Power Supply	UPS-01
ZX-01	Magnetic Linear Engagement Actuator	ZX-01
ZZ-01	Magnetic Platen Rotational Axis	ZZ-01



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Instance	Description	P&ID Ref.
FZ-01	Paddle Mixer 1	FZ-01
FZ-02	Paddle Mixer 2	FZ-02
FZ-03	Paddle Mixer 3	FZ-03
XY-01	Small Door Magnetic Lock	XY-01
StackLights	Light Tower (Bzr, Red, Yel, Grn, Blu)	Stack Lights
BCS-01	Barcode Scanner	N.A.

Table 4 P&ID component name abbreviation

5. CONTROL MODULE DEVICE CONFIGURATION

The control module configurations come factory set. In the event of Software updating or part replacement the configurations should be confirmed and may need to be updated.

5.1 Weigh Cell Calibration

▲ Caution

Calibration needs to be done with Mechanical Overload Protection (MOP) screws correctly set or adjusted so as not to interfere with the calibration. If MOP screws are adjusted outside of their operating range then care must be taken when calibrating to ensure weigh module is not overloaded and potentially damaged. See section 5.3

Weigh modules are to be calibrated annually or following equipment transport/change in installation position.

The calibration is a multi-point linear interpolation with functionality to extrapolate. Calibration points used are given in Table 6. ASTM E617 Class 5 minimum weights are recommended, or precision weight substitutes can be used if they are measured on a precision scale.

	Position #1	Weigh cell #2	Weigh cell #3	Weigh cell #4	Weigh cell #5
Capacity	N/A	3kg	3kg	3kg	3kg

Table 5 – Calibration Weights

Scale Point	Calibration weight		
0	0g, no hardware installed		
1	approx. 50g (weight of bag + 50g test weight)		
2	approx. 250g (weight of bag + 200g test weight)		
3	approx. 1000g (weight of bag + 1000g test weight)		

Table 6 – Calibration Weights



- 5.1.1 Weigh modules calibration procedure
 - 1. Source required equipment:
 - a. Bag hanger (included in "MSP platform")
 - b. 50g calibrated test weight (any calibrated weight between 0-100g may be used if a 200g calibrated weight is unavailable)
 - c. 200g calibrated test weight (any calibrated weight between 100-250g may be used if a 200g calibrated weight is unavailable)
 - d. 1000g calibrated test weight (any calibrated weight between 800-1250g may be used if a 1000g calibrated weight is unavailable)
 - e. Cradle to hold calibration weights (an empty bag with an opening is a suitable replacement for a cradle this procedure assumes a bag will be used)



Figure 9 Weigh cell calibration setup

- 2. Wear nitrile or latex gloves to handle test weights as they can be affected by oils present on skin.
- 3. Open the faceplate for the Weigh module #2.
- 4. Ensure "Number of scale points" is 3, adjust to 3 if not.
- 5. Remove the paddles from the paddle mixers, if necessary to fit the bag and test weights, by simply lifting the paddle up, so the black clips release from the mixer arms.
- 6. Enter the displayed value from "IO_Value" in the "Scale In Points 0" field. Ensure "Scale Out Points 0" = 0.0.
- 7. Weigh the hanger and an empty bag on a calibrated scale and note down "hanger + bag" weight.
- 8. Load the hanger + bag (empty) onto the weigh module.



- 9. Enter the displayed value of "IO_Value" in the "Scale In Points 0" field and enter the weight (recorded in step 7) of "Hanger + bag" in the "Scale Out Points 0" field.
- 10. Load the 50g test weight into the bag. Enter the displayed value of "IO_Value" in the "Scale In Points 2" field, and enter the total weight of the hanger + bag + test weight in the "Scale Out Points 1" field.
- 11. If necessary, adjust the "Scale In Points 1" value up/down (+/-10 ~ 0.1g) until the indicated weight matches "Scale Out Points 1".
- 12. Load the 200g test weight into the bag. Enter the displayed value of "IO_Value" in the "Scale In Points 2" field, and enter the total weight of the hanger + bag + test weight in the "Scale Out Points 2" field.
- 13. If necessary, adjust the "Scale In Points 2" value up/down (+/-10 ~ 0.1g) until the indicated weight matches "Scale Out Points 2".
- 14. Load the 1000g test weight into the bag. Enter the displayed value of "IO_Value" in the "Scale In Points 3" field, and enter the total weight of the hanger + bag + test weight in the "Scale Out Points 3" field.
- 15. If necessary, adjust the "Scale In Points 3" value up/down (+/-10 ~ 0.1g) until the indicated weight matches "Scale Out Points 3".
- 16. Remove test weight and if necessary, adjust the "Scale In Points 1" value up/down $(+/-10 \sim 0.1g)$ until the indicated weight matches "Scale Out Points 1".
- 17. Remove the bag and if necessary, adjust the "Scale In Points 0" up/down (+/-10 ~ 0.1g) until the indicated weight matches "Scale Out Points 0".
- 18. Confirm calibration by using Weigh Module Check procedure 5.2.1.
- 19. Repeat for all weigh modules
- 20. Refit paddle mixer paddles, and bag hangers.

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WE-01					WE	GH CELL					
RESET SIM ON SIM Status Gross Weight Tared Weight Volume IO_Value I RAG TARE VC Simulated Gross Simulated Weight Simulated Volume	OFF 18.6 g 0.0 g 0.0 mL 1093 LUME TARE 18.6 g 0.0 g 0.0 mL	Status Owner O Ma O Qu Au O Ao O Int	r ID anual Inhibit Jality Bad ailable quired terlock OK Device Statu Weight Hi Hi Volume Hi Hi Density Stable Volume Flov	IS ENABLE I O I O 1 • v 59	UMIT ALA 0 (0 0 (0 .0	wm D mL/Min	Device Cor Weight Hi H Volume Hi H Weight Hi H Volume Hi H	nfig Hi [Hi Delay] Hi Delay]	1000.0 g 1000.0 m 0.0 s		
Number of scale points Scale in Points	2 0 9350	1 11050	2 30050	3	4	5	6	7	8	9	10
Scale Out Points	0.00	18.00	237.92	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

Figure 10 Weigh cell face plate showing Scale In and Scale Out points

5.2 Weigh Module Check

Check points used are specified in Table 11. ASTM E617 Class 5 minimum weights are recommended, or precision weight substitutes can be used if they are measured on a precision scale.

Check Point	Calibration weight
0	0g, Tare with hardware and bag installed
1	+100g
2	+200g
3	+1000g

Table 11 Calibration check weights

5.2.1 Weigh modules check procedure

1. Wear nitrile or latex gloves to handle test weights as they can be affected by oils present on skin.



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- 2. Open the faceplate for the weigh module.
- 3. Load the Bobbin + bag (empty) onto the weigh module.
- 4. Press 'Bag Tare' button on HMI. Displayed mass should now display 0g.
- 5. Load the 100g test weight into the bag. Confirm that the displayed value is within the stipulated tolerance of 0.5% of the 100g test weight.
- 6. Confirm dynamic error (fluctuation in reading) is <0.2g
- 7. Remove the weight. Confirm that the displayed weight has returned to zero.
- 8. Repeat Step 5 7 for remaining test weights.

Invetech recommends documenting calibration results in a table as follows:

CALIBRATION	Point 0 (g)	Point 1 (g)	Point 2 (g)
Scale In Points	54.54		
Scale Out Points			
		50 I	150V
	CALIBRATION	I CHECK	
Applied mass (g)			
HMI indicated mass (g)			
Error (%)			2
Dynamic Error (± g)			

 Table 12 - Recommended calibration documentation table

5.3 Mechanical Overload Protection

To avoid loading beyond the safe load limit, the Invetech designed Weigh Module incorporates adjustable mechanical overload protection screws (MOP). Following are instructions for checking or making adjustment to the mechanical overload protection screws to prevent overloading and ensure correct weighing operation. When a device is received with a weigh cell incorporated then the MOP has been factory set and will not need adjustment. If a replacement Weigh Cell is received these MOP will be in a shipping configuration and after installation on the device they will need setting as per 5.3.1.

Below is a section image through an Invetech weigh module with MOP screws positions / designations outlined.



Figure 13 Invetech weigh module showing MOP screw positions

The load cell is mounted to the *load cell mounting bracket* which cantilevers forward and has 2 x set screws protruding from its cantilevered end which provide overload protection for the load cell in both upward and downward directions.

When loaded upwards, the upward direction MOP screw acts on the bottom inner surface of the *nose* component to restrict upward travel of the load cell beyond the stop screw position. When loaded downwards, the downward direction MOP screw acts on the underside surface of the load cell to restrict downward travel of the load cell beyond the stop screw position.

Typical deflection at rated capacity of the MT1022 load cells used is 0.3mm (0.012"). The MOP setting to achieve the 80% of rated load is a deflection of approximately 0.24mm (0.009").

The nylon locking patch assists the MOP set screws to stay in the set position.

IMPORTANT NOTE: Load cells can easily be damaged by incorrect adjustment of the MOP screws. Incorrect adjustment of the MOP can overload the load cell or reduce the working range.



IMPORTANT NOTE: The MOP features are not infallible and extreme overloads to the weigh module will damage the unit.

Locking	Patch-
---------	--------

	Weight	Unit
Load cell – rated capacity (RC)	3	kg
Load cell – safe load limit	4.5	kg
Alarm level (approx. 70% of RC)	2.2	kg
Upward MOP setting load (approx. 50% of RC)	0.0	kg
Downward MOP setting load (approx. 80% of RC)	2.5	kg

Table 14 Invetech weigh module specs and set points



5.3.1 MOP Adjustment procedure

IMPORTANT NOTE: MOP setting needs to be done after calibration is complete. If done with no calibration in place MOP screw settings will be incorrect and there is a high risk of damage to the unit.

- The Weigh Module output display is located on the Weigh Module faceplate accessed via the P&ID screen.
- Slide bellows backwards to reveal MOP screw adjustment access holes on the underside of the Nose.





Figure 15 Weigh Module MOP adjustment diagram

- 5.3.1.1 Upward direction MOP adjustment
 - a. Remove any hanging hardware from the Weigh Module
 - As bags hung on the Weigh Module only impart loads downward, the recommended setting for the upward direction MOP set screw is zero (as per Table 14).
 - c. Adjust front MOP set screw (3/32" hex key) until it just touches the nose and the displays indicates a small negative reading.
 - d. Back off the MOP set screw by less than 1/8 of a turn, or until the display just changes from showing a negative reading to 0g.
- 5.3.1.2 Downward direction MOP adjustment
 - a. Load the Bobbin + bag (empty) onto the weigh module, tare the weigh module
 - b. Carefully apply weights to achieve load recommended in Table 14.
 - c. Adjust rear MOP (3/32" hex key) until it just touches the nose and the display decreases by a small amount.



- d. Back off the MOP set screw by less an 1/8 of a turn, or until the display just changes from showing a reduced reading to the correct reading.
- e. Reinstall bellows.

5.3.2 MOP Checking procedure

The downward MOP should be checked annually to ensure that it is still providing overload protection and not set below the overload alarm threshold.

- a. Leave bellows in place.
- b. Open Weigh Module faceplate (accessed via P&ID screen).
- c. Load the Bobbin + bag (empty) onto the weigh module, tare the weigh module.
- d. Carefully re-apply recommended Downward MOP Setting Load as outlined in Table 14 above.
- e. If weigh module outputs a value less than applied load then the MOP requires adjustment.
- f. Apply a light touch to the Weigh Module to determine if at limit. If value deviates from the desired setting by >0.1kg, the MOP requires adjustment.

5.4 Bubble detector On and Off delay times

The Bubble detector has delays that can be set to allow time once air is detected in the line and the alarm is triggered. These delays are also used so a small bubble that would not affect the method will not result in the sensor cancelling the method. There are four delays 'On', 'Off', 'Warning' and 'Fault'. These are accessible for the P&ID. The on delay time will be longer for the bubble detector with tubing going to the cell collection bag to allow a section with air to be in the tube where RF welding will be conducted.

5.5 Pump scaling factor

The pump scaling factor is set in the pump screen from the P&ID, icon P-01 and P-02. The factor is in ml/rev (millilitres per revolution of the peristaltic pump motor). These scaling factors are initial default numbers but are adjusted by the software after initial readings are taken with each disposable tubeset loaded.

5.6 Magnet Z-axis engaged/disengaged positions

The Magnet Z-axis engaged position is set in the Linear axis screen from the P&ID, Icon ZX-01. The engaged value is nominally 0.3mm from the bottom of the magnetic platen plate. The disengaged value is 10mm below the home position flag. The engaged position value is found within the configuration management document for each unit.



5.7 Magnetic platen rotational Home offset

The Magnetic platen rotational home offset is set in the rotational axis screen from the P&ID, Icon ZZ-01. The offset allows you to adjust the angle of the platen by offsetting the position of the "home" flag bay a set amount of degrees. The Offset value is found within the configuration management document for each unit.

6. PROGRAMMED MAINTENANCE PROCEDURES

The following maintenance procedures and frequency are recommended by Invetech to ensure optimal MSP performance. If issues are found please consult with Invetech for for more information .

Step #	Requirement	Recommended frequency
0	Hardware inspection – degradation	Monthly
6.2	Hardware inspection – loose equipment	Monthly
6.3	Hardware inspection – functionality	Annually
6.4	Safety circuit inspection	Monthly
6.5	Pump cleaning	3 Monthly
5.2.1	Weigh module calibration check	3 Monthly
5.3.2	Weigh module MOP check	3 Monthly
5.1.1	Weigh module calibration	Annually
5.3.2	Weigh module MOP adjustment	Annually
10.1	Archive audit trail	As per site data retention policy

Table 16 Planned maintenance activities

6.1 Hardware inspection – degradation

- 1. Visually inspect MSP surfaces for any corrosion or degradation due to chemical or environmental influences. Inspect glass door and platen lid.
- 2. Visually inspect gaskets and silicone sealant for signs of splits or other degradation.
- 3. Visually inspect all external cables for abrasion or damage, inspect entire length, especially near connector.

6.2 Hardware inspection – loose equipment

1. Ensure all equipment peripherals securely fastened and oriented correctly.



- 2. Pay attention to bag hanging hardware, gently manipulate all bag hangers on the bag arm only (not weigh module), if they move, align to vertical and tighten.
- 3. Inspect the door to the Platen and Platen lid, confirm smooth open and close by hand. Pay attention to hinges if lose, adjust accordingly.

6.3 Hardware inspection – functionality

- 1. Navigate to P&ID screen and manually run each electromechanical device in turn.
- 2. Components must operate smoothly, listen for abnormal sounds that may indicate a module requires replacement or servicing.
- 3. Open & close each pinch valve.
- 4. Run each pump, P-01 & P-02, in both forward and reverse directions.
- 5. Install a tube into each of the bubble sensors so air and liquid can be moved though the tube passed the sensor and confirm output from the sensor in the P&ID screen for AE-01, 02, 03, 04, 05, 06, 07 & 09.
- 4. Run the Platen and asses for smooth operating function through full range of motion. Platen lid should be operated by hand and the locking function confirmed.
- 5. Run each paddle mixer using mix, open and close positions. Check for smooth operating and breakaway mechanisms are working correctly.

6.4 Safety circuit inspection

- 1. Inspect guard switches to confirm that none have been remounted to bypass safety system. The detector must be in place on the chassis. The latch and indicator elements must still be attached to the door.
- 2. Ensure platen door is closed and pump levers are closed, then navigate to platen faceplate via P&ID screen and reset safety circuit.
- 3. Unlatch platen door and confirm safety circuit trips.
- 4. Repeat step 2. Navigate to pump faceplate via P&ID screen, run pumps.
- 5. Open pump guard lever, pumps should stop and confirm safety circuit trips.

6.5 Platen seal cleaning

1. Without exerting force on the platen wipe behind the platen where the axel comes out from back wall.

6.6 Pump cleaning

1. Remove pump head by undoing the two thumb screws.

Be cautious pump guard cable which could be damaged if excessive force is applied. NOTE: Only applicable to devices with hardwired open head pump sensors

2. Wipe down pump head and motor coupling with 70% IPA.



- 3. Visually inspect that pump head and coupling are in good condition.
- 4. Reinstall pump head and tighten thumb screws. The tab from the back of the pump head must align with the slot in the pump drive motor.
- 5. Repeat for second pump.
- 6. To confirm pumps are correctly re-installed.
- 7. Navigate to pump faceplate via P&ID screen, run pumps.
- 8. Open pump guard lever, pumps should stop and an alarm raised

7. REINSTATING SYSTEM AFFER SERVICE AND MAINTINANCE

Before the device is considered finished with service and used again by the operators the self-check should be run. If an error occurs during self-check, a prompt will appear on the Operator Interface Panel that will notify the operator of the error.

- 1. Read the on-screen prompt and check the device for the cause of the error.
- 2. Once the error is resolved, select "Retry" on the Operator Interface Panel.

8. CLEANING

This section provides cleaning instructions for the device, as included in the MSP Instructions for Use. General directions are provided in 8.1, with acceptable cleaning agents and specific cleaning instructions for sensitive components addressed in subsequent sections (0 and 8.3).

8.1 General cleaning directions

Unless otherwise stated in 8.3 or anywhere else in this document, the general cleaning directions for the device are:

- Cleaning agents should only be applied to the device by wiping, or hand spray bottle.
- If using a hand spray bottle, apply the cleaning agent lightly and evenly. The agent must not run in large droplets down the device.
- Avoid pooling of cleaning chemicals on the device.
- Use of strong chemicals should be followed by application of IPA (unless a specific sensitivity to IPA is stated in 8.3) to remove the residual chemical.
- Wipe down the chassis in the direction of the brush grain (vertical).
- Inspect sealing of components when cleaning, do not spray if there is evidence of degradation. If there is evidence of peeling or degradation the sealant may need servicing.
- See section 8.2 for additional items to inspect while cleaning/on a routine basis.

▲ Caution

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

▲ Warning

Cleaning is only to be conducted by wiping and hand spray bottles. Do not use running fluid, pressure hose or powered spray tools when cleaning this device.

8.2 Acceptable cleaning agents

Unless otherwise stated in 8.3, the following are acceptable cleaning agents for the MSP device.

Active agent	Cleaning agent	Usage concentration
Isopropyl Alcohol	IPA	70%
Sodium Hypochlorite	Bleach	0.8% x 8.25% = 0.07% NaClO
		1% x 5% = 0.05% acetic acid
Alkaline / Phenolic	Steris	1:125 dilution
	Vesphene IIse	
Phosphoric Acid	Steris	1:250 dilution
	LpH se	
Hydrogen Peroxide	Steris	RTU
	Spor-Klenz	1% H ₂ O ₂
		0.08% C ₂ H ₄ O ₃
Quarternary	Steris	NH ₄ 21.3%
Ammonium	NPDst	1:256 dilution
		~ 0.08%
	Steris	NH ₄ 12 – 23%
	Vesta Syde	1:128 dilution
		~ 0.09 - 0.18%

Table 7 Acceptable cleaning agents

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8.3 Specific Cleaning Instructions

The following table calls out components that require special consideration during cleaning.

Relevant Parts	Sensitivity	Specific cleaning instruction
General exterior surfaces	Bleach	Wipe down exterior surfaces after
		exposure to bleach. Prolonged
		application of bleach can cause
		deterioration, corrosion or staining.
HMI	Bleach	Bleach solutions must not be applied
		to any part of the HMI.
Power Disconnect Receptacle	Bleach	Applications of IPA and bleach
Socket	IPA	should be limited as much as
		practicable as some degradation
		may occur with prolonged exposure.
		As this component is a mains power
		connection - avoid spraying the
		component and avoid allowing fluid
		to pool.
Barcode scanner and dock	Refer to	Refer to barcode scanner
	manufacturer's	manufacturer's instructions.
	instructions	
Weigh Cell	Force	When wiping down the weigh
		module, use a light touch as the load
		cell may be damaged with excessive
		force or impact.

Table 8 Specific cleaning instructions

8.4 Cleaning after a leak or spill

If a spill or leak occurs, use absorbent disposable wipes to remove bulk fluid then clean the device according to the instructions above, with consideration for the type of fluid which has spilt.

8.5 Removable parts for cleaning

8.5.1 Pump head

The Peristaltic pump heads are removed for cleaning by unscrewing two thumb screws.

Notice

When reassembling pump head on to valve plate tighten the screws by hand and **do not** use a tool. Failure to follow this could damage threads. The slot for a flat blade screwdriver is for loosening screws only.

Notice



Be cautious pump guard cable which could be damaged if excessive force is applied. NOTE: Only applicable to devices with hardwired open head pump sensors.

9. SERVICE

9.1 Critical spare parts

Refer to reference document DEBM_1186 for list of critical spare parts.

9.2 Service access

Access to device internals should not be regularly required. If access is required for service or inspection Back Panel must be unlocked and opened.

🔔 Warning

Before opening the Back Panel ensure mains power is isolated.

Unlock back panel with included safety Key and open doors as required.

Locking of the Back Panel is the reverse process of the removal steps shown above.

10. CONTROL SOFTWARE MAINTENANCE

10.1 Audit trail storage

Notice

The MSP device has limited on-board storage capacity. Audit Trail CSV files may be overwritten when storage capacity is exceeded.

The device is not rated for long term storage. Device owners must determine the acceptable risk level for how long the files can remain on the device. If long-term data back up and storage is required, the data must be copied from the device and archived elsewhere.

Copying the files can be achieved by connecting a laptop to external ethernet port. The Report PDF files are located on the device hard drive, D:\MSP.

10.1.1 Device setup for file sharing

First the device needs to be setup to perform file sharing. To do this:

- 1. Login as an Administrator, go to system settings then shutdown runtime. This will drop back into Windows environment, having shutdown the HMI software
- 2. With windows explorer, navigate to the following folder > D:\MSP
- 3. Long press to right click on the folder
- 4. Select Properties





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- 5. In the Properties Window, Click on the Sharing Tab
- 6. Click on Share



7. Choose Administrator, then click on Share

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8. Ensure this window is presented and noted circled address.





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10.1.2 Connecting to the device - via laptop

To connect to the device with a laptop:

- 1. On your laptop,
- 2. Configure to static IP 192.168.0.21 (or something that matches the Subnet)
- 3. Connect an ethernet cable to the Platform's external ethernet port to your laptop



Figure 10 External network port

- 4. In windows explorer, type in address to network location
 - a. (example: \\CP-4EF936\Archive)
 - b. Or <ip address>\Archive
- 5. User following default windows credentials
 - a. Username: Administrator
 - b. Password: 1
- 6. Copy relevant logs.



10.2 Anti-virus software

The system does not come with anti-virus software installed. This is 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 is to 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)