

ASSURANCE® GDS PPMX USER MANUAL



Table of Contents

I.	Safety
	Voltage
	Safety Interlock
	Pipette Heads
	Tip Waste Container
	Tray
	Liquids
	Replacement Parts
II.	Introduction 6
	Standard Equipment
	Documentation
	Protocol Types
	Disposables
	Technical Specifications
III.	Setup/Operation9
	Unpacking
	Removable Tray
	Rear Panel Connections
	Front Panel Connections
	UPS Battery Power and Line Conditioner
	Power On and Start Up
	Log In
	Change PPMX Serial Number in Software
	User Management
	Touchscreen Overview
	Alignment Protocol
	Add Pipette and PickPen™ Head(s)
	Set Date & Time
	Install Chime Sound Box
	Run a Protocol

		Step-by-step Wizard
		Pause or Stop a Running Protocol
		View Results
		Run Report
		Log Out
		Shut Down
		LIMS Compatibility
		Import Protocol
		Export Protocol
		Delete Protocol
IV.	. 1	Troubleshooting23
		Communication Loss
		Re-starting a Protocol after Communication Loss
		Hood Open
		Reporting an Error
		Technical Services
	V.	Maintenance
		Routine Cleaning
		Decontamination
		Pipette Head Calibration
		Alignment Calibration
		Preventative Maintenance
		Warranty
		Instrument Return Procedure
	VI.	Appendix A28
		Parts List
	VII.	Appendix B
		Before You Call Us
	VIII	. Appendix C31
		Maintenance Log
	IX.	Appendix D32
		Warranty Terms
	X.	Appendix E
		Pipette Verification
		Deck Layout for Pipette Calibration Verification

XI.	Appendix F	5
	Best Practices	
XII.	Appendix G	7
	Pack Up	
XIII.	Appendix H4	L
	Ordering Information	

Safety

Read this section before installing and operating the Assurance® GDS PickPen™ PIPETMAX® (PPMX).

This instrument is intended to be used in a laboratory environment by trained technical personnel.

For safe and proper use of this instrument, it is required that both operating and service personnel follow the instructions contained in this guide when installing, operating, cleaning, and maintaining the instrument.

The following safety precautions must be observed during all phases of operation, service, and repair of the instrument. Failure to comply with these precautions or with specific warnings elsewhere in this user's guide violates safety standards of design, manufacture, and intended use of the instrument. BioControl Systems assumes no liability for the customer's failure to comply with these requirements.

The PPMX has been certified to safety standards required in Canada, Europe, and the United States. Refer to the instrument rear panel label and the Declaration of Conformity document for the current standards to which the instrument has been found compliant.

The following electronic and hazard symbols may appear on the instrument:

Symbol	Explanation
===	Direct current
I	Electrical power ON
0	Electrical power OFF
<u>^</u>	Caution
	Mechanical hazard

The following safety notices may appear in this document:

∆WARNING	WARNING indicates a potentially hazardous situation which, if not avoided, may result in serious injury
∆CAUTION	CAUTION indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury
NOTICE	NOTICE indicates a potentially hazardous situation which, if not avoided, may result in equipment damage

Voltage

Access to the rear panel is necessary because the instrument must be detached from all voltage sources before service, repair, or exchange of parts.

Operate the instrument using the approved power supply provided and only at the voltage specified on the rear panel label of the instrument.

Safety Interlock

The PPMX is configured with a safety interlock, which is used when the rotating cover is installed on the instrument.

The safety interlock prevents the instrument from operating when the rotating cover is open.

Pipette Heads

The instrument is capable of generating significant forces that could cause potential injury to the user. For an instrument with the rotating cover installed, the safety interlock in the cover will disable the instrument movement if the cover on the instrument is open. For an instrument installed in a hood, the external safety interlock sensor mounted on the instrument will disable the instrument movement if the hood door is open.

Tip Waste Container

The tip waste container should be emptied in accordance with national and local safety regulations.

Tray

The moving tray is capable of causing injury by pinching. For an instrument with the rotating cover installed, the safety interlock in the cover will disable the instrument movement if the cover on the instrument is open.

Liquids

Observe safe laboratory practices when handling liquids. If working with biological samples or chemical substances, ensure that there is proper ventilation, and wear personal protective equipment (PPE), such as safety glasses, gloves, and protective clothing at all times.

Refer to the Safety Data Sheets for solvents before use.

Replacement Parts

Be sure to use only replacement parts specified in this user manual. Do not repair or change parts which are not listed in this user manual. If it is necessary to change parts not listed, please contact BioControl Systems technical services.

Introduction

The Assurance GDS PickPen™ PIPETMAX® (PPMX) is an automated magnetic particles and liquid handler. It is capable of dispensing Assurance GDS reagents which include, Concentration Reagent, Wash Solution, Resuspension Buffer and select media (BHI/DFB). Reagent dispense protocols have been created for all Assurance GDS assays. In addition, the PPMX has also been programmed to automate Assurance® GDS PickPen™ Immunomagnetic Separation (IMS) procedures. This user manual is intended to assist PPMX users with system start-up, basic operation, maintenance and service.



Standard Equipment

After the PPMX and accessories are unpacked, the following items should be present:

- PPMX Instrument with rotating cover
- Alignment Head
- Removable Tray 96 well
- Pipette Tip Reload Rack
- PickPen[™] Tip Reload Rack
- Tip Disposal Bin
- Power Supply (110V/220V)
- Power/USB Cabling kit
- Power Cords (US and EU only)
- USB Cable
- Back Plug, Black
- Allen Wrench, 5 mm
- MAX8x200 Pipette Head
- Assurance® GDS PickPen™ Magnetic Head
- Assurance® GDS Reagent Holder
- Tip Mover with Tip Box Holder
- Concentration Reagent Bottle Fill Level Sleeve
- Chime Sound Box with hardware
- Gel Cooling Block (2/cs)

Sold separately:

• Microsoft Surface laptop with software pre-loaded + US charger and Keyboard cover/pen For part numbers, refer to Appendix A, Parts List. For ordering information, refer to Appendix H, Ordering Information.

Documentation

The following documents are included with the PPMX:

- PPMX User Manual (Part no. 55240)
- Gilson Quick Setup Guide
- Gilson Installation and Operational Qualification (IQ/OQ) Procedures
- Gilson Declaration of Conformity
- Gilson Validation Certificate for TRILUTION® micro
- · Gilson Quality Control Report Pipette Head

Protocol Types

- Alignment Protocol
- Assurance® GDS Reagent Dispense protocols (R-)
- Assurance® GDS PickPen™ IMS protocols (IMS-)
- Assurance® GDS Combined Reagent and IMS protocols (C-)

Disposables

The items below are sold separately but are required for use:

- 200 µL Diamond Sterile Blister Filter Tip Packs
- Reagent Reservoirs
- Assurance® GDS PickPen™ Tips
- Adhesive Film Sheets & Strips
- Assurance® GDS Sample Wells & Bases
- Resuspension Plates

For part numbers, refer to <u>Appendix A, Parts List</u>. For ordering information, refer to <u>Appendix H, Ordering Information</u>.

Technical Specifications

Please be aware of the following before operating the PPMX.



Changes or modifications to this device not expressly approved by BioControl Systems could void

the warranty.

The instrument complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This instrument may not cause harmful interference, and (2) this instrument must accept any interference received, including interference that may cause undesired operation.

Shielded cables must be used with the instrument to ensure compliance with the FCC Class A limits.

Technical Specification	Definition
Communications	USB
0	Through IICD has to graph and an a IICD decise mant
Connections	Three USB host ports and one USB device port Two inputs (contact closure, TTL), two relay outputs, and one switched +12V DC 1A output NOTICE: Switching voltages higher than 30V or greater than 1A of current may damage the instrument.
Dimensions & Weight	W 54.4 X D 65.5 X H 53.1 cm (21.4 X 25.8 X 20.9 in), 24.9 kg (55 lbs.)
Environmental Conditions	Indoor use Altitude: up to 2000 m Temperature range: 5 °C – 40 °C Humidity: Maximum relative humidity 80% for temperatures up to 31 °C, decreasing linearity to 50% relative humidity at 40 °C
Power Requirements	External Power Supply Voltage I nput Frequency: 50 to 60 Hz Voltage: 100 – 240V AC Voltage Output Voltage: 24V DC Current Rating: 6.25A, 150W
Front Panel & Control	Two USB host ports and STOP button, Touchscreen tablet or laptop
XYZ Motion (Speed)	1-500 mm/sec in X dimension 1-550 mm/sec (350mm/sec default) in Y dimension (tray) 1-140 m/sec in Z dimension
IMS Head	PickPen™ magnetic head
IMS Tips	PickPen™ tip covers
Liquid Contact Materials	Tips – 100% Virgin Polypropylene Tip Disposal Bin – Polypropylene with colorant (Pro-fax 6523)
Liquid Handling Head & Tips	MAX8x200, DIAMOND filter tips (DF200)
Removable Tray Capacity	9-position
Safety & Compliance	Certified to safety standards specified for Canada, Europe and the United States. Refer to the instrument rear panel label and the Declaration of Conformity document for the current standards to which the instrument has been found compliant.

Setup/Operation

The Assurance® GDS PPMX and its components should be set up in the order described in this section. Gilson TRILUTION® micro provides software control of the PPMX during setup and operation as described in this section. For more information about TRILUTION® micro, view the help information in the software, accessible from the button.

Unpacking

The PPMX is delivered with most major components already assembled. **Please keep the original packaging** (both internal boxes and the external crate) in case the PPMX needs to be returned to BioControl Systems for repair.



It is recommended that two people lift the PPMX out of the box, as it weighs approximately 55 lbs. (24.9 kg).

- Open the crate by unscrewing the 4 bolts at the bottom of the crate (located just above the pallet).
 Use a 9/16" wrench if needed. Lift straight up using handles on both sides.
- 2 Remove the two grey foam pieces.
- 3 Remove the closed and open-ended cardboard accessories boxes by sliding them out from the bungee cords. Be careful not to drop the boxes while disassembling the cords.
- 4 Remove the plastic bag covering the PPMX.
- Grip the PPMX at the recesses near the base. There is one recess in the front, one in the back, and one on each side. Use these recesses when lifting the PPMX out of the foam-lined tray.



Do not attempt to lift the PPMX from the cover or

from the X-arm (the horizontal arm). Always lift the instrument from its base.

- 6 Place the PPMX on a stable, level surface such as a lab bench, lab cart. Refer to Section 1: Safety.
- 7 Remove the blue film or lab tape securing the rotating cover.
- Remove the shipping brace from the rear of the instrument. Loosen thumb screws securing the shipping brace to the PPMX. After removing the shipping brace, replace and tighten the thumb screws the back of the instrument.





9 Remove the shipping bracket that attaches the arm to the inside of the unit using the allen wrench (5 mm) provided.

Note: Some older units have 2 clear tubing pieces that are wrapped around the lead screw instead, these should be removed and saved.

- 10 Remove the white foam block preventing the tray from moving.
- Place all packaging materials inside the crate for longterm storage. DO NOT TROW AWAY the interior cardboard boxes as these are custom made for the PPMX.

NOTICE

Keep the shipping brace, shipping bracket, allen wrench and foam block with the packaging.

Removable Tray

A removable tray for placement of labware and tip racks is required. While holding the handles on the sides of the tray, lower the tray onto the metal carrier. It is keyed and will only mount one way. Observe that the tray is level and fully seated on the metal carrier.

Rear Panel Connections

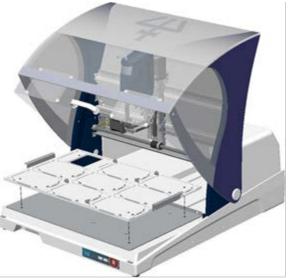
Refer to the diagrams on the next page when making the connections described in this section.

The input/output contacts on the rear panel are used for communication between the alignment head and TRILUTION® micro and for communication between the external safety interlock sensor and TRILUTION® micro. The contacts can also be used to control peripheral devices. Refer to the diagram for the location of the input/output ports.

Contact Inputs – The bottom terminal block on the PPMX has two paired input contacts that are labeled 4 and 5. Never connect voltages higher than 5V DC to an input. When using TTL signals, be sure to match GROUND connections.

Contact Outputs – The bottom terminal block on the PPMX has two paired, isolated-relay contact closures that are labeled 1 and 2.



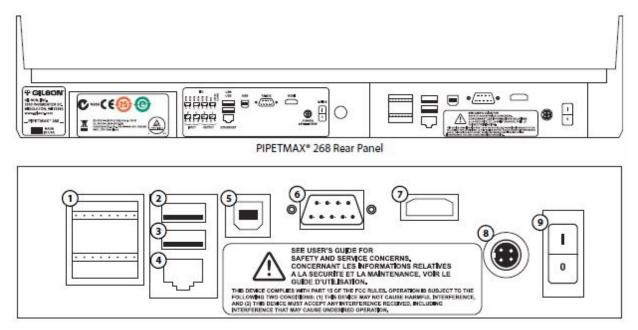


DC Power Output – The top terminal block has one +12V DC output, which is labeled.

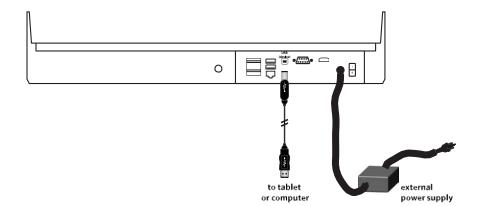
The PPMX has one functional USB host port (the middle port) on the rear panel. The top port on the rear panel is not supported. The USB ports can be used to connect USB drives (which can also be seen by the laptop when plugged into the PPMX), keyboard, mouse, or any other compatible device (heater/chiller, barcode scanner, or shaker, for example).

The USB device port is used for communication between the PPMX and the laptop. A USB cable is provided as a standard accessory. Refer to the diagram for the location of the USB device port.

The Ethernet Port, RS-232 and HDMI are not supported.



- 1 Input/Output (Green)
- 2 USB host (Not Supported)
- 3 USB host
- 4 Ethernet (Not Supported)
- 5 USB device
- 6 RS-232 (Not Supported)
- 7 HDMI (Not Supported)
- 8 Power receptacle
- 9 Power switch (MAINS)



Use the power cord on the external power supply to make the connection between the power receptacle on the PPMX and the external power supply. The connection from the external power supply to the PPMX uses a connector with a locking collar. Check the alignment of the pins and then push it in until it clicks and locks in place. To disconnect, pull back on the locking collar and then disconnect the cable from the rear panel of the PPMX. Locate the appropriate power cord for your line voltage and then make the connection between the external power supply and the AC power source. Install the Power/USB Cabling kit by following the supplied instructions.

Front Panel Connections

The PPMX has two functional USB host ports on the front panel. The USB ports can be used to connect USB drives (which can also be seen by the tablet/laptop when plugged into the PPMX), keyboard, mouse, or any other compatible device (heater/chiller, barcode scanner or shaker, for example).

In a situation where an emergency stop is required, pressing the STOP button stops the PPMX immediately. The protocol stops and results are displayed (after touching OK on the prompt).

- 1 USB host
- 2 STOP

UPS Battery Power and Line Conditioner

To prevent fluctuations in power to the PPMX and tablet/laptop, it is recommended that the following UPS battery backup be used with the system:

Tripp Lite SU750XL or equivalent



Power On and Start Up

To start the PPMX:

- 1 Make sure that the PPMX is connected to the external power supply and that the external power supply is connected to a power source.
- 2 On some models turn power on at the external power supply (O is off, I is on).
- 3 Turn the PPMX power on using the MAINS power switch located on the rear panel. The indicator light on the front panel will illuminate green.
- 4 Connect the laptop to the PPMX and power it on. Always make sure the PPMX is on prior to turning on the laptop.
- It may be necessary to charge the laptop for 2 h prior to first use.
- 6 Close the rotating cover door. The PPMX will not operate with the cover open.

Log In

When prompted, enter the "User name" and "Password", and then select **Accept** (or the X to cancel). Password is case-sensitive. It is recommended to change the password for the default **Administrator** (admin).

- Select the "User name (Full name)" in software to go to the "User properties" screen.
- 2 Enter a new Password for the user, and then enter the password again in the "Password confirm" field.
- 3 Select **Save**, or **Back** to return to the previous screen without saving.

NOTICE The default User name is admin and the Password is Gilson268

Change PPMX Serial Number in Software

To control a PPMX from TRILUTION® micro, the serial number of PPMX must be entered into TRILUTION® micro software. When TRILUTION® micro is factory-installed on the supplied laptop, the serial number of the corresponding PPMX is entered into the software. If installing a replacement laptop, follow the instructions below:

- 1 Go to the HOME screen.
- 2 Select **Settings**.
- 3 Enter Admin User ID and Password.
- 4 Select **Protocol settings**.
- 5 Enter the Serial number for PPMX.
- 6 Select **Back** and return to the HOME screen.



Log in

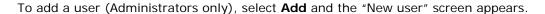


Accept X

User Management

The user management feature in TRILUTION micro provides a way for administrators to grant or restrict users access to programs and features in the software. User management is accessible from the main screen shown when the software starts.

- Select <u>Manage Users</u> in software to go to the "User management" screen, which displays a list of users.
- 2 Select a user from the list.
- 3 Select **Edit**. The "User properties" screen appears.
- 4 Edit any or all properties shown.
 - "User name" may not be modified for the logged in user.
 - For the default administrator (admin), only "Password" and "Feature permissions" may be modified.
- 5 Select **Save**, or **Back** to return to the previous screen without saving.



1 Enter a **User Name**.

- The user name cannot be the same as any other user name.
- The user name can be from 1 to 50 characters in length, must begin with an English letter or number and may contain the following special characters: _()-@.and,. Spaces are valid.
- 2 Enter the **Full name** for the user.
 - The full name can be from 1 to 100 characters in length, must begin with an English letter or number and may contain the following special characters: _()-@.and,. Spaces are valid.
- 3 Optionally, enter a "Password" for the user. The user can change the password at any time.
 - It can be from 1 to 50 characters in length, must begin with an English letter or number and may contain the following special characters: _()-@.and,. Spaces are valid.
 - It is case-sensitive, but it is not required (password can be blank).
 - If a password was entered, re-enter the password in the "Password confirm" field.
- 4 Select "Is administrator" to assign administrator access to the user. By default, "Is active" is selected. Clear the check box to deny the user access to the software. The user remains in the list and can be changed to active by an Administrator at any time.
- 5 Under "Feature permissions", clear the check box for any software to which the user should not have access. By default, a new user has access to all software.
- 6 Select **Save**, or **Back** to return to the previous screen without saving.

To delete a user (Administrators only), select a user from the list and select **Delete**. A message will appear asking if you wish to delete the user. Select **Yes** to delete, or **No** to close message without deleting the user.

Touchscreen Overview

The following icons appear on several screens in TRILUTION® micro.

Icon Description



Select to return to the "Home" screen.



Select to view the help information for the current screen.



Indicates invalid or missing data error.

- On the touchscreen tablet, touch and hold the icon, and then release to display details about the error. Touch to close.
- On a PC, right-click on the icon to display details about the error. Click to close.



Indicates that there is more information available to view.

- On the touchscreen tablet, touch and hold the icon, and then release to display the information. Touch to close.
- On a PC, right-click on the icon to display the information. Click to close.

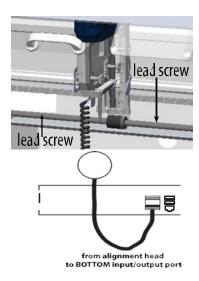
To view the options to shut down TRILUTION® micro, touch on the main menu:

- Touch Shutdown to close TRILUTION® micro
- Touch Restart TRILUTION micro to restart the software
- Touch Cancel to go back to the main menu

Alignment Protocol

Run the Alignment Protocol to ensure proper alignment of the PPMX. It is only necessary to run this protocol when setting up the instrument for the first time after a move or if an alignment issue is suspected.

- 1 Pass the end of the alignment cable cord with pre-wired connector through the outlet at the back of the PPMX. Be sure to go <u>under</u> the black lead screw to allow for the full range of motion.
- 2 The connector is labeled **BOTTOM** because it connects to the bottom set of green input/output ports on the rear panel of the PPMX. Make the connection.



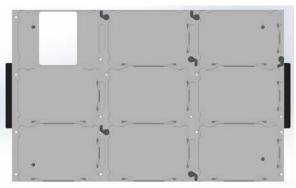
- The clips to secure the tip racks on the tray can interfere with the alignment. Ensure that the clips (

 are positioned as shown in the diagram below, and that the thumbscrews have been tightened.
- 4 Close the rotating cover.
- 5 The tablet starts TRILUTION® micro automatically on power up. If using a laptop, double click the TRILUTION® micro icon to start the software.
- 6 Select **Run/manage protocols**. Ignore the "Create protocol" and "Start utility" bars.
- 7 Select Run a protocol.
- 8 Select Alignment Protocol and then select **Next**.
- 9 The Scanning dialog appears while the software checks that the PPMX is connected. If connected, the software goes to the next screen. If not connected, a message will appear suggesting possible solutions.
- 10 Select **Skip setup** on Labware setup guide.
- 11 Select Run protocol.
- 12 Wait approximately 3 min while the Alignment Protocol runs.
- 13 A notification appears when the Alignment Protocol is complete.
- 14 Select Continue.
- 15 Select Home 🚺 to go to the main menu
- 16 To remove the alignment head start a protocol and follow the **Step-by-step wizard** until the arm moves to the middle of the instrument, then unplug the alignment head from the back of the instrument and unscrew it from the arm. Then stop the run to cancel.

Add Pipette and PickPen™ Head(s)

Each head that may be used now, or in the future, must be added per the instructions that follow.

- 1 On the TRILUTION micro main menu, select **Settings**.
- 2 On the Settings menu, select **Pipette heads**.
- 3 Enter the serial number located on the pipette head and the pipette type (i.e. 8x200).
- 4 The PickPen[™] head is added the same way using serial number **HN12017**. All PickPen[™] heads use this same serial number in the software (they are physically serialized on the back for tracking purposes). Choose PickPen[™] II as the type.
- 5 Select **Save**. There will <u>not</u> be a message that the settings were saved.
- 6 Repeat steps <u>3</u> 5 for additional heads. When finished adding heads, select **Back**.











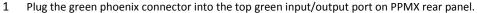


Set Date & Time

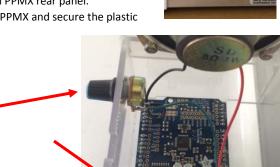
Set the date and time to ensure a correct date/time stamp on protocol runs. This should only have to be done once. On the Settings menu, select **Date/time**, and then set the date, time, and time zone.

Install Chime Sound Box

To enable sound on the PPMX, a separate chime sound box can be added to the back of the instrument per the instructions that follow:



- Position the sound box on the back center, above the shelf portion of the PPMX and secure the plastic holder using the provided hardware (the shorter screws are used on the top holes). If there are already screws in the locations specified, remove these first.
- 3 Adjust the volume using the volume dial.
- 4 There is also a reset button on the inside of the speaker. To use, push and then reboot the PPMX system.
- The Micro SD card will play any mp3 file in a loop as long as the name of the file is "track001.mp3" (i.e. if the mp3 file is named "thetwist.mp3, rename it to "track001.mp3" and it will work with the chime box. After changing the chime and re-inserting the Micro SD card, it may be necessary to press the reset button.



Run a Protocol

The Labware setup guide screen displays the options for confirming the instrument setup. Select **Step-by-step wizard** to do all of the following (in the order shown):

- Review a list of the materials.
- Review the layout of the tray and set up pipette head.
- Set up the pipette, tip rack and additional labware.
- Review protocol / deck.

For details, refer to <u>Step-by-step Wizard</u> on the next page. Select **Browse positions manually** to do any of the following:

- Review the layout of the tray and review pipette head.
- Select and set up specific labware.
- Review protocol / deck.

Select **Skip setup** to skip setup instructions and go to the Wizard complete screen. Protocol will be set to the default values or the values used the last time the protocol was run. This includes the number of samples and tips in the reload block.



Step-by-step Wizard

- 1 Select to go to the main menu.
- 2 Select Run a protocol.
- 3 Select your protocol, and then select **Next**.
- 4 The Scanning dialog appears while the software checks that the PPMX is connected. If connected, the software goes to the next screen. If not connected, a message will appear suggesting possible solutions.
- 5 Enter sample number, kit and reagent information manually or using a barcode reader and then select Next.
- 6 Select Step-by-step wizard.
- 7 Gather the materials in the Materials List and then select **Next**.
- 8 Wait for the software to finish "Preparing pipette head" and then open the rotating cover.

Steps 9-11 only need to be completed during installation or after running the alignment protocol.

- 9 Remove the alignment head by disconnecting the terminal block connector from the rear panel, and then removing the thumb nuts securing it to the upper pipette head assembly.
- 10 Install the pipette head on the left upper pipette head assembly using the thumb nuts. Ensure proper alignment of the pipette head against the upper pipette head assembly before tightening the thumb nuts.
- 11 Select the serial number that matches the installed pipette head from the drop-down list.
- 12 Install the PickPen[™] head on the right upper pipette head assembly by pushing it onto the two prongs. Ensure proper alignment of the PickPen[™] head against the head assembly, no gaps should be visible.

NOTE: The PickPen[™] head should <u>not</u> be used when running the R-protocols.

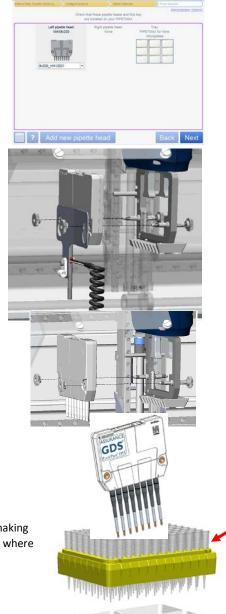
- 13 Select the serial number of installed PickPen™ head from the drop-down list, close the rotating cover, and then select **Next**.
- 14 Proceed through the Tip setup and Labware setup screens by reviewing the information, making any desired changes, and then selecting Next. The screens indicate the labware to use and where to place it on the tray.

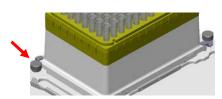
Each tip rack consists of a tip pack and a tip reload block. To assemble the tip rack:

- 1 Open the sealed blister pack.
- 2 Lift the tip pack out of the blister pack.
- 3 Set the tip pack on the tip reload block. Ensure that the tip pack is fully seated on the tip reload block.
- 4 Mark the clear cover with an X and remove.
- 5 Save the clear plastic box and cover on hand for unused tips.

To install the tip rack:

- 1 Loosen the elbow thumbscrew for each clip.
- 2 Place the tip rack on the removable tray with the beveled corner in the back left corner.
- 3 Rotate each clip so that it will effectively secure the tip rack on the tray as shown in the image below.
- 4 Tighten the elbow thumbscrew for each clip.



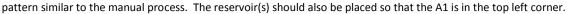


5 Pipette tips are used from the bottom right and moving up the column.

Use the Tip Mover to load the PickPen™ tips from the tip racks (the tip mover can also be used to refill pipette tip racks). PickPen™ tips are used from the top left and moving down the column.

NOTE: Always refill the pipette and PickPen[™] tips off the deck to prevent tips from falling into the open instrument tracks.

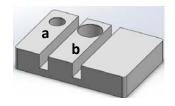
Place Sample Block(s) with the BioControl label on the left side, strips are filled starting in the top left well moving down a column. Place the Resuspension Plate(s) with the A1 in the top left corner, columns are filled starting in the top left well moving down a column. RS Plate columns are filled in a skipped









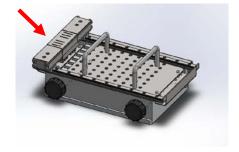


Place the Assurance GDS Reagent Holder on the deck so that the smaller hole is on the top left side

- Standard Concentration Reagent bottle (a)
- High Throughput (HT) Reagent bottle (b)

If using the standard bottle, select False. If using the HT bottle, select True. There are indentations for the CR bottle lids on the holder.

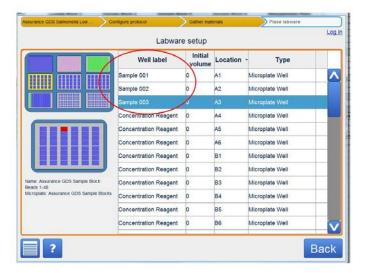
Place the Gel Cooling Block so that the brand name is to the front right side. If using HT tubes, place the HT Variable Spacing Amplification Tube Block with the slide bar on the left side. Before placing on the deck, slice the amp tubes and expand the plate prior to adding the lid.



15 If individual sample IDs need to be entered for each sample in the sample block, this can be done manually or using a barcode reader.

Select the sample that matches the location on the sample block, highlight the information in the field and either manually type the

sample ID or use the barcode reader to import the information for each well. The sample selected will be highlighted on the sample block. Samples are listed in rows starting with A1.





- 16 Review protocol / deck and then select Next.
- 17 Select Run protocol.
- 18 When prompted, **Skip** simulation request.



Pause or Stop a Running Protocol

While running a protocol from TRILUTION® micro, click or touch anywhere on the PIPET STATUS image to pause the run. The run will stop when it finishes its current action. The protocol run timer keeps advancing during the pause. When prompted, select **Continue** to resume the run, or **Stop** to end the run and view the results.

NOTICE

Do not pause the protocol while pipette tips are being picked up or ejected.

To stop the PPMX in an emergency, press the red STOP button on the front of the PPMX. This action will automatically end the current protocol run.





View Results

During and after a protocol run, information is available about reagent dispense volumes. After a protocol run, results for that run are automatically displayed. To view results:

- 1 Select to go to the main menu.
- 2 Select Results.
- 3 Select a protocol, and then select **Results**.
- 4 Select a protocol run, and then select **View**. Simulated runs are identified by
- 5 The first screen displayed when viewing results is the **Tray view** screen. The colors indicate the following information:

Red - Negative volume

Green - Volume in the tube or well

Blue - Empty tube or well

Pink - Tips



- 6 The top of the screen shows the status, the name of the protocol, the time it took to run or simulate the protocol and generate the results, and the time of execution for the last step.
- 7 The Volume view screen displays information about the volume in the selected well or reservoir.
- 8 The top of the screen shows the status, the name of the protocol, the time it took to run or simulate the protocol and generate the results, and the time of execution for the last step.
- 9 The text above the table lists the bed element name, the well location and label, and the current volume in the well. The table lists the actions that occurred in the well or reservoir in the following order:

Initial volume (if any)

Volume added and the source of the volume added (bed element name and plate index or reservoir number) Volume removed

- 10 The **Steps view** screen displays the steps that were run in the protocol in the order of execution.
- 11 The top of the screen shows the status, the name of the protocol, the time it took to run or simulate the protocol and generate the results, and the time of execution for the last step.

Run Report

The Run Report is a subset of the results and can be exported for viewing from the control tablet or laptop. It cannot be viewed from within the software or on the tablet. It includes basic information about the protocol run, the bed layout, and well tracking. It does not include the information about volume tracking.

- 1 Select to go to the main menu.
- 2 Select Results.
- 3 Select a protocol, and then select **Results**.
- 4 Select a protocol run, and then select **Export**.
- 5 Select the file type for the exported file: .htm (default), .xml or .csv.
- Browse for and select the USB drive, name the file (or accept the default name, which is the name of the protocol), and then touch **Save**. The Run Report is saved to the location.
- 7 Open the file on a laptop or desktop computer.

Log Out

- 1 Select to go to the main menu.
- 2 Select Return to TRILUTION micro.
- 3 Select **Log out** to allow another user to log in to the software.



Shut Down

To prevent communication issues between the PPMX and laptop, it is recommended that the instrument and laptop be shut down at least **once per day**.

- 1 To shut down the laptop, do not hold the button down at the top of the monitor like a cell phone, instead go to the Start menu and left click.
- 2 Select Power and Shut down.
- 3 To shut down PPMX, turn off the MAINS power switch located on the rear panel. The indicator light on the front panel will stop illuminating green.

LIMS Compatibility

The PPMX is LIMS compatible when using a network enabled laptop. To import data from a LIMS system, the following steps should be followed:

- 1 Select Start utility.
- 2 Select LIMS Assistant.
- 3 Select IMPORT.
- 4 Browse to select the LIMS import file for the PPMX protocol being run.
- 5 Select Import. A notice will appear saying import was successful. Minimize LIMS Assistant program window.
- 6 Select Run/manage protocols.
- 7 Select Run a protocol.
- 8 Select your protocol, and then select **Next**.
- 9 The Scanning dialog appears while the software checks that the PPMX is connected. If connected, the software goes to the next screen. If not connected, a message will appear suggesting possible solutions.
- 10 The sample number and reagent information will appear in the appropriate fields automatically and select Next.
- 11 Select **Step-by-step wizard** and follow prompts.
- 12 Sample ID / sample descriptions will appear for the individual sample block wells automatically.
- 13 Review protocol / deck and then select **Next**.
- 14 Select Run protocol.
- 15 When prompted, skip simulate.
- 16 Once run is over, maximize LIMS Assistant program window.
- 17 Select EXPORT.
- 18 Browse to select the PPMX protocol (choose the run that just completed).
- 19 Select Export. Choose location to save file. A notice will appear saying export was successful.

Import Protocol

To import a protocol:

- 1 Select to go to the main menu.
- 2 Connect a USB drive containing the protocol file to one of the USB ports on the front of the PPMX or the middle USB host port on the rear panel (the top USB port on the rear panel is not supported).
- 3 Select **Manage protocols** to go to the listing of protocols.





- 4 Select **Import** and then browse for your application protocol file (.sqlite) on the USB drive.
- 5 Select the file and then select **Open** to import the protocol file.

Export Protocol

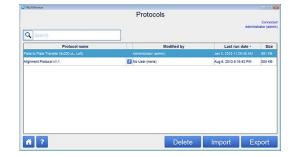
To export a protocol (and its results):

- 1 Select 1 to go to the main menu.
- 2 Select **Manage protocols** to go to the listing of protocols.
- 3 Select a protocol in the list. It will highlight when selected.
- 4 Select Export.
- 5 Browse for and select the destination (USB drive) for the protocol file, and then select **Open**. The protocol is saved to the location with a .SQLITE extension.

Delete Protocol

To delete a protocol (and its results):

- 1 Select to go to the main menu.
- 2 Select Manage protocols to go to the listing of protocols.
- 3 Select a protocol in the list. It will highlight when selected.
- 4 Select **Delete**.



Troubleshooting

TRILUTION® micro will display a message if a known error is encountered. This section describes some of the more common errors and how to prevent or resolve them.

Communication Loss

If a message appears that indicates that the PPMX cannot be found, check your settings (including serial number) and cabling.

To re-establish communication try the following:

- 1 Turn off the PPMX.
- 2 Turn off the tablet (press the power button on the HOME screen, then select Turn off tablet) or laptop.
- 3 Unplug the PPMX from the computer and disconnect the PPMX power cord from the unit.
- 4 Plug the computer into the power source to ensure the battery is charging.
- 5 Wait 5 10 min.
- 6 Reconnect the PPMX to the power supply and the computer to the PPMX.
- 7 Power the PPMX on first.
- 8 Power the computer on.
- 9 Proceed with selecting **Run a protocol** to check communication has been re-established.

Re-starting a Protocol after Communication Loss

If during a protocol there is a loss of communication between the computer and PPMX, the pipette head may be frozen in position. To manually reset the pipette head:

- 1 From the error message, choose "go to Manual control" or restart the protocol Step-by-step wizard and follow prompts but instead of Run protocol, select **Manual control**.
- 2 Check the box "Home in recovery mode" and select Home XYZ.
- 3 Pipette should return to the home position.

Hood Open

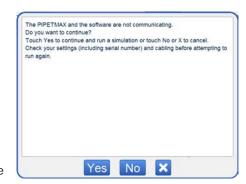
Close the rotating cover door. The PPMX will not operate with the cover or hood door open.



While the run is in progress, DO NOT open the hood; however, if the hood has been opened, you will see the following message. If you choose to continue the run, close the rotating cover door and then observe that the run resumes as expected.



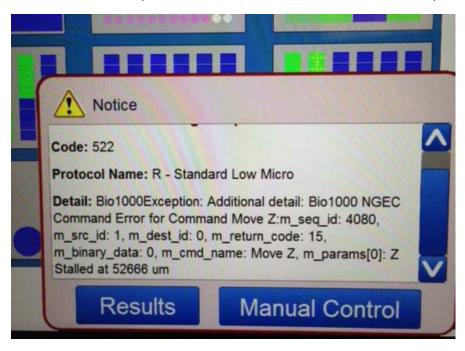
7



Reporting an Error

If an error window appears during a protocol, follow the instructions below:

Scroll to the bottom of the error box and take a photo or write down the additional **Detail** text information. This information is important for Technical Services to be able to adequately diagnose the issue.



- 2 From the error message, select **Manual control**.
- 3 Check the box "Home in recovery mode" and select **Home XYZ**.
- 4 Pipette should return to the home position.

Technical Services

If you need assistance, please contact Technical Services at <u>BioMTS@milliporesigma.com</u>. To help us serve you quickly and efficiently, please refer to <u>Appendix B. Before Calling Us</u>.

Maintenance

The Assurance® GDS PPMX is designed to require a minimum level of maintenance.

Routine Cleaning

To ensure proper performance of the PPMX the following routine cleaning procedures should be performed on a regular basis. It is recommended that these procedures be carried out at least **weekly** following reagent dispense protocols (i.e. R-protocols) or **after each run** following protocols where PickPen™ IMS is utilized (i.e. IMS- and C-protocols). However, based on the specific laboratory environment and equipment usage, more frequent cleaning may be necessary.

Always turn the power off to the PPMX before cleaning.

To clean the PPMX, lightly spray 70% isopropyl alcohol onto a paper towel and wipe the following non-disposable items:

- 1 Removable Tray
- 2 Pipette Head(s) [avoid introducing any liquid into the openings at the bottom]
- 3 Tip Reload Rack(s)
- 4 PickPen™ Magnetic Head [avoid introducing any liquid into the openings at the end of the carrier sleeves...exposure of magnets or the inside of the carrier sleeves to moisture may result in corrosion, preventing the device from operating properly]
- 5 GDS Reagent Holder
- 6 GDS Sample Bases
- 7 Tip Disposal Bin(s)/chutes
- 8 Amp Tube Capping Tool (HT only)
- 9 Amp Tube Cap Rack, 72 well (HT only)
- 10 Reagent Reservoir Base(s) (HT only)
- 11 Variable Spacing Amp Tube Holder, 72 well and Lid (HT only)

The Gel Cooling Block(s) and Aluminum Cooling Block, 72 well (HT only) should be cleaned by lightly spraying a paper towel with 10% bleach solution and wiping the outside surface. Follow with 70% isopropyl alcohol as described above to remove potentially corrosive residues. Alternatively, MilliporeSigma LookOut® DNA Erase (Part no. L9042-1L) can be sprayed directly on the surface of the cooling block and after 1 min should be rinsed off with water.

NOTICE

To prepare 10% bleach solution add 10 mL of commercially available bleach containing 5% sodium hypochlorite to

 $90\ \text{mL}$ of deionized water. The minimum final concentration of sodium hypochlorite in the bleach solution should

be 0.5%. The bleach solution is stable for 7 days from preparation. To prepare 70% isopropyl alcohol solution add

70 mL of isopropyl alcohol to 30 mL of deionized water.

All disposable reservoirs and reagent reservoir bases (HT only) should be autoclaved after 24 h of use.

To clean the laptop, wipe the screen with a low lint cloth designed for electronics.

NOTICE

Do not use pre-moistened alcohol or bleach wipes to clean the laptop screen.

Leave rotating cover down when instrument is not in use. For a maintenance log, please refer to Appendix C. Maintenance Log.

Decontamination

If biological or DNA amplicon contamination is suspected the equipment listed above (#1-11, including the cooling blocks) should be decontaminated by spraying 10% bleach solution and allowing the solution to remain on the surface for 15 min. Follow with 70% isopropyl alcohol as described in the Routine Cleaning section to remove potentially corrosive residues. Alternatively, LookOut® DNA Erase can be sprayed directly on the outside surface of the equipment and after 2 min should be rinsed off with water.

Pipette Head Calibration

To ensure proper performance of the pipette head cassette, it should be calibrated **annually** as a minimum. Contact Technical Services at <u>BioMTS@milliporesigma.com</u>.. To help us serve you quickly and efficiently, please refer to <u>Appendix B. Before Calling Us</u>.

It may be necessary to exchange pipette head cassettes while one is out for calibration. When exchanging a pipette head it is necessary to do two things:

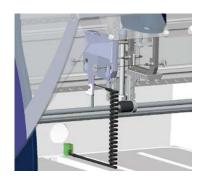
- 1 Add the pipette head to the software by scanning or entering the calibration values. For detailed instructions, refer to Add Pipette Head(s).
- 2 Physically install the head on the instrument. For detailed instructions and a diagram, refer to Step-by-step wizard.

To verify the pipette head performance, please refer to Appendix E. Pipette Verification.

ISO 17025 calibrated pipette heads are also available from Gilson for an additional cost, please contact Technical Services for additional information.

Alignment Calibration

It may be necessary to run the Alignment Protocol to ensure proper alignment of the PPMX if the unit is moved or an alignment issue is suspected. For detailed instructions and a diagram, refer to Run Alignment Protocol. It is recommended to run the alignment at least bi-annually. However, based on the specific environment and equipment usage a greater frequency may be necessary.



Preventative Maintenance

To ensure proper performance of the PPMX it is recommended that a preventative maintenance (PM) field visit be scheduled annually. This PM consists of the following:

- 1 Cleaning polyurethane running pads beneth fixed deck tray
- 2 Testing of removable tray for correct positioning
- 3 Cleaning/greasing the X rail
- 4 Cleaning/greasing the Y rails
- 5 Cleaning/greasing the Z lead screw
- 6 Cleaning/greasing the Z rails
- 7 Internal and external surface cleaning
- 8 Inspecting the X belt for excessive wear and proper tension
- 9 Inspecting tray elements for excessive wear
- 10 Re-alignment of system

Contact Technical Services at <u>BioMTS@milliporesigma.com</u>. to schedule. To help us serve you quickly and efficiently, please refer to <u>Appendix B. Before Calling Us</u>.

Warranty

Units that are under warranty will be repaired and returned to the user at no charge. Please refer to Appendix D. Warranty Terms. If you have any questions about applicability, contact your local sales representative. For out-of-warranty repairs, contact your local sales representative who will discuss service options with you.

Instrument Return Procedure

Contact Technical Services at <u>BioMTS@milliporesigma.com</u>. to obtain authorization before returning any PPMX equipment. To help us serve you quickly and efficiently, please refer to <u>Appendix B. Before Calling Us</u>. To return a piece of equipment:

- Carefully pack the unit in original container to prevent damage in transit. Please refer to <u>Appendix G. Pack Up</u>. Check with Technical Services regarding proper method of shipment. No responsibility is assumed for damage caused by improperly packaged instruments. Indicate the return authorization on the carton and on the packing slip.
- Always insure for the replacement value of the unit.

Appendix A

Parts List

Basic Equipment

BCS Part Number	Description
79100BC	ASSURANCE GDS PPMX WITH STANDARD COVER (INCLUDES ALL BASIC EQUIPMENT EXCEPT LAPTOP)
79145BC	MICROSOFT SURFACE PRO 4 LAPTOP WITH BCS TRILUTION MICRO SOFTWARE (INCLUDES KEYBOARD COVER, PEN, US POWER CORD)
79110BC	ALIGNMENT HEAD
79115BC	PPMX POWER SUPPLY 110V / 220V
79112BC	PPMX POWER CORD US
79113BC	PPMX POWER CORD EU
79116BC	USB CABLE
79147BC	PPMX PWR AND USB CABLING KIT
79121BC	BLACK PLUG FOR BACK COVER
79131BC	ALLEN WRENCH, 5 MM
79101BC	REMOVABLE TRAY 96 WELL
79105BC	PIPETTE TIP RELOAD RACK
79173BC	GDS PICKPEN™ TIP RELOAD RACK
79109BC	TIP DISPOSAL BIN
79103BC	GDS REAGENT HOLDER
79106BC	MAX8x200 PIPETTE HEAD
79144BC	GDS PICKPEN™ MAGNETIC HEAD QUICK RELEASE
79143BC	GDS PPMX CHIME SOUND BOX WITH HARDWARE
79155BC	GDS PPMX TIP MOVER WITH TIP BOX HOLDER
79156BC	GDS PPMX CONCENTRATION REAGENT BOTTLE FILL LEVEL SLEEVE
79174BC	PPMX GEL COOLING BLOCK SET – PINK (2/CS)

Optional Equipment

BCS Part Number	Description
79130BC	HAND HELD MICROSCAN 2D BARCODE READER
79114BC	PPMX POWER CORD UK
79198BC	PPMX SURFACE PRO POWER CORD EU
79199BC	PPMX SURFACE PRO POWER CORD UK
79129BC	PPMX RISER (OFF BED TIP DISPOSAL) (INCLUDES 2 PIECE TIP CHUTE & PLASTIC TUB) (HT ONLY)
79133BC	GDS PPMX HEAD STAND
79134BC	GDS VARIABLE SPACING AMP TUBE HOLDER, 72 WELL (HT ONLY)
79184BC	GDS VARIABLE SPACING AMP TUBE HOLDER LID, 72 WELL (HT ONLY)
79132BC	GDS AMP TUBE CAPPING TOOL (HT ONLY)
73093BC	GDS ALUMINUM COOLING BLOCK, 72 WELL (HT ONLY)
79197BC	GDS AMP TUBE CAP RACK, 72 WELL (HT ONLY)
79185BC	GDS PPMX REAGENT RESERVOIR BASE (HT ONLY)

Reagents

toagonto	
BCS Part Number	Description
61031BC	GDS WASH SOLUTION KIT (4 X 250 ML)
61020BC	GDS TOP STEC WASH SOLUTION KIT (4 X 250 ML) (TOP STEC ONLY)
34724BC	GDS RESUSPENSION BUFFER TQ (70 ML)
34745BC	GDS LISTERIA RESUSPENSION BUFFER TQ (70 ML)

Disposables

BCS Part Number	Description
79102BC	DIAMOND BLISTER, DF200ST, FILTER PIPETTE TIPS (100/CS)
79107BC	4-COLUMN REAGENT RESERVOIR (25/CS)
79119BC	1-COLUMN REAGENT RESERVOIR (25/CS) (ONLY FOR SOME PROTOCOLS)
79186BC	GDS PPMX REAGENT RESERVOIR REMOVABLE INSERTS (2/CS) (HT ONLY)
73004BC	ADHESIVE FILM SHEETS (100/CS)

Appendix B

Before You Call Us

Technical Services will be able to serve you more efficiently if you have the following information on hand:

- Serial number of the instrument(s) involved:
 - The serial number for the PPMX is located on the inside panel of the right support.
 - The serial number for the pipette head is located on the front outside casing.
 - o The serial number for the PickPen™ magnetic head is located on the back outside casing.
 - The serial number for the Surface laptop is located behind the support at the bottom.
- List of concise symptoms being exhibited by the instrument.
- List of operating procedures / protocols and conditions you were using when the problem arose.
- Be prepared to email the exported protocol that was running when the issue occurred, refer to Export Protocol.
- List of all instruments in the configuration and the connections to those instruments.
- List of other electrical connections in the room.

Appendix C

Maintenance Log

Assurance GDS PickPen PIPETMAX (PPMX) Maintenance Log	PMX) Maintenar	ice Log					X
Laboratory:	Instrument S/N:		Week No.:	Month/Year:	ar:		
After Run Maintenance Procedures	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Empty trash bin							
Wipe down removable tray, pipette head, itp reload rack, disposal bin, PickPen head, GDS sample bases, GDS reagent holder, Amp Tube Capping Tool, Amp Tube Capping Tool, Amp Tube Capping Tool, Amp Tube Cappared Rack, Reagent Resevoir Bases, Variable Spacing Amp Tube Holde and Lid with 70% isopropyl alcohol as described in user manual							
Wipe down ge! block and Aluminum cooling block with 10% bleach, followed by 70% isopropyl alcohol as described in user manual							
Wipe touchscreen of laptop with a low lint cloth designed for electronics							

Annual Maintenance Procedures	Date	Operator	Comments
Send pipette head to Gilson for calibration			
Schedule annual PM visit			

^{*} For detailed information regarding specific maintenance procedures refer to the Maintenance section of the Assurance GDS PPMX User Manual.

Operator/Supervisor Signature:

Appendix D

Warranty Terms

BioControl Systems, Inc. ("BioControl" or "BCS") warrants the Assurance® GDS PickPen™ PIPETMAX (PPMX) automation equipment to be free from defects in materials and workmanship, when given normal, proper, and intended usage for one (1) year from the date of delivery of this equipment to the original purchaser ("Buyer"). BioControl agrees during the applicable warranty period to repair or replace, at BioControl's option, all defective equipment within 5 days after date of return to BioControl and without cost to Buyer.

This Limited Warranty shall apply to the following EQUIPMENT included in the Assurance® GDS PIPETMAX System; Assurance® GDS PickPen™ PIPETMAX and laptop. BioControl shall not have any obligation under this Limited Warranty to make repairs or replacements which are required by normal wear and tear, or which result, in whole or in part, from catastrophe, fault or negligence of the Buyer, or anyone claiming through or on behalf of the Buyer, or from improper use of the equipment, or use of the equipment in a manner for which it was not designed, or by causes external to the equipment.

Buyer shall notify BioControl of any equipment believed to be defective during the warranty period. At BioControl's option, such equipment shall be returned by Buyer, transportation and insurance prepaid, to BioControl's designated facility for examination and testing. BioControl shall repair or replace, within 5 days of receipt by BioControl, any such equipment found to be defective and promptly return such equipment to Buyer, transportation and insurance prepaid. Should BioControl's examination and testing not disclose any defect covered by the foregoing warranty, BioControl shall so advise Buyer and return the equipment in accordance with buyer's instructions and at Buyer's sole expense. BioControl warrants its repair work and any replacement parts or equipment for a period of 30 days from receipt by the Buyer of the repaired or replaced equipment or for the remaining balance of the original warranty period set forth in the preceding paragraph, whichever is greater.

THE PROVISIONS OF THE FOREGOING LIMITED WARRANTY ARE IN LIEU OF ANY OTHER WARRANTY, WHETHER EXPRESS OR IMPLIED, WRITTEN OR ORAL INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. BIOCONTROL'S LIABILITY ARISING OUT OF THE MANUFACTURE, SALE OR SUPPLYING OF THE EQUIPMENT OR ITS USE OR DISPOSITION, WHETHER BASED UPON WARRANTY, CONTRACT, TORT OR OTHERWISE, SHALL NOT EXCEED THE ACTUAL PURCHASE PRICE PAID BY BUYER FOR THE EQUIPMENT. IN NO EVENT SHALL BIOCONTROL BE LIABLE TO BUYER OR ANY OTHER PERSON OR ENTITY FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING, BUT NOT LIMITED TO, LOSS OF PROFITS OR LOSS OF USE DAMAGES) ARISING OUT OF THE MANUFACTURE, SALE OR SUPPLYING OF THE EQUIPMENT. THE FOREGOING WARRANTIES EXTEND TO BUYER ONLY AND SHALL NOT BE APPLICABLE TO ANY OTHER PERSON OR ENTITY INCLUDING, WITHOUT LIMITATION, CUSTOMERS OF BUYER.

Appendix E

Pipette Verification

When neccesary, the following procedure can be used to verify PPMX pipette head performance:

- 1. Select "Run a protocol"
 - Select R Standard Low Micro Calibration Verification or R HT Standard Low Micro Calibration Verification protocol
- 2. Enter 8 samples
- 3. Weigh 2 empty GDS Sample Bases with one sample well strip each and 1 GDS Resuspension Plate prior to start and record weight
- 4. Load removable tray with disposables according to PPMX Step-by-step wizard
- 5. Enter correct number of missing tips if not using a full rack
- 6. Vortex Concentration Reagent and remove cap prior to adding bottle to the GDS Reagent Holder
- 7. Add correct volume of Wash Solution and Resuspension Buffer to reagent reservoir
- 8. Select "Run protocol"
- 9. Select "Skip" when asked to simulate
- 10. Select "Continue" to prompt

Resuspension Buffer _____ µL

11. When run is completed, weigh both filled GDS Sample Bases and the filled GDS Resuspension Plate and record weight

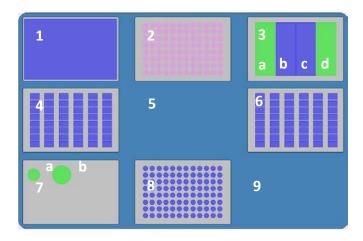
NOTE: The protocol will fill the CR and Resuspension Buffer 5x the standard amount, the wash 1x (this is the reason for the different calculations below).

12. Complete the following calculation for the Concentration Reagent & Resuspension Buffer:		
(FP - DP) / 40 wells =	x 1000 =	μL
13. Complete the following calculati	ion for the Wash Solution:	
(FP - DP) / 8 wells =	x 1000 =	μL

Dry Plate (DP) Weight of Sample Blocks/Resuspension Plate

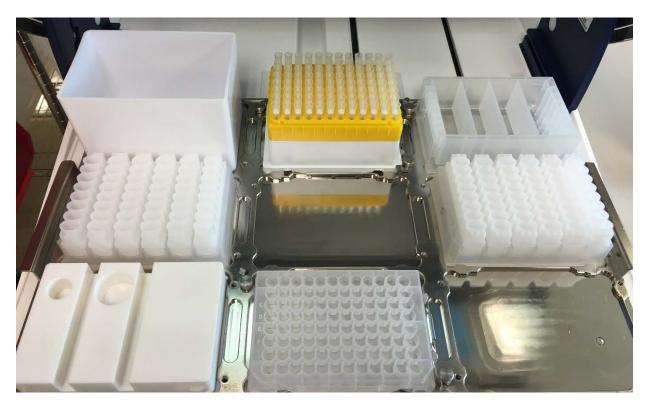
Concentration Reagentg Wash Solutiong RS Plate Resuspension Bufferg
Filled Plate (FP) Weight of Sample Blocks/Resuspension Plate
Concentration Reagentg Wash Solutiong RS Plate Resuspension Bufferg
Pipette should deliver 20 \pm 1 μL for Concentration Reagent, 1000 \pm 20 μL for Wash Solution, and 45 \pm 2 μL for Resuspension Buffer.
Concentration Reagent µL
Wash Solution ul

Deck Layout for Pipette Calibration Verification



- 1 Trash bin
- 2 Pipette tips (200 μL filter)
- 3 Reagent reservoir (a Wash, b&c Empty, d RS Buffer)
- 4 Sample block 1 (1-48 CR)
- 5 Empty
- 6 Sample block 3 (1-48 Wash)
- 7 Reagent holder (a Std or b HT CR bottle)
- 8 RS plate 1 (1-48 RS Buffer, skipped col.)
- 9 Empty

*Remove the PickPen™ Magnetic Head from the arm prior to running this protocol



Appendix F

Best Practices

- If using the R-protocol + IMS-protocol format, one removable tray should be for reagent dispensing (Work Zone 1) and the other removable tray for sample preparation (Work Zone 2). May be helpful to label the tray positions with adhesive labels. Always perform the alignment protocol with the removable tray for sample preparation.
- The Assurance® GDS PickPen™ Magnetic Head should be removed when running the R-protocols.
- Load the 0.2 mL amp tubes with the lid hinge to the right (so they open from the left), always load them all the same direction. Always skip columns (should match the resuspension plate format).
- For the 1-Column Reservoir:
 - During the R-Wash Solution/R-Wash Solution Dual Dispense protocols, PPMX switches to the second reservoir for samples 33 to 48 on sample block 5, when sample blocks 1 thru 4 are full (48 each).
 If sample blocks 1 thru 4 are partials then the second reservoir is used when the total sample reaches 225 to 240.
- For the 4-Column Reservoir, most protocols use the columns as follows:
 - Columns 1 & 2 are for Wash Solution (PPMX uses the first column for up to 48 samples, from sample 49 to 72, the second column is used)
 - Column 3 is for sterile media (BHI or DFB)
 - Column 4 is for Resuspension Buffer Tq
- Re-cap Concentration Reagent bottles after each run to prevent evaporative loss and store under refrigeration.
- Cover reservoirs with leftover Wash Solution, Resuspension Buffer and/or sterile media with an adhesive film sheet and store under refrigeration. Notate the date and lot numbers if applicable. Reservoirs with left over Wash and RS Buffer are good for 24 hours. All reservoirs are autoclavable.
- Always keep the reservoirs filled to the appropriate level for reagents that are aspirated from the top (i.e. Wash Solution and sterile media).

Container Type	Min Fill Level	Max Fill Level	Aspiration From the	Protocol Fill Levels
Standard CR Bottle	1 mL	4 mL	Bottom	2.4 mL
HT CR Bottle	1 mL	8 mL	Bottom	7 mL
4-Column Reservoir	1 mL	60 mL	Тор	Wash – 50 mL
			Тор	Media – 50 mL
			Bottom	RS Buffer – 15 mL
			Bottom	HT RS Buffer – 30 mL
1-Column Reservoir	15 mL	260 mL	Тор	Wash - 250 mL
			Тор	Media – 250 mL
Removable Reservoir Inserts				
(HT only)	3 mL	93 mL	Тор	Wash – 90 mL
			Bottom	HT RS Buffer - 20 mL
CR = Concentration Reagent HT = High Throughput RS = Resuspension				

• Refer to the Assurance® GDS Rotor-Gene® Q User Manual (Part no. 55342) for additional reagent time guard bands.

•	If using 0.1 mL HT amp tubes, follow Application Note: Multiplex Assays (FRMMK.7240).	Utilizing the PPMX to run GDS High Throughput Non

Appendix G

Pack Up

- 1. Unplug the Assurance® GDS PPMX, place the black power supply in the mini white cardboard box and put into the accessories box.
- 2. Unplug the laptop, place the black USB cable/ferrite cores in their plastic bag and put into the open-ended accessories box.
- Place laptop and charger back into the labeled computer box and put into the open-ended accessories box.
- Place all the deck accessories into their respective plastic bags and place into the accessories box.
 - a. Trash bin, tip reload racks, tip puck, reagent holder and power cords (US & EU) in large plastic bag
 - b. Place gel block in its mini white box
 - c. Dispose of used reservoirs, sample wells and tips

Accessories -

Secure the back by installing the shipping brace onto the rear of the instrument with thumb screws.



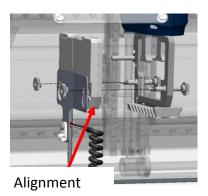


6. Remove the 8x200 Pipette Head by unscrewing the thumb nuts securing it to the left side of the arm. Wrap the Pipette Head in bubble wrap and place in the labeled manila envelope holding the Alignment Head – place in accessories box.





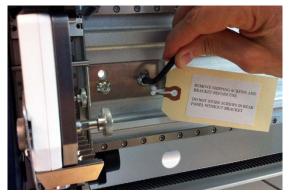
- 7. Install the Alignment Head on the left side of the PPMX arm by securing it to the upper Pipette Head assembly with the thumb nuts.
- 8. Remove the PickPen™ Magnetic Head. Wrap the PickPen™ Head in bubble wrap and place in the accessories box large plastic bag with other deck accessories.
- 9. Remove the deck tray and set aside, slide the attached metal bottom sheet back so that the rectangular hole aligns with the opening in the base and press the white foam block into the opening to prevent the sheet from moving during shipping.
- 10. Tape the Alignment Head cable to the foam block.





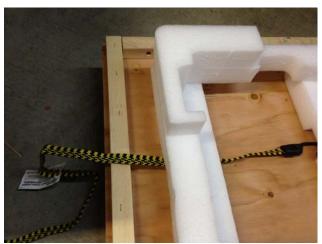
11. Install the shipping bracket to the arm and inside back of the PPMX by using the allen wrench (5 mm) provided to tighten both screws into place.

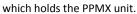
NOTE: Some older PPMX have two clear pieces of tubing that are attached to the lead screw in place of the shipping bracket. Be sure that the arm is in the middle of the lead screw when attaching these tubes.





- 12. Place the removable metal deck tray into its foam and cardboard wrapper prior to putting it in the open-ended accessories box.
- 13. Hook the bungee cords together and place under the white foam insert







14. Carefully lower the PPMX into the foam insert in the base of the shipping crate, the handholds on opposite ends of the instrument match with the clearance notches in the foam.

NOTE: Leave the rotating clear cover down when lifting PPMX to prevent damage from the lid crashing forward.

- 15. Rotate the clear cover open until it catches on the magnets, using lab tape, secure the lower cover to the upper cover.
- 16. Place the plastic bag over the unit.
- 17. Attach the bungee cords vertically around the PPMX unit. Next 2 steps require 2 people.
- $18.\,$ On the inside of the cords, slide the open-ended accessories box in the front of the PPMX, the strip of grey foam should rest just below the handle
- 19. Tape up the accessories box and slide it on the inside of the cords, on the back shelf of the PPMX unit.







20. Place the two grey foam inserts vertically on the sides of the PPMX for additional protection.



- 21. Gently lower the crate lid over the PPMX unit being careful not to loosen the grey foam pieces. This step requires 2 people.
- 22. Attach the 4 bolts to the bottom of the crate using a 9/16" wrench.



23. For Reference:

- Crate Shipping Size = 36"W x 32" L x 33"H
- Crate Shipping Weight = 166 lbs



Appendix H

Ordering Information

ATM kit components:

- 0.2 mL Amplification Tubes
- 7 mL Concentration Reagent (2 bottles)

Part No.	Description
71007-576ATM	GDS for <i>E. coli</i> O157:H7 Tq
71008-576ATM	GDS for <i>Salmonella</i> Tq
71022-576ATM	GDS for <i>Salmonella</i> HET Tq
71009-576ATM	GDS for <i>Listeria</i> spp. Tq
71010-576ATM	GDS for <i>Listeria monocytogenes</i> Tq

The following kits are sold separately but are required for the ATM kit:

Wash Solution

Part No.	Description
61031BC	GDS Wash Kit (4 x 250 mL)

•

• RS Buffer

Part No.	Description	
34724BC	Assurance GDS Resuspension Buffer Tq (70 mL)	
34745BC	Assurance GDS <i>Listeria</i> Resuspension Buffer Tq (70 mL)	

If running a single wash protocol the ratio is 2 ATM kits to 1 Wash and RSB kit [2:1]

OR

If running a double wash or double wash regrowth protocol the ratio is 1 ATM kit to 1 Wash and RSB kit [1:1]

MilliporeSigma 400 Summit Drive Burlington, MA 01803 United States



