

Instructions for Use for

HYDROFLEX PLUS



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- Serial number (SN) of your product
- Software and software version (if applicable)
- Description of the problem and contact person
- Date and time when the problem occurred
- Steps that you have already taken to correct the problem
- Your contact information (phone number, fax number, e-mail address, etc.)





WARNING

CAREFULLY READ AND FOLLOW THE INSTRUCTIONS PROVIDED IN THIS DOCUMENT BEFORE OPERATING THE INSTRUMENT.

Notice

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We would appreciate any comments on this publication.



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Declaration for EU Certificate

See the last page of these Instructions for Use.

Intended Use of Instrument

See chapter 2.2.1 HYDROFLEX PLUS Intended Use.

About the Instructions for Use (IFU)

Original instructions. This document describes the HYDROFLEX PLUS, designed to wash microplates.

It contains instruction for the use of the instrument and is intended as a reference for the user. It contains information about the following:

- 1. Installing the instrument
- 2. Operating the instrument
- 3. Programming of wash procedures
- 4. Defining of wash parameters
- 5. Cleaning and maintenance procedures



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| Symbols | | |
|------------------------------|--|--|
| *** | Manufacturer | |
| | Date of Manufacturing | |
| IVD | In vitro diagnostic medical device | |
| | Biological risks | |
| | Indicates the possible presence of a strong magnetic field. | |
| \bigcap i | Consult instructions for use | |
| C€ | CE conformity marking | |
| UK CA | United Kingdom Conformity Assessed marking shows that the labeled product is following the applicable regulation in Great Britain. | |
| REF | Catalogue number | |
| SN | Serial number | |
| UDI | Unique Device Identification The UDI symbol identifies the data carrier on the label. | |
| | WEEE symbol | |
| 50 | China ROHS symbol | |
| SID | TÜV SÜD MARK | |
| MAXIMUM FILLING LEVEL | MAXIMUM FILLING LEVEL | |
| WARNING : HEAVY WHEN FULL | WARNING! HEAVY WHEN FULL | |
| WASTE | WASTE | |



Liquid 1

Liquid 2

Liquid 3

Liquid 4

Liquid 1, Liquid 2, Liquid 3, Liquid 4,

Warnings, Cautions and Notes

The following types of notices are used in this publication to highlight important information or to warn the user of a potentially dangerous situation:



Note Gives helpful information.



CAUTION

INDICATES A POSSIBILITY OF INSTRUMENT DAMAGE OR DATA LOSS IF INSTRUCTIONS ARE NOT FOLLOWED.



WARNING

INDICATES THE POSSIBILITY OF SEVERE PERSONAL INJURY, LOSS OF LIFE OR EQUIPMENT DAMAGE IF THE INSTRUCTIONS ARE NOT FOLLOWED.



WARNING

THIS SYMBOL INDICATES THE POSSIBLE PRESENCE OF BIOLOGICALLY HAZARDOUS MATERIAL.
PROPER LABORATORY SAFETY PRECAUTIONS MUST BE OBSERVED.



ATTENTION

NEGATIVE ENVIRONMENTAL IMPACTS ASSOCIATED WITH THE TREATMENT OF WASTE.

- DO NOT TREAT ELECTRICAL AND ELECTRONIC EQUIPMENT AS UNSORTED MUNICIPAL WASTE.
- COLLECT WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT SEPARATELY.



WARNING

RISK OF FIRE AND EXPLOSION!



ETHANOL IS FLAMMABLE AND WHEN IMPROPERLY HANDLED CAN LEAD TO EXPLOSIONS. PROPER LABORATORY SAFETY PRECAUTIONS MUST BE OBSERVED.



Abbreviations

| Abbreviation | |
|--------------|--|
| A | Ampere |
| °C | Degrees Celsius |
| CE | CE conformity marking |
| cm | Centimeter |
| CV | Coefficient of Variation |
| ELISA | Enzyme-Linked Immuno Sorbent Assay |
| EN | European Norm: a voluntary European standard of the European Committee for Standardization or Comité Européen de Normalisation (CEN) |
| °F | Degrees Fahrenheit |
| hPa | Hectopascal |
| Hz | Hertz |
| IEC | International Electrotechnical Commission |
| IFU | Instructions for Use |
| in. | Inch |
| inHg | Inches of mercury |
| IVD | In vitro diagnostics |
| IVD-D | In Vitro Diagnostics Directive |
| IVDR | In Vitro Diagnostic Regulation (IVDR) (EU) 2017/746 |
| kg | Kilogram |
| l; L | Liter |
| m | Meter |
| mBar | Millibar |
| ml | Milliliter |
| mm | Millimeter |
| mS | Millisiemens |
| μl | Microliter |
| PCR | Polymerase Chain Reaction |
| ppm | Parts per million |
| QC | Quality Control |
| REF | Reference number/ Order number |
| S | Second |
| SN | Serial number |
| Т | Träge (Slow Blow Fuse) |
| torr | Torr – millimeter of mercury (mmHg) |
| TYPE | Name and type of instrument |
| USB | Universal Serial Bus |
| V | Volt |
| VA | Volt ampere |
| WEEE | Waste electrical and electronic equipment |



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1. Safety

1.1 Instrument Safety

- 1. Always follow basic safety precautions when using this product to reduce the risk of injury, fire, or electrical shock.
- 2. Read and understand all information in the IFU. Failure to read, understand, and follow the instructions may result in damage to the product, injury to operating personnel or poor instrument performance.
- 3. Observe all Warning and Caution notices in the IFU (see Warnings, Cautions and Notes on page 6 for a description of the notices used in this document).
- 4. Never open the HYDROFLEX PLUS while the instrument is plugged into a power source.
- 5. Observe proper laboratory safety precautions, such as wearing protective clothing and using approved laboratory safety procedures.



Note Suitable Compact Microplates

The HYDROFLEX PLUS supports the processing of flat, round, or v-shaped bottom microplates in 96-well format typically used for EIA, which conform to the standard defined by the Society of Biomolecular Screening. Other plate types in 96-well format such as deep-well plates and PCR-plates cannot be used with the HYDROFLEX PLUS.



CAUTION

BE CAREFUL WHEN USING STRIP PLATES THAT THE STRIPS ARE POSITIONED IN THE MICROPLATE AS DEFINED IN THE PROGRAM USED FOR PLATE WASHING, OTHERWISE SPILLING CAN OCCUR AND THE INSTRUMENT MAY BECOME CONTAMINATED (SEE 4.4 WASH MODES AND 5.2.2 DEFINE/EDIT A PROGRAM (DEFINE/EDIT MENU)).



To achieve proper wash-performance with strip plates ensure that:

- All strips have been properly inserted into the frame of the strip-plate to give a level surface.
- The number of strips used, matches the type of manifold used (8-way manifold: use minimum of one strip, 16-way manifold: use minimum of two strips).
- The current position of the strips within a strip plate matches the position of the strips as defined in program used for plate washing. See chapter 5.2.2 Define/Edit a Program (Define/Edit Menu).







WARNING

TO ENSURE PROPER WASH PERFORMANCE IT IS MANDATORY TO ADJUST THE HYDROFLEX PLUS TO THE TYPE / MANUFACTURER OF MICROPLATE OR STRIP-PLATE USED. THIS ALSO APPLIES FOR ANY PRE-DEFINED PLATE FILE, THAT WILL ALWAYS CONTAIN AVERAGE PLATE PARAMETERS ONLY, THAT HAVE TO BE VERIFIED WITH THE CORRESPONDING PLATE TYPE AND IF NECESSARY CORRECTED BEFORE PUTTING THE HYDROFLEX PLUS INTO USE.

IF THIS ADJUSTMENT PROCEDURE IS NOT PERFORMED PROPERLY, THIS MIGHT RESULT IN HIGH LEVELS OF RESIDUAL VOLUME PER WELL, AS WELL AS INSUFFICIENT WASHING OF THE WELLS AND MAY SERIOUSLY AFFECT ASSAY PERFORMANCE.

FOR DETAILS ON HOW TO ADJUST THE HYDROFLEX PLUS TO THE TYPE OF MICROPLATE OR STRIP-PLATE USED, SEE CHAPTER 6 SETTINGS MENU IN THIS MANUAL.

WARNING

WASTE BOTTLE - LIQUID LEVEL





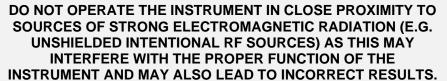
MAKE SURE THAT THE LIQUID LEVEL OF THE WASTE BOTTLE IS ALWAYS KEPT BELOW THE MAXIMUM LEVEL INDICATED ON THE BOTTLE TO AVOID POTENTIAL OVERFLOW. AS THE CONTENTS OF THE WASTE BOTTLE ARE POTENTIALLY INFECTIOUS; WEAR PROTECTIVE CLOTHING (GLOVES, LAB COAT AND SAFETY GLASSES) WHEN EMPTYING / HANDLING A WASTE BOTTLE (SEE 8.3.2 CLEANING THE LIQUID SYSTEM).

INQUIRE ABOUT APPROPRIATE COLLECTING POINTS AND APPROVED METHODS OF DISPOSAL IN YOUR COUNTRY, STATE OR REGION.

WARNING

THE INSTRUMENT COMPLIES WITH THE EMISSION AND IMMUNITY REQUIREMENTS DESCRIBED IN IEC 61326-2-6; HOWEVER, THE ELECTROMAGNETIC ENVIRONMENT SHOULD BE EVALUATED PRIOR TO THE OPERATION OF THE INSTRUMENT.











WHEN USING WASH BUFFERS THAT SHOW A STRONG TENDENCY OF FOAMING, EMPTY THE WASTE BOTTLE AS SOON AS THE FOAM-LEVEL HAS REACHED THE MAXIMUM FILLING LEVEL INDICATED ON THE WASTE BOTTLE. ADDITIONALLY, ADD A COMMERCIALLY AVAILABLE ANTI-FOAMING AGENT (SUCH AS SILICONE OIL) TO THE EMPTY WASTE BOTTLE TO REDUCE FOAMING.





IF FOAMING CONTINUES TO BE A PROBLEM, WE RECOMMEND SWITCHING TO A LARGER WASTE BOTTLE (NOT PROVIDED WITH THE HYDROFLEX PLUS) AND ADDITIONALLY INCREASE THE CONCENTRATION OF ANTI-FOAMING AGENT IN THE WASTE BOTTLE. TO HELP FACILITATE BREAKDOWN OF THE FOAM IN THE WASTE BOTTLE, CAREFULLY SWIRL THE WASTE BOTTLE FROM TIME-TO-TIME TO IMPROVE MIXING BETWEEN FOAM LAYER AND ANTI-FOAMING AGENT.

REFILL ANTI-FOAMING AGENT AFTER EMPTYING WASTE BOTTLE. FOR EXAMPLE, WHEN USING THE WACKER ANTI-FOAM EMULSION SE47 (WACKER ARTICLE CODE 21640582), THE RECOMMENDED CONCENTRATION IS 1ML OF ANTIFOAMING AGENT FOR 1 LITER OF WASTE SOLUTION.

FOR ANTIFOAMING AGENTS FROM OTHER MANUFACTURERS, USE CONCENTRATIONS AS RECOMMENDED BY CORRESPONDING MANUFACTURERS.



2. General

2.1 Introduction

The HYDROFLEX PLUS is an instrument for strip-wise processing of microplates in the 96-well format. The instrument is designed for professional use only and should only be operated by trained personnel.

CAUTION



THE WASH RESULTS OBTAINED WITH THE HYDROFLEX PLUS ARE INFLUENCED BY THE CORRECT USE OF THE INSTRUMENT, ACCORDING TO THE INSTRUCTIONS GIVEN IN THIS IFU, AS WELL AS THE LIQUID COMPOUNDS USED (REAGENTS, WASH BUFFER, CHEMICAL COMPONENTS). THE INSTRUCTIONS FOR USE, STORAGE, AND OTHER HANDLING IN CONNECTION WITH SAMPLES OR REAGENTS MUST BE STRICTLY FOLLOWED. TAKING THESE FACTS INTO CONSIDERATION, RESULTS MUST BE INTERPRETED CAREFULLY.

STOP

CAUTION

BEFORE THE INSTRUMENT IS INSTALLED AND SWITCHED ON IT SHOULD BE LEFT TO STAND FOR AT LEAST THREE HOURS, SO THERE IS NO POSSIBILITY OF CONDENSATION CAUSING A SHORT CIRCUIT.



CAUTION

BEFORE WASHING PROCEDURES ARE STARTED, MAKE SURE THAT THE MICROPLATE POSITION A1 IS INSERTED CORRECTLY.



2.2 Area of Application

2.2.1 HYDROFLEX PLUS Intended Use

The HYDROFLEX PLUS is a plate washer for professional use in a laboratory, for automated washing of 96-well microplates.

The instrument is intended primarily for in-vitro diagnostic use in Enzyme-linked immunosorbent assays (ELISA) for the semi-automation of plate washing-steps. The scheduled wash procedure, as well as the type of specimen is defined by the user selected assay.

The HYDROFLEX PLUS is intended for processing of qualitative and quantitative assays according to scheduled wash parameters and instrument specifications.

The product is intended for professional laboratory use by trained personnel. The product is not for home or lay person use.

CAUTION

MANDATORY SYSTEM VALIDATION BY OPERATING AUTHORITY



THE HYDROFLEX PLUS HAS BEEN VALIDATED ON REPRESENTATIVE ENZYME IMMUNO ASSAYS (EIA) ONLY IN EUROPE. IT IS THEREFORE THE RESPONSIBILITY OF ANY OPERATING AUTHORITY TO ENSURE THAT THE HYDROFLEX PLUS HAS BEEN VALIDATED ACCORDING TO APPLICABLE REGULATIONS FOR EACH SPECIFIC ASSAY USED ON THE INSTRUMENT.

If the HYDROFLEX PLUS plate washer is used differently from the intended use mentioned above, the instrument is no longer IVD conform; the user is responsible for the respective use and the necessary validation.

2.2.2 Principle of Operation

The HYDROFLEX PLUS can be used to wash plates for a variety of test routines, mainly in ELISA applications.

The HYDROFLEX PLUS is a microplate strip washer for automated washing, aspiration, dispensing, and shaking of 96-well microplates.

It can be configured with an 8-way manifold for washing one column of a 96-well plate at a time, or with a 16-way manifold for washing two columns of the plate simultaneously.

Each manifold is equipped with a set of aspiration needles to remove liquid from the wells, as well as with a set of dispense needles to fill wash buffer-solution into the wells.

An automated plate carrier is used for transporting a 96-well microplate from a plate-loading position to a wash-position underneath the manifold.

The HYDROFLEX PLUS can be configured with 1-, 2-, or 4-inlet channels for connecting one-, two-, or four wash buffer-solutions.

During the wash-step, liquid is removed from the wells using the manifold in combination with an integrated aspiration pump. This pump is running continuously while the aspiration needles are descending until they reach the bottom of the wells and the liquid has been removed. For efficient crosswise aspiration the HYDROFLEX PLUS can use two aspiration positions per well in 96-well plates with a flat-bottom surface.

When the manifold is in the upper position the desired volume of wash buffersolution is dispensed into the wells, using the dispense needles in combination with a dispense pump. For efficient washing of the wells use larger dispense



volumes. The HYDROFLEX PLUS is running both the aspiration pump and the dispense pump in parallel.

During a soak-step the HYDROFLEX PLUS supports linear shaking of the plate carrier.

2.2.3 User Profile

Professional User - Administrator Level

The administrator is a person who has suitable technical training and corresponding skills and experiences. If the product is used as intended, the person is able to recognize and avoid dangers.

The administrator has extensive skills and is able to instruct the end user or the routine user in assay protocols in connection with a Tecan product within the bounds of the intended use.

Computer application skills and good English skills are required.

End User or Routine User

The end user or routine user is a person who has suitable technical training and corresponding skills and experiences. If the product is used as intended, the person is able to recognize and avoid dangers.

Computer application skills and good language skills for the respective national language at the installation site and English are required.

Service Technician

The service technician is a person who has suitable technical training and corresponding skills and experiences. If the product needs to be serviced or maintained, the person is able to recognize and avoid dangers.

Computer application skills and good English skills are required.



Note

Training dates, their duration and frequency are available at your customer support.

Address and phone number can be found in the web: http://www.tecan.com/customersupport

2.2.4 HYDROFLEX PLUS Configurations and Options

The following instrument configurations and options are available for the HYDROFLEX PLUS:

HYDROFLEX PLUS configurations include:

- HYDROFLEX PLUS with 8-way manifold and 1, 2 or 4 inlet channels
- HYDROFLEX PLUS with 16-way manifold and 1, 2 or 4 inlet channels

Option for factory-installation on HYDROFLEX PLUS models include:

 Liquid Level Detection (LLD) – online monitoring of the liquid level of the liquid and waste bottles.





CAUTION

UNAUTHORIZED MODIFICATION OF THE HYDROFLEX PLUS, ANY OF ITS OPTIONS AND/OR COMPONENTS AS WELL AS ON ANY CORRESPONDING SOFTWARE OR SPARE PARTS WILL RESULT IN A LOSS OF WARRANTY AND A POTENTIAL LOSS IN INSTRUMENT PERFORMANCE.

CAUTION IT IS IMPORTANT TO LINDERSTAND THAT



IT IS IMPORTANT TO UNDERSTAND THAT THE PROPER INSTALLATION OF THE INSTRUMENT AND HYDROCONTROL SOFTWARE ALONE WILL NOT ENSURE COMPLIANCE WITH NATIONAL, REGIONAL OR LOCAL REGULATIONS. A RANGE OF POLICIES AND STANDARD OPERATING PROCEDURES ACCORDING TO APPLICABLE REGULATIONS MUST ADDITIONALLY BE ESTABLISHED.

2.3 Instrument Specifications



Note

Instrument specifications have been defined using Greiner flat-bottom compact 96-well microplates and may vary using other 96-well plates or 96-well strip-plates.

The table below lists the specifications for the instrument. All specifications listed below are based on the following instrument settings:

| Dispense/Wash rate: | 250 μl/s |
|---------------------|----------|
| Aspiration rate: | 3 |

| PARAMETERS | CHARACTERISTICS | |
|-------------------------------|---|--|
| General | | |
| Display unit | Liquid Crystal Display with two rows of sixteen digits | |
| Keyboard | Four key membrane keyboard | |
| Number of dispensing channels | Up to four channels | |
| Manifold types | 8 and 16-way manifold | |
| USB Interface | All connected devices must be approved and listed as per IEC 60950-1 Information Technology Equipment – Safety or equivalent local standards. | |
| Variable | | |
| Volume of solution dispensed | 50 - 3000 μl in 50 μl increments for washing 50 - 400 μl in 50 μl increments for dispensing | |
| Dispensing accuracy | <= 2 % | |
| | Measured under following conditions: | |
| | 8-way manifold, 300 μl , dispensing rate 3 (250 $\mu l/s$ /well), wash buffer, Greiner 96 well flat bottom plate | |

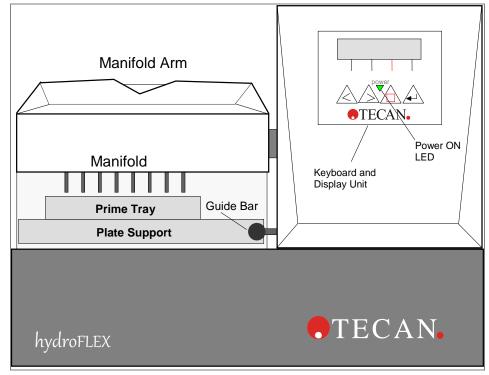


| PARAMETERS | CHARACTERISTICS | |
|-----------------------|--|--|
| Dispensing uniformity | <= 4 % CV | |
| | Measured under following conditions: | |
| | 8-way manifold, 300 μ l, dispensing rate 3 (250 μ l/s/well), wash buffer, Greiner 96 well flat bottom plate | |
| Residual volume | Measured under following conditions: | |
| | <= 2 μl / well (Greiner 96-well flat bottom plate) | |
| | Crosswise aspiration, 8-way manifold, aspiration rate: 3, aspiration time: 4 s, head speed: 10 mm/s, wash buffer. | |
| | Residual volume of <= 2 μl / well cannot be guaranteed if a 16-way manifold is used and if not, all wells are filled with liquid. | |
| | <= 5 μl / well (Greiner 96-well round bottom and V-shaped bottom plates) | |
| | - Single aspiration, 8-way manifold, aspiration rate: 3, aspiration time: 4 s, head speed: 10 mm/s, wash buffer. | |
| | Residual volume of <= 5 μl / well cannot be guaranteed if a 16-way manifold is used and if not, all wells are filled with liquid. | |
| Carry over | <= 1 ppm | |
| between wells | The Carry over between wells <= 1 ppm cannot be guaranteed if not all wells are filled with liquid. | |
| Power | | |
| Supply | Auto-sensing | |
| | 100 - 120 V or 220 - 240 V, 50/60 Hz | |
| Consumption | < 65 VA | |
| Physical | | |
| Outside dimensions | Width: 275 mm, Depth: 366 mm, Height: 180.5 mm (Width: 10.8 inches, Depth: 14.4 inches, Height: 7.1 inches) | |
| Weight | 6.6 kg | |
| Environmental | | |
| Ambient temperature | | |
| Operation | 15°C to 35°C (59°F to 95°F) | |
| Storage | -20°C to 60°C (-4°F to 140°F) | |
| Relative Humidity | | |
| Operation | 20 % to 80 % non-condensing | |
| Storage | 10 % to 80 % non-condensing | |
| Others | | |
| Overvoltage category | II | |
| Pollution degree | 2 | |
| Method of disposal | Electronic waste (infectious waste) | |



2.4 Instrument Description

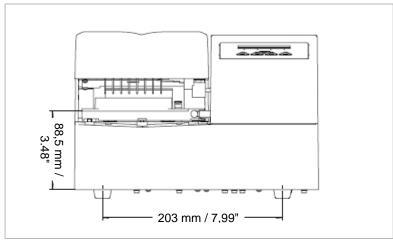
The diagram below shows the main components of the instrument:

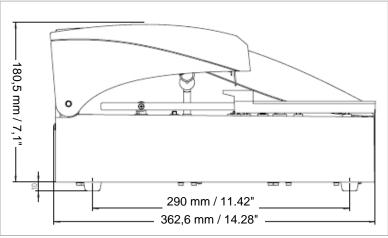


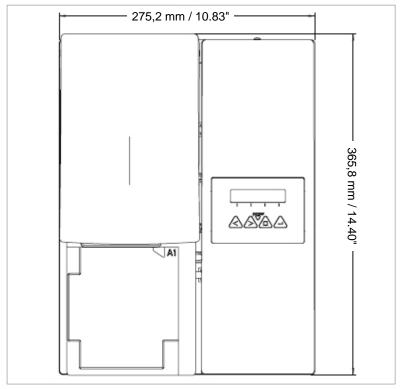


2.4.1 Instrument Dimensions

Standard Instrument - Dimensions



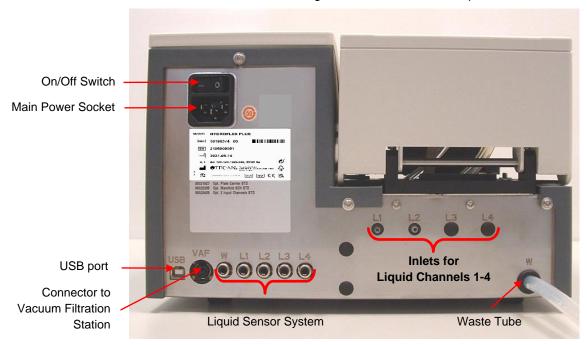






2.4.2 Rear Panel Connections

The instrument has the following connections on the rear panel:



HYDROFLEX PLUS Name Plate

Example name plate



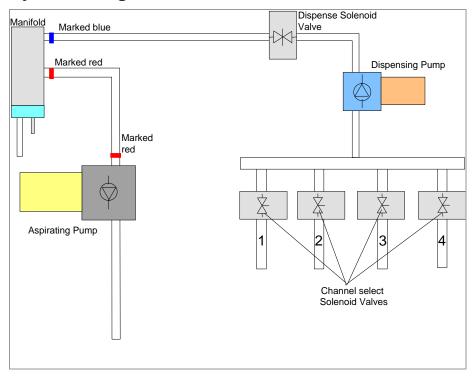
Contents of the name plate (e.g., model name and article number) may vary depending on the specific model.

For an overview of the various instruments for which these Instructions for Use are valid, see the Declaration of Conformity on the last page of this document.

All connected devices must be approved and listed as per IEC 60950-1 Information Technology Equipment – Safety or equivalent local standards.



2.4.3 Liquid System Diagram



2.5 HYDROFLEX PLUS Option

The HYDROFLEX PLUS can be delivered with the following option:

Liquid Level Detection (LLD)

The level of liquid is checked in the liquid bottle(s) and in the waste bottle.

An acoustic signal alerts the user when the bottles are empty or full.

2.5.1 Liquid Level Detection (LLD)

Liquid level sensors are built into the covers of all bottles to avoid overflow of waste bottles and to warn the user when the liquid bottles are almost empty.



2.5.2 Fitting and Connecting the Liquid Level Detection (LLD) (Optional)

Connect the liquid sensor cables into the appropriate sockets in the rear panel of the instrument. The Liquid Level Detection system can be extended to control up to four different liquid bottles and one waste bottle.









Fig. 2.1 Waste and Liquid Bottles with LLD Sensors

See chapter 3.3.1 Connection Diagram for further details.

2.6 Microplate Requirements

Only 96-well format microplates (round, v-shaped, and flat bottom - including strip plates) can be used with the HYDROFLEX PLUS.

| PARAMETERS | CHARACTERISTICS |
|-------------------------------|---|
| Max. overall plate height | 14.35 mm ± 0.76 mm (0.5650 inches ± 0.0299 inches) |
| Footprint (ANSI/SBS 1-2004) | 127.76 mm x 85.48 mm (5.0299 in x 3.3654 in) |
| Pitch size (center to center) | 9.0 mm (0.3543 inches) |
| Bottom shape | Round, v-shaped, and flat |



3. Installation

When installing, moving, or connecting the instrument, follow the instructions in this publication. Tecan does not accept the responsibility for injury suffered by anyone attempting these operations without following the instructions in this publication, nor for damage incurred to the instrument.

Make sure the laboratory meets all the requirements and conditions described in this chapter.

3.1 Installation Requirements

3.1.1 Required Working Area

Select a location to place the instrument that is flat, level, vibration free, away from direct sunlight, and free from dust, solvents and acid vapors.

Allow at least 10 cm (4 inches) between the instrument and the wall or any other equipment. Do not place any items close to the instrument that could obstruct airflow.

The liquid bottles should be positioned at the same height as the instrument. If the liquid bottles are placed above or below the instrument (maximum height difference of 1 meter is allowed), the dispensing pump must be recalibrated by a service technician.

For information regarding outer dimensions and weight of the instrument, see chapter 2.3 Instrument Specifications.

3.1.2 Power Requirements

The instrument is designed to operate at either 100 - 120 V or 220 - 240 V.

No voltage setting is required as the instrument automatically senses the supplied voltage. See 2.3 Instrument Specifications for further information.

Connect the instrument only to an electricity supply system with protective earth.



CAUTION

DO NOT REPLACE DETACHABLE MAIN POWER SUPPLY CORDS WITH INADEQUATELY RATED CORDS.

3.2 Unpacking and Inspection

- 1. Visually inspect the container(s) for damage before opening. Report any damage immediately.
- 2. Place the carton in an upright position and open it.
- 3. Lift the instrument out of the carton and place it in the selected location.
- 4. Remove the transport protection from the instrument and manifold.
- 5. Visually inspect the instrument for loose, bent or broken parts. *Report any damage immediately.*
- 6. Compare the serial number on the rear panel of the instrument with the serial number on the packing slip.
 - Report any discrepancy immediately.
- 7. Check the instrument accessories against the packing list.



8. Save packing materials for further transportation purposes. The HYDROFLEX PLUS must be shipped in the original packaging.

3.2.1 Unpacking and Inspection Checklist

The standard HYDROFLEX PLUS is shipped in one carton, which contains:

Carton 1:

- Instrument
- Accessory package which contains:
 - 6 Manifold screws and Allen key
 - Main power cable
 - 2 Cleaning needles
 - (1, 2 or 4) Solution tube(s) (1m) depending on instrument configuration
 - USB cable
- Bottle set containing:
 - (1, 2 or 4) Liquid bottle(s) (2.5 liter) depending on instrument configuration
 - 1 Waste bottle (5 liter)
- HydroControl software data medium
- Instructions for Use for HydroControl software (pdf-file on data carrier)
- Instructions for Use for HYDROFLEX PLUS (this manual; pdf-file on data carrier)

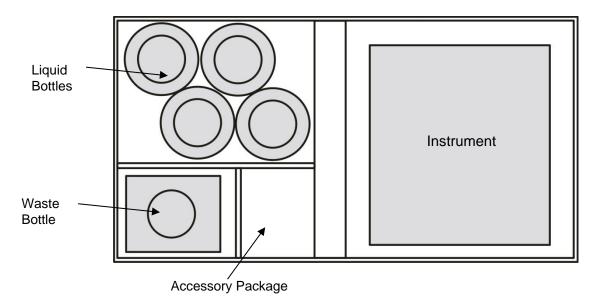


Fig. 3.1 The packaging for HYDROFLEX PLUS



3.3 Installation Procedure

After the instrument has been unpacked and the contents of the transport container have been checked for damages and completeness (see 3.2 Unpacking and Inspection), the instrument can be installed using the following procedure:



CAUTION

BEFORE THE INSTRUMENT IS INSTALLED AND SWITCHED ON, IT SHOULD BE LEFT TO STAND FOR AT LEAST THREE HOURS, SO THERE IS NO POSSIBILITY OF CONDENSATION CAUSING A SHORT CIRCUIT.



CAUTION

IF THE LIQUID BOTTLES ARE ATTACHED IMPROPERLY OR TO THE WRONG CONNECTOR ON THE BACK PANEL OF THE INSTRUMENT, THE WASH PERFORMANCE CAN BE SERIOUSLY AFFECTED.

- Connect the solution tubes (L1 L4) to the inlet connectors on the rear panel of the instrument (see 3.3.1 Connection Diagram). The instrument is supplied with one, two, or four 1-meter lengths of tubing (depending on instrument configuration). Connect the solution tubes to the corresponding liquid bottles. Connect the waste tube to the waste bottle (be aware of not kinking the tube!).
- Connect the Liquid Level Sensors, if available.
- Setup instrument options, if available.
- Ensure that the on/off switch in the rear panel of the instrument is in the off position, then connect the instrument to the power supply: insert the main power cable into the main power socket on the rear of the instrument.



3.3.1 Connection Diagram

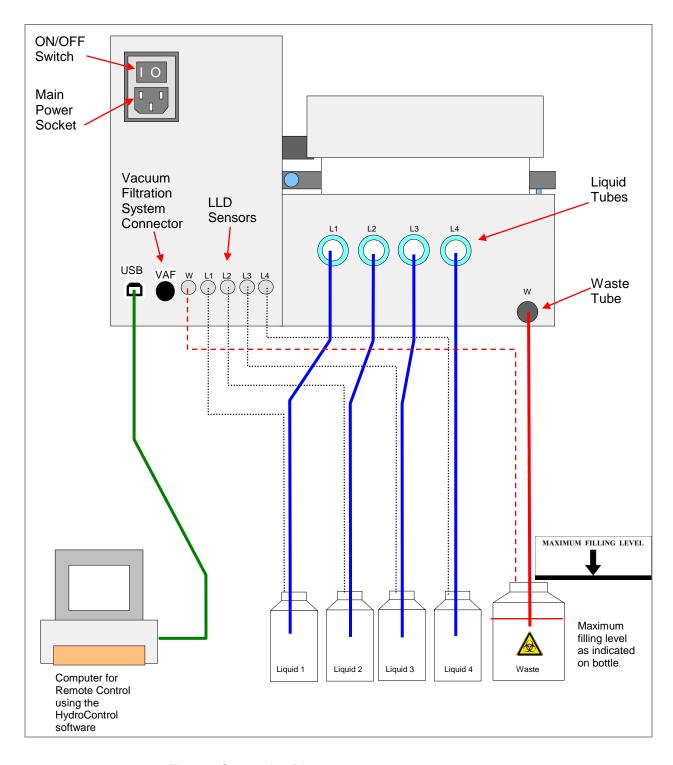


Fig. 3.2 Connection Diagram



4. Operating Instructions

4.1 Switching the Instrument On

Ensure the instrument has been correctly installed and the main power cable is connected into the main power socket in the rear panel of the instrument and the liquid tubes are connected to the correct liquid and waste bottle(s).

Switch ON the instrument, using the on/off switch in the rear panel of the instrument. The initialization procedure is performed and, depending on the instrument type, the following initialization message is displayed:

TECAN AUSTRIA HYDROFLEX

HYDROFLEX PLUS is the name of the instrument, which can be defined via the HydroControl software.

If a **Rinse** procedure was aborted before the instrument was switched off, the following message is displayed after the instrument initializes:

PLEASE RINSE OK

Press **OK** and then select a **Rinse** procedure (see chapter 8.1 Rinsing). After the rinsing procedure has been performed, the instrument proceeds to the standby mode and the following message is displayed:

PROGRAM < > OK



CAUTION

THE LIQUID SYSTEM MUST BE PRIMED WITH THE LIQUID THAT WILL BE USED (WASH BUFFER) BEFORE IT CAN BE USED. PLEASE ENSURE THAT THE DISPENSING AND ASPIRATION PUMPS ARE NOT RUN FOR LONGER THAN A FEW MINUTES WITHOUT LIQUID, OTHERWISE THEY WILL BE DAMAGED.



CAUTION

AT THE END OF EACH WORKING DAY, PERFORM THE RINSE NIGHT PROCEDURE WITH DISTILLED WATER TO ENSURE THE PROPER PERFORMANCE OF THE HYDROFLEX PLUS AND TO PREVENT NEEDLES FROM BECOMING BLOCKED, FOR DETAILS SEE CHAPTER RINSE NIGHT ON PAGE 59.



4.2 Instrument Firmware

The instrument firmware can be used to run and manage wash programs, define plate parameters, adjust certain instrument settings, and perform instrument procedures (rinse, prime and empty prime tray).

Following features are available:

- 20 user-definable washing programs, stored under program positions 1 to 20.
- Up to 60 processing steps per program, each processing step can be identical or different from the previous step.
- Adjustable soak time (5 seconds to 60 minutes and 59 seconds).
- Shaking: The following shaking settings are available:
 - High: Linear shaking with a shaking frequency of 25 Hz and a shaking amplitude of 1 mm
 - Medium: Linear shaking with a shaking frequency of 10 Hz and a shaking amplitude of 2 mm
 - Low: Linear shaking with a shaking frequency of 5 Hz and a shaking amplitude of 3 mm
- Adjustable dispense rate (Drip Mode to 500 μl/s)
- Adjustable aspirating speed (1 to 3)
- Adjustable bottom positions (Bottom, Custom, Overflow)
- Two rinse modes (Rinse Day and Rinse Night) can be used to select how the instrument is rinsed before it is left to stand or switched off.
- Automatic microplate centering: the microplate is automatically centered before starting any wash program.
- Programmable strip selection: the strips to be washed can be defined in the program before starting the washing procedure.

4.2.1 Instrument Firmware Menus

The instrument has the following menu options:

| Program | Start, Define/Edit, Show, Clear | |
|------------|-------------------------------------|--|
| Settings | Edit Plates, Options, Bubble Sensor | |
| Procedures | Prime, Rinse, Empty Prime Tray | |



Firmware Commands on the Display (in alphabetical order)

| DISPLAY | Meaning |
|------------------|--------------------------|
| ASP.RATE # | Aspiration rate # |
| ASPIRATE | Aspirate |
| BOTTOM POS. | Bottom position |
| BUBBLE ERROR | Bubble error |
| BUBBLE HIGH | Bubble high |
| BUBBLE LOW | Bubble low |
| BUBBLE MEDIUM | Bubble medium |
| BUBBLE OFF | Bubble OFF |
| BUBBLE SENSOR | Bubble sensor |
| BURN IN TEST | Burn in test |
| C# CYCLE | C# Cycle |
| C# CYCLEEND | C# Cycle End |
| C# P# ASP | C# P# Aspirate |
| C# P# CYCLE | C# P# Cycle |
| C# P# CYCLEEND | C# P# Cycle end |
| C# P# DISP | C# P# Dispense |
| C# P# SOAK | C# P# Soak |
| C# P# USER PR. | C# P# User Prompt |
| C# P# WASH | C# P# Wash |
| CH# PRIMED? | Channel# primed? |
| CHANNEL# | Channel # |
| CLEAN NO | No cleaning |
| CLEAN YES | Cleaning |
| CLEAR | Clear |
| CLEAR: # | Clear: # |
| CLR | Clear |
| CLR CHANNEL 1 | Clear channel 1 |
| CLR CHANNEL 2 | Clear channel 2 |
| CLR CHANNEL 3 | Clear channel 3 |
| CLR CHANNEL 4 | Clear channel 4 |
| CLR VAC.WASTE | Clear vacuum waste |
| CLR WASTE 1 | Clear waste 1 |
| Crossw.Asp NO | Crosswise Aspiration no |
| Crossw.Asp YES | Crosswise Aspiration yes |
| CYCLE NO # | Cycle number # |
| CYCLE NO # | Cycle number # |
| DEFINE EDIT | Define Edit |
| DISPENSE | Dispense |
| DISPENSE POS. | Dispense position |
| EDIT LLD CHANNEL | Edit LLD channel |

| DISPLAY | Meaning |
|------------------|----------------------|
| EDIT PLATES | Edit plates |
| EMPTY BOTTLES | Empty bottles |
| EMPTY PRIMETRAY | Empty prime tray |
| FINAL ASP? | Final aspiration? |
| FINAL ASPIRATE | Final aspiration |
| FL.RATE # ul/s | Flow rate # ul/s |
| FL.RATE DRIP | Flow rate Drip |
| H-SPEED # mm/s | Head speed: # mm/s |
| HYDROFLEX | HYDROFLEX |
| INIT | Initialize |
| INIT ERROR | Initialization error |
| INV CMD | Invalid command |
| INV PARAMETER | Invalid parameter |
| LIQUID BOTTLE OK | Liquid bottle OK |
| LLD ERROR | LLD Error |
| LLD OFF | LLD OFF |
| LLD ON | LLD ON |
| LOCKED | locked |
| MANIFOLD BROKEN | Manifold broken |
| MANIFOLD DETECT | Manifold detection |
| MANIFOLD UP | Manifold up |
| MISS. PARAMETER | Missing parameter |
| MOVE CUSTOM | Move custom |
| MOVE MANIFOLD | Move manifold |
| MOVE OVERFLOW | Move overflow |
| MOVE TRANSPORT | Move transport |
| NAME: | Name: |
| NO PLATE | No plate |
| NO PLATE FOUND | No plate found |
| NO PROGRAM | No Program |
| NO PROGRAM FOUND | No program found |
| NO. OF CYCLES # | Number of cycles # |
| NOT DEF | Not defined |
| OPTIONS | Options |
| OVERFLOW POS. | Overflow position |
| PARAMETER RANGE | Parameter range |
| PLATE | plate |
| Plate # | Plate # |
| PLATE INSERTED? | Plate inserted? |
| PLATE MODE | Plate mode |



4. Operating Instructions

| DISPLAY | Meaning |
|-----------------|---------------------|
| PLEASE EMPTY | Please empty |
| PLEASE INSERT | Please insert |
| PLEASE RINSE | Please rinse |
| POS. ASP1 | Position Aspirate 1 |
| POS. ASP2 | Position Aspirate 2 |
| POWERFAILURE | Power failure |
| PRIME | Prime |
| PRIME EXIT YES | Prime Exit Yes |
| PRIME SOL. OK? | Prime solution OK? |
| PROCEDURES | Procedures |
| PROGR # DELETED | Program # deleted |
| PROGR #: | Program #: |
| PROGRAM | Program |
| PROGRAM END? | Program End? |
| PROGRAM IS | Program is |
| REMOTE | Remote |
| REMOVE PLATE | Remove Plate |
| RINSE | Rinse |
| RINSE DAY | Rinse day |
| RINSE NIGHT | Rinse night |
| RINSE SOL. OK? | Rinse solution OK? |
| RS485 TIMEOUT | RS485 Timeout |
| RUN# | Run # |
| SENSOR DEFECT | Sensor defect |
| SET CHANNEL 1 | Set channel 1 |
| SET CHANNEL 2 | Set channel 2 |
| SET CHANNEL 3 | Set channel 3 |
| SET CHANNEL 4 | Set channel 4 |
| SET VAC.WASTE | Set vacuum waste |
| SET WASTE 1 | Set waste 1 |
| SETTINGS | Settings |

| DISPLAY | Meaning |
|------------------|----------------------|
| SHAKE HIGH | Shake high |
| SHAKE LOW | Shake low |
| SHAKE MEDIUM | Shake medium |
| SHAKE OFF | Shake off |
| SHAKE YES | Shake yes |
| SHOW | Show |
| SOAK | Soak |
| START | Start |
| STEPLOSS | Steploss |
| STRIP MODE | Strip mode |
| TECAN AUSTRIA | Tecan Austria |
| TIME | Time |
| TIME: # s | Time: # s |
| TIME: #min #s | Time: #min #s |
| USE OTHER NAME | Use other name |
| USER PROMPT | User prompt |
| VACUUM FILTR. | Vacuum filtration |
| VOLUME | Volume |
| VOLUME # ul | Volume # ul |
| WASH | Wash |
| WASTE BOTTLE OK? | Waste bottle OK? |
| WASTEBOTTLE | Waste bottle |
| Y-User Def # | Y-User Defined # |
| Z-POS: BOTTOM | Z-POS: Bottom |
| Z-POS: CELL | Z-POS: Cell |
| Z-POS: CUSTOM | Z-POS: Custom |
| Z-POS: OVERFLOW | Z-POS: Overflow |
| Z-POS:MOVE CUST. | Z-POS: Move customer |
| Z-POS:MOVE OVER. | Z-POS: Move overflow |
| Z-User Def # | Z-User Defined # |



4.3 Operating Instructions

4.3.1 Performing a Wash Procedure

Insert the 96-well microplate to be washed into the plate transport and ensure that the microplate is correctly oriented (position A1 of the plate corresponds to position A1 marked on the plate transport).

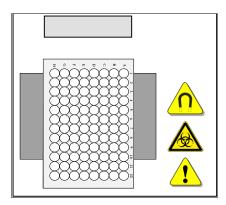


Fig. 4.1 Fitting a microplate

The operating procedure is dependent on the instrument options and the program settings.



CAUTION

BEFORE WASHING PROCEDURES ARE STARTED, MAKE SURE THAT THE MICROPLATE POSITION A1 IS INSERTED CORRECTLY.



CAUTION

BE CAREFUL WHEN USING STRIP-PLATES THAT THE STRIPS ARE POSITIONED IN THE MICROPLATE AS SELECTED IN THE PROGRAM, OTHERWISE SPILLING CAN OCCUR AND THE INSTRUMENT MAY BECOME CONTAMINATED (SEE 5.2.2 DEFINE/EDIT A PROGRAM (DEFINE/EDIT MENU)).



WARNING

WHEN THE INSTRUMENT IS BUSY, DO NOT TOUCH THE MANIFOLD!

AFTER THE INSTRUMENT HAS BEEN USED,
THE MANIFOLD AND PRIME TRAY MAY BE INFECTIOUS!





4.4 Wash Modes

The instrument can wash a microplate using the following wash modes:

| Plate Mode | Each program step is performed on all of the selected strips of a microplate sequentially, before proceeding to the next step. The entire plate or the defined plate range is processed for the defined soaking time. |
|------------|--|
| Strip Mode | The entire wash program is performed on one strip or two consecutive strips of a microplate before proceeding to the next strip(s) (1 strip for 8-way manifold or two strips for 16-way manifold). The strip or group of two strips is processed for the defined soaking time, before proceeding to the next strip or group of strips. |

4.5 Washing Positions

Wash, Dispense, and Aspirate steps can be defined in a wash program with the following Z-positions:

| | following 2-positions. |
|---------------|---|
| Overflow | For ELISA assays and Cellular assays. Overflow washing consists of a simultaneous aspiration and dispense step. It creates a circular flow of wash buffer in the well and ensures that the topmost parts of the well are also washed. |
| Bottom | For ELISA assays. |
| Custom | Any necessary washing position can be selected; the custom positions are not saved as *.pdf files in comparison to the overflow and bottom position. |
| Move Overflow | If Move Overflow (MOVE OVER.) is selected, the manifold moves stepwise from the bottom position to the Overflow position during dispensing. It is recommended for cell wash applications or any applications which must be treated with care. |
| Move Custom | If Move Custom (MOVE CUST.) is selected, the manifold moves stepwise from the bottom position to the user-defined Custom Z- position during dispensing. It is recommended for cell wash applications or any applications which must be treated with care. |

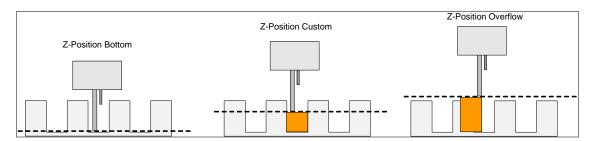


Figure 4.2 Wash Position Diagrams

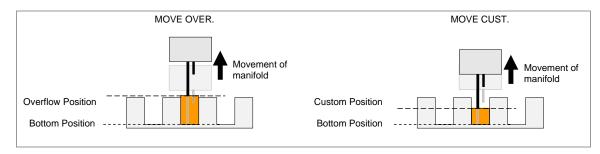


Figure 4.3 Movement Diagrams for Z-positions with MOVE



4.6 Aspirating Modes

To improve wash efficiency and to reduce the residual volume, the manifold must be positioned so that the aspirating needles are correctly positioned in the wells for round-bottom, v-shaped bottom, or flat-bottom well microplates.

Normal Aspiration Mode

For round-bottom or v-shaped bottom wells, the aspirating needles are placed in the middle of the wells. Only one aspiration position can be selected.

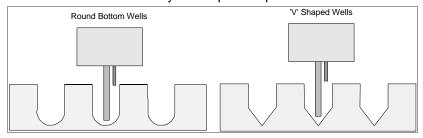


Fig. 4.4 Normal Aspirating Positions

Crosswise Aspiration Mode

With flat bottom wells, the instrument can perform crosswise aspiration using two aspiration positions per well.

The aspirating needles are set at two positions on the bottom of the wells (front edge and back edge).

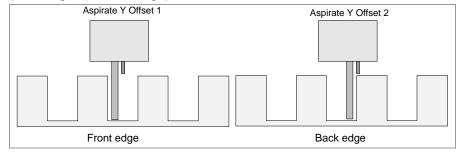


Fig. 4.5 Crosswise Aspiration for Flat Bottom Wells

WARNING

TO ENSURE PROPER WASH PERFORMANCE IT IS MANDATORY TO ADJUST THE HYDROFLEX PLUS TO THE TYPE / MANUFACTURER OF MICROPLATE OR STRIP-PLATE USED. THIS ALSO APPLIES FOR ANY PRE-DEFINED PLATE FILE, THAT WILL ALWAYS CONTAIN AVERAGE PLATE PARAMETERS ONLY, THAT HAVE TO BE VERIFIED WITH THE CORRESPONDING PLATE TYPE AND IF NECESSARY CORRECTED BEFORE PUTTING THE HYDROFLEX PLUS INTO USE.



IF THIS ADJUSTMENT PROCEDURE IS NOT PERFORMED PROPERLY, THIS MIGHT RESULT IN HIGH LEVELS OF RESIDUAL VOLUME PER WELL, AS WELL AS INSUFFICIENT WASHING OF THE WELLS AND MAY SERIOUSLY AFFECT ASSAY PERFORMANCE.

FOR DETAILS ON HOW TO ADJUST THE HYDROFLEX PLUS TO THE TYPE OF MICROPLATE OR STRIP-PLATE USED, SEE CHAPTER 6 SETTINGS MENU IN THIS MANUAL.



4.7 Drip Mode

The slowest dispensing mode is drip mode.

Drip mode is used for very sensitive applications, e.g., washing cell layers, because the instrument offers the possibility to dispense liquid in small drops. This minimizes the detachment of cells and increases the remaining cell percentage at the bottom of the wells.

The following example shows a typical wash program for working with adherent cells (as it would appear in the Define/Edit menu, see 5.2.2 Define/Edit a Program (Define/Edit Menu) for further information about defining programs).



Note

The following example program should not be used as a standard wash procedure for cell washing as it is necessary to adjust the wash parameters, such as Z-position "MOVE CUST.", dispensing and aspirating rates, head speed, etc., according to the cell type used.

When the **Move** function is selected in combination with dispensing, the wash head will first move down to the bottom of the wells and then upwards to the overflow position. To minimize cell detachment in drip mode, it is recommended to use a customized plate definition file with elevated z-position **Bottom** of approx. $7000 \ \mu m$.



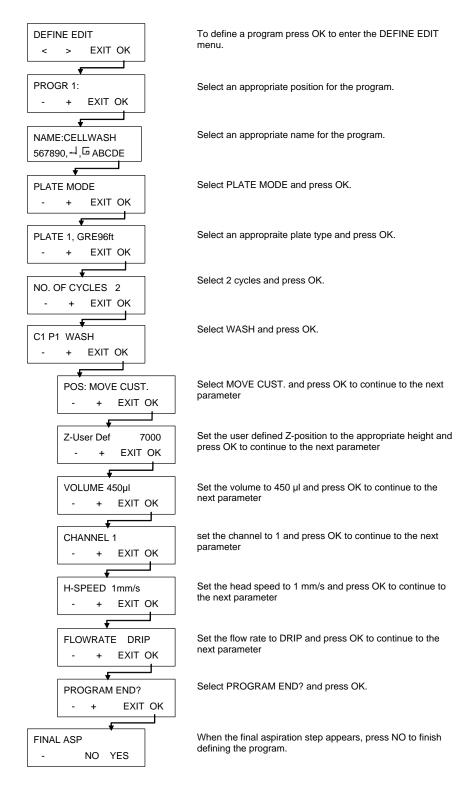


Figure 4.6 Example of a typical wash program for working with adherent cells



4.8 End of Operation

At the end of operation, the instrument can be either left switched on with the manifold in the rinsing solution or switched off after the correct maintenance has been performed.

4.8.1 Instrument Left Switched On

If the instrument will be left to stand for a short time (i.e., up to 2 hours), perform Rinse Day with distilled water or wash buffer.

- 1. Place the liquid tube into a bottle containing distilled water or wash buffer.
- 2. Use the **Rinse Day** rinsing procedure to rinse the wash system (see chapter Rinse Day on page 58).
- 3. When the rinsing procedure is completed the following message is displayed:

4. The manifold remains in the prime tray until END is pressed. Press STOP to abort the procedure (prime tray will not be aspirated).

If the instrument is left to stand for a longer period of time (e.g., overnight), use the following procedure to leave the instrument switched on with the manifold soaking in the distilled water at the end of operation:

- 1. Place the liquid tube into a bottle containing distilled water.
- 2. Use the **Rinse Night** rinsing procedure to rinse the wash system (see chapter Rinse Night on page 59).
- 3. When the rinsing procedure is completed the following message is displayed:

4. The manifold remains in the prime tray until END is pressed. Press STOP to abort the procedure (prime tray will not be aspirated).

4.8.2 Instrument Switched Off

If the instrument is to be switched off at the end of operation, the Rinse Night procedure should be performed before switching off the instrument to prevent the needles from becoming blocked.

- 1. Place the liquid tube into a bottle containing distilled water or deionized water.
- 2. Use the Rinse Night procedure to rinse the wash system (see chapter Rinse Night on page 59).
- 3. When the rinsing procedure is completed the following message is displayed:

- 4. The manifold remains in the prime tray until END is pressed. Press STOP to abort the procedure (prime tray will not be aspirated).
- 5. If the instrument will be left to stand for a long period of time (i.e. more than 1 day), prime the instrument without liquid to remove all liquid from the liquid system.
- 6. Switch the instrument off.

If the manifold is to be soaked overnight, do not switch the instrument off!



5. Programming Procedure

5.1 Introduction

The following program items are available:

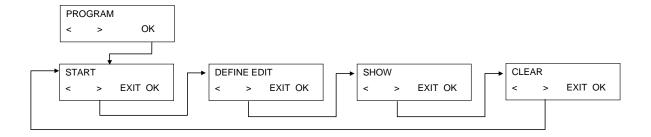
| CYCLE | The number of cycles the subsequent processing steps should be performed |
|----------------|--|
| ASP | An aspirate step removes liquid from the wells. |
| DISP | A dispense step fills the wells with liquid. |
| WASH | Liquid is dispensed and aspirated simultaneously creating a circular flow with a maximum volume of 3000 µl in one wash step for increased wash efficiency. |
| SOAK | During a soak step the liquid remains in the wells for the set time (with or without shaking). |
| USER PROMPT | User interaction is requested. |
| FINAL ASPIRATE | An aspirate step at the end of a program. |
| END PROGRAM | The program finishes. |

5.2 Program Menu

The **Program** menu has the following options:

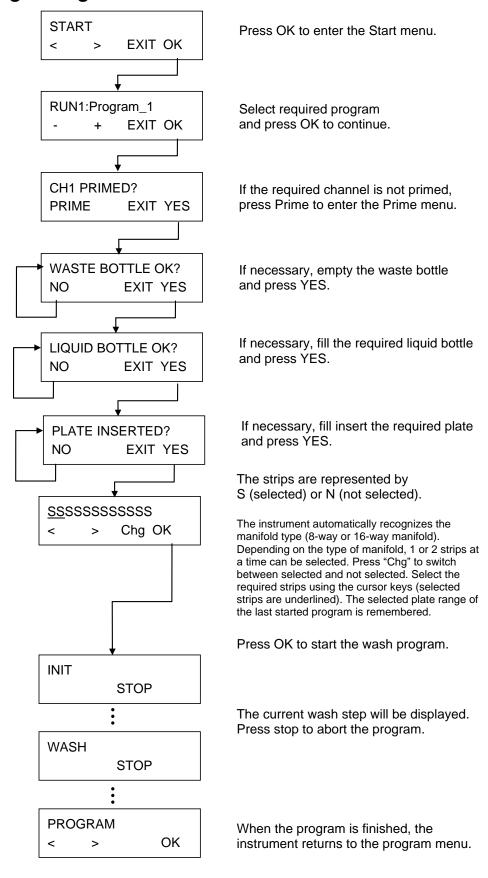
| Start | Run a defined wash program. | |
|-------------|--|--|
| Define/Edit | Define or edit a program on the instrument. | |
| Show | View the parameters of a defined program. | |
| Clear | Clear a wash program from the instrument's menu. | |

The **Program** menu has the following structure:



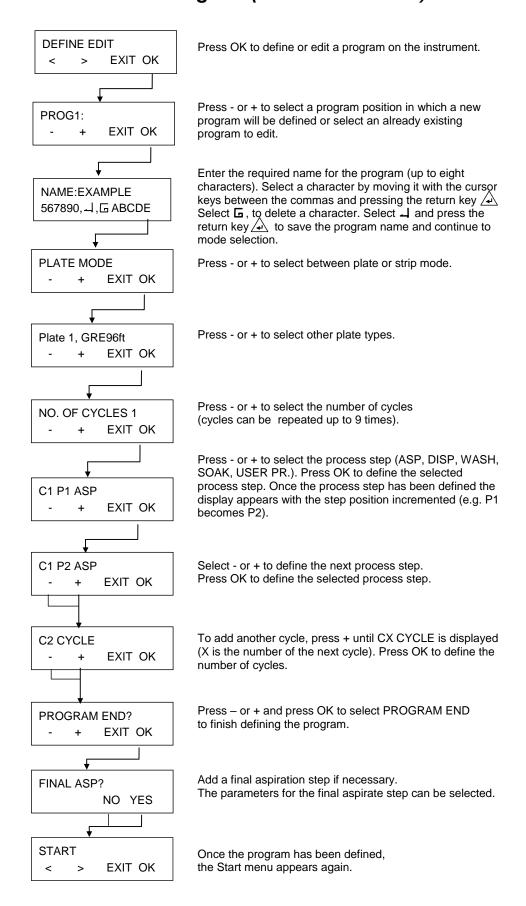


5.2.1 Starting a Program



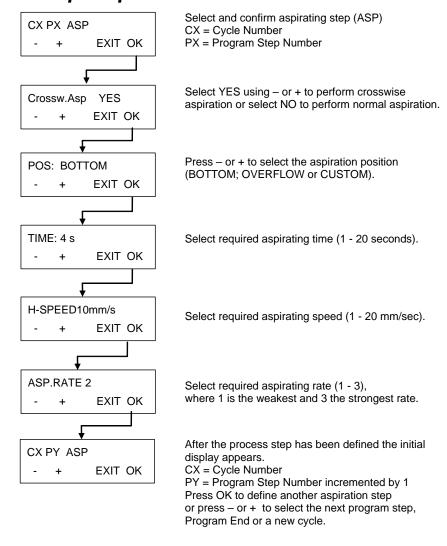


5.2.2 Define/Edit a Program (Define/Edit Menu)





5.2.3 Process Step: Aspirate





WARNING

RESIDUAL VOLUME OF <= 2 μ L / WELL CANNOT BE GUARANTEED IF NOT ALL WELLS IN A STRIP ARE FILLED WITH LIQUID. TO PREVENT CROSS CONTAMINATION THE HEAD SPEED SHOULD BE LOWERED.

Aspiration Position Diagrams

For further details, see also 4.5 Washing Positions.

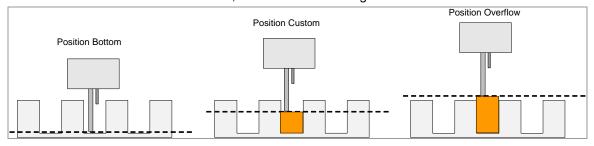
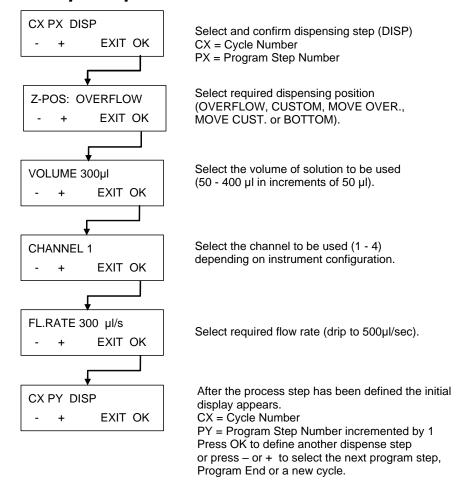


Figure 5.1 Aspiration Position Diagrams



5.2.4 Process Step: Dispense



Dispensing Position Diagrams

For further details, see also 4.5 Washing Positions.

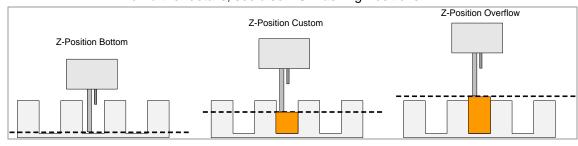


Figure 5.2 Z-Position Diagrams

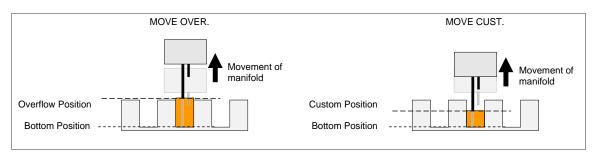
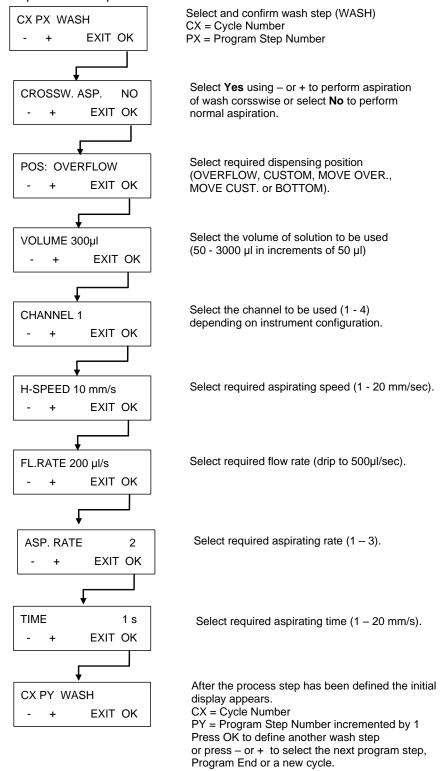


Figure 5.3 Movement Diagrams for Z-positions with MOVE



5.2.5 Process Step: Wash

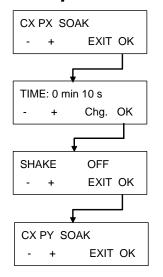
This process step is used to aspirate solution out of the wells and simultaneously dispense and aspirate the solution.



For further details, see also 4.5 Washing Positions.



5.2.6 Process Step: Soak



Select and confirm soak step (SOAK). CX = Cycle Number PX = Program Step Number

Select required soaking time using -/+ keys (0-60 min; 1-59 seconds)Press Chg. to select minutes or seconds.

The shaking speed can be selected (OFF, LOW, MEDIUM or HIGH).

After the process step has been defined the initial display appears.

CX = Cycle Number

PY = Program Step Number incremented by 1

Press OK to define another soak step
or press – or + to select the next program step,

Program End or a new cycle.

5.2.7 Process Step: User Prompt



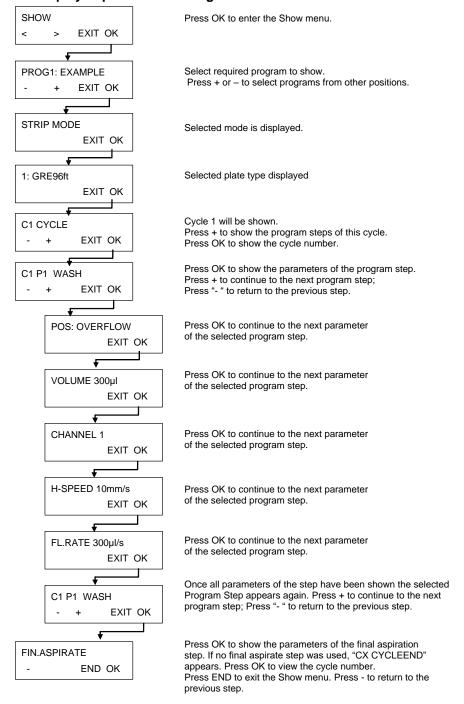
Select and confirm User Prompt strip on required position in current program.



5.3 Show Program

This submenu is used to display the parameters that have been defined for a program. An example wash program containing one cycle, one wash step and a final aspiration step will be used to demonstrate this menu.

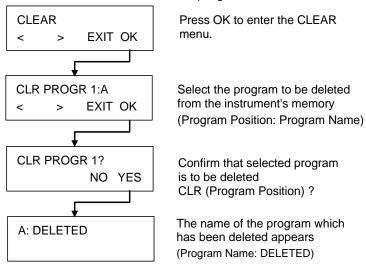
The displayed parameter settings cannot be altered in this submenu.





5.4 Clear Program

This submenu is used to clear a program from the instrument's memory.



If the program is locked it cannot be cleared and the following message is displayed:

PROGRAM IS LOCKED

The program can only be unlocked via the HydroControl software, by users with the appropriate rights.



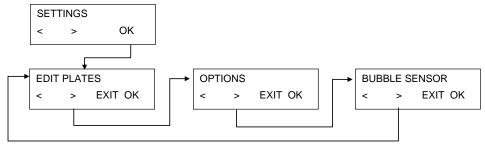
Settings Menu

6.1 Introduction

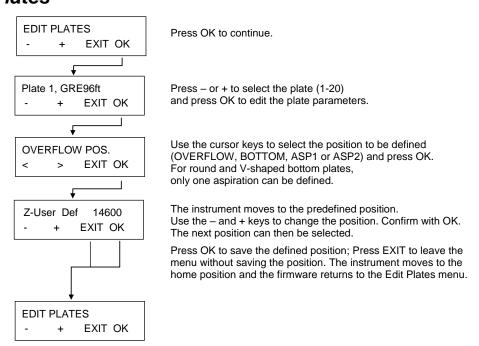
The **Settings** menu has the following options:

| Edit Plates | Adjustment procedure for setting the parameters for up to 20 different microplates. |
|---------------|--|
| Options | Depending on available options (e.g., Edit LLD Channels). |
| Bubble Sensor | The Bubble Sensor sensitivity can be set to Low , Medium , or High depending on liquids used (if this option is installed). If very foamy liquids are used the bubble sensor should be switched OFF . |

The **Settings** menu has the following structure:



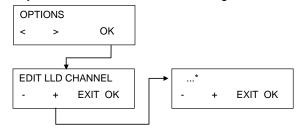
6.1.1 Edit Plates





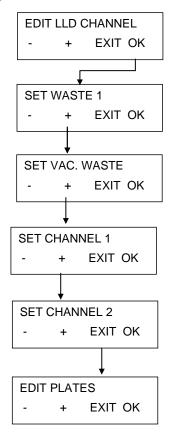
6.1.2 Options Submenu

The **Options** submenu has the following structure:



^{*} Depending on available options

Edit LLD Channel



Press OK to continue.

Press OK to activate LLD sensor for Waste 1. "CLR WASTE 1" will appear when the sensor is active. Press OK again to deactivate. Press + to move to the next sensor.

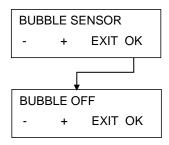
Press OK to activate LLD sensor for Vacuum Waste. "CLR VAC. WASTE" will appear when the sensor is active. Press OK again to deactivate. Press + to move to the next sensor.

Press OK to activate LLD sensor for Channel 1. "CLR CHANNEL 1" will appear when the sensor is active. Press OK again to deactivate. Press + to move to the next sensor.

Press OK to activate LLD sensor for Channel 2. "CLR CHANNEL 2" will appear when the sensor is active. Press OK again to deactivate. Press + to move to the next sensor.

Press EXIT when all sensors are set as desired.

6.1.3 Bubble Sensor



Press OK to continue.

Press – or + to select between OFF, LOW, MEDIUM and HIGH. Press OK to confirm.

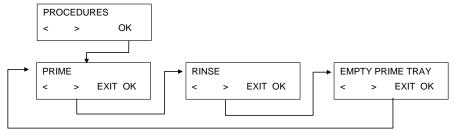


6.2 Procedures Menu

The **Procedures** menu has the following options:

| Rinse | Start rinse procedures. |
|-------------------------|--|
| Prime | Start prime procedures. |
| Empty Prime Tray | Aspirate liquid out of the prime tray. |

The **Procedures** menu has the following structure:



6.2.1 Rinse

For details, see chapter 8.1 Rinsing.

6.2.2 Prime

For details, see chapter 8.2 Priming.

6.2.3 Empty Prime Tray

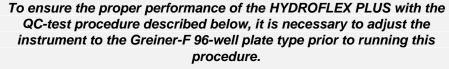
Press OK and the prime tray will be aspirated.



7. Performance Testing/ Quality Control Using Gravimetrical Method

This chapter describes a QC-procedure for the HYDROFLEX PLUS allowing to check the residual volume and dispense accuracy of the instrument by weighing a Greiner-F 96-well plate (flat-bottom) on a calibrated lab balance.

Note





If this adjustment procedure is not performed properly, this might result in high levels of residual volume left per well and can lead to failure of the performance test.

For details on how to adjust the HYDROFLEX PLUS to the type of microplate or strip-plate used, see chapter 6 Settings Menu of this manual.

Necessary Tools

- Calibrated lab-balance including cover for wind-protection, capable of reading milligrams
- Greiner F 96-well, flat-bottom, compact microplate
- Small plastic syringe to aliquot Tween 20 solution
- Clean 2.5-liter wash buffer bottle supplied with HYDROFLEX PLUS
- 5-liter waste bottle supplied with HYDROFLEX PLUS

Necessary Chemicals

- 1 liter of distilled water (alternatively deionized water can be used)
- 0.1% Tween 20 solution

Preparation of Solution for QC Procedure

- Prepare a 0.1% Tween 20 solution
 (1 liter of distilled or deionized water and 1 ml Tween 20).
- Fill solution in empty 2.5-liter wash-buffer bottle supplied with the HYDROFLEX PLUS, mix thoroughly and connect tubing to the appropriate channel on the rear panel of the instrument.



Note

The solution for the QC-procedure can be stored for a maximum of 1 month under refrigeration. If the solution becomes turbid, it must be disposed of and replaced with a fresh solution.



Programs Necessary for QC Procedure

Define the following programs to perform QC procedures:

QCDISP

- 1. Plate Mode
- 2. Plate Type: Greiner 96-well flat bottom
- 3. One Cycle
- 4. One Dispense step with the following parameters:
 - POS: OVERFLOW
 - VOLUME 200 μl
 - o CHANNEL 1
 - DISPENSE RATE 200 μl/s

QCASP

- 1. Plate Mode
- 2. Plate Type: Greiner 96-well flat bottom
- 3. One Cycle
- 4. One Aspiration step with the following parameters:
 - o Crossw. ASP
 - o POS: BOTTOM
 - o TIME: 4 s
 - o H-SPEED 10 mm/s
 - ASP.RATE 3

Residual Volume Check



Note

Ensure that the lab balance is calibrated. Ensure that the HYDROFLEX PLUS and the waste and liquid bottles are placed at the same height on a vibration-free surface according to the manufacturer's guidelines.

Record serial number of lab balance and the HYDROFLEX PLUS used, as well as name of operator for documentation purposes.

- 1. Connect HYDROFLEX PLUS to waste bottle as described in this manual in 2.4.2 Rear Panel Connections.
- Connect wash-buffer bottle containing solution for QC-procedure to channel 1
 of HYDROFLEX PLUS as described in this manual in 2.4.2 Rear Panel
 Connections.
- 3. Prime channel 1 of the HYDROFLEX PLUS for 10 seconds as described in 8.2 Priming.
- 4. Weigh empty and dry Greiner96ft specified above on lab-balance and record TARE.
- 5. Load Greiner-F microplate on HYDROFLEX PLUS to be checked and start program QCDISP to dispense 200µl of liquid into each well.
- 6. Weigh the filled microplate and record the weight. Check dispensing accuracy visually.
- 7. Start program QCASP to remove the dispensed liquid out of the wells.



8. Place Greiner-F plate back onto lab balance and record weight of remaining liquid.

Interpretation of Results for Residual Volume Check

- 1. Pass: average residual volume per plate has to be <= 0.190 grams.
- 2. Fail: average residual volume per plate > 0.190 grams.

Interpretation of Results for Dispense Accuracy

- 1. Pass: dispense accuracy per plate must be >= 18.8 grams and <= 19.6 grams.
- 2. Fail: dispense accuracy is outside of the above-mentioned range.

Troubleshooting the QC Procedure

- 1. If the HYDROFLEX PLUS has failed the above tests, perform thorough cleaning step using RINSE NIGHT procedure (see Rinse Night on page 59).
- 2. Disinfect manifold according to procedure described in chapter 8.8 Instrument Disinfection of this manual.
- 3. Clean the manifold using the provided cleaning-tool for aspiration needles.
- 4. Repeat QC-procedure mentioned above.
- 5. If results still fail, inform service technician.





WARNING

ALL PARTS OF THE INSTRUMENT THAT COME INTO CONTACT WITH POTENTIALLY INFECTIOUS MATERIAL MUST BE TREATED AS POTENTIALLY INFECTIOUS AREAS.

IT IS ADVISABLE TO ADHERE TO APPLICABLE SAFETY PRECAUTIONS, (INCLUDING THE WEARING OF POWDER-FREE GLOVES, SAFETY GLASSES AND PROTECTIVE CLOTHING) TO AVOID POTENTIAL INFECTIOUS DISEASE CONTAMINATION WHEN PERFORMING CLEANING PROCEDURES AND ALSO WHEN MAKING ADJUSTMENTS TO THE INSTRUMENT.



8. Maintenance and Cleaning

8.1 Rinsing

Rinsing is performed to flush the liquid system and to prevent needle blockages. During the rinse procedures, the needles are soaked in the prime tray.

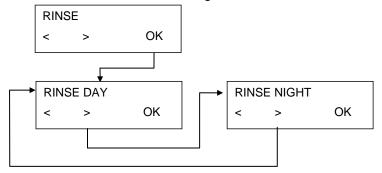
The rinsing procedure should be performed, if the instrument is left to stand or is switched off at the end of operation.

8.1.1 Rinse Menu

The Rinse menu has the following options:

| 5 1 | | | |
|-------------|--|--|--|
| Rinse Day | Perform Rinse Day , if the instrument will be left to stand for a short time (up to two hours). When Rinse Day is selected, a Time (how long the instrument rinses before the manifold is soaked in the prime tray) can also be selected (5 - 99 seconds). Rinse Day can be performed with wash buffer or distilled water. | | |
| Rinse Night | Perform Rinse Night for thorough rinsing and if the instrument will be left to stand for a longer time with the manifold soaking in distilled or deionized water (e.g., overnight). When Rinse Night is selected the Time cannot be set. Rinse Night must be performed with distilled water only. | | |

The Rinse menu has the following structure:



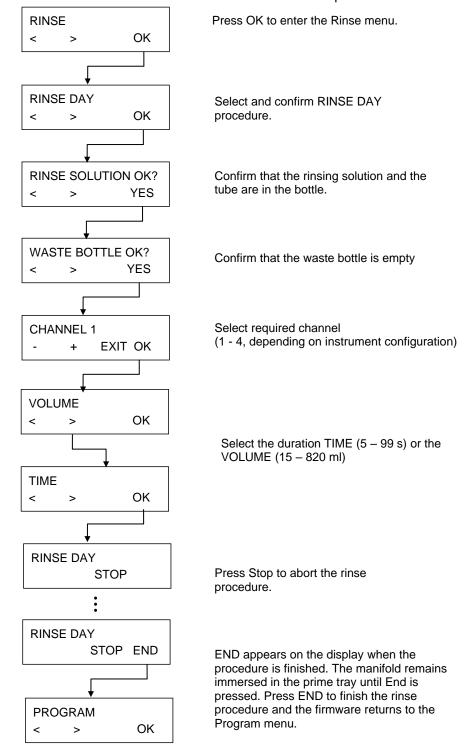


Rinse Day

This procedure is used to rinse the liquid system if the instrument is to be left to stand for up to 2 hours, for longer times use Rinse Night (see Rinse Night on page 59).

Alternatively, it can be used to rinse the liquid system after the instrument has been left for a long time.

Distilled water or a wash buffer can be used with this procedure.

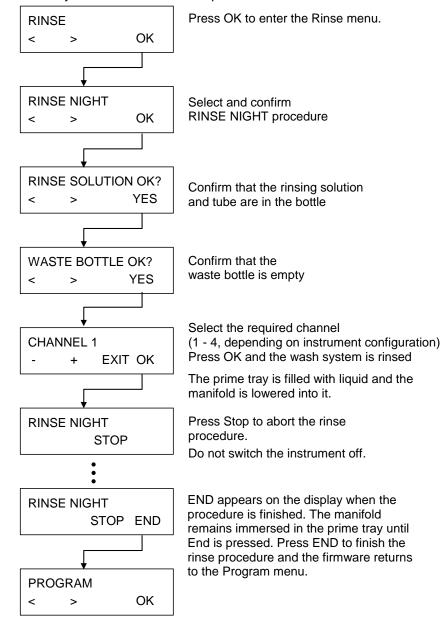




Rinse Night

This procedure is used to thoroughly rinse the liquid system and then soak the manifold in the prime tray full of solution at the end of operation.

Use only distilled water with this procedure.





8.2 Priming

Priming is performed to fill the liquid system of the HYDROFLEX PLUS with liquid and to remove all air from the tubes. A priming step must also be performed when switching between buffers.

If different wash buffers are used in a wash program, the instrument performs a prime step automatically before switching to the next liquid. A prime step is also automatically performed before a program is started.

If the instrument will be left to stand for a longer time, priming must be performed to remove all liquid from the system. For this purpose, remove all tubes from the liquid bottles.

WARNING

BEFORE THE INSTRUMENT IS USED, ALL DISPENSING CHANNELS NEEDED FOR THE WASH PROGRAM MUST BE PRIMED TO FILL THE LIQUID SYSTEM WITH THE REQUIRED LIQUID.



IF THE PRIMING PROCEDURE IS NOT PERFORMED PROPERLY, THIS CAN RESULT IN INSUFFICIENT WASHING OF THE WELLS AND CAN SERIOUSLY AFFECT ASSAY PERFORMANCE.

ENSURE THAT THE BOTTLE OF THE PRIMING SOLUTION IS ALWAYS FULL AT THE BEGINNING OF THE PRIMING PROCEDURE AND CHECK THAT THE INLET FILTERS IN THE LIQUID TUBES ARE CLEAN.

STOP

CAUTION

ENSURE THAT THE DISPENSING AND ASPIRATION PUMPS ARE NOT RUN FOR LONGER THAN A FEW MINUTES WITHOUT LIQUID OR THEY WILL BE DAMAGED.

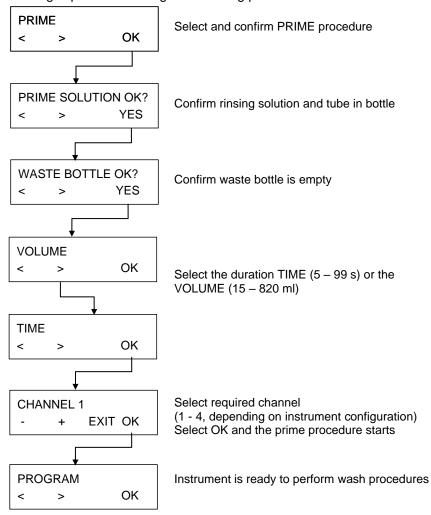


CAUTION

DO NOT USE THE INSTRUMENT TO ASPIRATE OR DISPENSE ANY ACIDIC SOLUTIONS AS THIS COULD DAMAGE THE INSTRUMENT.



Priming is performed using the following procedure:





8.3 Cleaning Procedures





WARNING

ALL PARTS OF THE INSTRUMENT THAT COME INTO CONTACT WITH POTENTIALLY INFECTIOUS MATERIAL MUST BE TREATED AS POTENTIALLY INFECTIOUS AREAS.

IT IS ADVISABLE TO ADHERE TO APPLICABLE SAFETY PRECAUTIONS, (INCLUDING THE WEARING OF POWDER-FREE GLOVES, SAFETY GLASSES AND PROTECTIVE CLOTHING) TO AVOID POTENTIAL INFECTIOUS DISEASE CONTAMINATION WHEN PERFORMING CLEANING PROCEDURES AND ALSO WHEN MAKING ADJUSTMENTS TO THE INSTRUMENT.

The most important cleaning procedure for this instrument is to rinse the liquid system with distilled water before the instrument is left to stand or switched off at the end of each day.

The manifold should be removed and thoroughly cleaned at least once every six months or whenever one or more of the needles are blocked.

8.3.1 Cleaning the Cover and Display

The outer surface of the instrument and the display may be cleaned periodically using a tissue moistened with a mild detergent solution (see chapter 8.5 Preventive Maintenance Plan).



CAUTION

NEVER USE ACETONE AS IT WILL DAMAGE THE COVERS.

8.3.2 Cleaning the Liquid System

To clean the liquid system, perform Rinse and Prime procedures as described in chapter 8.5 Preventive Maintenance Plan.



CAUTION

IF THE MANIFOLD IS NOT RINSED, THE NEEDLES WILL BECOME BLOCKED.

IF THIS OCCURS, THE MANIFOLD WILL NEED EXPENSIVE REPAIRS OR WILL HAVE TO BE REPLACED.



The manifold can be cleaned using:

- 1. The supplied cleaning needles (accessory box). The small cleaning needle is for the dispensing needles and the large cleaning needle is for the aspirating needles.
 - Carefully push the cleaning needles into the aspirating and dispensing needles. Rinse the manifold block with distilled water to ensure that all particles have been removed.
- 2. A gentle ultrasonic bath of warm distilled water for 15 minutes
- 3. Autoclaving (max. 130 °C, max. five times, manifold must be removed from the instrument).
- 4. Reinstall the manifold if necessary (see chapter 8.6 Replacing the Manifold).
- 5. After the manifold has been cleaned, switch the instrument on and perform the priming procedure using distilled water.



CAUTION

IF ADDITIONAL CLEANING IS REQUIRED, USE THE DELIVERED CLEANING NEEDLES AND ADHERE TO APPLICABLE SAFETY PRECAUTIONS, (INCLUDING THE WEARING OF POWDER-FREE GLOVES, SAFETY GLASSES AND PROTECTIVE CLOTHING) TO AVOID POTENTIAL INFECTIOUS DISEASE CONTAMINATION.

Cleaning Waste Bottles

Before cleaning the waste bottles empty them according to disposal regulations (see 8.9.3 Disposal of Operating Material).

The bottles must be cleaned regularly depending on the applications, using a mild detergent.



WARNING

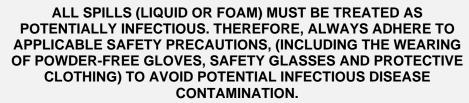
WHEN HANDLING WASTE BOTTLES, IT IS ADVISABLE TO ADHERE TO APPLICABLE SAFETY PRECAUTIONS, (INCLUDING THE WEARING OF POWDER-FREE GLOVES, SAFETY GLASSES AND PROTECTIVE CLOTHING) TO AVOID POTENTIAL INFECTIOUS DISEASE CONTAMINATION.



8.4 Liquid or Foam Spills

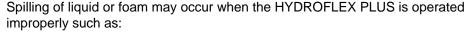
WARNING

ALWAYS SWITCH-OFF THE HYDROFLEX PLUS BEFORE REMOVING ANY KIND OF SPILLS ON THE INSTRUMENT.





IF THE SPILL OCCURS IN THE INSTRUMENT, A SERVICE TECHNICIAN IS REQUIRED.



- 1. Used microplate not matching installed manifold.
- 2. Positions of the strips in the strip-plate do not match the positions defined in the program used for processing.
- 3. Plate parameters not properly adjusted.
- 4. Waste bottle not emptied when liquid level or foam level reaches maximum filling level.
- No anti-foaming agent used with wash buffers showing strong tendency to foam

Always remove spills immediately after they have occurred. Use paper tissue to soak-up spills and wipe-surface dry.





WARNING WASTE BOTTLE - LIQUID LEVEL

MAKE SURE THAT THE LIQUID LEVEL OF THE WASTE BOTTLE IS ALWAYS KEPT BELOW THE MAXIMUM LEVEL INDICATED ON THE BOTTLE TO AVOID POTENTIAL OVERFLOW.

THE CONTENTS OF WASTE BOTTLE ARE POTENTIALLY INFECTIOUS, SO IT IS IMPORTANT TO WEAR PROTECTIVE CLOTHING (GLOVES, LAB COAT AND SAFETY GLASSES) WHEN EMPTYING / HANDLING A WASTE BOTTLE.



8.5 Preventive Maintenance Plan





WARNING

ALL PARTS OF THE INSTRUMENT THAT COME INTO CONTACT WITH POTENTIALLY INFECTIOUS MATERIAL MUST BE TREATED AS POTENTIALLY INFECTIOUS AREAS.

IT IS ADVISABLE TO ADHERE TO APPLICABLE SAFETY PRECAUTIONS, (INCLUDING THE WEARING OF POWDER-FREE GLOVES, SAFETY GLASSES AND PROTECTIVE CLOTHING) TO AVOID POTENTIAL INFECTIOUS DISEASE CONTAMINATION WHEN PERFORMING CLEANING PROCEDURES AND ALSO WHEN MAKING ADJUSTMENTS TO THE INSTRUMENT.





WARNING

RISK OF FIRE AND EXPLOSION!

PRIOR TO CLEANING THE OUTER SURFACE OF THE INSTRUMENT AND THE DISPLAY, SWITCH OFF THE INSTRUMENT AND DISCONNECT IT FROM THE MAIN POWER SUPPLY!

8.5.1 Daily

- 1. Prime the liquid system if necessary.
- 2. Perform Rinse Day with distilled water or wash buffer if the instrument is left to stand for a short time (up to 2 hours).
- 3. Perform Rinse Night only with distilled water if the instrument is left to stand overnight.
- 4. If necessary (due to particles, soiling, etc.), prime the instrument several times with distilled water.
- 5. If the instrument will be left to stand for a longer period of time (more than one day), prime with distilled water and then prime without liquid.

8.5.2 Weekly

- 1. Perform Rinse Night with distilled water.
- 2. Prime the instrument without liquid to empty the entire liquid system.
- 3. Check the filter(s) in the liquid bottle(s) for particles and rinse liquid filter(s) with distilled water.
- 4. Clean the plate carrier guide bar with 70% ethanol.



8.5.3 **Every Six Months**

Clean the plate carrier guide bar with 70% ethanol.

Check the centering mechanism of the plate carrier and clean if necessary, with 70 % ethanol.

Clean the manifold aspirating and dispensing needles using the cleaning needles supplied with the instrument.



Note

Clean the aspirating and dispensing needles periodically or immediately if they become clogged with particles or crystals.

Yearly (Service Engineer Required) 8.5.4

The yearly maintenance is performed by the service engineer.

Replacing the Manifold 8.6



WARNING

AFTER THE INSTRUMENT HAS BEEN USED, THE MANIFOLD MAY BE INFECTIOUS!

BEFORE THE MANIFOLD IS REMOVED IT MUST BE THOROUGHLY DISINFECTED.

IT IS ADVISABLE TO ADHERE TO APPLICABLE SAFETY PRECAUTIONS, (INCLUDING THE WEARING OF POWDER-FREE GLOVES, SAFETY GLASSES AND PROTECTIVE CLOTHING) TO AVOID POTENTIAL INFECTIOUS DISEASE CONTAMINATION.





WARNING

PRIME THE INSTRUMENT WITHOUT LIQUID TO EMPTY ALL LIQUID FROM THE SYSTEM, BEFORE REMOVING THE MANIFOLD.



8.6.1 General Description of the Manifold

The HYDROFLEX PLUS is delivered with the manifold already installed. The instrument can be used with the following types of manifolds:

- Standard 8-way and
- Standard 16-way

The manifolds for the HYDROFLEX PLUS have the same basic components:

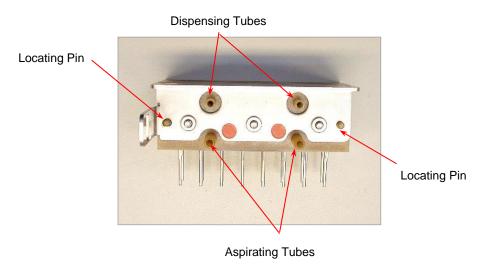


Fig. 8.1 The Rear of the Manifold



Note
Always wear powder free gloves when handling the manifold.

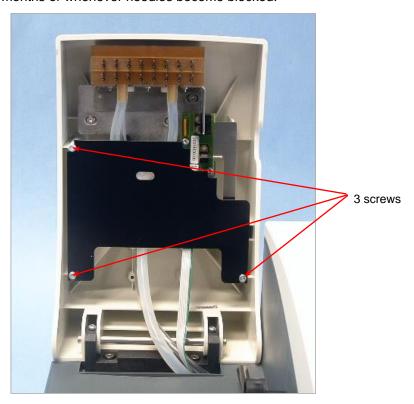


8.6.2 Removing the Manifold

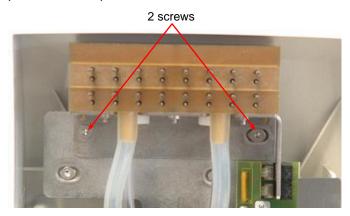


WARNING PRIME WITHOUT LIQUID TO REMOVE ANY LIQUIDS FROM THE TUBING SYSTEM.

The manifold should be removed and thoroughly cleaned at least once every 6 months or whenever needles become blocked.



1. Lift the manifold arm and remove the black manifold arm guard plate by sliding it out from behind the three screws – the screws do not need to be removed to perform this step.



- 2. Lift the manifold arm and remove the two screws that attach the manifold to the instrument using the Allen key provided.
- 3. Carefully pull the tubing off the connectors on the rear of the manifold and remove the manifold.



8.6.3 Installing the Manifold





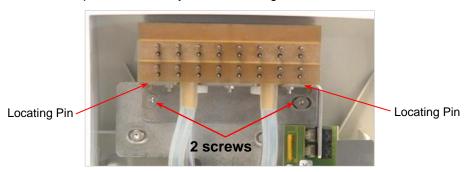
WARNING

ALL PARTS OF THE INSTRUMENT THAT COME INTO CONTACT WITH POTENTIALLY INFECTIOUS MATERIAL MUST BE TREATED AS POTENTIALLY INFECTIOUS AREAS.

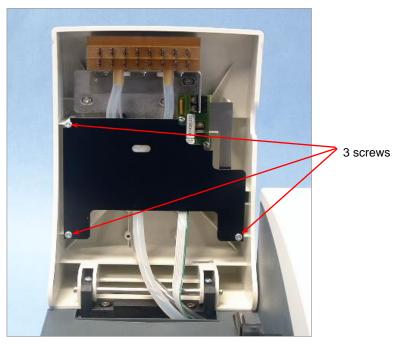
IT IS ADVISABLE TO ADHERE TO APPLICABLE SAFETY PRECAUTIONS, (INCLUDING THE WEARING OF POWDER-FREE GLOVES, SAFETY GLASSES AND PROTECTIVE CLOTHING) TO AVOID POTENTIAL INFECTIOUS DISEASE CONTAMINATION WHEN PERFORMING CLEANING PROCEDURES AND ALSO WHEN MAKING ADJUSTMENTS TO THE INSTRUMENT.

The standard manifolds are installed using the following procedure:

- 1. Lift the manifold arm.
- 2. Carefully fit the manifold onto the manifold arm and ensure that the locating pins are correctly inserted through the holes in the bracket.



- 3. Tighten the manifold into place using the two screws using the Allen key provided.
- 4. Fit the dispensing tubes (marked blue) onto the top connector on the rear of the manifold.
- 5. Fit the aspirating tubes (marked red) onto the two bottom connectors on the rear of the manifold (marked with red labels).





- Reattach the black manifold guard plate by sliding it into place behind the three screws.
- 7. Lower the manifold arm and prime the instrument before starting a wash program.

8.7 Replacing the Plate Carrier





WARNING

ALL PARTS OF THE INSTRUMENT THAT COME INTO CONTACT WITH POTENTIALLY INFECTIOUS MATERIAL MUST BE TREATED AS POTENTIALLY INFECTIOUS AREAS.

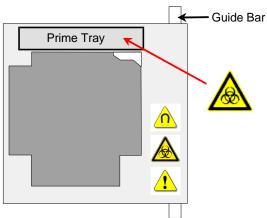
IT IS ADVISABLE TO ADHERE TO APPLICABLE SAFETY PRECAUTIONS, (INCLUDING THE WEARING OF POWDER-FREE GLOVES, SAFETY GLASSES AND PROTECTIVE CLOTHING) TO AVOID POTENTIAL INFECTIOUS DISEASE CONTAMINATION WHEN PERFORMING CLEANING PROCEDURES AND ALSO WHEN MAKING ADJUSTMENTS TO THE INSTRUMENT.

The instrument is delivered with the plate carrier already installed. If the plate carrier is removed, for example for cleaning, it can be replaced using the following procedure:

- 1. Switch the instrument off.
- 2. Lift the manifold arm
- 3. Slightly tilt the plate carrier towards the right.



4. Carefully slide the plate carrier with the prime tray at the rear over the guide bar.



The plate carrier must be slightly tilted so that it goes over the pin that activates the automatic microplate centering mechanism.

To reinstall the plate carrier, follow the procedure listed below:

- 1. Push the plate carrier so that it is fully inserted into the instrument.
- 2. Lower the plate carrier.
- 3. Lower the manifold arm.



8.8 Instrument Disinfection





WARNING

THE DISINFECTION PROCEDURE SHOULD BE PERFORMED ACCORDING TO NATIONAL, REGIONAL, AND LOCAL REGULATIONS.





WARNING

ALL PARTS OF THE INSTRUMENT THAT COME INTO CONTACT WITH POTENTIALLY INFECTIOUS MATERIAL MUST BE TREATED AS POTENTIALLY INFECTIOUS AREAS.

IT IS ADVISABLE TO ADHERE TO APPLICABLE SAFETY PRECAUTIONS, (INCLUDING THE WEARING OF POWDER-FREE GLOVES, SAFETY GLASSES AND PROTECTIVE CLOTHING) TO AVOID POTENTIAL INFECTIOUS DISEASE CONTAMINATION WHEN PERFORMING THE DISINFECTION PROCEDURE.

It is very important that the instrument is thoroughly disinfected before it is removed from the laboratory or any servicing is performed on it.

Before the instrument is returned to the service center for service or repair, it must be disinfected, and a disinfection certificate completed by the operating authority. If a disinfection certificate is not supplied, the instrument may not be accepted by the service center or it may be held by the customs authorities.

8.8.1 Disinfection Solutions

Use the following disinfection solutions for the disinfection procedure:

- Decon 90 (Decon Laboratories Limited)
- Decon neutracon (Decon Laboratories Limited)
- Microcide SQ (Global Biotechnologies)
- Ethanol





WARNING

RISK OF FIRE AND EXPLOSION!

ETHANOL IS FLAMMABLE AND WHEN IMPROPERLY HANDLED CAN LEAD TO EXPLOSIONS. PROPER LABORATORY SAFETY PRECAUTIONS MUST BE OBSERVED.



8.8.2 Disinfection Procedure

The instrument should be disinfected using one of the solutions mentioned in the previous chapter.



WARNING RISK OF FIRE AND EXPLOSION!

PRIOR TO CLEANING THE OUTER SURFACE OF THE INSTRUMENT AND THE DISPLAY, SWITCH OFF THE INSTRUMENT AND DISCONNECT IT FROM THE MAIN POWER SUPPLY!



CAUTION

BEFORE STARTING THE DISINFECTION PROCEDURE
USE A RINSE PROCEDURE (RINSE DAY)
WITH DISTILLED OR DEIONIZED WATER (LAB QUALITY) TO FLUSH
THE SYSTEM.





WARNING

THE DISINFECTION PROCEDURE SHOULD BE PERFORMED IN A WELL-VENTILATED ROOM BY AUTHORIZED TRAINED PERSONNEL WEARING DISPOSABLE POWDER-FREE GLOVES, PROTECTIVE GLASSES AND PROTECTIVE CLOTHING.

Please note that the disinfectant can influence the performance of your instrument if it comes into contact with the electronics!

The following procedure should be used to disinfect the instrument:

- 1. Wear protective powder-free gloves, protective glasses, and protective clothing.
- 2. Prepare an autoclave bag for all disposables used during the disinfection procedure, label it with autoclave tape and put it in the autoclave or follow the procedure defined in chapter 8.9.3 Disposal of Operating Material.
- 3. Prime the liquid system with disinfectant. Perform the Rinse Night procedure with disinfectant solution and stop the procedure after five hours.
- 4. Switch off the instrument and disconnect the instrument from the mains power supply.
- Disconnect the instrument from any accessories that are used for example: Liquid Level Detection System, computer, etc. Accessories that should be shipped together with the instrument have to be included in the disinfection procedure.
- 6. Carefully spray the disinfectant solution (or use a disposable soft tissue paper towel soaked in the disinfectant) on all outer surfaces of the instrument.
- 7. After a minimum contact time of 10 minutes, repeat step 6 of this procedure.
- 8. Wipe dry the outer surfaces of the instrument.
- 9. Pack the instrument and its accessories.
- 10. Wash your hands with a mild detergent and then disinfect them.
- 11.Complete a disinfection certificate and attach it to the outside of the box so that it is clearly visible. (See below for an example of the disinfection certificate).



Disinfection Certificate

A disinfection certificate label **MUST** be completed and attached to the top of the package (visible from the outside of the shipping container!) in which the instrument is returned, before shipping it to the service center for service or repair.

The instrument **MUST** be disinfected at the operating authority's site.

The disinfection procedure must be performed in a well-ventilated room by authorized and trained personnel wearing disposable powder-free gloves, protective glasses, and protective clothing.

The disinfection procedure should be performed according to national, regional, and local regulations.

| - Disinfection Certificate - |
|--|
| I declare that the instrument in this package has been decontaminated or disinfected to remove or inactivate any biological material, which could be dangerous to service personnel, or that it has never been exposed to any hazardous biological material. |
| Contact person |
| Company: |
| Function: |
| Phone/Fax: |
| E-mail: |
| Date of decontamination: |
| Method of decontamination applied: |
| |
| Date: |
| Signature: |
| |



8.9 Disposal of Instrument

8.9.1 Introduction

This chapter gives instructions on how to lawfully dispose of waste material accumulating in connection with the HYDROFLEX PLUS.



CAUTION

OBSERVE ALL FEDERAL, STATE AND LOCAL ENVIRONMENTAL REGULATIONS.



ATTENTION

DIRECTIVE 2012/19/EU ON WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT (WEEE)

NEGATIVE ENVIRONMENTAL IMPACTS ASSOCIATED WITH THE TREATMENT OF ELECTRICAL AND ELECTRONIC EQUIPMENT WASTE

- DO NOT TREAT ELECTRICAL AND ELECTRONIC EQUIPMENT AS UNSORTED MUNICIPAL WASTE.
- COLLECT WASTE FROM ELECTRICAL AND ELECTRONIC EQUIPMENT SEPARATELY.

8.9.2 Disposal of Packing Material

According to Directive 94/62/EC on packaging and packaging waste, the manufacturer is responsible for the disposal of packing material.

Returning Packing Material

If you do not intend to keep the packing material for future use, e.g. for transport and storage purposes:

Return the packaging of the product, spare parts and options via the field service engineer to the manufacturer.



8.9.3 Disposal of Operating Material





WARNING

CHEMICAL AND BIOLOGICAL HAZARDS CAN BE ASSOCIATED WITH THE WASTE MATERIAL (MICROPLATE) OF PROCESSES RUN ON THE HYDROFLEX PLUS.

TREAT THE USED MICROPLATE, WASTE BOTTLE, PRIME TRAY ON THE PLATE CARRIER, DISPOSABLES AND ALL SUBSTANCES USED, IN ACCORDANCE WITH GOOD LABORATORY PRACTICE GUIDELINES.

INQUIRE ABOUT APPROPRIATE COLLECTING POINTS AND APPROVED METHODS OF DISPOSAL IN YOUR COUNTRY, STATE OR REGION.

8.9.4 Disposal of the HYDROFLEX PLUS

Please contact your local Tecan service representative before disposing of the instrument.



CAUTION

ALWAYS DISINFECT THE INSTRUMENT BEFORE DISPOSAL.

| Pollution degree | 2 (IEC/EN 61010-1) |
|--------------------|--------------------|
| Method of Disposal | Contaminated Waste |





WARNING

DEPENDING ON THE APPLICATIONS, PARTS OF THE HYDROFLEX PLUS MAY HAVE BEEN IN CONTACT WITH BIOHAZARDOUS MATERIAL.

- MAKE SURE TO TREAT THIS MATERIAL ACCORDING TO THE APPLICABLE SAFETY STANDARDS AND REGULATIONS.
- ALWAYS DECONTAMINATE ALL PARTS BEFORE DISPOSAL (I.E. CLEAN AND DISINFECT).



Trouble Shooting and Error Messages

9.1 Errors

The following errors can occur, which will not yield an error message from the standard instrument's firmware:

| Error Description | Possible Causes | See Chapter |
|----------------------------|-----------------------------|---|
| Display and LED dark | Fuse is defective. | Contact your local Service Representative |
| No or incorrect dispensing | Dispensing needles blocked. | 8.3.2 Cleaning the Liquid System |
| No or incorrect aspirating | Aspirating needles blocked. | 8.3.2 Cleaning the Liquid System |

9.2 Error Messages

9.2.1 Standard Instrument: Error Messages

Plate Error

If the plate sensor does not recognize the plate or no plate is inserted on the plate carrier, the following message is displayed:

Press **OK** and insert the plate correctly on the plate carrier

Program Too Big Error

If the program has been defined with more than 60 process steps (each cycle is worth 2 steps), the following message is displayed:

Press **OK** and define a program with less than 60 process steps.

Transport Error

If the instrument cannot move the plate carrier, the following message is displayed:



Press **OK** to remove the error message and the instrument returns to the standby mode.

Check that the plate carrier is correctly inserted and that the plate carrier system is clear.



Manifold Arm Error

If the manifold arm cannot be lowered correctly due to obstruction of its normal movement, the following message is displayed:

Press **EXIT** to remove the error message and to return to the standby mode.

Check that the microplate is correctly inserted into the plate carrier.

Check that the manifold arm is not blocked.

Check if the needles are catching on the side of the microplate; use the Settings menu to adjust the positions for that particular type of microplate.

Sensor Defect Error

The following message error is displayed when the dispensing pump or the dispensing sensor is defective.

Press **OK** to remove the error message and to return to the standby mode.

Make sure that drip mode has not been selected using distilled water. Change the program parameters.

If the program parameters are correct and the error continues, call the service technician.

9.2.2 Liquid Level Detection: Error Messages

Waste Bottle Full at Start

If the waste bottle is full, the following message is displayed:

Press **OK** to remove the message and return to the start and the following message is displayed:

Empty the waste bottle and restart the program.

Waste Bottle Full during Procedure

If the waste bottle becomes full during the washing procedure, the instrument will beep; however, no error message is displayed during or after the instrument has completed the washing procedure.



CAUTION

THE INSTRUMENT DOES NOT STOP A PROCEDURE WHEN THE WASTE BOTTLE BECOMES FULL.







WARNING

WASTE BOTTLE - FOAMING

THE LIQUID LEVEL SENSOR IS UNABLE TO DETECT FOAM;
THEREFORE, IT IS IMPORTANT THAT THE WASTE BOTTLE IS
EMPTIED AS SOON AS THE FOAM LEVEL HAS REACHED THE
MAXIMUM FILLING LEVEL INDICATED ON THE WASTE BOTTLE.

WARNING

WASTE BOTTLE - FOAMING

WHEN USING WASH BUFFERS THAT SHOW A STRONG TENDENCY OF FOAMING, EMPTY THE WASTE BOTTLE AS SOON AS THE FOAM-LEVEL HAS REACHED THE MAXIMUM FILLING LEVEL INDICATED ON THE WASTE BOTTLE. ADDITIONALLY, ADD A COMMERCIALLY AVAILABLE ANTI-FOAMING AGENT (SUCH AS SILICONE OIL) TO THE EMPTY WASTE BOTTLE TO REDUCE FOAMING.





IF FOAMING CONTINUES TO BE A PROBLEM, WE RECOMMEND SWITCHING TO A LARGER WASTE BOTTLE (NOT PROVIDED WITH THE HYDROFLEX PLUS) AND ADDITIONALLY INCREASE THE CONCENTRATION OF ANTI-FOAMING AGENT IN THE WASTE BOTTLE. TO HELP FACILITATE BREAKDOWN OF THE FOAM IN THE WASTE BOTTLE, CAREFULLY SWIRL THE WASTE BOTTLE FROM TIME-TO-TIME TO IMPROVE MIXING BETWEEN FOAM LAYER AND ANTI-FOAMING AGENT.

REFILL ANTI-FOAMING AGENT AFTER EMPTYING WASTE BOTTLE. FOR EXAMPLE, WHEN USING THE WACKER ANTI-FOAM EMULSION SE47 (WACKER ARTICLE CODE 21640582), THE RECOMMENDED CONCENTRATION IS 1ML OF ANTIFOAMING AGENT FOR 1 LITER OF WASTE SOLUTION.

FOR ANTIFOAMING AGENTS FROM OTHER MANUFACTURERS, USE CONCENTRATIONS AS RECOMMENDED BY CORRESPONDING MANUFACTURERS.

Liquid Bottle Empty

If the liquid bottle is empty before a program is started, the following message is displayed:

LLD ERROR OK

Fill the liquid bottle and press OK to remove the message and start the program again.



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Declaration of Conformity

We, TECAN Austria GmbH herewith declare under our sole responsibility that the product identified as:

Product Type: Microplate Washer

Model Designation: HYDROFLEX PLUS

Article Numbers: 30190374

Address: Tecan Austria GmbH

Untersbergstr. 1A A-5082 Grödig, Austria

is in conformity with the provisions of the following EC Directive(s)/Regulation(s) when installed in accordance with the installation instructions contained in the product documentation:

Regulation IVD-R

on in vitro diagnostic devices

Machinery Directive RoHS Directive

is in conformity with the relevant U.K. legislation for UKCA-marking when installed in accordance with the installation instructions contained in the product documentation:

Electromagnetic Compatibility (EMC) Regulations
Supply of Machinery (Safety) Regulations
The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations

The current applicable versions of the directives and regulations as well as the list of applied standards which were taken in consideration can be found in separate CE & UK declarations of conformity.

These *Instructions for Use* and the included *Declaration of Conformity* are valid for all HYDROFLEX PLUS instruments with the article numbers listed above. The model designation varies depending on the specific model with different article number.