

Seegene STARlet Operator's Manual



* For use with Seegene Launcher

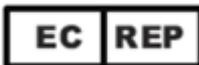


In Vitro Diagnostic Use



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User manuals translated into other languages are available at sgarchive.seegene.com/file/manual or can be requested from Seegene Inc.

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1. Safety and General Information

Seegene STARlet (in the following summarized as STARlet) is a pipetting workstation. This Operator's Manual is designed to help you get the most out of your STARlet.

You should carefully read through the entire manual before beginning to operate your workstation. This first section should be read with particular attention. It contains important information about the use of the STARlet and this manual.

1.1 About this Manual

This manual refers to STARlet Software. This manual helps users operate the STARlet correctly and safely. To achieve this goal, the manual describes the different components of the STARlet and their functionality. The manual describes both the hardware and software of the STARlet in depth, enabling the user to operate the instrument.

After introducing you to the various parts of the STARlet, we will show you step by step how to operate the instrument. After you have read through this manual, you should be capable of operating the STARlet.

Warnings and **Notes** are part of this manual to emphasize important and critical instructions.

Symbols used in this manual for these warnings and notes are:



ATTENTION

Any special problems, warning or important information will be accompanied by this symbol. Read these items carefully.



NOTE

Information is given to the programmer that is useful but not essential to the task at hand.

1.2 Intended Use of the Seegene STARlet

[Atitiktis_4](#)

Seegene STARlet is intended as a liquid pipetting system for analytical and clinical use.

Seegene STARlet is a workstation for the pipetting of liquid including sample and reagents. The liquid pipetting system excute tube-to-plate transfer, tube-to-tube transfer, plate-to-plate transfer and reagent dispensing. Seegene STARlet can be operated using disposable tips and provides the highest flexibility for carryover-free pipetting. Typical applications are:

- Sample preparation for DNA / RNA isolation and for amplification techniques
- Sample archiving and pooling

Seegene STARlet is not a fully automated PCR test device; Seegene STARlet is an automated system for nucleic acid extraction and PCR setup.

The STARlet is intended for use in an in vitro diagnostic environment.

Seegene STARlet should only be used by trained laboratory technicians.

1.3 Operation

The operator of the STARlet must have attended an official training course. The procedures contained within this manual have been tested by the manufacturer and are deemed to be fully functional. Any deviation from the procedures given here could lead to erroneous results or malfunction.

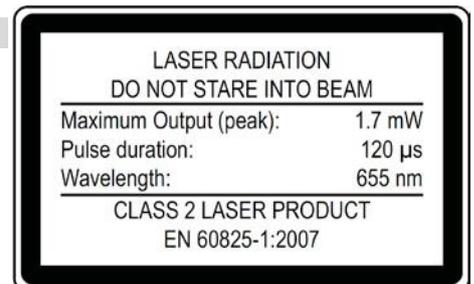
During instrument operation, stand clear of all moving parts and the working deck of the instrument. In general, never lean over or into the instrument while it is in operation.



ATTENTION: LASER BEAM

The Barcode Scanner on the Autoload of the STARlet has a Class II Laser Diode. Do not stare into the beam.

Laser device designated for use solely as a component of overall automated pipetting instrument and therefore is not within the scope of FDA Section 1040.11 for complete laser products. Laser devices are only to be installed, repaired, or replaced by an authorized service technician.



If the STARlet is used in a manner not specified by Seegene, the protection provided by the equipment may be impaired.

The STARlet is operated by means of control software. Specific methods, programmed by specially trained method programmers according to assay descriptions serve as job instructions for the control software. The operator should not modify methods except in consultation with the persons responsible for the programming and/or the assay supplier. Improper method changes can lead to false results.

In order to ensure error-free operation of the instrument, the content of the maintenance and verification procedures needs to be understood. In addition, the mandatory verification process must be carried out within the required timeframe and the verification process must be documented.

After the life cycle of the instrument has terminated, please contact Seegene for disposal regulations. Give due regard to the parts labeled with the bio-hazard warning symbol in the Section 1.6.5 Hazards.

1.4 Training

Training courses will be held by Seegene representative. Please feel free to contact your Seegene representative to arrange for an operator training.

1.5 Legal Regulations

All local, state and federal laws which prescribe the use, application, and/or the handling of dangerous materials in connection with the instrument must be strictly followed.

1.6 Safety Precautions and Hazards

The following section describes the main safety considerations, electrical and biological, in operating this product and the main hazards involved.



ATTENTION

Read the following safety notices carefully before using the STARlet.

1.6.1 General Precautions

1.6.1.1 Instrument Installation and Relocation

The Seegene STARlet is installed or relocated by an authorized service technician. Installations of instrument options and accessories are also done by an authorized service technician.

The STARlet conforms to European norms regarding interference immunity. However, if the STARlet is subjected to electromagnetic RF fields or if static electricity is discharged directly onto the STARlet, its Liquid Level Detection ability may be negatively affected. It is therefore recommended that the STARlet is kept away from other equipment that emits electromagnetic RF fields in the laboratory, and that static electricity is minimized in its immediate environment.

During operation, the STARlet must be shielded from direct sunlight and intense artificial light.

The instrument should be positioned in the laboratory in a way permitting personnel to access the front and sides of the instrument in order to operate, maintain, open and close the protective

covers. Accordingly, to calculate how much space is needed, consider the dimensions of the instrument (see the [Section 7.1.1 Dimensions and Weight](#)) and sufficient space for a person to move and work comfortably.

Never lift a fully installed instrument to transport it from one place to another. It must be re-installed in the new work location by an authorized service technician.

The instrument weighs approximately 140kg. Necessary precautions should be taken when transporting the instrument.

1.6.1.2 Maintenance, Service and Repair

Only trained field service engineers are authorized by Seegene to perform mechanical maintenance on the STARlet.

For repair or shipment, all mechanical parts must be put in their rest positions. A STARlet sent away for repair must also be decontaminated (see the [Section 6 Decontamination](#)) if it was in a laboratory environment with infectious or hazardous materials. The STARlet must be repacked in the original shipping crate only by an authorized service technician (contact Seegene or your local Seegene representative). There must be no containers or tips on the STARlet during transportation.

The authorized service technician and the laboratory share the responsibility for the Installation Qualification (IQ) and the Operation Qualification (OQ), i.e. Verification and Training. The Process Qualification (PQ) is the sole responsibility of the laboratory.

Only spare parts and tools provided by Seegene may be used with the STARlet, e.g. Carriers, Racks, CO-RE Tips, and Waste Containers. Commercially available Liquid Containers, such as Microplates and Tubes, may of course be used.

A breakdown of the power supply during a run may cause loss of data. If data loss is unacceptable, use an independent power supply or an Uninterruptible Power Supply (UPS).

1.6.1.3 Operating the Instrument

When using the STARlet, Good Laboratory Practices (GLP) must be observed. Suitable protective clothing, safety glasses and protective gloves must be worn, particularly when dealing with a malfunction of the instrument where the risk of contamination from spilled liquids exists.

Electrostatic discharge can cause damage to the instrument and can influence labware behavior and stability, therefore avoid any electrostatic charge onto labware and disposable tips during handling and manual loading of these to or from the STARlet.

During instrument operation, stand clear of all moving parts and the working deck of the instrument. In general, never lean over or into the instrument while it is in operation.

If the STARlet is used in a manner not specified by Seegene, the protection provided by the equipment may be impaired.

Any persons operating the STARlet and the PC running the STARlet Software must have attended a certified training course. Any departure from the procedures given here could lead to erroneous results or a STARlet malfunction.

1.6.1.4 Method Programming

Programming and Validation of new methods is the responsibility of every customer.

Pay close attention to all instructions and parameters given in test kit package inserts when programming test methods for the STARlet.

Perform test runs first with water and then with the final liquids, prior to routine use. Test all liquid classes which will be used. A newly programmed test method must first be run on the STARlet with the final liquids, prior to validation of the method and routine use. The method programmer should supervise this run.

Only use Validated Methods! Before using any newly created or modified method for routine test purposes, a comparison study between the method previously used and the new one must be carried out by the laboratory supervisor to ensure that the processing and data evaluation of both methods produce equal results.

When working with samples, which will be used in particularly sensitive tests, take into account the evaporation and condensation that may occur while the method is running.

When pipetting without Total Aspiration and Dispense Monitoring (TADM), incorrect pipetting caused by blocked tips, mechanical defects of the pipetting channel or tips that do not conform to the instrument or to the pipetting requirements are not detected by the system. Pipetting without TADM is only to be used for specific types of pipetting such as blood group determination, and must be checked visually.

Always use filter tips for pipetting without TADM to prevent pipetting channels from being contaminated.

If sampling aggressive liquids, use filter tips. Also use filter tips for tasks which are sensitive to cross- contamination (aerosols).

The inner diameter of sample tubes, reagent vessels, etc. must be greater than the channel diameter of 9mm.

**ATTENTION**

Liquid Level Detection needs to be explicitly tested when working with foamy liquids.

Foam may affect the accuracy of liquid level detection.

- *The liquid must be conductive so that dual LLD can be utilized.*
- *The tolerance between the first and last allowable detection must be defined empirically.*
- *Then the immersion depth value has to be defined large enough to ensure that the tip is located below the foamy layer before aspiration. This requires some test runs as well. The starting point of the immersion depth is where both LLD's are triggered.*

**ATTENTION**

Never disable any safety measure.

1.6.1.5 Loading

Do not exchange positions of sample or reagent tubes or switch microplates after they have been identified by the barcode reader. This could result in incorrect test data or instrument crash.

Microplates must be placed on the carrier such that well A1 is in the position defined in the deck layout of the method.

When pouring liquid into the containers, ensure that there is no foam on the surface of the liquid. Note that foam may cause pipetting problems.

Do not overfill reagent containers, tubes or other liquid containers.

Do not mix tip size and type (e.g. with or without filter or different volumes) in the same tip rack.

Do not fill up partially consumed tip racks with tips from another rack. Tips should be loaded in the tip racks as they are provided in the original packaging. They are individually labeled with a barcode for identification.

1.6.1.6 Work Routine

Periodic maintenance (daily maintenance, weekly maintenance, six-monthly maintenance) is a mandatory part of the work routine.

User access to the cabinets underneath the instruments during a run may interfere with automatic loading and unloading of carriers (the carriers protrude).

If the system is paused, do not wait too long before resuming the run. Loss of liquid from a full tip may result in invalid data.

Discard used tips and do not reuse them. Do not empty the tip waste during a run. Do not try to open the front cover during a run. It may cause an abort of the run.

Do not leave tips on the pipetting channels for a long period of time (for example, overnight). This may cause damage to the CO-RE O-rings. A daily maintenance procedure will eject the tips.

1.6.2 Biohazard Precautions

If the STARlet becomes contaminated with bio-hazardous or chemical materials, it should be cleaned in accordance with the maintenance procedures (see the Section 4 Maintenance and Section 6 Decontamination). Observe and carry out the maintenance procedures given. Failure to do so may impair the reliability and correct functioning of the STARlet.

If working with bio-hazardous samples, observe and carry out the maintenance procedures, paying particular attention to cleaning and decontamination. Wear gloves when handling the X-Arm and pipetting channels, the carriers, racks, containers and tips.

Avoid touching tips discarded into the laboratory-supplied waste container. Any surfaces on which liquid is spilled must be decontaminated.

Do not use disinfecting materials, which contain hypochlorite (Javel water, Chlorox) or other bleaching fluids.

If working with bio-hazardous or chemical materials, the user must not touch them. The STARlet will drop its used tips into a waste container, which should be emptied during the daily maintenance or as soon as it is full.

1.6.3 Computer Precautions

Use the necessary precaution to guard against software viruses. Use only manufacturer's original installation DVD/CD-ROM sets for the operating system. Use only the original STARlet Software supplied a DVD/CR-ROM.

Any manipulation of the STARlet Software data files or other information determining or affecting STARlet functions can result in erroneous test results or instrument failure.

Only the STARlet Software may be used to control the STARlet.

For reasons of data safety and integrity, use of an Uninterruptible Power Supply (UPS) is recommended, since a loss of power may cause data to be lost or corrupted.

To avoid computer breakdowns, configure a hard disk of sufficient space in the computer.

Ensure that there is always enough storage capacity on your hard drive. Delete log files from time to time. Generated data within the Log Files Directory, e.g. traces, TADM data and pipetting

files, must be backed up onto the laboratory's host device and deleted from the control PC's hard disk at weekly intervals.

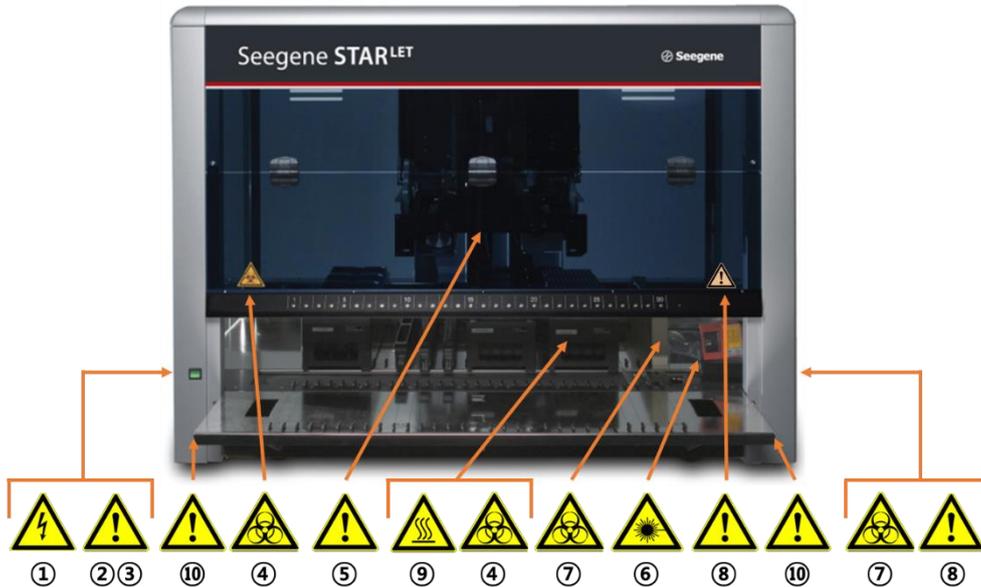
1.6.4 Electrical Safety Precautions

Before removing a mechanical or electrical component, the STARlet must be switched off and disconnected from the main electricity supply and from the PC.

Every installation and de-installation of an electrically powered STARlet component must be done by an authorized service technician.

1.6.5 Hazards

Location and explanation of warning and attention labels:



①		Power Connection Connect only to earth-grounded outlet	⑥		Laser Beam (Autoload) Do not stare into beam of class 2 laser of the barcode reader
②		Connection to PC Use only the appropriate shielded cables	⑦		Biohazard Warning Waste may contain bio-hazardous or chemically contaminated materials
③		USB Connection Having a total cable distance of more than 5m, signal loss may occur	⑧		Moving Parts Moving arm inside transparent cover. Aborts the run if cover is opened
④		Biohazard Warning Deck may contain bio-hazardous or chemically contaminated materials	⑨		Hot Surface Avoid contact of HHS. Surfaces are hot and may cause personal injury if touched
⑤		X-Arm Do not move X-Arm by hand	⑩		Side Guards Be careful not to break the side guards

**ATTENTION**

Laser device designated for use solely as a component of overall automated pipetting instrument and therefore is not within the scope of FDA Section 1040.11 for complete laser products. Laser devices are only to be installed, repaired, or replaced by an authorized service technician.

1.6.5.1 Substance Related Hazards**ATTENTION**

Chemical, biological and radioactive hazards can be associated with the substances used or the samples processed with the instrument. The same applies to waste disposal. The handling of substances and the disposal of waste may be subject to local, state or federal law or regulations with regard to health, environment or safety.

- *Always be aware of possible hazards associated with these substances*
- *Use appropriate protective clothing, goggles and gloves*
- *Strictly observe the corresponding provisions*

**ATTENTION**

Caustic substances can cause burns and eye injury.

- *Always be aware of possible hazards associated with these substances*
- *Avoid exposure to caustic substances*
- *Use appropriate protective clothing, goggles and gloves*

**ATTENTION**

Fire Hazards.

- *Use caution when using flammable materials. The instrument is not explosion protected nor for use in Ex zones.*

1.6.5.2 Safety Measures

- **Access to Power Switch/Power Cord**

Ensure there is enough room to access the power switch and power cord.

- **Working Area**

The safety concept assumes that the doors are always closed and locked during normal operation.

- **Surrounding Area**

Make sure the ventilation outlets of the instrument are not impaired by obstacles placed in the surrounding area.

**ATTENTION**

Rapid temperature changes or direct sunlight may affect certain functions such as barcode reading and pipetting accuracy.

- *Do not open windows next to the instrument*
- *Do not expose the instrument to direct sunlight or intense artificial light during operation*

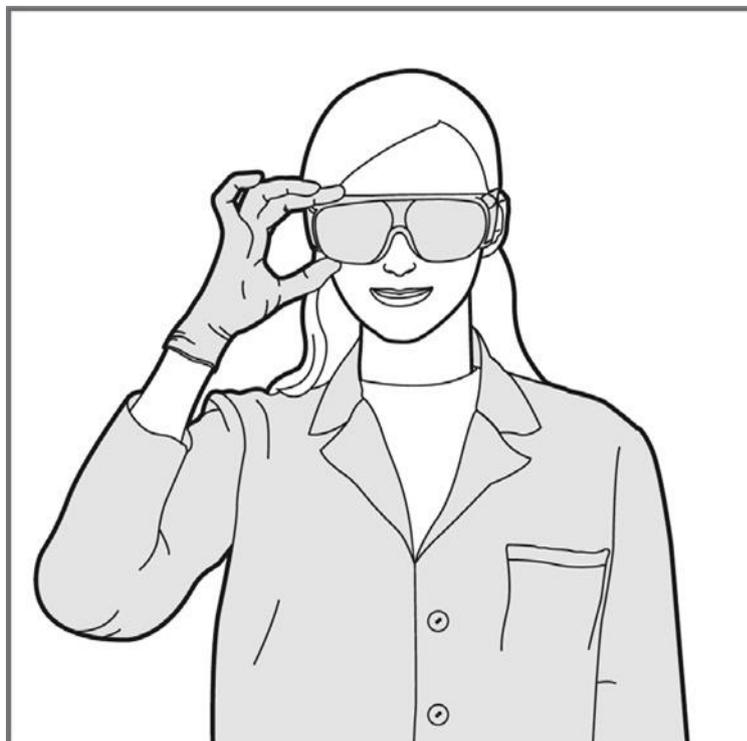
Use appropriate:

Protective clothing

Goggles



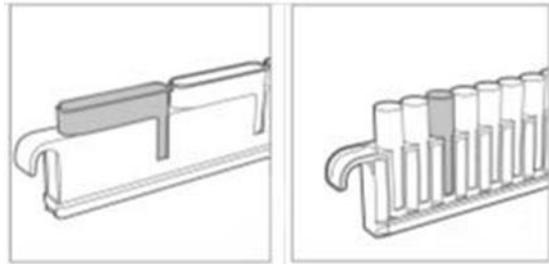
and Gloves.



1.6.5.3 Loading Reagents and Samples

Loading Reagents and Samples:

- The 1T Reagent Racks and 1T Sample Racks can tip over during sample and reagent loading and unloading



ATTENTION

Secure 1T Reagent Racks and 1T Sample Racks to prevent the risk of spillage of reagents or samples.

1.6.5.4 Loading Tray

Loading Tray:

- The instrument loading tray is a part of the instrument and must be treated with care



ATTENTION

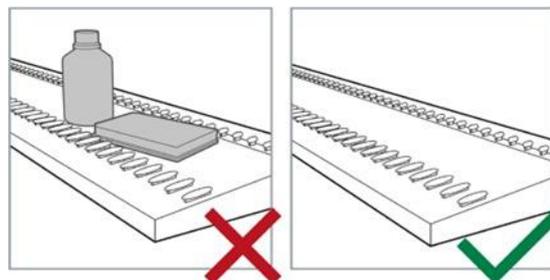
Risk of damage to equipment. Leaning onto the instrument loading tray will lead to damage of the loading tray.

- *Do not lean onto the loading tray.*



Foreign object damage:

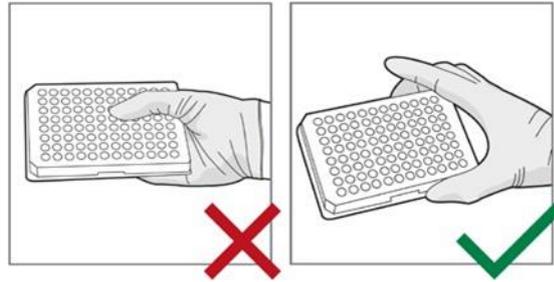
- Make sure that the loading tray has been cleared from foreign objects before running the instrument
- Foreign objects may obstruct the instrument and lead to damage to the equipment



1.6.5.5 Holding Labware

Holding Labware:

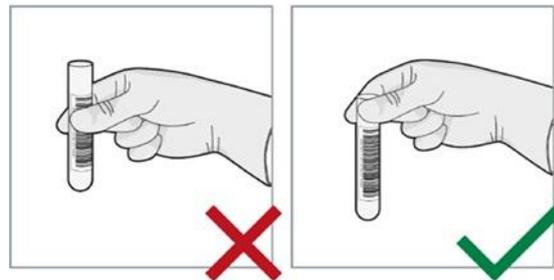
- Hold microplates by its sides



1.6.5.6 Holding Tubes

Holding Tubes:

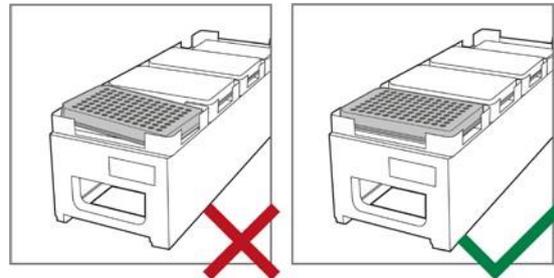
- Avoid holding tubes on barcodes
- Hold the tubes as shown



1.6.5.7 Placing Labware

Placing labware onto carriers:

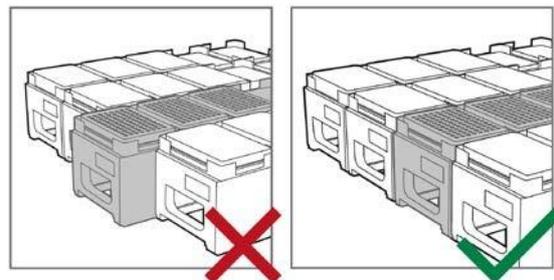
- Make sure labware is placed onto the carrier correctly
- Incorrectly placed labware will lead to collision or malfunction



1.6.5.8 Loading Plate Carriers

Loading Plate Carriers:

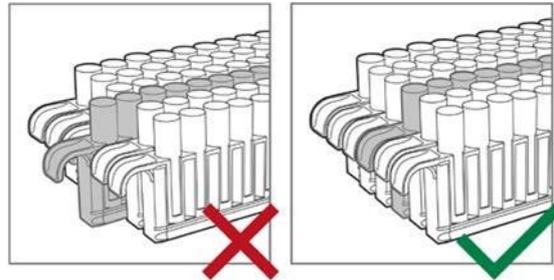
- Make sure the carriers have been pushed to the mechanical stop of the instrument
- Incorrectly positioned carriers will lead to malfunctions or collision



1.6.5.9 Loading Tube Carriers

Loading Tube Carriers:

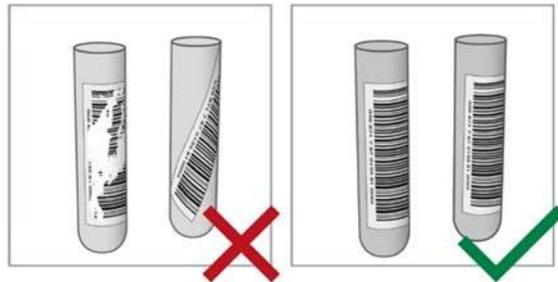
- Make sure the tube carriers have been pushed to the mechanical stop of the instrument.
- Incorrectly positioned tube carriers will lead to malfunctions or collision.



1.6.5.10 Barcodes Placement

Barcode quality:

- Make sure that all barcodes are readable as well as correctly applied
- Unreadable, scratched, smudged or incorrectly positioned barcodes on tubes will not be processed

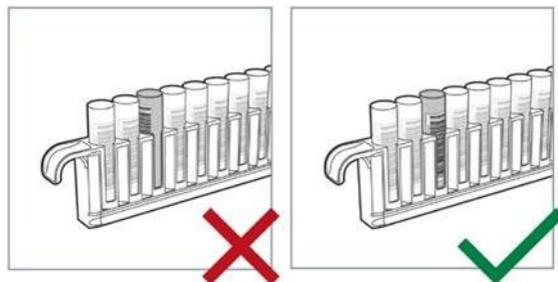


Refer to the barcode types and quality

requirements in Section 7.4 Autoload: Barcodes and Reader Specifications.

Barcode orientation:

- Make sure all tube barcodes have the correct orientation
- Incorrectly placed tube barcodes will not be readable

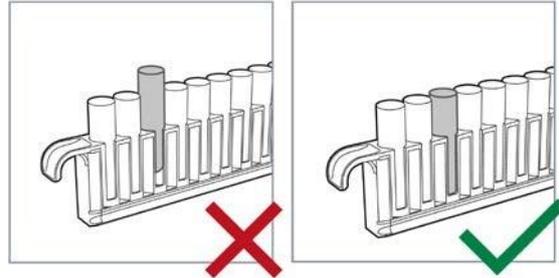


1.6.5.11 Tube Placement

Tube position:

When placing tubes into tube carriers:

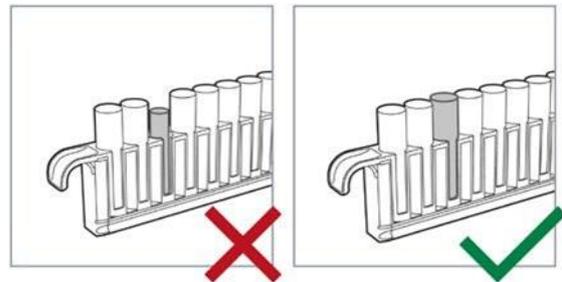
- Make sure the tubes are pushed all the way down into the tube carrier
- Incorrectly placed tubes may lead to malfunctions



Tube height:

When placing tubes into tube carriers:

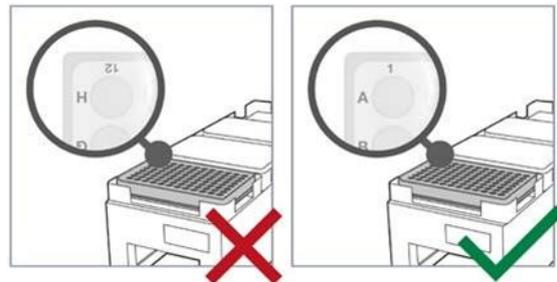
- Make sure that all tubes placed into the tube carrier are the same height
- Different tube heights will lead to incorrect calculation of sample volumes and lead to malfunctions



1.6.5.12 Labware Orientation

Labware orientation on carriers:

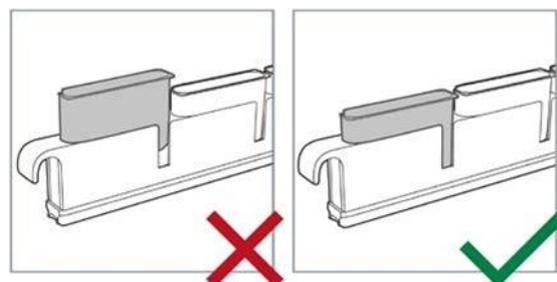
- Make sure plates have the correct orientation on the carrier
- The well position A1 has to be in the upper left



1.6.5.13 Trough Position

Placing troughs into trough carriers:

- Make sure the troughs are pushed all the way down into the carrier
- Incorrectly placed troughs will lead to spillage and/or malfunctions



1.7 Electrical Safety Compliance

Seegene STARlet has been tested and found to follow all applicable requirements of the following safety and electromagnetic standards:

• EN 61010-1:2010	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements
• EN 61010-1:2010/A1:2019	
• IEC 61010-1:2010	
• IEC 61010-1:2010/AMD1:2016	
• EN 61010-2-010:2014	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of material
• IEC 61010-2-010:2019	
• EN IEC 61010-2-010:2020	
• EN 61010-2-101:2017	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
• IEC 61010-2-101:2018	
• EN IEC 61010-2-101:2022	

1.8 Electromagnetic Compatibility (EMC)

Seegene STARlet has been tested and found to follow all applicable requirements of the following electromagnetic compatibility standards:

• IEC 61326-1:2020	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements
• EN IEC 61326-1:2021	
• IEC 61326-2-6:2020	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment
• EN IEC 61326-2-6:2021	
• CISPR11:2015+A1:2016+A2:2019	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement
• EN 55011:2016+A2:2021	
• IEC 61000-3-2:2018+A1:2020	Electromagnetic compatibility (EMC) - Part 3-2:

<ul style="list-style-type: none"> • EN IEC 61000-3-2:2019 • EN 61000-3-2:2014 	Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)
<ul style="list-style-type: none"> • IEC 61000-3-3:2013+A1:2017 • EN 61000-3-3:2013+A1:2019 • EN 61000-3-3:2013 	Electromagnetic compatibility (EMC) - Part 3-3: Limits -Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection
<ul style="list-style-type: none"> • IEC 61000-4-2:2008 • EN 61000-4-2:2009 	Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test
<ul style="list-style-type: none"> • IEC 61000-4-3:2020 • EN IEC 61000-4-3:2020 • EN 61000-4-3:2006/A1:2008/A2:2010 	Electromagnetic compatibility (EMC) - Part 4-3 : Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test
<ul style="list-style-type: none"> • IEC 61000-4-4:2012 • EN 61000-4-4:2012 	Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test
<ul style="list-style-type: none"> • IEC 61000-4-5:2014+A1:2017 • EN 61000-4-5:2014+A1:2017 	Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test
<ul style="list-style-type: none"> • IEC 61000-4-6:2013 • EN 61000-4-6:2014 	Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields
<ul style="list-style-type: none"> • IEC 61000-4-8:2009 • EN 61000-4-8:2010 	Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test
<ul style="list-style-type: none"> • IEC 61000-4-11:2020 • EN IEC 61000-4-11:2020 	Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests for equipment with input current up to 16 A per phase

This equipment may negatively affect Liquid Level Detection functionality if it is in an electromagnetic radio frequency area or is electrostatic affected. Therefore, the equipment should be used far away from other machines emitting electromagnetic radio frequencies. In addition, the equipment surrounding environment should have minimal electrostatic effects. If not installed and used in accordance with the user's manual, it may cause harmful interference in wireless communication.

1.9 Packing List

The instrument and its accessories are well packed in a package. Check for the quantity and quality of the items in the package according to the packing list below. Report any damages or lacks the local Seegene's distributor or to Seegene.

#Seegene STARlet

No	Part number	Description	Qty
Accessories kit #1			
1	N/A	[Document] Unpacking Instructions, ML STAR	1
2	N/A	[Document] Installation Qualification, ML STAR, IVD	1
3	N/A	[Document] Measurement Protocol ML STAR IVD	1
4	N/A	[Document] EU Declaration of Conformity, ML STAR, IVD	1
5	N/A	[Document] Declaration of Quality, Base Assembly Unit	1
6	N/A	[Document] Declaration of Quality, ML STAR, IVD	1
7	N/A	[Document] STARLINE Packing Checklist	1
8	N/A	[Document] Maintenance (Barcode, Position, Weekly)	1
9	N/A	[Document] Channel Adjust Value for Guldi Device	1
10	N/A	[Document] STARLINE Electrical Safety Test Report	1
11	173240	Loading Table, 30T	1
12	185091-RNO	Side Cover Plexiglas right(Flip up)	1
13	186571	Side Cover Plexiglas left	1
14	186572	REAR Plexiglas Cover 30T(for STARlet)	1
15	186573	TOP Panel Plexiglas Cover 30T(for STARlet)	1
16	190201	LEFT REAR CORNER COVER (with Black)	1
17	190202	RIGHT REAR CORNER COVER (with Black)	1
Accessories kit #2			
18	96718-01	ASSY, LIQ WASTE, 5L, 4L-SENSOR	1
19	53873-07	SOLID WASTE CONTAINER	1
20	54698-01	Liquid and Tip Waste System, User Guide, Rev B	1
21	54802-01	Solid-Liquid Waste Sensor V1.3, Rev B	1
22	911265-01	VENUS FOUR SW & MANUAL STAR IVD 4.5, Rev X1	1
23	182238	32 Inserts for 1.5ml Eppendorf Cups	3
24	184089	CORE Gripper (Screw x 4ea included)	1
25	182136	Teaching Needle(8ea)	1

26	53894-01	SEPARATOR, MAGNETIC, NUCLEO	1	
27	58938-01	Tip Eject Plate(DEFLECTOR, TIP, LIQUID WASTE)	1	
28	3892-01	POWER CORD, STD, CEE 7/7	1	
29	3892-05	POWER CORD, USA, NEMA 5-15P	1	
30	355171	CABLE USB 2.0 A-B 3M FERRIT	1	
31	363013	FUSE 6.3AT	2	
32	420629	SCREW M4x16	1	
33	53866-01	FITTING, QIK-CON, 3/8 IDX 3/8BARB	1	
34	54200-01	ASSY, FILTER, AEROSOL, LIQ WASTE	1	
Transport materials				
35	N/A	(Channel support)X-Arm Holding brackets	2	
36	190148	TRANSPORT SUPPORT BAR LEFT	1	
37	186675	Support Bar on Top (for Top Plexiglas Cover)	1	
Accessories kit #3, Upper box				
38	53686-01	BAG, BIO-HAZARD, 14.5 x 8.2 x 18, 200/CS	1	
39	173410	3 Carrier for 32 Tubes(11x60 - 14x120mm)	1	
40	182085	TIP CARRIER, 5 TIP RACKS	2	
41	97076-01	ASSY, CAR, 7T, HHS, 4MFX	1	
		97432-01	PED, ADAPTER, SMALL TUBE, SEEG	2
		403453	SCREW, FLHX M3X8, DIN7991, A2SS	4
		400263	SCREW, SOHX, M3X8, DIN912, A2SS	2
		N/A	HHS Base Plate	1
42	97319-01	ASSY, CAR, MFX, 6T, REAG, DW, MTP	1	
43	62964-03	RENO KIT 3, STAR VERIFY KIT	1	
44	235969	STD VOL CO-RE TIPS FIL 5x96	1	
45	235970	HIGH VOL CO-RE TIPS FIL 5x96	1	
46	199034	Hamilton Heater & Shaker (HHS)	1	
47	99088-24	Hamilton Heater Shaker Manual	1	
48	N/A	Stop Barcode	1	

#Seegene STARlet with CO-RE 96 Probe Head

- Accessories kits for Seegene STARlet

No	Part number	Description	Qty
Accessories kit #1			

1	N/A	[Document] Unpacking Instructions, ML STAR	1
2	N/A	[Document] Installation Qualification, ML STAR, IVD	1
3	N/A	[Document] Measurement Protocol ML STAR IVD	1
4	N/A	[Document] EU Declaration of Conformity, ML STAR, IVD	1
5	N/A	[Document] Declaration of Quality, Base Assembly Unit	1
6	N/A	[Document] Declaration of Quality, ML STAR, IVD	1
7	N/A	[Document] STARLINE Packing Checklist	1
8	N/A	[Document] Maintenance (Barcode, Position, Weekly)	1
9	N/A	[Document] Channel Adjust Value for Guldi Device	1
10	N/A	[Document] STARLINE Electrical Safety Test Report	1
11	N/A	[Document] Declaration of Quality (96x1000ul II Head)	1
12	173240	Loading Table, 30T	1
13	185091-RNO	Side Cover Plexiglas right(Flip up)	1
14	186571	Side Cover Plexiglas left	1
15	186572	REAR Plexiglas Cover 30T(for STARlet)	1
16	186573	TOP Panel Plexiglas Cover 30T(for STARlet)	1
17	190201	LEFT REAR CORNER COVER (with Black)	1
18	190202	RIGHT REAR CORNER COVER (with Black)	1
Transport materials			
19	N/A	(Channel support)X-Arm Holding brackets	2
20	190148	TRANSPORT SUPPORT BAR LEFT	1
21	186675	Support Bar on Top (for Top Plexiglas Cover)	1
Accessories kit #2, Upper box			
22	96718-01	ASSY, LIQ WASTE, 5L, 4L-SENSOR	1
23	53873-07	SOLID WASTE CONTAINER	1
24	54698-01	Liquid and Tip Waste System, User Guide, Rev B	1
25	54802-01	Solid-Liquid Waste Sensor V1.3, Rev B	1
26	911265-01	VENUS FOUR SW & MANUAL STAR IVD 4.5, Rev X1	1
27	182238	32 Inserts for 1.5ml Eppendorf Cups	3
28	184089	CORE Gripper (Screw x 4ea included)	1
29	182136	Teaching Needle(8ea)	1
30	53894-01	SEPARATOR, MAGNETIC, NUCLEO	1
31	58938-01	Tip Eject Plate(DEFLECTOR, TIP, LIQUID WASTE)	1
32	3892-01	POWER CORD, STD, CEE 7/7	1
33	3892-05	POWER CORD, USA, NEMA 5-15P	1

34	355171	CABLE USB 2.0 A-B 3M FERRIT	1	
35	363013	FUSE 6.3AT	2	
36	420629	SCREW M4x16	1	
37	53866-01	FITTING, QIK-CON, 3/8 IDX 3/8BARB	1	
38	54200-01	ASSY, FILTER, AEROSOL, LIQ WASTE	1	
39	53686-01	BAG, BIO-HAZARD, 14.5 x 8.2 x 18, 200/CS	1	
40	173410	3 Carrier for 32 Tubes(11x60 - 14x120mm)	1	
41	182085	TIP CARRIER, 5 TIP RACKS	2	
42	97076-01	ASSY, CAR, 7T, HHS, 4MFX	1	
		97432-01	PED, ADAPTER, SMALL TUBE, SEEG	2
		403453	SCREW, FLHX M3X8, DIN7991, A2SS	4
		400263	SCREW, SOHX, M3X8, DIN912, A2SS	2
		N/A	HHS Base Plate	1
43	97319-01	ASSY, CAR, MFX, 6T, REAG, DW, MTP	1	
44	62964-03	RENO KIT 3, STAR VERIFY KIT	1	
45	235969	STD VOL CO-RE TIPS FIL 5x96	1	
46	235970	HIGH VOL CO-RE TIPS FIL 5x96	1	
47	199034	Hamilton Heater & Shaker (HHS)	1	
48	99088-24	Hamilton Heater Shaker Manual	1	
49	N/A	Stop Barcode	1	

- Accessory kit for CO-RE 96 Probe Head

No	Part number	Description	Qty	
Accessory kit for CO-RE 96 Probe Head #1-1				
1	188039	MultiFlex Carrier Base (6 tracks)	3	
2	188042	MultiFlex Deepwell Plate Module	7	
		400262	SCREW M3X6 (25/PK)	28
		187405	Position Pin	28
3	188160	MultiFlex Tip for holding tip frame&tip	7	
		400262	SCREW M3X6 (25/PK)	28
		187405	Position Pin	28
4	188049	MultiFlex PCR Plate Module 96	2	
		400262	SCREW M3X6 (25/PK)	8
		187405	Position Pin	8
5	97074-01	Plate, Module, 7T carrier, Seeg (each)	1	

Accessory kit for CO-RE 96 Probe Head #1-2				
6	92573-01	CHUTE,WASTE,MPH,FRONT	1	
7	6602584-01	POST, REAR, LEFT	1	
8	182040	CO-RE 96 HEAD TIP ADAPTOR	1	
9	6604143-01	CHANNEL CABLE BRACKET	1	
10	6603867-01	PLATE, CABLE SUPPORT	1	
11	6602583-01	Y-FLAG, 96-ARM	1	
12	173312	CABLE CHANNEL, UNIVERSAL ARM STANDARD	1	
13	186570	FRONT SIDE PANEL BRACKET	1	
14	400263	SCREW,SOHX,M3X8,DIN912,A2SS	6	
15	400308	SCREW,SOHX,M4X20,DIN912,A2SS	4	
16	420074	SCREW,SOHX,M4X16,DIN912,A2SS	4	
17	50230-01	SCREW,BTHX,M5X,8X12MM,A2SS(25)	3	
Accessory kit for CO-RE 96 Probe Head #1-3				
18	67120-01	BRACKET,LFT,HSE EXT 96 HEAD	1	
19	186487	AUBRIGHT	1	
20	186484-RNO	WASTE, MPH	1	
21	190082	ASSY X-MOTOR 40W REPLACEMENT	1	
22	186574	PLEXIGLAS GUIDE CLIP	2	
23	N/A	Communication Cable(Black & White)	2	
24	N/A	Energy Chain (Partial)	1	
25	N/A	Y/Z Drive Cable Protector	1	
26	N/A	SCREW/WASHER SET	14	
		420115	SCREW,SOHX,M6X14,DIN912,A2SS	4
		400304	SCREW,SOHX,M4X12,DIN912,A2SS	4
		403491	SCREW,FLHX,M4X8,DIN7991,A2SS	3
		8372-01	SCREW,SOHX,M3x10,SST (25/PK)	1
		409281	WASHER,FLAT,M3,DIN9021B,A2SS	1
		400262	SCREW M3X6 (25/PK)	1
Accessory kit for CO-RE 96 Probe Head #1-4				
27	62964-04	RENO KIT 4,STAR VERIFY KIT	1	
		279403	MICROWELL PLATE	10
		235900	STAR CO-RE TIPS 10 μ l (CO-RE II, Non-filtered)	1

		235904	CO-RE TIPS 1ML (CO-RE II, Non-filtered)	1
Accessory kit for CO-RE 96 Probe Head #2				
28	188122	HOUSING LEFT FOR MPH		1
29	N/A	Z-Shaped Block		1

2. Description of the STARlet

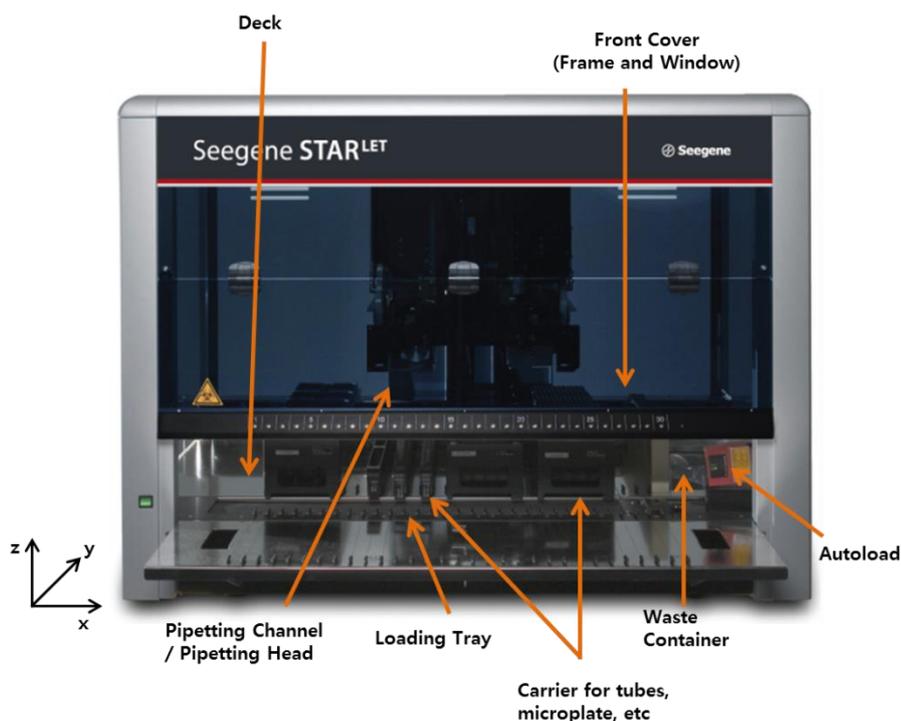
2.1 Platforms

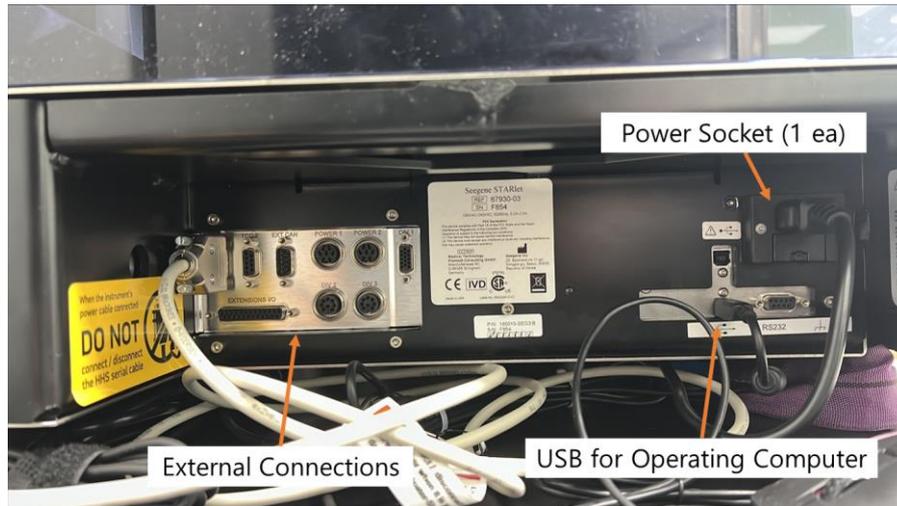
The STARlet work surface, called a 'deck', for placing loadable carriers, is available in two different sizes. These carriers hold reagent containers, such as tubes, Microplates, and other kinds of Labware.

The instrument deck is divided into equal tracks (T) for loading carriers in pre-determined positions. This eliminates the need for precise measurement of positions. The deck has partitions of 22.5mm, which is equivalent to 1-T (track). The labware carriers are adapted to those partitions, e.g. 1-T carriers for sample tubes, or 6-T carriers for microplates or CO-RE tips, etc. An additional partition provides space for the tip waste container.

2.1.1 Seegene STARlet

The STARlet is the version of instrument with the smallest deck width for loading carriers. The deck has partitions for a maximum of 30 1-T carriers for sample tubes, or a maximum of five 6-T carriers for microplates and CO-RE tips. This means that a total of 25 SBS (Standard format of the Society for Biomolecular Screening) positions can be placed onto a STARlet Deck.





See Appendix F. Glossary for a description of each part of Seegene STARlet.

2.1.2 Pipetting Channels

The STARlet can be equipped with 1000 μ l pipetting channels.

2.1.2.1 1000 μ l Pipetting Channels

The STARlet is available with maximum eight 1000 μ l pipetting channels working in parallel for simultaneous transfer of liquids. Each pipetting channel moves independently on the Y-Axis, as well as on the Z-Axis. Each pipetting channel uses its own high-precision motors and electronics to reach any position on the deck without the need of teaching.

The 1000 μ l pipetting channels support pipetting with disposable CO-RE tips.



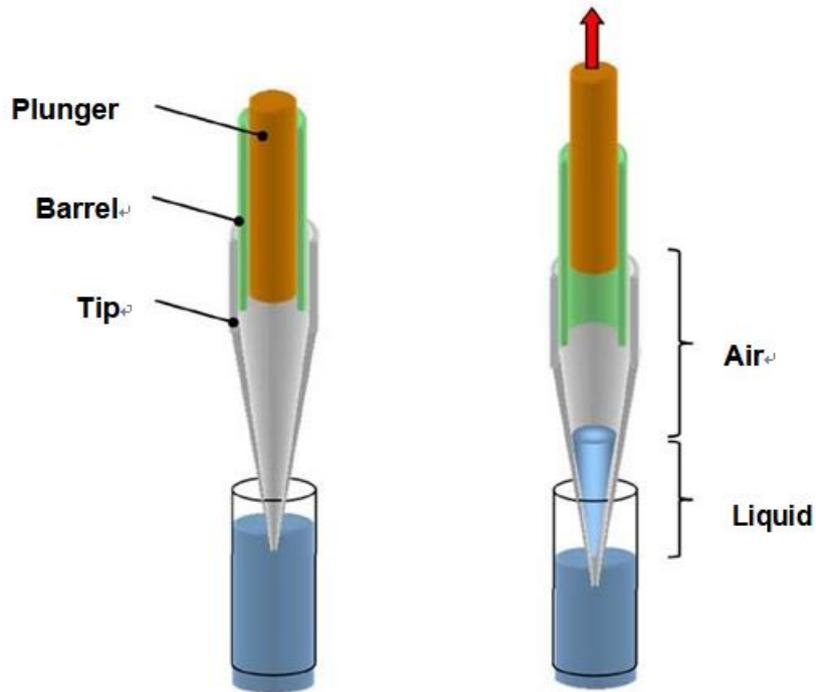
The minimum distance between two 1000 μ l pipetting channels on the Modular X-Arm is 9mm (for Thin Arm 18mm).

The pipetting channels have a set 'traverse height' of 245mm above the origin or 145mm between the top of the disposable tip and the deck of the instrument. This means, when a pipetting channel is to move from one location on the deck to another, it automatically does so at that particular height. This is a safety precaution, so that pipetting channels will not collide with any items that may be on the deck.

An instrument equipped with eight 1000 μ l pipetting channels has full 'random access space', which is the area where any of the pipetting channels is able to reach.

2.1.3 The Air Displacement Pipetting Principle

The STARlet is based on the air displacement pipetting principle, comparable to the functionality of handheld pipettes. Air displacement means that the liquid is aspirated into and dispensed from a disposable tip or needle by the movement of a plunger. Between the plunger and the liquid surface is air. No system liquid of any kind is involved in the STARlet.



The air displacement pipetting principle

2.1.4 Tip Pick-up with the CO-RE Technology

The first task for the STARlet pipetting head is to pick up a Hamilton disposable tip. Due to the unique (CO-RE) Compression-induced O-Ring Expansion) technology, precise tip attachment and positioning is achieved. The system requires no vertical force for tip attachment or tip ejection, thus eliminating mechanical stress and improving overall system reliability along with pipetting speed and capability.



NOTE

The principle of the CO-RE technology has the following advantages:

- *Enables coupling of disposable tips or washable needles within the same run*
- *Allows use of different sizes of tips on the same pipetting head in the same run*
- *Picking up a gripper and other tools is possible with a pipetting channel*
- *Prevents aerosols upon tip ejection*

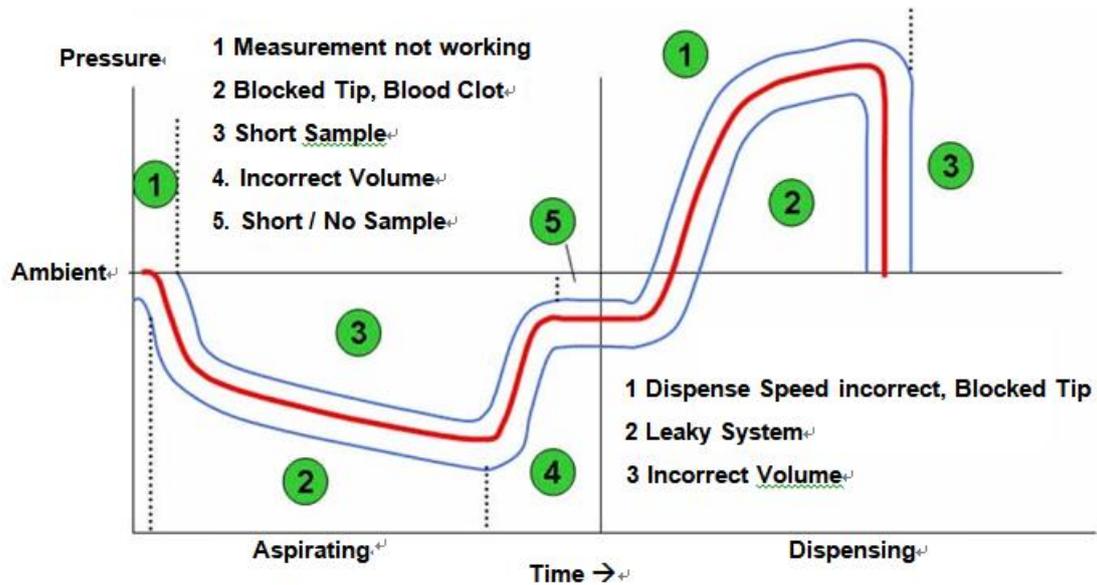


ATTENTION

Only Hamilton CO-RE tips should be used for coupling to the pipetting heads of the STARlet. Other tips may cause contaminated or damaged pipetting channels and may lead to erroneous results.

2.1.5 Total Aspiration and Dispensing Monitoring: TADM [Atitiktis_6](#)

During crucial sample transfers, the STARlet can monitor aspiration and dispense steps in real time. TADM verifies that a sample has been transferred by using a traceable digital audit trail. The function of TADM is a software option and therefore not available by default. TADM is available for individual pipetting channels.



2.2 Accessories

Accessories are defined as products that support liquid pipetting system on Seegene NIMBUS and Seegene STARlet. They provide a high degree of adaptability and permit customizing for multiple applications.

2.2.1 CO-RE Gripper

The CO-RE Gripper is the plate handling tool picked up by two pipetting channels during a run. The CO-RE Gripper transports microplates, lids for microplates, archive plates etc. to and from positions on the deck of the STARlet. Plates can be gripped in landscape or portrait format within the working area. Rotation of plates is not an option.



CO-RE Gripper holder with jaws for the 1000µl pipetting channels (inner positions)

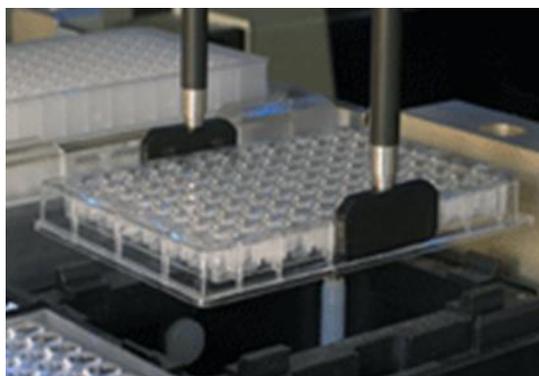


Plate being moved with CO-RE Gripper using 1000µl pipetting channels

The CO-RE Gripper holder for the two different gripper jaws is mounted on the waste block, so it does not occupy any plate position.

2.2.2 HAMILTON Heater Shaker

The HAMILTON Heater Shaker (HHS) is designed to heat and shake microplates in SBS format. Loading and unloading as well the independent heating or shaking function of the HHS is fully controlled by the STARlet Software.

Before shaking, the plates are locked and positioned in the center of the HHS. When the shaking process has finished, the plates are unlocked and can be easily removed from the heater shaker, either using CO-RE Gripper (do not move/remove plates manually from the HHS). The HHS adapters fitted to your plate type allow optimal heating of your samples. The maximum set temperature of the HHS is 105°C. To ensure reliable heating performance, two sensors permanently control the temperature which guarantees the abundance of the user-

defined temperature range. In addition, a cut-off temperature will protect your samples from over-heating.



HHS with standard universal flat bottom adapter



ATTENTION

Only labware which complies with the HHS dimensions can be used in order to prevent any loss of plates and/or liquids. When shaking labware, the velocity must be adjusted to the type of labware and the volume within the labware to prevent cross contamination due to spillages. Flammable liquids must not be heated by the HHS as they might cause fire. Make sure that the plate used with the HHS is heat resistant (maximum temperature 105°C).



NOTE

An efficient heating of the liquid is only achieved if the appropriate adapter for the labware is used. The heating time and the maximum temperature, which can be reached for the liquid inside the plate, is dependent on the amount of liquid, the size and weight of the used labware, the shape of the used adapter and the heating effectiveness between the plate and the adapter. The maximum speed of the HHS depends on the eccentric tappet and the labware used. Shaking can be performed clockwise or counter-clockwise.

2.2.2.1 Operation of the Hamilton Heater Shaker

For operation of the HHS, a specific library is required.



ATTENTION

When working with samples used in particularly sensitive tests, take into account the evaporation that may occur while the HHS is running. Be aware that heating of liquids will affect the pipetting process, also shaking the labware can influence the precision of pipetting.



ATTENTION

When shaking labware, the speed has to be adjusted to the type of labware and the volume within the labware to prevent cross-contamination due to spillage.



ATTENTION

Do not touch the HHS while running, and shortly after finishing a run, as it might be hot. Wait until the HHS has cooled down to room temperature, which can take up to 1 hour.



NOTE

The maximum shaking speed of the HHS depends on the orbit and the type of labware used (see Section 7.3.2 Hamilton Heater Shaker Specifications).



NOTE

An efficient heating of the liquid is only achieved if the appropriate adapter for the labware is used. The heating time and the maximum temperature, which can be reached for the liquid inside the plate, is dependent on the amount of liquid, the size / weight of the used labware, the size / weight of the used adapter and the connection between the plate and the adapter.

2.2.3 UV Light Kit

[Atitiktis_8](#)

The STARlet UV Light Kit (P/N 68146-01) provides STARlet platform the ability to perform routine germicidal decontaminations or as part of applications with cross-linking DNA. Available for both manual load and Autoload configurations.



STARlet IVD with UV Light

Use the following products when installing the UV Light Kit on the Seegene STARlet with CORE 96 Probe Head.

- Kit, UV, STARlet, AL with MPH (P/N 97310-23)

2.2.4 Vial Cap Management System(VCMS)

The Vial Cap Management System, or VCM System, integrates seamlessly with a STARlet to mix (vortex), de-cap, process and re-cap up to 96 large tubes or specimen vials in a single run.



The vials are pre-loaded, eight at a time, into a transport chain designed to accommodate 96 sample positions. During a run, the vials are processed four at a time and can either be mixed (vortexed) prior to being de-capped or processed and re-capped. The VCM System's de-capping positions occupy the three leftmost tracks on the deck to allow direct access for liquid transfers.

2.2.5 AIOS

AIOS is an accessory to combine Seegene STARlet with real-time polymerase chain reaction (PCR) equipment (CFX96 Dx, Manufacturer: Bio-Rad), and plate sealer (manufacturer: SAMICK THK) to form an automated linkage structure of nucleic acid extraction to PCR.



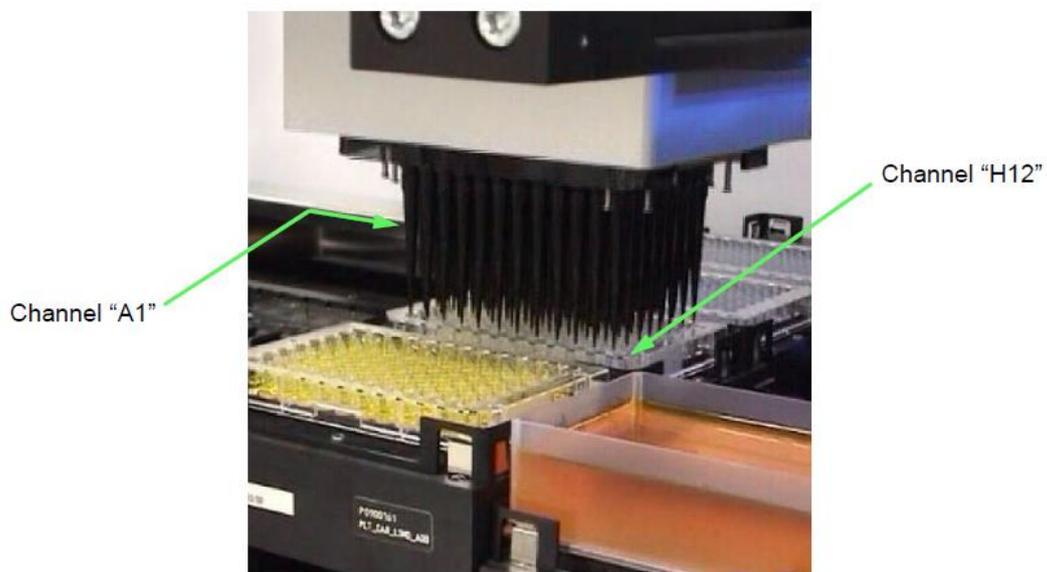
AIOS is an accessory of Seegene STARlet and has a built-in plate handling module and dedicated software (AIOS Controller). For more information about AIOS, please refer to AIOS User's manual.

2.2.6 CO-RE 96 Probe Head

The CO-RE 96 Probe Head is a high-throughput pipettor built with the CO-RE technology as a Seegene STARlet pipetting channel. The CO-RE technology guarantees fast and accurate pick-up and release of disposable tips.



cLLD (capacitive Liquid Level Detection) is available on the two special channels A1 and H12.



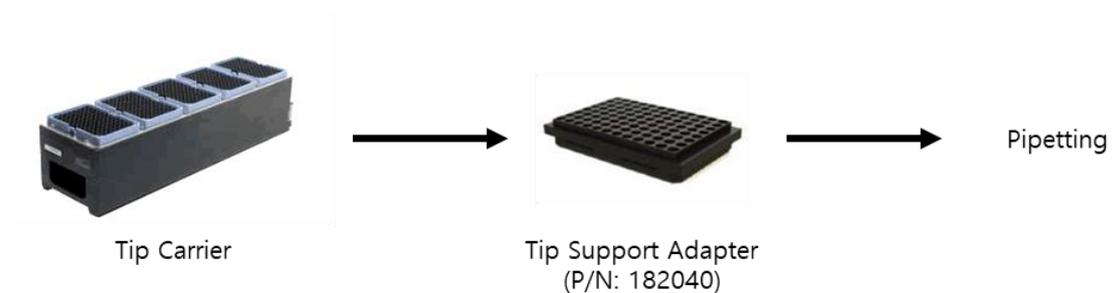
View from the Right to Left Side of the Instrument

The CO-RE 96 Probe Head is available with 96x 1000 μ l-pipetting channels. The 96 pipetting channels always work simultaneously with the same volume.

The CO-RE 96 Probe Head supports pipetting with high volume (1000µl) disposable tips. The following table gives an overview of disposable tips which can be used with the CO-RE 96 Probe Head. Other combinations may be possible, but require special attention.

CO-RE 96 Probe Head	Tips for Working Volume and Purpose
Plate Type	1000µl CO-RE Tip
 <p>96 Deep Well Micro Plate</p>	

The use of a tip support makes picking up one or more columns, rows, a single quadrant or even a single tip feasible from Tip Carrier with the CO-RE 96 Probe Head.



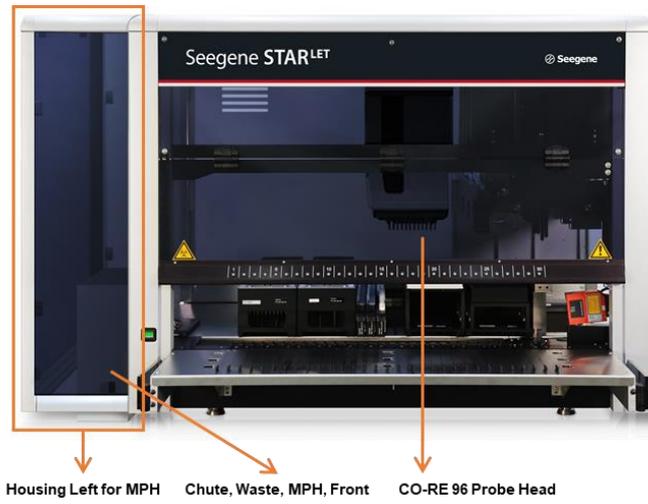
NOTE

For shifted tip pickup, make sure to use a tip support(P/N 182040) as an intermediate storage position for tips. It allows picking up of a single tip/row/column using the CO-RE 96 Probe Head.

Housing Left for MPH (P/N 188122) is required to connect the CO-RE 96 Probe Head to the Seegene STARlet. This can be mounted on left side of Seegene STARlet.

If used on Seegene STARlet with CO-RE 96 Probe Head, the following waste has to be ordered.

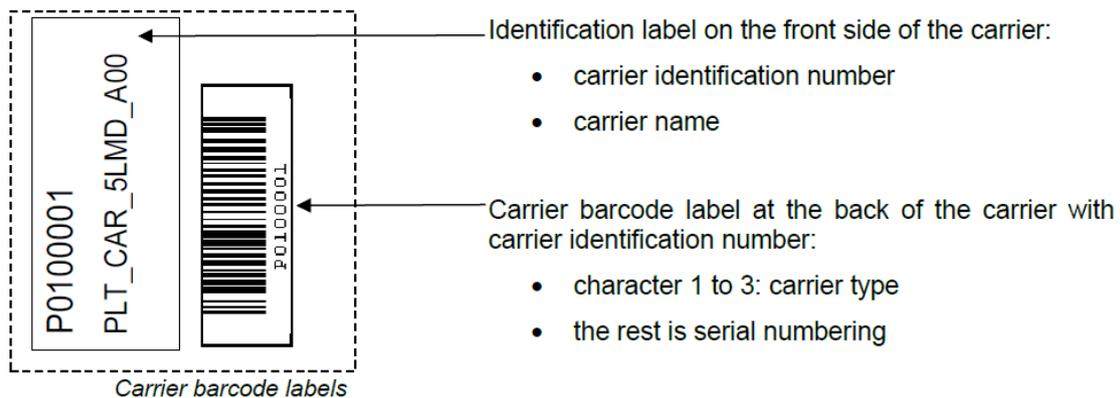
- Chute, Waste, MPH, Front (P/N 92573-01)



2.3 Carriers

Labware is placed on special carriers which are loaded onto the STARlet deck. Every carrier is equipped with at least 2 labels, one identification label and one barcode label. The identification label is readable by the operator; it contains the carrier name and barcode information. The carrier name on the identification label is the one used by the STARlet Software.

The barcode label is for purposes of automatic identification.



2.4 Tips

Hamilton's CO-RE tips are the only tips designed to work with the STARlet developed to meet the demands of the most flexible and reliable automated pipetting tasks. Pipetting channels lock into the tip rather than the standard method of forcing a tip on a mandrel (see Section 2.1.5 Tip Pick-up with the CO-RE Technology). This design assures superior tip alignment, seals the tip to the pipette channel, eliminates tip distortion, and mitigates aerosol contamination.

The use of non-Hamilton tips is not supported on the STARlet. Non-Hamilton tips do not have the annular space to receive the O-ring. This may result in non-intended deformation of the O-ring and the tip material itself. It may lead to misalignment of the tip, improper sealing, reduced O-ring life, improper drop-off, and potential aborted runs from randomly dropped tips. Therefore, Seegene does not support the use of non-Hamilton tips on the STARlet.

**ATTENTION**

Only Hamilton needles and disposable tips should be used for coupling to the pipetting channels and pipetting heads of the STARlet. Other tips may cause contaminated or damaged pipetting channels.

**NOTE**

Pipetting specifications are only guaranteed when using Hamilton Tips. Hamilton's proprietary technologies for tip attachment (CO-RE) and air displacement pipetting together with the use of Hamilton tips facilitate maximum pipetting accuracy and reliability.

Hamilton disposable CO-RE tips are produced under clean room conditions (class 8), based on ISO 14644 standards. "Biological purity tested" tips are free of DNA, DNase/RNase, PCR inhibitors and endotoxin (non-pyrogenic). In addition to these criteria, "Biological purityPLUS" tips are sterile, according to ISO 11135, and free of ATP.

Filter tips are available for preventing aerosol contamination.

Clear tips are available as well as conductive (black) tips specifically designed for cLLD.

**NOTE**

Make sure to match the tip type(s) used with the method and channel(s) / probe head(s). Please refer to Section 2.1.5 Tip Pick-up with the CO-RE Technology.

**NOTE**

Be aware that different tip classes (with and without filter, black or clear, non-sterile versus irradiated, etc.) can have different performance when pipetting liquids. Pipetting parameters and liquid class settings may have to be adjusted when changing from one tip type to another in order to achieve accuracy and precision which is within published specifications.

2.4.1 CO-RE tips for 1000 μ l Pipetting Channels

Disposable CO-RE tips for the 1000 μ l pipetting channel are available in 2 different sizes with filter:

- Medium (standard) volume CO-RE tip, 10 - 300 μ l
- High volume CO-RE tip, 10 - 1000 μ l

The medium (standard) volume CO-RE tip, 10-300 μ l, is available as conductive (black) tip for use with cLLD, with and without filter. It is compatible with Monitored Air Displacement (MAD) and Total Aspiration and Dispensing Monitoring (TADM). The medium volume CO-RE tips come in trays of 96 tips. One blister pack contains 5 trays. The trays are barcode labeled for automatic identification during the loading process.



Clear and Conductive CO-RE Tip, 10 – 300 μ l



Tip Tray and Color Code Label for CO-RE Tips, 10 – 300 μ l (Yellow Label)

The high volume CO-RE tip, 10-1000 μ l, is available as conductive (black) tip for use with cLLD, with and without filter. It is compatible with Monitored Air Displacement (MAD) and Total Aspiration and Dispensing Monitoring (TADM). The high volume CO-RE tips come in trays of 96

tips. One blister pack contains 5 trays. The trays are barcode labeled for automatic identification during the loading process.



Conductive CO-RE Tip, 10 – 1000 μ l



Tip Tray and Color Code Label for CO-RE Tips, 10 – 1000 μ l (White Label)



ATTENTION

To avoid any cross contamination use only tips with filter.



ATTENTION

Only HAMILTON disposable CO-RE tips should be used with the STARlet. Non-HAMILTON tips may cause contamination or damage of the pipetting channels or may lead to incorrect pipetting.



NOTE

The tip type is printed in plain text on the barcode label of the tip rack for visual identification. E.g. '300 μ l' for the middle volume CO-RE tips.

2.5 Computer Requirements

The STARlet and its accessories are controlled by dedicated STARlet Software which controls all functions for daily work routine, method programming, running methods and other services.

The STARlet and the computer are linked via Universal Serial Bus Interface (USB). For the recommended PC model refer to Section 7.1 Basic Instrument STARlet. And, Screen resolution must be 1600X900 display.

To avoid data loss, we recommend an uninterruptible power supply (UPS) for the PC.

2.6 STARlet Software

The STARlet Software provides everything to control the STARlet.

It is a Windows-based, menu-driven interface allowing the method programmer to program layouts and methods and then to run the STARlet.

The STARlet Software allows programming and running different methods for aspirating and dispensing liquids, also to control accessories.



NOTE

STARlet functionality has been verified using Windows 10. Running the STARlet under any other operating system may lead to severe problems and/or malfunction. Each programmed method must be validated by the programmer.

The STARlet will be unpacked and installed and the initial set-up will be performed by an authorized service technician according to the IQ Form.

2.7 Power / Voltage

Make sure that the STARlet is connected to a 100-240 VAC (50 Hz or 60Hz) socket. The STARlet automatically recognizes any voltage within that range, without user intervention.

We recommend using an Uninterruptible Power Supply (UPS) for the STARlet. Ensure that the instrument is correctly grounded when connected to the power supply. The main plug is on the left-hand front side of the instrument.

The fuses for the instrument are placed in the main power socket (see picture below).

During installation / IQ, the appropriate fuse is selected by the authorized service technician.

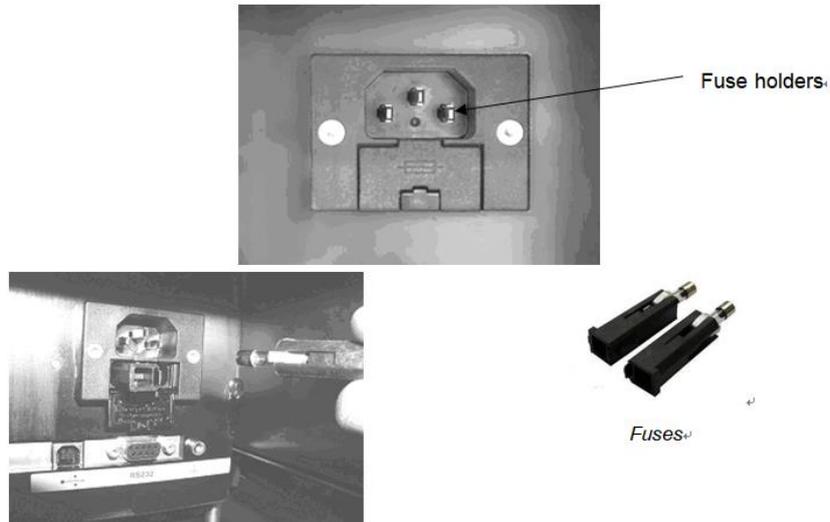
Plug the main cables for the computer and the instrument into the same electrical outlet.

Connect them only to a grounded outlet.



ATTENTION

Do not exchange the supplied/installed power cord. In case of damage or loss of the power cord, consult a local Seegene representative for a replacement. If replacing the power cord by inadequately rated power cords, the protection provided by the equipment may be impaired.

**ATTENTION**

When replacing a fuse, make sure to use the appropriate fuse (see Section 7 Technical Specifications) and place it into the main power switch before switching on the instrument.

3. Routine Use

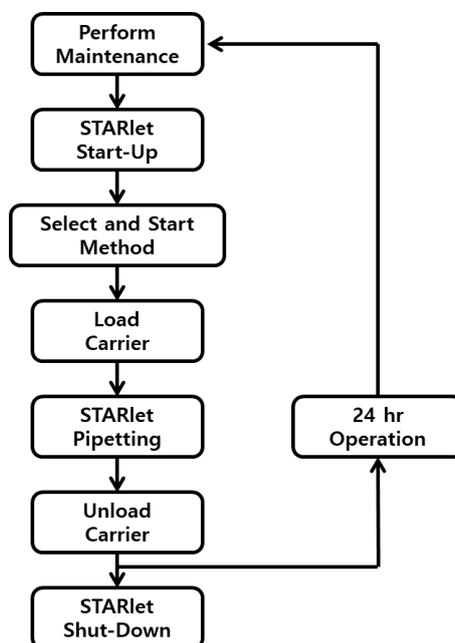


NOTE

This section can vary due to different applications and method programming.

3.1 Daily Work Routine

Below is a flow chart giving the logical flow of the daily work routine using the STARlet. Each of these steps is explained in detail in the following pages.



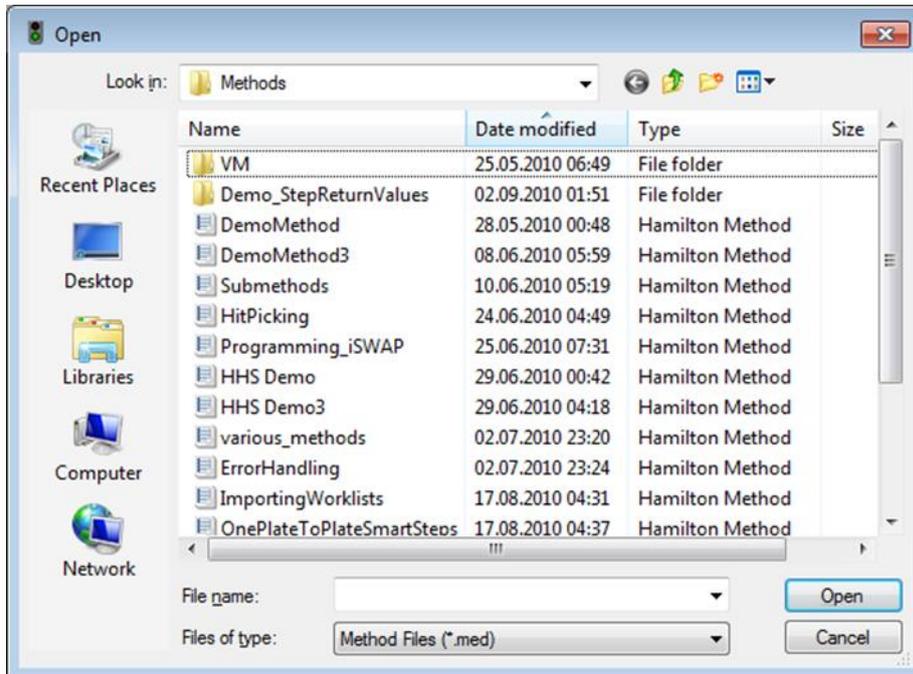
To perform the periodic maintenance, see the Section 4 Maintenance.

3.2 Starting the STARlet

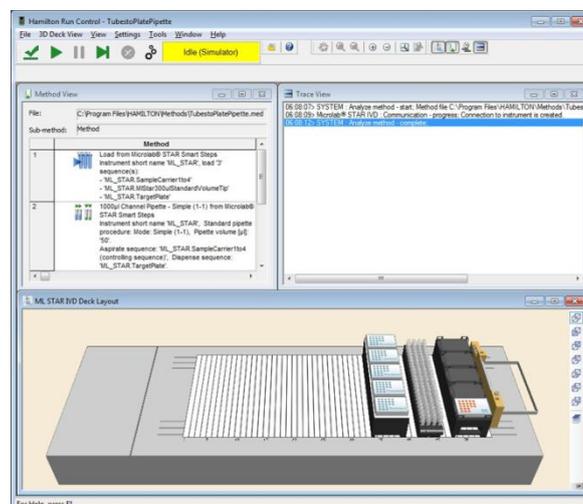
Turn on the STARlet and the connecting PC and enter your username and password (optional).

3.3 Selecting a Method

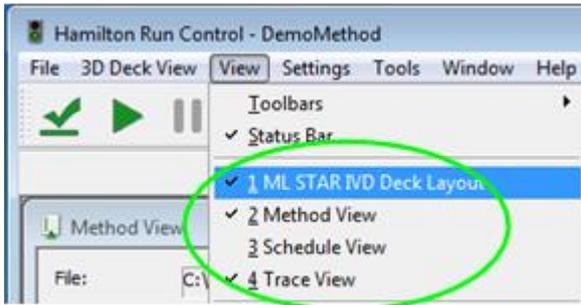
1. Select the protocol to run by Launcher. For details, please refer to the Launcher manual.



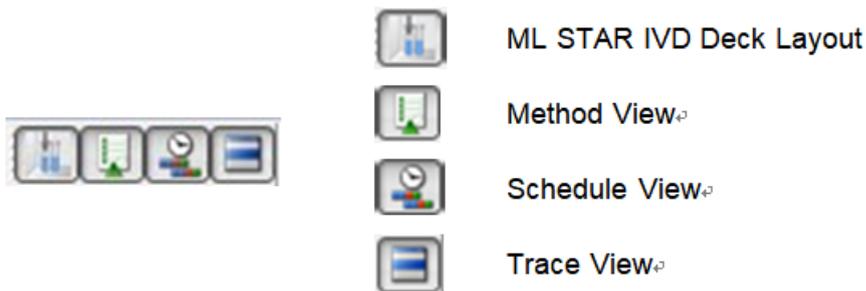
2. When the method is opened, it is analyzed. This procedure may take up to a minute, depending on the size of the method.
3. The relevant deck layout along with the “Trace View” and “Method View” appears.



4. The free area available after starting “Run Control” can display various windows: The windows may be enabled / disabled by means of the “View” menu (click the desired menu entry).



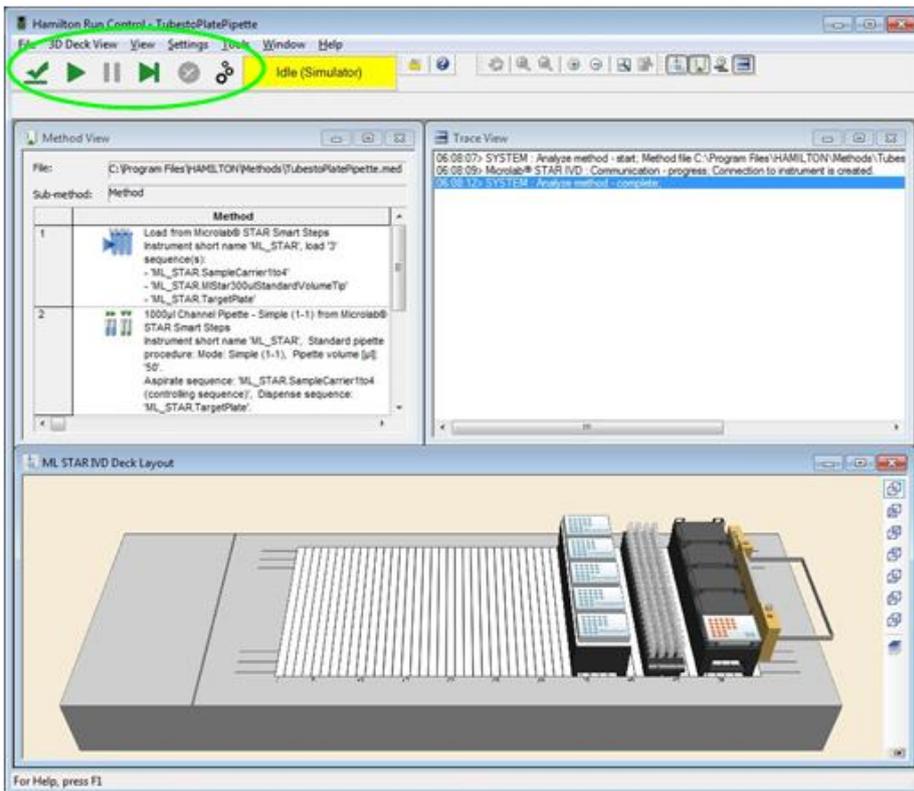
Or by clicking on the appropriate icon in the “Views” Toolbar (to enable, go to “View → Toolbars”).



5. Arrange the windows using the menu “Window”. In the window shown above, the method view, deck layout and the trace view are visible.

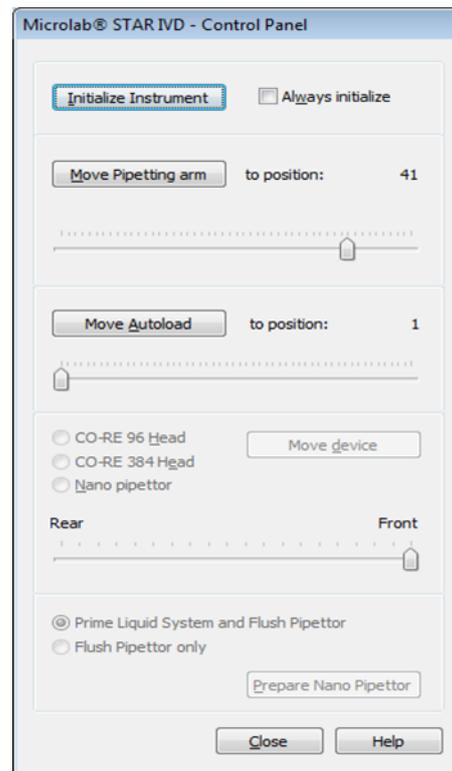
3.4 Run Execution

The “Start”, “Pause”, “Abort” and other Control Buttons which can be used in the Run Control are located at the top of the Run Control window.

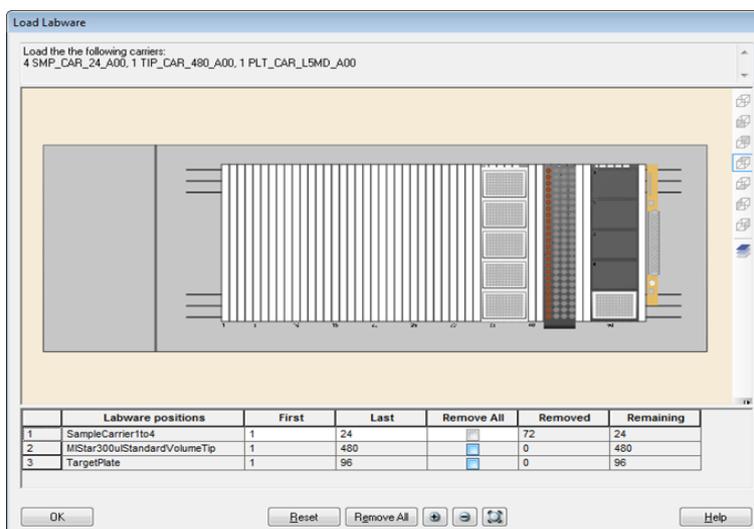


-  Analyze Only
-  Start
-  Pause
-  Single Step
-  Abort
-  Control Panel

Opening the Control Panel will allow the initialization and movement of the instrument prior to the run:



1. Press the “Start” Button to run the method. The steps in the method are traced to the “Trace View” frame as the method runs.
2. If a loading step is part of the method, a dialog appears that requests a reduction of the number of positions on the sample carrier, as well as a start position for the tips to be picked up. Both pieces of information are optional.



3. Enter the number of samples, tips or wells on the source plate for this run, delete wells graphically from the sequence or accept the default.

Generally, whenever the system finds a “Load Carrier” command in the method, the operator is requested to place the carrier holding the appropriate labware onto the autoloader tray. The correct position is highlighted by LEDs on the instrument. Alternatively, all carriers can be placed directly in their correct positions on the autoloader tray.



ATTENTION

It is important to ensure that adequate amounts of the correct liquids are placed in the correctly labeled containers. When pouring reagents into the reagent containers, ensure that there is no foam on the surface of the liquid. Do not overfill reagent containers: fill approximately 10mm below the top of the container to avoid spilling liquids. Handle labware (tips, microplates, tubes, etc.) with care to avoid spilling liquids. Always use the proper labware (tips, microplates, tubes, etc.) corresponding to the definitions of the method’s layout. Never load incomplete strip plates. Incomplete plates should be filled with uncoated strips (dummy strips). The use of dummy strips is the responsibility of the user. Place the microplates correctly such that well #A1 is placed according to the deck layout. Handle any 1-track carrier (such as a sample carrier) with particular care, as this type of carrier can fall over and cause injury or contamination. Position it on the autoloader tray (see figure below), or place several carriers together to minimize this risk.

4. Insert the carriers into the tracks between the front and rear slide blocks of the autoloader tray until they touch the stop hooks on the far side of the tray.



Slide Blocks and Stop Hooks for Carriers



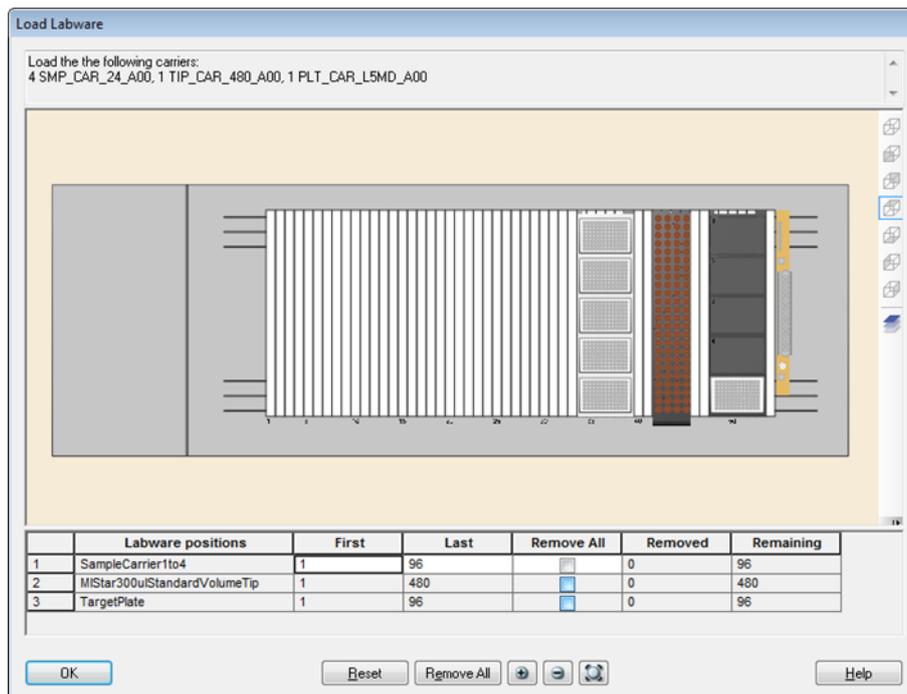
ATTENTION

Make sure the carriers are inserted completely until they touch the stop hooks on the Autoload Tray. Make sure there are no carriers loaded on the same tracks as already loaded carriers on the deck (indicated by LEDs).

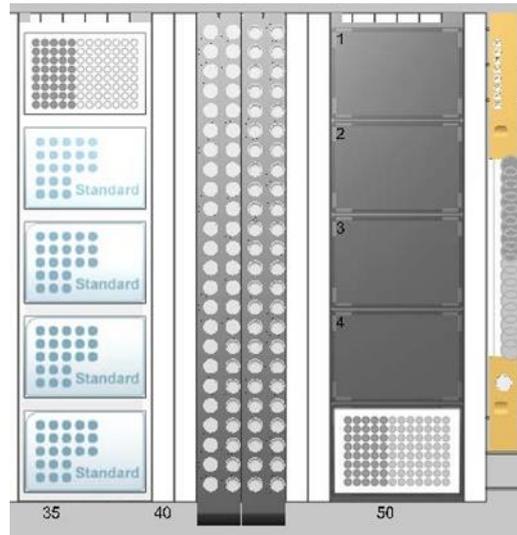
5. Click [OK] in the dialog. The carriers are loaded onto the deck automatically by the “Load Carrier” command in the method. During loading, the barcodes of carriers and labware are read and stored in a file.

Or Load the carriers onto the defined positions of the autoload tray before starting the method. Loading and barcode reading will then be performed without operator input.

6. If using smart steps and walk-away mode is not selected, the Load Labware dialog still pops up:



7. During run execution of a method, the instrument steps are automatically logged and displayed in the run views as well as written in the trace file with the same name as the method file (see Section 3.6 Trace View). In the deck layout, the currently used deck positions are highlighted and the processed positions are grayed out.



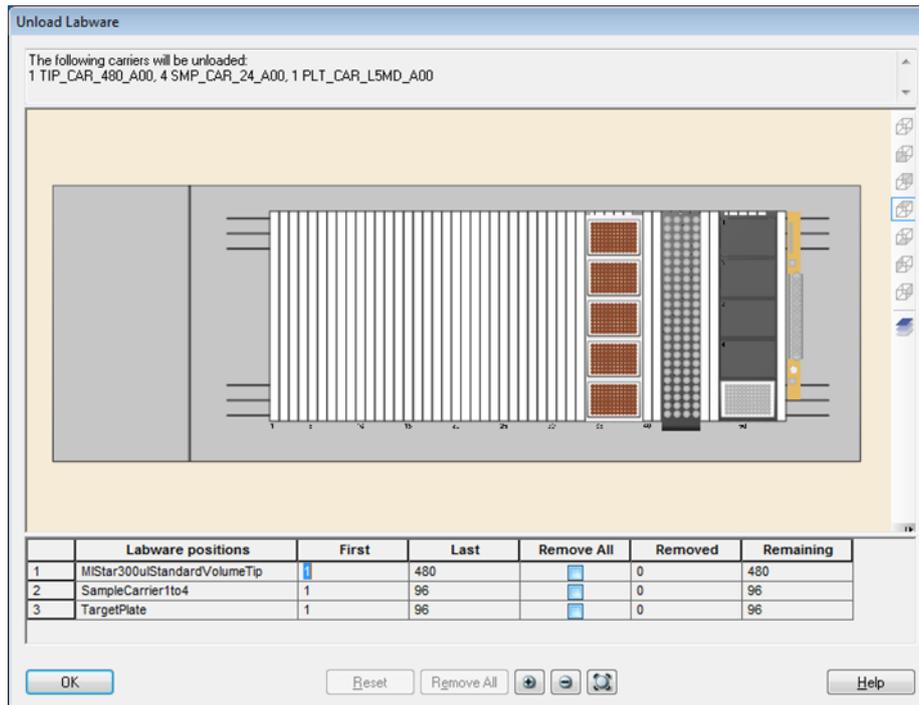
8. To pause the method, click on the [Pause] Button of the Run Control. When the current pipetting step is finished, the method will be paused. Paused methods can be resumed or aborted. Click on the pause dialog to stop the beeping.
9. To abort the method, click the [Abort] Button. You will be prompted to confirm the abort.

**ATTENTION**

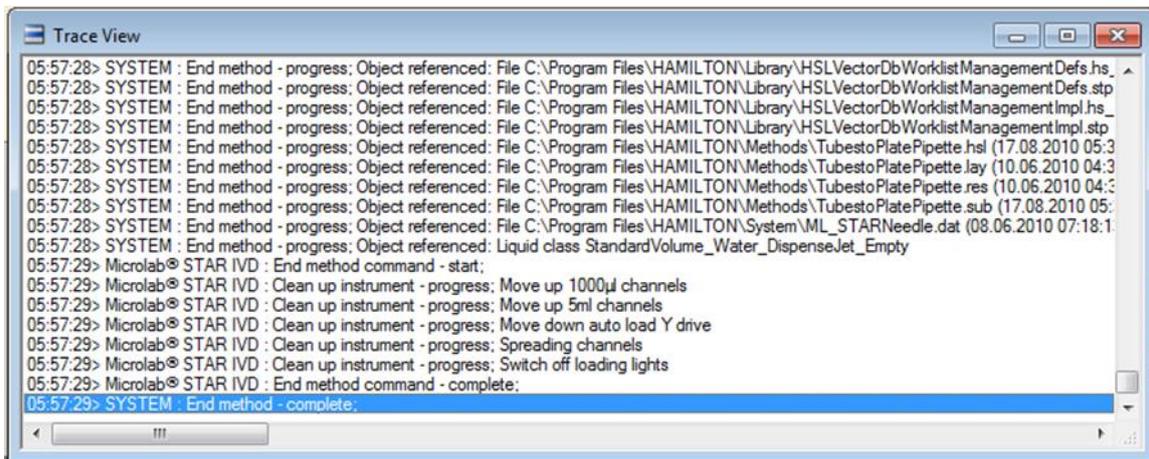
An abort may cause the loss of data. Therefore methods once aborted cannot be resumed. An aborted run, e.g. one stopped by pulling out an inserted carrier, cannot be restarted.

If many tips are used during the runs and if the capacity of the laboratory-supplied tip waste container is insufficient, the waste container should be emptied more often than the regularly scheduled maintenance intervals.

10. If unload smart step is part of the method, you are requested to unload the carriers from the deck. The following dialog box opens:



11. Click [OK] in the dialog to unload the carriers to the Autoload Tray.
12. The method is finished. The run status is back to 'idle'. Method completion information is visible in the "Trace View" window.



3.5 After a Run

When a run is complete:

1. Remove the empty racks of tips and the processed labware.
2. Remove or replenish reagents. If spills occur, clean them up immediately. Check under, around, and on affected pedestals. See “4. Maintenance” section.
3. Empty the waste bin, if it is full.
4. At the end of the day, perform Daily or Weekly maintenance. Turn off the STARlet and shut down the STARlet computer.

3.6 Trace View

Each executed instrument step is logged in the “Trace View”.

To view or print out method traces use the menu option “File Print Runtime Trace” within the Run Control.

3.6.1 Method Trace

The method trace file is stored under: '<method name>_<run id>_<Trace>.<trc>' within the ...\\HAMILTON\Logfiles directory, e.g.:

- MyNiceMethod_9361B39894C24630818226446A04E4E9_Trace.trc

The method traces can be sorted according to date using the “Modified” column. They are not overwritten or appended. The run ID of trace files is unique and all files of the same run have the same run ID.

Name	Date modified	Type	Size
 ComTrace_Simulator20100927.trc	27.09.2010 06:55	TRC File	74 KB
 DEMO_3e0c14f12d9c454899548b9d6f52884a_Trace.trc	27.09.2010 06:55	TRC File	11 KB
 DEMO_Barcodes	27.09.2010 06:55	Text Document	1 KB

Other trace files are generated for:

- TADM data: '<method name>_<run id>_<TADM>.<mdb>'
- Maintenance reports: '<method name>_<run id>_MV<type>.<xls>'

The file type abbreviations 'Trace', 'Tadm', 'Track' and 'MV' are not case-sensitive.



ATTENTION

At a weekly interval, the operator should save all files in the Log files directory on the host device and delete them from the hard disk.

Files of other directories must not be deleted.

3.6.2 Communication Trace

A communication trace file is also generated under the “communication name” (Simulator, HxUSBComm) and current date, where the communication of each run of the method will be appended. If barcode information is generated, its data will be stored in a file labeled with the method’s name followed by “*_Barcodes.txt”.



NOTE

From time to time all unused method traces and com traces should be deleted from the hard disk (backup on a separate device).

3.7 Run-Time Error Handling

Before using the run time error handling, several types of problems causing errors have to be solved. Among these are:

- Syntax errors when programming in HSL (e.g. forgotten “;”)
- Logical errors (e.g. “tip eject” before “pick-up”, or “asp 20µl”, “disp.100µl”)
- Semantic errors (e.g. wrong pipetting pattern)
- Method / deck interaction errors (e.g. dispense 100µl into the first well of a 1536-well MTP)
- Liquid handling/application errors (e.g. droplets, foam, non-pipetted wells)
- User-related errors (e.g. sample tubes not filled completely, wrong deck loading)

These problems cannot be handled by any run time error handling. They have to be solved in advance, while or after the programming.

Problems that can be handled during run time are:

- Not enough liquid
- Liquid level not found (if it occurs exceptionally)
- No tip picked up
- Clot detected
- Barcode unreadable (if it occurs exceptionally)
- Execution error (channel no. 1 has an error (e.g., not enough liquid), then channel no. 2-8 have an execution error because they have been stopped before completion of the step)

Call an authorized service technician if an error occurs except for the following.

**NOTE**

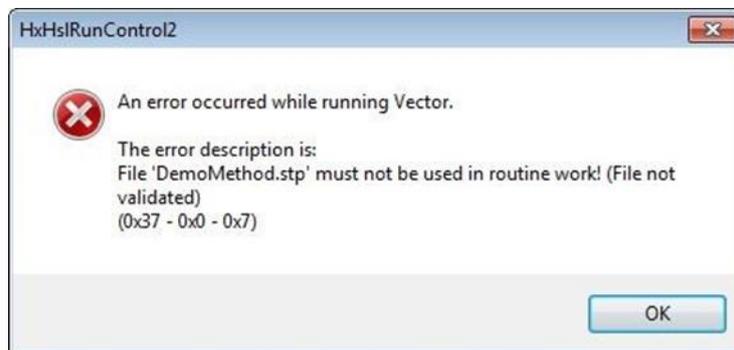
In principle, each pipetting channel may have one or more different types of errors at a time. If all pipetting channels have the same error at the same time, a collective recovery can be made.

3.7.1 Run-Time Error Handling Examples

We focus on some important examples. A detailed description is available in the online help. Click on [Error Settings] within the single step dialogs of the STARlet specific commands. Then click [Help].

3.7.1.1 Method not Validated Error

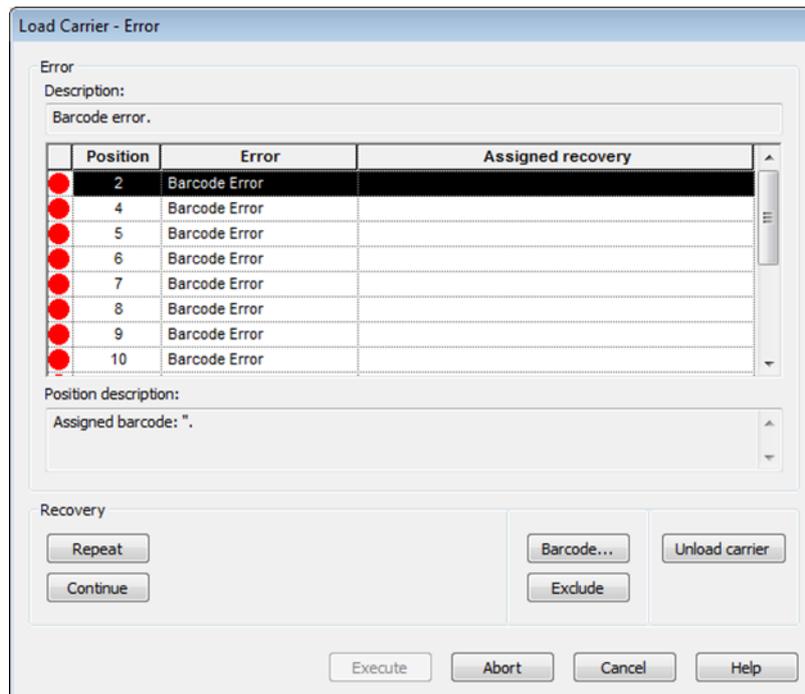
If the user tries to run a method which is not validated, the following error message appears:



If this message appears, the method must be validated before routine use.

3.7.1.2 Barcode Reading Error

1. In the case of an error, the process can be continued using the error handling procedure. If, for example, a barcode of a carrier cannot be read, a dialog window opens up:



2. The error recovery can be programmed to:

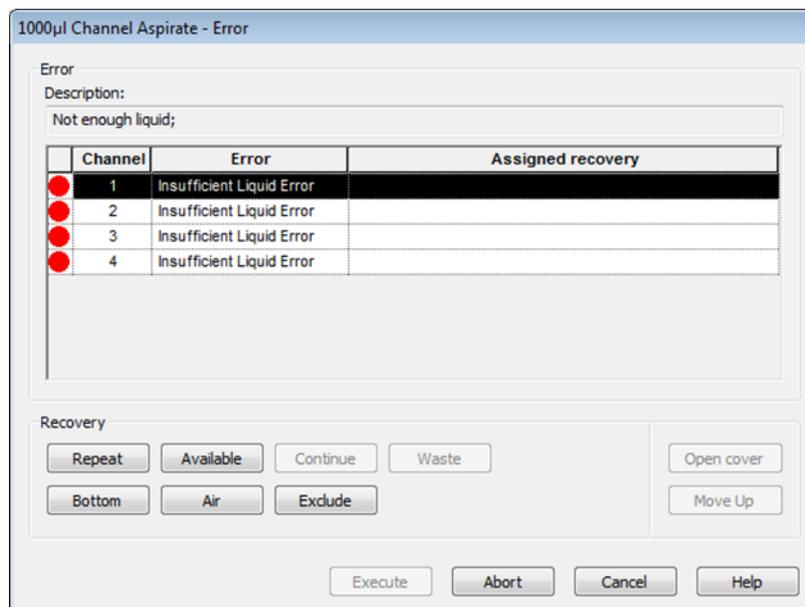
- **Continue** Ignore the error message (here, failure of barcode reading)
[Continue] makes no sense in the case of a barcode reading error - at least a manual entry has to be made so that barcode data exists for further processing.
- **Repeat** Try to read the barcode once again
Often a repetition of reading will solve the problem because the reading speed is reduced then. The selected action is displayed in the field [Assigned recovery].
- **Barcode...** Enter the barcode manually
Clicking [Barcode] opens an entry dialog box where a barcode can be entered (no entry is also allowed).

3. Assign a recovery option. The [Execute] button becomes active.
4. Click on [Execute] and the instrument proceeds.

3.7.1.3 Pipetting Error

1. If an error occurs with the pipetting channels, a displayed error dialog shows its error state and its recovery options for every single channel (Different channels can have different errors).

For example, in case of an LLD error such as no liquid in the container while aspirating, a window similar to the following pops up:



2. All pipetting channels which produced an error are listed with a red dot on the left. A short error description is given. A detailed error description is shown at the top text field labeled "Description:" for the selected pipetting channel. There may be different errors which lead to the same short error description.
3. The "Recovery" buttons offer several possible actions to solve the problem:
 - [Repeat]: Executes the command which caused the error once again
 - [Available]: Aspirates the available volume from the source and fills up the missing volume with air
 - [Continue]: Continues as if no error was recognized

- [Waste]: Means that the erroneous tip is ejected to the waste and the channel is excluded.

- [Bottom]: Activates the channel to move down to the bottom of the container, and the available volume is aspirated without LLD
- [Air]: Means air is pipetted instead of liquid and the method will continue
- [Exclude]: Allows disabling any further action on the error-affected pipetting channel
- [Move Up]: This is not a real error recovery procedure, but useful (e.g. to manually a clot).
 - move the barcode reader of the Autoload (if present) to the very right
 - move the selected pipetting channel up by 10mm
- [Open Cover / Close Cover]: this button does not start any error recovery actions either, but triggers the following actions:
 - [Open Cover]: enables opening the front cover during error recovery
 - [Close Cover]: enables closing the front cover before executing error recovery

4. Selecting a pipetting channel followed by any possible recovery procedure assigns the selected recovery procedure to all error-affected pipetting channels from the selected to the last one. If you would like to assign a different recovery procedure (this would be unusual) to each faulty pipetting channel, you would have to assign the first procedure to the top-most pipetting channel, which will assign this recovery procedure to all lower-listed pipetting channels. Then, you would have to select the next pipetting channel down, and assign the desired recovery procedure to it. Continue this way until a recovery procedure for each faulty pipetting channel is assigned.

5. If any recovery procedure is assigned to a pipetting channel (even one you do not wish to assign), the dot in the first column changes color to green.

6. Some recovery buttons are disabled, to prevent further faulty steps, e.g. an error-affected aspiration step cannot be [Continued], to prevent any later dispense with insufficient volume. When the last pipetting channel is assigned to a recovery procedure, the [Execute] button becomes active and the system can proceed.

In any case the method can be aborted without further recovery options.

**NOTE**

For IVD Applications, the error handling can be restricted by the programmer according to the application specifications.

4. Maintenance

Periodic maintenance routines need to be run in order to ensure safe and reliable operation of your STARlet and the accessories.

For IVD use, the maintenance routines are mandatory.

4.1 Maintenance Intervals

In order to maintain the STARlet in good condition, the following maintenance intervals are foreseen:

- Daily: Maintenance carried out on a daily basis either before or after use.
- Weekly: Maintenance carried out on a weekly basis either before or after use.
- Verification: Maintenance serviced by qualified engineers every six months.

Verification must be carried out by authorized engineers ONLY.



NOTE

If the operator decides not to run either daily or weekly maintenance before shutdown, these routines must be executed at the next run start.

If any parts of the instrument, carriers, or racks have become contaminated, the weekly maintenance procedure must be performed.

4.2 Materials Required

- Disposable latex gloves
- Protective glasses
- Lab coat
- Paper towels
- Lint-free cloths or Q-tips
- Ethanol (70%)
- Distilled water



ATTENTION

Use cleaning, disinfecting and decontaminating fluid in accordance with the manufacturer's instructions. Do not use disinfecting materials which contain hypochlorite (Javel water, Chlorox) or bleaching fluids.

Prepare disinfectant fluids according to their labeling.

4.3 Maintenance Procedures

The operator will be guided by the STARlet Software through the maintenance procedures.



ATTENTION

Always wear disposable gloves during maintenance. Do not clean the instrument in the vicinity of open flames or devices which could create sparks. Do not use hot air blowers to dry the instrument. The liquids used for cleaning are flammable. When cleaning the CO-RE gripper tool, be very careful of sharp edges on the gripper's pincers. This manual provides indications regarding general disposal of waste. In addition, any regulations specific to the country of operation must be taken into account and observed.

Routine Completion

A maintenance routine is completed once the procedure has been fully executed and the results are within the specifications.

Aborting Maintenance Procedures

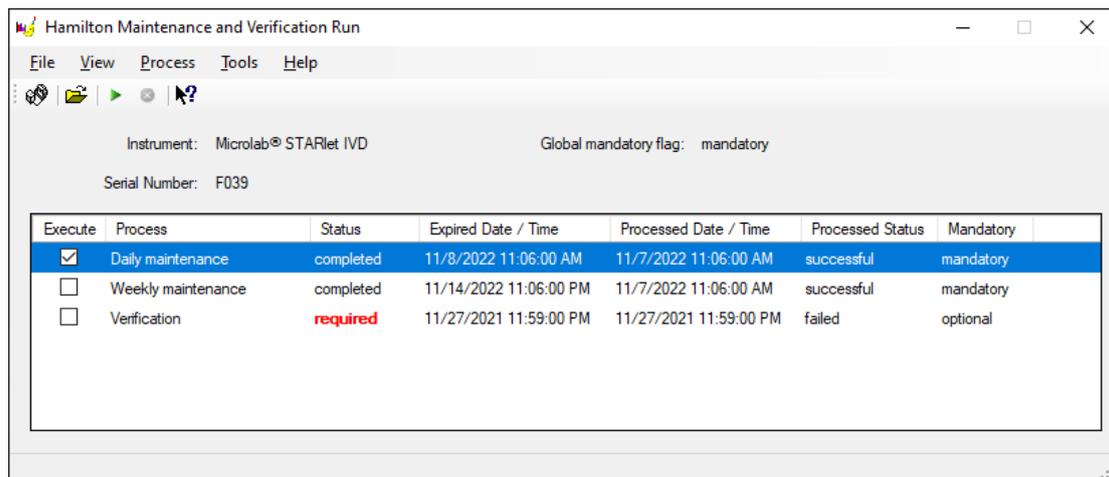
Aborting a maintenance procedure will lead to a 'failed' status, and maintenance will need to be started again.

4.3.1 Accessing the Maintenance Utility



To access the Maintenance Utility:

1. Double-click the icon named Seegene Launcher on the desktop. The Seegene Launcher window will appear. Click Maintenance button.
2. Check the serial number of the STARlet. The serial number is on a label at the top of inner back wall of STARlet.



“Maintenance and Verification Run” Window

3. Choose Maintenance Type and click Arrow (▶) to launch the selected maintenance protocol.

4.3.2 Daily Maintenance

Daily Maintenance requires the following tasks be performed:

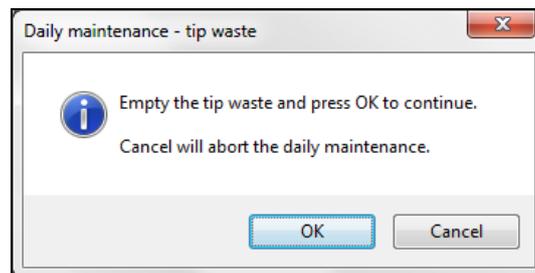
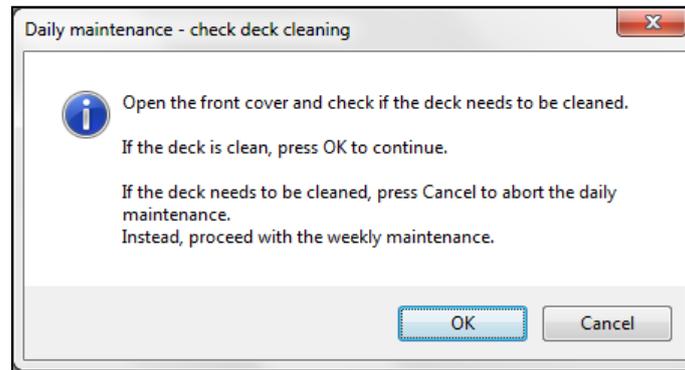
- Inspect deck and carriers for cleanliness.
- Empty a tip waste/liquid waste.
- Check pipetting channels for tightness.
- Check cLLD.

The following procedure describes these steps in detail. Refer to “4.3.1 Accessing the Maintenance Utility” for information for accessing the Maintenance Utility.



To perform Daily Maintenance:

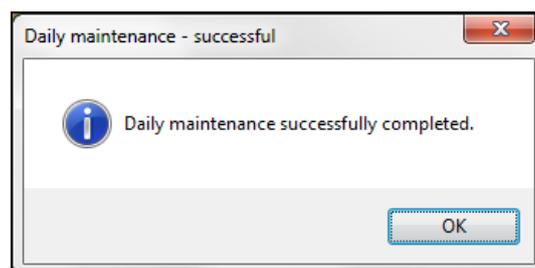
1. Run Hamilton maintenance program and select Daily maintenance. Then click Arrow to launch.
2. Inspect deck, carriers, and Tip Waste for cleanliness. Wipe up any spills. Spray Ethanol (70%) on a deck or carrier surfaces you want to decontaminate, and then wipe them dry with dry paper towels. Make sure the tip waste bag is empty. After finished, click OK.



3. The following procedure is the check of pipetting channels' tightness. The pipetting arm will move to the right side to pick up the maintenance needles. Tightness is checked for twice: first, the over-pressure and second, under-pressure check.

4. For the capacitive liquid level (cLLD) check, the needles are picked up again. Channels are checked one by one for the proper functioning of cLLD.

5. Click OK on the "Daily maintenance successfully" completed checkbox.

**ATTENTION**

The tip waste is always to be regarded as contaminated.

6. The daily maintenance process status is saved on the instrument and a report file is created (See 4.4 Printing a Report).

**NOTE**

If any parts of the instrument, carriers or racks have become contaminated, the weekly maintenance procedure must be performed.

4.3.3 Weekly Maintenance

Weekly Maintenance requires the following tasks to be performed:

- Cleaning the deck and carriers
- Inspect conditions of carriers and other devices.
- Empty and clean a tip waste/liquid waste.
- Inspect pipette channels for tightness.
- Check cLLD.
- Clean each pipette head: stop disk, O-ring and tip eject sleeve.
- Clean side covers and autoloader protecting ribbon.

The following procedure describes these steps in detail. Refer to “4.3.1 Accessing the Maintenance Utility” for information for accessing the Maintenance Utility.



To perform Weekly Maintenance:

1. Clean the tip eject sleeve (outer part of the pipetting heads) with a lint-free cloth soaked in distilled water.

**ATTENTION**

Take care that no liquid gets inside the pipetting channel.

Whenever it is necessary to move the pipetting channels on the X-Arm, move them gently by pushing close to their Y-slide. Never force them as this may lead to damage. If possible, switch on the instrument as this will result in a smoother motion when the pipetting channels have to be moved on the X-Arm.

2. Clean the stop disk and the O-rings of the pipetting head (exterior part of the pipetting channels) with a lint-free cloth soaked in distilled water.

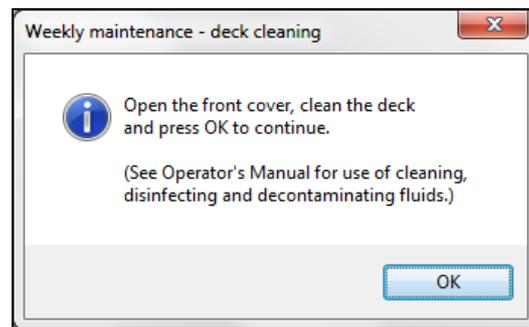
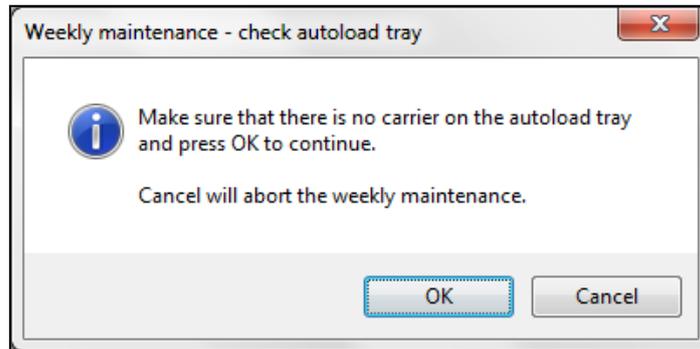


3. Spray the front and side cover with Ethanol (70%) and wipe dry.

**ATTENTION**

Do not spray directly at the Autoload unit or at electrical boards or connectors.

4. Clean the autoload protecting ribbon with cloth soaked in Ethanol (70%) and wipe without putting pressure.
5. Run Hamilton maintenance program and select Weekly maintenance. Then click Arrow to launch.
6. Unload carriers from the deck. Spray them with Ethanol (70%) and wipe them clean with paper towels. Carriers must be completely dry before reinstallation and reuse. When finished, click OK.



7. Remove the tip eject plate placed near the waste bag. Spray it with 70 % EtOH and wipe it with paper towels. Remove the frame that holds the waste bag in place and dispose the waste bag in the laboratory's trash for contaminated items. Pull a new waste bag over frame and re-attach it. Put the clean tip eject plate back in place.

**ATTENTION**

The tip waste, the tip eject plate and the plastic bag are always to be regarded as contaminated.

**ATTENTION**

Do not spray the maintenance needles.

8. To prevent wrong barcode reading, check the laser scanner window of the barcode scanner and clean it with a lint-free cloth or Q-tips lightly soaked in 70 % EtOH.

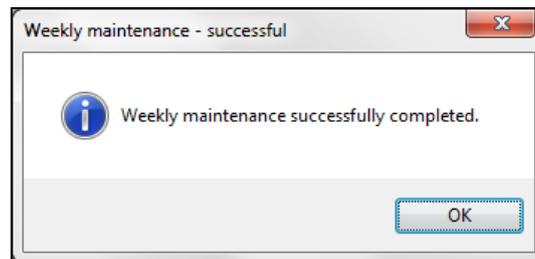
**ATTENTION**

The laser scanner window must be completely dry and free from dust and fibers before the instrument can be reused.

9. Check tightness of the pipetting channels. The pipetting arm will move to the right side to pick up the maintenance needles. Tightness is checked for twice: first, the over-pressure and second, under-pressure check.

10. For the capacitive liquid level (cLLD) check, the needles are picked up again. Channels are checked one by one for the proper functioning of cLLD.

11. Click OK on the Weekly maintenance successfully completed checkbox.



12. The weekly maintenance process status is saved on the instrument and a report file is created (See 4.4 Printing a Report).

**NOTE**

Carriers must be completely clean and dry before re-using.

4.4 Printing a Report

The maintenance process status can be printed. To print such a report:

1. Go to “File” – “Open Report”. All maintenance and verification processes which are found in the default “Report Path” are listed.
2. If necessary, change the report path using the browse button [...].
3. Select a report and click the [Open] button. The Report Viewer displays the selected report file.
4. Go to “File” – “Print” to print the report file.

4.5 If Maintenance Fails

If an error is encountered during a maintenance procedure, try to resolve the problem and restart the maintenance procedure. If you cannot resolve the error yourself, contact your local Seegene representative.

5. Verification

The STARlet must be verified by an authorized service technician upon initial set-up, and thereafter at regular intervals. If any verification procedures are due and have not been successfully completed, it is not possible to start a run or method.

The STARlet must be verified:

- During the instrument installation
- Twice a year (every 200 days)
- After a repair or service of the instrument

To perform the verification, the appropriate Field Verification 2 Kit must be used. This kit contains all the necessary tools to verify the instrument in your laboratory.

For more information about the contents of the verification kit, please consult the corresponding Field Verification 2 Manual. This manual explains and illustrates the functions to verify and the entire procedure in detail.

6. Decontamination

To follow is the recommended procedure for decontaminating the STARlet:

- Spray the front and side cover with Ethanol (70%).
- Open the front cover and wipe the deck with a cloth saturated with Ethanol (70%). The slide blocks in particular must be checked for cleanliness.
- Remove the tip eject plate of the tip waste station and clean it.
- Spray Ethanol (70%) directly onto the surface of the tip waste station.
- Remove the frame that holds the plastic bag in place, and discard the plastic bag in the laboratory's contaminated waste. Put the tip eject plate back in place.
- Clean the tip eject sleeve (outer part of the pipetting channels) with a lint-free cloth soaked in distilled water.
- Clean all carriers with Ethanol (70%) and let them dry.

7. Technical Specifications

7.1 Basic Instrument STARlet

7.1.1 Dimensions and Weight

Dimensions

Seegene STARlet	Width: 1124mm Height: 903mm Depth: 795mm (without loading deck, i.e. transport size) 1010mm (with loading deck) 1200mm (with loading deck and carriers on loading deck)
Seegene STARlet (with CO-RE 96 Probe Head)	Width: 1374mm Height: 903mm Depth: 795mm (without loading deck, i.e. transport size) 1010mm (with loading deck) 1200mm (with loading deck and carriers on loading deck)

Weight

Seegene STARlet	Approximately 140kg
Seegene STARlet (with CO-RE 96 Probe Head)	150kg

7.1.2 Operating Data

Maximum Power Consumption	600 VA
Voltage	100-240 VAC
Frequency	50/60 Hz

Delayed Action Fuse	115 VAC: 6.3 A (T6.3AL250) 230 VAC: 3.15 A (T3.15A250)
Installation Category	II
Pollution Degree	2
Temperature Range	15°C – 30°C
Relative Humidity	15% – 85% (no condensation)
Noise Level	< 65dBA (regarding EN27779)
Altitude	Up to 2000 meters above sea level
Indoor Use Only	

7.1.3 Transportation and Storage

Temperature Range	-25°C – +70°C
Relative Humidity	10% – 90% (no condensation, indoors)
Indoor Storage Only	

7.1.4 Computer Requirements (Computer not included in shipment)

Recommended Minimum System Requirements	3 GHz Processor, 4GB RAM, 250GB HD, 16x DVD+/-RW DirectX 9 Graphics device Windows 10 Professional or Ultimate, 32 bit or 64 bit
Communication	5+ USB ports, 2 RS232 ports, 1 parallel

7.2 Functional Specifications

7.2.1 Work Area

Work Area Dimensions	Width (X)	Height (Z)	Depth (Y)
Seegene STARlet	675mm (30 tracks)	136mm	465mm

7.2.2 Tip Size for 1000µl Pipetting Channel

Available CO-RE Tips	Volume
Medium (standard) volume CO-RE tip (with and without filter)	10 - 300µl
High volume CO-RE tip (with and without filter)	10 - 1000µl

7.2.3 Pipetting Specification for 1000µl Pipetting Channel

Volume [µl]	Tip Size			Accuracy [%]	Precision [%]
	50µl	300µl	1000µl		
10	X	X	---	± 10	5.0
50	X	X	X	± 5	2.5
100	---	X	X	± 5	2.0
200	---	X	X	± 5	1.5
1000	---	---	X	± 5	1.5

Test conditions:

The Pipetting Specifications listed above are valid under the following conditions and obtained from measurements at HAMILTON Bonaduz AG.

1000µl Pipetting Channel	
Test method	Gravimetric testing at Hamilton. The scatter of the test method must be less than 1/6 of the specified precision (for one channel).
Accuracy / Precision	The values given refer to use of 8 pipetting channels.
Test size	≥ 10 single pipetting's per pipetting channel with disposable CO-RE tips (pick-up and dispense, tip used only once) and specified volume.
Test mode	Volumes ≥ 20µl as jet dispense, < 20µl as (liquid) surface dispense
Test temperature	20 ± 2°C
Test fluid	Deionized water with 0.1% NaCl, 0.01% Tween

7.3 Accessories Specification

7.3.1 CO-RE Gripper Specifications

Labware format	Microtiter footprint, plate height ≤ 43mm
Transport mass	300g (filled deep well plate)

7.3.2 Hamilton Heater Shaker Specifications

	Width (X)	Height (Z)	Depth (Y)
Dimensions	150mm	90mm	105mm
Weight	2500g		
Labware*	Universal flat bottom adapter for 96 MTP (customized adapter available upon request)		

*Maximum weight including adapter 500g

Temperature Control	From 5°C above ambient temperature to 105°C			
Heater Specifications*	Set temperature	Time to reach set temperature	Deviation to set temperature	Deviation on heating plate

	37°C	< 3min	± 1.0°C	± 2.0°C
	60°C	< 10min	± 1.5°C	± 3.0°C
	90°C	< 20min	± 2.0°C	± 4.0°C
	105°C	< 35min	± 2.5°C	± 5.0°C

*Measured with HHS equipped with universal flat bottom adapter

Shaking Directions	Clockwise and counter-clockwise	
Shaking Orbit	2.0mm, 3.0mm	
Maximum Rotation Speed	2500 rpm (with 2.0mm orbit)	
	2400 rpm (with 3.0mm orbit)	
Shaker Specifications*	Set rotation speed	Deviation to set rotation speed
	30 rpm	± 1.5 rpm
	500 rpm	± 25 rpm
	1000 rpm	± 50 rpm
	2000 rpm	± 100 rpm

*Measured with HHS equipped with universal flat bottom adapter

Operating Data	Maximum Power Consumption	140 VA
	Installation Category	II
	Pollution Degree	2
	Temperature Range	15°C – 30°C (operation) -25°C - +70°C (storage, transport)
	Relative Humidity	15% - 85% (operation) 10% - 90% (storage, transport) No condensation

	Noise Level	< 65dBA at max speed
	Altitude	Up to 2000m above sea level
	Indoor Use Only	
	Communication	CAN via TCC connector or USB
	Life time*	6 years

*The life time is not a shelf life, so Hamilton Heater Shaker often work well past its life time and Seegene advises users to keep using the device so long as it function properly. The life time is just established to allow users to plan potential replacements of devices and to assess when repairs may not be worthwhile.

7.3.3 UV Light Kit Specifications

Kit Dimensions	Length: 983 mm Height: 109 mm Depth: 140 mm
Kit Weight	6.0 kg
Power Supply	
Voltage	Mains supply voltage fluctuation up to $\pm 10\%$ of the nominal voltage
Frequency	50 / 60Hz $\pm 5\%$
Power	120/240V, 100 W
Operating Environment	
Operating Environment	Please refer to the Operator's Manual of the Seegene STARlet.
Storage and Transportation	
Temperature range	-25°C to +70°C
Relative humidity range	10% to 90% (no condensation)
PC Requirements	
Note: PC is not included	
Recommended PC	Please refer to the Operator's Manual of the Seegene STARlet.
Communication	USB 2.0 port
Instrument Life Cycle	

Instrument Life Cycle	<p>The UV Kit is designed for a life cycle of 7 years.</p> <p>Note: UV tubes are consumable articles.</p>
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7.3.4 Vial Cap Management System(VCMS) Specifications

Parameter	Specification
Power	
Input Power (Primary), Universal Supply	100-240 VAC, 50/60 Hz, 13 A – 6 A
Output Power (Secondary)	42 VDC, 1000 W
Physical Dimensions	
Length	899.5 mm / 35.413 in
Width	1058.25 mm / 41.663 in
Height (door closed)	436 mm / 17.2 in
Height (door open)	771 mm / 30.4 in
Weight	41.6 kg / 91.5 lbs.
Operation	
Maximum Decapping Torque	SurePath: 1.13 N·m (0.834 ft·lb) ThinPrep: 2.26 N·m (1.67 ft·lb)
Maximum Vortex Rate	1500 rpm
Capacity	96 vials max
Communication	USB, Ethernet
Operating Temperature	15-33°C (59-91°F)
Relative Humidity	15-55% non-condensing
Noise Level	≤60 dB within 1 m in any direction
Storage	
Storage Temperature	-20-70°C
Relative Humidity	10-90% non-condensing
Regulatory	
CSA Certification Installation Category	II
Pollution Degree	2
<p>Note: "Pollution degree 2" is defined as "normally only non-conductive pollution occurs (addition of foreign matter, solid, liquid, or gaseous (ionized gasses), that may produce a reduction of dielectric strength or surface resistivity)." Occasionally, however a temporary conductivity cause by condensation must be expected.</p>	

7.3.5 AIOS Specifications

Category		Specification
Size & Weight	Width	1500mm
	Depth	800mm
	Height	880mm
	Weight	280kg
Electrical condition	Operation voltage & Frequency	100-240 VAC, 50/60Hz
	Electrical energy	300W
Environmental conditions (Operation)	Operating temperature	15~30°C
	Operating humidity	15~80% relative humidity, non-condensing
	Altitude	Maximum 2000m
	Interval	Minimum 150mm
Environmental condition (Storage)	Storage temperature	25~70°C
	Storage humidity (relative humidity)	10~80% relative humidity, non-condensing

7.3.6 CO-RE 96 Probe Head Specification

Item	Value
Maximum outer dimensions	Width: 110 mm Height: 410 mm Depth: 170 mm
Weight of 1000ul CO-RE 96 Probe Head	6.8 kg
Electrical requirements	
- Maximum power consumption	130 VA
- Voltage	50 V

CO-RE 96 Probe Head Pipetting Specifications for Disposable Tips*	Disposable Tip Size	Volume	Trueness R (%)	Precision CV (%)
1000µl CO-RE 96 Probe Head	10ul	1ul	5.0%	5.0%
Maximum pipetting volume: 1000µl	10ul	5ul	2.5%	2.0%
	10ul	10ul	1.5%	1.5%

* Test Criteria Available Upon Request	50ul	1ul	5.0%	5.0%
	50ul	5ul	2.5%	2.0%
	50ul	50ul	1.5%	1.0%
	300ul	10ul	3.0%	2.0%
	300ul	50ul	1.5%	1.0%
	300ul	300ul	1.0%	1.0%
	1000ul	10ul	7.5%	3.5%
	1000ul	100ul	2.0%	1.0%
	1000ul	1000ul	1.0%	1.0%
For pipetting of less than 10µl, Seegene recommends 10µl/ 50µl Volume Disposable Tips to achieve the highest pipetting precision.				

7.4 Autoload: Barcodes and Reader Specifications [Atitiktis_21](#)

Carriers, containers, racks and tip racks will be identified by a barcode, which a reader, mounted on the Autoload slide, scans. The system allows specification of ranges (barcode mask) for plausibility checking of barcode information.



ATTENTION

Laser device designated for use solely as a component of overall automated pipetting instrument and therefore is not within the scope of FDA Section 1040.11 for complete laser products. Laser devices are only to be installed, repaired, or replaced by an authorized service technician.

7.4.1 Barcode Symbologies

Seegene recommends use of the following 3 types of barcode symbologies:

- Code 128 (subset B and C)
- Code 39
- Codabar

For the highest reading safety, Seegene recommends:

1. To use barcode type Code128 (subset B and C).
2. Disabling the unused barcode types in the configuration editor of the STARlet Software.
3. Defining a barcode mask via the Labware Editor, Deck Layout Editor or the Method Editor of the STARlet Software.



NOTE

Enable only barcode types which will be used on the system. Disabling the unused barcode types will improve the reliability of the readings.

7.4.2 Reading Accuracy

The rate of inaccurate readings of sample plates and container barcodes is less than 1 ppm.

The above-mentioned specification is valid under the following conditions:

- Barcode Symbology Module: ISBT Standard

- Code Density: 0.0065" (0.1651mm)
- Print Quality: as defined in Section 7.4.4 Barcode Specifications
- Recognized errors are defined as an accurate reading

7.4.3 Barcode Scanner Specifications

Type:	Class II Laser Diode
Wavelength:	655 nm
Pulse Duration:	120 μ s
Maximum Output (peak):	1.7 mW
Nominal Ocular Hazard Distance (NOHD):	≤ 0 mm
Applied Standard:	IEC/EN-60825-1:2007

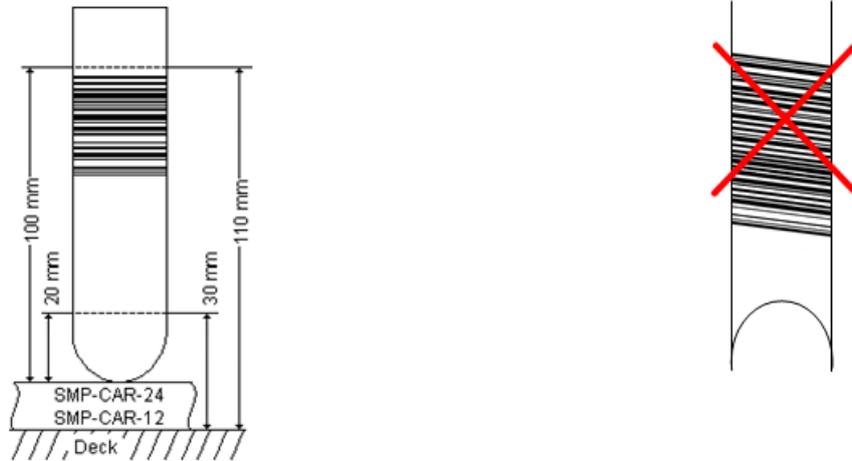
7.4.4 Barcode Specifications

Length of String	Maximum 20 characters excluding start, stop and check characters, depending on the code length (see label dimensions).	
Code Density, Tolerance	Minimum module width (X dimension) including a print tolerance: ≥ 0.0065 " (0.1651mm) Maximum module width (X dimension) including a print tolerance: ≤ 0.02 " (0.508mm) Best reading performance with X dimension between 0.0075" (0.1905mm) and 0.01" (0.254mm)	
Check Character	Code 128	One character
	Code 39	None, optional check character to be checked within programming
	Codabar	None, optional check character to be checked within programming

Quiet Zone	≥ 10 times the X dimension, but at least 3mm.
Print quality	<p>The barcode print must be of a high quality. A printed barcode with an ISO/EC 15416 grade 4 (A) or 3 (B) is required. Offset, typographic, intaglio and flexographic printing are suitable.</p> <p>Mechanical dot matrix and thermo matrix printing are not suitable.</p> <p>The surface may be treated, sealed or plastic-coated.</p>

7.4.5 Sample Barcodes

<p>Barcode Specifications</p> <p>For general barcode specifications, see Section 7.4.4 Barcode Specifications.</p>				
	Dimension		Min.	Max.
	A	Label Length	–	80mm
	B	Code Length	–	74mm
	C	Quiet Zone	3mm	–
	D	Label Width	12mm	–
	E	Code Width	12mm	–
	F	Distance from Code to Label Edge	–	1mm
<p>Positioning Barcode Labels</p> <p>The label must be glued within a range of between 20mm to 100mm from the bottom of the tube. The label must fit tightly at an angle of approximately 90° to the tube.</p>				



The label must fit tightly over its whole length.

7.4.6 Reagent Barcodes

Label Specification

For general barcode specification, see Section 7.4.4 Barcode Specifications.



Dimension		Min	Max
A	Label Length	–	66mm
B	Code Length	–	60mm
C	Quiet Zone	3mm	–
D	Label Width	15mm	–
E	Code Width	12mm	–
F	Distance from Code to Label Edge	–	1mm

Positioning Barcode Labels:


The label must be positioned on the upper edge, in the middle of the container. The label must fit tightly over its whole length.

7.4.7 Plate Barcodes
Label Specification

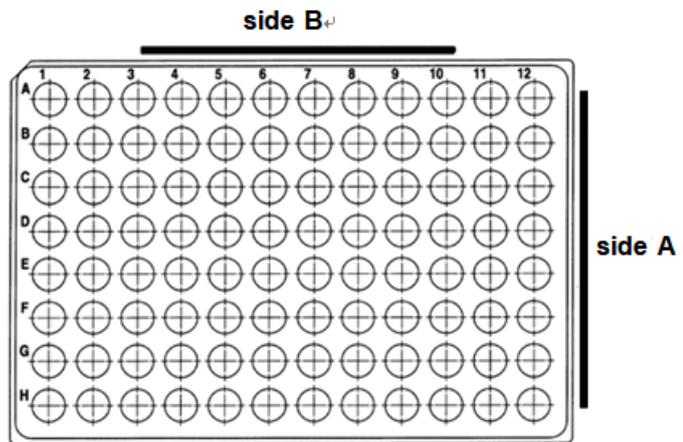
For general barcode specification, see Section 7.4.4 Barcode Specifications.



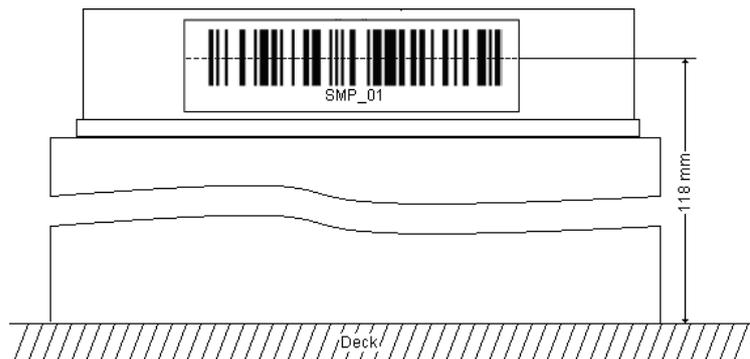
Dimension		Min	Max
A	Label length	–	66mm
B	Code length	–	30mm
C	Quiet zone	3mm	–
D	Label width	10mm	–
E	Code width	7mm	–
	Distance from Code to Label Edge (if necessary)	–	1mm

Positioning Barcode Labels:

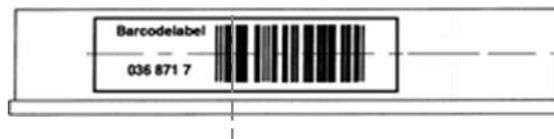
The barcode must fit on side A or Side B of the plate.



The barcode must be positioned in the middle of the plate.



The barcode must be centered and parallel to the edge of the plate.



The barcode label must not protrude above or below the edge of the plate.



8. Explanation of Symbols

Symbol	Explanation
	In vitro diagnostic medical device
	Catalogue number
	Serial number
	Authorized representative in the European Community
	Manufacturer
	Caution
	Consult instructions for use
	Canadian Standard Association
	Waster Electrical and Electronic Equipment (WEEE)
	Temperature limit
	Keep dry
	Fragile, handle with care
	This way up
	Do not stack
	Unique Device Identifier (UDI)

9. Label

Made in USA Automated nucleic acid extraction system

Seegene STAR^{LET}

REF 67930-03 **SN** X000

100-240VAC, 50/60Hz, 600VA
 Dimensions (W x D x H) : 112.4 x 120 x 90.3cm
 Weight : 140kg

FCC Declaration
 This device complies with Part 15 of the FCC Rules and the Radio Interference Regulations of the Canadian DOC. Operation is subject to the following two conditions:
 (1) This device may not cause harmful interference.
 (2) This device must accept any interference received, including interference that may cause undesired operation.

EC REP **Medical Technology Promedt Consulting GmbH**
 Altenhofstrasse 80,
 D-66386 St. Ingbert,
 Germany

Seegene Inc.
 Taewon Bldg., 91, Ogeum-ro,
 Songpa-gu, Seoul, 05548,
 Republic of Korea

Label No: 6606948-01/A

2022-05-02

172731
 US

 -25°C ~ 70°C




 (01)08809240109007
 (11)220502
 (21)X000





<Instrument attachment label>

Made in USA Automated nucleic acid extraction system

Seegene STAR^{LET}

REF 67930-03 **SN** X000

100-240VAC, 50/60Hz, 600VA
 Dimensions (W x D x H) : 112.4 x 120 x 90.3cm
 Weight : 140kg

EC REP **Medical Technology Promedt Consulting GmbH**
 Altenhofstrasse 80, D-66386 St. Ingbert, Germany

Seegene Technologies (Subsidiary)
 325 Nothr Wiget lane, Suite 140
 Walnut Creek, CA 94598, USA
 TEL : +1-925-448-8172 / info@seegenetech.com

Seegene Inc.
 Taewon Bldg., 91, Ogeum-ro, Songpa-gu, Seoul, 05548, Republic of Korea

Label No: PALB-041-KR2205-STARlet

2022-05-02

172731
 US

 -25°C ~ 70°C








 (01)08809240109007
 (11)220502
 (21)X000





<Outer box attachment label>

Appendix A. Getting Technical Assistance

If you require additional assistance with your STARlet, please contact your authorized Seegene distributor or the Seegene directly.

Please have the following information available when requesting technical assistance:

- STARlet model number
- STARlet serial number
- STARlet configuration
- Description of the problem
- Your contact information

If possible, please also supply the following additional information:

- What was happening at the time of the error
- What you have tried so far to solve the problem
- Version of software (see “A.2 Finding the Software Version” section)
- Screen shots of any errors (see “A.3 How to Get a Screen Shot” section)
- Photos that could more readily illustrate the problem
- Trace files, log files (found in the “Hamilton Company / Logfiles” directory)

A.1 Technical Support

Seegene’s global partner or Seegene directly.

A.2 Finding the Software Version



To determine which software version you have:

1. From Windows START, click All Programs > Hamilton > Version Info

A.3 How to Get a Screen Shot



If an error appears on the screen, follow these instructions to make a screen shot:

1. Click on the window or error dialog you wish to copy.
2. On the keyboard, click Alt+PrtScr. This will copy a picture of the window. (To make a screen shot of the visible desktop -not just the selected window - use Ctrl+PrtScr.)
3. Open Microsoft Word or WordPad. Right-click into the document and select Paste.
4. Save the document.

Appendix B. Regulatory Affairs

CE conformity is issued and maintained for the Seegene STARlet. See the Declaration of Conformity provided with the instrument as well as the information in the following sections.

B.1 In Vitro Diagnostics

The Seegene STARlet is an In Vitro Diagnostic Device and therefore regulated by the Regulation (EU) 2017/746 of the European Parliament and of the Council of 2017-06-05 on in vitro diagnostic medical devices.

B.2 Declaration of Conformity

Each individual instrument includes a Declaration of Conformity showing the directives and standards it conforms with.

B.3 Declaration of Quality

Each individual instrument includes a Declaration of Quality. It will be filled out according to the results of the final inspection and is valid for the specific instrument serial number entered.

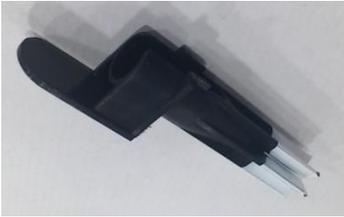
B.4 WEEE Declaration

After the life cycle of the Seegene STARlet has ended, disposal must be considered. The Seegene STARlet contains electrical materials; they should be disposed of as unsorted waste and must be collected separately, according to European Union Directive 2012/19/EU on waste electrical and electronic equipment – WEEE Directive.

Before disposal, contact your local Seegene's partner for recycling the Seegene STARlet in accordance with EC directive WEEE (see Appendix A "Getting Technical Assistance").

Appendix C. Labware

Table 1. Labwares for operation

		
<p>Heater & Shaker</p>	<p>1000 µL / 300 µL Filter tip carrier</p>	<p>Plate carrier - Extraction Reagent rack : 2 ea - 96 DWP rack : 1 ea - PCR plate rack : 2 ea</p>
		
<p>Small tube rack carrier - Magnetic separate : 1 ea - 1 mL Filter tip pedestal : 1 ea - Small tube rack : 2 ea</p>	<p>[96 Head] Tip & Plate carrier - 1000 µL Filter tip pedestal : 2 ea - 300 µL Filter tip pedestal : 2 ea - 96 DWP rack: 1 ea</p>	<p>[96 Head] Buffer Carrier - 96 DWP rack : 5 ea</p>
		
<p>[96 Head] Small tube rack carrier - Magnetic separate : 1 ea - 96 DWP rack : 1 ea - Small tube rack : 2 ea</p>	<p>[96 Head] Plate carrier - 1000 µL Filter tip pedestal : 2 ea - 300 µL Filter tip pedestal : 1 ea - PCR plate rack: 2 ea</p>	<p>32 sample carrier</p>
		
<p>Sample insert</p>	<p>24 sample carrier [Optional]</p>	<p>12 sample carrier (Thinprep) [Optional]</p>

		
Waste plastic bag	Liquid waste bottle	

Appendix D. Materials Required But Not Provided

Table 1. Basic materials for operation

Basic Item
Absolute EtOH
Disposable powder free gloves (latex or nitrile)
Desktop centrifuge
Ice or cooler box
Pipettes (adjustable) and sterile aerosol resistant pipette tips
Vortex mixer

Table 2. Purchasing materials for operation

Purchasing Item	Cat. No.	Manufacturer
SMP-CAR-24-Tube Carrier Set-4 (24 sample carrier)	173440	Hamilton
SMP CAR 12 D35 (12 sample carrier)	185052	Hamilton
1.5 mL sterile microtubes	MCT-150-C	Axygen
96 Deep Well Micro Plate	SDP0096	Supercon
MicroAmp® Optical 8-Tube Strip (0.2 mL)	4316567	Applied Biosystems
Hard-Shell® PCR plates 96-well WHT/WHT	HSP9655	Bio-Rad
Low Tube Strip, WHT	TLS0851	Bio-Rad
Mini-centrifuge	MFC2360	Labnet
PCR plate centrifuge	-	-
UPS	HP 910	Sampoongpower

Appendix E. Ordering Information

Table 16. Ordering Information

Product Name		Cat. No.	Unit	Manufacturer
Instrument	Seegene STARlet	67930-03	EA	Seegene
Accessory	Laptop Computer	HP6560b	EA	HP
	Bar-code Reader (USB)	1900GSR-2	EA	Honeywell
	UV Light Kit	68146-01	EA	Hamilton
	Kit, UV, STARlet, AL with MPH	97310-23	EA	Hamilton
	Vial Cap Management System (VCMS)	660053-01	EA	Hamilton
	AIOS	SG72100	EA	Seegene
	Auto Heat Sealer (SAHS M Series)	SAHS-M-A01	EA	SAMICK THK
CO-RE 96 Probe Head	MultiFlex PCR Plate Module 96	188049	2EA / Kit	Hamilton
	Plate, Module, 7T carrier, Seeg (each)	97074-01	1EA / Kit	Hamilton
	STARLINE,FOAM SUPPORT, 96-HEAD	68233-01	1EA / Kit	Hamilton
	FIELD UPGRADE 96 HEAD I	199091-C1	1EA / Kit	Hamilton
	PREP ARM UPGRADE KIT	67951-01	1EA / Kit	Hamilton
	RENO KIT 4,STAR VERIFY KIT	62964-04	1EA / Kit	Hamilton
	CHUTE,WASTE,MPH,FRONT	92573-01	1EA / Kit	Hamilton
	CO-RE 96 HEAD TIP ADAPTOR	182040	1EA / Kit	Hamilton
	HOUSING LEFT FOR MPH	188122	1EA / Kit	Hamilton
	MultiFlex Carrier Base (6 tracks)	188039	3EA / Kit	Hamilton
	Multiflex Deepwell Plate Module	188042	7EA / Kit	Hamilton
	MultiFlex Tip for holding tip frame&tip	188160	7EA / Kit	Hamilton
Nucleic Acid Extraction Kit	STARMag™ 96 X 4 Universal Cartridge Kit	744300.4.UC384	384T / box	Seegene
	STARMag™ 96 x 4 Universal Plus Cartridge Kit	EX00006C	384T / box	Seegene
	STARMag™ 96 x 4 Viral DNA/RNA 200 C Kit	EX00013C	384T / box	Seegene
	STARMag™ S96H Kit	EX00032P	48T / box	Seegene
		EX00033P	480T / box	
		EX00034P	96T / box	
EX00035P		960T / box		
STARMag™ S96H N Kit	EX00036P	480T / box	Seegene	
	EX00037P	960T / box		
Consumable	High Volume Tips (1 mL)	235905	3,840 tips / box	Hamilton
	Standard Volume Tips (300 µL)	235903	5,760 tips / box	Hamilton

	Waste bag	199203	25 ea / pkg	Hamilton
	VFV consumable Kit	182506	EA	Hamilton

Appendix F. Glossary

Term	Definition
<i>Air Displacement Tip</i>	Hamilton CO-RE disposable tip
<i>Aliquot</i>	Aliquots are identical small volumes of liquid.
<i>Aspirate</i>	To draw up liquid into a pipetting device.
<i>Autoload</i>	Hardware assembly that enables automatic loading of the STARlet. It consists of a loading head movable in Y direction, which draws the carriers into the STARlet and reads the barcodes on them.
<i>Autoload Tray</i>	Hardware unit. The carriers can be placed on it and held outside the STARlet. The loading tray is attached to the STARlet, to support the automatic loading and unloading process.
<i>Barcode Mask</i>	The barcode mask defines the basic structure of a barcode. It is a pattern to which a barcode must conform. The assignment of a specific Labware item can be done in this manner. The barcode mask can require a barcode to contain specific strings at fixed positions. It can also contain wildcards.
<i>Barcode Reader</i>	Device for reading sample/plate Barcodes. Part of the Autoload.
<i>Carrier</i>	Unit for loading plates, tubes and tips on the STARlet deck. Loading process is carried out by the autoload unit.
<i>Container</i>	A container defines a tube, vessel or a single well of a plate.
<i>Container identification</i>	Barcode for the identification of a container. Serves for a unique identification of a vessel, e.g. a sample test tube.
<i>Continuous Loading</i>	Refers to the loading of elements onto the STARlet after processing has been started.
<i>Deck</i>	The work surface (work area) of the STARlet. The area where the pipetting channels perform liquid handling or transport steps. The deck is divided into tracks, which are occupied by labware.
<i>Deck Layout</i>	A collection of labware placed upon a deck.
<i>Dispense</i>	To distribute quantities of liquid from a pipetting device.

Term	Definition
<i>Docking Station</i>	The long bar at the back of the STARlet for guiding the cables and the tubing for accessories.
<i>Firmware</i>	Lower Level program code that is carried out on the processors of the STARlet.
<i>Front Cover</i>	Protective covering for the STARlet, featuring a hinged front window made of transparent Plexiglas. With this option and assembly, the work surface of the STARlet is covered in such a way that it is shielded from user intervention and other outside influences (such as dust). At the same time, it protects the user from the movements of the STARlet.
<i>Hardware Error</i>	Type of error that is caused by a technical problem with the hardware.
<i>HSL</i>	Hamilton Standard Language
<i>HHS</i>	Hamilton Heater Shaker. Unit to heat and/or shake microplates in SBS format.
<i>HSB</i>	Heater Shaker Box. Interface unit which is needed if more than two HHS are being used.
<i>Instrument</i>	Hardware of the STARlet (mechanics, electronics, and firmware)
<i>Instrument Steps</i>	The commands made available by the firmware for controlling the STARlet.
<i>Labware</i>	Refers to movable items to be placed on the STARlet deck, such as carriers, containers, or racks.
<i>LIMS</i>	Higher level data processing system, generally known as Laboratory Information Management System, also LMS.
<i>Liquid</i>	Includes all kinds of liquids, among which are included reagents, controls, standards, wash fluids.
<i>LLD</i>	Liquid Level Detection – Detection of liquid surface which may be achieved either by pressure or capacitive signal detection.
<i>Loading/Unloading</i>	The process by which plate, tube and tip carriers are brought on and off the STARlet deck. This is automatically performed via autoloader unit.
<i>Method</i>	The method contains all instruction that must be executed during a run.
<i>STARlet Software</i>	Software to run the STARlet.

Term	Definition
<i>MTP (Microtiter Plate)</i>	In general, a microtiter plate is assumed to have 96 wells (8 x 12) 9mm wide. There are also plates with 384 wells (16 x 24 / 4.5mm), or others with a different size
<i>Pause</i>	Interruption of processing. The current processing steps are completed.
<i>Pipetting</i>	Transfer of liquids from one container to another.
<i>Pipetting Arm</i>	Assembly equipped with the pipetting device and/or plate handler, as well as the common X-drive.
<i>Pipetting Channel</i>	Hardware assembly including the function of picking up a tip aspirating, dispensing, tip eject, liquid level detection and the Y/Z-movements
<i>Pooling</i>	Pipetting of different liquids in one well; 1, 2, 3...to n and n to 1, 2, 3...
<i>Processing Step</i>	Defines what must be carried out on the STARlet, as well as the location it must be carried out and possible interaction with other system components or labware. The action is defined in accordance with the methods, the loading and the tasks.
<i>P/N</i>	Part number
<i>Rack</i>	Group of containers, as DWP, MTP, etc.
<i>Rack Identification</i>	Barcode for rack identification
<i>Random Access</i>	Means that every channel can access any position anywhere on the work area.
<i>Run</i>	Execution of the processing steps defined in the method with the aim of processing one or more liquids and containers (e.g. MTP). The run is a series of timed commands, in order to carry out processing on the STARlet according to the processing plan. The run can include a reloading of elements.
<i>Run Abort</i>	Cancelled run by the user or by the STARlet
<i>Run Visualization</i>	Visualization of the current run, reporting the status of the STARlet.
<i>Sample</i>	Refers to a liquid in a unique identified container which is to be processed.
<i>Stacker</i>	Storage unit for racks

Term	Definition
<i>TADM</i>	Total Aspiration and Dispense Monitoring. The pressure inside each individual pipetting channel is monitored, during aspiration and dispensing.
<i>Tip</i>	Disposable tip for pipetting
<i>Tip Rack</i>	Frame that holds the tips.
<i>Tip Waste</i>	Container for ejected tips.
<i>Touch-Off</i>	Type of dispensing where the tip approaches the bottom of the empty container so close as to allow the dispensed droplet to have simultaneous contact with the tip and the container bottom.
<i>Trace</i>	Record of the status during processing
<i>Tube</i>	A container for liquid, usually having a circular cross-section, and a cylindrical length section.
<i>Waste Container</i>	A device on the STARlet deck to collect used disposable tips.
<i>Well</i>	The individual container of a MTP or DWP.
<i>Well Type</i>	Geometrical shape of the well, such as U, V or flat.
<i>Work Area</i>	The area of the STARlet to which access is provided during the processing. Elements to be pipetted or handled can be placed in this area.
<i>Worklist</i>	Information according to which a method is to be executed on the STARlet. A worklist may contain different parameters e.g. Pipetting volume, heating temperature, shaking speed, etc.

Appendix G. Seegene Contacts

Headquarters

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- [Seegene CANADA Inc. \(https://seegenecanada.com/\)](https://seegenecanada.com/)
- [Seegene MIDDLE EAST \(https://www.seegeneme.com/\)](https://www.seegeneme.com/)
- [Seegene Mexico \(https://www.seegene.com.mx/\)](https://www.seegene.com.mx/)
- [Arrow Diagnostics S.r.l \(Italy\) \(http://www.arrowdiagnostics.it/it/home/\)](http://www.arrowdiagnostics.it/it/home/)
- [Seegene Brazil Diagnosticos LTDA \(https://seegenebrazil.com.br/\)](https://seegenebrazil.com.br/)

Appendix H. Warranty

Warranty Criteria

- Seegene offers repair parts free of charge by selecting a short period within 15 months of the release date and 12 months from the installation date.

Warranty application

- Seegene will support compensation shipping after the engineer confirms the specific evidence (photos, videos, log files, etc.) for errors and failures.

Appendix I. Notification of Incidents to Authorities

If any serious incident* occurred in relation to the device, please report to Seegene and the competent authority of the Member State in which the user and/or the patient is established.

*‘Serious incident’ means any incident that directly or indirectly led, might have led or might lead to any of the following:

- (a) the death of a patient, user or other person,
- (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,
- (c) a serious public health threat