altona
DIAGNOSTICS

AltoStar®
Automation System AM16
Operator`s Manual IVD

10/2017 EN

AltoStar®

CE   **IVD**

Important notice

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HAMILTON

Table of Contents

1 Safety and General Information

AltoStar® Automation System AM16 (in the following summarized as AltoStar® AM16) is a pipetting workstation. This Operator's Manual is designed to help you get the most out of your AltoStar® AM16.

You should carefully read through the entire manual before beginning to operate your workstation. This first chapter should be read with particular attention. It contains important information about the use of the AltoStar® AM16 and this manual.

This manual serves altona Diagnostics GmbH as the exclusive distributor of the AltoStar® AM16.

1.1 About this Manual

This manual refers to the AltoStar® Connect Software (in the following summarized as AltoStar® Connect SW), for the AltoStar® AM16.

This manual helps users operate the AltoStar® AM16 correctly and safely. To achieve this goal, the manual describes the different components of the AltoStar® AM16 and their functionality.

The manual describes the hardware of the AltoStar® AM16, enabling the user to operate the instrument. For in depth information regarding the functionality of the AltoStar® Connect SW, refer to the AltoStar® Connect Software Manual IVD.

After you have read through this manual and the AltoStar® Connect Software Manual IVD, you should be capable of operating the AltoStar® AM16.

This manual is based on the Microlab STAR IVD / STARlet IVD Operator's Manual.

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 user that is useful but not essential to the task at hand.

___ References to manuals, figures, chapters, etc.

1.2 Additional Manuals

The following manuals are included in the delivery of the AltoStar® AM16:

- AltoStar® Connect Software Manual IVD   Manual PN 627109
- Microlab STAR UV Kit   Manual PN 624684
- Microlab STAR Liquid Waste   Manual PN 624208
- Hamilton Heater Shaker   User Manual PN 624175

1.3 Intended Use of the AltoStar® Automation System AM16

The AltoStar® AM16 together with the AltoStar® Connect SW is intended to be used in combination with the AltoStar® Purification Kit 1.5 and the AltoStar® Internal Control 1.5 for automated purification of nucleic acids and automated assay setup for *in vitro* diagnostic purposes.

The AltoStar® AM16 is intended for use by professional users trained in molecular biological techniques and the operation of the AltoStar® AM16 instrument.

1.4 Operation

The operator of the AltoStar® AM16 must be trained in the operation of the AltoStar® AM16 instrument. Training will be performed by altona Diagnostics GmbH after the initial installation of the AltoStar® AM16.

The procedures contained within this manual have been tested and are deemed to be fully functional. Any deviation from the procedures given here could lead to erroneous results or malfunction.

The AltoStar® AM16 is operated by means of the AltoStar® Connect SW.

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 AltoStar® AM16 is used in a manner not specified in this manual and the AltoStar® Connect Software Manual IVD, the protection provided by the equipment may be impaired.

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.

When the life cycle of the instrument has ended, please contact altona Diagnostics GmbH for disposal regulations. Give due regard to the parts labeled with the bio-hazard warning symbol (see Chapter 1.5.4 Hazards).

1.5 Safety Precautions and Hazards

The following chapter 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 AltoStar® AM16.

1.5.1 General Precautions

1.5.1.1 Instrument Installation and Relocation

The AltoStar® AM16 Instrument is installed or relocated by a Hamilton trained field service engineer.

The AltoStar® AM16 conforms to European norms regarding the interference immunity. However, if the AltoStar® AM16 is subjected to electromagnetic RF fields or if static electricity is discharged directly onto the AltoStar® AM16, its Liquid Level Detection ability may be negatively affected. It is therefore recommended that the AltoStar® AM16 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 AltoStar® AM16 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, for operation, maintenance, opening and removal of protective covers, and so on. Accordingly, to calculate how much space is needed, consider the dimensions of the instrument (see Chapter 8.1.1 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 a Hamilton trained field service engineer.

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

1.5.1.2 Maintenance, Service and Repair

Only Hamilton trained field service engineers are authorized to perform mechanical maintenance on the AltoStar® AM16.

For repair or shipment, all mechanical parts must be put in their rest positions. An AltoStar® AM16 sent away for repair must also be decontaminated (see Chapter 5 AltoStar® AM16 Decontamination) if it was in a laboratory environment with infectious or hazardous materials. The AltoStar® AM16 must be repacked in the original shipping crate only by a Hamilton trained field service engineer (contact altona Diagnostics GmbH). There must be no carriers on the AltoStar® AM16 during transportation.

The Hamilton trained field service engineer and the laboratory (or altona Diagnostics GmbH) share the responsibility for the Installation Qualification (IQ) and the Operation Qualification (OQ). The Process Qualification (PQ) is the sole responsibility of the laboratory.

Only original AltoStar® AM16 specific parts and tools may be used with the AltoStar® AM16, e.g. carriers, racks, CO-RE tips, and waste containers. Commercially available sample tubes that fulfill the following requirements can be tested for applicability by the user:

- Height below 100 mm

- Inner diameter greater than 9 mm

- Diameter within the specifications of the carrier type used

Correct aspiration from the sample tubes is always verified via TADM. Unsuitable tube types can be identified during testing by failing aspiration during transfer of the samples. For further information and assistance, contact altona Diagnostics GmbH.

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

Never disable any security measure.

1.5.1.3 Operating the Instrument

When using the AltoStar® AM16, 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.

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.

The AltoStar® AM16 in conjunction with the AltoStar® Connect SW was developed to control sample purification utilizing the AltoStar® Purification Kit and the AltoStar® Internal Control and PCR setup. These reagents were explicitly developed, verified and validated for use in combination with the AltoStar® AM16 by altona Diagnostics GmbH. Therefore, the information given in this manual needs to be seen in conjunction with these products and their respective manuals provided by altona Diagnostics GmbH.

1.5.1.4 Loading

Insert the carriers into the tracks between the front and rear slide blocks of the Loading Tray until they touch the stop hooks on the far side of the tray (see Fig. 1.: Slide Blocks and Stop Hooks for Carriers).

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 on the left side.

When loading reagents, ensure that there is no foam on the surface of the liquid.

	NOTE
	Foam may affect the accuracy of liquid level detection and cause pipetting problems.

Do not overfill sample tubes.

Do not mix tip sizes in the same tip rack.

Do not fill up 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.

For further information see <u>Chapter 3.2 Starting the AltoStar® Connect SW</u> and <u>Chapter 3.3 AltoStar® Workflow: Purification</u>.
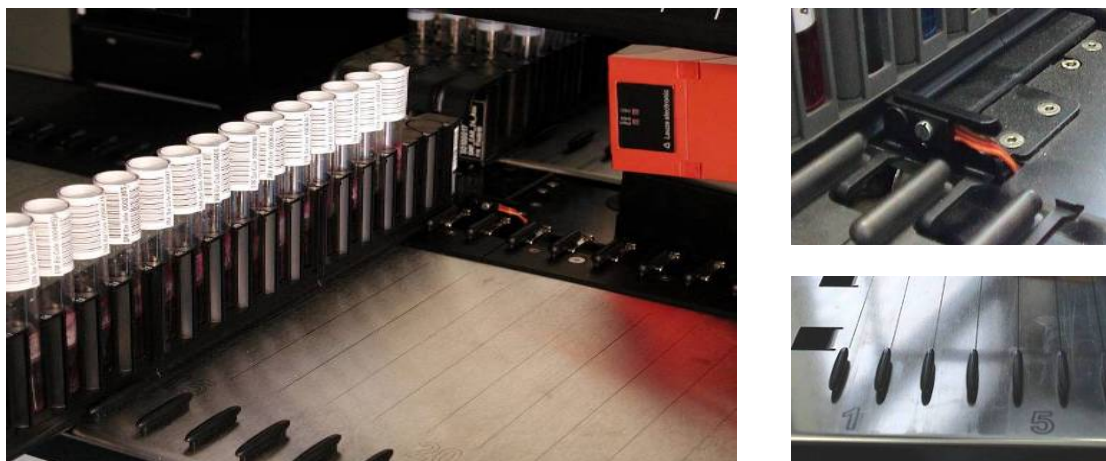
Fig. 1.: Slide Blocks and Stop Hooks for Carriers

ATTENTION

Make sure the carriers are inserted completely until they touch the stop hooks on the Loading Tray.

Make sure there are no carriers loaded on the same tracks as already loaded carriers on the deck.

ATTENTION

Ensure that there is no foam on the surface of reagents.

Do not manipulate the filling volumes of reagent containers or tubes.

Handle consumables and reagents with care to avoid spilling liquids.

Only use consumables specified for use with the AltoStar® AM16 and the AltoStar® reagents (see <u>manuals of the AltoStar® Purification Kit 1.5 and the AltoStar® PCR kits</u>).

Position Eluate Plate and PCR Plate correctly such that well A1 is placed to the left side.

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 Loading Tray, or place several carriers together to minimize this risk.

1.5.1.5 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).

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 (say, overnight). This may cause damage to the CO-RE O-rings. A daily maintenance procedure will remove the tips.

1.5.2 Biohazard Precautions

If the AltoStar® AM16 becomes contaminated with bio-hazardous or chemical material, it should be cleaned in accordance with the maintenance procedures (see Chapter 4 Maintenance). Observe and carry out the maintenance procedures given. Failure to do so may impair the reliability and correct functioning of the AltoStar® AM16.

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 pipetting arm and channels, the carriers, racks, containers and tips.

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

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

If working with bio-hazardous or chemical materials, the user must not touch them. The AltoStar® AM16 will drop its used tips into a waste container, that should be emptied during the daily maintenance or as soon as it is full.

1.5.3 Computer Precautions

Use the necessary precaution to guard against software viruses. Any manipulation of AltoStar® AM16 data files or other information determining or affecting AltoStar® AM16 functions can result in erroneous test results or instrument failure.

Only the AltoStar® Connect SW may be used to control the AltoStar® AM16.

For reasons of data security 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, ensure that there is always enough storage capacity on your hard drive. Archive the log files from time to time.

For further information regarding the computer and the software installation refer to Chapter 2.3 Computer Requirements and the AltoStar® Connect Software Manual IVD.

1.5.4 Hazards

Location and explanation of warning and attention labels:
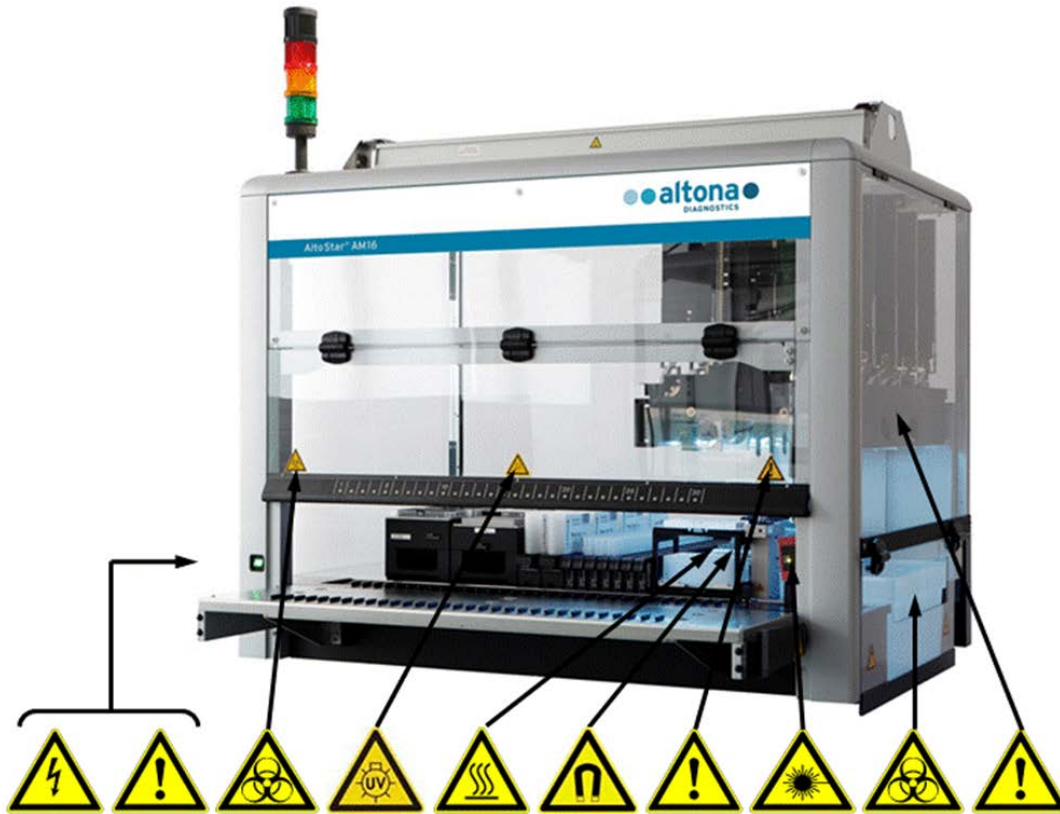
Fig. 2.: AltoStar® AM16 with the Location of Warning and Attention Labels

Table 1: Explanation of Warning and Attention Labels

⚡	**Power Connection** Connect only to earth-grounded outlet	🧲	**Strong Magnetic Field (Magnetic Bead Separation Block)** Interaction with metallic objects may produce Pinch Hazards. Pacemaker wearers stay back 30cm.
⚠	**Connection to PC** Use only the appropriate shielded cables	⚠	**Moving Parts** Moving arm inside transparent cover. Aborts the run if cover is opened.
⚠	**USB Connection** At a total cable length of more than 5 m, signal loss may occur	☢	**Laser Beam (Autoload)** Do not stare into beam of class 2 laser of the barcode reader
☣	**Biohazard Warning** Deck may contain bio-hazardous or chemically contaminated materials	☣	**Biohazard Warning** Waste may contain bio-hazardous or chemically contaminated materials
☢	**UV Lights** Avoid exposure to UV light. Exposure may cause severe eye or skin injury. Wear a suitable face shield, gloves and protective clothing.	⚠	**X-Arm** Do not move X-Arm by hand
🔥	**Hot Surface** Avoid contact of HHS. Surfaces are hot and may cause personal injury if touched		

1.5.4.1 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.
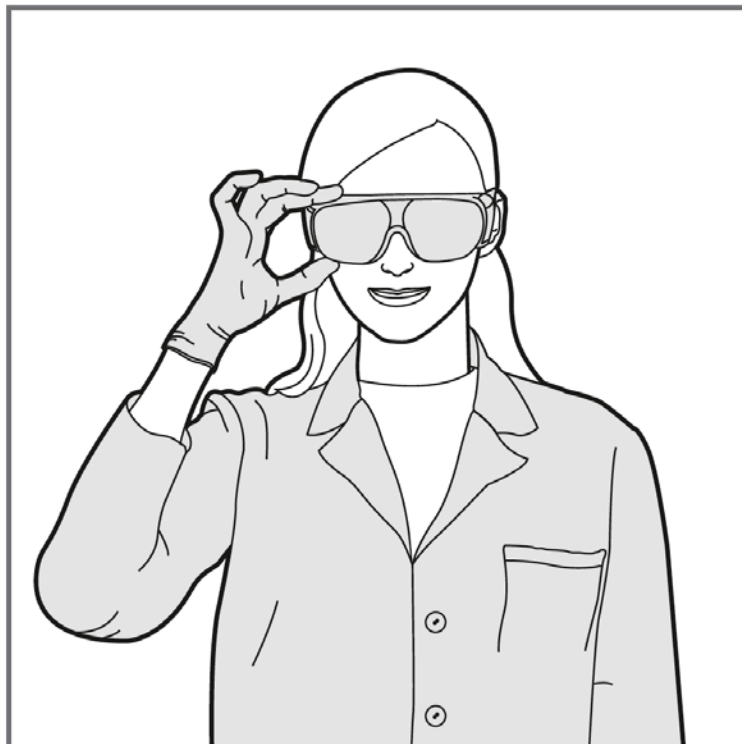
1.5.4.2 Loading Tray

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.*
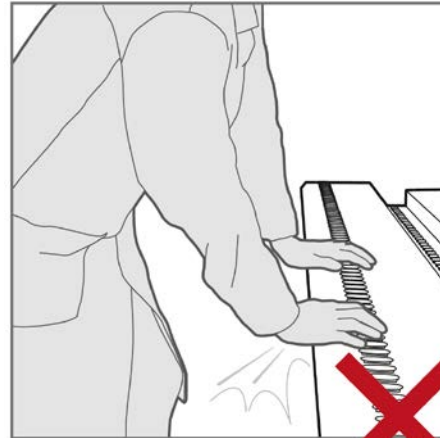
Foreign object damage:

- 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
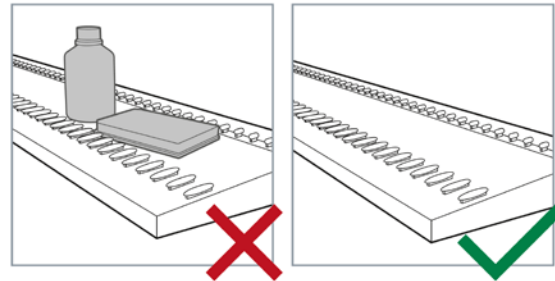
2   Description of the AltoStar® AM16

The AltoStar® AM16 is a robotic pipetting workstation used for sample purification and PCR setup controlled by the AltoStar® Connect SW.

2.1 AltoStar® AM16 Instrument

The AltoStar® AM16 work surface is called a 'deck', for placing loadable carriers. These carriers hold reagent containers, such as tubes, microplates, and other kinds of labware.

Fig. 3.: AltoStar® AM16 Instrument

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.

An additional partition provides space for the tip waste container.

2.1.1 Liquid Waste

Description of the Liquid Waste:

To avoid liquid waste accumulation in the waste station, the liquid waste is disposed separately into the Liquid Waste. The collection tray for the liquid waste is located underneath the (slotted) Tip Eject Sheet on the waste block. From this collection tray, the liquid waste flows into a monitored liquid waste container, located underneath the instrument.

Overflow into Waste Station

Collection Tray

Tubing to Liquid Waste Container

Fig. 4.: Description of the Liquid Waste

Before the tips are discarded into the tip waste, the remaining liquid will be drained into the liquid waste. An overflow will prevent overfilling of the collection tray if the main tubing is clogged. An overflowing liquid is passed into the liquid waste, preventing contamination of the deck.

Liquid Waste Container

Cap with Liquid Level Detection

Fig. 5.: Liquid Waste Container and Cap with Liquid Level Detection

Biohazard Warning

Liquid Waste may contain bio-hazardous or chemically contaminated materials

ATTENTION

Dispose of hazardous and biological waste in compliance with local and national regulations. The product should not be allowed to enter sewage, water courses or the soil.

The Liquid Waste contains a cap presence sensor. The cap, using its liquid level detection sensor, can monitor the fill level status. The liquid level detection sensor will give a "full" signal if the fill level is reaching approximately 80 % of the container's capacity (4.8 l). The fill level status is automatically checked before each run, preventing the start of a run if the container's residual capacity is below approximately 20 %. In absence of this signal, the residual capacity is sufficient for a full run.

2.1.2 UV Kit

The UV Kit has been developed in order to offer the possibility of UV decontamination of the AltoStar® AM16 workspace. The required duration and frequency of the UV decontamination process is dependent on the substances used on the instrument and the user is responsible to choose the appropriate duration and frequency.

Fig. 6.: UV Light on top of the AltoStar® AM16

The UV Kit must be used with the AltoStar® Connect SW.

For detailed information regarding the UV decontamination process refer to <u>Chapter 6 AltoStar® AM16 UV Decontamination</u>. The UV Kit is not suitable for decontamination of accessories such as carriers, modules, etc. as the UV (ultra-violet) light cannot reach all surfaces of such complex structures.

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

NOTE

The UV Kit is only intended to be used in combination with the AltoStar® AM16.
A stand-alone operation of the UV Kit is not foreseen.

The UV Kit components bear the following labels

Hot Surface

Avoid contact with the UV light. Surfaces are hot and may cause personal injury if touched.

UV Light

Avoid exposure to UV light. Exposure may cause severe eye or skin injury. Wear a suitable face shield, gloves and protective clothing.

2.1.3 Signal Light

A Signal Tower on top of the AltoStar® AM16 visually and audibly indicates the operating states of the system.

The green light indicates normal processing of the AltoStar® AM16.

The orange light indicates that a user interaction with the system is required.

The red light indicates aborting the run due to an error. The red signal may or may not be accompanied by a warning sound depending on the system settings of the AltoStar® Connect SW.

For further information refer to the AltoStar® Connect SW Manual.

Fig. 7.: Signal-Light on top of the AltoStar® AM16

2.1.4 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 the AltoStar® Processing Plate between positions on the deck of the AltoStar® AM16.

Fig. 8.: CO-RE Gripper Holder with Jaws for the 1000 µl Pipetting Channels (inner positions)
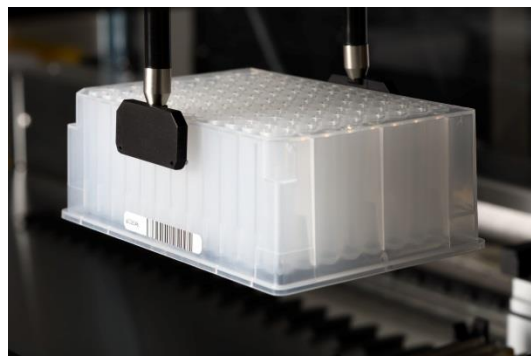
Fig. 9.: Plate Being Moved with CO-RE Gripper using 1000 µl Pipetting Channels

2.1.5 HAMILTON Heater Shaker

The HAMILTON Heater Shaker (HHS) is used to heat and shake the AltoStar® Processing Plate. Loading and unloading, as well the independent heating or shaking function of the HHS is fully controlled by the AltoStar® Connect SW.

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 HAMILTON Heater Shaker by the CO-RE Gripper (do not move/remove plates manually from the HHS).

The HHS adapter fitted to the AltoStar® Processing Plate allows optimal heating. To ensure reliable heating performance, two sensors permanently control the temperature which guarantees the abidance of the set temperature range. In addition, a cut-off temperature will protect from over-heating.

Fig. 10.: HHS with Adapter for AltoStar® Processing Plate

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.

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).

2.1.6 Magnetic Stand

The Magnetic Stand is used to collect the magnetic beads at the bottom of the AltoStar® Processing Plate.
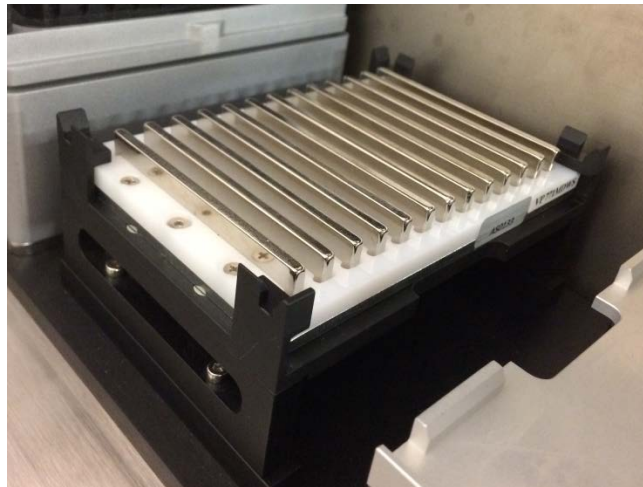
Fig. 11.: Magnetic Stand for AltoStar® Processing Plate

ATTENTION

Strong Magnetic Field (Magnetic Bead Separation Block)

Interaction with metallic objects may produce Pinch Hazards. Pacemaker wearers stay back 30 cm.

2.2 Carriers

Labware is placed on special carriers which are loaded onto the AltoStar® AM16 instrument 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 AltoStar® AM16 Software.

The barcode label is for purposes of automatic identification.

Identification label on the front side of the carrier:

- carrier identification number
- carrier name

Carrier barcode label at the back of the carrier with carrier identification number:

- character 1 to 3: carrier type
- the rest is serial numbering
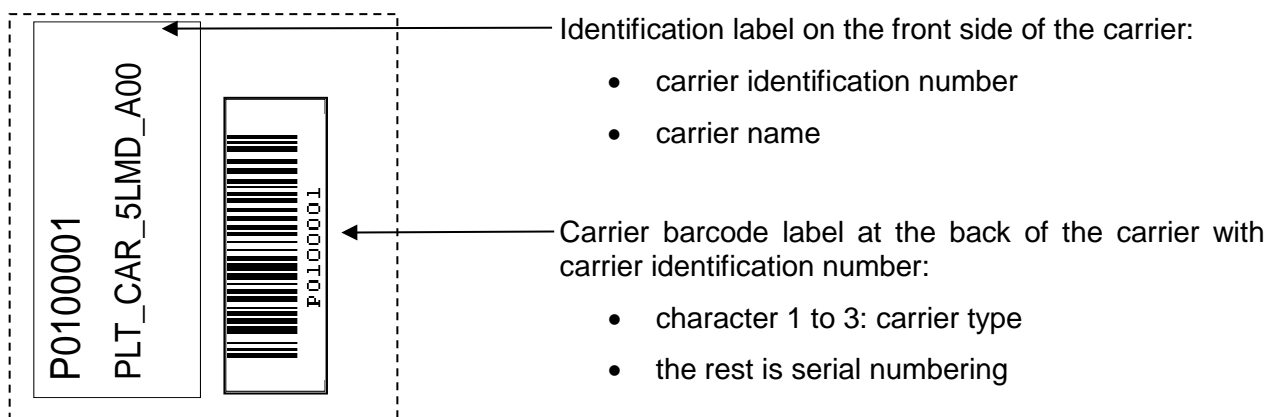
Fig. 12.: Carrier Barcode Labels
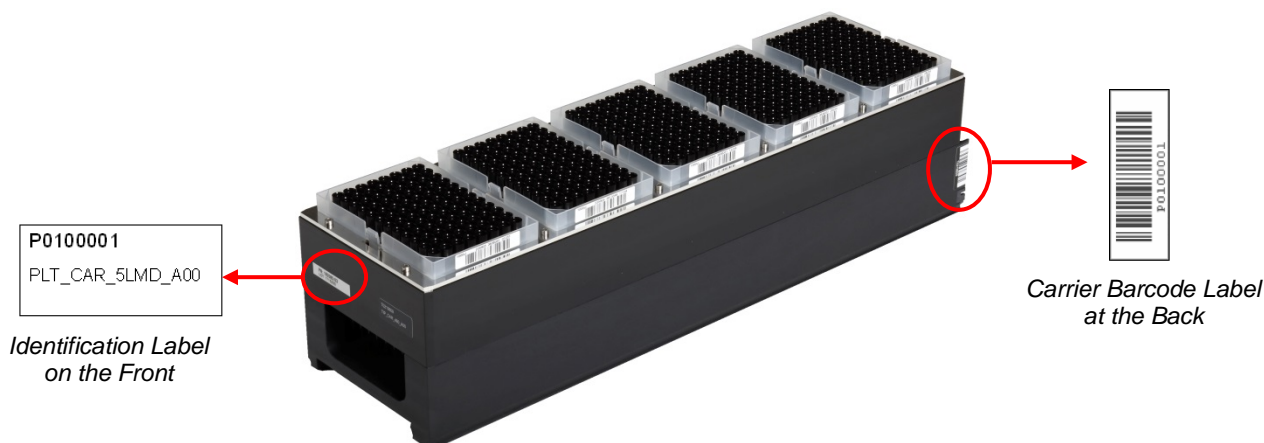
Fig. 13.: 1000 µl Tip Carrier

For more information regarding the used carriers and loading please see <u>Chapter 3.3.5 Instrument Loading for a Purification Run</u> and <u>Chapter 3.4.3 Instrument Loading for the PCR Setup Run</u>.

2.3 Computer Requirements

The AltoStar® AM16 and its accessories are controlled by the dedicated AltoStar® Connect SW which controls all functions for daily work routine, running purification runs and PCR setup runs and other services.

The computer running the AltoStar® Connect SW is delivered by altona Diagnostics GmbH. Do not use a different computer for the operation of the AltoStar® AM16.

The AltoStar® AM16 and the computer are linked via Universal Serial Bus interface (USB).

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

> **NOTE**
>
> *Use password protected user accounts in the Microsoft Windows® installation to prevent unauthorized access.*

2.4 Power / Voltage

Make sure that the AltoStar® AM16 is connected to a 115 or 230 VAC (50Hz or 60Hz) socket. The AltoStar® AM16 automatically recognizes any voltage within that range, without user intervention.

We recommend using an <u>U</u>ninterruptible <u>P</u>ower <u>S</u>upply (UPS) for the AltoStar® AM16.

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 trained field service engineer.

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, contact altona Diagnostics GmbH for a replacement. If replacing the power cord by inadequately rated power cords, the protection provided by the equipment may be impaired.

Fuses

Fuse Holders
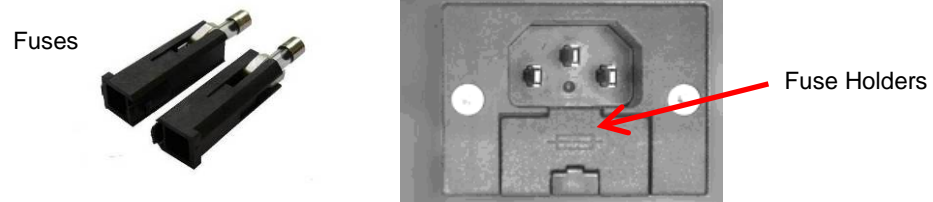
Fig. 14.: Main Power Socket with Appropriate Fuses

ATTENTION

When replacing a fuse, make sure to use the appropriate fuse and place it into the main power switch before switching on the instrument.

ATTENTION

Place the appropriate fuse (see Chapter 8 Technical Specifications) in the main power switch before switching the instrument on.

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

When replacing a fuse, make sure to use the appropriate fuse (see Chapter 8 Technical Specifications) and place it into the main power switch before switching on the instrument.

3 AltoStar® Connect SW

The AltoStar® Connect SW comes preinstalled on a computer provided by altona Diagnostics GmbH.

It is the sole responsibility of the user to ensure sufficient protection against:

- Unauthorized access to the computer via computer network.

- Unauthorized local access to the software. Use password protected user accounts in the Microsoft Windows® installation to prevent unauthorized access.

- Software viruses and malware.

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

NOTE

Use password protected user accounts in the Microsoft Windows® installation to prevent unauthorized access.

The AltoStar® Connect SW has a graphical user interface that enables the user to interact with the system. With the AltoStar® Connect SW the user can:

- Manage the system settings (depending on user account privileges)

- Manage the purification and assay protocols (depending on user account privileges)

- Perform instrument maintenance

- Perform an AltoStar® workflow run consisting of:
    - o Programming a run
    - o Performing a sample purification run
    - o Viewing sample purification results
    - o Performing a PCR setup run
    - o Viewing PCR setup results
    - o Transfer of the PCR plate and run information to the connected real-time PCR cycler.

- Perform a Sample Transfer workflow run consisting of:
    - o Programming a run
    - o Performing a sample transfer run for purification on an external purification instrument
    - o Viewing sample transfer results
    - o Performing a PCR setup run with eluates from the external purification instrument
    - o Viewing PCR setup results
    - o Transfer of the PCR plate and run information to the connected real-time PCR cycler.

- Perform an External Purification workflow run consisting of:
  - o Programming a run
  - o Performing a PCR setup run with eluates from an external purification instrument
  - o Viewing PCR setup results
  - o Transfer of the PCR plate and run information to the connected real-time PCR cycler.

3.1 User Accounts

The AltoStar® Connect SW can be used from different user accounts created in the Microsoft Windows® operating system of the computer that runs the AltoStar® Connect SW. The computer is delivered with the two user accounts 'Laboperator' and 'Labadmin' preinstalled. These accounts have different privileges:

Table 2: User Accounts

	Laboperator	Labadmin
Windows® user group	**Lab Operator**	**Lab Service**
Perform instrument maintenance	✔	✔
Perform an AltoStar® workflow run	✔	✔
Perform a Sample Transfer workflow run	✔	✔
Perform an External Purification workflow run	✔	✔
Manage the System Settings	X	✔
Manage the Purification and Assay protocols	X	✔

It is recommended to create one Windows® user account per user to ensure traceability. The Windows user account used for a workflow run is traced in the run report files.

When creating a user account in Windows®, it has to be associated with a specific Windows® user group to grant the privileges illustrated in Table 2: User Accounts.

To grant the privileges of a normal user, add the new Windows® user account to the Windows® user group 'Lab Operator' in the Windows® 'Local Users and Groups management' (lusrmgr.exe).

To grant the privileges of an administrator, add the new Windows® user account to the Windows® user group 'Lab Service' in the Windows® 'Local Users and Groups management' (lusrmgr.exe).

For further information and assistance, contact altona Diagnostics GmbH.

3.2 Starting the AltoStar® Connect SW

To start up the system, switch on the AltoStar® AM16 instrument and the computer that runs the AltoStar® Connect SW. The order in which the instrument and the computer are started is irrelevant.

Turn on the instrument with the front left green switch and start the computer by pressing the power button.

Once Windows® has booted, start the AltoStar® Connect SW using the **a*** icon on the Windows® desktop, the Windows task bar or in the Windows® start menu.

The software opens and displays the start screen. The start screen depicts the available workflow options as set in the system settings. The boxes depict the discrete stages of each workflow and can be clicked to access the respective user interface.
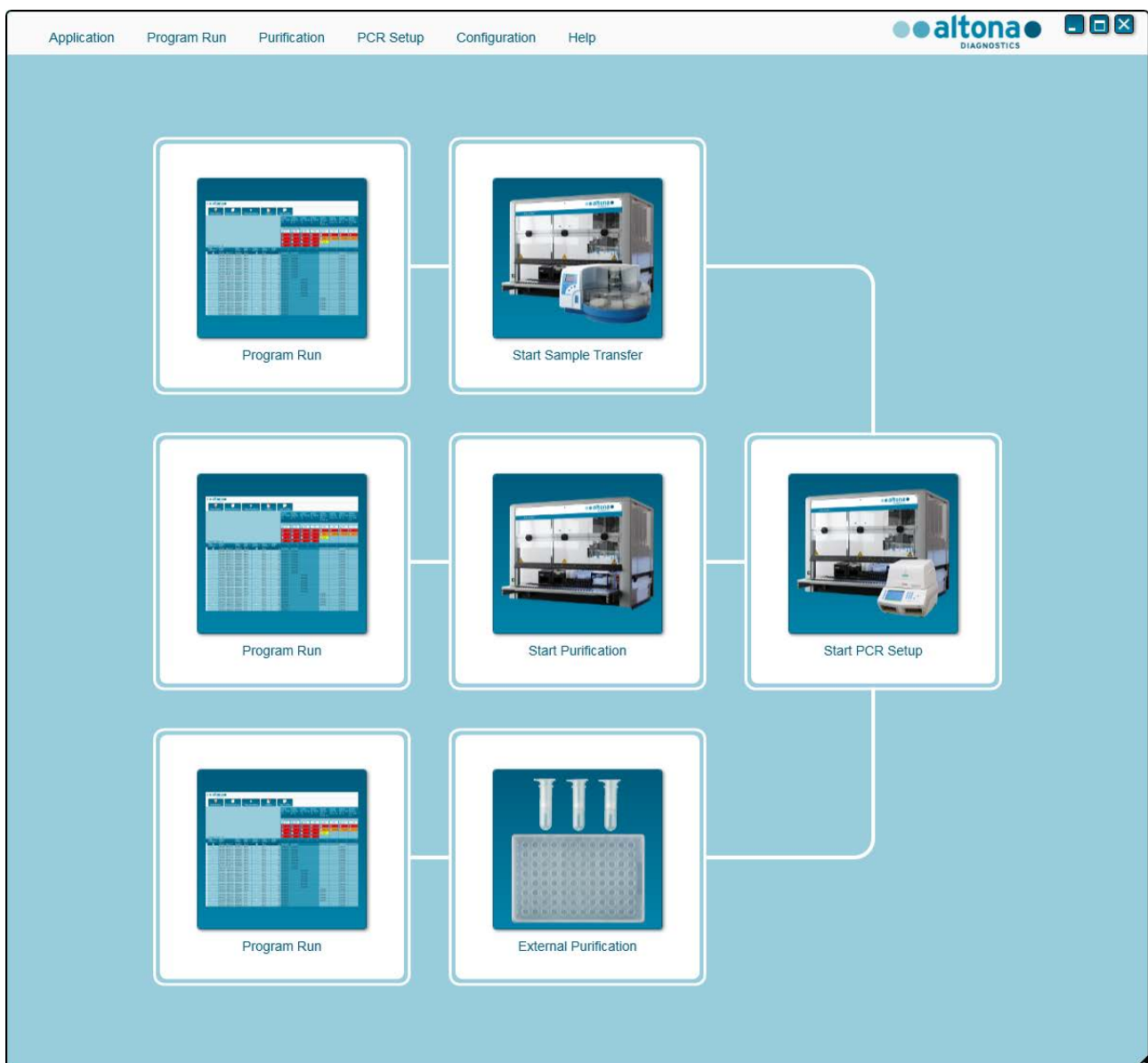
Fig. 15.: Start Screen of the AltoStar® Connect SW

3.3 Workflows

The AltoStar® Connect SW facilitates the processing of samples through the sample purification and the PCR setup process. The purification can be performed in one of three workflow options:

- On the AltoStar® AM16 instrument in conjunction with the AltoStar® Purification Kit 1.5 (**AltoStar Workflow**)

- On an external purification instrument with the AltoStar® AM16 instrument transferring the samples from the sample tubes to the processing plate of the external purification instrument (**Sample Transfer Workflow**)

- On an external purification instrument without sample transfer on the AltoStar® AM16 instrument (**External Purification Workflow**)

Regardless of the chosen purification workflow option, the PCR setup procedure is the same and is performed on the AltoStar® AM16 instrument for all three purification options. The following chapters will illustrate the processing of the AltoStar workflow purification and the PCR setup process.

For further information regarding the processes illustrated here and the Sample Transfer and External Purification workflows refer to the AltoStar® Connect Software Manual IVD Chapters 3.9: Sample Transfer Workflow: Purification and 3.10: External Purification Workflow: Purification.

3.4 AltoStar® Workflow: Purification

The AltoStar® Connect SW facilitates the processing of the AltoStar® Workflow: Purification on the AltoStar® AM16 instrument. The workflow consists of the following sequential steps:

1. Programming of the complete workflow process for a fixed set of samples in the AltoStar® Connect SW.

2. Specimen preparation: Refer to the AltoStar® Purification Kit 1.5 Manual for instructions

3. Sample purification on the AltoStar® AM16 as programmed in step 1.

4. PCR setup on the AltoStar® AM16 as programmed in step 1.

5. PCR on a CFX96™ DW as programmed in step 1. (refer to respective altona Diagnostics PCR Kit Manual)

For further information, please see the AltoStar® Connect Software Manual IVD.

NOTE

The programming for the complete workflow process is concluded in step 1. No alterations to the programmed process are possible in later phases of the workflow.

NOTE

Before starting the workflow, ensure that all required material and devices are available.

NOTE

Before starting the workflow, ensure that the Daily and Weekly Maintenance have been conducted and that the semi-annual maintenance and verification procedure is not overdue. Otherwise. the instrument will not process any samples or reagents. It is recommended to conduct the Daily Maintenance when the device is turned on the first time each day and to conduct the Weekly Maintenance at the end of the week before shut-down of the system. The maintenance routine verifies the correct functionality of the instrument and will prompt necessary user actions including cleaning of the instrument.

3.4.1 Overview of the AltoStar® Workflow Purification
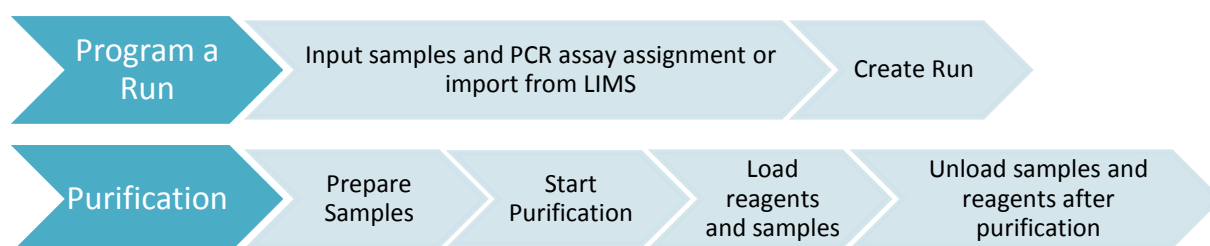
Fig. 16.: Overview of the AltoStar® Workflow Purification

3.4.2 Sample Preparation

For preparation and pretreatment of samples, please refer to the <u>AltoStar® Purification Kit 1.5 Manual</u>.

3.4.3 Preparing Reagents for a Purification Run

All reagent containers are barcoded for automated identification, localization and verification of lot conformity and non-expiry by the AltoStar® system.

NOTE

Ensure that the last four Lot Number digits of all Lysis Buffer, Wash Buffer, Magnetic Bead, Enhancer and Elution Buffer containers used in a run are identical. The software verifies lot conformity during loading and instructs the user accordingly. For your convenience, these four digits are displayed as Loading Number on the outside of each component box.
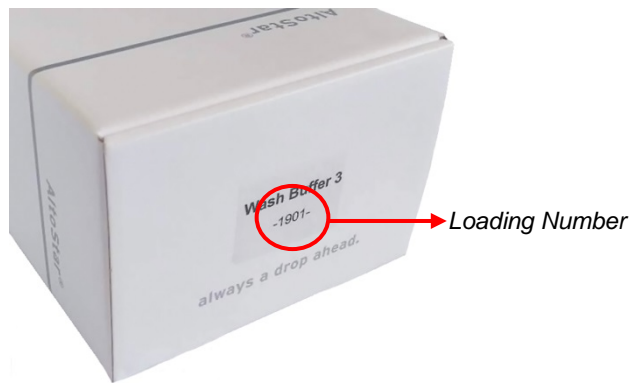
Fig. 17.: Side View of the Box with the Loading Number

NOTE

Ensure that your AltoStar® Purification Kit 1.5 reagents are not expired. During loading the software verifies use within the shelf life of the reagents and instructs the user accordingly.

3.4.4 Starting a Purification Run

To start the purification run, go back to the **Start Window** of the AltoStar® Connect SW and select **Start Purification** or select **Purification → Start Purification** in the menu bar. Your purification run definitions are displayed in the **Programmed Purification Runs** table on the left side of the screen.
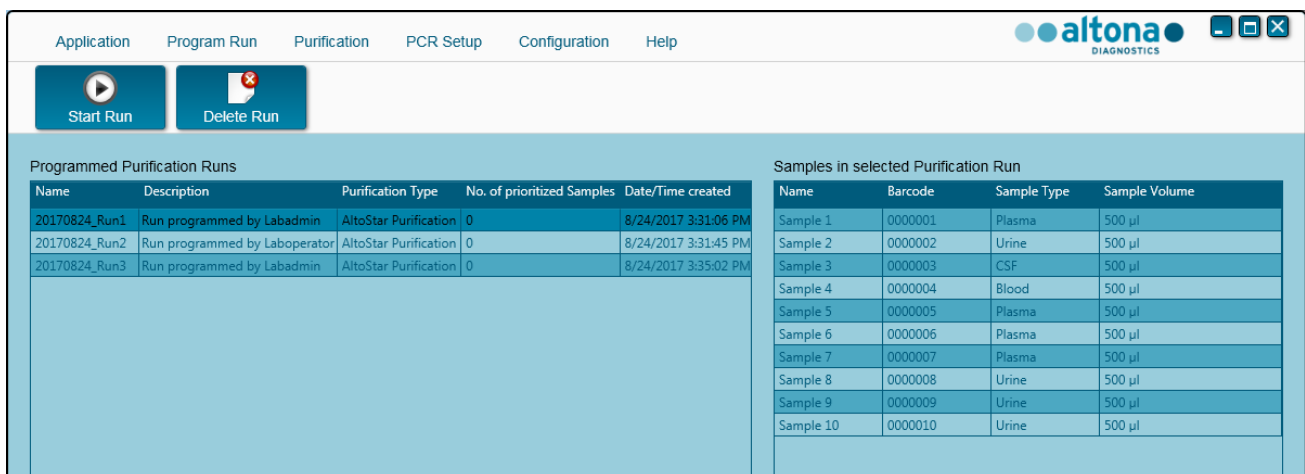
Fig. 18.: Start Run Screen

- Select the purification run definition to be started in the **Programmed Purification Runs** table

- The samples included in the selected run definition are displayed in the table on the right side of the screen **(Samples in selected Purification Run)**

- Click the **Start Run** button in the tool bar

Click **Delete Run** to completely delete the selected programmed purification run. By clicking **Delete Run** all associated programmed PCR Setup runs will also be deleted.

3.4.5 Instrument Loading for a Purification Run

At the start of a run the **Loading** dialog is displayed (see Fig. 19.: Purification Loading Dialog). The material, reagents and samples have to be loaded onto suitable carriers, before these carriers can then be loaded onto the respective tracks on the Loading Tray of the instrument:

Table 3: Carrier Description for Purification Run

Carrier No.	Track	Material	Carrier Name	Image	Notes
1	1 - 6	5 racks of 1000 µl tips	Tip Carrier		Only exchange completely empty Tip Racks for completely full ones. Do not handle individual tips.
2	7 - 12	3 racks of 300 µl tips 1 Elution Plate	Tip and Plate Carrier		Only exchange completely empty Tip Racks for completely full ones. Do not handle individual tips.
					Always place plates with well A1 to the left of the respective plate position.
					For PCR-Setup, the PCR plate must be placed at the front position and the Eluate plate at the second front position.
3-4	13-16	Up to four Lysis Buffer and Wash Buffer containers per carrier	Container Carrier		One or two carriers can be loaded.
					The position of the individual containers on the carriers is arbitrary.
					Gently push the containers down all the way to the bottom of the carrier.
5	17	Up to 24 Internal Control, Magnetic Bead, Enhancer and Elution Buffer tubes	Tube Carrier 24		The position of the individual tubes on the carrier is arbitrary.
					Ensure all tube barcodes are visible through the carrier windows.
					Gently push the tubes down all the way to the bottom of the carrier.

Carrier No.	Track	Material	Carrier Name	Image	Notes
6 - 11	18 - 23	Up to 96 samples on any combination of these two carrier types	Tube Carrier 24		Up to 24 sample tubes of 14.5 mm - 18 mm diameter per carrier.
					The position of the individual tubes on the carriers is arbitrary.
					Ensure all tube barcodes are visible through the carrier windows.
					Gently push the tubes down all the way to the bottom of the carrier.
			Tube Carrier 32		Up to 32 sample tubes of 11 mm - 14 mm diameter per carrier.
					The position of the individual tubes on the carriers is arbitrary.
					Ensure all tube barcodes are visible through the carrier windows.
					Gently push the tubes down all the way to the bottom of the carrier.
12	24 - 30	1 Processing Plate 1 Tip Park Plate 1 Tip Park Rack	Heater Shaker Carrier		This carrier is not removable and is therefore not loaded by the Autoload. The items are placed by hand onto the carrier in the instrument.
					Ensure both plates and the rack are seated correctly in their positions.

⚠️ **ATTENTION**

Remove the lids of all tubes before loading the carriers onto the Loading Tray. Leaving them on may lead to false results, aborted runs and damage to the instrument. Store the lids in a clean space to avoid contamination. Reuse the lids to close the tubes after the run.

⚠️ **ATTENTION**

Remove the sealing foils of all buffer containers before loading the carriers onto the Loading Tray. Leaving them on may lead to false results, aborted runs and damage to the instrument. Dispose of the sealing foils. To close the buffer containers after the run use new Re-sealing foils.

ATTENTION

Always use a fresh Processing Plate to avoid false results.

NOTE

Before loading carriers on the Loading Tray:

- *Ensure that no carriers are loaded on the deck inside the instrument.*

- *Ensure that the barcode on each carrier is toward the rear facing right (toward the barcode reader on the Autoload).*

Carrier	Track	Material	Comment
1	1 - 6	Tips 1000 µl	Replace empty Tip Racks with completely filled new ones
2	7 - 12	Tips 300 µl	Replace empty Tip Racks with completely filled new ones
2	7 - 12	Eluate Plate	New Eluate Plate
3 - 4	13 - 16	Lysis Buffer Wash Buffer 1 Wash Buffer 2 Wash Buffer 3	One or several containers of each buffer anywhere on these carriers
5	17	Enhancer Internal Control Magnetic Beads Elution Buffer	One or several tubes of each component anywhere on this carrier
6 - 11	18 - 23	Samples	1 samples on up to 6 carriers
12	24 - 30	Processing Plate	One new Processing Plate
12	24 - 30	Tip Park Plate	One new Processing Plate
12	**24 - 30**	**Tip Park Rack**	**Empty unused Tip Rack**

☐ Reset 1000µl tip counter
☐ Reset 300µl tip counter

Ok   Cancel

Fig. 19.: Purification Loading Dialog

The **Loading** dialog consists of a visual representation of the instrument deck at the top half and a table specifying all items to be loaded in the bottom half.

Begin by selecting the lines of the table by clicking them one by one, starting at the top.

The position of the material currently selected in the **Loading** dialog table is further visualized:

- In red in the image at the top.

- By flashing Loading Lights of the instrument above the tracks where the carrier holding the respective items must be placed.

Follow the instructions in the **Comment** column carefully.

To load the carriers, insert them into the tracks between the front and rear slide blocks of the Loading Tray until they touch the stop hooks on the far side of the Loading Tray. Do not push the carriers past the stop hooks.

> **ATTENTION**
>
> *Do not move or remove individual tips on a Tip Rack as this will interfere with the tip counter of the software. In case the tip positions were modified by the user, the tip counters for the 1000 µl tips and the 300 µl tips can be reset by checking the respective check boxes at the bottom of the **Loading** Dialog. In this case, all tip positions on carriers 1 and 2 have to be filled completely. The user has to confirm that all Tip Racks are completely filled in the subsequent **Reset Tip Counters** dialog.*

> **ATTENTION**
>
> *When handling patient samples, wear personal protective apparel, including disposable gloves, to avoid infection. Wash hands thoroughly after removing gloves, and dispose of gloves as biohazardous waste.*

> **ATTENTION**
>
> *To prevent damage to the carriers and decrease the risk of contamination, extend the safety guards whenever carriers are loaded on the Loading Tray.*

> **ATTENTION**
>
> *Always use a fresh Deep Well Plate in the Tip Park Module to avoid false results.*

> **ATTENTION**
>
> *Always use an empty Tip Rack in the Tip Park Module which hasn´t been used in that position before.*

NOTE

Do not exchange positions of any loaded material after it has been drawn into the instrument by the Autoload, as this could result in incorrect test results, aborting the run and damage to the instrument.

NOTE

Check that the Tip Eject Sheet and the Tip Waste Container are in the correct position and a new Waste Bag is placed in the container.

After all carriers are loaded on the correct tracks of the Loading Tray, click **OK** in the loading dialog. By clicking **Cancel**, the run will be cancelled, but it can be started again.

After clicking **OK**, the **Tip Park Plate** dialog is displayed (see Fig. 20.: Tip Park Plate Dialog). The plate barcode has to be scanned in duplicate with the handheld barcode scanner or entered by keyboard to ensure that the plate has not been used in prior runs. Click **OK** to confirm the input.

Fig. 20.: Tip Park Plate Dialog

The instrument loads the carriers with the Autoload and automatically verifies:

- Correct identity and localization of the loaded carriers

- Correct identity of the items loaded on the carriers

- Positions of the items loaded on the carriers

- Lot conformity of the Lysis Buffer, the Wash Buffers, the Magnetic Beads, the Enhancer and the Elution Buffer

- Non-expiry of all loaded reagents

- Presence of sufficient reagent volumes

- Singularity of sample barcodes

- Correct positioning of the items loaded manually on the Heater Shaker Carrier
- Correct positioning of the Tip Eject Sheet

If any of these checks fail, the user is prompted with a message dialog specifying the problem at hand and instructions to correct the issue accordingly. For further information regarding error handling see the AltoStar® Connect Software Manual IVD.

When all checks have passed, the **Loading Complete** dialog is displayed. Confirm the **Loading Complete** message by clicking **OK** or wait 10 seconds.

Fig. 21.: Loading Complete Dialog

The system now performs the purification automatically, no further user interaction is required until the run has finished. If you click **Cancel**, the run will abort. When canceling, the run up to this time it can be started again later.

> **ATTENTION**
>
> *Do not push or pull carriers or the instrument door during a run as this may abort the run.*

> **NOTE**
>
> *Aborting the run after the **Loading Complete** dialog is closed will void the run definition, preventing a restart.*

> **NOTE**
>
> *The sample volume is not checked by the system prior to the sample transfer. Short samples will be error flagged during the sample transfer step and will not be processed further.*

3.4.6 During the Purification Run

The purification run will be conducted without user intervention after starting. After the sample transfer into the Processing Plate, the sample carrier(s) can be unloaded at any time. The **Unload samples** button in the tool bar will be active and can be clicked. The sample carrier(s) will be unloaded from the deck and the samples tubes can be removed. The run will not be interrupted.

Fig. 22.: Unload Samples Button

3.4.7 Forced Abort

The run can be aborted by clicking the **Abort run** button in the tool bar and confirming to abort the run in the subsequent **Abort Run** dialog.

> ⚠️ **ATTENTION**
>
> *Once aborted, a run cannot be restarted. All data and used reagents will be lost and the run will be error flagged.*

3.4.8 End of the Purification Run

At the end of the run, the **Run Finished** dialog is displayed. Make sure the Loading Tray is empty and confirm the **Run Finished** dialog by clicking **OK**. The instrument will unload the carriers. Make sure not to stand in the way of the unloading carriers.

After unloading, the **Maintenance** dialog is displayed (see Fig. 23.: Maintenance Dialog After Finished Run). Follow the instructions of the **Maintenance** dialog.

Maintenance

Please perform the following actions:
- empty the Tip Waste
- check if the Liquid Waste needs to be emptied
- clean the Tip Eject Sheet
- clean the deck

The following reagents can be used again:

Reagent	Carrier Barcode	Position
Wash Buffer 2	R1700041	1
Wash Buffer 1	R1700041	2
Wash Buffer 1	R1700041	3
Lysis Buffer	R1700041	4
Wash Buffer 3	R1700125	5
Enhancer	S0174172	6
Magnetic Beads	S0174172	12
Elution Buffer	S0174172	23

Ok

Fig. 23.: Maintenance Dialog After Finished Run

Use the table of the dialog to identify reagents that can be used again in subsequent runs. Dispose of all reagents **not** listed in the table. Refer to the <u>AltoStar® Purification Kit 1.5 Manual</u> for information regarding sealing, storage and disposal.

Confirm the **Maintenance** dialog by clicking **Ok**.

For further information see the <u>AltoStar® Connect Software Manual IVD</u>.

3.5 PCR Setup

The PCR setup process is the same irrespective of the purification workflow chosen for the samples (AltoStar® workflow, Sample Transfer workflow or External Purification workflow).

3.5.1 Preparing Reagents for a PCR Setup Run

All reagents should be thawed completely, mixed (by pipetting or gentle vortexing) and centrifuged briefly before use. For detailed information, refer to the respective <u>altona Diagnostics PCR Kit Manual</u>.

All reagent tubes are barcoded for automated identification, localization and verification of lot conformity and non-expiry by the AltoStar® system.

ATTENTION

Always wear protective disposable powder-free gloves when handling kit components.

ATTENTION

Do not manually transfer any liquids.

NOTE

Ensure that all components of the altona Diagnostics PCR Kit are from the same lot. The software verifies lot conformity during loading and instructs the user accordingly.

NOTE

Ensure that your altona Diagnostics PCR Kit reagents are not expired. The software verifies use within the shelf life of the reagents during loading and instructs the user accordingly.

NOTE

Required components of the altona Diagnostics PCR Kit for a given run can be previewed in the AltoStar® Connect SW (see Chapter 3.4.2 Starting a PCR Setup Run). This allows for preparation of the required components during the preceding purification run.

NOTE

The subsequent PCR run must be started within 30 minutes after the completion of the PCR Setup.

Before starting the PCR Setup run, ensure that the material required for the subsequent PCR run will be available and ready to use at the end of the PCR Setup run to avoid prolonged storage of the completed PCR plate:

- PCR Plate Sealing Foil

- Heat Sealer

- CFX96™ DW Cycler

3.5.2 Starting a PCR Setup Run

The PCR Setup for an AltoStar® PCR Kit can be started as soon as the associated purification run is complete. How to program a run and start a purification run is explained in the AltoStar® Connect Software Manual IVD in the Chapters Programming a Run and Starting a Purification Run as well as Chapters Programming a Run and Starting a Sample Transfer Run. To start the PCR setup run, go back to the **Start Window** of the AltoStar® Connect SW and select **Start PCR Setup** or select **PCR → Start PCR Setup** in the menu bar. Your PCR setup run definitions are displayed in the **Programmed PCR Setup Runs** table on the left side of the screen.

Fig. 24.: Start Screen for PCR Setup

- Select the PCR setup run definition to be started in the **Programmed PCR Setup Runs** table.

- The samples included in the selected run definition are displayed in the **Samples in selected PCR Setup Run** table on the top right side of the screen.

- The controls included in the selected run definition are displayed in the **Controls in selected PCR Setup Run** table on the middle right side of the screen.

- The number of master reagent tubes required for the selected run definition is displayed in the **Required master tubes for the selected PCR Setup Run** table on the bottom right side of the screen.

- Click the **Start Run** button in the tool bar to start the selected PCR setup run definition.

- Click **Delete Run** to completely delete the selected programmed PCR Setup run.

For further information see the AltoStar® Connect Software Manual IVD.

NOTE

The PCR setup run definitions can be accessed any time after programming, including during an ongoing purification or PCR setup run. This way, the required reagents for an upcoming PCR setup run can be previewed and prepared in advance so that a PCR setup run can be started right after the end of the ongoing run.

NOTE

*If the **Start Run** button is inactive, the purification leading up to the currently selected PCR setup run definition has not been completed. Refer to column **Purification Status** in the table **Programmed PCR setup Runs** for information.*

3.5.3 Instrument Loading for the PCR Setup Run

At the start of a run the **Loading** dialog is displayed (see Fig. 25.: PCR Setup Loading Dialog). The material, reagents and samples have to be loaded onto suitable carriers, before these carriers can then be loaded onto the respective tracks on the Loading Tray of the instrument:

Table 4: Carrier Description: PCR Setup Run

Carrier No.	Track	Material	Carrier Name	Image	Notes
1	1 - 6	5 racks of 1000 µl tips	Tip Carrier		Only exchange completely empty Tip Racks for completely full ones. Do not handle individual tips.

Carrier No.	Track	Material	Carrier Name	Image	Notes
2	7 - 12	3 racks of 300 µl tips 1 Elution Plate 1 PCR Plate	Tip and Plate Carrier		Only exchange completely empty Tip Racks for completely full ones. Do not handle individual tips.
					Always place plates with well A1 to the left of the respective plate position.
					The PCR plate is placed at the front most position, the elution plate at the second front most position of this carrier.
3	13	One Pooling Tube per assay	Tube Carrier 24		One carrier can be loaded.
					The position of the individual tubes on the carriers is arbitrary.
					Gently push the tubes down all the way to the bottom of the carrier.
4 - 7	14 - 17	Master tubes and standard/control tubes of the assays	Reagent Tube Carrier 32		The position of the individual tubes on the carrier is arbitrary.
					Ensure all tube barcodes are visible through the carrier windows.
					Gently push the tubes down all the way to the bottom of the carrier.

ATTENTION

Remove the lids of all tubes before loading the carriers onto the Loading Tray. Dispose of all lids. To close tubes after the run use new lids.

NOTE

Before loading carriers on the Loading Tray:

- *Ensure that no carriers are loaded on the deck inside the instrument.*

- *Ensure that the barcode on each carrier is toward the rear facing right (toward the barcode reader on the Autoload).*

Fig. 25.: PCR Setup Loading Dialog

The **Loading** dialog consists of a visual representation of the instrument deck at the top half and a table specifying all items to be loaded in the bottom half.

Begin by selecting the lines of the table by clicking them one by one, starting at the top.

The position of the material currently selected in the **Loading** dialog table is further visualized:

- In red in the image at the top
- By flashing Loading Lights of the instrument above the tracks where the carrier holding the respective items must be placed.

Follow the instructions in the **Comment** column carefully.

To load the carriers, insert them into the tracks between the front and rear slide blocks of the Loading Tray until they touch the stop hooks on the far side of the Loading Tray. Do not push the carriers past the stop hooks.

ATTENTION

Always wear protective disposable powder-free gloves when handling kit components.

ATTENTION

To prevent damage to the carriers and decrease the risk of contamination, extend the safety guards whenever carriers are loaded on the Loading Tray.

ATTENTION

*Do not move or remove individual tips on a Tip Rack as this will interfere with the tip counter of the software. In case the tip positions were modified by the user, the tip counters for the 1000 µl tips and the 300 µl tips can be reset by checking the respective check boxes at the bottom of the **Loading** Dialog. In this case, all tip positions on carriers 1 and 2 have to be filled completely. The user has to confirm that all Tip Racks are completely filled in the subsequent **Reset Tip Counters** dialog.*

NOTE

Do not exchange positions of any loaded material after it has been drawn into the instrument by the Autoload, as this could result in incorrect test results, aborting the run and damage to the instrument.

NOTE

Use only material as described in the AltoStar® PCR Manual.

NOTE

Check that the Tip Eject Sheet and the Tip Waste Container are in the correct position and a new Waste Bag is placed in the container.

After all carriers are loaded on the correct tracks of the Loading Tray, click **OK** in the loading dialog. By clicking **Cancel**, the run will be cancelled, but it can be started again.

The instrument loads the carriers with the Autoload and automatically verifies:

- Correct identity and localization of the loaded carriers

- Correct identity of the items loaded on the carriers

- Positions of the items loaded on the carriers

- Lot conformity of the reagents of the individual kits

- Non-expiry of all loaded reagents

- Correct positioning of the Tip Eject Sheet

If any of these checks fail, the user is prompted with a message dialog specifying the problem at hand and instructions to correct the issue accordingly.

For further information regarding error handling, see the AltoStar® Connect Software Manual IVD.

When all checks have passed, the **Loading Complete** dialog is displayed. Confirm the **Loading Complete** message by clicking **OK** or wait 10 seconds.

Fig. 26.: Loading Complete Dialog

The system now performs the PCR setup automatically, no further user interaction is required until the run has finished. If you click **Cancel**, the run will abort. When canceling the run up to this time, it can be started again later.

ATTENTION

Do not push or pull carriers or the instrument door during a purification run as this may abort the run.

NOTE

*Aborting the run after the **Loading Complete** dialog is confirmed will void the run definition, preventing a restart.*

NOTE

The volumes of the loaded reagents are not checked during loading. Make sure to only load unused Master reagent tubes. The tubes containing the controls and quantification standards contain sufficient volumes for four runs. Do not use the controls and quantification standard tubes for more than four runs.

3.5.4 During the PCR Setup Run

The PCR setup run will be conducted without user intervention after starting.

3.5.5 Forced Abort

The run can be aborted by clicking the **Abort run** button in the tool bar and confirming to abort the run in the subsequent **Abort Run** dialog.

> ⚠️ **ATTENTION**
>
> *Once aborted, a run cannot be restarted. All data and used reagents will be lost and the run will be error flagged.*

3.5.6 End of the PCR Setup Run

At the end of the run, the **Run Finished** dialog is displayed. Make sure the Loading Tray is empty and confirm the **Run Finished** dialog by clicking **OK**. The instrument will unload the carriers. Make sure not to stand in the way of the unloading carriers. After unloading the **Maintenance** dialog is displayed (see Fig. 27.: Maintenance After Run Dialog).
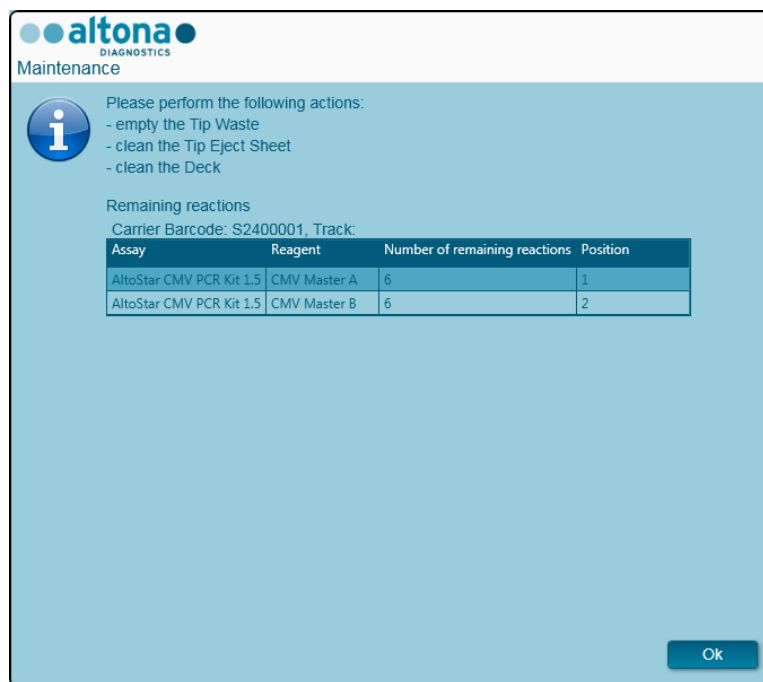
Fig. 27.: Maintenance After Run Dialog

Confirm the **Maintenance** dialog by clicking **Ok**.

For further information regarding maintenance see the AltoStar® Connect Software Manual IVD.

4   Maintenance

Periodic maintenance routines need to be run in order to ensure safe and reliable operation of your AltoStar® AM16 instrument and the accessories.

For IVD use, the maintenance routines are mandatory and are enforced by the software. It is not possible to start runs when maintenance or verification is overdue.

4.1 Maintenance Intervals

- **Daily Maintenance**: Has to be executed every 24h. Recommended after AltoStar® AM16 start-up.

- **Weekly Maintenance**: Has to be executed every 7 days. Recommended at the end of the week before AltoStar® AM16 shut-down. If any parts of the instrument, carriers, or racks have become contaminated, the weekly maintenance procedure must be performed.

- **Verification**: Has to be executed every 200 days. Preventive maintenance and verification is carried out by a Hamilton trained field service engineer.

> **NOTE**
>
> *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%)

- De-ionized water

- MICROLAB Disinfectant Spray

- MICROLAB Detergent and Disinfectant

> **ATTENTION**
>
> *Use cleaning, disinfecting and decontaminating fluid in accordance with the manufacturer's instructions. Do not use disinfecting materials which contain hypoclorite (Javel water, Chlorox) or bleaching fluids.*
>
> *Prepare disinfectant fluids according to their labeling.*
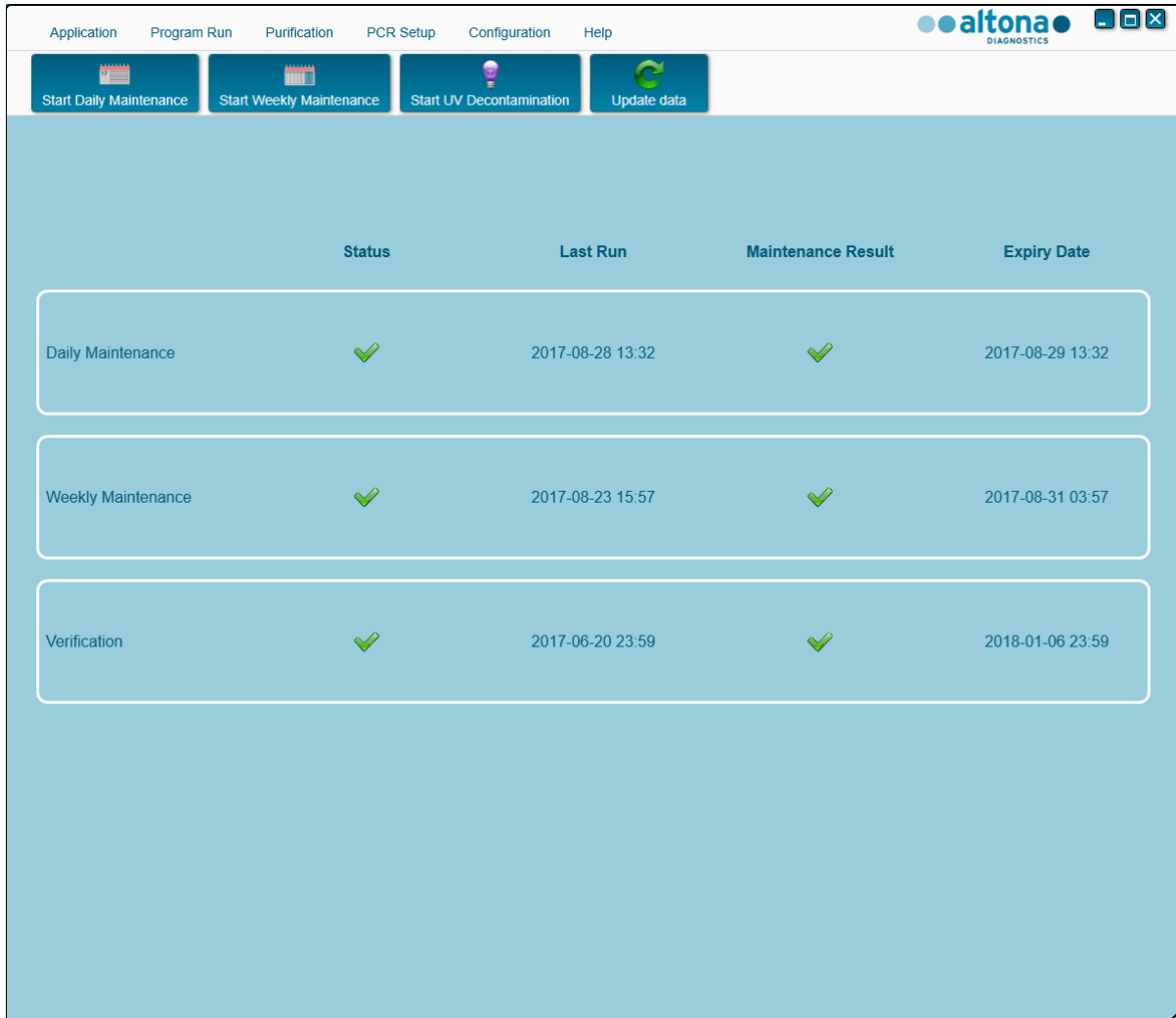
4.3 Maintenance Procedures

Access the Maintenance screen by clicking **Application → Instrument Maintenance** in the menu bar.

A valid status of the Daily Maintenance, Weekly Maintenance and the semi-annual Verification is depicted by a green check mark ✔ in the column **Status**. If a red **X** mark is displayed in this column, the respective maintenance procedure has to be performed by clicking the corresponding button in the tool bar. Follow the on screen instructions to complete the maintenance procedure.

By clicking **Update data**, the maintenance data which are saved on the instrument will be newly read out and will be shown in the Maintenance Dialog.

Fig. 28.: Maintenance Screen

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.

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.

4.4 Daily Maintenance

The following tasks are part of the daily maintenance:

- Checking if the deck is clean
- Emptying the tip waste and liquid waste
- Checking the tightness of the pipetting channel
- Verifying the cLLD function

1. Start the daily maintenance by clicking the **Start Daily Maintenance** button in the tool bar. The software will issue on-screen instructions detailing all procedures required to perform the daily maintenance routine.

2. Once the maintenance procedure has been started, the Pipetting Arm moves to the left side. The operator now has access to the deck to check if cleaning is needed or not.
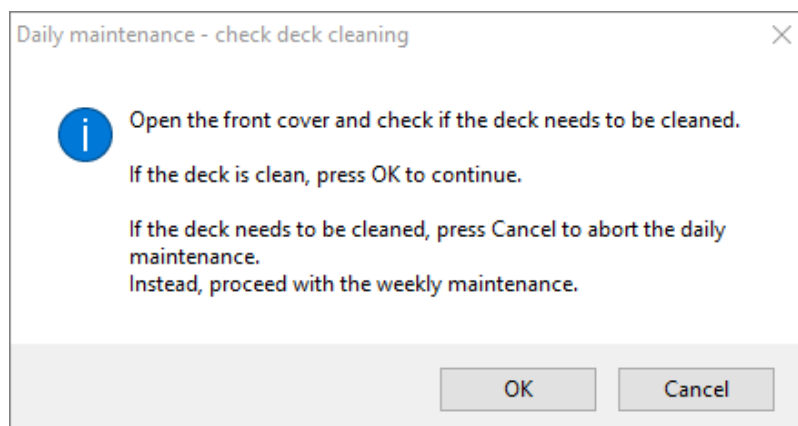
Fig. 29.: Daily Maintenance – Check Deck Cleaning Dialog

Exact wording of content of the dialog displayed in Fig 29:

> Open the front cover and check if the deck needs to be cleaned.
>
> If the deck is clean, press OK to continue.
>
> If the deck needs to be cleaned, press Cancel to abort the daily maintenance.
> Instead, proceed with the weekly maintenance.

3. Remove the Tip Eject Sheet of the tip waste station and spray MICROLAB Disinfectant Spray directly onto the surface and wipe dry. Put the clean Tip Eject Sheet back in place.
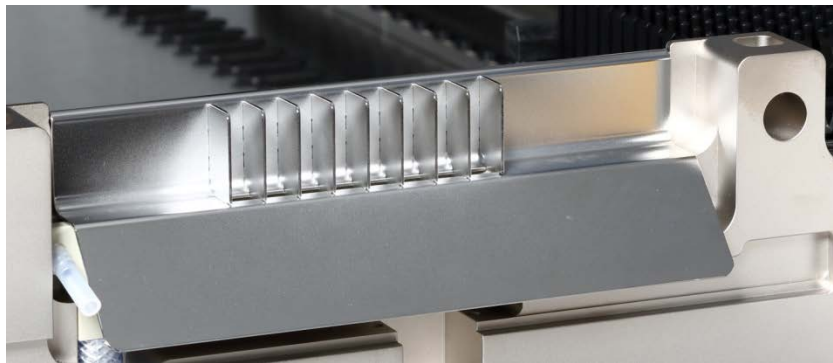
Fig. 30.: Tip Eject Sheet

4. If the deck is clean, continue with the daily maintenance.

5. If the deck needs to be cleaned, the daily maintenance can be interrupted. Instead of the daily maintenance carry out the weekly maintenance.

6. Continuing the daily maintenance procedure will lead the user to the next maintenance task. The tip waste needs to be emptied. Dispose of it with the rest of the laboratory's contaminated waste.
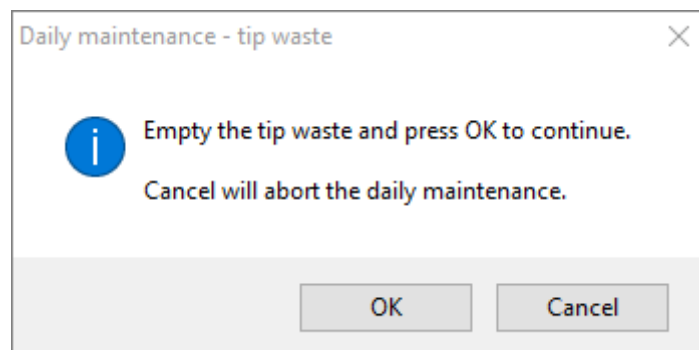
Fig. 31.: Daily Maintenance – Tip Waste

Exact wording of content of the dialog displayed in Fig 31.:

> Empty the tip waste and press OK to continue.
>
> Cancel will abort the daily maintenance.

> ⚠ **ATTENTION**
>
> *The tip waste is always to be regarded as contaminated.*

7. Empty the liquid waste container and check the liquid waste

   o Inspect tubing for clogs, kinks and leakage. Tubing must be replaced if damaged.

   o Check and clean any liquid spills.

   o Check overflow for clogs and clean if required.

> ⚠ **ATTENTION**
>
> *The tip waste, the Tip Eject Sheet, the Liquid Waste Container and Tubings, and the plastic bag are always to be regarded as contaminated.*

8. For the next steps, the maintenance needles are required.

Fig. 32.: Maintenance Needles for 1000 µl Pipetting Channels

9. The procedure continues with the tightness check of the pipetting channels. The Pipetting Arm will travel to the right side to pick up the maintenance needles. Two checks are done with the pipetting channels, the over-pressure and under-pressure check.

10. For the capacitive liquid level (cLLD) check, the needles are picked up again. One pipetting channel after the other is checked for proper cLLD function.

Fig. 33.: Daily Maintenance – Successful

Exact wording of content of the dialog displayed in Fig. 33.:

Daily maintenance successfully completed.

11. The daily maintenance process status is saved on the instrument and a report file is created.

NOTE

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

4.5 Weekly Maintenance

The following tasks are carried out by the weekly maintenance:

- Cleaning the deck and carriers
- Checking the condition of the carriers
- Emptying and cleaning of the tip waste and liquid waste
- Checking the tightness of the pipetting channel
- Verifying the cLLD function
- Cleaning of the pipetting head: stop disk, O-ring, tip eject sleeve
- Cleaning of the covers, Autoload protecting ribbon

1. Start the weekly maintenance by clicking the **Start Weekly Maintenance** button in the tool bar. The software will issue on-screen instructions detailing all procedures required to perform the weekly maintenance routine.
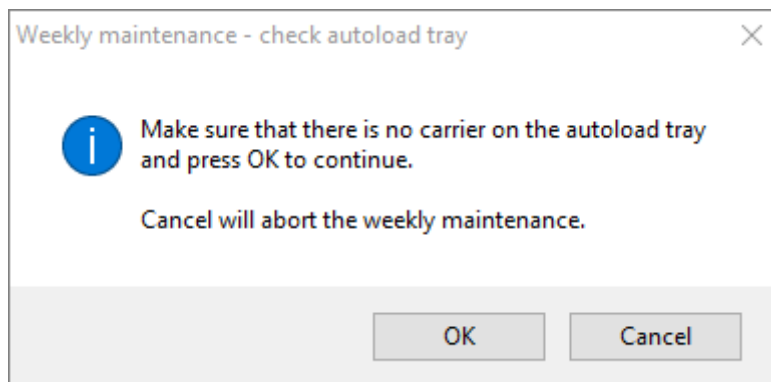
Fig. 34.: Weekly Maintenance – Check Autoload Tray

Exact wording of content of the dialog displayed in Fig. 34.:

> Make sure that there is no carrier on the autoload tray and press OK to continue.
>
> Cancel will abort the weekly maintenance.
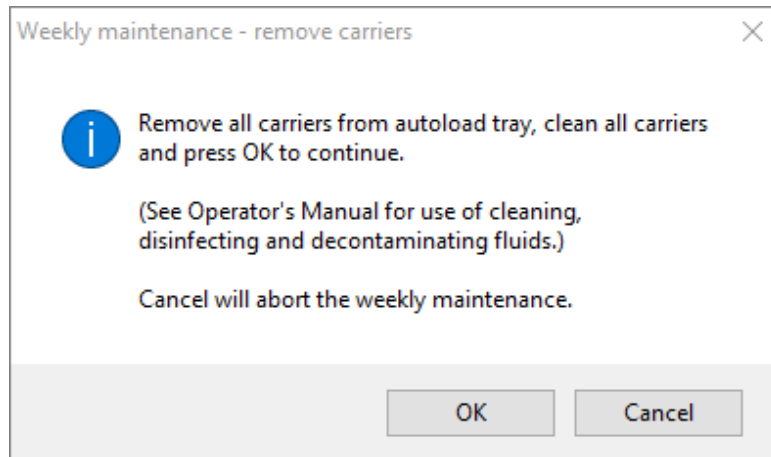
Fig. 35.: Weekly Maintenance – Remove Carriers

Exact wording of content of the dialog displayed in Fig. 35.:

Remove all carriers from autoload tray, clean all carriers and press OK to continue.

(See Operator's Manual for use of cleaning, disinfecting and decontaminating fluids.)

Cancel will abort the weekly maintenance.
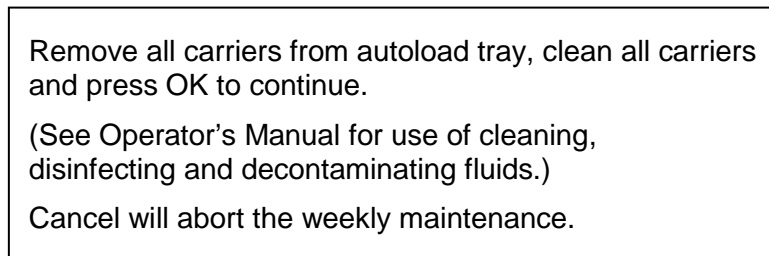
2. Clean all carriers with the MICROLAB Disinfectant Spray and leave them to dry. If they are heavily soiled, soak these carriers afterwards in a solution of MICROLAB Detergent and Disinfectant (see the product data sheet for further information).

3. Examine each carrier for scratches on the barcode and any signs of damage. If damage is apparent, replace with new carriers.

 ATTENTION

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

4. Continuing the weekly maintenance program will advise the Autoload to move to the right hand side of the instrument.
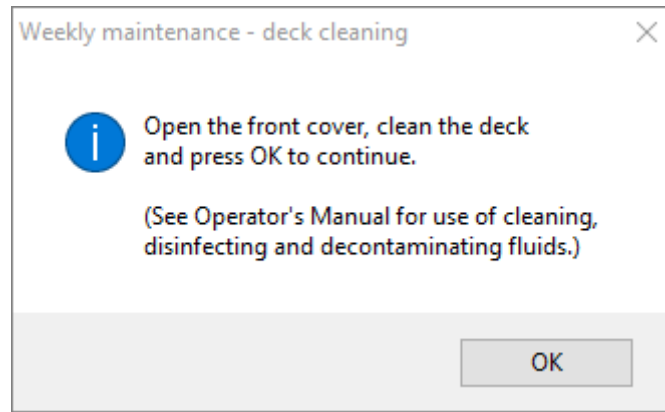
Fig. 36.: Weekly Maintenance – Deck Cleaning

Exact wording of content of the dialog displayed in Fig. 36:

Open the front cover, clean the deck
and press OK to continue.

(See Operator's Manual for use of cleaning,
disinfecting and decontaminating fluids.)
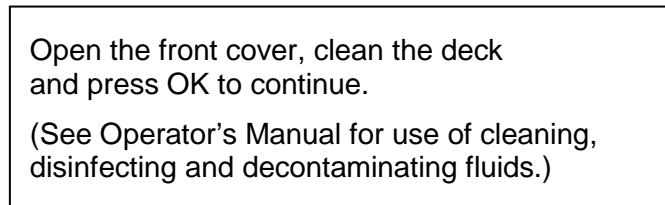
5. Open the front cover and wipe the deck with a cloth saturated with MICROLAB Disinfectant Spray. The slide blocks in particular must be checked for cleanliness. Close the front cover.

6. The next step of the maintenance procedure will advise the Autoload to move to the left hand side of the instrument. The tip waste needs to be emptied and cleaned. Dispose of tip waste with the rest of the laboratory's contaminated waste.
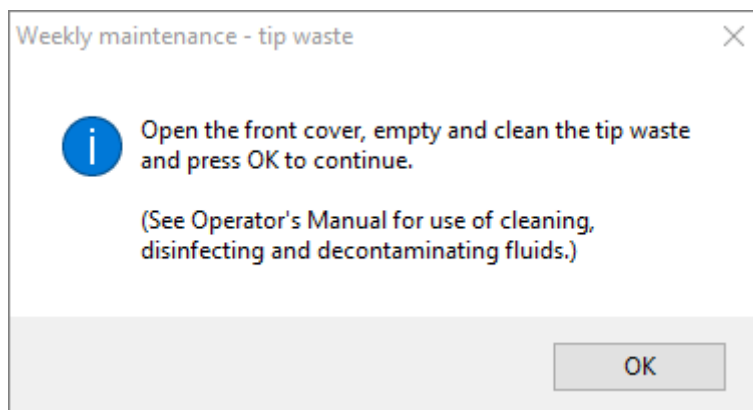
Fig. 37.: Weekly Maintenance – Tip Waste

Exact wording of content of the dialog displayed in Fig. 37.:

Open the front cover, empty and clean the tip waste
and press OK to continue.

(See Operator's Manual for use of cleaning,
disinfecting and decontaminating fluids.)
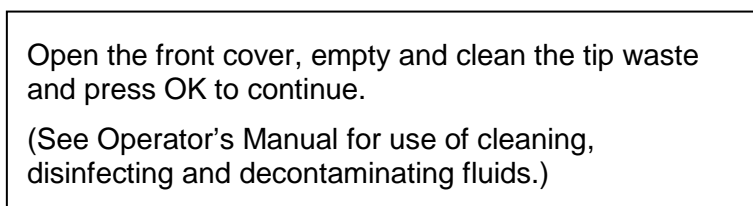
7. Remove the Tip Eject Sheet of the tip waste station and spray MICROLAB Disinfectant Spray directly onto the surface and wipe. Remove the plastic bag from the tip waste container and discard the plastic in the laboratory's contaminated waste. Place a new plastic bag in the tip waste container. Put the clean Tip Eject Sheet back in place.

8. Emptying and cleaning of the liquid waste

    a. Empty the liquid waste container.

    b. Inspect tubing for clogs, kinks and leakage. Tubing must be replaced if damaged.

    c. Check and clean any liquid spills.

    d. Check overflow for clogs and clean if required.

    e. Clean collection tray, tubing and liquid waste container using Ethanol (70%) to flush.

> ⚠️ **ATTENTION**
>
> *Do not spray the maintenance needles.*

> ⚠️ **ATTENTION**
>
> *The tip waste, the Tip Eject Sheet, the Liquid Waste Container and Tubings and the plastic bag are always to be regarded as contaminated.*

9. To prevent unreliable barcode reading, check the laser scanner window of the barcode reader and clean it with a lint-free cloth or Q-tips lightly soaked in Ethanol (70%).

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

10. For the next steps, the maintenance needles are required.

Fig. 38.: Maintenance Needles 1000 µl Pipetting Channels

11. The procedure continues with the tightness check of the pipetting channels. The Pipetting Arm will travel to the right hand side to pick up the maintenance needles. Two checks are done with the pipetting channels, the over-pressure and under-pressure check.

12. For the capacitive liquid level (cLLD) check, the needles are picked-up again. One pipetting channel after the other is checked for proper cLLD function.
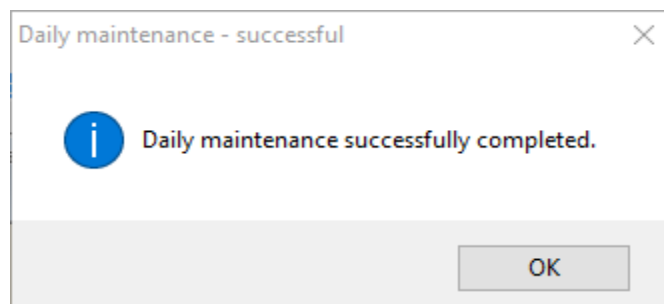
13. The end of the weekly maintenance program is displayed:
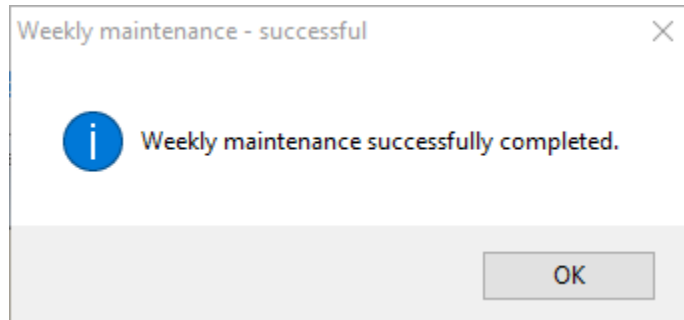
Fig. 39.: Weekly Maintenance – Successful

Exact wording of content of the dialog displayed in Fig. 39.:

Weekly maintenance successfully completed.

14. The weekly maintenance process status is saved on the instrument and a report file is created.

15. Clean the tip eject sleeve (outer part of the pipetting heads) with a lint-free cloth soaked in MICROLAB Disinfectant Spray.

Fig. 40.: Cleaning the Tip Eject Sleeve

ATTENTION

Take care that no liquid gets inside the pipetting channel.

Whenever it is necessary to move the pipetting channels on the Pipetting 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 Pipetting Arm.

16. Clean the stop disk and the O-rings (outer part of the pipetting heads, see <u>Fig. 41.: Cleaning the Stop Disk and O-Ring</u>) with a lint-free cloth soaked in MICROLAB Disinfectant Spray.
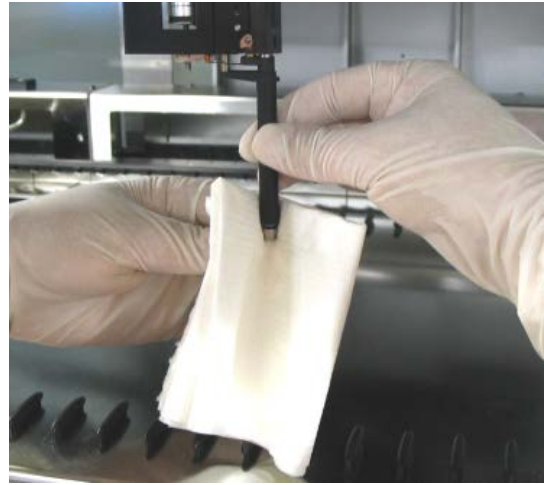
Fig. 41.: Cleaning the Stop Disk and O-Rings

> ⚠ **ATTENTION**
>
> *Take care that no liquid gets inside the pipetting channel.*

17. Spray the front and side cover with MICROLAB Disinfectant Spray and wipe dry.

18. Clean the Autoload protecting ribbon with a cloth soaked in MICROLAB Disinfectant Spray, and wipe without exerting pressure.

> ⚠ **ATTENTION**
>
> *Do not spray directly at the Autoload unit or at electrical boards or connectors.*

19. Clean the Pipetting Arm guide shaft behind the upper front cover with a dry cloth at least once a month.

> 📝 **NOTE**
>
> *Carriers must be completely clean and dry before re-using.*

4.6 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 altona Diagnostics GmbH.

5   AltoStar® AM16 Decontamination

The following is the recommended procedure for decontaminating the AltoStar® AM16 instrument:

1. Spray the front and side cover with MICROLAB Disinfectant Spray.

2. Open the front cover and wipe the deck with a cloth saturated with MICROLAB Disinfectant Spray.

    • The slide blocks in particular must be checked for cleanliness

3. Remove the Tip Eject Sheet of the tip waste station and clean it.

    • Spray MICROLAB Disinfectant Spray directly onto the surface of the tip waste station and wipe.

Fig. 42.: Tip Eject Sheet

4. Discard the plastic bag in the laboratory's contaminated waste.

5. Put the Tip Eject Sheet in place.

6. Clean the tip eject sleeve (outer part of the pipetting channels) with a lint-free cloth soaked in MICROLAB Disinfectant Spray.

7. Clean all carriers with MICROLAB disinfectant spray and let them dry.

    • If they are heavily soiled, soak them afterwards in a solution of MICROLAB detergent and disinfectant (see the product data sheet for further information).

8. Empty the liquid waste container and check the liquid waste

    • Check and clean any liquid spills.

> ⚠️ **ATTENTION**
>
> *The tip waste, the Tip Eject Sheet the Liquid Waste Container and Tubings and the plastic bag are always to be regarded as contaminated.*

9. Emptying and cleaning of the liquid waste

    • Empty the liquid waste container.

    • Clean collection tray, tubing and liquid waste container using Ethanol (70%) to flush.

6   AltoStar® AM16 UV Decontamination

A UV-Lamp assembly (Microlab STAR Line UV Kit, Hamilton) has been installed in order to offer the user the option of UV decontamination of the AltoStar® AM16. The required duration and frequency is dependent on the used substances and on the frequency the system is used. The user is responsible for setting the appropriate duration and frequency.

Carriers and other accessories are not meant to be decontaminated by the UV Kit. The UV light cannot reach all surfaces of complex structures. Remove the carriers for UV decontamination.

ATTENTION

Only use the UV decontamination with appropriate protection especially the UV front cover of the system.

NOTE

Read the UV Kit Manual before using the UV Kit! (Microlab STAR Line UV Kit, Hamilton)

6.1 Operating the UV Kit

This chapter is dedicated to the user and focuses on a safe operation of the UV Kit based on the standard UV decontamination method.

NOTE

Read the UV Kit Manual before using the UV Kit! (Microlab STAR Line UV Kit, Hamilton)

ATTENTION

Wear suitable face shield, gloves and protective clothing. Make sure that the UV cover is placed in the correct position to completely close the instrument before switching on the UV light.

6.1.1 Mounting the UV Front Cover

The UV front cover shall be used to close the instrument completely whenever the UV light is switched on. Place the UV front cover as indicated in the picture below.

ATTENTION

Do not use the UV front cover during a different method run, as carriers could be unloaded automatically and crash into the cover.

Fig. 43.: Mounting the UV Front Cover

6.1.2 Running the UV Decontamination Method

NOTE

The UV decontamination method enables automated UV irradiation. Therefore, the user can set the duration for how long the irradiation shall take place and a delay defining when the irradiation shall start.

1. Start the UV decontamination by clicking the **Start UV Decontamination** button in the tool bar (see Fig. 28.: Maintenance Dialog). The software will issue on-screen instructions detailing all procedures required to perform the UV decontamination routine.

2. The first dialog refers to a check of the UV light. This step is performed in order for the user to check if the UV light is working properly.
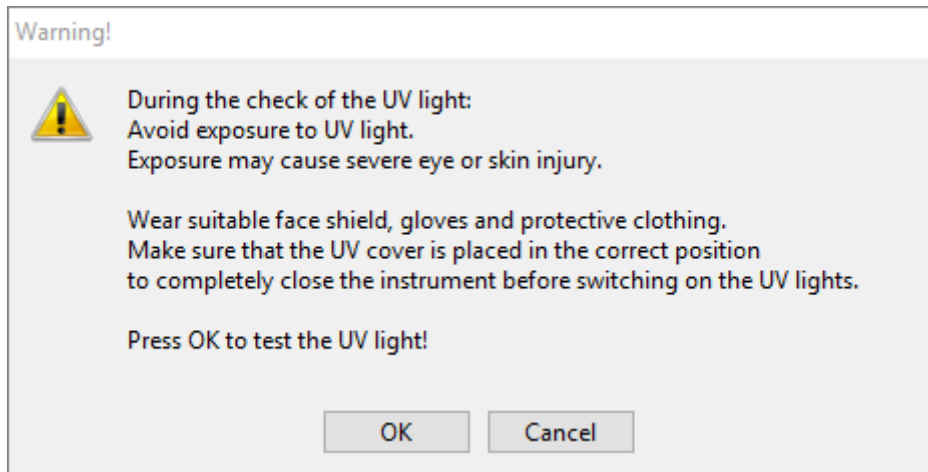
Fig. 44.: Warning Dialog

Exact wording of content of the dialog displayed in Fig. 44.:

> During the check of the UV light:
> Avoid exposure to UV light.
> Exposure may cause severe eye or skin injury.
>
> Wear suitable face shield, gloves and protective clothing.
> Make sure that the UV cover is placed in the correct position
> to completely close the instrument before switching on the UV lights.
>
>
> Press OK to test the UV light!
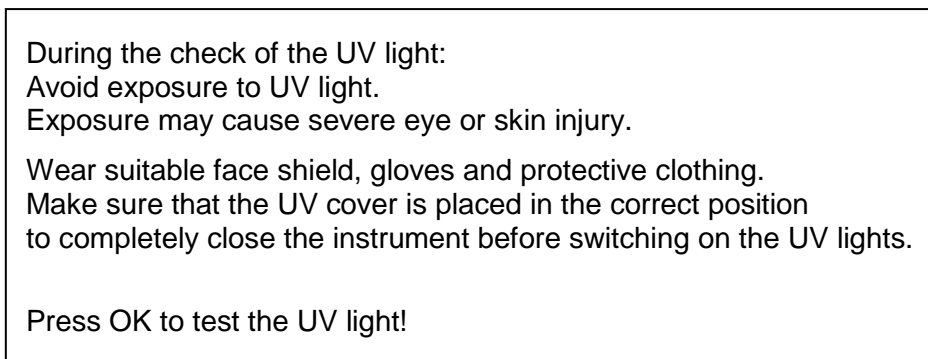
3. Additionally, precautions and hazards are mentioned as well as protective measures. Make sure that all these protective measures are performed and that no collision can happen inside the instrument (the arm will move during the decontamination process!). Then, select **[OK]** to proceed to the UV light test.

4. The UV light will be switched on for a short moment. Observe if the UV light flashes.
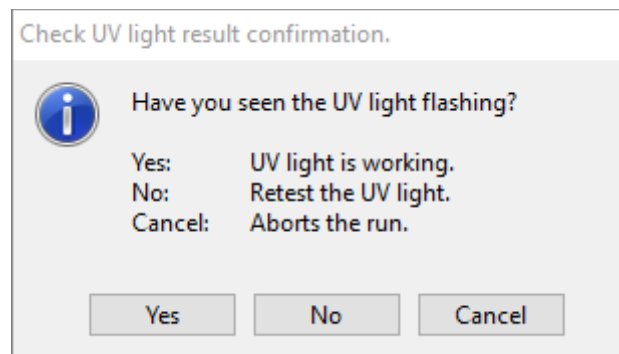
Fig. 45.: Check UV Light Result Confirmation

Exact wording of content of the dialog displayed in Fig. 45.:

> Have you seen the UV light flashing?
>
> Yes: UV light is working.
>
> No: Retest the UV light.
>
> Cancel: Aborts the run.

5. If the UV light was shining for a moment, confirm with **[Yes]**. Else, select **[No]** for a retest of the UV light or **[Cancel]** to abort the run.

⚠ **ATTENTION**

In case the UV light flashing cannot be observed upon several retests, the power connections should be checked.

If all connections are fine but the UV light flashing can still not be observed, the UV light may be defective. Please contact altona Diagnostics GmbH in this case.

6. If the UV light flashing could be observed and **[Yes]** has been selected, the UV light timer settings dialog is shown.

UV light timer: Please set the decontamination duration and delay timer for the UV light (in minutes).

Prompt	Value	Minimum	Maximum
Decontamination duration (minutes)	10	1	60
Time to wait before decontamination starts (minutes)	0	0	10

OK   Help

Fig. 46.: UV Light Timer Settings Dialog

7. Enter the desired duration for UV decontamination in the upper **"Value"** field. The lower **"Value"** field can be used to enter the desired delay when the UV irradiation shall start. In this case, the user can leave the room during this duration until the UV irradiation starts. Whole numbers are required, otherwise a warning will be displayed and the value has to be changed. The **"Minimum"** and **"Maximum"** values to be used are indicated in the corresponding fields.

8. Select **[OK]** to proceed.
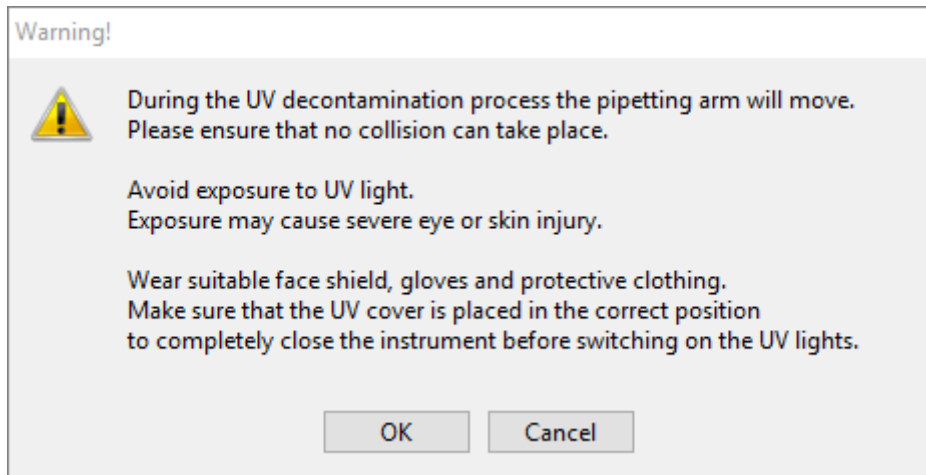
Fig. 47.: Warning Dialog

Exact wording of content of the dialog displayed in Fig. 47.:

During the UV decontamination process the pipetting arm will move.
Please ensure that no collision can take place.

Avoid exposure to UV light.
Exposure may cause severe eye or skin injury.

Wear suitable face shield, gloves and protective clothing.
Make sure that the UV cover is placed in the correct position
to completely close the instrument before switching on the UV lights.

ATTENTION

Make sure that no collision can take place, the instrument arm will move and that the instrument is closed with the UV covers.

9. A warning is displayed, read it carefully. If no collision can take place and all protective measures have been performed, press **[OK]** in order to start the decontamination method.

10. If a delay has been specified, a timer is started showing the time elapsed and the time remaining. If the button **[Stop Timers]** is pressed, the timer is terminated and the UV light is switched on immediately afterwards.
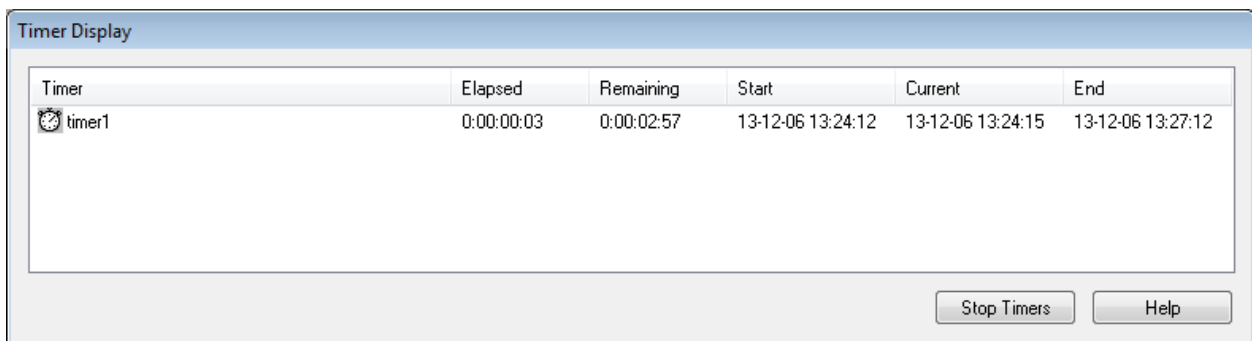
Fig. 48.: Timer Display Dialog

11. After the termination of the timer or immediately after pressing **[OK]** in the UV decontamination timer settings dialog, if no delay has been defined, the UV light will be switched on automatically and the Pipetting Arm is moving from left to right in steps every few seconds for an even irradiation of the workspace.

12. After the decontamination duration specified, the UV light will be switched off, the Pipetting Arm will stop and the following message appears.
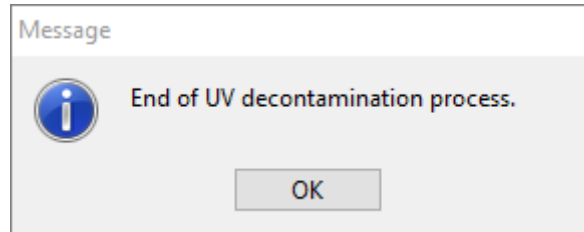
Fig. 49.: End of UV Decontamination Process Dialog

Exact wording of content of the dialog displayed in Fig. 49.:

End of UV decontamination process.

13. To close the UV decontamination method, press **[OK]**. Afterwards, the UV front cover can be removed. The UV decontamination method has finished.

7 AltoStar® AM16 Verification

The AltoStar® AM16 instrument must be verified by a Hamilton trained field service engineer 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.

The AltoStar® AM16 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.

8 Technical Specifications

8.1 Basic Instrument AltoStar® AM16

8.1.1 Dimensions and Weight

Dimensions

AltoStar® AM16	Length:	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)

Weight

AltoStar® AM16	Approx. 140kg

8.1.2 Operating Data

Maximum Power Consumption	≤ 600VA
Voltage	115 VAC / 230 VAC ± 10%
Frequency	50 / 60 Hz
Delayed Action Fuse	115 V~: 6.3 A (T6.3AL250) 230 V~: 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 2000m above sea level
Indoor Use Only	

8.1.3 Transportation and Storage

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

8.1.4 Instrument Life Cycle

The instruments have been designed for a life cycle of 6 years[1] under the assumption that the user maintenance and preventative maintenance is performed at the appropriate intervals.

[1] Limiting conditions: Life cycles are related to an average of 5300 pipetting steps per working day.

8.2 Functional Specifications

8.2.1 Work Area

Work Area Dimensions	Width (X)	Height (Z)	Depth (Y)
AltoStar® AM16	675mm (30 tracks)	136mm	465mm

8.2.2 Tip Size for 1000µl Pipetting Channel

Available CO-RE tips	Volume
Medium (standard) volume CO-RE tip (with filter)	10 - 300µl
High volume CO-RE tip (with filter)	10 - 1000µl

8.2.3 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

Applied statistics:

$$\mathrm{Pr}\,ecision = \frac{s}{\overline{x}} \bullet 100\%$$

$$Accuracy = \frac{\overline{x} - x_t}{x_t} \bullet 100\%$$

$$\overline{x} = \frac{\sum_{i=1}^{n} x_i}{n}$$

$$s = \sqrt{\frac{\sum_{i=1}^{n}(x_i - \overline{x})^2}{n-1}}$$

n = number of measured values

x_i = volume dispensed in pipetting cycle i [µl]

x_t = nominal volume [µl]

s = standard deviation [µl]

$\overline{x}$ = mean [µl]

Test conditions:

The specifications mentioned above are valid under the following conditions and obtained from measurements at HAMILTON Bonaduz.

Pipetting Channel	1000µl
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 channel with disposable CO-RE tips (pick-up and dispense, tip used only once) per channel 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

8.3 Accessories Specification

8.3.1 CO-RE Grip Specifications

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

8.3.2 Hamilton Heater Shaker Specifications

	Width (X)	Height (Z)	Depth (Y)
Dimensions	150mm	90mm	105mm
Weight	2500g		
Labware [2]	AltoStar® Processing Plate adapter		

[2] Maximum weight including adapter 500g

Temperature Control	From 5°C above ambient temperature to 105°C			
Heater Specifications [3]	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

[3] 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 [4]	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

[4] 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

8.4 Autoload: Barcodes and Reader Specifications

Carriers, containers, racks and tip racks will be identified by a barcode, which a reader, mounted on the Autoload slide, scans.

8.4.1 Barcode Symbologies

The following barcode symbologies can be detected by the system:

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

For the highest reading safety HAMILTON recommends:

1. To use barcode type Code128 (subset B and C)
2. Disabling the unused barcode types in the System Configuration Editor

8.4.2 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 "Barcode Specifications"
- Recognized errors are defined as an accurate reading

8.4.3 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
	Codabar	None
Quiet Zone	≥ 10 times the X dimension, but at least 3mm.	
Print quality	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. Mechanical dot matrix and thermo matrix printing are not suitable.	
	The surface may be treated, sealed or plastic-coated.	

8.4.4 Sample Barcodes

Barcode Specifications

For general barcode specification, see Chapter 8.4.3 Barcode Specifications.

036 871 7

	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

Positioning Barcode Labels

The label must be glued within a range of between 20mm to 100mm from the bottom of the tube.
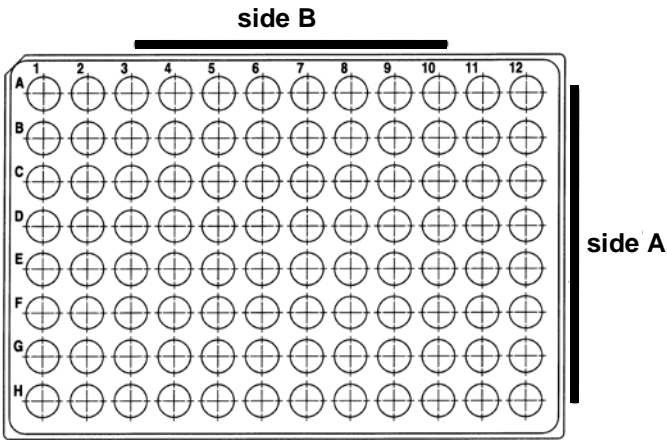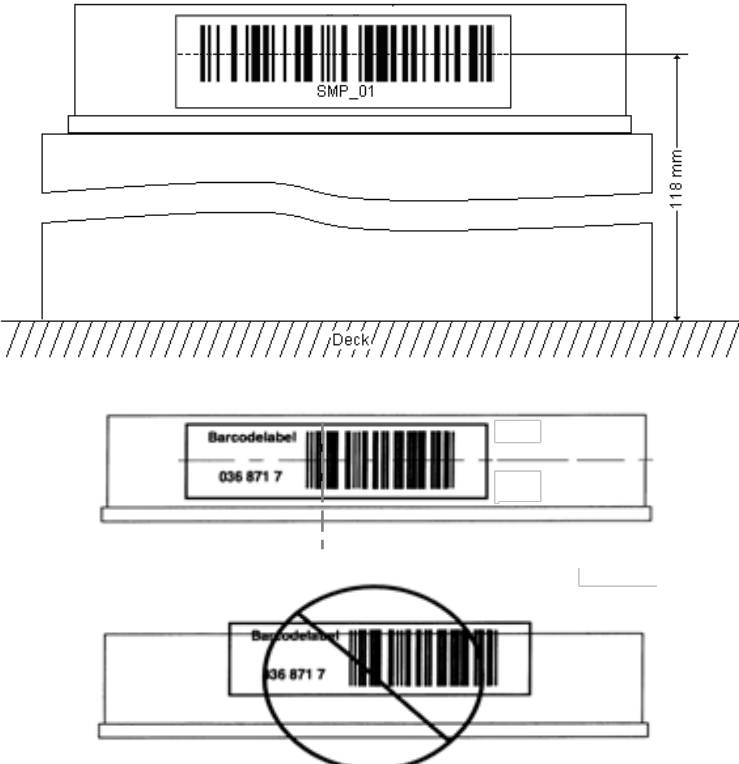
The label must fit tightly at an angle of approximately 90° to the tube.
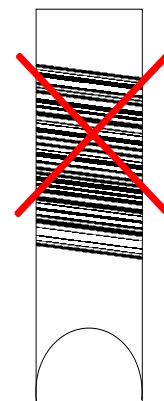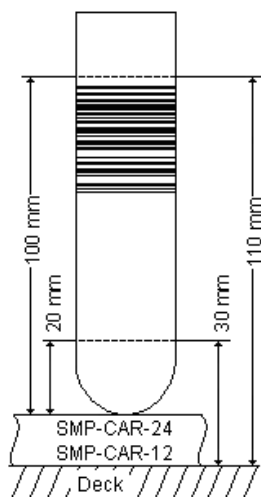
The label must fit tightly over its whole length.

8.4.5 Plate Barcodes

Label Specification					
For general barcode specification see Chapter 8.4.3 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	-
	F	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.	

9   Appendices:

9.1   Appendix A:

9.1.1   Regulatory Affairs

CE conformity is issued and maintained for the AltoStar® AM16. See the Declaration of Conformity provided with the instrument as well as the information in the following sections.

9.1.2   Radio Interference (USA and Canada)

This equipment has been tested and found to comply with the limits for a Class "A" digital device, pursuant to both Part 15 of the FCC Rules and the radio interference regulations of the Canadian Department of Communications. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the present user manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference, in which case the user will be required to correct the interference at his own expense.

Pursuant to the Canadian Radio Interference Regulations, ICES-001 Notice for Industrial, Scientific and Medical Radio Frequency Generators, this ISM apparatus meets all requirements of the Canadian Interference-Causing Equipment Regulations. Please note that this requirement is only for generators which operate at over 10,000 Hz.

9.1.3   In Vitro Diagnostics

The AltoStar® AM16 is an In Vitro Diagnostic Device and therefore regulated by the Directive 98/79/EC of the European Parliament and of the Council of 1998-10-27 on in vitro diagnostic medical devices.

9.1.4   Applied Company Quality Management Systems

Applied company quality management systems EN ISO 9001 and EN ISO 13485 Certification Body is TÜV Rheinland LGA Products GmbH, Am Grauen Stein 29, D-51105 Köln-Poll, Germany.

9.1.5   Declaration of Conformity

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

9.1.6   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.

9.1.7 WEEE Declaration

9.1.7.1 Recycling of an AltoStar® AM16

Recycling of a AltoStar® AM16 Instrument in accordance to EC directive WEEE

The European Community requires from manufacturers to organize the disposal and waste of electrical and electronic equipment (WEEE). For this reason, Hamilton Bonaduz AG took part in an initiative to organize the disposal of ML STAR products since AltoStar® AM16 is based on the ML STAR IVD it will run through the same organization, a European disposal network called RENE. RENE is the largest recycling network for the disposal of electronic equipment in Europe. The mission of RENE is a European-wide, WEEE-compliant, high quality recycling for electrical and electronic equipment through a dense network with both innovative and SMB-sized partner companies. As a result, Hamilton Bonaduz AG gets a turn-key-solution that includes all processes from treatment of incoming orders over collection, logistics and recycling down to reporting and management of material flows.

Hamilton offers a WEEE process in collaboration with Toolpoint and RENE AG:

- Request for the collection of the Hamilton instrument via Toolpoint Home Page (www.toolpoint.ch)
- Completion of the decontamination confirmation form
- Preparation for transport: packing
- Activation of the recycling order
- Archiving of the decontamination confirmation
- Disposal of the instrument

Responsibilities	
Ordering party	Decontamination Preparation for transport Note: The cost for decontamination and preparation for shipment is paid by the ordering party. On request, HAMILTON offers to take care for that part of the recycling process.
RENE	Transport Disposal
Toolpoint	Registration Invoice the disposal to HAMILTON
HAMILTON	Organize the disposal according to the WEEE directive

9.1.7.2 Recycling Process

1. Request for disposal of the instrument

   Access to the order registration is given by the Toolpoint homepage www.toolpoint.ch

   ☒ Recycling ☒ Order registration form

2. Completion of the Decontamination form

   Once the form has been completed, the request for disposal is automatically activated and transferred to Toolpoint. The confirmation of the order will be sent to the registered contact person.

3. Decontamination

The responsibility for decontamination remains at the ordering party. It is mandatory to sign the decontamination form and send a copy electronically to Toolpoint. Toolpoint forwards the documentation to RENE, who is in charge of instrument disposal.

4. Packing / Preparation for shipment

For the transportation of instruments with a weight of over 30kg need to be fixed on a euro pallet. Instruments below 30kg can be packed in a cardboard or plastic box. A signed copy of the decontamination form needs to be added to the outer part of the shipping box or instrument.

Refer to the Technical Note <u>Recycling Passport AltoStar® AM16</u> in accordance to EC directive WEEE".

9.1.8 RoHS Compliance

Since July 2016 AltoStar® AM16 instruments are in compliance with RoHS II Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011, on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS II) and its amendments.

9.2 Appendix B: Glossary

Term	Definition
Autoload	Hardware assembly that enables automatic loading of the AltoStar® AM16. It consists of a loading head movable in Y direction, which draws the carriers into the AltoStar® AM16 and reads the barcodes on them.
Barcode Reader	Device for reading sample/plate barcodes. Part of the Autoload.
Carrier	Unit for loading plates, containers, tubes and tips on the AltoStar® AM16 deck. Loading process is carried out by the Autoload unit.
Deck	The work surface (work area) of the AltoStar® AM16. The area where the pipetting channels perform liquid handling or transport steps. The deck is divided into tracks, which are occupied by labware.
Dispense	To distribute quantities of liquid from a pipetting device.
Firmware	Lower level program code that is carried out on the processors of the AltoStar® AM16 Instrument.
Front Cover	Protective covering for the AltoStar® AM16 Instrument, featuring a hinged front window made of transparent Plexiglas. With this option and assembly, the work surface of the AltoStar® AM16 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 AltoStar® AM16.
HHS	Hamilton Heater Shaker. Unit to heat and shake the AltoStar® Processing Plate.
Instrument	Hardware of the AltoStar® AM16 (mechanics, electronics, and firmware)
Labware	Refers to movable items to be placed on the AltoStar AM16 deck, such as carriers, containers, or racks.
Loading Tray	Hardware unit. The carriers can be placed on it and held outside the AltoStar® AM16. The loading tray is attached to the AltoStar® AM16, to support the automatic loading and unloading process.
LIMS	Higher level data processing system, generally known as Laboratory Information Management System, also LIS.
LLD	*Liquid Level Detection* – Detection of liquid surface achieved by capacitive signal detection.
Loading/Unloading	The process by which plate, tube and tip carriers are brought on and off the AltoStar® AM16 deck. This is automatically performed via the Autoload unit.
AltoStar® Connect *SW*	Software to run the AltoStar® AM16.
Pipetting	Transfer of liquids from one container to another.
Pipetting Arm	Assembly equipped with the pipetting device and/or plate handler, as well as the common X-drive.
Pipetting Channel	Hardware assembly including the function of picking up a tip aspirating, dispensing, tip eject, liquid level detection and the Y/Z-movements

Term	Definition
Pooling	Pipetting of different liquids in one well; 1, 2, 3…to n
P/N	Part number
Sample	Refers to a liquid in a unique identified container which is to be processed.
TADM	Total Aspiration and Dispense Monitoring. The pressure inside each individual pipetting channel is monitored during aspiration and dispensing.
Tip	Disposable tip for pipetting
Tip Rack	Frame that holds the tips.
Tip Waste	Container for ejected tips.
Tube	A container for liquid, usually having a circular cross-section, and a cylindrical length section.
Waste Container	A device on the AltoStar® AM16 deck to collect used disposable tips.
Well	The individual container of a microtiter plate or a Deep Well Plate.
Work Area	The area of the AltoStar® AM16 to which access is provided during the processing. Elements to be pipetted or handled are placed in this area.

9.3 Appendix C: Manual Update Information

Modifications of the AltoStar® Automation System AM16 Operator's Manual are listed here.

Date of Change	Revision	Description of Change
October 2017	00	Initial Version

9.4 Appendix D: Forms

The appendix contains the following forms:

- Instrument update information record: to be used to record the instrument configuration after software and firmware upgrades have been installed on the AltoStar® AM16.

- Maintenance and Preventive Service Maintenance Log forms: to be used for recording details of maintenance carried out on the AltoStar® AM16.

AltoStar® AM16
Instrument Upgrade Record

Computer Serial No.: _____

Instrument Serial No.: ………………………

Installed by	Date	Initials	Remarks	Supervisor Check

AltoStar® AM16 Maintenance Log

Month/Year: ……………….

Laboratory Name: ………………………

Instrument Serial No.: ………………………

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Daily Maintenance																															
Instrument deck clean																															
Waste container empty																															
Weekly Maintenance																															
All carriers clean																															
Carriers intact																															
Instrument deck clean																															
Waste container empty and clean																															
Nothing else contaminated																															

Check each item and initial the appropriate box opposite 'Daily' and 'Weekly' upon completion of each maintenance.

Date/Initials of Supervisor: ....

AltoStar® AM16
Preventative Service Maintenance Log

Laboratory Name: ………………………

Instrument Serial No.: ………………………

Date	Notes	Initials	Supervisor Check

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