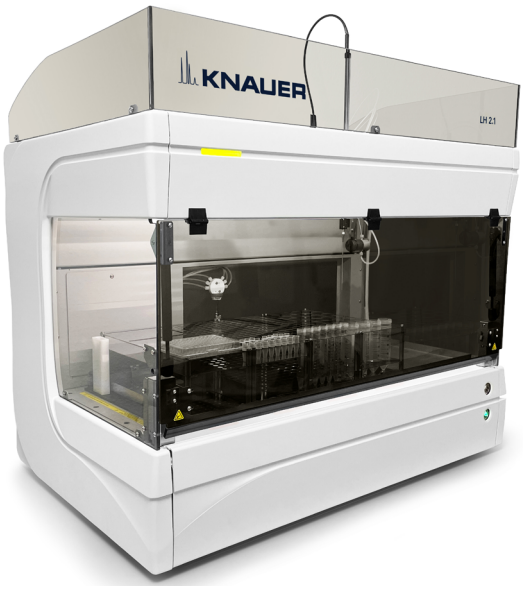
Science with Passion

KNAUER

Liquid Handler 2.1

Instructions



Document no. V6761

Note: For your own safety, read the instructions and follow the warnings and safety information on the device and in the instructions. Keep the instructions for future reference.

Note: In case you require this instruction in another language, please submit your request including the corresponding document number via e-mail or fax to KNAUER.

Support: Do you have questions about the installation or the operation of your instrument or software?

Support in Germany, Austria and Switzerland:

Telefon: +49 30 809727-111 (workdays 9-17h CET)

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Contact your local KNAUER partner for support:
www.knauer.net/en/Support/Distributors-worldwide

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These instructions apply to products with the product number DLAXXYYZZ (X, Z=0-9 or empty; Y=A-Z or empty)

The information in this document is subject to change without prior notice. For the latest version of the instructions, visit our website: www.knauer.net/library.

Table of contents

1. General

Note: This is only an additional instruction manual. Follow the safety instructions given in the Cavro® Omni Operator's Manual which is saved on the USB flash drive and part of the scope of delivery.

1.1 About these instructions

These operating instructions allows a safe and efficient operation of the device. These operating instructions are an integral part of the device. It has to be kept in the immediate vicinity of the device and accessible to the user at all times. The user must have carefully read and understood these operating instructions before starting any work.

The basic prerequisite for safe working is the compliance of all safety instructions (see chap. "2. Basic safety instructions" on page 3). In addition to the safety and warning notices in these instructions, the local accident prevention regulations and the national health and safety regulations are in effect.

You can download these and other instructions from the KNAUER website: www.knauer.net/library

1.2 Signal words

Possible dangers related to the device are distinguished in personal and material damages.

Symbol	Meaning
⚠ DANGER	DANGER (red) indicates a highly hazardous situation. If not avoided, it will result in death or serious injury.
⚠ WARNING	WARNING (orange) indicates a hazardous situation. If not avoided, it could result in death or serious injury.
⚠ CAUTION	CAUTION (yellow) indicates a moderate hazardous situation. If not avoided, it could result in minor or moderate injury.
NOTICE	NOTICE (blue) is used to address issues which are not related to physical injury.

1.3 Additional typographical conventions

Note: Specific information are prefixed with the word "Note" and an information icon.

Note: This is an example.

1.4 Legal information

1.4.1 Liability limitation

The manufacturer is not liable for the following issues:

- Non-compliance of these instructions
- Non-observance of necessary safety precautions
- Improper use
- Operation of the device by unqualified personnel (see chap. “2.2 User qualification” on page 3)
- Use of non-approved spare parts
- Technical changes by the user such as opening the device and unauthorized modifications
- Violations of General Terms and Conditions (GTC)

1.4.2 Transportation Damages

The packaging of our devices provides the best possible protection against transport damage. However, check the packaging for transport damage. In case you notice any damage, inform the Technical Support and the shipping company within three workdays.

1.4.3 Warranty Conditions

Please inform yourself about our terms and conditions on the KNAUER website: https://www.knauer.net/terms.

1.4.4 Declaration of conformity

The declaration of conformity is enclosed as a separate document with the product and can be obtained online: www.knauer.net/en/Support/Declarations-of-conformity.

2. Basic safety instructions

The device was designed and constructed in such a way that risks are largely excluded if used appropriately. Nevertheless, the following safety instructions have to be observed in order to exclude residual hazards.

2.1 Intended Use

Only use the device for applications that fall within the range of the intended use. Otherwise, the protective and safety equipment of the device could fail.

2.1.1 Operating ranges

The device is intended to be used indoors for chromatographic applications.

2.1.2 Foreseeable misuse

Refrain from the use of the device for the following purposes or conditions:

- Medical purposes. The device is not approved as a medical product.
- Operating outdoors. Otherwise, the manufacturer KNAUER does not guarantee the functionality and safety of the device.

2.2 User qualification

The users are qualified to handle the device if all of the following points apply:

- They have at least a basic knowledge of liquid chromatography.
- They have knowledge about the properties of the used solvents and their health risks.
- They are trained for the special tasks and activities in the laboratory and know the relevant standards and regulations.
- Due to their technical training and experience, they can understand and carry out all the work described in the operating instructions on the instrument and recognize and avoid possible dangers independently.
- Their ability to react is not impaired by the consumption of drugs, alcohol or medication.
- They have participated in the installation of an instrument or training by KNAUER or an authorized company.

If users do not meet these qualifications, they have to inform their supervisors.

2.3 Operator responsibility

The operator is any person who operates the device himself or leaves it to a third party for use and who bears the legal product responsibility for the protection of the user or third parties during operation.

The obligations of the operator are listed below:

- Know and follow the applicable work safety regulations.
- Identify hazards arising from the working conditions at the place of use in a risk assessment.
- Set up operating instructions for the operation of the device.
- Regularly check whether the operating instructions correspond to the current status of the regulations.
- Clearly regulate and specify responsibilities for installation, operation, troubleshooting, maintenance and cleaning.
- Ensure that all personnel who work with the device have read and understood these operating instructions.
- Train the personnel who work with the device at regular intervals and inform them about the dangers.
- Provide the necessary safety equipment to the employees working with the unit (see section below).

2.4 Personal safety equipment

When working with the device, take measures according to lab regulations and wear protective clothing:

- Safety glasses with side protection
- Protective gloves in accordance with the prevailing ambient conditions and used solvents (e.g. heat, cold, protection against chemicals)
- Overall
- Personal safety equipment which is specified in the particular laboratory

2.5 Safety features on the device

- Power switch: The device can be switched off using the power switch (toggle switch on the back side of housing) at any time, this causes no damage to the device. To switch off devices of the AZURA® S series, remove the plug from the power socket or use the toggle switch of the power supply unit.
- Device door: The device features a device door that serves as a splash and accident protection.
- Leak tray: The device features a leak tray that is located at the front of the device. The leak tray collects leaking solvents and protects components from potential damage caused by discharging liquid.

2.6 Working with solvents

2.6.1 General requirements

- The user is trained for handling different solvents.
- Note recommended solvents and concentrations in these instructions in order to avoid personal injury or damage to the device. For example, certain chemicals may cause PEEK capillaries to swell or burst (see chap. “17. Chemical compatibility wetted materials” on page 40).
- Note that organic solvents are toxic above a certain concentration. For handling hazardous solvents see the following section.
- Mobile phases and samples may contain volatile or combustible solvents. Avoid the accumulation of these substances. Ensure good ventilation of the installation site. Avoid open flames and sparks. Do not operate the instrument in the presence of flammable gases or vapors.
- Only use solvents which do not self-ignite under given conditions. This applies especially to the use of a thermostat where liquids could get onto hot surfaces in the interior.
- Degas solvents before use and observe their purity.

2.6.2 Contamination by health-threatening solvents

- Contamination with toxic, infectious or radioactive substances poses a hazard for all persons involved during operation, repair, sale, and disposal of a device.
- All contaminated devices have to be decontaminated properly by a specialist company or the operating company before they can be recommissioned, repaired, sold, or disposed (see chap. “2.9 Service request form and decontamination report” on page 6).

2.6.3 Avoiding leakage

Risk of electrical shock or short circuit if solvents or other liquids leak into the interior of the device. You can avoid a leakage through the following measures:

- Tightness: Visually check the device or system regularly for leaks.
- Solvent tray: The use of a solvent tray prevents liquids get from the bottles into the inside of the device.
- Eluent lines: Install capillaries and hoses in such a way that, in case of a leak, liquids cannot get into the interior of the devices underneath.
- In case of leakage: Switch off the system. Only take the device into operation if the cause of the leak has been resolved.

2.7 Specific environments

2.7.1 Explosive environment

Never use the system in potentially explosive atmospheres without appropriate protective equipment. For further information, contact the Technical Support of KNAUER.

2.7.2 Cooling room

The device can be used in a room that is not cooler than 10 °C. To prevent condensation, note the following instructions:

- Allow the device to acclimatize for min. 3 hours before taking it into operation.
- After taking the device into operation, it should stay switched on.
- Avoid temperature fluctuations.

2.7.3 Wet room

Never use the device in wet rooms.

2.8 Maintenance, care and repair

- Avoiding electric shock: Before performing any maintenance and service work, disconnect the device from the power supply.
- Tools: Use only tools recommended or prescribed by the manufacturer.
- Spare parts and accessories: Only use original parts and accessories made by KNAUER or a company authorized by KNAUER.
- PEEK fittings: Use PEEK fittings only for a single port or brand-new PEEK fittings in order to avoid dead volume or not exactly fitting connections.
- Column care: Follow KNAUER or other manufacturer's instructions on caring for the columns (see www.knauer.net/columncare)
- Used capillaries: Do not use any used capillaries elsewhere in the system in order to avoid dead volumes, not exactly fitting connections and spreading contamination.
- Safety features: The device may only be opened by the KNAUER Customer Support or any company authorized by KNAUER (see chap. “1.4.1 Liability limitation” on page 2).
- For more information visit the KNAUER website: www.knauer.net/hplc-troubleshooting.

2.9 Service request form and decontamination report

Devices which are shipped without the completed document “Service request form and decontamination report” will not be repaired. If you would like to return a device to KNAUER, make sure to enclose the completed document: www.knauer.net/servicerequest.

3. Product information

3.1 Scope of delivery

Note: The inlet capillary for the fractionation valve is not included in the scope of delivery. The flat bottom fittings needed for the 1/8" and 1/16" capillaries are part of the accessory kit.

The following articles are included in the scope of delivery:

- Device Liquid Handler LH 2.1 incl. control interface
- Power supply incl. power cable
- Accessory kit Liquid Handler LH 2.1

Valid documents:

- Instruction manual Liquid Handler LH 2.1 (Document no. V6761)
- Declaration of Conformity

3.2 Views

3.2.1 Front View

Legend

① Dispenser syringe
② Selection valve for wash solutions
③ Status LED
④ Device door with lock
⑤ Fractionation valve
⑥ Injection needle
⑦ Confirmation button to open the device
⑧ Power button
⑨ Storage compartment

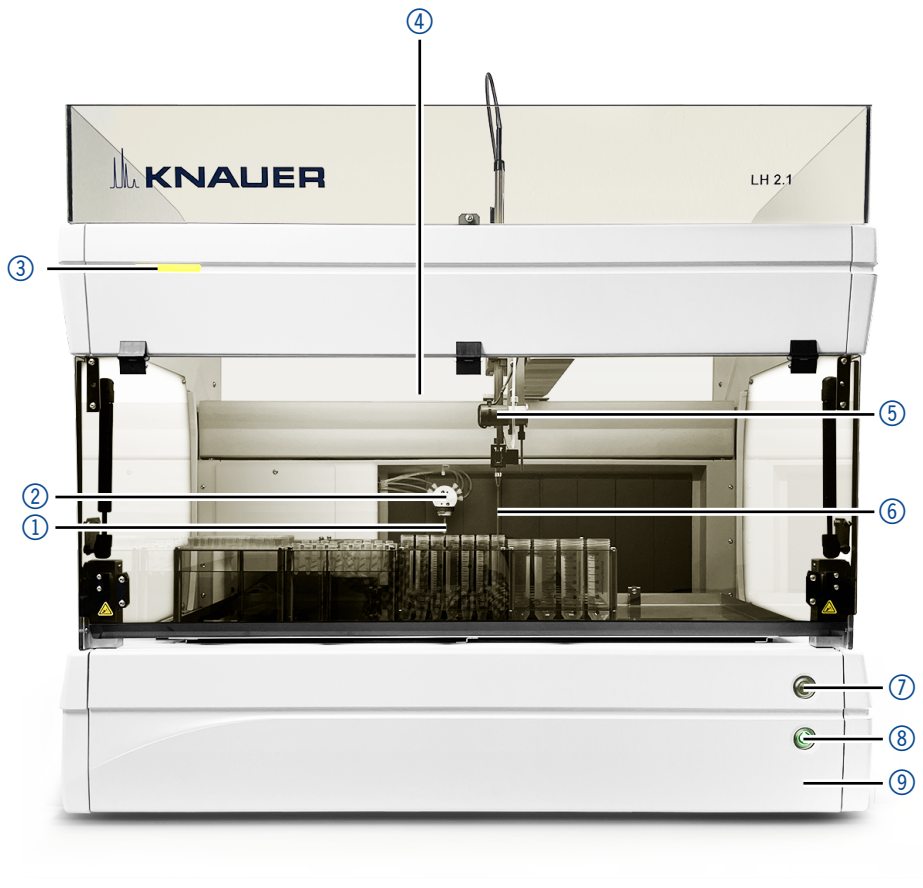


Fig. 1: Liquid Handler LH 2.1 - Front view

3.2.2 Rear view

On the rear side of the Liquid Handler LH 2.1 you can find the power plug, a LAN connection as well as the serial number of the device.

Service interface

Note that the LAN connection is only used during maintenance work. The control interface establishes the connection between PC and LH 2.1 via RS-232. You can find the needed RS-232 interface behind the cover on the rear of the device. You can find the RS-232 cable that is needed to connect the control interface in the storage compartment.

Legend

① Power Plug
② Serial number
③ LAN connection (for service only)

Fig. 2: Liquid Handler LH 2.1 - Rear view

3.3 Symbols and Signs

The following symbols and signs can be found on the device:

Symbol	Meaning
	Danger of electric shock. In the event of non-observance, it will result in death, serious injuries, or damage or destruction of the device.
	Danger of electrostatic-discharge. Damage to the system, the device, or components of the device can occur.
	There is a risk of crushing caused by the closing device door and the injection needle. In the event of non-observance, it can result in (serious) hand injuries.
	The device falls under the WEEE directive (directive 2012/19/EU Waste electrical and electronic equipment). Do not dispose the device in domestic waste and collect it separately (see chapter “13.1 Taking the device out of operation” on page 34).
	A device or system marked with CE fulfills the product specific requirements of European directives. This is confirmed in a Declaration of Conformity.

4. Installation and start-up in general

Before you specify the location, read the technical data (see chapter "15. Technical data" on page 36). There are listed all device-specific information about electricity, ambient conditions and humidity.

Note: Only if the requirements for ambient conditions of the operating environment are met, the intended use can be ensured.

4.1 Unpacking

⚠ CAUTION

Lifting hazards

The device weighs more than 18 kg. When lifting, carring or installing the device it may fall and cause injuries.

➔ Lift the device only centrally on the side of the housing.

➔ Only carry the device with at least two people.

Procedure

Process
1. Set-up the package to open in such a way that you can read the label.
2. Check the packaging, the device and accessories for transport damage.
3. Check the delivery scope. In case any parts are missing, contact the Technical Support.
4. When lifting, carrying or moving the device, grab the device only from below on the sides. Do not hold it on the front cover, the cover of the storage department, or the drainage tray as these parts are only loosely attached.

Further steps

- Keep the attached list with the scope of supply for subsequent orders.
- Keep the original packaging for safe storage and/or transport of the device.

4.2 Ambient conditions

4.2.1 Location

Observe the following requirements for the operation site so that the measurement results are not influenced:

- The device is placed on a stable and even surface.
- The device is protected against direct exposure to sunlight.
- The device is not exposed to air drafts (e.g. air conditioning systems).
- The device is not set near to other machines that cause floor vibrations.

- There are no sources of high frequency close to the device.
- The device is ventilated adequately (see chapter “4.2.1 Location” on page 10).
- The device is not exposed to temperature fluctuations (see chapter “4.2.1 Location” on page 10).

4.2.2 Ambient temperature

If the ambient temperature of the device is abruptly changed, condensation will form inside the device and may cause damage to the device. Allow the device to acclimate for 3 h, before it is connected to the power supply and taken into operation.

4.2.3 Space requirements

- Make sure that the power plug on the power supply (wall socket or power strip) is always accessible, so that the device can be disconnected from the power supply.
- Ensure adequate ventilation around the device, otherwise it may overheat and malfunction:
  - Min. 5 cm distance if another device is set on one side.
  - Min. 10 cm distance if further devices are set on both sides.
  - At least 15 cm to the cooler fan on the rear.
- The mounting of a small device to an AZURA L device with a mounting bracket does not affect the performance of either device. The space requirements specified in both device instructions do not apply in this case.

4.3 Power supply

Power supply requirements

- Failure-free power supply: For failure-free operation, the electrical voltage shall be free of fluctuations, residual currents, voltage peaks and electromagnetic interference. The device has to receive sufficient voltage and reserve capacity.
- Check voltage: Only connect devices to a power supply whose voltage corresponds to the permissible voltage of the device.
- Power consumption: The nominal power of the connected devices shall not exceed 50 % of the highest connected power capacity, since higher currents can flow briefly when the device is switched on.
- Main connection: The electrical power supply at the operation site has to be connected directly to the nearest main power connection.
- Grounding: The connectors for the voltage have to be grounded accordingly.

Power supply cables and plugs

- Original parts: For power supply, use the supplied power cable and plug to meet the specifications (see chapter “15. Technical data” on page 36). Do not replace detachable power cables with other cable types.
- Country-specific plugs: Before switching on the device, check whether the supplied plug is approved for your country. An overview of the device-specific and country-specific plug types by KNAUER can be found: www.knauer.net/plugs
- Power strips: If several devices are connected to one power strip, always consider the maximum power consumption of each device.
- Damaged power supply cables and plugs: For safety reasons, damaged or faulty cables and plugs shall not be used to connect the device to the power supply. Replace defective cables and plugs only with accessories from KNAUER.

5. Installation and start up of the Liquid Handler

5.1 Functional parts of the Liquid Handler

The following figures summarizes the functional parts of the Liquid Handler LH 2.1.

Legend

① Dispenser syringe
② Selection valve for wash solutions
③ Status LED
④ Device door with lock
⑤ Fractionation valve
⑥ Injection needle
⑦ Confirmation button to open the device
⑧ Power button
⑨ Storage compartment

Fig. 3: Functional parts of the Liquid Handler LH 2.1

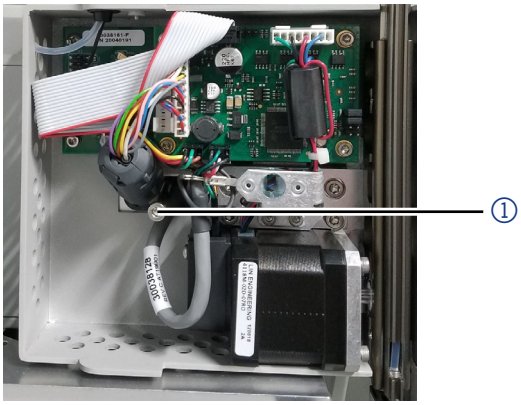
Legend

① Injection valve with sample loop
② Drainage tray
③ Wash station
④ Racks with vessels
⑤ Outlet fraction collection
⑥ Control interface
⑦ Storage compartment

Fig. 4: Functional parts of the Liquid Handler LH 2.1

5.2 Loosen transport locking device

Tool
- Allen screwdriver, size 3 mm

Process	Figure
1. Remove the cover of the housing of the Z-axis. 2. Remove the safety screw ① by using an Allen screwdriver.	 **Fig. 5:** Opened housing of the Z-axis drive

5.3 Connecting the device to the control interface

On the rear of the control interface you will find the connectors for the single components of the LH 2.1.

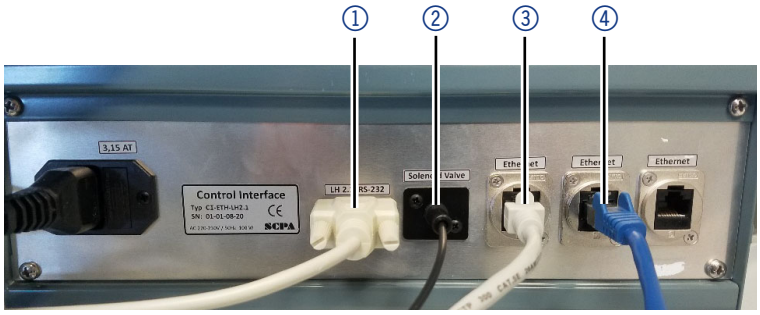
Connection	Figure
1. The RS-232 cable ① that is connected from the inside to the rear of the LH 2.1 has to be connected to the control interface. 2. By using the barrel connector ② connect the BNC cable to the control interface. Connect the other end of the cable to the fractionation valve. 3. Via the LAN cable ③ a connection to the injection valve VU 4.1 is established. 4. Via an additional LAN cable ④ the control interface is connected to the switch.	

Fig. 6: Rear view of the control interface

5.4 Connecting the drainage tubes

A drain tubing that drains spilled liquid off is located at the back of the drainage tray and the wash station. Make sure that the tubings point downwards so that the liquid can drain off completely.

Legend

① Drainage tray

② Drain tubing

Fig. 7: Drainage tray with drain tubing

Legend

① Wash station
② Drain tubing
③ Drainage tray

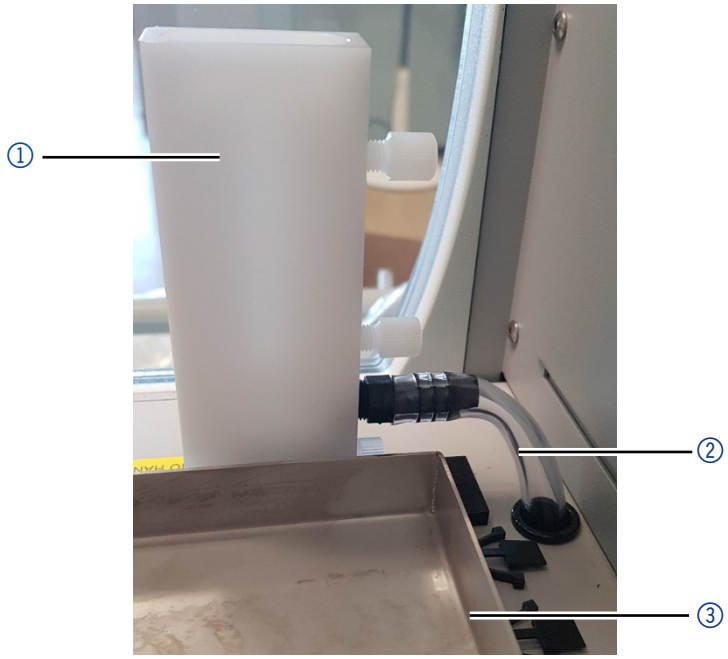


Fig. 8: Wash station with drain tubing

5.5 Connecting selection valve to wash solution

The ports of the selection valve are connected to the wash solutions via capillaries. The ports have a 1/4-28 UNF Flat Bottom thread.

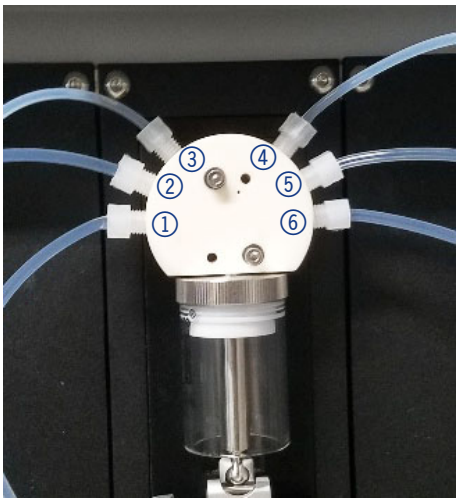
Process	Figure
1. By using the 1/8" Flat Bottom fittingconnect port ① of the selection valve via the buffer tubing (tube 600 cm, 1/8") with port 1 of the injection valve. 2. Connect port ② of the selection valve via the tube 177 cm, 70" with the waste bottle. 3. Connect the ports ③ to ⑥ with the corresponding wash solutions (tube 177 cm, 70").	

Fig. 9: Selection valve with capillaries

4. Connect the needle tubing (tube 457 cm, 180") of the injection needle ("tip") with port ② of the injection valve.
5. Place the sample loop between port ③ and ⑥ of the injection valve.
6. Port ④ of the injection valve is connected to the pump and port ⑤ is connected to the column.

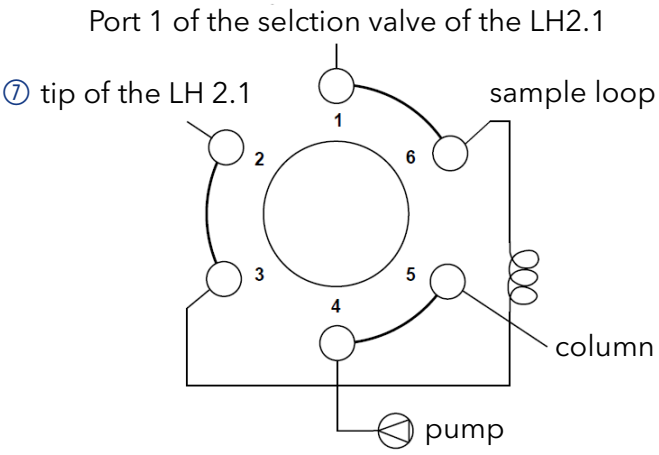


Fig. 10: Connection of the LH 2.1 to the injection valve

5.6 Connecting the fractionation valve

Guide the tubing via the mounting bracket on the z-housing downwards and connect it to the upper port of the fractionation valve. There are two more ports on the underside of the solenoid switching valve. The left port, which is labeled NO (normally open), is used to connect the waste tubing. The drop former (fraction collection outlet) is screwed into the right port (NC, normally closed).

Legend

① Waste port (NO, normally open)
② Z-housing with mounting bracket
③ Inlet port
④ Fractionation valve
⑤ Outlet port (NC, normally closed)
⑥ Outlet fraction collection

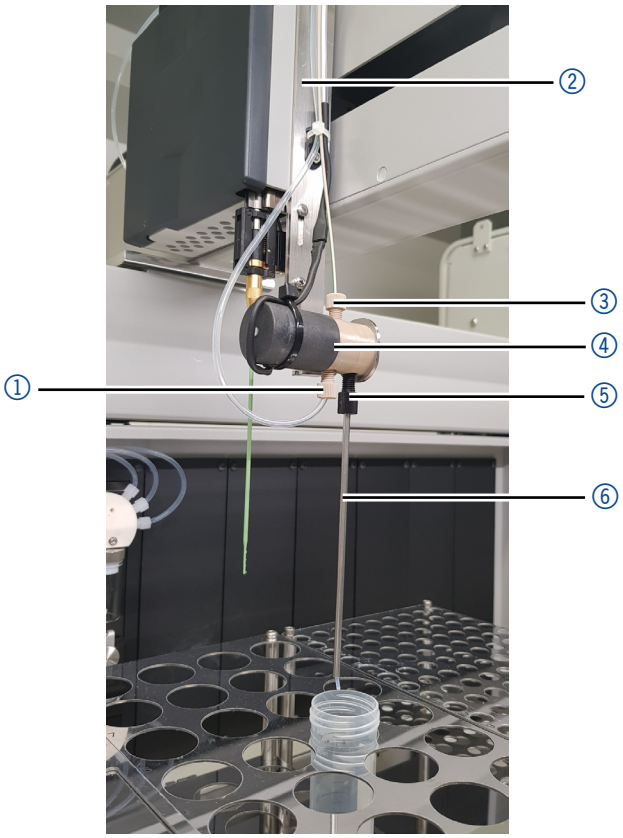


Fig. 11: Fractionation valve of the Liquid Handler LH 2.1

6. Switching on and status display

6.1 Switching on

The devices have to be switched on in the following order:

1. LH 2.1 Device
2. VU 4.1 with injection valve
3. Control interface

6.2 Initialization

After the device has been switched on a five-stage initialization process starts.

1. The light inside the LH 2.1 will be switched on.
2. The front cover will be locked.
3. The injection needle will move in the directions X, Y, and Z and will afterwards move into HOME position.
4. Short up and down movements of the dispenser syringe
5. Switching operation of the injection valve VU 4.1

A successfully completed device initialization is indicated by a green status LED.

6.3 Status display

The device status is indicated by a LED on the front of the device. The color of the LED shows the current status.

Fig. 12: Status LED at the front of the device

LED	Color	Status
	Green	Device is ready for operation.
	Flashes green	Device initialization
	Yellow	Front cover is open.
	Flashes yellow	Injection running.
	Red	Device error/Communication error
	Flashes red	User requested unlocking of the front cover.

Note: When the error message *KOMMANDO-TIMEOUT* occurs, an acoustic signal will sound once for 200 ms. The acoustic error signal for the *KOMMANDO-ERROR* will sound three times for 200 ms each.

7. Configuring the Liquid Handler LH 2.1

7.1 HTTP configuration surface

You can use the HTTP configuration surface to configure the network. Enter the IP address of the LH 2.1 (192.168.1.126) in your web browser. From there you can go to the service menu. You can use the HTTP configuration surface simultaneously to the control of the LH 2.1 by PurityChrom® software. If you are using Chromeleon to control the device, we recommend making the configurations in Chromeleon directly and not in your web browser.

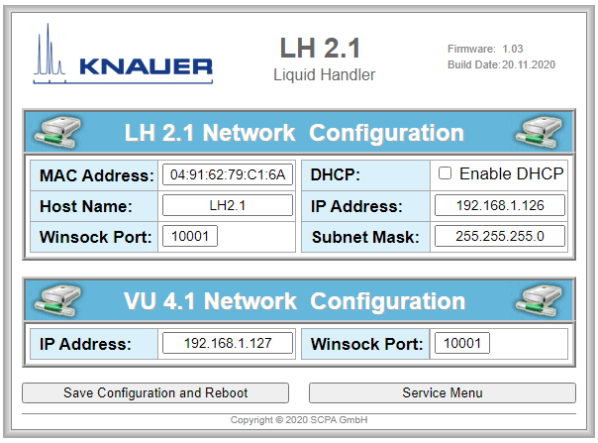


Fig. 13: HTTP configuration surface of the LH 2.1

7.2 Service menu – Configuring the LH 2.1

You can make basic settings in the service menu of the LH 2.1. The access is password protected.

- User: *admin*
- Password: service

The maximum dimensions of the working space as well as the firmware version of the control interface are displayed in the upper right of the menu.

Indication of the direction for the injection needle (“tip”) (view inside the device from the front):

- X-movement: Movement to the left and the right. The distance is given in mm and is measured from left to right.
- Y-movement: Movement to the front and to the back. The distance is given in mm and is measured from back to front.
- Z-movement: Movement up and down. The distance is given in mm and is measured from top to bottom.

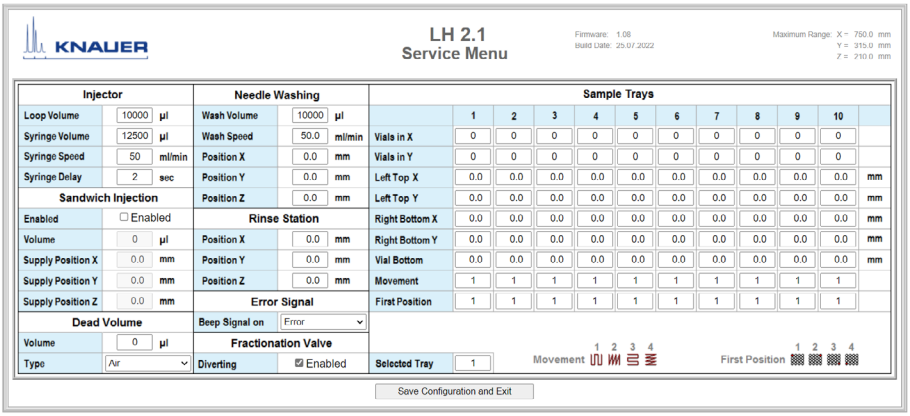


Fig. 14: Service menu

Menu	Meaning
Injector	Settings for autosampler: ■ *LOOP VOLUME* - Volume of the sample loop of the VU 4.1 injection valve (µl) ■ *SYRINGE VOLUME*- Volume of the syringe (µl) ■ *SYRINGE SPEED* – Aspiration speed (ml/min) of the dispenser syringe when picking up the sample out of the sample vial. After the injection the remaining fluid will be disposed of out of the syringe with the speed *WASH SPEED* (see chapter “8.1 Injection” on page 26). ■ *SYRINGE DELAY* – Delay of the syringe after aspirating the sample. The sample needle (“tip”) will remain inside the vial during this time after the aspiration has been completed. This applies to the sample aspiration as well as the compensation of the dead volume.
Sandwich injection	The sample is located between two segments of fluid. The set volume will be picked up out of the *SUPPLY POSITION* before and after sample aspiration. The distance of the *SUPPLY POSITION* is defined by the direction X-, Y- and Z in mm.
Error signal	You can adjust the following settings concerning the error signal. ■ Disabled: The acoustic signal is deactivated. ■ Error: The acoustic signal will only sound in case of a device error. ■ Error and Timeout: The acoustic signal will sound in case of a device error and in case of a communication interruption.

Menu	Meaning
Needle washing	Wash volume, wash speed and the position of the hole in the front of the wash station for needle washing ("needle wash position") as X-, Y-, and Z-coordinates in mm (see chapter "8.3 Tip washing" on page 28). *WASH SPEED* – Aspiration speed and release speed of the syringe during the washing process in ml/min. The speed is also used as release speed after the injection. After the switching operation of the injection valve from Load to Inject the remaining fluid will be released with this speed.
Rinse station	Position of the center hole of the wash station in the directions X, Y and Z given in mm (see chapter "8.3 Tip washing" on page 28). At this position the remaining liquid left inside the dispenser syringe after the injection will be released. The released liquid will be drained off via the connected waste tube.
Dead volume	Volume between injection needle ("tip") and injection valve in µl. The dispenser syringe aspirates the programmed *DEAD VOLUME* after sample/sandwich aspiration. You can choose between three options: ■ *AIR* - The tip leaves the sample vial, and air is aspirated. ■ *SAMPLE* - The tip stays inside the sample vial, and the sample is aspirated. ■ *SANDWICH* – The tip moves to the programmed *SUPPLY POSITION* and aspirates the sandwich solution. As well as after the sample aspiration the injection needle ("tip") stays in the chosen position after the aspiration of the dead volume for the *SYRINGE DELAY*-time.
Sample trays	Programming the sample racks (only symmetric) - 10 sample racks can be programmed. Every rack is defined by the following specifications: ■ Number of vessels in x-axis and y-axis ■ Position of the upper left and lower right vial in the directions X, Y, and Z given in mm
Movement	The autosampler moves along the rows with sample vessels of a sample rack in the shown movement pattern.
First position	The first position of the sample rack is chosen.
Selected tray	The autosampler numbers the vessels for all configured racks, starting with the rack which is chosen under "selected tray". Racks which have been configured with "Vessels in X=0" and "Vessels in Y=0" will not be included.
Diverting	Is this option activated the injection valve shortly switches into waste position with every change of position. Is this option deactivated drops of fractionation solution can drop onto the rack or onto the drainage tray.

7.3 Configuration Tool

You can not use the LH 2.1 configuration surface simultaneously to the control of the LH 2.1 by a different software. The application /.exe has to be run as a administrator once (see Fig. 15). If you are not doing this, a runtime error will be displayed in the *COMMUNICATION LOGS*.

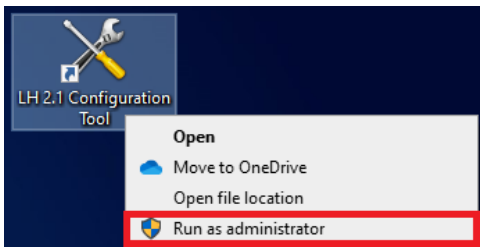


Fig. 15: Configuration Tool, run as administrator

Additionally to the basic settings which can be made over the HTTP configuration surface, the LH 2.1 Configuration Tool features further functions:

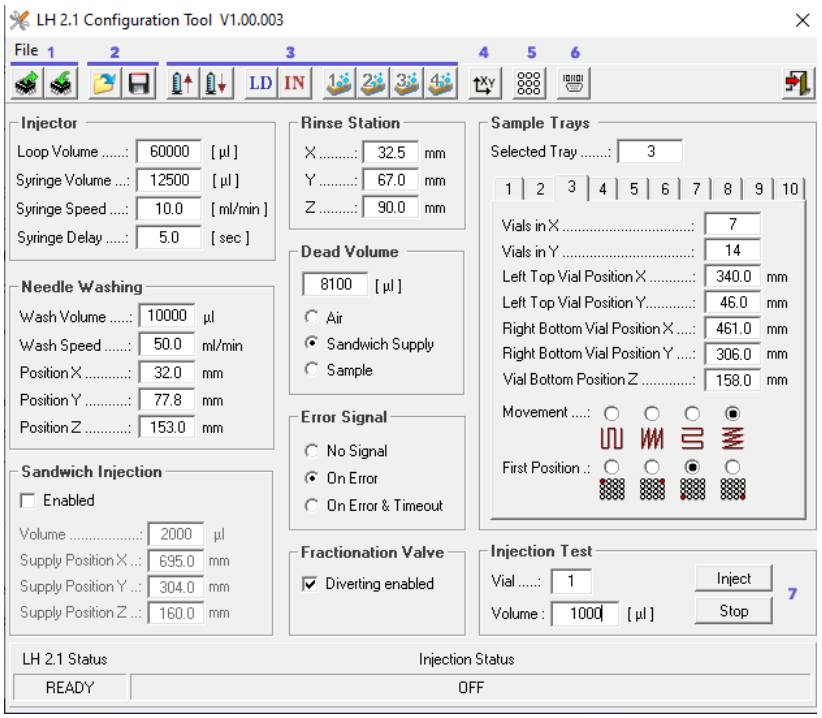


Fig. 16: Configuration Tool

Legend

① Reading and storing of the settings into the device

② Loading and storing of the configuration of the LH 2.1

③ Toolbar for executing the individual functions such as emptying the syringe, switching injection valve into the position Load or Inject, washing injection needle ("tip") with wash solution 1, 2, 3 or 4

④ Manual control of the position of the LH 2.1

⑤ Opening/Closing of the rack visualization with numbering of single vessels

⑥ Displayingthe *COMMUNICATION LOGS*

⑦ Starting a test injection out of a chosen sample vial with a defined injection volume

7.3.1 Connecting Configuration Tool with the device

FILE – In order to connect the LH 2.1 to the Configuration Tool you have to choose the corresponding Winsock Port or the serial interface.

READ/ WRITE – With the buttons you can read the settings of the LH 2.1 or send the shown parameter to the device. We recommend to create a backup copy of the configuration of the LH 2.1 (see chapter “4.2.1 Location” on page 10).

7.3.2 Saving and loading a configuration of the LH 2.1

SAVE CONFIGURATION saves the currently shown configuration in a .set file.

LOAD CONFIGURATION loads the settings out of the configuration file in the display of the Configuration Tool.

With *WRITE* the LH 2.1 accepts the settings.

7.3.3 Visualization of the autosampler

The visualization of the racks displays all configured racks starting with “selected tray” with numbering of the single vessels as well as the movement pattern of the injection needle. Racks which have been configured with “Vessels in X = 0” and “Vessels in Y = 0” will not be included.

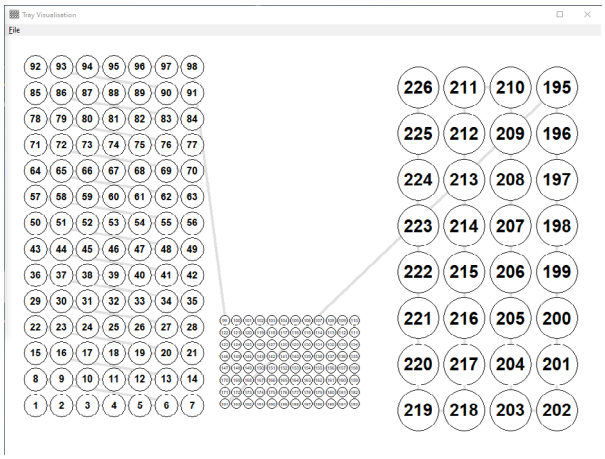


Fig. 17: Rack Visualization

7.3.4 Controlling the position manually

Use the *TEACHING WINDOW* to position the LH 2.1 step by step or enter the X-coordinate, Y-coordinate and Z-coordinate in order to move it at the desired position. You can choose from step lengths of 50 mm, 10 mm, 1 mm, and 0.1 mm. Always execute Z=0 first to assure that the tip has reached its maximum height before further coordinates are sent. This prevents a collision of the tip with the racks or vessels inside the LH 2.1.

Legend

① Selection of the step length

② Step by step control

③ Positioning by entering the X-, Y-, and Z-coordinates

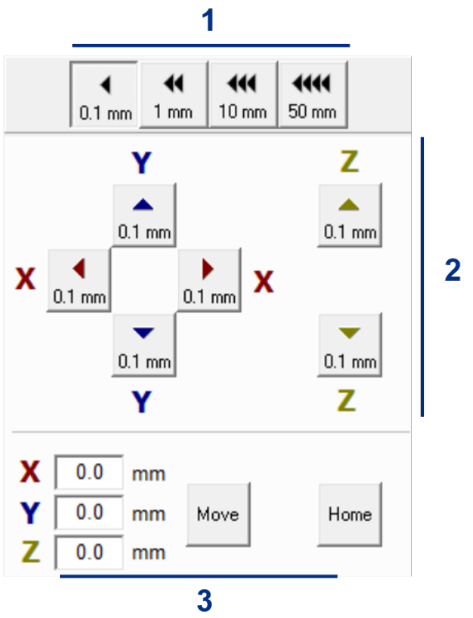


Fig. 18: Controlling the position manually in the Teaching Window

8. Mode of operation Liquid Handler LH 2.1

⚠ CAUTION

Stabing injuries

Inside Liquid Handler and behind the front cover is a needle that transports samples automatically. Unthoughtfulness can cause injuries.

➔ Only use the device with closed front cover.

➔ Stop the operation before opening the front cover.

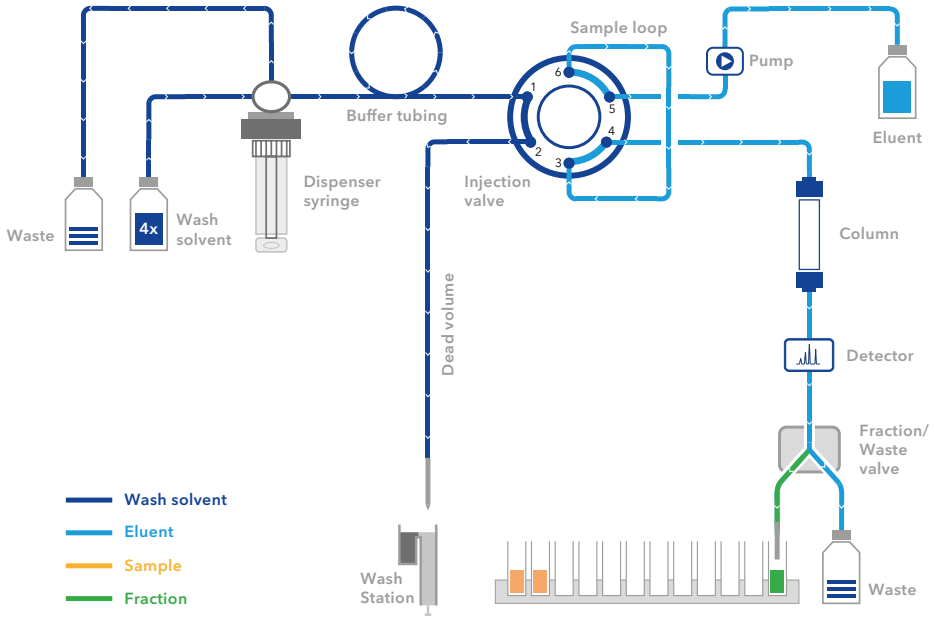


Fig. 19: Visualization of the flow path of the LH 2.1 with autosampler and fractionation function

8.1 Injection

The following steps will be performed automatically during the injection:

1. The injection valve switches to the *LOAD POSITION 1*.
2. The tip moves to the selected sample vessel.
3. The sample is aspirated into the sample loop by the dispenser syringe (see chap. “8.2 Sample aspiration during sandwich injection” on page 27).
4. After the aspiration the tip stays inside the vessel for the programmed retention time *SYRINGE DELAY*. The dispenser syringe will be filled more than once if the sample volumes add up to more than one volume of the dispenser syringe. The fluid inside the dispenser syringe will be led off through the waste tube (selection valve position 2).

5. The dispenser syringe aspirates the programmed dead volume *DEAD VOLUME*. After the aspiration the injection needle (“tip”) stays inside the vessel for the programmed retention time *SYRINGE DELAY*.
   AIR – The injection needle (“tip”) leaves the vessel, and air is aspirated.
   SAMPLE – The injection needle (“tip”) stays inside the vessel, and the sample is aspirated.
   SANDWICH – The injection needle (“tip”) moves to the programmed *SUPPLY POSITION* and aspirates the sandwich solution.
6. The injection valve switches to the *INJECT POSITION 2*.
7. The remaining fluid will be led off via the *RINSE STATION* (the hole in the middle of the wash station) into the waste.
8. The injection needle (“tip”) will be purged with the selected wash solution *NEEDLE WASH POSITION* (front hole of the wash station) (see chap. “8.3 Tip washing” on page 28).
9. The injection needle (“tip”) moves to the next position for the fractionation.

Inside the capillaries between dispenser syringe and injection needle (needle tubing, sample loop and buffer tubing) are different segments of liquids in the following order:

Dispenser syringe

- Wash solution
- Sample
- *DEAD VOLUME*:
  - Air - *AIR*
  - Sample - *SAMPLE*
  - Sandwich solution - *SANDWICH*

Injection needle (“Tip”)

8.2 Sample aspiration during sandwich injection

Before aspirating the sample the injection needle (“tip”) moves into *SUPPLY POSITION* and aspirates the preset volume of sandwich solution. After aspirating the sample the injection needle (“tip”) again moves into *SUPPLY POSITION* and aspirates the same volume of sandwich solution.

Inside the capillaries between injection needle (“tip”) and dispenser syringe (needle tubing, sample loop and buffer tubing) are different segments of liquids in the following order:

Dispenser syringe

- Wash solution
- Sandwich solution
- Sample
- Sandwich solution
- *DEAD VOLUME*:
  - Air - *AIR*
  - Sample - *SAMPLE*
  - Sandwich solution - *SANDWICH*

Injection needle (“Tip”)

8.3 Tip washing

The hole in the front of the *WASH STATION* is used for washing the injection needle ("tip") (*NEEDLE WASHING*). The hole in the middle of the wash station is used to dispose of excess solution from the dispenser syringe and is connected with the waste tube directly. The third hole will not be used.
For washing the injection needle ("tip") you can choose between four different wash solutions but you can not combine them.

Note: During *NEEDLE WASHING* the sample loop will not be purged.

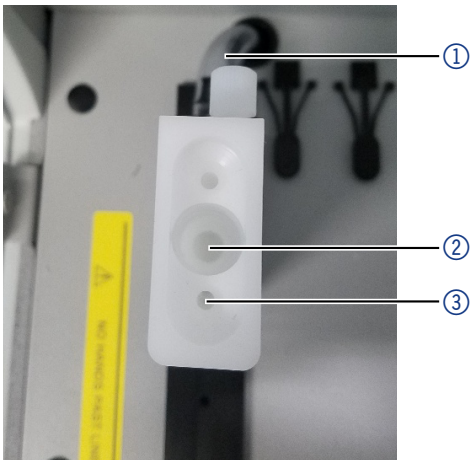
Process	Figure
1. The injection needle ("tip") moves into *NEEDLE WASHING POSITION* ③ . **2.** The dispenser syringe aspirates the wash solution volume 1-4 (port 3, 4, 5 and 6 of the selection valve) set in the configuration (needle washing) (see chap. "4.1 Unpacking" on page 10). **3.** The wash solution will be dispensed through the injection needle ("tip") (port 1 of the selection valve). **4.** The overflow drain leads to the dent of the *RINSE STATION* ② and over the waste tube ① into the waste.	

Fig. 20: Wash station

Note: Empty the waste bottle frequently in order to avoid an overflowing of waste solution.

9. General notes

- The autosampler mode of the Liquid Handler 2.1 has priority over the fractionation collecting mode. Movements that belong to the autosampler mode will be performed before the movements of the fractionation collecting mode will be performed. The last position of the fractionation collecting mode will be saved when it is interrupted by the autosampler mode or the opening of the front cover, but it will proceed after the autosampler mode is completed or the front cover is closed again.
- When no electric current is flowing through the device, the x-axis, Y-axis and the Z-axis can be moved manually. This makes changing the injection needle ("tip"), among other things, easier.
- Restart the device after changing the injection needle ("tip") or the dispenser syringe.
  If you need to change the dispenser syringe see chapter "5.3.3 Replacing a Syringe" in the Operating Manual Cavro® Centris Pump. You can find all information needed for changing the tip in chapter "4.8 Attaching Probes and Disposable Tips" in the instructions Cavro® Omni Operator's Manual Cavro® Omni Robot. Both instructions are delivered electronically on a USB flash drive that is part of the accessory kit.
- Wash volumes and sample volumes can be bigger than the volume of the dispenser syringe. In order to achieve this the selection valve of the dispenser syringe has not only ports for the wash solutions and the buffer tubing, but also a waste port (port 2) with which excess solution can be disposed of.
- Sample vessel racks of the Liquid Handler 2.1 can be organized symmetrically (see chap. "7. Configuring the Liquid Handler LH 2.1" on page 20). By using the PurityChrom® software the fractionation racks for the Liquid Handler 2.1 can be organized symmetrically and asymmetrically. Chromeleon only allows symmetric organization of the racks.
- Racks can at the same time be organized for the autosampler mode as well as for the fractionation mode. This makes the reinjection of collected samples possible.
- In order to prevent contamination of the dispenser syringe with sample solutions, the set injection volume shall not exceed the volume of the sample loop by a maximum of the buffer tubing volume (tube between selection valve and injection valve, 21 ml by default).
- To assure that the sample solution enters the sample loop completely, we recommend to set a slightly larger dead volume *DEAD VOLUME*. Use the DEAD VOLUME TYPE: *SANDWICH* in order to prevent air entering the system. If you are working with the *DEAD VOLUME TYPE: AIR*, there is a risk that air enters the system and the risk of fluid loss caused by little drops left inside the tube.

10. Functionality Tests

Note: Standard processes regarding IQ and OQ in single devices may be handled differently in individual cases.

10.1 Installation Qualification (IQ)

The customer may request the Installation Qualification, which is free of charge. In case of a request, the technical support of KNAUER or a provider authorized by KNAUER performs this functionality test during the installation.

The Installation Qualification is a standardized document that includes the following:

- Confirmation of flawless condition at delivery
- Check if the delivery is complete
- Certification on the functionality of the device

You can either use the IQ document attached to this instruction manual or download a digital version from our website:

10.2 Operation Qualification (OQ)

The Operation Qualification includes an extensive functionality test according to KNAUER standard OQ documents. The Operation Qualification is a standardized document and free of charge. It is not part of the delivery. Contact the Technical Support in case of request.

The Operation Qualification includes the following:

- Definition of customer requirements and acceptance terms
- Documentation on device specifications
- Device functionality check at installation site

Test Intervals To make sure that the device operates within the specified range, you should test the device regularly. The test intervals depend on the usage of the device.

Execution The test can be carried out either by the Technical Support of KNAUER or from a provider authorized by KNAUER (for a fee). For further information visit our website:

11. Troubleshooting

First measures for troubleshooting:

- Check all cables and fittings.
- Check whether air has gotten into the supply lines.
- Check the device for leaks.

Further measures:

- Compare the current problem with the list of possible problems (see following sections)
- Contact the Technical Support.

11.1 LAN

Go through the following steps, in case no connection between the computer and the devices can be established. Check after each step if the problem is solved. If the problem cannot be located, contact the Technical Support.

1. Check the status of the LAN connection in the Windows task bar:

 Connected	 Not connected

   If no connection was established, carry out the following tests:
   - Is the router switched on?
   - Is the patch cable connected correctly to the router and the computer?
2. Check the router settings:
   - Is the router set to DHCP server?
   - Is the IP-address range sufficient for all the connected devices?
3. Check all connections:
   - Are the patch cable connected to the LAN ports and not the WAN port?
   - Are all cable connections between devices and router correct?
   - Are the cables plugged in tightly?
4. If the router is integrated into a company network, pull out the patch cable from the WAN port.
   - Can the devices communicate with the computer, even though the router is disconnected from the company network?
5. Turn off all devices, router, and computer. First switch on the router and wait until it has successfully completed its self-test. Turn on the devices and then the computer.
6. Replace the patch cable of the device to which no connection can be established.
7. Make sure that the IP port of the device matches the port in the chromatography software.

11.2 Possible problems and rectifications

Problem	Solution
Control interface can not connect with the valve drive VU 4.1.	If the control interface is turned on and off while the VU 4.1 is turned on, connecting problems can occur. In this case, turn off all devices and then turn them on in the following order: **1.** LH 2.1 **2.** VU 4.1 **3.** Control interface
Dripping injection needle/incorrect retrieved injection volume	Check the injection path (needle tubing, sample loop, buffer tubing) for leakages and air bubbles. In order to eliminate air bubbles ensure that the sample loop has been purged with eluent sufficiently and carry out the Needle Wash a few times, e.g. by using the Configuration Tool. Check whether the retaining screw is fastened together with the dispenser syringe onto the syringe driver and fasten it if necessary.
Decreasing injection accuracy through out a sequence	Check whether the wash volume chosen in the method is sufficient to purge the needle tubing and the buffer tubing during the Needle Wash procedure at least once. The preinstalled needle tubing volume is 8.1 ml and the delivered buffer tubing can hold 21 ml.

12. Maintenance and care

Proper maintenance of your HPLC device will ensure successful analyses and reproducible results. In case there are any maintenance tasks on that you do not find instructions here, contact your supplier or the Technical support.

NOTICE

Electronic defect

Performing maintenance tasks on a switched on device can cause damage to the device.

➔ Switch off the device.

➔ Pull the power plug.

12.1 Maintenance contract

The device may only be opened by the Technical Service of KNAUER or any company authorized by KNAUER. This maintenance work is covered by a separate maintenance contract.

12.2 Cleaning and caring for the device

NOTICE

Device defect

Intruding liquids can cause damage to the device.

➔ Place solvent bottles next to the device or in a solvent tray.

➔ Moisten the cleaning cloth only slightly.

All smooth surfaces of the device can be cleaned with a mild, commercially available cleaning solution, or with isopropanol.

Display The screen can be cleaned with isopropanol and wiped dry with a soft, lint-free cloth.

12.3 Removing a leak

Prerequisites The device is switched off.

Auxiliary means Cloth

Procedure

Process
1. Remove the leak.

Next step Afterwards, take the device into operation.

13. Transport and storage

Regarding the following information, carefully prepare the device for transport or storage.

13.1 Taking the device out of operation

Prerequisites The device is switched off.

Procedure

Process
1. Pull the power plug out of the socket and afterwards out of the device.
2. Pack the power cable together with the device.

Next steps

- Disconnect further electrical connections.
- Remove the accessories and pack the device for transport or storage.
- Screw the transport locking screw back on the drive of the z-axis (see chapter “5.2 Loosen transport locking device” on page 14).

13.2 Packing the device

- Original packaging: Ideally use the original transport packaging.
- Lifting: Grab the device around the center of both sides and lift it into the packaging. Do not hold onto front cover, drainage tray or cover of the storage department, as these parts are loosely attached to the device. Carry the device with at least two persons.

13.3 Transporting the device

- Documents: If you want to return your device to KNAUER for repairs, enclose the completed document Service Request Form which can be downloaded from our KNAUER.
- Device data: For a secure transport, note the weight and Dimensions of the device (see chapter “15.1 Main features” on page 36).

13.4 Storing the device

- Flushing solution: Pay attention that all hoses and capillaries have been emptied or filled with flushing solution (e. g. isopropanol) before storage. To prevent algae formation, do not use pure water.
- Seals: Close all inputs and outputs with fittings.
- Ambient Conditions The device can be stored under the ambient conditions that are specified in the technical data (see chapter “15. Technical data” on page 36).

14. Disposal

Hand in old devices or disassembled old components at a certified waste facility, where they will be disposed of properly.

14.1 AVV marking

According to the German "Abfallverzeichnisverordnung" (AVV) (January, 2001), old devices manufactured by KNAUER are marked as waste electrical and electronic equipment: 160214.

14.2 WEEE registration number

KNAUER as a company is registered by the WEEE number DE 34642789 in the German "Elektroaltgeräteregister" (EAR). The number belongs to category 8 and 9, which, among others, comprises laboratory equipment.

All distributors and importers are responsible within the meaning of the WEEE directive for the disposal of old devices. End-users can send their old devices manufactured by KNAUER back to the distributor, the importer, or the company free of charge, but would be charged for the disposal.

14.3 Eluents and other operating materials

All eluents and other operating materials have to be collected separately and disposed of properly.

All wetter components of a device, e. g. flow cells of detectors or pump heads and pressure sensors for pumps, have to be flushed with isopropanol first and water afterwards before being maintained, disassembled or disposed.

15. Technical data

15.1 Main features

Dispenser syringe	Volume	12.5 ml
	Resolution	181.490 Increments
Available wash solutions		4
Robot module	Repeatability	■ X-axis: ≤ 0.2 mm ■ Y-axis: ≤ 0.2 mm ■ Z-axis: ≤ 0.4 mm
	Precision	■ X-axis: ± 0.3 mm ■ Y-axis: ± 0.3 mm ■ Z-axis: ± 0.4 mm
Valve Drive		■ Not part of the scope of delivery. ■ Valve Unifier VU 4.1 with 2 position injection valve is supported
Injection valve		■ Not part of the scope of delivery. ■ 1/16" or 1/8" injection valve V 4.1 is supported
Sample loop		10 ml loop per default, further loops available
Sample rack	Capacity	5 KNAUER sample racks
	Type	■ Not part of the scope of delivery, selectable ■ Sample racks for microtiter plates ■ 2 ml, 15 ml and 50 ml vessels available
Maximum capacitiy of the cuvette		■ 15 x microtiter plates ■ 810 x 2 ml vessel ■ 490 x 15 ml vessel ■ 160 x 50 ml vessel
Teaching mode for individual racks		Yes. The maximum distance between drainage tray and outlet of the fractionation is 12 cm, the distance between drainage tray and injection needle is 15 cm.
Dead volume compensation (low loss injection)		Air or sandwich solution
Sandwich injection mode		Yes, selectable

Adjustable parameters	■ Loop volume (volume of sample loop) ■ Syringe volume (volume of syringe) ■ Syringe speed (aspiration speed) ■ Syringe delay (delay of the dispenser syringe) ■ Sandwich injection ■ Injection volumes ■ Wash volumes ■ Wash speed ■ Dead volume

15.2 Communication and software

Supported software	■ PurityChrom® 5 ■ Chromeleon

15.3 Wetted materials

Dispenser valve	Aluminium oxide 99.5 %
Dispenser syringe	■ Borosilicate glass ■ PTFE
Drainage tube	FEP
Tip/Injection needle	AISI 316L, surface PTFE coated
Fractionation valve	■ PEEK ■ PTFE
Material certificates (FDA, 3.1)	Not available

15.4 General

Device	Dimensions (W × H × D)	96 cm x 104 cm x 70 cm
	Weight	Approx. 82 kg
	Use	For indoor use only
	Work space (W × D)	70 cm x 30 cm
	Power supply	100 - 240 V, 10 - 5 A, 50 / 60 Hz
	Air humidity	30 - 80 %, non-condensing
	Operating altitude	Max. 2 000 meters above sea level
	Ambient temperature	10 – 35 °C

16. Repeat orders

The list of repeat orders is up-to-date at the time of publication. Deviations are possible at later points in time.

Use the included packing list for repeat orders of spare parts. If there are any questions concerning repeat orders, contact the Technical Support.

Further Information

Further information on spare parts and accessories can be found online: www.knauer.net.

16.1 Device

Name	Order no.
Liquid Handler LH 2.1	A5080

16.2 Accessories and spare parts

Name	Order no.
Rack for 3 x microtiter plates	A50801
Rack for 162 x 2 ml vessels	A50802
Rack for 98 x 15 ml vessels	A50803
Rack for 32 x 50 ml vessels	A50804
Rack for 3 x 24 deep-well plates	A50805
Rack fixation	A50806
Tubing for tip, ID 1.5 mm, 180", 457 cm, FEP	A50807
Tubing for wash solution, ID 2 mm, 70", 177 cm, FEP	A50808
Dispenser syringe 1 ml	A50813
Dispenser syringe 2.5 ml	A50812
Dispenser syringe 5 ml	A50811
Dispenser syringe 12.5 ml	A50809
Buffer tubing 21 ml	A50814
Tip/Injection needle	A50810
Accessory kit Liquid Handler LH 2.1	F5080
LH 2.1 wash station	A50815

17. Chemical compatibility wetted materials

Note: The user takes the responsibility for using the fluids and chemicals in an appropriate and safe way. If there is any doubt, contact the Technical Support.

17.1 General

The device is very resistant against a variety of commonly used eluents. However, make sure that no eluents or water come in contact with the device or enter into the device. Some organic solvents (such as chlorinated hydrocarbons, ether) may cause coating damage or loosen glued components by improper handling. Even small quantities of other substances, such as additives, modifiers, or salts can influence the durability of the materials. Exposure time and concentration have a high impact on the resistance.

The following list contains information about the chemical compatibility of all wetted materials which are used in devices made by KNAUER. The data bases on a literature research on the manufacturer specifications of the materials. The wetted materials of this device are listed in the chapter "Technical data".

All resistances mentioned here are for use at temperatures up to 40 °C, unless stated otherwise. Note that higher temperatures can significantly affect the stability of different materials.

17.2 Plastics

Polyetheretherketone (PEEK):

PEEK is a durable and resistant plastic and, next to stainless steel, the standard material in HPLC. It can be used at temperatures up to 100 °C and is highly chemical resistant against almost all commonly used solvents in a pH range of 1 – 12.5. PEEK is potentially moderate resistant against oxidizing and reducing solvents.

Therefore, following solvents should not be used: Concentrated and oxidizing acids (such as nitric acid solution, sulfuric acid), halogenated acids (such as hydrofluoric acid, hydrobromic acid) and gaseous halogens. Hydrochloric acid is approved for most applications.

In addition, following solvents can have a swelling effect and may have an impact on the functionality of the built-in components: Methylene chloride, THF and DMSO in any concentration such as acetonitrile in higher concentrations.

Polyethylene terephthalate (PET, outdated PETP)

PET is a thermoplastic and semi-crystalline material with high wear resistance. It is resistant against diluted acids, aliphatic and aromatic hydrocarbons, oils, fats and alcohols, but not against halogenated hydrocarbons and ketones.

Since PET belongs chemically to esters, it is not compatible with inorganic acids, hot water and alkalis. Maximum operating Temperature: up to 120 °C.

Polyimide (Vespel®):

This material is wear-resistant and permanent resilient thermically (up to 200 °C) as well as mechanically. It is chemically broadly inert (pH range 1 – 10) and is especially resistant against acidic to neutral and organic solvents, but vulnerable to pH strong chemical or oxidizing environments: It is incompatible with concentrated mineral acids (such as sulfuric acid), glacial acetic acid, DMSO and THF. In addition, it will be disintegrated by nucleophilic substances like ammonia (such as ammonium salts under alkaline conditions) or acetate.

Ethylene-tetrafluorethylene copolymer (ETFC, Tefzel®)

This fluorinated polymer is highly resistant against neutral and alkaline solvents. Some chlorinated chemicals in connection with this material should be handled with care. Maximum operating temperature is 80 °C.

Perfluorethylenpropylen-Copolymer (FEP), Perfluoralkoxy-Polymer (PFA)

These fluorinated polymers hold similar features as PTFE, but with a lower operation temperature (up to 205 °C). PTA is suitable for ultrapure appilcations, where as FEP can be used universally. They are resistant against almost all organic and inorganic chemicals, except elemental fluorine under pressure or at high temperatures and fluorine-halogen compounds.

Polyoxymethylene (POM, POM-HTF)

POM is a semi-crystalline, high-molecular thermoplastic material which stands out due to its high stiffness, low friction value and thermal stability. It can even substitute metal in many cases. POM-HTF is a combination of PTFE fibers and acetal resin and is softer and has better slip properties as POM. The material is resistant against diluted acids (pH > 4) as well as diluted lyes, aliphatic, aromatic and halogenated hydrocarbons, oils and alcohols. It is not compatible with concentrated acids, hydrofluoric acid and oxidizing agent. Operating Temperature: up to 100 °C.

Polyphenylene sulfide (PPS)

PPS is a soft polymer which is known for its high break resistance and very high chemical compatibility. It can be used with most organic, pH neutral to pH high, and aqueous solvents at room temperature without concerns. However, it is not recommended for using with chlorinated, oxidizing and reducing solvents, inorganic acids or at higher temperatures. Operating Temperature: up to 50 °C.

Polytetrafluorethylene (PTFE, Teflon®)

PTFE is very soft and anti-adhesive. This material is resistant against almost all acids, lyes and solvents, except against fluid natrium and fluoride compounds. In addition, it is temperature-resistant from -200 °C to +260 °C.

Systec AF™

This amorphous perfluorinated copolymer is inert against all commonly used solvents. However, it is soluble in perfluorinated solvents like Fluorinert® FC-75 and FC-40, and Fomblin perfluor-polyether solvents from Ausimont. In addition, it is affected by Freon® solvents.

Polychlortrifluorethylene (PCTFE, Kel-F®):

The semi-crystalline thermoplastic material is free of plasticizer and dimensionally stable, even in a wide temperature range (−240 °C to+205 °C). It is moderately resistant against ether, halogenated solvents and toluene. Halogenated solvents over +60 °C and chlorine gas should not be used.

Fluorinated rubber (FKM):

The elastomer consisting of fluorinated hydrocarbon stands out due to a high resistance against mineral oils, synthetic hydraulic fluids, fuels, aromatics, many organic solvents and chemicals. However, it is not compatible with strong alkaline solvents (pH value > 13) like ammonia, and acidic solvents (pH value < 1), pyrrole and THF. Operating temperature: Between -40 °C and +200 °C.

Perfluorinated rubber (FFKM):

This perfluoro elastomer has a higher fluorine content as fluorinated rubber and is therefore chemically more resistant. It can be employed at higher temperatures (up to 275 °C). It is not compatible with Pyrrole.

17.3 Metals

Stainless steel

Stainless steel is, apart from PEEK, the standard material in HPLC. Steels with WNr. 1.4404 (316L) are used, or with a mixture of higher compatibility.

They are inert against almost all solvents. Exceptions are biological applications which are metal ion sensible, and applications with extreme corrosive conditions. These steels, in comparison to commonly used steels, are increasingly resistant against hydrochloric acid, cyanides and other halogen acids, chlorides and chlorinated solvents.

The use in ion chromatography is not recommended. In case of electrochemical applications, a passivation has to be executed first.

Hastelloy®-C:

This nickel-chrome-molybdenum alloy is extremely resistant to corrosion, especially against oxidizing, reducing and mixed solvents, even at high temperatures. This alloy may be used in combination with chlor, formic acid, acetic acid and saline solutions.

Titanium, titanium alloy (TiA16V4):

Titanium has a low weight and a high hardness and stability. It stands out due to its very high chemical compatibility and biocompatibility. Titan is applied when neither stainless steel nor PEEK are usable.

17.4 Non-metals

Diamond-like carbon (DLC)

The diamond-like carbon (DLC) is characterized by a high hardness, a low coefficient of friction and thus low wear. In addition, it is highly biocompatible. DLC is inert against all acids, alkalis and solvents commonly used in HPLC.

Ceramic

Ceramic is resistant against corrosion and wear and is fully biocompatible. An incompatibility against acids, alkalis and solvents commonly used in HPLC is not known.

Aluminum oxide (Al_2O_3)

Due to their high resistance to wear and corrosion, alumina ceramic is used as a coating for mechanically stressed surfaces. It is a biocompatible material with low thermal conductivity and low thermal expansion.

Zirconium oxide (ZrO_2)

Zirconia ceramics are characterized by their high mechanical resistance, which makes them particularly resistant to wear and corrosion. It is also biocompatible, has low thermal conductivity and is resistant to high pressures.

Sapphire

Synthetic sapphire is virtually pure monocrystalline alumina. It is biocompatible and very resistant to corrosion and wear. The material is characterized by a high hardness and a high thermal conductivity.

Ruby

Synthetic ruby is monocrystalline alumina and gets its red color by the addition of some chromium oxide. It is biocompatible and very resistant to corrosion and wear. The material is characterized by a high hardness and a high thermal conductivity.

Mineral wool:

This insulating material consists of glass or stone wool fibers and insulates in high oxidizing conditions and at high temperatures. Mineral wool is valid as commonly inert against organic solvents and acids.

Glass, glass fiber, quartz, quartz glass:

These mineral materials are resistant against corrosion and wear and are mostly chemical inert. They are compatible with oils, fats and solvents and show a high resistance against acids and lyes up to pH values of 3 – 9. Concentrated acids (especially hydrofluoric acid) may embrittle and corrode the minerals. Lyes may ablate the surfaces slowly.

Annex: Installation Qualification (IQ)

Installation Qualification (IQ) for a Device

	Generated	Reviewed	Approved
Function			
Name			
Date			
Signature			

0. Customer approval

Prior to installation at the customer site, the customer has reviewed the OQ document and agrees with the design and scope.

Company name:

Name	Function	Reviewed & approved	Date	Signature
		☐		
		☐		
		☐		
		☐		
		☐		
		☐		
		☐		
		☐		

Installation Qualification (IQ) for a Device

1. Definition of the Installation Qualification

The qualification document „Installation Qualification (IQ)“ is part of the quality management system at the company KNAUER Wissenschaftliche Geräte GmbH.

2. Scope

The customer can request the Installation Qualification. In case of a request, the technical support of KNAUER or a provider authorized by KNAUER performs this functionality test during the installation. The IQ is a standardized document and includes the following:

- Confirmation of flawless condition at delivery
- Check if the delivery is complete
- certification on the functionality of the device

3. Instructions

All deviations from the specifications that occurred during installation have to be recorded in this document.

In addition, all measures taken to eliminate the deviations have to be noted down as comments in the list of rectifications (LOR) „“ on page 4.

If certain items in the report are not applicable, this has to be indicated in the table as„N/A“(not applicable).
Major sections that are not used have to be crossed out (diagonal line), marked„N/A“, dated and signed.

All required documents have to be completed by the end of the installation. The document has to be reviewed and approved by an authorized person. The review and approval have to be documented with signature and date (DD/MM/YYYY).

The tests have to be carried out in a suitable environment, as described in the user instruction of the device.

4. About this document

The information in this document is subject to change without prior notice. This document may not be used, reproduced or translated without written consent of KNAUER Wissenschaftliche Geräte GmbH. Depending on the customer’s quality assurance system, the signed document either has to be filed in the device folder or scanned and stored in an electronic archive.

5. Device data

Device name		Product number	
Serial number		Order number	
Firmware version			
Operating environment			

Installation Qualification (IQ) for a Device

6. Customer and manufacturer data

	Customer	Manufacturer
Company		KNAUER Wissenschaftliche Geräte GmbH
Customer number		-
Contact person/agent		
Address		Hegauer Weg 38
Postal code/City		14163 Berlin
Phone		+49 30 80 97 27 111
E-mail		support@knauer.net

7. Installation Qualification Tests

Test	Description	Specification	Passed	Failed	N/A	Comment/LOR no.
1	Identify the device.	The name on the device matches the name on the delivery order.	☐	☐	☐	
2	Check the device for transport damage.	No transport damage is observed.	☐	☐	☐	
3	Check the delivery scope.	The scope of delivery matches the packing list and/or the delivery order.	☐	☐	☐	
4	Check that the technical documentation provided is correct and complete (material documentation of wetted parts, calibration certificates etc.)	The documentation is correct and complete.	☐	☐	☐	
5	Check that all equipment is properly and correctly labeled according to the delivery order and/or the labeling specifications document, if applicable.	The equipment is labeled correctly.	☐	☐	☐	
6	Connect all loose parts (e.g. capillaries, tubings, measuring head) according to the user instructions.	The device is fully assembled and ready to use.	☐	☐	☐	

Installation Qualification (IQ) for a Device

7	Ensure that the installation site is suitable according to the user instructions.	The installation site matches the specifications in the user instructions.	☐	☐	☐	
8	Connect the device to the power supply and switch it on.	The device starts (operating noise). The power LED or the display lights up.	☐	☐	☐	

8. List of rectifications (LOR)

Comment/ LOR no.	Test no.	Type of deviation*	Description of deviation	Measures	Persons responsible	Due date	Date/ signature

* Type of deviation:

A = acceptable (e.g. not a GMP-critical deviation)

N = not acceptable
Continuation of qualification activities into the next qualification phase is only possible when deviation is rectified.

T = temporarily acceptable
a) Release and use of the system is possible, even when the deviation is not rectified.
b) A continuation of qualification activities into the next qualification phase is possible, even when the deviation is not rectified

Installation Qualification (IQ) for a Device

9. List of changes to the document

Revision no.	Description of change	Additional information	Date/signature

Installation Qualification (IQ) for a Device

10. Certificate and approval

A KNAUER employee or an person authorized by KNAUER has checked the device and performed all tests described in the IQ.

The IQ form has to be signed by an authorized person. The scope of the IQ meets the customer's requirements.

The results of the IQ, any changes made as well as the IQ process have been documented in this form in writing. The users listed below have been instructed and are familiar with how to operate the device. Both parties confirm that the IQ has been performed to the customer's satisfaction by signing it.

10.1 Customer approval

Name	Function	Date	Signature

10.2 KNAUER agent approval

Name	Function	Date	Signature

11. Comments/recommendations

Installation Qualification (IQ) for a Device

Annex: List of supporting documents

No.	Test no.	Description

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www.knauer.net/library

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