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# IJM NanoProducer System Instructions



Document no. V6741



**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?

**International Support:**

Contact your local KNAUER partner for support:

[www.knauer.net/en/Support/Distributors-worldwide](http://www.knauer.net/en/Support/Distributors-worldwide)

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These instructions apply to products with the product number A48028/A48028V1, A48029, A48038XYZ and A48039XYZ. X,Y,Z = 0-9, or A-Z, or blank.

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](http://www.knauer.net/library).



**Sustainability:** The printed versions of our instructions are printed on recycled paper that has been awarded the Blue Angel.

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# 1. General

## 1.1 About these instructions

These operating instructions enable the safe and efficient operation of the device. The user must have carefully read and understood these operating instructions before starting any work.





The basic prerequisite for safe operation is compliance with all safety instructions (see chapter 2 on page 3). In addition to the safety and warning instructions in these operating instructions, the local accident prevention regulations and the national industrial safety regulations apply.

These operating instructions are an integral part of the device. It must be kept in the immediate vicinity of the device and accessible to the user at all times.

You can download these and other instructions from the KNAUER website: [www.knauer.net/library](http://www.knauer.net/library)

## 1.2 Signal words

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

Symbol	Meaning
	DANGER (red) indicates a highly hazardous situation. If not avoided, it will result in death or serious injury.
	WARNING (orange) indicates a hazardous situation. If not avoided, it could result in death or serious injury.
	CAUTION (yellow) indicates a moderate hazardous situation. If not avoided, it could result in minor or moderate injury.
	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 chapter 2.2 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 Transport damage

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

For information on warranty please refer to our general terms and conditions on the website: [www.knauer.net/terms](http://www.knauer.net/terms)

### 1.4.4 Warranty seal

A blue or orange warranty seal is affixed to some devices.

- A blue seal is used by KNAUER's Manufacturing or Customer Support for devices to be sold.
- After repair, service technicians attach an orange seal onto the identical position.

If unauthorized persons tamper with the device or if the seal is damaged, the warranty will lapse.



### 1.4.5 Declaration of conformity

The declarations of conformity for the single devices of the NanoProducer can be obtained online:

[www.knauer.net/en/Support/Declarations-of-conformity](http://www.knauer.net/en/Support/Declarations-of-conformity)



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## 2. Basic safety instructions

The device has been developed and constructed in such a way that hazards arising from its intended use are largely excluded. Nevertheless, the following safety instructions must 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 lipid nanoparticle formulations.

#### 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 does not guarantee the functionality and safety of the device.
- Operation in potentially explosive areas without special and additional explosion protection. Contact the KNAUER Customer Support for more information.

### 2.2 User qualification

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

- They have completed training as pharmaceutical-technical assistants or chemical-technical assistants or comparable vocational training.
- They have fundamental knowledge of the technical equipment for the formation of lipid nanoparticles.
- 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 must 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 and set clear rules
- 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

The protective measures required in the laboratory must be observed and the following protective clothing worn during all work on the device:

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

## 2.5 Safety features on the device

- Power switch: Devices of the AZURA® L series may 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.
- Front cover: Devices of the AZURA® L series have a front cover as a splash protection for the user
- Leak tray: Devices of the AZURA® L series have a leak tray on the front side. The leak tray collects leaking solvents and protects components from potential damage caused by discharging liquid.
- Lamp: For the detectors AZURA® DAD 2.1L, DAD 6.1L and MWD 2.1L, the lamp switches off automatically when the cover is opened.

## 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 "14 Chemical compatibility of wetted materials", p. 45).
- Note that organic solvents are toxic above a certain concentration. For handling hazardous solvents see the following section.
- Solvents and samples may contain volatile or combustible/flammable chemicals. 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 must be properly decontaminated by a specialist company or the operating company before they can be recommissioned, repaired, sold, or disposed (see "11 Disposal", p. 49).

### 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.
- Solvents 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 Earthquake-endangered areas

In earthquake-endangered areas, do not stack more than 3 devices on top of each other. Otherwise there is risk of injury due to falling devices or loose parts.

## 2.7.2 Explosive environment

Never use the system in potentially explosive atmospheres without appropriate protective equipment. For more information, contact the KNAUER Customer Support.

## 2.7.3 Cooling room

You may operate the device in a cooling room. To prevent condensation, note the following instructions:

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

## 2.7.4 Wet room

The device must not be operated 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.
- 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 chapter 1.4.1 on page 2).
- For more information visit the KNAUER website:  
[www.knauer.net/hplc-troubleshooting](http://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](http://www.knauer.net/servicerequest)

## 3. Product information

### 3.1 Intended use



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

KNAUER's IJM NanoProducer systems are designed for high-flow production of nanoparticles (LNP, micro-emulsions, etc).

Depending on the number of mixing units, the IJM NanoProducer can be used to produce lipid encapsulated nucleotides at a rate of up to 1 to 2 litre/min.

LNP Impingement Jets Mixing Technology (IJM) enables the formulation and production of high-quality lipid nanoparticles carrying API (e.g. for mRNA vaccines). The encapsulation process of active pharmaceutical ingredients with lipids is based on Impingement Jets Mixing Technology, where two streams collide at high velocity in a jet mixing chamber. One of the streams contains the lipids in organic solvents and the other stream the API in buffer. The mixing at high velocity reduces the solubility of the lipids so that homogeneous nanoparticles are formed. The quality of nanoparticles depends on the flow stability of the two streams, the mixer geometry and the fluid velocities. As a final step, the mixture is quenched to stop particle growth.

### 3.2 Features

The IJM NanoProducer is made for small and large scale production of lipid nanoparticles. Equipped with our lipid nanoparticle producing Impingement Jets Mixing (IJM) technology the NanoProducer allows the production of lipid encapsulated nucleotides at a rate of up to 1 to 2 l/min.

The IJM NanoProducer is available in two standard configurations, a Single Core and a DuoCore set-up.

The IJM SingleCore NanoProducer consists of one mixing unit with four pumps enabling all the steps from predilution of the concentrated Active Pharmaceutical Ingredient (API), Impingement Jets Mixing of lipid and API phase and finally the quenching of the nanoparticle solution. Furthermore, the unit is equipped with four flowmeters for flow monitoring, one jets mixer and two mixers for predilution and quenching.

The IJM DuoCore NanoProducer contains two parallel mixing units. Each unit consists of four pumps equal to the unit of the SingleCore. Concentrated Active Pharmaceutical Ingredient (API) solution is diluted first and then mixed with the organic phase. These active pharmaceutical ingredients include complex or delicate API like RNA, mRNA, siRNA, and DNA-based molecules, or products that need specific entry into target cells. Finally, the mixture is quenched in a third mixer. Both units can be operated independently.

All IJM NanoProducers are built in a stainless steel frame on casters and are suitable for CIP cleaning procedures in pharmaceutical production.

The formulation process can be remotely controlled by software operated on a conventional PC or laptop. Our CDS software provides an intuitive and easy operating of the IJM NanoProducer. The system visualization offers a graphical representation and allows easy handling of the complex flow processes. Additionally, each device that is displayed in the fluidic scheme can be manually controlled. Optimize, change, and adapt your conditions also during the run. The software complies with 21 CFR Part 11 and GAMP 5 (for PurityChrom® 6).



**Fig.1** System layout: IJM SingleCore



**Fig.2** System layout IJM DuoCore NanoProducer

## 3.3 Scope of delivery



**Note:** Only use original parts and accessories made by KNAUER or a company authorized by KNAUER.

### 3.3.1 IJM SingleCore NanoProducer (standard configuration)

- 4 x KNAUER high-pressure dosing pumps 80P
- 4 x Coriolis flowmeters
- 1 x KNAUER IJM mixer
- 2 x Mixers
- 1 x 2-port multiposition valve
- 1 x Valve Unifier VU 4.1
- Inlet for Lipid and mRNA (Sanitary Clamp Connector)
- Inlet for buffer (Sanitary Clamp Connector)
- Outlet for LNP solution (Sanitary Clamp Connector)
- Internal piping
- Frame (stainless steel system 1.4301)
- CDS software, 21 CFR part 11 compliant and GAMP 5 (for PurityChrom® 6) compliant
- Chromatography workstation with 27" monitor (for A48028/A48029)
- Touch Industrial PC 24" (for A48038XYZ/A48039XYZ)
- Installation & familiarization by KNAUER
- FAT (Factory Acceptance Test) at KNAUER Berlin
- SAT (Site Acceptance Test) at customer site

Valid documents:

- Declarations of conformity for single devices
- Material Documentation of wetted surfaces
- VOQ-IJM-NanoProducer

### 3.3.2 IJM DuoCore NanoProducer (standard configuration)

- 8 x KNAUER high-pressure dosing pumps 80P
- 8 x Coriolis flowmeters
- 2 x KNAUER IJM mixers
- 4 x Mixers
- 2 x 2-port multiposition valves
- 2 x Valve Unifier VU 4.1
- Inlet for Lipid and mRNA (Sanitary Clamp Connector)
- Inlet for buffer (Sanitary Clamp Connector)
- Outlet for LNP solution (Sanitary Clamp Connector)
- Internal piping
- Frame (stainless steel system 1.4301)
- CDS software, 21 CFR part 11 compliant and GAMP 5 (for PurityChrom® 6) compliant
- Chromatography workstation with 27" monitor (for A48028/A48029)
- Touch Industrial PC 24" (for A48038XYZ/A48039XYZ)
- Installation & familiarization by KNAUER
- FAT (Factory Acceptance Test) at KNAUER Berlin
- SAT (Site Acceptance Test) at customer site

#### Valid documents:

- Declarations of conformity for single devices
- Material Documentation of wetted surfaces
- VOQ-IJM-NanoProducer

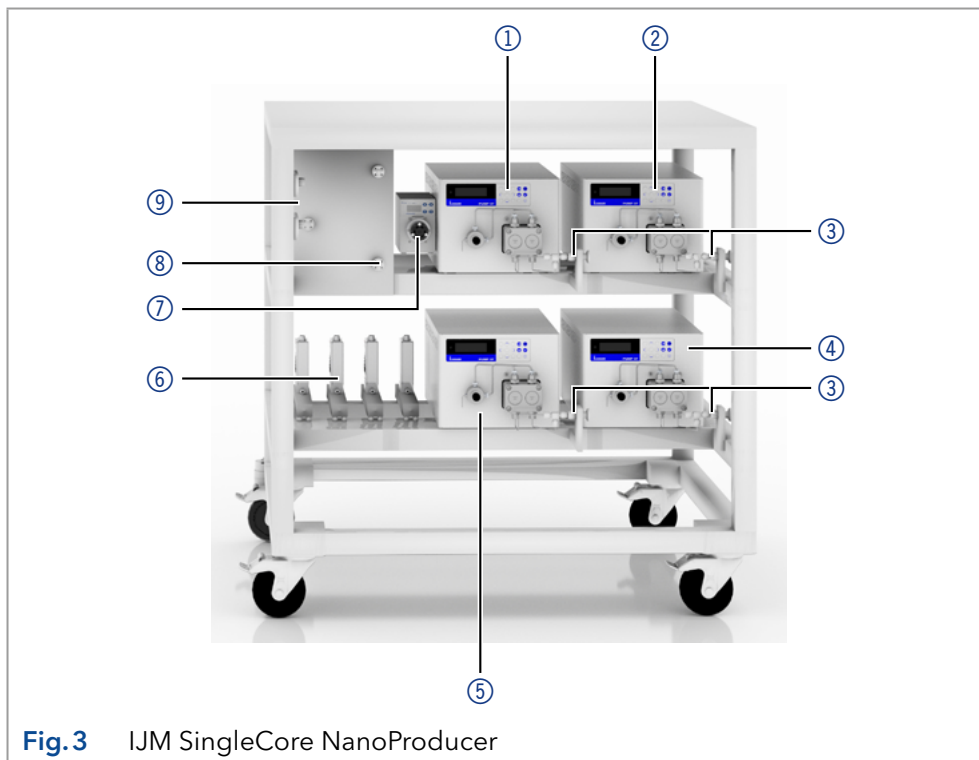


### 3.4 Views

#### 3.4.1 Front view

**Legend**

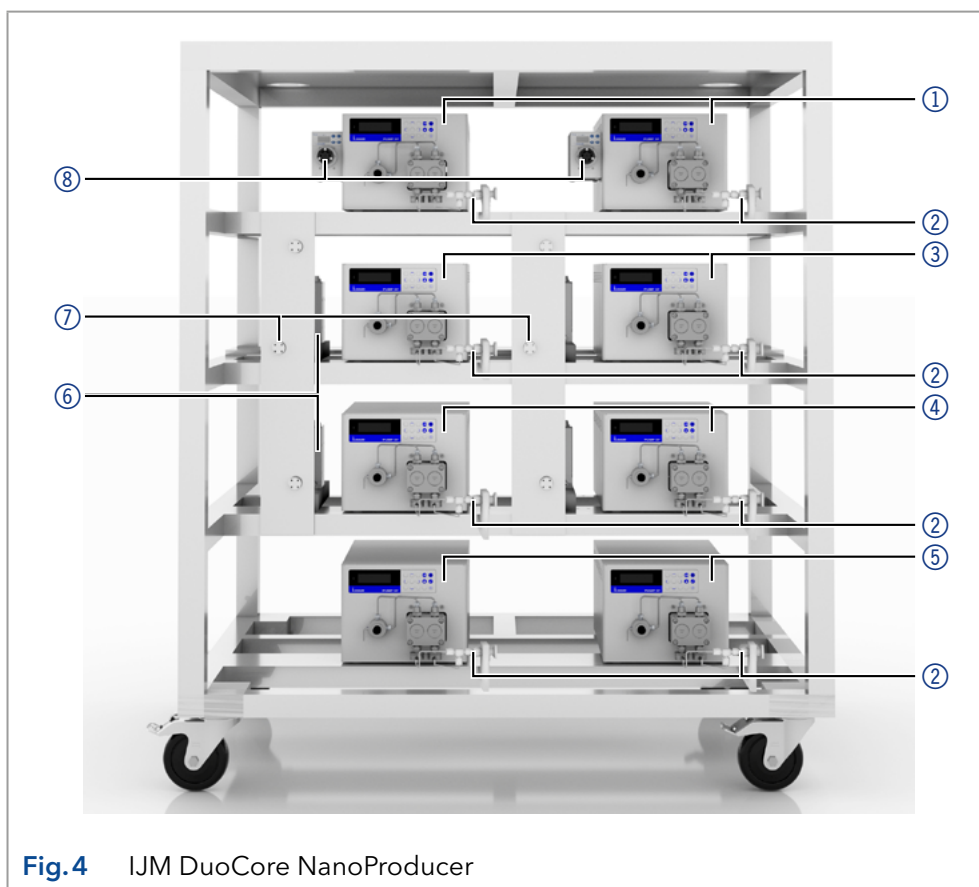
- ① API (mRNA) pump
- ② Lipid pump
- ③ Pump inlets
- ④ Quench pump
- ⑤ Dilution pump
- ⑥ Flowmeters
- ⑦ Valve with valve drive
- ⑧ Impingement Jets Mixer (IJM)
- ⑨ System outlets



**Fig.3** IJM SingleCore NanoProducer

**Legend**

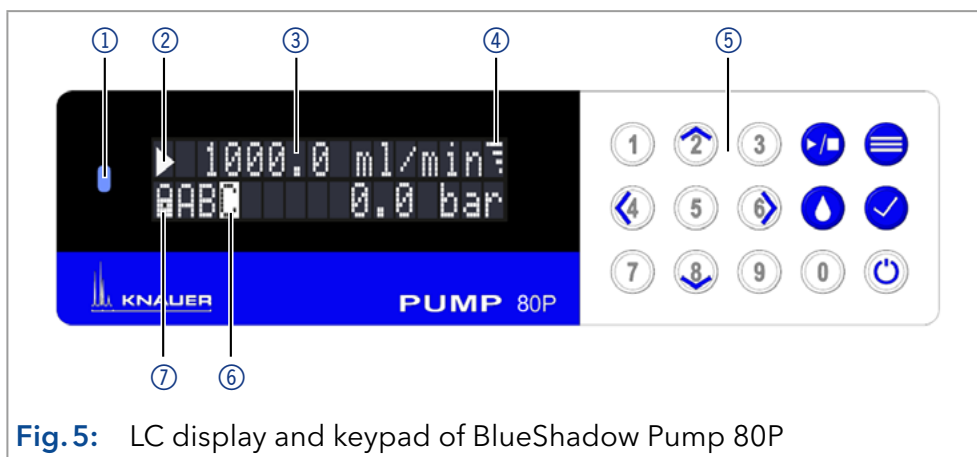
- ① Lipid pumps
- ② Pump inlets
- ③ API (mRNA) pumps
- ④ Dilution pumps
- ⑤ Quench pumps
- ⑥ Flowmeters
- ⑦ Impingement Jets Mixers (IJM)
- ⑧ Valves with valve drives



**Fig.4** IJM DuoCore NanoProducer

**Legend:**

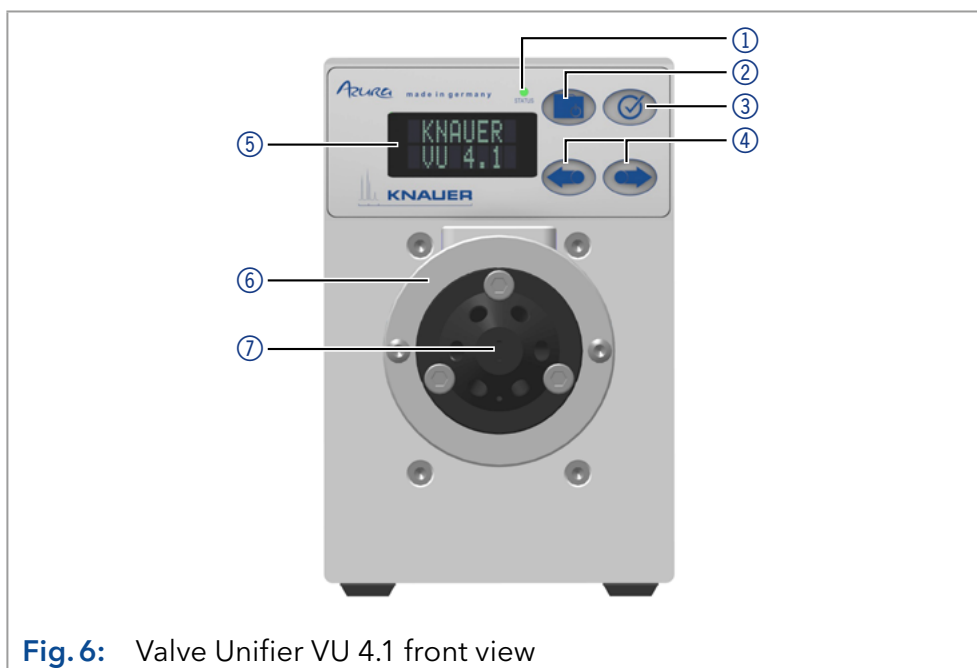
- ① Status LED
- ② Status Play/Stop
- ③ Parameters and values
- ④ RFID recognition of the pump head
- ⑤ Keypad
- ⑥ Gradient modus
- ⑦ Remote control



**Fig. 5:** LC display and keypad of BlueShadow Pump 80P

**Legend:**

- ① Status display (LED)
- ② Selection button
- ③ Confirmation button
- ④ Navigation buttons
- ⑤ Display
- ⑥ Adapter
- ⑦ Valve



**Fig. 6:** Valve Unifier VU 4.1 front view

### 3.4.2 Rear view

#### Legend

- ① Socket for the LPG valve block
- ② Events connector
- ③ Opening of the fan
- ④ Warranty seal
- ⑤ Power switch
- ⑥ Power supply
- ⑦ CE-mark
- ⑧ Remote connector
- ⑨ Interface RS-232
- ⑩ LAN connection
- ⑪ Serial number

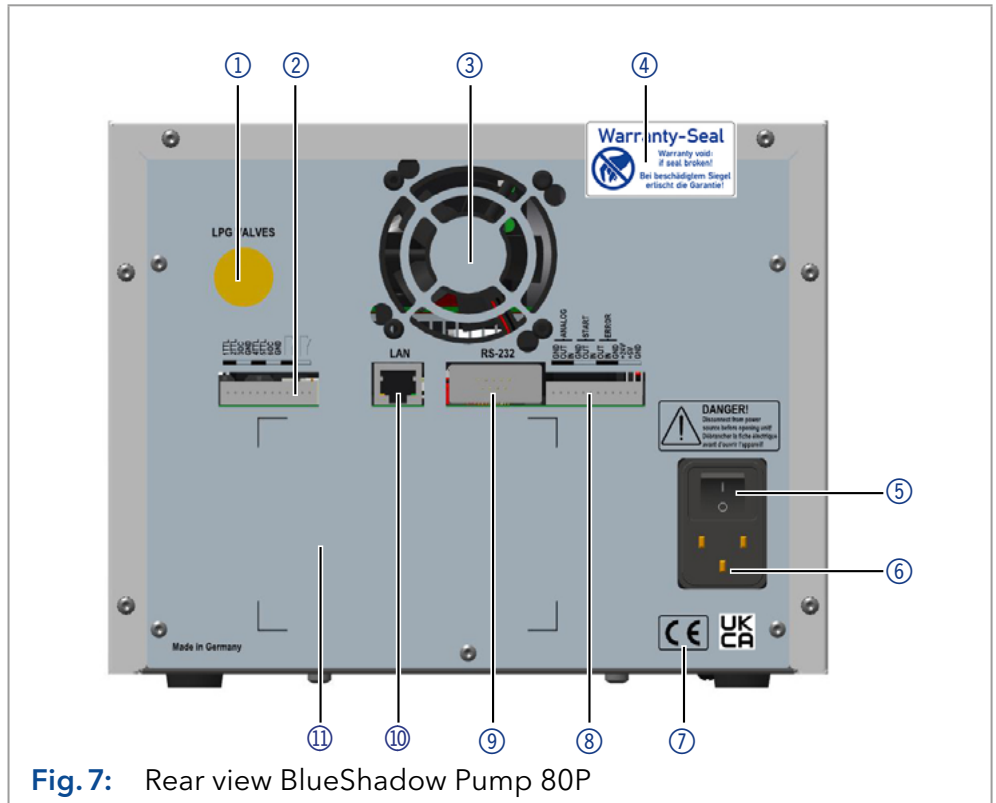


Fig. 7: Rear view BlueShadow Pump 80P

#### Legend:

- ① Serial number and signs
- ② LAN port 1
- ③ LAN port 2
- ④ Terminal strip
- ⑤ Service interface (USB)
- ⑥ Power connection
- ⑦ Ground connection

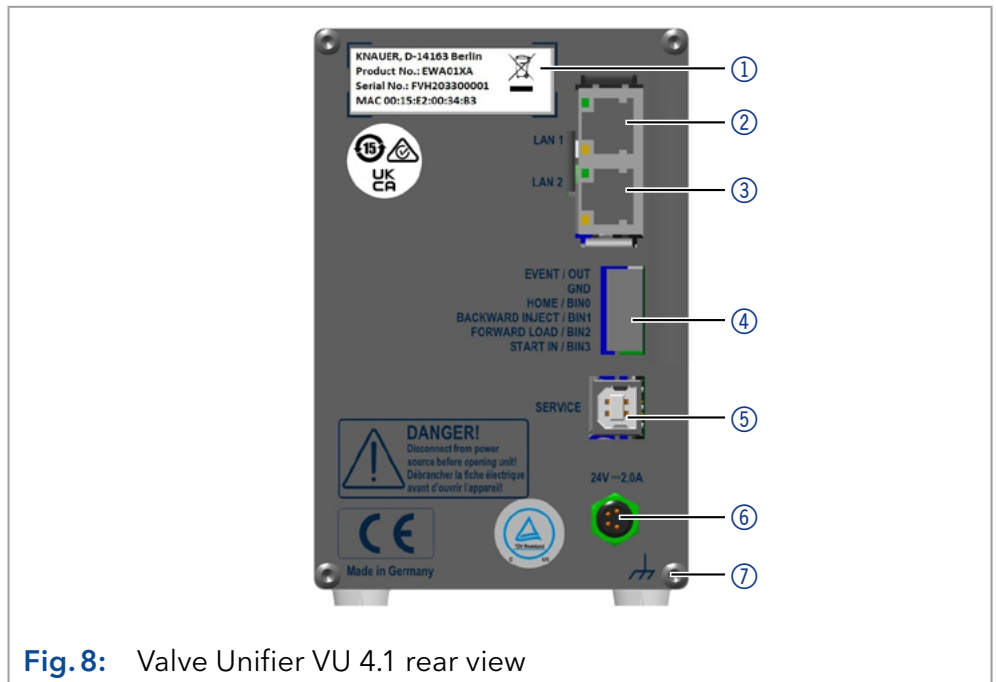


Fig. 8: Valve Unifier VU 4.1 rear view

### 3.5 Meaning of the LEDs

The status of the devices is indicated by an LED on the front side. The color of the LED shows the status.

LED		Status		
		Pump 80P <sup>1</sup>	Valve Unifier VU 4.1 <sup>2</sup>	Flowmeter <sup>3</sup>
●	Green	Device is ready (idle status).		
	Short flash (0.1 s)	-	-	Initialization mode
	Green flashing	Pump is running.	Method in software is paused.	Special function mode; the instrument is busy performing a special function (e.g. auto-zero or self-test).
●	Yellow	Firmware upload in progress.	-	-
	Yellow flashing	Device initialization.	-	-
●	Red	A serious error occurred.		Liquid application: measuring error (no liquid in measuring tube) OR Critical error (the instrument needs servicing before it can be used).
	Short flash (0.1 s)	-	-	Node occupied: re-install instrument.
	Long flash (2.0 s)	-	-	Requested parameter not available.
	Red flashing	An acknowledgeable error occurred.		Waiting for communication (check communication settings of all FLOW-BUS devices in the fieldbus set-up). Usually the 'last node address' setting of one of the devices is incorrect.
●	Blue	Device in standby.		-
●	Cyan flashing	Pump is purging.	-	-
●	Grey	-	Not ready. The valve position must be set to Home.	-





<sup>1</sup> For more information, see the instructions for the Blue Shadow Pump 80P ([V7685](#))

<sup>2</sup> For more information, see the instructions for the Valve Unifier VU 4.1 ([V6855](#))

<sup>3</sup> For more information, see the instructions for the mini CORI-FLOW™ M1x series ([917050-Manual-mini-CORI-FLOW](#))

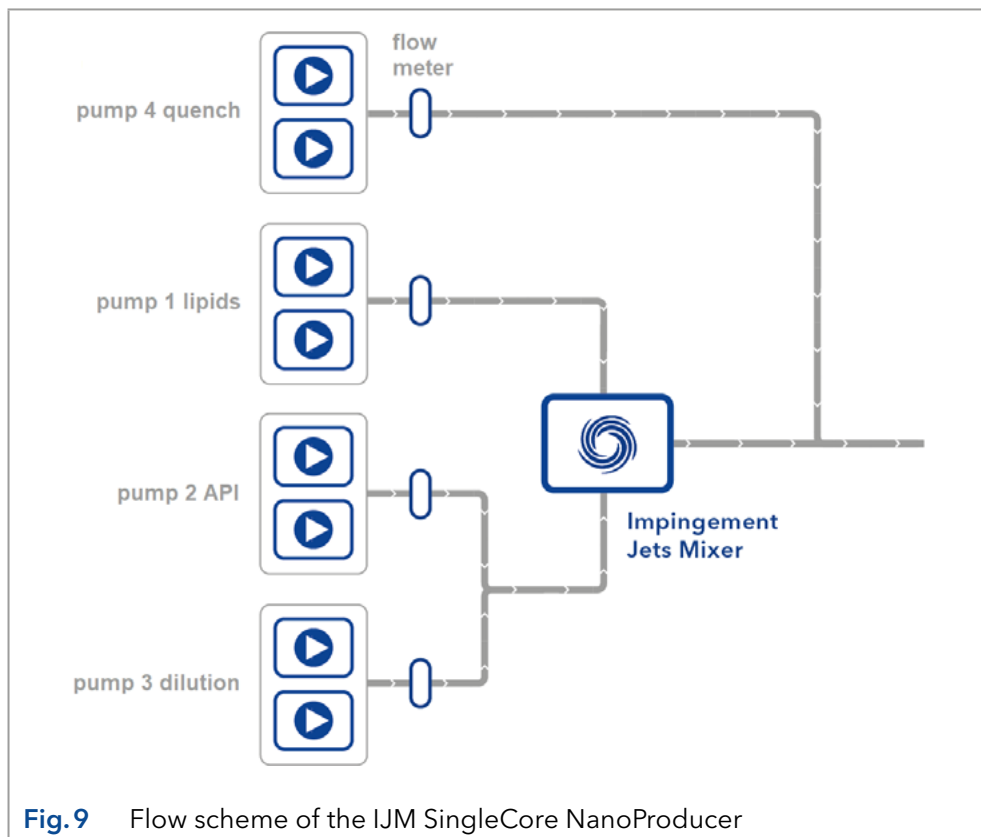
### 3.6 Symbols and signs

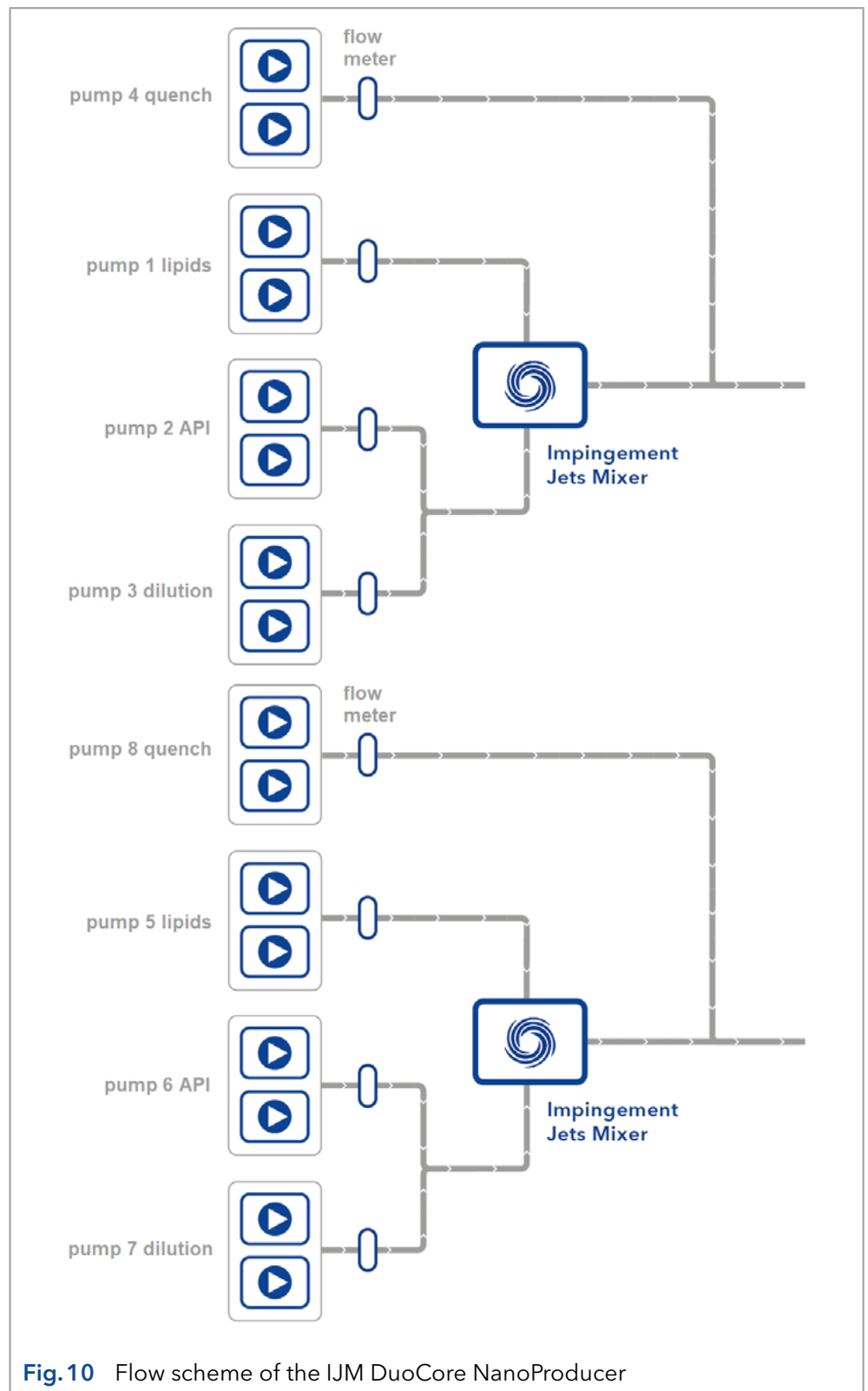
The following symbols and signs can be found on the device:

Symbol	Meaning
	Electric shock hazard. Failure to observe this warning may result in loss of life, serious injury, or damage to or destruction of the device.
	Electrostatic discharge hazard. Damages to system, device, or sensitive electronic components can occur.
	Obey maximum load for leak tray during transportation, installation and operation.
	The device is covered by the Waste Electrical and Electronic Equipment Directive (WEEE Directive). It may not be disposed of as unsorted municipal waste and must be collected separately.
	A device or system marked with CE fulfills the product specific requirements of European directives. This is confirmed in a Declaration of Conformity.
	The device complies with the product-specific requirements of the United Kingdom.
	Testing seals in Canada and the USA at nationally recognized testing centers (NRTL). The certified device or system has successfully passed the quality and security tests.
	On some devices, a warranty seal is attached. For more information see section "1.4.4 Warranty seal" on p. 2.

## 4. Operation

In the standard configuration, the IJM SingleCore and DuoCore NanoProducer feature the flow schemes shown below.





Each unit consists of four pumps, four flowmeters, a valve drive with valve, an IJM mixer and two additional mixers. Concentrated Active Pharmaceutical Ingredient (API) solution is diluted first and then mixed with the organic phase. These active pharmaceutical ingredients include complex or delicate API like RNA, mRNA, siRNA, and DNA-based molecules, or products that need specific entry into target cells. Finally, the mixture is quenched in a third mixer.

## 5. Installation and initial startup

Before you determine the operation site, read the chapter “Technical Data” (see chapter 12 on page 39). There you will find all device-specific information on power supply, ambient conditions and humidity.



**Note:** The intended use is only ensured if the requirements for ambient conditions of the operating environment are met.

The IJM System will be set up, installed and commissioned by KNAUER or a company authorized and contracted by KNAUER.



**Note:** KNAUER recommends inviting future users to be present while setting up and commissioning the module so that they can become familiar with the device and know how to handle it.

### 5.1 Unpacking

#### Process

#### Procedure

1. Place the packaging in such a way that the lettering on the label is in the correct position.
2. Check the packaging, the device and the accessories for transport damage.
3. Check the scope of delivery. In the event of incomplete delivery, contact Technical Support immediately.
4. When lifting, carrying or moving the device, grab the unit only from below on the sides. Do not hold on to front cover or leak tray, as these parts are loosely attached to the device.

#### Next steps

- Keep the included packing list for repeat orders.
- Keep the original packaging for safe storage or transportation.

### 5.2 Ambient conditions

#### 5.2.1 Operation site

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

- Place on a firm, level and straight surface.
- Protect against direct sunlight.
- Do not expose to air drafts such as air conditioning systems.
- Do not set up next to other machines that cause floor vibrations.
- Keep from high frequency sources.
- Ensure adequate ventilation (see 5.2.3 on page 19).
- Avoid temperature fluctuations (see 5.2.2 on page 19).



## 5.2.2 Ambient temperature

If the ambient temperature of the device is abruptly changed (e.g. when it is installed in a cooling chamber), 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.

## 5.2.3 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.

## 5.3 Power supply

### NOTICE

#### Electronic defect

Electronic hazard when using an identically constructed power adapter from another manufacturer.

→ Only use spare parts and accessories from KNAUER or a company authorized by KNAUER.

#### Power supply requirements

- Failure-free power supply: For failure-free operation, the electrical voltage has to be free of fluctuations, residual currents, voltage peaks and electromagnetic interference. The device must 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 must 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 which are described in the chapter "Technical Data" (see chapter 12 on page 39). Detachable power cables are not allowed to be replaced with other cable types.
- Country-specific plugs: Before switching on the device, check whether the supplied plug is approved for your country. Overview of the device- and country-specific plug types from KNAUER: [www.knauer.net/plugs](http://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 must not be used to connect the device to the power supply. Replace defective cables and plugs only with KNAUER accessories.

## 5.4 Installation of flowmeters

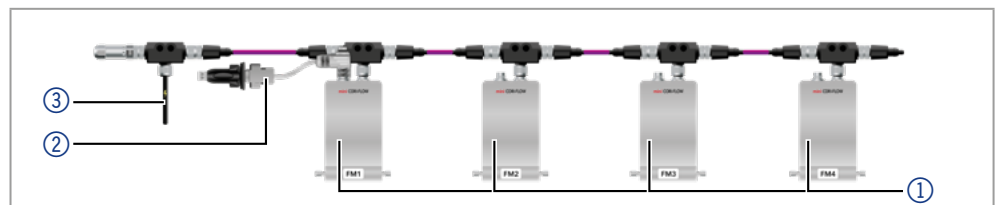
The IJM NanoProducer systems utilizes FLOW-BUS to interconnect its flowmeters ①. Data transmission occurs through a dedicated data cable ② extending from the initial flowmeter to the PC. Power is supplied uniformly to all flowmeters via a single power cable ③. The IJM SingleCore (refer to Fig. 1) comprises 4 flowmeters, while the IJM DuoCore (refer to Fig. 2) comprises 8. Consequently, cable connections vary based on the number of flowmeters.



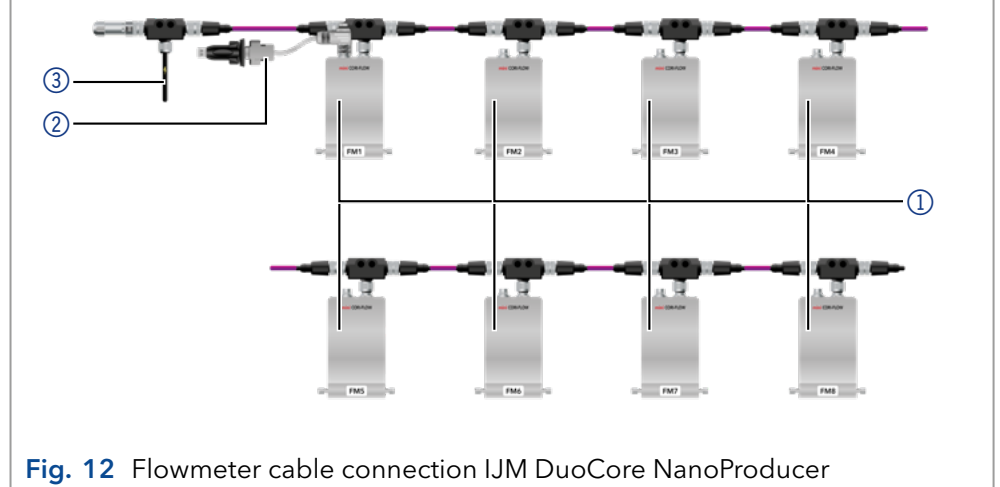
**Note:** KNAUER pre-configures the connections of the flowmeters for the delivered IJM NanoProducer systems.

### Legend

- ① Flowmeter
- ② Data cable
- ③ Power cable



**Fig. 11** Flowmeter cable connection IJM SingleCore NanoProducer



**Fig. 12** Flowmeter cable connection IJM DuoCore NanoProducer

## 5.5 Connecting the piston backflushing

The pump is equipped with automatic piston backflushing. It increases the service life of the seals and pistons, and removes contaminants from the area behind the seals.

### Functional principle

The piston backflushing function automatically flushes the rear piston area of the pump head upon switch-on and in continuous operation.

- Upon switch-on: The rear piston area of the pump head is flushed automatically for 15 seconds.
- In continuous mode: The rear piston area of the pump head is flushed automatically every 30 minutes, for 15 seconds.

### Legend

- ① Flush pump's inlet
- ② Pump head's outlet
- ③ Pump head's inlet
- ④ Flush pump's outlet

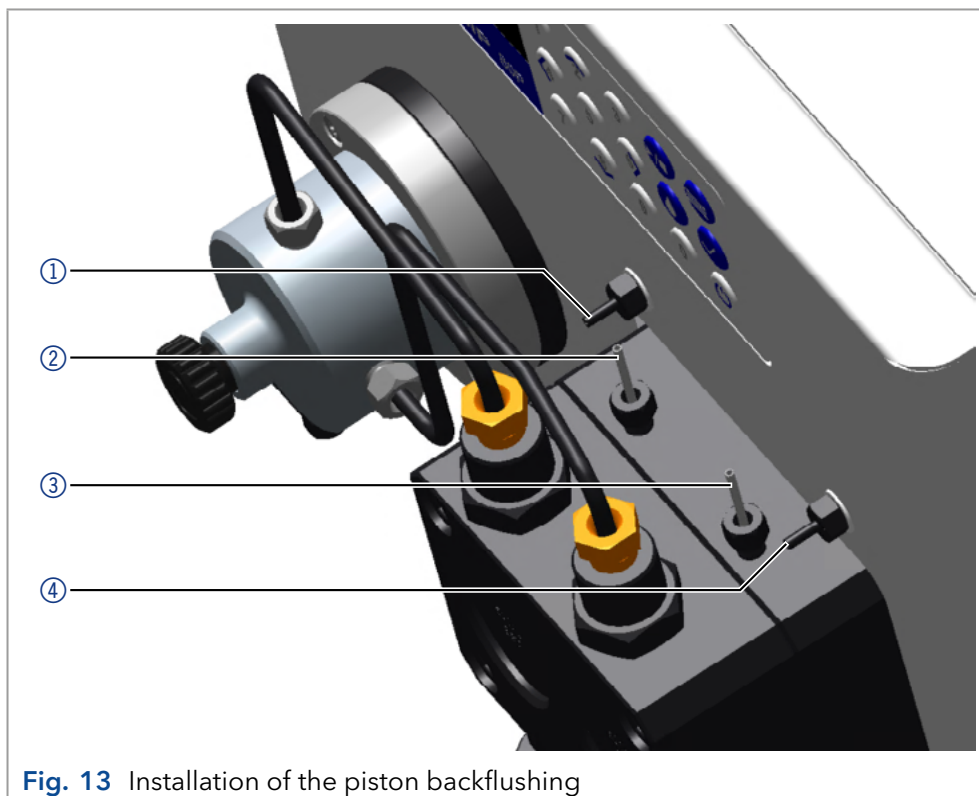


Fig. 13 Installation of the piston backflushing

### Process

1. Lead a tube from the solvent bottle to the pump head's inlet ③ and fasten it.
2. Lead a tube from the flush pump's inlet ① to the pump head's outlet ② and fasten it.
3. Fasten a tube to the flush pump's outlet ④ and lead to the waste bottle.



**Note:** Each piston backflushing has to be connected separately for each pump. KNAUER recommends a mixture of water (70 %) and ethanol (30 %).

## 5.6 Initial start-up checklist

Use this checklist to determine if the system is ready for initial start-up:

- Devices are positioned in the correct location.
- The power plugs are connected.
- The network connection is established.
- The software has been installed by KNAUER or a company authorized by KNAUER.
- The capillaries are connected.



**Note:** Place the solvent bottle at least at the height of the pump head or generate a back pressure of at least 50 mbar.

## 5.7 SOP: IJM System power-up and shut-down

### 5.7.1 Power-up

#### Procedure

#### Steps

1. Connect to every pump and valve drive a power plug and LAN cable.
2. Connect the piston backflushing of all pumps (see chapter 5.5).
3. Screw the flowmeter data cable to the flowmeter number 1.

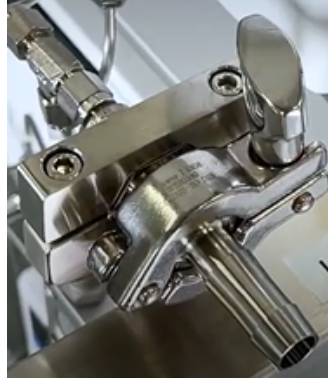


**Fig. 14:** Data cable of the flowmeters

4. Connect the RS-232 connection to the PC.
5. Connect the hose adapter to each inlet and outlet port.

## Procedure

## Steps



**Fig. 15:** Installed hose adapter



**Note:** When installing the hose adapter, check that the gasket is seated correctly.

6. Connect a hose to each inlet and outlet port.



**Note:** Use hose clamps for fastening.

7. Power up the switch and wait until the self-test is performed.
8. Switch on all instruments, wait 5 minutes and then switch on the PC.
9. If a user management is used on the PC, login with the correct credentials.
10. Start the software with double click on the desktop icon.

## 5.7.2 Shut down

## Procedure

## Steps

1. Close the software.
2. Turn off the PC.
3. Turn off all instruments.
4. Turn off the switch.

## 5.8 SOP: IJM System start-up

Follow this procedure to perform an IJM system start-up.

When delivered the system is filled with 80 % water / 20 % isopropanol.



**Note:** When using the IJM DuoCore NanoProducer, start with the left mixing unit (unit 1)!

Procedure	Steps
	1. Power-up the system.
	2. Switch all valves to the "Drain" position.
	3. Fill the inlet hose with deionized water. To do this, connect a funnel to the desired hose and fill it until no more air bubbles are visible. When the hose is filled, insert it into the desired solvent bottle.
	4. Open the purge valve of pump 1 (Lipid) and connect it to a syringe with a silicon tubing.
	5. Set the flow rate at 10 % of the pump heads maximum flow.
	6. Purge with deionized water.
	7. When no more air bubbles are visible in the inlet tubing, stop the pump and close the purge valve.
	8. Repeat steps 4 to 7 with pump 2 (API/mRNA), pump 3 (dilution) and pump 4 (quench).
	9. Flush the system with water for 10 min, using 20 % of the maximum flow rate for every pump.
	10. Switch all valves to the "Product" position.
	11. Flush the system with water for 10 min, using 20 % of the maximum flow rate for every pump.
	12. For the IJM DuoCore NanoProducer, repeat steps 2 to 11 with the right mixing unit (unit 2).

## 5.9 SOP - NanoProducer

### 5.9.1 Preparation



**Note:** When using the IJM DuoCore NanoProducer, start with the left mixing unit (unit 1).

Procedure	Steps
	1. Open the purge valve of pump 1 (Lipid) and connect it to a syringe with a silicon tubing.
	2. Set the flow rate at 10 % of the pump heads maximum flow.
	3. Purge with your preferred solvent (e.g. ethanol/buffer).
	4. When no more air bubbles are visible in the inlet tubing, stop the pump and close the purge valve.
	5. Repeat steps 1 to 4 with pump 2 (mRNA/API), pump 3 (dilution) and pump 4 (quench).
	6. Flush the system with water for 10 min, using 20 % of the maximum flow rate for every pump.

Procedure	Steps
	<ol style="list-style-type: none"><li>7. Switch all valves to the "Drain" position. Flush the system for 6 min as follows:<ul style="list-style-type: none"><li>■ Pump 1: 25 ml/min</li><li>■ Pump 2: 25 ml/min</li><li>■ Pump 3: 50 ml/min</li><li>■ Pump 4: 50 ml/min</li></ul></li><li>8. After 3 minutes, switch all valves to the "Product" position.</li><li>9. After 6 minutes, turn off the pumps.</li><li>10. For the IJM DuoCore NanoProducer, repeat steps 1 to 9 with the right mixing unit (unit 2).</li></ol>

## 5.10 Cleaning the system

All following cleaning procedures are basic suggestions. Depending on raw materials, formulations and extent of use of the device they may be adapted. Validation by the user as to whether the cleaning is sufficient or needs to be extended is strongly recommended.

- Materials**
- Deionized water
  - 0.1 M NaOH
  - Ethanol
  - Luer adapter
  - Syringe
  - Beaker

## 5.11 IJM cleaning procedure



**Note:** KNAUER recommends to carry out one of these cleaning procedures under the following circumstances:

- Change of IJMs
- Clogging of IJM

Cleaning the IJM manually is necessary when a blockage occurs. Indications are sudden increases in pressure of the API or lipid pump.

- Tool**
- Open-end wrench, size 5.5 mm

**Procedure****Steps**

1. Remove all screw connections of the intended IJM.
2. Connect a Luer adapter and a syringe on the lipid/ethanolic port of the IJM and close the API port with a blind plug (Fig. 16). Use a beaker to collect the waste below the open port.



**Fig. 16:** Manual cleaning of the IJM

3. Inject at least 3 ml of ethanol to remove any lipid residue.
4. Inject 3 ml of NaOH 0.1 M.
5. Inject 3 ml of deionized H<sub>2</sub>O.
6. Equilibrate with 3 ml of ethanol.
7. Repeat the procedure from steps 4 to 5 (ethanol step is not needed) by placing the blind plug on the outlet port of the IJM.
8. Repeat steps 4 to 5 by placing the syringe with a Luer adapter on the API port and a blind plug on the lipid port. Use a beaker to collect the waste of the open port.
9. Repeat the procedure from steps 4 - 5 by placing the blind plug on the outlet port of the IJM. Use a beaker to collect the waste of the open port.
10. If a blockage can not be removed with the above described procedure, remove the IJM from the threaded rods.
  - First remove the two screws by using the open-end wrench and remove all necessary IJMs.
  - Clean the IJM with isopropanol in an ultrasonic bath for at least 10 min.
  - Reinstall the IJMs and both screws.



## 5.12 Cleaning the full system



**Note:** KNAUER recommends to carry out this cleaning procedure under the following circumstances:

- Before starting to work with the system.
- At the end of a working day.
- Before short and long time storage.



**Note:** Before short or long time storage flush the system according to recommendation in section "10.4 Storing the device" on page 37. The flow rate for all pumps in all steps is 50 ml/min.

### Step 1

	Pump 1	Pump 2	Pump 3	Pump 4
<b>Solvent</b>	Ethanol	Deionized H <sub>2</sub> O	Deionized H <sub>2</sub> O	Deionized H <sub>2</sub> O
<b>Valve position</b>				
Drain	Flush system for 30 min			
Product	Flush system for 30 min			

### Step 2

	Pump 1	Pump 2	Pump 3	Pump 4
<b>Solvent</b>	Deionized H <sub>2</sub> O	Deionized H <sub>2</sub> O	Deionized H <sub>2</sub> O	Deionized H <sub>2</sub> O
<b>Valve position</b>				
Drain	Flush system for 30 min			
Product	Flush system for 30 min			

### Step 3

	Pump 1	Pump 2	Pump 3	Pump 4
<b>Solvent</b>	NaOH 0.1 M	NaOH 0.1 M	NaOH 0.1 M	NaOH 0.1 M
<b>Valve position</b>				
Drain	Flush system for 30 min			
Product	Flush system for 30 min			

### Step 4

Repeat step 2.

### Step 5

Repeat step 1.

## 5.13 Recommended flow rates for the system

The following table contains the recommended flow rate ranges for the encapsulation of mRNA in the standard mixing ratio 1:3:2 (lipid : mRNA (API + dilution) : quench).



**Note:** The maximum operating parameters for flow and pressure depend on the viscosity of the solvents, the customer application, the inner diameter of the capillaries used and the back pressure spike caused by switching the valves.

Higher flow rates are possible if the standard capillaries are replaced by capillaries with a larger inner diameter and without switching the valves.

Flow rate pump 1/pump 5 (Lipid) [ml/min]	Flow rate pump 2/pump 6 (API) [ml/min]	Flow rate pump 3/pump 7 (Dilution) [ml/min]	Flow rate pump 4/pump 8 (Quench) [ml/min]
30-130	20-80	90-300	80-250

## 6. Computer control

This chapter describes how to set up a LNP system in a local area network (LAN) and how a network administrator can integrate this LAN into your company network. The description applies to the operating system Windows® and all conventional routers.



**Note:** LNP devices from KNAUER only work with IP addresses, which have been assigned by IPv4. IPv6 is not supported.



**Note:** The devices of the IJM NanoProducer are set to fixed IP addresses. We recommend not to change the settings. In the standard configuration the system is connected to the network card of the computer via a switch. The computer features a second network card to integrate the computer in a company network. The following chapters describe the options of LAN settings in case you want to change the standard direct connection to the computer.



**Note:** When using PurityChrom® software, static IP addresses are needed (see section 6.3 on page 30).

### 6.1 Setting up LAN

The LAN between computer and system is preconfigured and no further configuration of the LAN is necessary.

#### Process

#### Procedure

1. Open the Control Panel on the computer and check the LAN properties.
2. Connect the switch to the devices and the computer.
3. Install the chromatography software.
4. Switch on the device and run the chromatography software.

#### Next steps

Integrate the computer into the company network (see section 6.2).

### 6.2 Integrating the computer into the company network

A network administrator can integrate the computer into your company network. In this case you use the second network card of the computer.

#### Prerequisites

- There is a patch cable for the connection.

#### Process

#### Procedure

1. Make sure that there is no overlap between the IP addresses of the first network card and the corporate network.
2. Use the patch cable to connect the second network card port to the company network.
3. Restart all devices, including the computer.

#### Result

The LAN is now integrated into the company network.

## 6.3 Setting IP addresses via software



**Note:** Check the IT security standards for your lab before intervening in the LAN settings.

**PurityChrom®** Static IP addresses are required to run the chromatography software PurityChrom®. For a comprehensive overview on how to set static IP addresses for PurityChrom®, refer to the document “PurityChrom® Installation Guide” on the PurityChrom® installation CD.

## 6.4 Connecting the pin header

To control one device through another, the pin header is used. To use remote control, you have to connect cables to the pin header. The single ports are used to exchange control signals.

- Prerequisites**
- The device is switched off.
  - The power plug is disconnected from the device.

- Tools**
- Depressor tool

### NOTICE

#### Electronic defect

Connecting cables to the multi-pin connector of a switched on device causes a short circuit.

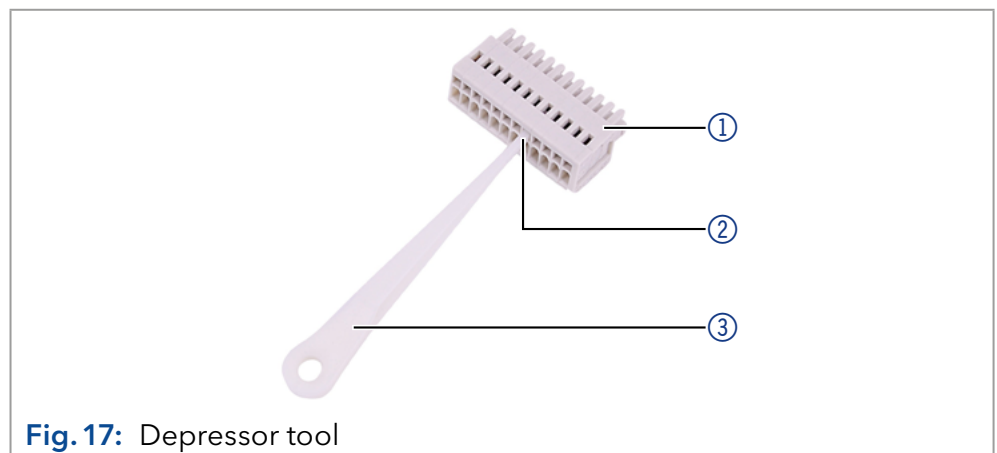
- Turn off the device before connecting cables.
- Pull the power plug.

### NOTICE

#### Electronic defect

Electrostatic discharge can destroy the electronics.

- Wear a protective bracelet against electrostatic discharge and ground.



**Fig. 17:** Depressor tool

**Process**

1. Insert the depressor tool ③ in an upper small opening at the front of the pin header ①.
2. Insert the cable into the opening ② underneath the inserted depressor tool
3. Pull out the depressor tool.

**Next steps** Check whether the cables are tightly attached. Press the pin header onto the connector. Finish the installation. Bring the device into operation.

## 7. Functionality tests



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

### 7.1 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:



### 7.2 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. Please contact the technical support in case of a request.

The Operation Qualification includes the following:

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

**Test intervals** To make sure that the system operates within the specified range, you should test the system 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 by a provider authorized by KNAUER (for a fee). For further information visit our website:



## 8. Troubleshooting

### 8.1 First measures

- Check all cables and fittings.
- Check all screw fittings.
- Check whether air has entered the supply lines.
- Check the device for leaks.
- Pay attention to system messages.

Further measures:

- Compare occurring errors with the list of possible errors (see below).
- Contact the Customer Support.

### 8.2 LAN

Go through the following steps if no connection can be established between the computer and the devices. After each step, check if the problem is solved. If the problem cannot be found, call technical support.

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



If no connection was established, test the following:

- Is the switch powered on?
  - Is the patch cable properly connected to the switch and the computer?
2. Check all connections:
    - Are the patch cables connected to the LAN ports and not the WAN port?
    - Are all cable connections between devices and switch correct?
    - Are the cables plugged in tightly?
  3. Restart the system in the following order:
    - Turn off all devices, the switch, and the computer.
    - Turn on the switch first and wait for it to successfully complete its self-test.
    - Turn on the devices and the computer.
  4. Replace the patch cable to the device which could not be connected.
  5. Make sure that the IP port of the device matches the port that is set in the chromatography software.

## 8.3 Possible problems and solutions



**Note:** If you have problems with the handling of a single device, refer to the troubleshooting section of the respective instructions.

Problem	Possible cause	Solution
Sudden overpressure on Lipid, API and/or dilution pump	Clogged IJM port	Cleaning of IJM (see section 5.11 on page 25).
	Clogged capillaries from pump pressure sensor to IJM	<ul style="list-style-type: none"> <li>Step by step investigation which capillary from pressure sensor to IJM is clogged.</li> <li>Cleaning or replacement of clogged capillary.</li> </ul>
Pressure higher than normal	Partly clogged IJM or capillary	<ul style="list-style-type: none"> <li>Cleaning of IJM (see section 5.11 on page 25).</li> <li>Step by step investigation which capillary from pressure sensor to IJM is clogged.</li> <li>Cleaning or replacement of clogged capillary.</li> </ul>
Pump flow lower than set flow	Clogged check valve	<ul style="list-style-type: none"> <li>Cleaning procedure check valve (see <a href="#">V7685 - BlueShadow Pump 80P instructions</a> page 53).</li> <li>Replacement of check valve.</li> </ul>
Pump flow higher than set flow	Pump works out of calibrated range	Contact Customer Support, possible recalibration of pump.
Pulsation of flow rate	Clogged check valve	<ul style="list-style-type: none"> <li>Cleaning procedure check valve (see <a href="#">V7685 - BlueShadow Pump 80P instructions</a> page 53).</li> <li>Replacement of check valve.</li> </ul>
No flow	Empty eluent	<ul style="list-style-type: none"> <li>Check the eluent reservoir.</li> <li>Check if the purge valve still open. Close purge valve.</li> </ul>
	Leakage	Check capillary connection and devices.
Communication error		Perform SOP System power up. If error still exists, contact the Customer Support.
Detected flow signal without flow	Flowmeter	<p>Autozero flowmeter (see <a href="#">Instruction Manual mini CORI-FLOW™ M1x series</a> on page 27).</p> <p><b>Note:</b> Wait at least 30 minutes after the pump stopped before starting the Autozero.</p>



## 9. Maintenance and care

### 9.1 Removing a leakage

**Prerequisites** The device has been switched off.

**Material** Cloth

**Procedure**

**Process**

1. Remove the leakage.
2. Dry the device with the cloth.
3. Confirm the error message via the chromatography software.

**Next step** Put the device back into operation.

### 9.2 Checking the fittings

**Tools** Torque wrench

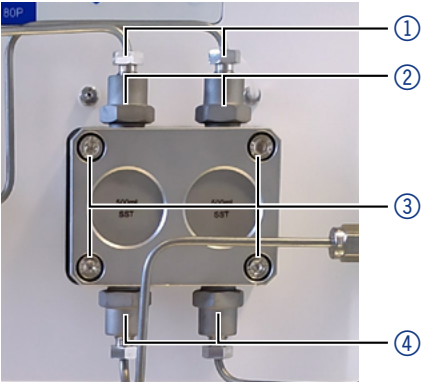
#### 9.2.1 Torque values of the system

Component	Torque
1/16" screw fitting on IJM, dilution and quench mixer	3.5 Nm
1/8" screw fitting on dilution and quench mixer and on pump head inlet	9.5 Nm
1/8" screw fitting on valves	5.0 Nm
Swagelok fitting	8.5 Nm

#### 9.2.2 Torque values of the pump head

Pump head, stainless steel	Torque
100 ml	15 Nm
250 ml	15 Nm
500 ml	12 Nm
1000 ml	12 Nm

### 9.2.3 Tightening the fittings

Process	Figure
<ol style="list-style-type: none"><li>1. Always tighten the outlet screws ② and the inlet screws ④ with a torque wrench.</li><li>2. Always hold the outlet fitting with a wrench when the capillary fitting ① is being tightened with a wrench.</li><li>3. Using an Allen wrench, screw in the opposite pairs of fastening screws ③ evenly and alternately to prevent the pump pistons on the inside from jamming.</li></ol>	 <p data-bbox="1002 683 1428 761"><b>Fig. 18:</b> Screw fittings on the pump head</p>

# 10. Transport and storage



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

## 10.1 Taking the device out of operation

**Prerequisite** The device has been switched off.

**Procedure**

**Process**

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

**Next steps** Disconnect all electrical connections. Remove the accessories and pack the device for transport or storage.

## 10.2 Packing the device

- Original packaging: Ideally you should use the original transport packaging.
- Lifting: Grab the unit only from below on the sides and lift it into the packaging. Do not hold onto front cover or leak tray, as these parts are loosely attached to the device.

## 10.3 Transporting the device

- Documents: If you want to return your device to KNAUER for repairs, enclose the „[Service request form and decontamination report](#)“ which can be downloaded from our website.
- Device data: For a secure transport, note the weight and dimensions of the device in chapter “11. Disposal” on page 38.

## 10.4 Storing the device

- Flushing solution: Pay attention that all hoses and capillaries have been filled with isopropanol before storage. To prevent algae formation, do not use pure water. KNAUER recommends isopropanol for long time storage. For short time storage (e.g. over weekends or between production runs) at least 70 % isopropanol or ethanol can be used.
- Seals: Close all inputs and outputs with cap fittings.
- Ambient conditions: The device can be stored under ambient conditions which are listed in chapter “12. Technical data” on page 50.

# 11. Disposal

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

## 11.1 AVV-Marking Germany

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

## 11.2 WEEE registration number



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

All distributors and importers are responsible for the disposal of old devices, as defined by the WEEE directive. 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.

## 11.3 Eluents and other operating materials

All eluents and other operating materials must 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.

## 12. Technical data

### 12.1 General system parameters

	SingleCore	DuoCore
Number of Impingement Jets Mixers	1	2
Number of pumps	4	8
Number of flow meter	4	8
Number of valves	1	2
Process connection inlet <sup>1</sup>	1/2" Tri-clamp (4 inlets)	1/2" Tri-clamp (A48029: 6 inlets, A48039XYZ: 8 inlets)
Process connection outlet <sup>1</sup>	1/2" Tri-clamp (2 outlets)	1/2" Tri-clamp (4 outlets)
Volumetric flow rate	up to 1 l/min (60 l/h) <sup>2</sup>	up to 2 l/min (120 l/h) <sup>2</sup>
Maximum operating pressure <sup>3</sup>	95 bar (1378 psi)	
Liquid temperature range	4 - 60 °C (39.2 - 140 °F)	
Hold-up volume <sup>4</sup>	A48028: 93 ml A48038XYZ: 94 ml	A48029: 165 ml A48039XYZ: 179 ml
Sound emission	The A-weighted emission sound pressure level at the operator's position is less than 70 dB(A) at any time during all foreseeable uses of this system.	
Software	CDS, 21 CFR part 11 and GAMP 5 compliant	

<sup>(1)</sup> different connections on request

<sup>(2)</sup> depends on IJM and viscosity of solvents

<sup>(3)</sup> depends on specific pump configuration and application

<sup>(4)</sup> inlet tubings of pumps are not considered

### 12.2 Technical parameters

	SingleCore	DuoCore
<b>Ambient conditions</b>		
Supported software package	PurityChrom® 6	
Temperature range	4 - 40 °C; 39.2 - 104 °F	
Air humidity	Below 90 % humidity (non-condensing)	
Interfaces	<b>Pump:</b> LAN, RS-232, pin header connectors; <b>Flow meter:</b> RS-232, FLOW-BUS™; <b>Valve drive:</b> LAN	

	SingleCore	DuoCore
Power supply	<b>Pump:</b> 100-240 V AC single phase, 50/60 Hz; <b>Flow meter:</b> 115/230 V AC single phase, 50/60 Hz 24 V DC Power supply; <b>Valve drive:</b> 115/230 V AC single phase, 50/60 Hz 24 V DC Power supply; <b>PC:</b> 100-240 V AC single phase, 50/60 Hz; <b>Monitor</b> (only for A48028/A48029): 100-240 V AC single phase, 50/60 Hz; <b>Network switch:</b> 100-240 V AC single phase, 50/60 Hz, 12 V DC Power supply	
Power consumption (per device)	<b>Pump:</b> maximum 320 W; <b>Flow meter:</b> 3 W; <b>Valve drive:</b> 65 W; PC: 1 000 W; <b>Monitor</b> (only for A48028/A48029): 380 W; <b>Network switch:</b> 50 W	
Dimensions (Width × Height × Depth)	<b>A48028:</b> 900 mm x 915 mm x 700 mm <b>A48038XYZ:</b> 900 mm x 915 mm x 800 mm	<b>A48029:</b> 1 000 mm x 1 290 mm x 700 mm <b>A48039XYZ:</b> 1 000 mm x 1 290 mm x 800 mm
Net weight (approx.)	150 kg	250 kg

## 12.3 Wetted materials



**Note:** For chemical compatibility of wetted materials see chapter “14. Chemical compatibility of wetted materials” on p. 45.

The materials of the wetted parts are subject to change without notice. Detailed information on the materials of the wetted parts are listed in the technical documentation and must be ordered separately.

The components of the LNP system contain the following wetted parts:

	Material	Description
Impingement Jets Mixer	Stainless steel	AISI 316L (1.4404)
Pumps	Stainless steel	AISI 316L (1.4404)
	Stainless steel	AISI 630 (1.4542/1.4548) <sup>1</sup>
	Polyetheretherketone	PEEK
	Aluminum oxide	Al <sub>2</sub> O <sub>3</sub>
	Graphite fiber reinforced polytetrafluoroethylene	GFP 55 HT (PTFE) <sup>1</sup>
	Hastelloy	Alloy C276 (EN 10088-3-2.4819) <sup>1</sup>

Perfluoroelastomere	FFKM
Ultra-high molecular weight polyethylen	UP30 <sup>2</sup>
Zirconium oxide	ZrO <sub>2</sub>

<sup>(1)</sup> for A48028/A48028V1/A48029

<sup>(2)</sup> for A48038XYZ/A48039XYZ

	Material	Description
<b>Valves</b>	Polyetheretherketone (Rotor seal)	PEEK
	Stainless steel DLC <sup>(3)</sup> (Stator)	AISI 318LN (1.4462)

<sup>(3)</sup> stainless steel, coated with diamond-like carbon

	Material	Description
<b>Flowmeters</b>	Stainless steel	AISI 316L (1.4404)

	Material	Description
<b>Capillaries, fittings &amp; gaskets</b>	Stainless steel	AISI 316L (1.4404)
	Stainless steel	AISI 316L (1.4435)
	Polyoxymethylene	POM <sup>(1)</sup>
	Ethylene propylene diene monomer rubber	EPDM

<sup>(1)</sup> for A48028/A48028V1/A48029

## 13. Reorders

The list of repeat orders is current at the time of publication. Deviations at a later time are possible. Use the enclosed packing list for reordering spare parts. If you have any questions regarding spare parts or accessories, please contact our Customer Support.

**Further information** Current information on spare parts and accessories can be found on the Internet at [www.knauer.net](http://www.knauer.net).

### 13.1 Device

Name	Order no.
Pump 80P (250 ml pump head sst)	APD30LA <sup>1</sup>
Pump 80P (500 ml pump head sst)	APD30MA <sup>1,2</sup>
Pump 80P (500 ml pump head sst)	APD31MA97 <sup>3</sup>
Valve Unifier VU 4.1	AWA01XA <sup>1,2</sup>
Valve Unifier VU 4.1	AWA01XA97 <sup>3</sup>
2Port MultiPos. valve V 4.1	AVT84AH <sup>1,2</sup>
2Port MultiPos. valve V 4.1 (EVT84AH97)	AVT84AH97 <sup>3</sup>

<sup>1</sup> A48029

<sup>2</sup> A48028

<sup>3</sup> A48038XYZ/A48039XYZ

### 13.2 Accessories and spare parts

	Name	Order no.
<b>Pumps</b>	Pump head (250 ml, sst)	A4021-1 <sup>1</sup>
	Pump head (500 ml, sst)	A4038-1 <sup>2</sup>
	Pump head (500 ml, sst)	A4038XA97 <sup>3</sup>
	Maintenance kit pump head E4021-1	ARH43 <sup>1</sup>
	Maintenance kit pump head E4037-1	ARH45 <sup>2</sup>
	Maintenance kit pump head E4037XA97	ARH51 <sup>3</sup>
	Piston rod 250 ml pump head	A1017
	Piston rod 500 ml pump head	A1478
	Set of gaskets 250 ml pump head	A1046 <sup>1</sup>
	Set of gaskets 500 ml pump head	A1479 <sup>1,2</sup>
	Set of gaskets 500 ml pump head (M1389V2)	A71200X97 <sup>3</sup>
	Check valve 250 ml pump head	A1122
	Check valve 500 ml pump head	A1080
<b>Valves</b>	Stator for 8 Port valve for EVT84AH	A205150 <sup>1,2</sup>
	Maintenance kit rotor seal for EVT84AH	ARV42 <sup>1,2</sup>
	Stator for 8 Port valve for EVT84AH97	A205150 <sup>3</sup>



	<b>Name</b>	<b>Order no.</b>
	Maintenance kit rotor seal for EVT84AH97	ARV42 <sup>3</sup>
<b>Mixer</b>	Impingement Jets Mixer No. 6 Certified	A5886
	Dilution and Quench Mixer Certified	A5833
<b>Capillaries - SingleCore</b>	Pump head inlet set Tri-clamp 1/2" for A48028	A71020
	Capillary set pressure sensor of pumps to flowmeters for A48028	A71021
	Capillary set flowmeters to IJM, dilution and quench mixer for A48028	A71022
	Capillary set valve 1 and system outlets of A48028	A71023
	Capillary connector 1 and 2 from pump head outlet to pressure sensor for pump 80P	A1075 <sup>1,2</sup>
	Capillary pressure sensor venting	G2704
	Kit to connect a tubing ID 12 to a 1/2" Tri-clamp consists of: 1 x Mini hose adapter 1 x Flat clamp gasket (EPDM), 1 x Clamp end cap	A71019 <sup>1,2</sup>
	Pump head inlet set Tri-clamp 1/2" for A48038XYZ	A71020X97
	Capillary set pressure sensor of pumps to flowmeters for A48038XYZ	A71021X97
	Capillary set flowmeters to IJM, dilution and quench mixer for A48038XYZ	A71022X97
	Capillary set valve 1 and system outlets of A48038XYZ	A71023X97
	Capillary connector 1 and 2 from pump head outlet to pressure sensor for pump 80P	A1075X97 <sup>3</sup>
	Capillary pressure sensor venting	A2704X97 <sup>3</sup>
	Kit to connect a tubing ID 12 to a 1/2" Tri-clamp consists of: 1 x Mini hose adapter, 1 x Flat clamp gasket (EPDM), 1 x Clamp end cap	A71019X97
<b>Capillaries - DuoCore</b>	Pump head inlet set Tri-clamp 1/2" for A48029, for pump 1 or 2 or 5 or 6 (lipid or API pump)	A71030
	Pump head inlet set Tri-clamp 1/2" for A48029 for pump 3 and 4 or 7 and 8 (dilution and quench pump)	A71031
	Capillary set pressure sensor of pumps to flowmeters for A48029 left or right unit for pumps P1, P2, P3, P4 or for pumps P5, P6, P7, P8	A71032
	Capillary set flowmeters to IJM, dilution and quench mixer for A48029 left or right unit	A71033
	Capillary set valve 1 and system outlets of A48029 left unit	A71034
	Capillary set valve 2 and system outlets of A48029 right unit	A71035
	Capillary connector 1 and 2 from pump head outlet to pressure sensor for pump 80P	A1075 <sup>1,2</sup>

Name	Order no.
Capillary pressure sensor venting	G2704 <sup>1,2</sup>
Kit to connect a tubing ID 12 to a 1/2" Tri-clamp Consists of: 1 x Mini hose adapter 1 x Flat clamp gasket (EPDM), 1 x Clamp end cap	A71019 <sup>1,2</sup>
Pump head inlet set Tri-clamp 1/2" for A48039X97	A71030X97
Capillary set pressure sensor of pumps to flowmeters for A48039X97 left or right unit for pumps P1, P2, P3, P4 or for pumps P5, P6, P7, P8	A71032X97
Capillary set flowmeters to IJM, dilution and quench mixer for A48039X97 left or right unit	A71033X97
Capillary set valve 1 and system outlets of A48039X97 left unit	A71034X97
Capillary set valve 2 and system outlets of A48039X97 right unit	A71035X97
Capillary connector 1 and 2 from pump head outlet to pressure sensor for pump 80P	A1075X97 <sup>3</sup>
Capillary pressure sensor venting	A2704X97 <sup>3</sup>
Kit to connect a tubing ID 12 to a 1/2" Tri-clamp consists of: 1 x Mini hose adapter, 1 x Flat clamp gasket (EPDM), 1 x Clamp end cap	A71019X97 <sup>3</sup>

<sup>1</sup> A48029<sup>2</sup> A48028<sup>3</sup> A48038XYZ/A48039XYZ

# 14. Chemical compatibility of 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 of the manufacturer.

## 14.1 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. Please note that higher temperatures can significantly affect the stability of different materials.

## 14.2 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 thermally (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). PFA is suitable for ultrapure applications, 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 thermic stability. It can even substitute metal in many cases. POM-H-TF is a combination of PTFE fibres 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. Maximum operating Temperature is 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. Maximum operating temperature: 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 sodium 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.

**Polychlorotrifluoroethylene (PCTFE, Kel-F®)**

The semi-crystalline thermoplastic material is plasticizer-free 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, and 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.

## 14.3 Non-metals

**Diamond-like carbon (DLC)**

This material 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.

**Alumina (Al<sub>2</sub>O<sub>3</sub>)**

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<sub>2</sub>)**

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 fibres and isolates in high oxidizing conditions and at high temperatures. Mineral wool is valid as commonly inert against organic solvents and acids.

**Glass, glass fibre, 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.

## 14.4 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 must 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 chlorine, formic acid, acetic acid and saline solutions.

**Titanium, titanium alloy (TiAl6V4)**

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.

## Installation Qualification (IQ) for a System

	Created	Reviewed	Approved
Function			
Name			
Date			
Signature			

### 0. Customer pre-approval

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

Company name:

Name	Function	Reviewed & approved	Date	Signature

## Installation Qualification (IQ) for a System

### 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 system

### 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 52.

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. System data

System name	
Project name*	
System description	
Installation location	
Comments	

\* made up of customer/order number

### 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



## Installation Qualification (IQ) for a System

### 7. Installation Qualification Tests

Test	Description	Specification	Passed	Failed	N/A	Comment/LOR No.
1	Identify the system.	The article number and project number (made up of customer/order number) on the label attached to the skid frame matches the article number and customer/order number on the packing list.  For systems without frame, the name of the system on the delivery documentation matches the name on the delivery note.				
2	Check the system for transport damage.	No transport damage is observed.				
3	Check the scope of delivery.	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 P&ID, list of piping, list of devices, instrument layout diagram, if applicable.	The equipment is labeled correctly.				
6	Ensure that the installation site is suitable according to either the user instructions or pre-installation guide.	The installation site matches the specifications in the user instructions.				
7	Connect all loose parts (e.g. capillaries, tubings) and mount capillaries according to P&ID or other installation documentation, if applicable.	The system is fully assembled and ready to use.				
8	Connect the devices to the power supply and switch the system on.	The devices start (operating noise). The power LEDs or the displays light up.				

## Installation Qualification (IQ) for a System

### 8. List of rectifications (LOR)

LOR No.	Test No.	Type of deviation*	Description of the deviation	Action plan	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 System

### 9. List of changes to the document

Revision no.	Description of change	Additional information	Date/signature

## Installation Qualification (IQ) for a System

### 10. Certificate and approval

A KNAUER employee or an employee 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 were 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

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### Installation Qualification (IQ) for a System

#### Appendix: List of supporting documents

No.	Test no.	Description

Science with Passion



Latest KNAUER instructions online:  
[www.knauer.net/library](http://www.knauer.net/library)

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