Installation Qualification (IQ) for a Device

	Created	Reviewed	Approved
Function	Technical Editor	Engineering	Head of Quality
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Date	23/02/2023	23/02/2023	23/02/2023
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
		☐		
		☐		
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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			
Installation location			

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

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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 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 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.	☐	☐	☐	
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.	☐	☐	☐	

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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

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9. List of changes to the document

Revision no.	Description of change	Additional information	Date/signature

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10. Certificate and appoval

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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Appendix: List of supporting documents

No.	Test no.	Description