

Installation Qualification (IQ)

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.

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

Instructions

Any deviations to the specifications and problems encountered during installation have to be recorded as comments in the document. In addition, all courses of action undertaken to resolve the problems and remove the deviations have to be recorded as comments in the section „Comments/recommendations“.

If certain items in the report are not applicable, this has to be indicated by 'n/a' (not applicable) in the table. Larger sections that are not used have to be crossed out (diagonal line through them), marked with 'n/a' and date (DD-MM-YYYY) and signed.

All required documents have to be completed during the installation (of the system).

The document will be reviewed by a person authorized by the laboratory director. The inspection must be documented with the date of the inspection (DD-MM-YYYY).

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

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.

Device data

Device name		Product number	
Serial number		Firmware version:	
Location			
Manufacturer/ supplier	KNAUER Wissenschaftliche Geräte GmbH Hegauer Weg 38, 14163 Berlin	Phone : +49 30 809727-111 E-Mail: support@knauer.net	
KNAUER agent			

Customer data

Customer		Customer number	
Company			
Contact person			
Address			
Postal code		City	
Phone		E-Mail	
Location		Place of installation	

Packing list, list of hardware and software

Please compare the article numbers listed on the packing list to the provided products. Note deviations here:

Position	Device/accessory	Order number	Comment

Initial startup

Step	Action	Result	Passed	Failed	Comment
1	Identify the device.	The device is correct.			
2	Check the device for transport damage.	No transport damage is observed.			
3	Check the scope of delivery.	The scope of delivery is complete.			
4	Connect the device to the power supply.	The device is connected.			
5	Connect all loose parts (e.g. capillaries, tubings, measuring head).	The device is fully assembled and ready to use.			
6	Switch on the device.	The device starts (operating noise). The power LED or the display lights up.			

Comments/recommendations

Change list

No.	Description of deviation	Additional information	Date/signature
1			
2			
3			

Certificate

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 a person who is authorized by the customer's head of laboratory. 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 with date and signature.

Customer _____
 Name (capital letters) Date Signature

KNAUER agent _____
 Name (capital letters) Date Signature