

The following IQ / OQ is intended to be a guideline, local IQ / OQ procedures can vary depending on application and items stored in the Gram BioLine cabinet.

Deviations from the specifications dictated in the PQ are to be reported in the deviation report.

The IQ / OQ is concluded if all criteria of acceptance are approved and the possible deviations are rectified or accepted.

This IQ / OQ is intended for the following product series:

BioUltra

Customer:

Location of installation:

Model:

Serial number:

Item number - manual:

Status of operation:

- Active
- Inactive

Name of distributor:

Warranty:

Start: _____

End: _____

Instructions on use to starting the cabinet:

- 1. Training of the responsible party Date: _____ By: _____
- 2. Operational test of the cabinet Date: _____ By: _____
- 3. Responsible party _____ Tel: _____

Instructions to users:

The responsible party is trained in use of the cabinet in reference to the user manual

- General use of cabinet
- Service & maintenance
- The cabinet was delivered without defects/damage.
The cabinet started as specified in the user manual

Objections to the mentioned:

Set values:

- Setpoint temperature _____ °C

Local alarm settings

- High temperature alarm _____ °C
- Low temperature alarm _____ °C

External alarm settings

(See voltage free contact in user manual)

- High temperature alarm _____ °C
- Low temperature alarm _____ °C

Factory settings:

Model / Setpoint temp.		LHL	LLL	EHL	ELL
UL 570	-86 °C	+25 °C	-99 °C	+25 °C	-99 °C

Date: _____ Name of trained user: _____ Signature: _____ Name of instructor: _____ Signature: _____

Model: _____ SN: _____

Installation Qualification - IQ

ID	Description of installation	Reference in manual	Comply		Attachmet	Notes
			YES	NO		
I-1	Ensure the cabinet is installed indoors.	Page 6				
I-2	Ensure the cabinet is installed in a sufficiently dry/ventilated area.	Page 6				
I-3	Ensure the cabinet is not in direct contact with sunlight or other heat sources.	Page 6				
I-4	Ensure that the ambient operating temperature is within the allowed range.	Page 6				
I-5	Ensure that the cabinet is not installed in a corrosive environment.	Page 6				
I-6	Ensure that the protective film on the cabinet is removed.	Page 6				
I-7	Ensure that the cabinet is cleaned.	Page 6				
I-8	Ensure that the cabinet has stood upright for 24 hours if it has lain down.	Page 6				
I-9	Ensure that at least two legs are deployed when cabinet is in position.	Page 6				
I-10	Ensure that the cabinet is levelled.	Page 6				
I-11	Ensure that the cabinet has been visually inspected.	Page 6				
I-12	Ensure that the cabinet is minimum 50mm from the back wall.	Page 7				
I-13	Ensure that there is minimum a gap of 30mm between cabinets.	Page 7				
I-14	Ensure that the holes in the front of the cabinet are not covered.	Page 7				
I-15	Ensure that electrical appliances are not being operated in the cabinet.	Page 7				
I-16	Ensure that the interior fittings are mounted in accordance with instructions.	Page 8				

Model: _____ SN: _____

Installation Qualification - IQ

ID	Description of installation	Reference in manual	Comply		Attachmet	Notes
			YES	NO		
I-17	Ensure that the outer door operates in accordance with the intructions.	Page 9				
I-18	Ensure that the inner doors can operate in accordance with the instructions.	Page 10				
I-19	Ensure the correct electrical connection (compare local values with type/nr plate)	Page 12				
I-20	Ensure that the power cord is secured in the terminal box with hanger.	Page 13				
I-21	Mark power cord with: "Do not separate when energized".	Page 13				
I-22	Mark power cord with: "Do not separate when energized".	Page 13				

Model: _____ SN: _____

Operation Qualification - OQ

ID	Description of operation	Reference in manual BCII	Comply		Attachmet	Notes
			YES	NO		
O-1	Turn on the cabinet - Display test (software version and variant).	Page 16				
O-2	Set/adjust set-point temperature.	Page 16				
O-3	Set/adjust LHL - Upper alarm limit (local).	Page 19				
O-4	Set/adjust LLL - Lower alarm limit (local).	Page 19				
O-5	Set/adjust LHd - delay for upper alarm limit (local).	Page 20				
O-6	Set/adjust LLd - delay for lower alarm limit (local).	Page 20				
O-7	Activate / deactivate bU - acoustic alarms (local).	Page 21				
O-8	Set/adjust EHL - Upper alarm limit (external).	Page 22				
O-9	Set/adjust ELL - Lower alarm limit (external)	Page 22				
O-10	Set/adjust EHd - delay for upper alarm limit (external).	Page 23				
O-11	Set/adjust ELd - delay for lower alarm limit (external).	Page 23				
O-12	Activate / deactivate bU - acoustic alarms (external).	Page 24				
O-13	Select reference sensor for the display (A or E).	Page 27				

Model: _____ SN: _____

Deviation Report

Deviations to the criteria of acceptance are to be documented in the deviation report. A separate deviation report shall be made for each deviation. Mark the entry with the relevant “-ID” specified in the left column in the test specifications.

-ID: _____

Description of deviation:

Extent to which the deviation has been alleviated:

Additional notes:

Person responsible for test:

Name: _____

Date: _____

Company: _____

Signature: _____

Person responsible for verification of test:

Name: _____

Date: _____

Company: _____

Signature: _____

Model: _____ SN: _____

Approval of test results - Installation Qualification (IQ)

- The steps in the Installation Qualification - IQ were completed with positive results
- The steps in the Installation Qualification - IQ were completed with negative results

ID of steps with negative results: _____

Approval of test results - Operation Qualification (OQ)

- The steps in the Operation Qualification - OQ were completed with positive results
- The steps in the Operation Qualification - OQ were completed with negative results

ID of steps with negative results: _____

Customer / Responsible party _____

Trainer / Responsible party _____

Stamp & Signature _____

Stamp & Signature _____

Tel. _____

Tel. _____

E-mail _____

E-mail _____

Location & Date _____

Location & Date _____

Model: _____ SN: _____

NOTES:

Lined area for handwritten notes.

Model: _____ SN: _____