

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:

### **BioCompact / BioCompact II**

Revision: 10/10/2017\_001

Customer:

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Location of installation:

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Model:

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Serial number:

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Item number - manual:

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Status of operation:

- Active
- Inactive

Name of distributor:

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Warranty:

Start: \_\_\_\_\_

End: \_\_\_\_\_

Model: \_\_\_\_\_ SN: \_\_\_\_\_

**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
RF	-20 °C	+25 °C	-35 °C	+25 °C	-35 °C
RR	+5 °C	+25 °C	0 °C	+25 °C	0 °C

Date: \_\_\_\_\_ Name of trained user: \_\_\_\_\_ Signature: \_\_\_\_\_ Name of instructor: \_\_\_\_\_ Signature: \_\_\_\_\_

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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 4				
I-2	Ensure the cabinet is installed in a sufficiently dry/ventilated area.	Page 4				
I-3	Ensure the cabinet is not in direct contact with sunlight or other heat sources.	Page 4				
I-4	Ensure that the ambient operating temperature is within the allowed range.	Page 4				
I-5	Ensure that the cabinet is not installed in a corrosive environment.	Page 4				
I-6	Ensure that the protective film on the cabinet is removed.	Page 4				
I-7	Ensure that the cabinet is cleaned.	Page 4				
I-8	Ensure that the cabinet has stood upright for 24 hours if it has lain down.	Page 4				
I-9	Ensure that the cabinet is levelled if it is equipped with legs.	Page 4				
I-10	Ensure a level surface if the cabinet is equipped with wheels/casters.	Page 4				
I-11	- If equipped with wheels/casters - Ensure wheels/casters are locked after positioning	Page 4				
I-12	- If equipped with drawers / glass door - Ensure that tilt-bracket is mounted.	Page 5				
I-13	Ensure that the cabinet is maximum 75mm from the back wall.	Page 6				
I-14	Ensure that there is minimum a gap of 30mm between cabinets.	Page 6				
I-15	Ensure that the top of the cabinet is not covered.	Page 6				
I-16	Ensure that electrical appliances are not being operated in the cabinet.	Page 6				

Model: \_\_\_\_\_ SN: \_\_\_\_\_

## Installation Qualification - IQ

ID	Description of installation	Reference in manual	Comply		Attachmet	Notes
			YES	NO		
I-17	Ensure connection from voltage-free contact to external monitoring system (optional).	Page 7				
I-18	Ensure the correct set-point for the low temperature protection (if applicable).	Page 8				
I-19	Ensure the correct electrical connection (compare local values with type/nr plate).	Page 9				
I-20	Ensure that the power cord is secured in the terminal box with hanger.	Page 9				
I-21	Mark power cord with: "Do not separate when energized".	Page 9				

Model: \_\_\_\_\_ SN: \_\_\_\_\_

Please note: Page references to the manual are dependent on the model in question.

### Operation Qualification - OQ

ID	Description of operation	Reference in manual BCII	Reference in manual BC	Comply		Attachmet	Notes
				YES	NO		
O-1	Turn on the cabinet - Display test (software version and variant).	Page 10	Page 26				
O-2	Set/adjust set-point temperature.	Page 10	Page 26				
O-3	Set/adjust LHL - Upper alarm limit (local).	Page 13	-				
O-4	Set/adjust LLL - Lower alarm limit (local).	Page 13	-				
O-5	Set/adjust LHd - delay for upper alarm limit (local).	Page 14	-				
O-6	Set/adjust LLd - delay for lower alarm limit (local).	Page 14	-				
O-7	Activate / deactivate dA - door alarm (local).	Page 15	Page 29				
O-8	Set/adjust dAd - delay for door alarm (local).	Page 15	Page 29				
O-9	Activate / deactivate bU - acoustic alarms (local).	Page 16	Page 30				
O-10	Set/adjust EHL - Upper alarm limit (external).	Page 17	-				
O-11	Set/adjust ELL - Lower alarm limit (external).	Page 17	-				
O-12	Set/adjust EHd - delay for upper alarm limit (external).	Page 18	-				
O-13	Set/adjust ELd - delay for lower alarm limit (external).	Page 18	-				
O-14	Activate / deactivate dA - door alarm (external).	Page 19	Page 31				
O-15	Set/adjust dAd - delay for door alarm (external).	Page 19	Page 31				
O-16	Activate / deactivate bU - acoustic alarms (external).	Page 20	Page 32				
O-17	Set/adjust defrost cycles per 24 hours (factory setting: 4).	Page 22	Page 34				
O-18	Select reference sensor for the display (A or E).	Page 23	-				

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:

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Extent to which the deviation has been alleviated:

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Additional notes:

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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: \_\_\_\_\_

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Model: \_\_\_\_\_ SN: \_\_\_\_\_

