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Biostorage you can depend on

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:

bioline

BioUltra

Rev.: 11102017-001

Customer:	
Location of installation:	
Model:	
Serial number:	
ltem number - manual:	
Status of operation:	
○ Active	
○ Inactive	
Name of distributor:	
Warranty:	
Start:	
End:	

SN:

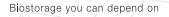
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Instructions on use to starting	g the c	abinet:							
1. Training of the responsible party	Date:			Ву:					
2. Operational test of the cabinet	Date:			By:					
3. Responsible party	Tel:								
Instructions to users: The responsible party is trained in us	se of the	cabinet in r	eference to	the user i	manual				
O General use of cabinet			Object	ions to th	e mentio	ned:			
O Service & maintenance									
O The cabinet was delivered without The cabinet started as specified		0							
Set values:		Factory s	ettinas:						
O Setpoint temperature	°C	Model /	ottings.						
Local alarm settings		Setpoint te	emp.	LHL	LLL	EHL	ELL		
O High temperature alarm	_ °C	UL 570	-86 °C	+25 °C	-99 °C	+25 °C	-99 °C		
O Low temperature alarm	°C								
External alarm settings (See voltage free contact in user manual)									
O High temperature alarm	°C								
O Low temperature alarm	_ °C								
Date: Name of trained user:	Signatu	re:	Name of	instructo	or: S	Signature	:		
	Model:			SN:					

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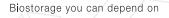
Ins	tallation Qualification -	IQ					
ID	Description of installation	Reference in manual	Cor YES	nply NO	Attachmet	Notes	
I-1	Ensure the cabinet is installed indoors.	Page 8					
I-2	Ensure the cabinet is installed in a sufficiently dry/ventilated area.	Page 8					
I-3	Ensure the cabinet is not in direct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

Model:

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SN: _____

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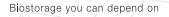
Ins	tallation Qualification -	IQ					
ID	Description of installation	Reference in manual	Cor YES	nply NO	Attachmet	Notes	
I-17	Ensure that the outer door operates in accordance with the intructions.	Page 11					
I-18	Ensure that the inner doors can operate in accordance with the instructions.	Page 12					
I-19	Ensure the correct electrical connection (compare local values with type/nr plate)	Page 14					
I-20	Ensure that the power cord is secured in the terminal box with hanger.	Page 14					
I-21	Mark power cord with: "Do not separate when energized".	Page 14					
I-22	Mark power cord with: "Do not separate when energized".	Page 14					

Model:_____

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Ор	eration Qualification -	OQ					
ID	Description of operation	Reference in manual BCII	Cor YES	nply NO	Attachmet	Notes	
O-1	Turn on the cabinet - Display test (software version and variant).	Page 15					
0-2	Set/adjust set-point temperature.	Page 15					
O-3	Set/adjust LHL - Upper alarm limit (local).	Page 18					
O-4	Set/adjust LLL - Lower alarm limit (local).	Page 18					
O-5	Set/adjust LHd - delay for upper alarm limit (local).	Page 19					
O-6	Set/adjust LLd - delay for lower alarm limit (local).	Page 19					
O-7	Activate / deactivate bU - acoustic alarms (local).	Page 20					
O-8	Set/adjust EHL - Upper alarm limit (external).	Page 21					
O-9	Set/adjust ELL - Lower alarm limit (external)	Page 21					
O-10	Set/adjust EHd - delay for upper alarm limit (external).	Page 22					
O-11	Set/adjust ELd - delay for lower alarm limit (external).	Page 22					
O-12	Activate / deactivate bU - acoustic alarms (external).	Page 23					
O-13	Select reference sensor for the display (A or E).	Page 24					

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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:		Person responsible for verification of test:
Vame:		Name:
Date:		Date:
Company:		Company:
Signature:		Signature:
	Model:	SN:

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Approval of test results - Installation Qualification (IQ))
The steps in the Installation Qualification - IQ were completed	I with positive results
C The steps in the Installation Qualification - IQ were completed	I 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
O The steps in the Operation Qualification - OQ were completed with negative results
ID of steps with negative results:

Trainer / Responsible party

Stamp & Signature		Stamp & Signature	
Tel.		Tel.	
E-mail		E-mail	
Location & Date		Location & Date	
	Model:	SN:	
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NOTES:		
	Model:	SN:
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