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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

BioBlood

Customer:

Location of installation:

Model:

Serial number:

Item number - manual:

Status of operation:

○ Inactive

Name of distributor:

Warranty:

Start:

End: _____

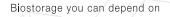
Model:

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Instructions on use to startin	g the cabinet:		
1. Training of the responsible party	Date:	Ву:	
2. Operational test of the cabinet	Date:	Ву:	
3. Responsible party		Tel:	
Instructions to users: The responsible party is trained in us	se of the cabinet in refe	rence to the user manual	
O General use of cabinet		Objections to the mentioned:	
O Service & maintenance			
 The cabinet was delivered witho The cabinet started as specified 			

Set values:

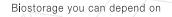
			Factory set	tings:				
 Setpoint Local alarm 	temperature	°C	Model / Setpoint terr	ıp.	LHL	LLL	EHL	ELL
-	nperature alarm	∘C	RF / BF	-20 °C	+25 °C	-35 °C	+25 °C	-35 °C
O Low tem	perature alarm	°C	EF/PF 425	-40 °C	+25 °C	-60 °C	+25 °C	-60 °C
External ala	arm settings		EF/PF 6XX	-35 °C	+25 °C	-45 °C	+25 °C	-45 °C
	e contact in user manual)		ER	+5 °C	+25 °C	-5 °C	+25 °C	-5 °C
O High tem	nperature alarm	°C	RR	+5 °C	+25 °C	0°C	+25 °C	0 °C
O Low tem	perature alarm	°C	BR	+4 °C	+6 °C	+2 °C	+25 °C	0 °C
Date:	Name of trained user:	Signatu	re:	Name of	instructo		Signature	:
/\ ∕\ bic	bline							



Installation Qualification - IQ							
ID	Description of installation	Reference in manual	Cor YES	mply NO	Attachmet	Notes	
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 con- tact with sunlight or other heat sources.	Page 4					
I-4	Ensure that the temperature operating range is correct.	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. (applicable to 500, 6xx, 1270/1400).	Page 6					
I-16	Ensure that the holes in the front of the cabinet are not covered.	Page 6					

Model:______ SN:_____

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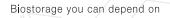


Installation Qualification - IQ						
ID	Description of installation	Reference in manual	Cor YES	nply NO	Attachmet	Notes
I-17	Ensure that electrical appliances are not being used in the cabinet.	Page 6				
I-18	Ensure connection from voltage-free contact to external monitoring system (optional).	Page 7				
I-19	Ensure the correct set-point for the low temperature protection (if applicable).	Page 8				
I-20	Ensure the correct electrical connection (compare local values with type/nr plate).	Page 9				
I-21	Ensure that the power cord is secured in the terminal box with hanger.	Page 9				
I-22	Mark power cord with: "Do not separate when energized".	Page 9				

Model:

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SN: _____



ID	Description of operation	Reference	Cor	nply	Attachmet	Notes	
		in manual BCII	YES	NO			
O-1	Turn on the cabinet - Display test (software version and variant).	Page 10					
0-2	Set/adjust set-point temperature.	Page 10					
O-3	Set/adjust LHL - Upper alarm limit (local).	Page 15					
0-4	Set/adjust LLL - Lower alarm limit (local).	Page 15					
0-5	Set/adjust LHd - delay for upper alarm limit (local).	Page 16					
0-6	Set/adjust LLd - delay for lower alarm limit (local).	Page 16					
0-7	Activate / deactivate dA - door alarm (local).	Page 17					
O-8	Set/adjust dAd - delay for door alarm (local).	Page 17					
0-9	Activate / deactivate bU - acoustic alarms (local).	Page 18					
O-10	Set/adjust EHL - Upper alarm limit (external).	Page 19					
O-11	Set/adjust ELL - Lower alarm limit (external).	Page 19					
0-12	Set/adjust EHd - delay for upper alarm limit (external).	Page 20					
O-13	Set/adjust ELd - delay for lower alarm limit (external).	Page 20					
0-14	Activate / deactivate dA - door alarm (external).	Page 21					
O-15	Set/adjust dAd - delay for door alarm (external).	Page 21					
O-16	Activate / deactivate bU - acoustic alarms (external).	Page 22					
O-17	Set/adjust defrost cycles per 24 hours (factory setting: 4).	Page 24					
O-18	Select reference sensor for the display (A or E).	Page 25					

Model:

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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:
Name:		Name:
Date:		Date:
Company:		Company:
Signature:		Signature:
	Model:	SN:

Q&OQ Gram BioLine - Page 7	Biostorage you can depend on
Approval of test results - Installation Qualification (IQ)	
O The steps in the Installation Qualification - IQ were completed with	positive results
O 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:

Trainer / Responsible party

Stamp & Signature		Stamp & Signature	
 Tel.		Tel.	
E-mail		E-mail	
Location & Date		Location & Date	
0	Model:	SN:	
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	Q Gram BioLine - Page 8	GRAM
	Gram BioLine - Page o	Biostorage you can depend on
NOTES:		
NOTEO.		
	Model:	SN:
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Customer:	Location of installation:	_
Model: S	SN: Item number: (manual)	_
<text></text>	Person responsible for the cabinet: Name: Date: Signature: Person responsible for test: Name: Date: Company: Signature: Person responsible for verification of test: Name: Company: Date: Date: Company: Date: Company: Signature: Test duration: Initation (date/time): Conlusion (date/time):	-
	Model: SN:	

Biostorage you can depend on

Name lis	st - Persons involved in th	e test procedure and subsequer	nt report	
Date	Name	Company	Signature	

Model:

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SN:_____

Biostorage you can depend on

Deviations from the specifications dictated in the PQ, are to be reported in the deviation report. The PQ is concluded if all criteria of acceptance are approved and the possible deviations are rectified or accepted.

Meas	urement - Prerequisites				
ID	DESCRIPTION			ACCE YES	PTED
P-1	The cabinet must be empty while cond such as drawers, shelves etc. Attachment: Notes:	ducting tests, ie without in	terior fittings		
P-2	The measurements must be conducted measured in air with thermocouples or Attachment: Notes:		0068-3-5,		
P-3	The positioning of the sensors in the c sketch and/or a photograph. Attachment: Notes:	abinet must be documen	ted with a		
Cor	Name:	Signature:	Approved (Yes / No):	Date:	
Inspected /	verified by:				

Model:

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Deviations from the specifications dictated in the PQ, are to be reported in the deviation report. The PQ is concluded if all criteria of acceptance are approved and the possible deviations are rectified or accepted.

Meas	urement - Prerequisites			
ID	DESCRIPTION			CEPTED
			YES	S NO
P-4	Measurements made during the PQ tests attached to the PQ.	s must be documented and		
	Attachment:			
	Notes:			
P-5	Specify setpoint temperature:	_ °C		
	Specify the ambient temperature:	_ °C		
	Attachment:			
	Notes:			
P-6	Allowed temperature fluctuations - Select	t the tolerance, according to the n	nodel being	
	tested. Find model-specific temperature fluctuations	in appendix.		
	Tolerance: +/ K			
	Attachment:			
	Notes:			
	Name:	Signature: Ap	proved Date:	

Conducted by:			
Inspected / verified by:			
	Model: _	SN:	
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\mathbf{PQ} Performance Qualification - Page 5

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Deviations from the specifications dictated in the PQ, are to be reported in the deviation report. The PQ is concluded if all criteria of acceptance are approved and the possible deviations are rectified or accepted.

Meas	urement	: - Temperature s	tabilization			
ID	DESCRIPTIO	NC			ACCE YES	PTED NO
P-7	the cabined The tempe working sp When the s setpoint ter Duration: _	irements throughout the c ne PQ.	nust be stabilized - where aintained the same tempe nt ordinary operation of th mperature specified in P-	e all the points in the erature. ne cabinet at the -5.		
P-8	Are the me ? Attachment Notes:	easurements inside the allo	owed temperature fluctua	tions specified in P-6		
Cor Inspected /	nducted by: verified by:	Name:	Signature:	Approved (Yes / No):	Date:	
		Model	:	SN:		

$-\mathbf{Q}$ Performance Qualification - Page 6

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Deviations from the specifications dictated in the PQ, are to be reported in the deviation report. The PQ is concluded if all criteria of acceptance are approved and the possible deviations are rectified or accepted.

Meas	urement	- Door openir	ng test			
ID	DESCRIPTIC	N			ACCE YES	PTED
P-9	inside the c The tempe the working setpoint ter When the s	cabinet subsequently rature inside the cabir g space have reached mperature is specified system is stable, oper irements, throughout ed the PQ.	after a door opening. net must be stabilized and maintained the s i in P-5. n the door at 90° for 60			
P-10		net, been achieved wi	thin the set time-frame	ared in the absolute centre		
Cor	nducted by:	Name:	Signature:	(Yes / No):	Date:	
Inspected /	verified by:					

Model:

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Deviations from the specifications dictated in the PQ, are to be reported in the deviation report. The PQ is concluded if all criteria of acceptance are approved and the possible deviations are rectified or accepted.

Meas	urement	- Pull-down				
ID	DESCRIPTIC	DN			ACCE YES	PTED NO
P-11	cabinet to re The initial ter The tempera When the sy		re specified in P-5. ace is the ambient temperati t be stabilized in all points of power to the cabinet.	ure specified in P-5. the working space.		
P-12	measured i the append Duration:	riteria been met?	•			
Cor Inspected /	nducted by: verified by:	Name:	Signature:	Approved (Yes / No):	Date:	
Λ		Model:		SN:		

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Deviations from the specifications dictated in the PQ, are to be reported in the deviation report. The PQ is concluded if all criteria of acceptance are approved and the possible deviations are rectified or accepted.

Meas	urement - Hold-over				
ID	DESCRIPTION			ACCE YES	PTED NO
P-13	The test is intended to provide substantiati inside the cabinet to reach the terminal ten Ambient temperature and setpoint temper The temperature inside the cabinet must working space have reached and maintai the temperature fluctuations are specified When the system is stable, turn off the po The measurements, throughout the hold- attached the PQ. Attachment: Notes:	nperature specified in the ap erature is specified in P-5. be stabilized - where all the ned the same temperature I in P-6. ower to the cabinet.	ppendix. e points in the throughout,		
P-14	The times it takes the inside of the cabine must at least be the time specified in the Duration: Have the criteria been met? Attachment: Notes:		iperature,		
Cor	Name: ducted by:	Signature:	Approved (Yes / No):	Date:	

Inspected / verified by:

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Model:

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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 "P-ID" specified in the left column in the test specifications.

P-ID: _____

Description of deviation:

Extent to which the deviation has been alleviated:

Additional notes:

Person responsible for test:	Person responsible for verification of test:
Name:	Name:
Date:	Date:
Company:	Company:
Signature:	Signature:
Ν	odel: SN:

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Location & Date	Location & Date
E-mail	E-mail
Tel.	Tel.
 Stamp & Signature	Stamp & Signature
Person responsible for test	Person responsible for verification of test
Additional notes:	
	on - PQ were completed with <u>positive</u> results on - PQ were completed with <u>negative</u> results

PQ	Performance Qualification - Page 11	Biostorage you can depend on	
NOTES:			
	Model:	SN:	
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Appendix:						
	Model	Temperature fluctuations	Door opening - recovery time	Pull-down	Hold-over range*	Hold-over
	BioBlood					
	500 (Solid door)		3 Minutes	22 Minutes		72 Minutes
	500 (Glass door)		4 Minutes	28 Minutes		42 Minutes
	600D / 600W (Solid door)		3 Minutes	20 Minutes		70 Minutes
BR	600D / 600W (Glass door)	+/- 2K	4 Minutes	25 Minutes	5°C → 10°C	41 Minutes
	660D / 660W (Solid door)		3 Minutes	20 Minutes		70 Minutes
	660D / 660W (Glass door)		4 Minutes	25 Minutes		41 Minutes
	1270 / 1400 (Solid door)		5 Minutes	23 Minutes		78 Minutes
	1270 / 1400 (Glass door)		7 Minutes	29 Minutes		45 Minutes

* The temperature span between the initial temperature and the terminal temperature in the hold-over test P-13,14

Note:

<u>BR:</u>

Ambient temperature +25°C Setpoint temperature +5°C

	Name:	Signature:	Approved (Yes / No):	Date:
Conducted by:				
Inspected / verified by:				
٨	Model:		SN:	
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Appendix:						
	Model	Temperature fluctuations	Door opening - recovery time	Pull-down	Hold-over range*	Hold-over
BF	BioBlood					
	425		9 Minutes	45 Minutes		55 Minutes
	500		7 Minutes	45 Minutes		55 Minutes
	600D / 600W	+/- 5K	7 Minutes	42 Minutes	-20°C → -10°C	55 Minutes
	660D / 660W		7 Minutes	42 Minutes		55 Minutes
	1270 / 1400		10 Minutes	45 Minutes		58 Minutes
	425	+/- 9K	40 Minutes	107 Minutes	-40°C → -10°C	108 Minutes
PF	600W / 660W	+/- 10K	30 Minutes	57 Minutes	-35°C → -10°C	170 Minutes

* The temperature span between the initial temperature and the terminal temperature in the hold-over test P-13,14

Note:

<u>BF:</u>

Ambient temperature +25°C Setpoint temperature -20°C

PF (425):

Ambient temperature +25°C Setpoint temperature -40°C

<u>PF (600W/660W):</u>

Ambient temperature +25°C Setpoint temperature -35°C

	Name:	Signature:	Approved (Yes / No):	Date:
Conducted by:				
Inspected / verified by:				
	Model:		SN:	
∧	^			