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:

BioBlood

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
RF / BF	-20 °C	+25 °C	-35 °C	+25 °C	-35 °C
EF/PF 425	-40 °C	+25 °C	-60 °C	+25 °C	-60 °C
EF/PF 6XX	-35 °C	+25 °C	-45 °C	+25 °C	-45 °C
ER	+5 °C	+25 °C	-5 °C	+25 °C	-5 °C
RR	+5 °C	+25 °C	0 °C	+25 °C	0 °C
BR	+4 °C	+6 °C	+2 °C	+25 °C	0 °C

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

Model: _____ SN: _____

Installation Qualification - IQ

ID	Description of installation	Reference in manual	Comply YES	Comply 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 contact 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: _____

Installation Qualification - IQ

ID	Description of installation	Reference in manual	Comply YES	Comply 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: _____ SN: _____

Operation Qualification - OQ

ID	Description of operation	Reference in manual BCII	Comply YES	Comply NO	Attachmet	Notes
O-1	Turn on the cabinet - Display test (software version and variant).	Page 10				
O-2	Set/adjust set-point temperature.	Page 10				
O-3	Set/adjust LHL - Upper alarm limit (local).	Page 15				
O-4	Set/adjust LLL - Lower alarm limit (local).	Page 15				
O-5	Set/adjust LHd - delay for upper alarm limit (local).	Page 16				
O-6	Set/adjust LLd - delay for lower alarm limit (local).	Page 16				
O-7	Activate / deactivate dA - door alarm (local).	Page 17				
O-8	Set/adjust dAd - delay for door alarm (local).	Page 17				
O-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				
O-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				
O-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: _____ 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:	Person responsible for verification of test:
Name: _____	Name: _____
Date: _____	Date: _____
Company: _____	Company: _____
Signature: _____	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:

Model: _____ SN: _____

GRAM
Biostorage you can depend on

Customer: _____

_____

_____

Location of installation: _____

_____

_____

Model: _____ SN: _____ Item number: _____
(manual)

The PQ consists of inspections of the correct operation of the cabinet under predefined conditions and procedures. Prerequisites for the PQ are IQ (Installation Qualification) and OQ (Operation Qualification), these must be concluded successfully prior to the initiation of the PQ.

This PQ is intended for the following product series:

BioBlood

Person responsible for the cabinet:

Name: _____
Date: _____
Signature: _____

Person responsible for test:

Name: _____
Date: _____
Company: _____
Signature: _____

Person responsible for verification of test:

Name: _____
Date: _____
Company: _____
Signature: _____

Test duration:

Initation (date/time): _____
Conlusion (date/time): _____

Model: _____ SN: _____

Name list - *Persons involved in the test procedure and subsequent report*

Date	Name	Company	Signature

Model: _____ SN: _____

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.

Measurement - Prerequisites

ID	DESCRIPTION	ACCEPTED YES	ACCEPTED NO
P-1	The cabinet must be empty while conducting tests, ie without interior fittings such as drawers, shelves etc. Attachment: Notes:		
P-2	The measurements must be conducted in accordance to IEC 60068-3-5, measured in air with thermocouples or comparable equivalent. Attachment: Notes:		
P-3	The positioning of the sensors in the cabinet must be documented with a sketch and/or a photograph. Attachment: Notes:		

	Name:	Signature:	Approved (Yes / No):	Date:
Conducted by:				
Inspected / verified by:				

Model: _____ SN: _____

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.

Measurement - Prerequisites

ID	DESCRIPTION	ACCEPTED YES	ACCEPTED NO
P-4	Measurements made during the PQ tests must be documented and attached to the PQ. Attachment: Notes:		
P-5	Specify setpoint temperature: _____ °C Specify the ambient temperature: _____ °C Attachment: Notes:		
P-6	Allowed temperature fluctuations - *Select the tolerance, according to the model being tested.* *Find model-specific temperature fluctuations in appendix.* Tolerance: +/- _____ K Attachment: Notes:		

	Name:	Signature:	Approved (Yes / No):	Date:
Conducted by:				
Inspected / verified by:				

Model: _____ SN: _____

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.

Measurement - Temperature stabilization

ID	DESCRIPTION	ACCEPTED YES	ACCEPTED NO
P-7	The test is intended to provide substantiation for the temperature stability inside the cabinet during normal operation The temperature inside the cabinet must be stabilized - where all the points in the working space have reached and maintained the same temperature. When the system is stable, document ordinary operation of the cabinet at the setpoint temperature and ambient temperature specified in P-5. Duration: _____ The measurements throughout the operation test, must be documented and attached the PQ. Attachment: Notes:		
P-8	Are the measurements inside the allowed temperature fluctuations specified in P-6 ? Attachment: Notes:		

	Name:	Signature:	Approved (Yes / No):	Date:
Conducted by:				
Inspected / verified by:				

Model: _____ SN: _____

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.

Measurement - Door opening test

ID	DESCRIPTION	ACCEPTED YES	ACCEPTED NO
P-9	The test is intended to provide substantiation for the temperature recovery time inside the cabinet subsequently after a door opening. The temperature inside the cabinet must be stabilized - where all the points in the working space have reached and maintained the same temperature, the setpoint temperature is specified in P-5. When the system is stable, open the door at 90° for 60 seconds. The measurements, throughout the door opening test, must be documented and attached the PQ. Duration: _____ Attachment: Notes:		
P-10	Have the setpoint temperature specified in P-5, measured in the absolute centre of the cabinet, been achieved within the set time-frame? Attachment: Notes:		

	Name:	Signature:	Approved (Yes / No):	Date:
Conducted by:				
Inspected / verified by:				

Model: _____ SN: _____

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.

Measurement - Pull-down

ID	DESCRIPTION	ACCEPTED YES	ACCEPTED NO
P-11	The test is intended to provide substantiation for the time it takes for the inside of the cabinet to reach the setpoint temperature specified in P-5. The initial temperature in the working space is the ambient temperature specified in P-5. The temperature inside the cabinet must be stabilized in all points of the working space. When the system is stable. Turn on the power to the cabinet. The measurements, throughout the pull-down test, must be documented and attached the PQ. Attachment: Notes:		
P-12	The time it takes the inside of the cabinet to achieve the setpoint temperature measured in the absolute centre, must not exceed the time-frame specified in the appendix. Duration: _____ Have the criteria been met? Attachment: Notes:		

	Name:	Signature:	Approved (Yes / No):	Date:
Conducted by:				
Inspected / verified by:				

Model: _____ SN: _____

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.

Measurement - Hold-over

ID	DESCRIPTION	ACCEPTED YES	ACCEPTED NO
P-13	The test is intended to provide substantiation for the time it takes for the temperature inside the cabinet to reach the terminal temperature specified in the appendix. Ambient temperature and setpoint temperature is specified in P-5. The temperature inside the cabinet must be stabilized - where all the points in the working space have reached and maintained the same temperature throughout, the temperature fluctuations are specified in P-6. When the system is stable, turn off the power to the cabinet. The measurements, throughout the hold-over test, must be documented and attached the PQ. Attachment: Notes:		
P-14	The times it takes the inside of the cabinet to reach the terminal temperature, must at least be the time specified in the appendix. Duration: _____ Have the criteria been met? Attachment: Notes:		

	Name:	Signature:	Approved (Yes / No):	Date:
Conducted by:				
Inspected / verified by:				

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 “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: _____

Model: _____ SN: _____

Approval of test results - Performance Qualification (PQ)

◯ The steps in the Performance Qualification - PQ were completed with positive results

◯ The steps in the Performance Qualification - PQ were completed with negative results

ID of steps with negative results: _____

Additional notes:

_____

_____

_____

_____

_____

Person responsible for test	Person responsible for verification of test
_____	_____
Stamp & Signature	Stamp & Signature
_____	_____
Tel.	Tel.
_____	_____
E-mail	E-mail
_____	_____
Location & Date	Location & Date

Model: _____ SN: _____

NOTES:

Model: _____ SN: _____

Appendix:

	Model	Temperature fluctuations	Door opening - recovery time	Pull-down	Hold-over range*	Hold-over
BR	**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
	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:

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

	Name:	Signature:	Approved (Yes / No):	Date:
Conducted by:				
Inspected / verified by:				

Model: _____ SN: _____

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
PF	425	+/- 9K	40 Minutes	107 Minutes	-40°C → -10°C	108 Minutes
	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:

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

PF (425):
Ambient temperature +25°C
Setpoint temperature -40°C

PF (600W/660W):
Ambient temperature +25°C
Setpoint temperature -35°C

	Name:	Signature:	Approved (Yes / No):	Date:
Conducted by:				
Inspected / verified by:				

Model: _____ SN: _____