

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:

BioPlus, BioMidi

Revision 15/09/2023_003

<p>Person responsible for the cabinet:</p> <p>Name: _____</p> <p>Date: _____</p> <p>Signature: _____</p> <p>Person responsible for test:</p> <p>Name: _____</p> <p>Date: _____</p> <p>Company: _____</p> <p>Signature: _____</p> <p>Person responsible for verification of test:</p> <p>Name: _____</p> <p>Date: _____</p> <p>Company: _____</p> <p>Signature: _____</p> <p>Test duration:</p> <p>Initiation (date/time): _____</p> <p>Conclusion (date/time): _____</p>
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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	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. 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	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 tolerances - <i>Select the tolerance, according to the model being tested. Find model-specific tolerances in appendix.</i> 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	NO
P-7	<p>The test is intended to provide substantiation for the temperature stability inside the cabinet during normal operation.</p> <p>The temperature inside the cabinet must be stabilized - where all the points in the working space have reached and maintained the same temperature.</p> <p>When the system is stable, document ordinary operation of the cabinet at the setpoint temperature and ambient temperature specified in P-5.</p> <p>Duration: _____</p> <p>The measurements throughout the operation test, must be documented and attached the PQ.</p> <p>Attachment:</p> <p>Notes:</p>		
P-8	<p>Are the measurements inside the allowed tolerances specified in P-6 ?</p> <p>Attachment:</p> <p>Notes:</p>		

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	NO
P-9	<p>The test is intended to provide substantiation for the temperature recovery time inside the cabinet subsequently after a door opening.</p> <p>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.</p> <p>When the system is stable, open the door at 90° for 60 seconds.</p> <p>The measurements, throughout the door opening test, must be documented and attached the PQ.</p> <p>Duration: _____</p> <p>Attachment:</p> <p>Notes:</p>		
P-10	<p>Has the setpoint temperature specified in P-5, measured in the absolute centre of the cabinet, been achieved within the set time-frame specified in the appendix?</p> <p>Attachment:</p> <p>Notes:</p>		

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	NO
P-11	<p>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.</p> <p>When the system is stable. Turn on the power to the cabinet.</p> <p>The measurements, throughout the pull-down test, must be documented and attached the PQ.</p> <p>Duration: _____</p> <p>Attachment:</p> <p>Notes:</p>		
P-12	<p>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.</p> <p>Have the criteria been met?</p> <p>Attachment:</p> <p>Notes:</p>		

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	NO
P-13	<p>The test is intended to provide substantiation for the time it takes for the temperature inside the cabinet to reach the end temperature specified in the appendix. Ambient temperature and setpoint temperature is specified in P-5.</p> <p>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 tolerances are specified in P-6.</p> <p>When the system is stable, turn off the power to the cabinet.</p> <p>The measurements, throughout the hold-over test, must be documented and attached the PQ.</p> <p>Attachment:</p> <p>Notes:</p>		
P-14	<p>The times it takes the inside of the cabinet to reach the end temperature, must at least be the time specified in the appendix.</p> <p>Duration: _____</p> <p>Have the criteria been met?</p> <p>Attachment:</p> <p>Notes:</p>		

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:

Name: _____

Date: _____

Company: _____

Signature: _____

Person responsible for verification of test:

Name: _____

Date: _____

Company: _____

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: _____

Appendix:

	Model	Tolerances	Door opening - recovery time	Pull-down	Hold-over range*	Hold-over
RR	BioMidi	+/- 3K			5°C → 10°C	
	425 (Solid door)		3 Minutes	20 Minutes		63 Minutes
	425 (Glass door)		4 Minutes	25 Minutes		37 Minutes
	625 (Solid door)		3 Minutes	20 Minutes		63 Minutes
	625 (Glass door)		4 Minutes	25 Minutes		37 Minutes
ER	BioPlus	+/- 2K			5°C → 10°C	
	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)		4 Minutes	25 Minutes		41 Minutes
	660D / 660W (Solid door)		3 Minutes	20 Minutes		70 Minutes
	660D / 660W (Glass door)		4 Minutes	25 Minutes		41 Minutes
	930 (Solid door)		5 Minutes	22 Minutes		65 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 end temperature in the hold-over test P-13,14

Note:

RR/ER :

Ambient temperature +25°C

Setpoint temperature +5°C

Name:

Signature:

Approved
(Yes / No):

Date:

Conducted by:

Inspected / verified by:

Model: _____

SN: _____

Appendix:

	Model	Tolerances	Door opening - recovery time	Pull-down	Hold-over range*	Hold-over
RF	BioPlus 500		7 Minutes	45 Minutes		55 Minutes
	600D / 600W		7 Minutes	42 Minutes		55 Minutes
	660D / 660W	+/- 5K	7 Minutes	42 Minutes	-20°C → -10°C	55 Minutes
	930		-	76 Minutes		63 Minutes
	1270 / 1400		10 Minutes	45 Minutes		58 Minutes
EF	BioMidi 425	+/- 9K	40 Minutes	107 Minutes	-40°C → -10°C	108 Minutes
	BioPlus 600W / 660W	+/- 10K	30 Minutes	57 Minutes	-35°C → -10°C	170 Minutes

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

** Please contact your local distributor for current information.

Note:

RF:

Ambient temperature +25°C

Setpoint temperature -20°C

EF (425):

Ambient temperature +25°C

Setpoint temperature -40°C

EF (600W/660W):

Ambient temperature +25°C

Setpoint temperature -35°C

Name:

Signature:

Approved
(Yes / No):

Date:

Conducted by:

Inspected / verified by:

Model: _____

SN: _____