

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:

BioCompact, BioCompact II, BioPlus, BioMidi

Revision 19/02/2019_002

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:
Initiation (date/time): _____
Conclusion (date/time): _____

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	BioCompact/BioCompact II	+/- 3K	210 (Solid door)	5 Minutes	25 Minutes	5°C → 10°C	55 Minutes	
	210 (Glass door)		6 Minutes	35 Minutes	30 Minutes			
	310 (Solid door)		5 Minutes	25 Minutes	55 Minutes			
	310 (Glass door)		6 Minutes	30 Minutes	32 Minutes			
	410 (Solid door)		6 Minutes	28 Minutes	62 Minutes			
	410 (Glass door)		7 Minutes	35 Minutes	35 Minutes			
	610 (Solid door)		3 Minutes	20 Minutes	66 Minutes			
	610 (Glass door)		3 Minutes	25 Minutes	40 Minutes			
	BioMidi	+/- 3K	425 (Solid door)	3 Minutes	20 Minutes	5°C → 10°C	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	500 (Solid door)	3 Minutes	22 Minutes	5°C → 10°C	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	BioCompact/BioCompact II						
	210	**	**	60 Minutes	-20°C → -10°C	48 Minutes	
	310	**	**	60 Minutes		50 Minutes	
	410	**	**	62 Minutes		52 Minutes	
		610	+/- 5K	8 Minutes	55 Minutes		55 Minutes
		BioMidi					
		425	+/- 5K	9 Minutes	45 Minutes	-20°C → -10°C	55 Minutes
		625		8 Minutes	42 Minutes		55 Minutes
		BioPlus					
		500	+/- 5K	7 Minutes	45 Minutes	-20°C → -10°C	55 Minutes
		600D / 600W		7 Minutes	42 Minutes		55 Minutes
		660D / 660W		7 Minutes	42 Minutes		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:

