Documentation #: IQ Serial NO. 9999999

Protocol Name:	Installation Qualification Protocol
Protocol Number:	FRM630-02.03
Prepared by (Signature / Date):	M. Nijssen (Sales Manager) 05/06/2019:
Approved by (Signature / Date):	A. van Gastel (Quality Manager) 05/06/2019
Document Date:	05/06/2019
Customer:	End User Company Name
Tuttnauer Distributor:	Tuttnauer Distributor
Country:	Country
Steam Sterilizer Model:	5075ELV-D
Serial Number:	9999999
OPTIONS on Sterilizer:	
Fast Cooling:	COOLING50xxELV-D
Super Fast Cooling (FAN support):	FAN-50
Stand-alone Air compressor	COM-050 Serial number: 888888
Vacuum System:	VAC-38/50
Bio Hazard Filter system:	BHF-B
Automatic water filling system:	Included in model
Steam Generator:	N/a
Printer:	THE002-0080
Independent Recording:	IAR-001
Remote PC Reporting Software:	ADD222-0461

PROTOCOL APPROVALS

Protocol Name:	Installation Qualification Protocol
Protocol Number:	FRM630-02.03
Prepared by (Signature / Date):	M. Nijssen (Sales Manager) 05/06/2019
Approved by (Signature / Date):	A. van Gastel (Quality Manager) 05/06/2019
Steam Sterilizer Model:	5075ELV-D
Serial Number:	9999999
Customer:	End User Company Name
Tuttnauer Distributor:	Tuttnauer Distributor
Country:	Country
IQ Date:	

Remarks:

If all signatures below are completed below then this protocol is approved and effective:

Department	Name	Signature	Date
Tuttnauer Distributor Technician			
End User Company Name Quality Control			
End User Company Name Quality Management			

VALIDATION FINAL REPORT APPROVALS

Protocol Name:	Installation Qualification Protocol
Protocol Number:	FRM630-02.03
Prepared by (Signature / Date):	M. Nijssen (Sales Manager) 05/06/2019
Approved by (Signature / Date):	A. van Gastel (Quality Manager) 05/06/2019
Steam Sterilizer Model:	5075ELV-D
Serial Number:	9999999
Customer:	End User Company Name
Tuttnauer Distributor:	Tuttnauer Distributor
Country:	Country
IQ Date:	

Remarks:

If all signatures below are completed below then this protocol is approved and effective:

Department	Name	Signature	Date
Tuttnauer Distributor Technician			
End User Company Name Quality Control			
End User Company Name Quality Manager			

TABLE OF CONTENTS

1.0 OBJECTIVE

A. To verify that the autoclave is installed correctly and will consistently perform the intended sterilization process.
B. All sensors and instruments permanently installed with the equipment will be functioning properly and can be calibrated (if required). Utility connections must be correctly installed. Functional testing and field adjustment of the installed control mechanisms will be made in coordination with the autoclave vendor. This IQ will ensure that the equipment is installed as designed.
C. The equipment and system will be ready for Operational Qualification.

2.0 DESCRIPTION

A. This protocol is to be executed prior to OQ and PQ.
B. Some subsections of the protocol may be repeated following 'significant' changes in the process or operation according to the Change Control Protocol.
C. The qualification study will establish sterilization exposure time/temperature conditions adequate to assure a probability of non-sterility not greater than 10^{-6} for each approved loading configuration.

3.0 REFERENCES

The following documents are the references for the facility validation.

A. Standard Operating Procedure System: _____
B. Calibration Procedure System: _____
C. Validation Protocol: _____
D. Autoclave Manual and adequate rev.: _____

4.0 BACKGROUND

Active background provides a reason for executing the installation qualification.

- Installing a new autoclave
- Replacing an old autoclave with a new autoclave.
  Old brand/Type: _____
- Moving the existing autoclave to a new / other location"
  Old Location / Area: _____
- Other : _____

_____

5.0 SCOPE

The scope of the Installation Qualification is limited to the equipment listed in the table below.

Equipment	
AUTOCLAVE:	5075ELV-D Sn: 9999999

6.0 RESPONSIBILITIES

The following roles have been assigned and responsibilities assumed:

A. Advisor (End User Company Name)

1. Review and Approve Validation documents.
2. Provide guidance for the parties involved in the validation effort.

B. Validation Team (Tuttnauer Distributor)

1. Review and Approve Validation document.
2. Execute Validation including Qualification of the systems and subsystems.
3. Provide coordination for the parties involved in the validation effort.
4. Calibration of instrumentation.

C. QA/QC (Tuttnauer Distributor and End User Company Name)

1. Review and Approve Validation documents.
2. Provide GMP and regulatory guidance.
3. Test samples generated from execution of validation protocols.

D. Equipment Maintenance (Tuttnauer Distributor)

1. Review and approve Validation documents.
2. Develop Preventative Maintenance program for the plant.
3. Develop spare parts list and purchase spare parts.
4. Provide technical support to validation effort.
5. Assist with calibration of instruments.
6. Assist in execution instrument calibration and loop(s).
7. Number of verifications agreed on:_____

7.0 INSTALLATION QUALIFICATION

The Installation Qualification is the documentation process which verifies that the physical components of a system have been installed according to design specifications. The installation of the system will be verified by reviewing the equipment installed using the referred attachments provided in this protocol. The forms will be utilized to document the installation of the system and to verify that the system components conform to design specifications.

A. Identification (Attachment #10.1A to #10.1C)

Name, ID number, location, equipment manufacturer, purchase order numbers, model number, serial number: any other specified data such as finish, materials of construction and dimensions. Pressure vessels will require a Certification Number for test ratings from the Government Agency.

B. Basic Utility Verification (Attachment #10.2A to #10.2G)

Verify that utilities are as described in the specification and that connections are made correctly per the drawings.

Utilities for autoclave model 5075ELV-D:

Attachment	Utility	Description
10.2A	Electrical Power	3-Ph+N+E 16A-400V 180°/6h
10.2B	City Water	2-3 bar ; connection: 1/2' or 3/4" Male
10.2C	DEMI Water	2 - 3 bar; connection 1/2' or 3/4" Male
10.2D	Drain	40 - 50 mm Open or Vented
10.2E	Compressed Air	6 - 8 bar ; 50 l/min; connection Schneider Female NW7,2
10.2F	Other	Room Temp;5 - 40 °C Relative Humidity: 85 % Air Conditions: etc.
10.2G	Installation Tests	Tests to be carried out during / after installation

C. Engineering Documentation (Attachment #10.3A)

The existence and location of all equipment maintenance manuals and documentation will be verified as to location to include all applicable drawings.

D. Critical and Reference Instrument List (Attachment #10.4A & #10.4B)

List, identify, and verify all instruments and gauges used during the Installation Qualification. Designate the instruments as critical or reference only. Where applicable, Instruments will be calibrated. Verification will be made that all test procedures have been written and approved for instrument/gauge calibration to include the required intervals for recertification. A final report, to include all data on instrument/gauge parameters, will be submitted stating that installation qualifications are in accordance with the specifications.

E. Preventive Maintenance Verification (Attachment #10.5A)

In order to complete this form, the following must be verified: equipment name & tag number, existence of an approved PM program that follows manufacturer's recommendations and verifications that the PM has been performed as scheduled.

F. Installation Qualification Summary (Attachment #10.6A)

In order to complete the document, there is a summary of the Installation Qualification performed by the technician from Tuttnauer Distributor.

G. Comment / Action Items (Attachment #10.7A)

Together with the summary this shows an overview of open actions for follow up defining the actions to be taken and those responsible.

H. Comment / Action Form (Attachment #10.7B)

In order to complete the document, there is a follow-up form for the Comment / Action to be performed by the technician from Tuttnauer Distributor.

8.0 IQ ACCEPTANCE CRITERIA

All inspections, reviews and documentation requirements for the system will be completed and approved. The installation qualification will document that the system has been installed in accordance with applicable specifications and is ready for the operational qualification.

8.1 Utility Requirement

Unless otherwise specified, voltage range must be within 10% of nominal voltage. Current must not exceed specified current rating of breaker.

8.2 Documentation

Turn over Package (ToP) for system includes documents specified by the project, engineering and validation departments.

TOP	Document	Description
1	O & M Manual	Operation & Maintenance Manual 5075ELV-D MAN999-9999999EN Revision : Rev X
2	Technical Manual	Technical Manual 5075ELV-D MAN888-8888888EN Revision : Rev Y
3	FCP	Factory Callbration Report
4	Cert SVL	Certificate of Safely Valve sterilizer
5	Cert SG-SVL	Certificate of Safely Valve Steam Generator (If Applicable)
6	DoC	Declaration of Conformity: - General Data Sheet - Drawing sterilizer chamber - BOM (Bill of Materials) - Hydrostatic Test Report
7	LB	Autoclave Logbook
8	YWC	Yellow Warranty Card

8.3 Instrument Calibration

Measurement Instruments must be classified as either Critical or Reference Only. Critical instruments must conform to drawings, specifications, and data sheets. Instruments must be calibrated according to Local traceable standard and be within its calibration interval. Instrument linked to a recorder or controller must be loop calibrated.

8.4 Preventive Maintenance (PM) Verification

- PM program exists for the system.
- Manufacturers approved Preventative Maintenance schedule.
- PM has been scheduled as suggested.

9.0 COMMENTS/ACTION ITEMS (Attachment # 10.7A; # 10.7B)

All comments, action and follow-up items are attached in Attachments 10.7A & 10.7B.

10.0 IQ ATTACHMENTS

10.1A.	Identification: Autoclave
10.1B.	Identification: (Internal / External) Steam Generator
10.1C.	Identification: Parts supplied with the Autoclave
10.2A.	Utility Requirement: Electrical
10.2B.	Utility Requirement: City Water
10.2C.	Utility Requirement: DEMI Water
10.2D.	Utility Requirement: Drain
10.2E.	Utility Requirement: Compressed Air
10.2F.	Utility Requirement: Others
10.2G.	Utility Requirement: Installation Tests
10.3A.	Documentation
10.4A.	Instrument Calibration: Critical Instrument
10.4B.	Calibration values Bacsoft (FRM 630-05.00)
10.4C.	Instrument Calibration: Reference Instrument
10.5A.	Preventive Maintenance Verification
10.6A.	Installation Qualification Summaries
10.7A.	Comments/Action Items
10.7B.	Comments/Action Form

ATTACHMENT #10.1A
IDENTIFICATION: AUTOCLAVE

Contract No:	
Customer:	End User Company Name
Location:	
Area:	
Item No:	
Item Name:	
Model:	5075ELV-D
Serial Number:	9999999
Software Version:	9.9.9
Software Revision No:	.9
Software Revision Date:	x-xx-yyyy
Installed By:	Tuttnauer Distributor
Approved By:	End User Company Name
Volume (Total in Liters):	28
Chamber Dimensions:	
Diameter (mm):	500
Depth (mm):	750
Outside Dimensions:	
Width (mm):	870
Length (mm):	770
Height (mm):	1090
Weight (kg):	190
Operating Temp (°C):	105 - 137
Operating Pressure (bar):	0 - 2,52
Design Pressure (bar):	2,8 absolute (142°C)
Volume Reservoir (l):	N/a
Internal Finish:	
Material of Construction:	AISI 316 L
Electro Polish:	Yes
External Finish:	
Material of Construction:	AISI 304

Document any discrepancies from the design specification on the Installation Qualification Summary.

Compiled by: _____ **Date:** _____

Reviewed by _____ **Date:** _____

ATTACHMENT #10.1B
IDENTIFICATION: (INTERNAL / EXTERNAL) STEAM GENERATOR

Contract No:	
Customer:	End User Company Name
Model:	5075ELV-D
Serial Number:	9999999
Software Version:	9.9.9
Software Revision No:	.9
Software Revision Date:	x-xx-yyyy
Location:	
Area:	
Item No:	
Item Name:	
Installed By:	Tuttnauer Distributor
Approved By:	End User Company Name
Steam Generator Information	
Serial Number:	999999
Volume (Liters):	N/a
Voltage (V):	N/a
Power (W):	N/a
Operating Pressure (bar):	N/a
Design Pressure (bar):	N/a
Position of Steam Generator:	N/a

Document any discrepancies from the design specification on the Installation Qualification Summary.

Compiled by: _____ **Date:** _____

Reviewed by _____ **Date:** _____

ATTACHMENT #10.1C
IDENTIFICATION: PARTS SUPPLIED WITH THE AUTOCLAVE

Contract No:		
Customer:	End User Company Name	
Model:	5075ELV-D	
Serial Number:	9999999	
Software Version:	9.9.9	
Software Revision No:	.9	
Software Revision Date:	x-xx-yyyy	
Location:		
Area:		
Item No:		
Item Name:		
Installed By:	Tuttnauer Distributor	
Approved By:	End User Company Name	
Parts Supplied with Autoclave	**Article number**	**Checked**
Bottom Plate / Tray holder + (x* Trays) ;Tray handle:	CMT507-0089	☐
Tap Water connection hose (St. St. 2m):	GAS086-0102 + TB-MET-0710445	☐
Pressure reducer 1,5 bar for Tap water:	SUA109-0049	☐
DEMI Water connection hose (St. St. 2m):	GAS086-0102 + TB-MET-0710445	☐
Pressure reducer 1,5 bar for DEMI water:	SUA109-0049	☐
Drain connection hose (black 2m):	GAS084-0031	☐
Drain Tube (Manual Draining):	N/a	☐
Compressed air connection hose (blue 5m):	D740012	☐
Electrical Power cord:	Fixed connection 3-P+N+E 16A-400V 180°/6h	☐
Power Conversion Box:	ELE387-1610	☐
UTP Cable for Ethernet connection:	CABLE-UTP-2M	☐
Auxiliary Dry Contacts (Conn. to BM-System):	ADC-001	☐
Shelve system:	N/a	☐
Wire Basket(s) Model I (Qty) / Model II (Qty):	**WBA50-23 ((3)) / WBA50-35 ((2))**	☐
Closed Basket(s) Model I (Qty) / Model II (Qty):	**CBA50-23 ((3)) / CBA50-35 ((2))**	☐
Loading / Lifting Systems:	LIFT-001	☐
Support Tables (Table) / (wheels/panels):	N/a / N/a	☐

Document any discrepancies from the design specification on the Installation Qualification Summary.

Compiled by: _____ **Date:** _____

Reviewed by _____ **Date:** _____

ATTACHMENT #10.2A
UTILITY REQUIREMENT

Equipment/System Item No.: _____

Equipment/System Description: _____

UTILITIES - ELECTRICITY

	Specified	Checked
Model:	5075ELV-D	
System:		
Source:	Separate group required	☐
Purpose:	Power for control system and heating	
Voltage (VAC):	400 Measured values: L1-N : L2-N : L3-N : L-L :	☐
Current (A):	13 Measured values (Heater): L1 : L2 : L3 :	☐
Phase (Ph):	3+N+E	☐
Power (W):	9000	☐
Circuit Breaker (A):	=> 16	☐
Frequency (Hz):	50	☐
Connection on autoclave:	Cord with plug 3-Ph+N+E 16A-400V 180°/6h	☐
Connection required on-site:	3-Ph+N+E 16A-400V 180°/6h	☐
Conductor Material:		☐
Conductor Size:		☐
Insulation Material:		☐
Conduit Size:		☐
Grounding:	Non-Floating	☐

Comments: _____

Utility Requirements Satisfied:

Yes _____ **No** _____

Document any discrepancies on the Installation Qualification Summary.

Compiled by: _____ **Date:** _____

Reviewed by _____ **Date:** _____

ATTACHMENT #10.2B
UTILITY REQUIREMENT

Equipment/System Item No.: _____

Equipment/System Description: _____

UTILITIES – CITY WATER

	Specified	Checked
Model:	5075ELV-D	
System:		
Source:		☐
Purpose:	Cooling of exh; Fast Cooling; Vacuum System	
Pressure (bar):	2-3	☐
Shut-off tap required:	Required (Not supplied)	☐
Pressure Regulator Installed (1,5 bar):	Required (Supplied) Mount direct on Tap	☐
Temperature (°C):	±15	☐
Hardness (TDS):	between 0.7 mmol/l and 2.0 mmol/l	☐
Back Flow Prevention:	Required (Not supplied)	☐
Connection on autoclave:	1/2" Male	☐
Connection required on-site:	1/2' or 3/4" Male	☐
Pipe Material:		☐
Pipe Size:		☐
Pipe Insulation:		☐

Comments: _____

Utility Requirements Satisfied:

Yes _____ **No** _____

Document any discrepancies on the Installation Qualification Summary.

Compiled by: _____ **Date:** _____

Reviewed by _____ **Date:** _____

ATTACHMENT #10.2C
UTILITY REQUIREMENT

Equipment/System Item No.: _____

Equipment/System Description: _____

UTILITIES – DEMI WATER

	Specified	Checked
Model:	5075ELV-D	
System:		
Source:		☐
Purpose:	Steam Production	
Pressure (bar):	2 - 3	☐
Shut-off tap required:	Required (Not supplied)	☐
Pressure Regulator Installed (1,5 bar):	Required (Supplied) Mount direct on Tap	☐
Temperature (°C):	15 - 22	☐
Water Quality (compliance with EN285):	According to EN285:2006	☐
Back Flow Prevention:	Required (Not supplied)	☐
Connection on autoclave:	1/2" Male	☐
Connection required on-site:	1/2' or 3/4" Male	☐
Pipe Material:		☐
Pipe Size:		☐
Pipe Insulation:		☐

Comments: _____

Utility Requirements Satisfied: **Yes** _____ **No** _____

Document any discrepancies on the Installation Qualification Summary.

Compiled by: _____ **Date:** _____

Reviewed by _____ **Date:** _____

ATTACHMENT #10.2D
UTILITY REQUIREMENT

Equipment/System Item No.: _____

Equipment/System Description: _____

UTILITIES – DRAIN

	Specified	Checked
Model:	5075ELV-D	
System:		
Source:		☐
Purpose:	Automatic Draining	
Open or Vented:	Open or Vented	☐
Temperature resistant (°C):	80 constant ; 120 in case of malfuntion	☐
Temperature resistant min. length (m):	3	☐
Max. height of the drain-pipe (mm):	20	☐
Connection on autoclave:	1/2" Male	☐
Connection required on-site:	40 - 50	☐
Pipe Material:		☐
OVERFLOW connection:		
Location on autoclave:	N/a	☐
Connection on autoclave:	N/a	☐
Connection required on-site:	N/a	☐

Comments: _____

Utility Requirements Satisfied: **Yes** _____ **No** _____

Document any discrepancies on the Installation Qualification Summary.

Compiled by: _____ **Date:** _____

Reviewed by _____ **Date:** _____

ATTACHMENT #10.2E
UTILITY REQUIREMENT

Equipment/System Item No.: _____

Equipment/System Description: _____

UTILITIES – COMPRESSED AIR

	Specified	Checked
Model:	5075ELV-D	
System:		
Source:		☐
Purpose:	Cooling Back Pressure	
Air Flow (l/min):	50	☐
Pressure (bar):	6 - 8	☐
Shut-off tap:	Required (Not supplied)	☐
Pressure Regulator Installed (1,5 bar):	Yes (Build-In)	☐
Connection on autoclave:	1/2" Male with fitted Schneider Male NW7,2	☐
Connection required on-site:	Schneider Female NW7,2	☐
Water:	Free of water droplets > 25µm	☐
Oil:	Free of Oil droplets > > 2µm	☐
Pipe Material:		☐
Pipe Size:		☐

Comments: _____

Utility Requirements Satisfied: **Yes** _____ **No** _____

Document any discrepancies on the Installation Qualification Summary.

Compiled by: _____ **Date:** _____

Reviewed by _____ **Date:** _____

ATTACHMENT #10.2F
UTILITY REQUIREMENT

Equipment/System Item No.: _____

Equipment/System Description: _____

UTILITIES – OTHER

	Specified	Checked
Model:	5075ELV-D	
System:		
Source:		☐
Purpose:	General	
Surface to place the sterilizer on:	Leveled	☐
Support table carrying weight:	N/a	☐
Free space around the autoclave:	For maintenance and service purposes	☐
Room Temperature (°C):	5 - 40	☐
Room Relative Humidity (Max. %):	85	☐
Conditioned Room:	N/a	☐
Air Replacements per hour:	N/a	☐
		☐
		☐
		☐

Comments: _____

Utility Requirements Satisfied: **Yes** _____ **No** _____

Document any discrepancies on the Installation Qualification Summary.

Compiled by: _____ **Date:** _____

Reviewed by _____ **Date:** _____

ATTACHMENT #10.2G
UTILITY REQUIREMENT

Equipment/System Item No.: _____

Equipment/System Description: _____

UTILITIES – INSTALLATION TESTS

	Remarks	Checked
Model:	5075ELV-D	
System:		
Source:		☐
Purpose:	Testing	
Integrity Check:	Visual check to verify that there are no dents, scratches, broken gauges, etc.	☐
Leveling Check:	Check that the sterilizer is leveled	☐
Utility Check 1:	All Utilities according to requirements	☐
Utility Check 2:	Check that all Utilities are working and shut-off taps are opened	☐
Leakage Check:	Check all connections to the sterilizer for leakages:	☐
Grounding Check:	Check the ground connection of the customers power supply:	☐
Leakage current Check:	Test the current leakage relay of the customers power supply:	☐
		☐
		☐

Comments: _____

Utility Requirements Satisfied:

Yes _____ **No** _____

Document any discrepancies on the Installation Qualification Summary.

Compiled by: _____ **Date:** _____

Reviewed by _____ **Date:** _____

ATTACHMENT #10.3A
DOCUMENTATION

Equipment/System Item No.: _____

Equipment/System Description: _____

DOCUMENTS

Document	Specified	Available
Title:	O & M Manual	☐
Number:	MAN999-9999999EN	☐
Revision No.:	Rev X	☐
Storage Location of Document:		
Title:	Technical Manual	☐
Number:	MAN888-8888888EN	☐
Revision No.:	Rev Y	☐
Storage Location of Document:		
Title:	Safety testing Manual	☐
Number:	MOD777-77777EN	☐
Issue Date:	Rev Z	☐
Storage Location of Document:		
Title:		☐
Number:		☐
Issue Date:		☐
Storage Location of Document:		

Comments: _____

Document any discrepancies on the Installation Qualification Summary.

Compiled by: _____ **Date:** _____

Reviewed by _____ **Date:** _____

ATTACHMENT #10.4A
INSTRUMENT CALIBRATION

Equipment/System Item No.: _____

Equipment/System Description: _____

CRITICAL INSTRUMENTATION 1 of 2

ID 1 :	
Type 1:	
Range 1:	
Scale Division 1:	
Manufacturer 1:	
Use 1:	
MOC 1:	
Calibration Date 1:	
Calibration Interval 1:	
Calibration Cert. No. 1:	
ID 2 :	
Type 2:	
Range 2:	
Scale Division 2:	
Manufacturer 2:	
Use2 :	
MOC 2:	
Calibration Date 2:	
Calibration Interval 2:	
Calibration Cert. No. 2:	
ID 3:	
Type 3:	
Range 3:	
Scale Division 3:	
Manufacturer 3:	
Use 3:	
MOC 3:	
Calibration Date 3:	
Calibration Interval 3:	
Calibration Cert. No. 3:	

CRITICAL INSTRUMENTATION 2 of 2

ID 4:	
Type 4:	
Range 4:	
Scale Division 4:	
Manufacturer 4:	
Use 4:	
MOC 4:	
Calibration Date 4:	
Calibration Interval 4:	
Calibration Cert. No. 4:	
ID 5:	
Type 5:	
Range 5:	
Scale Division 5:	
Manufacturer 5:	
Use 5:	
MOC 5:	
Calibration Date 5:	
Calibration Interval 5:	
Calibration Cert. No. 5:	
ID 6:	
Type 6:	
Range 6:	
Scale Division 6:	
Manufacturer 6:	
Use 6:	
MOC 6:	
Calibration Date 6:	
Calibration Interval 6:	
Calibration Cert. No. 6:	

Document any discrepancies from the design specification on the Installation Qualification Summary.

Compiled by: _____ **Date:** _____

Reviewed by _____ **Date:** _____

ATTACHMENT #10.4B
CALIBRATION VALUES BACSOFT (FRM 630-05.00)

Model:	5075ELV-D	Serial number:	9999999
Request number:		Engineer:	

Chamber Temperature (J2)		Ref Temerature (J3)	
Actual Value	Read value	Actual Value	Read value
80.0 °C		80.0 °C	
130.0 °C		130.0 °C	

Drain Temperature (J5)		Bio Hazard Filter Temperature (J6)	
Actual Value	Read value	Actual Value	Read value
20.0 °C		80.0 °C	
80.0 °C		130.0 °C	

Actual Value	Read value	Actual Value	Read value
°C		°C	
°C		°C	

Chamber Pressure J7:1)		Generator Pressure (J7:2)	
Actual Value	Read value	Actual Value	Read value
kPa	kPa	kPa	kPa
kPa	kPa	kPa	kPa

Actual Value	Read value	Actual Value	Read value
kPa	kPa	kPa	kPa
kPa	kPa	kPa	kPa

Calibration equipment			
ID:		Description:	
ID:		Description:	

Calibration checked by: _____ **Date:** _____

ATTACHMENT #10.4C
INSTRUMENT CALIBRATION

Equipment/System Item No.: _____

Equipment/System Description: _____

REFERENCE INSTRUMENTATION 1 of 2

ID 11:	
Type 11:	
Range 11:	
Scale Division 11:	
Manufacturer 11:	
Use 11:	
MOC 11:	
Calibration Date 11:	
Calibration Interval 11:	
Calibration Cert. No. 11:	
ID 12:	
Type 12:	
Range 12:	
Scale Division 12:	
Manufacturer 12:	
Use 12:	
MOC 12:	
Calibration Date 12:	
Calibration Interval 12:	
Calibration Cert. No. 12:	
ID 13:	
Type 13:	
Range 13:	
Scale Division 13:	
Manufacturer 13:	
Use 13:	
MOC 13:	
Calibration Date 13:	
Calibration Interval 13:	
Calibration Cert. No. 13:	

REFERENCE INSTRUMENTATION 2 of 2

ID 14:	
Type 14:	
Range 14:	
Scale Division 14:	
Manufacturer 14:	
Use 14:	
MOC 14:	
Calibration Date 14:	
Calibration Interval 14:	
Calibration Cert. No. 14:	
ID 15:	
Type 15:	
Range 15:	
Scale Division 15:	
Manufacturer 15:	
Use 15:	
MOC 15:	
Calibration Date 15:	
Calibration Interval 15:	
Calibration Cert. No. 15:	
ID1 6:	
Type 16:	
Range 16:	
Scale Division 16:	
Manufacturer 16:	
Use 16:	
MOC 16:	
Calibration Date 16:	
Calibration Interval 16:	
Calibration Cert. No. 16:	

Document any discrepancies from the design specification on the Installation Qualification Summary.

Compiled by: _____ **Date:** _____

Reviewed by _____ **Date:** _____

ATTACHMENT #10.5A
PREVENTIVE MAINTENANCE VERIFICATION

Equipment/System Item No.: _____

Equipment/System Description: _____

PM Document Title:	
PM Document No.:	
Revision Date:	
Storage Location of Document:	
Manufacturers PM Document Title:	N/a (part of MAN999-9999999EN-Rev X)
Manufacturers PM Document No.:	N/a (part of MAN999-9999999EN-Rev X)
PM has been performed as Scheduled:	

Is the current PM document in accordance to the Manufacturers Document?

Comments: _____

PM Verification Satisfied: **Yes** _____ **No** _____

Document any discrepancies on the Installation Qualification Summary.

Compiled by: _____ **Date:** _____

Reviewed by _____ **Date:** _____

ATTACHMENT #10.6A
INSTALLATION QUALIFICATION SUMMERY

Equipment/System Item No.: _____

Equipment/System Description: _____

Discrepancy/variation

_____

_____

Resolution: _____

_____

_____

Satisfactorily completed?: (Y/N) _____ _____ _____
Signature **Date**

Discrepancy/variation: -------- _____

_____

_____

Resolution: _____

_____

_____

Satisfactorily completed?: (Y/N) _____ _____ _____
Signature **Date**

SUMMARY: _____

_____

_____

All items in the Installation Qualification section of this protocol have been satisfactorily completed and all variations or discrepancies satisfactorily resolved. Therefore, this system is ready for Operational Qualification.

Compiled by: _____ **Date:** _____

Reviewed by _____ **Date:** _____

ATTACHMENT #10.7A
COMMENT / ACTION ITEMS

Equipment/System Item No.: _____

Equipment/System Description: _____

This attachment contains a listing of all issue, deviations, and exceptions that were recorded during protocol execution. A listing of all items is included below, and Comment/Action item forms are attached. This comment form summarizesthose items as well as any corrective actions taken or responsive justifications.

Comment #	Who	Date Added	Follow Up Required (Yes/No)	Signature	Date Follow Up Completed
					☐
					☐
					☐
					☐
					☐
					☐
					☐
					☐
					☐
					☐
					☐
					☐

Compiled by: _____ **Date:** _____

Reviewed by _____ **Date:** _____

ATTACHMENT #10.7B
COMMENT / ACTION ITEM FORM

Equipment/System Item No.: _____

Equipment/System Description: _____

Comment: _____

_____

_____

_____

Response/Corrective Action/Justification: _____

_____

_____

_____

Follow-up Required: (Yes/No) _____ Requested by: _____

Explanation of Follow-up: _____

_____

_____

_____

Completed Date: _____ Signature: _____

Compiled by: _____ Date: _____

Reviewed by _____ Date: _____