N2 NITROSOURCE PSA

IQ/OQ (Installation Qualification/Operational Qualification)

EN Original Language

aerospace
climate control
electromechanical
filtration
fluid & gas handling
hydraulics
pneumatics
process control
sealing & shielding

Parker domnick hunter

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CONTENTS

1 System Certification

Study data has determined that the system described in this document either meets all criteria outlined on this IQ and OQ Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for specified usage.

1.1 Instrument:

	Model	Serial No.
Generator		
GC		
Autosampler		
Other		
Customer System ID		

Report Prepared By:

Name: _____

Title: _____

Date: _____

Certificate of Authorisation:

Name: _____

Title: _____

Date: _____

Customer Authorisation:

Name: _____

Title: _____

Site: _____

Date: _____

2 Validation Protocol and Procedures

2.1 Pre-Approval of Installation and Operation Qualification

This pre-approval of the attached validation protocol shall be the joint responsibility of the following personnel:

Parker domnick hunter Authorisation:

Signature: _____

Name: _____

Position: _____

Date: _____

Customer Authorisation:

Signature: _____

Name: _____

Position: _____

Date: _____

2.2 Authorised Qualifiers

Note:Qualifier signature and initials to be filled in.

Qualifier	Title	Signature	Initials

Completed by: _____ Title: _____ Date: _____

Verified by: _____ Title: _____ Date: _____

2.3 Instructions on completing this document

1 Not all records are appropriate to all generator models, where one does not apply enter N/A next to the question.

2 An authorised **Parker domnick hunter** representative will check each module and perform the various tests as outlined in the appropriate System IQ and OQ section of this manual. Each result will be noted and dated.

3 Care to be taken when entering data such that records are neat and legible.

4 All entries must be filled in using a black ink pen.

5 Dates to be in format 01June 2002 not 01/06/02.

6 The qualifier will check each result, **sign** (full signature) and date each page that includes a **'Completed by'** option.

7 Any table sections/boxes or comments space that do not require an entry must have a line through, a note 'N/A' applied and be initialled and dated.

8 All deviations from normal specification to include any problems with installation will be noted under 'COMMENTS'. All resolutions to such problems will also be noted in the 'COMMENTS' section. Additional space is provided at the end of each section.

9 All results that have not achieved required specification must be documented and placed in the rear of the manual.

10 Correction ***must*** be initialled and dated.

11 When correcting an entry, the entire entry must be replaced, not merely amended i.e.: ~~123.1~~123.3 and not 123.~~1~~3

12 Any changes to the protocol must be thoroughly documented and explained.

Completed by: _____ Title: _____ Date: _____

Verified by: _____ Title: _____ Date: _____

13 Do not adjust or amend the entries of another qualifier.

14 Results must be recorded to the same level of accuracy as displayed by the measuring device i.e. DMM. When reporting a pass or fail result, the value recorded should be interpreted to the same level of significance as the acceptance criteria. (For example, a reading of 0.0325mV passes an acceptance criteria of ≤ 0.03mV).

15 Where separate boxes exist for PASS or FAIL the qualifier should tick the appropriate box. Where a column has PASS/FAIL above it, the word PASS or FAIL should be written.

16 All attached pages should be incrementally labelled as the page number preceding plus the suffix A, B, C etc. For example, Certificate appended after page 21 of 22 should be labelled 21A of 22.

17 Certificate of Test Compliance must be attached to the end of this section.

18 Interpretation of Results
Analytical results observed in the laboratory (or calculated from experimental measurements) are compared with specifications to determine conformance with test requirements. The observed or calculated values will usually contain more significant figures than are stated in the specification. The observed or calculated values must therefore be rounded to the same number of significant figures as present in the upper and lower limit of the specification.

19 This document contains proprietary information and is not to be copied or duplicated in any way without expressed written authorisation from **Parker domnick hunter**.

Completed by: _____ Title: _____ Date: _____

Verified by: _____ Title: _____ Date: _____

2.4 Scope of the Procedures

This Installation Qualification / Operational Qualification protocol will be performed on the instrumentation located at:

Company: _____

Department: _____

Address: _____

_____

Laboratory: _____

- This protocol will define the methods and documentation that will be used to evaluate the Instrument documented in accordance with the manufacturer'' specifications of intended use. Successful completion of this protocol will verify that the Instrumentation operates in accordance with specification.
- Instrument calibration and adjustment will be verified.
- Functional testing of the integrated Instrumentation will be performed to ensure system integrity.
- Trained, Authorised, knowledgeable personnel will perform qualification studies.
- Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All data will be documented.
- On any page that contains a written entry, or data gathered by a **Parker domnick hunter** qualifier, the page must be ***signed*** (full signature) and dated.

Completed by: _____ Title: _____ Date: _____

Verified by: _____ Title: _____ Date: _____

2.5 Test Equipment

The following equipment has been used to obtain measurements during system qualification. Attach a copy of the calibration certificate to the rear of this document.

Equipment	Manufacturer	Model	Serial Number	Certificate Number	Expiry Date

Additional Equipment _____

_____

_____

_____

_____

Completed by: _____ Title: _____ Date: _____

Verified by: _____ Title: _____ Date: _____

2.6 Instrument Listing Including Generator, Gas Chromatograph etc

Manufacturer	Model	Serial Number

Completed by: _____ Title: _____ Date: _____

Verified by: _____ Title: _____ Date: _____

3 Installation Qualification and Operation Qualification

3.1 Equipment Description

NITROSOURCE generators deliver a continuous stream of [ ]% pure nitrogen gas with a residual oxygen content of <[ ]ppm without the need for secondary purification

3.2 Nitrogen Generator Identification

Model: _____

Serial Number: _____

ID Number: _____

3.3 Unpacking and Inspection

Any damage evident on instrument/accessory packaging?

For verification: Damage? Yes ☐ No ☐

Comments: _____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Completed by: _____ Title: _____ Date: _____

Verified by: _____ Title: _____ Date: _____

3.4 Power Requirements

A measured Ground to Neutral potential of greater than 3 volts AC/DC indicates earth problems may need correction before an instrument may be operated reliably.

Measured Mains Voltage:**Volts230±10%**

Measured Mains Voltage:**Volts115±10%**

Measured Ground to Neutral**Volts<3 Volts**

For Verification: Power Pass ☐ Fail ☐

Comments: _____

_____

_____

_____

_____

_____

_____

_____

_____

Completed by: _____ Title: _____ Date: _____

Verified by: _____ Title: _____ Date: _____

3.5 Environmental Considerations

At least a clearance of 500mm around the generator is required for ventilation purposes.

For Verification: Conditions acceptable? Yes ☐ No ☐

Comments: _____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Completed by: _____ Title: _____ Date: _____

Verified by: _____ Title: _____ Date: _____

3.6 Installation / Customer Connections

	Pipe Size	Material
Air Inlet		
N2 to Buffer		
Buffer to Generator		
Outlet to Process		
Electrical		
Dryer Power	YES / NO	YES / NO
Purge Economy	YES / NO	YES / NO
Alarm Output	YES / NO	YES / NO
Remote Start/Stop	YES / NO	YES / NO
Modbus	YES / NO	YES / NO
4 - 20mA	YES / NO	YES / NO

Test 1

Test Name: Setting the Air Inlet Pressure

Purpose: Verify operation of start up Procedure

Method: Follow the start up procedure. In the Installation, Commissioning, Operation & Maintenance Guide.

Inlet Pressure as Specified on order **Pass** ☐ **Fail** ☐

Completed by: _____ Title: _____ Date: _____

Verified by: _____ Title: _____ Date: _____

Test 2

Test Name: Start Up Sequence

Purpose: Verify operation of start up Procedure

Method: Follow the start up procedure in the user guide.

	Pass	Fail
Start Up sequence - Rapid cycle (4x40)	☐	☐
Illumination of amber outlet LED	☐	☐
Illumination of GREEN outlet LED	☐	☐
Analyser display showing O2 reading	☐	☐

Completed by: _____ Title: _____ Date: _____

Verified by: _____ Title: _____ Date: _____

Test 3

Test Name: Pressure Regulators

Purpose: Verify correct operation of the pressure regulators

Method: 1: Verify, on start-up of the generator:
That the air inlet pressure builds to specified level.
That the buffer pressure increases.
The outlet pressure builds to the required level.

Parameter Values for Verification

Parameter	Pass	Fail
Air inlet pressure	☐	☐
Buffer pressure	☐	☐
Outlet pressure	☐	☐

Completed by: _____ Title: _____ Date: _____

Verified by: _____ Title: _____ Date: _____

Test 4

Test Name: Nitrogen Flow Test

Purpose: Verify correct operation of flows

Method: 1: Connect the flow control unit to the outlet of the generator. Verify the flow reaches the maximum flow capacity of the generator using a calibrated flowmeter.

Model	Capacity (M3/hr)	Measured Flow (M3/hr)	Pass / Fail

Completed by: _____ Title: _____ Date: _____

Verified by: _____ Title: _____ Date: _____

Test 5

Test Name: Nitrogen purity

Purpose: Verify correct nitrogen purity

Method: 1: Connect an oxygen analyser to the outlet of the generator

Parameter Values for Verification

Model	Purity	Measured Purity	Pass / Fail

Completed by: _____ Title: _____ Date: _____

Verified by: _____ Title: _____ Date: _____

4 Certificate of Training

Analyst Training:

This certifies that the analysts listed below have received basic user training for the modules and system described in this IQ/OQ.

The training has been conducted by _____ who is certified by **Parker domnick hunter** to conduct such training.

		Initials	Date
☐	Instrument Set-up		
☐	Basic Operation of Module		
☐	System Operation		
☐	Basic Troubleshooting and Maintenance		

Operator Training:

The users responsible for the operation of this instrumentation will be trained in the proper usage of the system. Training will focus on the basic operation and maintenance of the system. The training of operators will be documented and the training records will be filed as indicated below:

Operator	Location	Initials	Date

Comments: _____

_____

_____

_____

_____

_____

_____

_____

Completed by: _____ Title: _____ Date: _____

Verified by: _____ Title: _____ Date: _____

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