Customer:	ACME Inc.	**Document code:**	PR0001 IQ
Project:	Prototype	**Revision:**	1.0
Order number:	#0123456 date 01 June 2007	**Date:**	12 September 2008

IQ Protocol

Model	Description	Serial N°
PROT	A simple prototype	001/2008

Document approval:

Company Name	Responsibility	Name	Date	Signature
Supplier	Area Sales Manager	A. Smith		
Supplier	Quality Assurance Manager	R. Green		
ACME Inc.	Project engineer	M. Brown		
ACME Inc.	Project quality assurance	E. Scott		

Editor:		F. Piraneo G.		

Issued by: IFACE Industrial Automation – Morbio Inferiore, Switzerland.

This document contains a Front Cover and 25 pages.

Machine Model	PROT	Document	PR0001 IQ
Serial Number	001/2008	Date	12 September 2008
Customer	ACME Inc.	Version	1.0

Table of contents

Machine Model	PROT	Document	PR0001 IQ
Serial Number	001/2008	Date	12 September 2008
Customer	ACME Inc.	Version	1.0

1. Introduction

This installation qualification protocol has been produced for ACME Inc. by IFACE.

The purpose of this document is to define the qualification tests for the following machine:

Item	Machine type	Model	Machine S/N
1	PR0001 FDS	Functional design specification for Simple Prototype machine;	001/2008

The item above will be referred through the entire document as: "machine".

This document conforms to the development appendix D6 "Testing of an Automated System" of the GAMP-4.

Machine Model	PROT	Document	PR0001 IQ
Serial Number	001/2008	Date	12 September 2008
Customer	ACME Inc.	Version	1.0

2. REVISION HISTORY

Revision	Issue date	Description / Changes
Draft A	03 June 2008	Initial draft release
1.0	12 September 2008	Revised introduction;

Machine Model	PROT	Document	PR0001 IQ
Serial Number	001/2008	Date	12 September 2008
Customer	ACME Inc.	Version	1.0

3. TESTING PROCEDURE

- Tester has to read and understand the single test before executing on the machine;
- Tester has to perform all the test with the indicated order;
  - ○ If the test is successfully completed, tester has to:
    - ■ Indicate "Pass" on the "Test result" column of the applicable try;
    - ■ Signature and date "Tester column" under applicable try;
    - ■ Cross out remaining "Try" columns with N/A, sign and date.
    - ■ Move to next test;
  - ○ If the test is not successful tester has to:
    - ■ Suspend the test;
    - ■ Compile and number an incident sheet that will be appended to the protocol;
    - ■ Indicate the incident sheet number on "Test result" column of the applicable try;
    - ■ Correct the problem;
    - ■ Close the incident sheet indicating the solution used to correct the problem;
    - ■ Repeat the test from the beginning;
    - ■ Indicate "Pass" in the "Test result" column.
    - ■ Signature and date "Tester column" under applicable try;
- Witness has to put his name, date and signature when the test is successful on the reserved box.
- Comments added in the "Tester's note" box must be signed and dated.

Machine Model	PROT	Document	PR0001 IQ
Serial Number	001/2008	Date	12 September 2008
Customer	ACME Inc.	Version	1.0

4. VERIFICATION OF DESIGN REQUIREMENTS

4.1. TEST SCOPE

- Checkout that the mechanical dimensions of the machine conforms to the actual revision of layout. Use a highlighter pen and highlight the dimensions checked. Attach to the protocol;

- Check the design requirements as reported;

4.2. INSTRUMENTS NEEDED

- Tape measure at least five meters long.

4.3. TEST SHEET

Test #	Test	Expected result	Try #1		Try #2		Try #3	
			Result	Tester	Result	Tester	Result	Tester
1	Verify mechanical dimensions against the machine's layout 1234- rev._____;	All mechanical dimensions should conform to layout;						
2	Equipment must be of sanitary design, including finishes, seals, process valves and fittings and designed to facilitate good house keeping practices;	Everything as requested;						
3	Parts shall be easily disassembled for sanitizing and cleaning;	Everything as requested;						
4	The machine shall be easy to inspect for remaining products;	Everything as requested;						
5	There shall be no dead spots where remaining products can be hidden;	Everything as requested;						

IQ Protocol

Machine Model	PROT	Document	PR0001 IQ
Serial Number	001/2008	Date	12 September 2008
Customer	ACME Inc.	Version	1.0

Test #	Test	Expected result	Try #1		Try #2		Try #3	
			Result	Tester	Result	Tester	Result	Tester
6	Exhausted air is piped out from the GMP area;	Everything as requested;						
7	Lubricants, coolants etc. doesn't reach the direct product contact surfaces;	Everything as requested;						
8	Design must facilitate cleaning of the machine and bottle contact surfaces;	Everything as requested;						

Test witnessed by:		Date:		Signature:	

Machine Model	PROT	Document	PR0001 IQ
Serial Number	001/2008	Date	12 September 2008
Customer	ACME Inc.	Version	1.0

Tester's notes

Machine Model	PROT	Document	PR0001 IQ
Serial Number	001/2008	Date	12 September 2008
Customer	ACME Inc.	Version	1.0

5. CHECKOUT OF DOCUMENTATION

5.1. TEST SCOPE

Checkout that all requested documentation is readily available.

- Three paper copies in English.

- Document current revision number in the "Document code" column.

5.2. INSTRUMENTS NEEDED

None.

5.3. TEST SHEET

Test #	Document	Format	Document code	Version	Try #1		Try #2		Try #3	
					Result	Tester	Result	Tester	Result	Tester
1	Layout drawings	One for the whole line Electronic & Paper	9876							
2	P&ID	Electronic & paper	L05104							
3	Quality and project plan	One for the whole line Electronic & Paper	PR0001 QP							
4	Functional design specification for prototype	Electronic & paper	PR0001 FDS							
5	Hardware design specification for prototype	Electronic & paper	PR0001 HDS							

IQ Protocol

Machine Model	PROT	Document	PR0001 IQ
Serial Number	001/2008	Date	12 September 2008
Customer	ACME Inc.	Version	1.0

Test #	Document	Format	Document code	Version	Try #1		Try #2		Try #3	
					Result	Tester	Result	Tester	Result	Tester
6	Software module design specification	One for the whole line Electronic & paper	PR0001 SMDS							
7	Software design specification for prototype	Electronic & paper	PR0001 SDS							
8	Hardware acceptance test specification for prototype	Electronic & paper	PR0001 HATS							
9	SW module test specification	One for the whole line Electronic & paper	PR0001 SMTS							
10	SW integration test specification for prototype	Electronic & paper	PR0001 SITS							
11	System software acceptance test specifications for prototype	Electronic & paper								
12	Software list for prototype	Electronic & paper								
13	Instrument list for prototype	Electronic & paper								
14	Historian tag list for prototype	Electronic & paper	PR0001 VTL							
15	Configuration management	One for the whole line Electronic & paper	PR0001 QP							
16	Disaster recovery for prototype	Electronic & paper	PR0001 DR							

	IQ Protocol	

Machine Model	PROT	Document	PR0001 IQ
Serial Number	001/2008	Date	12 September 2008
Customer	ACME Inc.	Version	1.0

Test #	Document	Format	Document code	Version	Try #1		Try #2		Try #3	
					Result	Tester	Result	Tester	Result	Tester
17	Screen navigation procedure for prototype	Electronic & paper	Check user's manual							
18	Alarm list for prototype	Electronic & paper	PR0001 AL							
19	IQ test protocol for prototype	Electronic & paper	PR0001 IQ							
20	OQ test protocol for prototype	Electronic & paper	PR0001 OQ							
21	HMI manual for prototype	Electronic & paper	Check user's manual							
22	Training documentation for prototype	Electronic & paper	PR0001 TM							
23	Hardcopies of application software & Backup of application software for prototype;	Electronic & paper								
24	Operator's and maintenance manual for prototype, including preventive maintenance schedules;	Electronic & paper	Check user's manual							
25	Allen Bradley system manuals	One for the whole line Electronic								
26	List of components for prototype	Electronic & paper								

IQ Protocol

Machine Model	PROT	
Serial Number	001/2008	
Customer	ACME Inc.	

	Document	PR0001 IQ
	Date	12 September 2008
	Version	1.0

Test #	Document	Format	Document code	Version	Try #1		Try #2		Try #3	
					Result	Tester	Result	Tester	Result	Tester
27	Data sheets (for all components on P&ID) for prototype	Paper								
28	Certificates for prototype: • FDA approved gaskets; • Material certificates (surfaces in product contact); • Passivation certificate; • Filter certificate. • Calibration certificate	Paper								
29	Modification report and log	Electronic & paper								
30	Built version report	Electronic & paper	PR0001 BVR							
31	Procedure to create a new Back-up	Paper	PR0001 DR							

Test witnessed by:		Date:		Signature:	

IQ Protocol

Machine Model	PROT	Document	PR0001 IQ
Serial Number	001/2008	Date	12 September 2008
Customer	ACME Inc.	Version	1.0

Tester's notes

Machine Model	PROT	Document	PR0001 IQ
Serial Number	001/2008	Date	12 September 2008
Customer	ACME Inc.	Version	1.0

6. PLC APPLICATION PROGRAM REVIEW

6.1. TEST SCOPE

Check that all required information are reported on PLC application program header; needed informations are:

- ACME;
- Process Name PLC Program;
- Written for the "*Processor Type*";
- Authored by "*Author's Name*" – (Author's Employer);
- Date *DD-MMM-YYYY*;
- Revised by "*Revision Author's Name*" – (Revision Author's Employer);
- Revision # Date *DD-MMM-YYYY*.

6.2. INSTRUMENTS NEEDED

None.

6.3. TEST SHEET

Test #	Test	Expected result	Try #1		Try #2		Try #3	
			Result	**Tester**	**Result**	**Tester**	**Result**	**Tester**
1	Check that all requested information as detailed above are reported on PLC program;	All information are reported on PLC program;						
2	Check that the installed version of software is the same as declared on "Software list for prototype";	The installed version of software (declared on "Software list for prototype") is the same as the PLC and HMI version;						

Test witnessed by:		Date:		Signature:	

IQ Protocol

Machine Model	PROT	Document	PR0001 IQ
Serial Number	001/2008	Date	12 September 2008
Customer	ACME Inc.	Version	1.0

Tester's notes

	Machine Model	PROT	Document	PR0001 IQ
	Serial Number	001/2008	Date	12 September 2008
	Customer	ACME Inc.	Version	1.0

7. CHECKOUT OF P&ID COMPLIANCE

7.1. TEST SCOPE

Checkout that all devices reported on P&ID are mounted on the machine and vice versa. Use a highlighter pen and highlight the components checked. Attach to the protocol.

7.2. INSTRUMENTS NEEDED

None.

7.3. TEST SHEET

Test #	Test	Expected result	Try #1		Try #2		Try #3	
			Result	Tester	Result	Tester	Result	Tester
1	Check against the P&ID 12345 rev._____ that all components on the schematic are mounted on the machine;	All components drawn on P&ID are mounted on the machine and properly tagged;						
2	Check against the machine that all relevant components are drawn on the P&ID;	All relevant components are drawn on P&ID;						

Test witnessed by:		Date:		Signature:	

Machine Model	PROT	Document	PR0001 IQ
Serial Number	001/2008	Date	12 September 2008
Customer	ACME Inc.	Version	1.0

Tester's notes

Machine Model	PROT	Document	PR0001 IQ
Serial Number	001/2008	Date	12 September 2008
Customer	ACME Inc.	Version	1.0

8. CHECKOUT OF ELECTRICAL DEVICES

8.1. TEST SCOPE

Checkouts that all electrical devices reported on schematics are mounted on the machine and vice versa. Use a highlighter pen and highlight the devices checked. Attach to the protocol. Check that:

1. The hardware is undamaged and clean;
2. The hardware is installed and labeled according to drawings and specification;
3. The hardware is of correct manufacturer and model according to drawings and specification;
4. The hardware is configured according to drawings and specification;
5. Note Serial number (if visible) on electrical schematics used for this test;
6. Wiring (within cabinet and in field) shall be installed and labeled according to electrical diagram:
7. Check the presence of a PLC;

8.2. INSTRUMENTS NEEDED

None.

8.3. TEST SHEET

Test #	Test	Expected result	Try #1		Try #2		Try #3	
			Result	Tester	Result	Tester	Result	Tester
1	Hardware visual check;	Hardware is undamaged and clean;						
2	Hardware installation check;	1.The hardware is installed and labelled according to drawings and specification; 2.The hardware is of correct manufacturer and model according to drawings and specification; 3. Wiring (within cabinet and in field) shall be installed and labelled according to electrical diagram;						

		IQ Protocol		
The ladder and beyond				

Machine Model	PROT		Document	PR0001 IQ
Serial Number	001/2008		Date	12 September 2008
Customer	ACME Inc.		Version	1.0

Test #	Test	Expected result	Try #1		Try #2		Try #3	
			Result	Tester	Result	Tester	Result	Tester
3	Hardware configuration check;	The hardware is configured according to drawings and specification;						
4	Serial number registration of the major devices;	Note serial number (if visible) of the major devices on the electrical schematics ref. # 08A036017;						
5	The system must be automated with an industrial programmable controller for executing real-time control and monitoring of the equipment;	A PLC is mounted into the electrical cabinet;						

Test witnessed by:			**Date:**		**Signature:**	

Machine Model	PROT	Document	PR0001 IQ
Serial Number	001/2008	Date	12 September 2008
Customer	ACME Inc.	Version	1.0

Tester's notes

Machine Model	PROT	Document	PR0001 IQ
Serial Number	001/2008	Date	12 September 2008
Customer	ACME Inc.	Version	1.0

9. CHECKOUT OF SYSTEMS INTERCONNECTIONS

9.1. TEST SCOPE

Checkout that the interconnection between systems exists as reported on the table below.

9.2. INSTRUMENTS NEEDED

None.

9.3. TEST SHEET

Test #	Starting point	Ending point	Cable type	Try #1		Try #2		Try #3	
				Result	Tester	Result	Tester	Result	Tester
1	Main PLC	Machine Ethernet switch	Straight Ethernet						
2	Machine Ethernet switch	HMI	Straight Ethernet						
3	PLC inverter communication card	PowerFlex VFD	Modbus cable						
4	Machine Ethernet switch	Line Ethernet switch	Straight Ethernet						

Test witnessed by:		Date:		Signature:	

Machine Model	PROT	Document	PR0001 IQ
Serial Number	001/2008	Date	12 September 2008
Customer	ACME Inc.	Version	1.0

Tester's notes

Machine Model	PROT	Document	PR0001 IQ
Serial Number	001/2008	Date	12 September 2008
Customer	ACME Inc.	Version	1.0

10. CHECKOUT OF PNEUMATIC DEVICES

10.1. TEST SCOPE

Checkouts that all pneumatic devices reported on schematics are mounted on the machine and vice versa. Use a highlighter pen and highlight the devices checked on the schematics. Attach to the protocol.

10.2. INSTRUMENTS NEEDED

None.

10.3. TEST SHEET

Tag	Component	Description	Manufacturer	Location	Try #1		Try #2		Try #3	
					Result	Tester	Result	Tester	Result	Tester
19SP1	PEV-1/4-B	Pharmaceutical air pressure switch	Festo	Field						
19SP2	AP-31P	Vacuum sensor	Keyence	Field						
R1	LFR1/4 D5 MINI	Pharmaceutical air pressure regulator	Festo	Field						
R2	LFMA-1/4-D-MIDI	Pharmaceutical air filter $\leq$ 0.45µm	Festo	Field						

Test witnessed by:		Date:		Signature:	

IQ Protocol

Machine Model	PROT	Document	PR0001 IQ
Serial Number	001/2008	Date	12 September 2008
Customer	ACME Inc.	Version	1.0

Tester's notes

Machine Model	PROT	Document	PR0001 IQ
Serial Number	001/2008	Date	12 September 2008
Customer	ACME Inc.	Version	1.0

11. CHECKOUT OF COMMERCIAL MECHANICAL PARTS

11.1. TEST SCOPE

Checkouts that all commercial mechanical parts reported below are mounted on the machine.

Note: Not all mechanical parts has a tag.

11.2. INSTRUMENTS NEEDED

None.

11.3. TEST SHEET

Tag	Component type	Manufacturer	Manufacturer code	Try #1		Try #2		Try #3	
				Result	Tester	Result	Tester	Result	Tester
6M2	Motor	Siemens	1LA70534AB12						

Test witnessed by:		Date:		Signature:	

Machine Model	PROT	Document	PR0001 IQ
Serial Number	001/2008	Date	12 September 2008
Customer	ACME Inc.	Version	1.0

Tester's notes