

Customer:ACME Inc.Document code:PR0001 IQProject:PrototypeRevision: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 |
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This document contains a Front Cover and 25 pages.

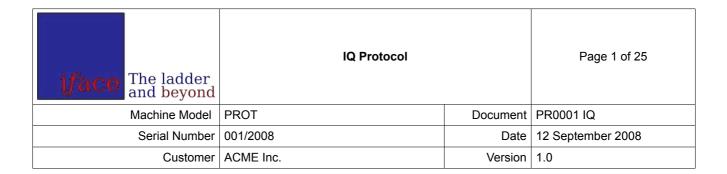


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1. Introduction

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.

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2. Revision HISTORY

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

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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;
 - O 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;
 - O 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.

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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.

| Test # | Test | Expected requit | Try #1 | | Try #2 | | Try #3 | |
|--------|---|---|--------|--------|--------|--------|--------|--------|
| rest # | | Expected result | 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; | | | | | | |

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| Test # | Test | Everanted manufe | Try #1 | | Try #2 | | Try #3 | |
|--------|--|--------------------------|--------|--------|--------|--------|--------|--------|
| rest # | Test # Test | Expected result | 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: | |
|--------------------|-------|------------|--|
|--------------------|-------|------------|--|

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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.

| Test | Document | Format | Document code | Version | Try | #1 | Try #2 | | Try #3 | |
|------|---|---|---------------|---------|--------|--------|--------|--------|--------|--------|
| # | Document | Format | Document code | Version | 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 | | | | | | | |



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| Test | Document | Format | Document code | Varaion | Try #1 | Try | / #2 | Try #3 | | |
|------|--|---|---------------|-----------|--------|--------|--------|--------|--------|--------|
| # | Document | Format | Document code | Version — | 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 | | | | | | | |



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| Test | Document | Format | Document code | Vorcion | Try | #1 | Try | <i>t</i> #2 | Try | #3 |
|------|--|--------------------------------------|---------------------|---------|--------|--------|--------|-------------|--------|--------|
| # | Document | Format | Document code | | 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 | | | | | | | | |

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| Test | Document | Format | Document code | | Try #1 | | Try #2 | | Try #3 | |
|------|--|--------------------|---------------|--|--------|--------|--------|--------|--------|--------|
| # | Document | Format | Document code | | Result | Tester | Result | Tester | Result | Tester |
| 27 | Data sheets (for all components on P&ID) for prototype | Paper | | | | | | | | |
| 28 | Certificates for prototype: | 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: | | |
|--------------------|-------|--|------------|--|--|
|--------------------|-------|--|------------|--|--|

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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.

| Test | Toet | Test Expected result | Try #1 | | Try #2 | | Try #3 | |
|------|--|---|--------|--------|--------|--------|--------|--------|
| # | lest | Expected result | 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; | | | | | | |

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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.

| Test | Test Expected result | | #1 | Try #2 | | Try #3 | | |
|------|--|--|--------|--------|--------|--------|--------|--------|
| # | lest | Expected result | Result | Tester | Result | Tester | Result | Tester |
| 1 | Check against the P&ID 12345 revthat 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: |
|-------------------------------------|
|-------------------------------------|

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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.

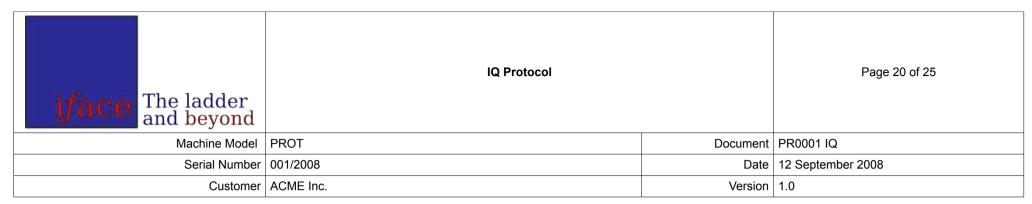
| Test | Test Expected result | | Try | #1 | Try | #2 | Try | #3 |
|------|------------------------------|---|--------|--------|--------|--------|--------|----|
| # | Test Expected result | Result | Tester | Result | Tester | Result | Tester | |
| 1 | Hardware visual check; | Hardware is undamaged and 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; | | | | | | |

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| Test | Test | Expected result | Try #1 | | Try | <i>ı</i> #2 | Try #3 | |
|------|--|---|--------|--------|--------|-------------|--------|--------|
| # | # lest | Expected result | 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: | | |
|--------------------|--|-------|--|------------|--|--|
|--------------------|--|-------|--|------------|--|--|

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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.

| Test # | Test # Starting point Ending point Cable type | | Cable type | Try #1 | | Try #2 | | Try #3 | |
|--------|---|-------------------------|-------------------|--------|--------|--------|--------|--------|--------|
| 1651# | Starting point | Enaing point | Cable type | Result | Tester | Result | Tester | Result | Tester |
| 1 | Main PLC | Machine Ethernet switch | Straight Ethernet | | | | | | |
| 2 | Machine Ethernet switch | НМІ | Straight Ethernet | | | | | | |
| 3 | PLC inverter communication card | PowerFlex VFD | Modbus cable | | | | | | |
| 4 | Machine Ethernet switch | Line Ethernet switch | Straight Ethernet | | | | | | |

| Date: | Signature: | |
|-------|------------|------------------|
| | Date: | Date: Signature: |

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Customer ACME Inc. Version 1.0 Tester's notes

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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.

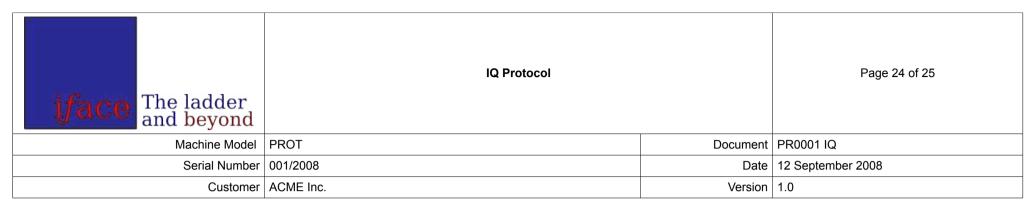
10.2. INSTRUMENTS NEEDED

None.

| Tog | Component | Description | Manufacturer | Manufacturer Location | Try | #1 | Try | / #2 | Try | #3 |
|-------|-----------------|---------------------------------------|---------------|-----------------------|--------|--------|--------|--------|--------|--------|
| Tag | Component | Description | Wallulacturer | Location | 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 ≤ 0.45µm | Festo | Field | | | | | | |

| Test witnessed by: | Date: | Signature: | |
|--------------------|-------|------------|--|
|--------------------|-------|------------|--|

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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.

| Tog | Component type Manufacturer Manufacturer code | g Component type Manufacturer Manufacturer code | | Try | #1 | Try | / #2 | Try | #3 |
|-----|---|---|-------------------|--------|--------|--------|--------|--------|--------|
| Tag | Component type | Wandacturer | Manufacturer code | Result | Tester | Result | Tester | Result | Tester |
| 6M2 | Motor | Siemens | 1LA70534AB12 | | | | | | |

| Test witnessed by: Date: Signature: | |
|-------------------------------------|--|
|-------------------------------------|--|

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