

Customer name

Operational Qualification

Version 1.0x of gg/mm/aa

Document and Protocol Preparation



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APPROVAL OF THE PROTOCOL

Department	Signature	Name & Function	Date
Quality Assurance			
Engineering			
Projects			


Your signature above indicates that this protocol has been reviewed and approved for implementation.

Remarks

APPROVAL OF THE OPERATIONAL QUALIFICATION

Department	Signature	Name & Function	Date

The Qualification has been completed. Your signature above indicates that the results have been reviewed or approval and satisfy all protocol requirements.

	IQ/OQ	Autoclave Operational Qualification	
Customer	Autoclave Model	NF	Process Controller
	FOFx		Thema 3

Foreword.

Over recent years sterilisation techniques have become progressively more advanced and complex. It is our policy to stay at the forefront of these developments, with a commitment to Research and Technological Development that allows us to offer the most advanced designs of autoclave available.


At the same time the regulatory regimes being applied are becoming more and more exacting. The time and effort now needed to qualify an autoclave for production use is many times greater than it once was.

As part of our effort to provide not only the most technologically advanced equipment, but also the highest levels of customer support available, we have prepared a scheme of qualification tests that in our judgement provides a fully rigorous examination of Fedegari autoclaves.

All our products are comprehensively tested at each stage of production, and this is done to recognised testing standards in a way that provides auditable documentary evidence. These tests cover the build of the autoclave itself, the software used by the process controller, and the performance of the equipment.


Other tests can only be successfully performed at the customer's site. This document offers a complete set of on-site *Operational Qualification* tests as recommended by our company. The package includes test protocols, specialised test equipment and procedures guiding their use.

We trust this package proves useful, and would welcome any comments.

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1. Introduction

Each autoclave is made to a detailed specification agreed with the customer. Each of the major system components - chamber, doors, load conveyancing equipment, hydraulic system, electrical system, process control system - is subject to detail testing during manufacture. The successful integration of these is verified during Pre-delivery Factory Acceptance Tests.

On delivery and installation at the customer's premises it is necessary to verify autoclave conformance to specification in its intended operational environment. This is considered at three levels:


1. **Installation Qualification (IQ).**
Has the Autoclave been built and configured to the agreed Technical Specification?
2. **Operational Qualification (OQ).**
Does the Autoclave perform to the agreed Functional Specification?
3. **Performance Qualification (PQ).**
When operated within set parameters, does the autoclave consistently produce results meeting its pre-determined specification?

Purpose

This document sets out the **Operational Qualification** tests recommended Qualitech Srl to verify the conformity of Autoclave and Process Controller to the approved Technical Specification.

This plan is designed to guide Operational Qualification in accordance with the main principles set out in 'GAMP' Appendix N. These principles encourage disciplined pre-planning, execution and quality control of the testing process.

The document includes a total package which may be used to plan, manage, conduct and document the Installation Qualification to the standard required by regulatory bodies. Any modification of this protocol must be required to Qualitech/Fedegari that will provide to a new issue according to the customer request.

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2 Overview

2.1 Scope

The document covers Installation Qualification of the specified autoclave and Process Controller only, at the customer's premises. It does not cover the Operational Qualification required to verify conformance to the Functional Specification, (which should follow this IQ) nor the Performance Qualification required to validate consistently effective process results.

All components and sub-systems of the autoclave are included. If executed in full, a comprehensive validation of the autoclave can be achieved, as required after initial commissioning or after a *Major Change*. Provision is made within the Test Plan section to allow a controlled reduced set of tests to be performed, as may be require after a '*Minor Change*', or when some existing documentary evidence of compliance is already in place (e.g. as a result of Factory Acceptance Tests).

The tests included cover the full range of components likely to be installed on Fedegari Autoclaves with Thema 3 controllers. However, it is very unlikely that a specific autoclave will have all these components. Thus some of the tests may be eliminated as 'Not Required' as they are not applicable. Examples may include Extension keyboards, Air Detectors and Steam Generators.

2.2 Testing philosophy

No testing can be completely exhaustive. The objectives of the test plan is to achieve a reasonable level of assurance on every component and sub-system of the autoclave, while giving particular emphasis to those elements most sensitive to the site assembly and commissioning processes.

All tests are designed to verify the system against unambiguous, documented, pre-determined acceptance criteria.

The protocols are designed to ensure that the testing follows clear, pre-determined methods approved in advance.


All tests are designed to be conducted by properly authorised personnel, supported by relevant documentation and test equipment. Detailed compliance with GAMP would demand that tests be independently witnessed; this is left to the discretion of the customer.

The documentation is designed to collect all the documentary evidence needed to retrospectively audit the validity of the results.

The procedures call for the test results to be formally reviewed before being regarded as finally accepted.

2.3 Identification

The Autoclave model and Serial No, and the Process Controller model are identified on the front page and in the header of each subsequent page.

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2.4 Tests Included

The Operational Qualification verifies :

- I. The correct function of the Process Controller hardware .Monitors, keyboards, printers; Clocks and timers RAM EEROM and EPROM memory; Battery backup.
- II. The correct operation of the following critical Process Controller software functions.
 - Program Utilisation
 - Program Management
- III. Clocks
- IV. Control of Door Operations
- V. Sterilisation Control
- VI. Control of Ancillary Operations
- VII. Management of Excess Conditions
- VIII. Alarms
- IX. Input and Output loop verification.
- X. Systems Resilience
- XI. Verification of Customer Cycles

2.5 Functions not tested

Software-only functions that have been adequately verified through formal Software Validation are not re-tested here. These include:


- Password definition and control,
- Operator language selection,

Functions accessible only by Fedegari authorised personnel are not verified here.

2.6 Phase Group Testing

Sterilisation programs are composed of a series of Phases arranged in Phase Groups. These Phase Groups are provided on an EPROM library and are not subject to amendment on site. Program control is achieved by use of variable parameters. All Phase Groups in the library are fully validated over the full range and combination of parameters before being installed on a customer's autoclave. They are not subject to detailed, fully comprehensive re-testing in this Operational Qualification. They *are* tested under the more limited range of parameter values specified for each client specified cycle.

Verification of Input/ Output loops is included in the Operational Qualification, after those OQ tests that involve disturbing field connections.

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3. Personnel and Procedures:

3.1 Personnel

All tasks must be carried out by properly qualified and authorised personnel.

The following table records the authorised personnel for each category of approval, and provides examples of their signatures and initials.

One person may be authorised for more than one category, but a 'Tester' cannot review his own work.

Authority (& 'Accountability' Title)	Name	Job Title	Signature	Initials
Conduct Tests (<i>'Tester'</i>)				
Review Tests (<i>'Test Reviewer'</i>)				

3.2 Procedure

3.2.1 Preparing a test plan

The designated 'Test Manager' must complete the **Test plan** by:

1. Identifying all aspects of the Installation Qualification to be covered;
2. Reviewing the verification tests included in this document, and ensuring that all IQ requirements have been included;

The Method and Acceptance criteria of all protocols in the finalised Test plan must be approved in advance by a qualified 'Test Approver' who must sign off each test section as it is approved. All tests in the finalised Test plan are to be performed by properly authorised 'Testers' as set out in the **Test plan** in section 8.

Take note of all reference instrumentation used fore the activities and fill section 7.1 of the protocol and include all documentation evidence (Conformity cert. , Specifications, Calibration certificates etc.)

3.2.2 Conducting tests

Each test must be conducted by an authorised 'Tester' using the **Method** set out in its protocol. Should the method be unsuitable then a variation must be documented and authorised by the 'Test Approver'

Each test protocol includes a statement of the **Acceptance criteria** that must be achieved for the test to be passed. This may be the combined result of many test steps.

The results must be recorded as required in the **Results** section

Where the result confirms that the **expected result** has been achieved, the results table will allow for a clear statement (Yes / No) of this.


Yes will always confirm a satisfactory result. **No** will always denote non-conformance.

Where the method calls for retention of documentary evidence (e.g. Printouts) these must

- 1 be given a unique identity (e.g. 'Printout 7') and this noted clearly on them;
- 2 have the protocol(s) to which they relate noted on them,
- 3 be signed and dated by the tester.
- 4 be retained in the Test Results Documentation section 10.

The unique identity of each document providing supporting evidence of the results must be recorded in the **Document or Printout reference** section of the Protocol sheet.

Where the method requires the use of a calibrated measuring instrument, the unique identity of the instrument used must be recorded in the **Testing resource** section of the protocol, and the reference of the Calibration certificate recorded in the **Testing resource documentation** section of the Protocol sheet.

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3.2.3 Confirming test compliance.

When the results show that all Acceptance criteria have been satisfied, the 'Tester' must sign and date the **Test plan** section. The Protocol sheet must then be filed in the **Completed tests** section 9.1.

Should any Acceptance Criterion remain not satisfied, the 'Tester' must not initial the Test Plan but write "failed", file the Protocol sheet **I/OQX.Y** and the relevant documentation in the **Failed test list** section 11.1 For each failed test, fill in the **Test incident form** and inform the 'Test Manager'. The problem must be solved and the test repeated on a new protocol sheet. This must be progressively renamed as **I/OQX.Ya, b, c....**

3.2.4 Reviewing passed tests

When each test has been satisfactorily completed an authorised 'Test Reviewer' must review the results to verify that

- the test has been properly conducted by authorised personnel, and signed off;
- all the results are satisfactory;
- all the required supporting documentation has been identified, signed, dated and retained.

The 'Tester' must sign and date the **Test plan** section. The Protocol sheet must then be filed in the **Reviewed Completed tests** section 9.2

When satisfied that all is in order, the 'Test Reviewer' must sign off the protocol sheet as reviewed, file it in the Reviewed tests section 9.2 and fill initial the 'Completed' column in the Reviewed Test plan, Section 8.

3.2.5 Reviewing failed tests

When a test has been failed, its results must be assessed by the *Test Reviewer* or a Review Group called by the *Test Manager*. The review shall decide which course of action to take, and in the event of a change or modification, decide the amount of subsequent re-testing to be done.

The above actions must be documented for each failed test filling a Incident Follow - Up section of the **Test Incident Form** Review Report filed in section 11.2.1 – 11.2.10


Three actions are possible:

- Repeat the test, using a new protocol sheet;
- Apply a change or modification to the equipment and repeat the test;
- Abandon the test, and possibly others.

When the new results show that all Acceptance Criteria have been satisfied, the 'Tester' and the 'Test Reviewer' must indicate this clearly, writing **Yes** in the **Compliance** section at the end of each form, then sign and date the section. The Protocol sheet must then be filed in the **Repeated test result** section 12.1. The relevant documentation must be retained in the **Documentation on Repeated test** section 12.2.

The 'Tester Reviewer' must then also initial the corresponding item as 'Done' in the **Repeated test** section 12.

3.2.6 At the end of the /Operational Qualification activities any action to be done according to the I/OQ results must be reported in the **Conclusion** section 13.

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4. Glossary

Acceptance Criterion. (ANSI/IEEE): The criterion a system must meet to successfully complete a test phase or to achieve delivery requirements.

Configuration: The documented physical and functional characteristics of a particular system. A change converts one configuration into a new one.

Critical Process Parameter: A process-related variable which, when out-of-control, can potentially cause an adverse effect on fitness-for-use of an end product.

Documentation: (ANSI N45.2.10-1973): Any written or pictorial information describing, defining, specifying, reporting or certifying activities, requirements, procedures or results.

Installation Qualification [IQ] (PMA CSVC): Documented verification that all key aspects of hardware installation adhere to appropriate codes and approved design intentions and that the recommendations of the manufacturer have been suitably considered.

Integration Testing: An orderly progression of testing in which the software elements, hardware elements, or both are combined and tested until the entire system has been integrated.

Loop Testing: Checking the installed combination of elements characterising each type of input/ output loop.

Major Change (PMA CSVC): A change to a validated system that, in the opinion of the change-control reviewers, necessitates a revalidation of the system.

Minor Change (PMA CSVC): A change to a validated system that, in the opinion of the change-control reviewers, does not necessitate a complete revalidation of the system.

Operating Environment: All outside systems that interface with the equipment, including humans.

Operational Qualification [OQ] (PMA CSVC): Documented verification that the equipment-related system or subsystem performs as intended throughout representative or anticipated operational ranges.

Performance Qualification [PQ]: Documented verification that the process and/or the total process-related system performs as intended throughout all anticipated operating ranges.

PLC: Programmable Logic Controller.

Procedure (PMA CSVC): The combination of process equipment, support systems (such as utilities), and procedures used to execute a process.

Qualification Protocol: A prospective experimental plan that when executed is intended to produce documented evidence that a system or subsystem has been properly qualified.

Simulation (ANSI/ IEEE/ ISO): The representation of selected characteristics of the behaviour of one physical or abstract system by another system. In a digital computer system, simulation is done by software; for example, (a) the representation of physical phenomena by means of operations performed by a computer system, (b) the representation of operations of a computer system by those of another computer system.


Tester: A person performing the tests.

Testing, Structural and Functional: Both forms of testing are essential. *Neither form can be exhaustive.*

User (ANSI/ IEEE Std 830-1984): The person or persons who operate or interact directly with the system.

Validation: "Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality attributes". - FDA Guidelines on General Principles of Process Validation, May 1987

Validation Protocol: A prospective experimental plan that when executed is intended to produce documented evidence that the system has been validated.

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5. Test protocols

Each test is specified by a protocol set out on one page in a consistent format:

Header - Identifying the Autoclave's unique serial number and Customer.

Test reference - Unique identification of the test, with version number;

Test Title

Purpose - a brief statement of the aims of the test;

Method - the steps to be taken to conduct the test satisfactorily,
including where appropriate any preparation, and documentation;

Acceptance criteria - the conditions that must be met for the test to be passed.

Failure to meet one or more Acceptance Criteria causes the test to fail.

Test results - a form for recording of test results

Comments - a section for recording any relevant supplementary comments.

In addition, where appropriate the protocols will include:

Document references - a section for noting the references of any further documents that are needed as supportive evidence - e.g. printouts, calibration certificates.


Instrumentation identities - a section for recording the reference identities of any calibrated measuring instrumentation required.

In the Test plan section:

Approval signature - confirmation that the test method has been formally approved by an authorised 'Test Approver' before being used;

Compliance signature - a section for a clear, unambiguous statement (Yes / No) as to whether the test has been passed, to be completed, signed and dated by the authorised 'Tester'.

Review signature - a section for confirmation that after the tests have been completed, the results have been formally reviewed by an authorised 'Test Reviewer'.

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6. Testing requirements

To conduct these tests the following must be available:

The autoclave with all services attached and operational;

All Fedegari supplied trolleys, drums, conveyancing systems;

A copy of the **Operating Manual**, including:

- P & I D
- Installation Drawings
- Configuration documentation
- Electrical wiring diagrams
- All other Customer Documentation supplied by Fedegari SpA


A copy of the **Technical specification**;

This **Test plan** and all required **Test protocols**.

Test equipment as specified in each protocol.

- a Voltmeter
- thermometer measuring environmental Temperature
- Manometer.
- Calibrated thermo-meter
- Temp. source eg hot block
- Calibrated Pressure Tester
- Analog Input Simulators
- Calibrated Ampere-meter

Further documentation and test equipment as specified in each protocol

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8. Test Plan


This section gives a full index of available tests.

The *Tester* must then initial each remaining test as it is completed with satisfactory results.

OQ

- **Control System hardware function**
 - Main Panel On/ Off/ Emergency Stop.
 - Keyboard On / Off test.
 - HCS300- Hardware tests
 - HCS186 Hardware tests
 - HSL100- Board Test
 - Power Failure (Battery backup) test.
- **Input and Output loops Verification.**
 - Digital Inputs verification.
 - Digital Outputs verification.
 - Analogue Outputs verification.
- **Safety Critical Devices Check**
 - Safety Valves
 - Jacket Pressure Switches Safeties
 - Door Safety Devices (1)
 - Electrical Protections
 - Load Transportation System Safeties
 - Mechanical Protection
- **Not Critical Devices Verification**
 - Pressure Switches.
 - Manometers.
- **Control of Ancillary Operations**
 - Vacuum Pump Efficiency.
 - Drain Temp. Control.
- **Alarms**
 - Utilities and Services
 - Cycle Management
 - Door Control
 - Instrumentation
 - Motors
 - Valves
 - Autoclave Status
 - Sterilisation Control
 - Miscellaneous

Verification of Customer Cycles.

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Test sheet example:

Test Ref.	OQ9.2	Test Title	Alarms: Utilities
Purpose			
To verify that the utilities monitoring alarms 2,3 operate correctly.			
Method			

Preparation
 Check that the expected alarm responses tabled below match the documented alarm configuration.
 Switch Process Controller OFF then ON to clear alarm list.

Test
 Load a test program, enter *Prepare Sterilizer*. Start program.
 For each available utility in turn:
 a. Turn off utility supply. Verify whether corresponding alarm responds as expected.
 b. Restore utility supply. Verify whether the alarm is cancelled as expected.
 If controller enters *Emergency* phase, verify ability to revert to *Prepare Sterilizer* by using PHASE STEP.
 End program using END key.

Documentation
 At end of cycle print alarm summary showing alarms activated. Retain with cycle printouts..

Results												
Alarm n°	Message	Expect sum	Print (1)	Ac.Al. (2)	Eme. (4)	Pr.on (8)	Displ. (16)	Sum. (32)	S.on (64)	S.L. (128)	Tot. sum	Accept. Yes/No
2	COMPRESSED AIR LACK											
3	TAP WATER LACK											

Printout ref.:	Comments:

Tests Approved by :	Date:
HAVE ALL THE ACCEPTANCE CRITERIA BEEN MET? (YES/ NO)	
Tests Conducted by :	Date:
Tests Reviewed by:	Date: