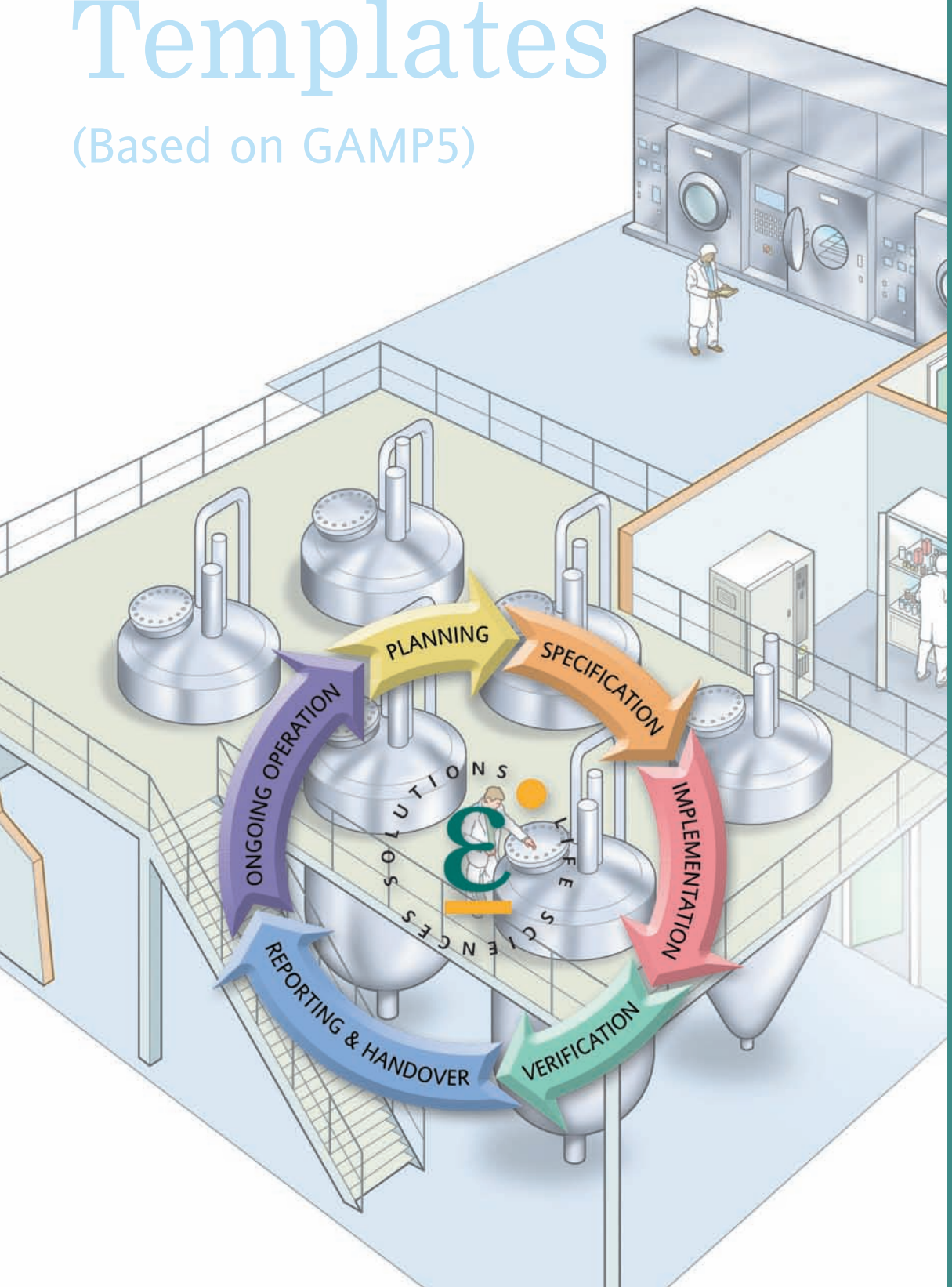
EUROTHERM FLEXIBLE SOLUTIONS

Validation Documentation Templates

(Based on GAMP5)



invensys®
EUROTHERM®

Validation Documentation Templates

(Based on GAMP5)

Contents

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Title	Double-click HERE and type Project Title
Customer	Double-click HERE and type Customer Name
Eurotherm Reference	Double-click HERE and type Eurotherm Reference
Customer Reference	Double-click HERE and type Customer Reference

Explanatory note (delete this before publication):
1) enter all fields above plus date and issue number below
2) search for 'TBA' to find items which need entering on a per-project basis.
3) if not based in the UK, replace the header with the appropriate one from your local letterhead

Specimen

QUALITY & PROJECT PLAN

Prepared by	..... Sign / Date	..... Printed Name	..... Title
Quality Review by (Eurotherm)	..... Sign / Date	..... Printed Name	..... Title
Quality Approval by (Customer) Approved for use as Basis for Project Activities	..... Sign / Date	..... Printed Name	..... Title
Issue	Enter Issue No		
Date	Enter Date		

CONTROLLED CIRCULATION		
Copy	Issued to	**This Copy**
Master	Double-click HERE and type Customer Name	
Copy 1	Project File	

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CONTENTS

Specimen

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1. DOCUMENTATION RECORDS

TEMPLATE DETAILS			
HISTORY:			
T1	Template document written to accompany Eurotherm systems engineering procedure SEP013 issue 1. Explanatory notes added in italics.		03 Jul 2003
T2	Template updated following re-issue of Eurotherm System Engineering Procedures in form suitable for use across all group companies. SEP013 now SEP109.		25 Jan 2006
T3	Template updated for GAMP5		27 May 2008
APPROVAL DETAILS FOR CURRENT TEMPLATE			
Template prepared by	Karen Ashworth	Validation Officer	27 May 2008
Template reviewed for Technical Content	Malek Madani	Technical Manager	27 May 2008
Template reviewed for Quality Assurance	Martin Greenhalgh	Global Quality Manager	27 May 2008

DOCUMENT REVISION HISTORY		
Issue	Detail	Issue Date
1a	Project version 1 developed from template T3 and issued for internal review	TBA Enter Issue Date

TBA Explanatory note (delete this before publication):
Once internal review is complete, an additional entry needs to be made for version 1 saying something like 'Internal review comments included. Document issued for customer approval'
All subsequent issues (eg version 2) need to detail the changes which have been made including the section reference and the reason for the change (eg ref to customer comment). When creating a new version: accept all previously tracked comments; make changes with change tracking enabled; hide mark-up (in the VIEW menu) before printing or issuing the document.

Specimen

2. INTRODUCTION

TBA: Explanatory note (delete this before publication): The quality plan is Eurotherm's response to the customer's quality requirements (in the same way that a functional specification is the response to the customer's functional requirements). It is a key document in defining the project lifecycle. It allows agreement of which procedures (Eurotherm, customer, GAMP,...) will be used to control and document each project activity. It is often extremely helpful to discuss a draft version during the bid process in order to make sure that Eurotherm and customer expectations (eg with regard to documentation deliverables and site testing requirements) are agreed.

2.1 Purpose

A Quality Plan is a key document in defining the project lifecycle. It sets out the proposed method of meeting the customer quality requirements and allows agreement of the controlling procedures for each project activity.

2.2 Scope

This document defines the method for meeting customer quality requirements on the control system required by Double-click HERE and type Customer Name for their Double-click HERE and type Project Title Project.

2.3 Contractual Status

This document, once approved, provides the basis for project implementation. On project completion, this document passes to the customer for archiving.

2.4 Relationship to Other Documents

2.4.1 Applicable Standards

This document has been written to meet the guideline for quality and project planning contained in GAMP5 A Risk-Based Approach to Compliant GxP Computerized Systems Appendix M6.

2.4.2 Relationship to Customer Validation Requirements

TBA: Explanatory note (delete this before publication): The validation requirements may be in the URS or may be in a separate validation plan. Include references here to the relevant document(s). It is normal to include version numbers for these base documents for contractual reasons, though this may be worth exploring with the customer as it means an update of the quality plan if the customer issues a new URS/VP in order to keep it up to date with changes resulting from design reviews or risk assessments.

The customer quality requirements in this document are derived from the lifecycle attributes listed in the following documents:

Project / Document Ref	
Title	
Issue	

A cross-reference table showing how these requirements are to be met is included in Appendix A of this Quality Plan.

2.4.3 Non-Conformances with User Requirements

TBA: Explanatory note (delete this before publication):
List out any non-conformances
The following non-conformances exist between this document and the User Requirement Specification:

Specimen

Requirement Reference	Requirement	Comment

2.4.4 Relationship to Supplier's Quality System

TBA: Explanatory note (delete this before publication): include detail on the formal quality management systems in use

Example for applications engineered by Eurotherm in the UK (group companies with their own ISO certification will be similar):
The Quality Management System of Eurotherm Limited has been approved by Lloyd's Register Quality Assurance to ISO9001:2000 and the TickIT guide Issue 5.

Example for applications engineered in Eurotherm Group companies without their own ISO certification who act as satellite offices and use UK procedures):
All Eurotherm Limited products used on this project have been developed and manufactured under a Quality Management System approved by Lloyd's Register Quality Assurance to ISO9001:2000 and the TickIT guide Issue 5.
All project activities are controlled according to this Quality Plan including the use of the same Systems Engineering Procedures approved in the UK to ISO9001:2000 and the TickIT guide Issue 5.

Specimen

3. OVERVIEW

3.1 Project Background

3.1.1 Process to be Controlled

TBA: Explanatory note (delete this before publication):
Describe the business process as understood from the customer's URS

3.1.2 Key Benefits

TBA: Explanatory note (delete this before publication):
Describe the key objectives / benefits as understood from the customer's URS

3.1.3 Relevant GxP Regulations

TBA: Explanatory note (delete this before publication):
Describe the relevant GxP regulations as understood from the customer's URS
Summarise whether 21CFR part 11 applies and if so to which records and/or signatures

3.1.4 Impact on Patient Safety, Product Quality and Data Integrity

This system has been classified by the end user as:
TBA: Explanatory note (delete this before publication): -
The customer should already have done the first step of the risk assessment and the GxP criticality / impact level of the system should be available either in the URS or a separate risk assessment document.
Update this table as relevant to the project and if necessary add some words about what the customer means by high/medium/low.

GxP Critical	Yes / No
Impact Level	High / Medium / Low

3.2 Project Boundaries and Interfaces

TBA: Explanatory note (delete this before publication):
Modify the drawing to show the correct boundary for the scope of supply / validation
– remove right hand boxes from each if no external interfaces are involved, specify what equipment (eg 'Siemens PLC') and what type of interface (eg 'Modbus interface') if they are involved.

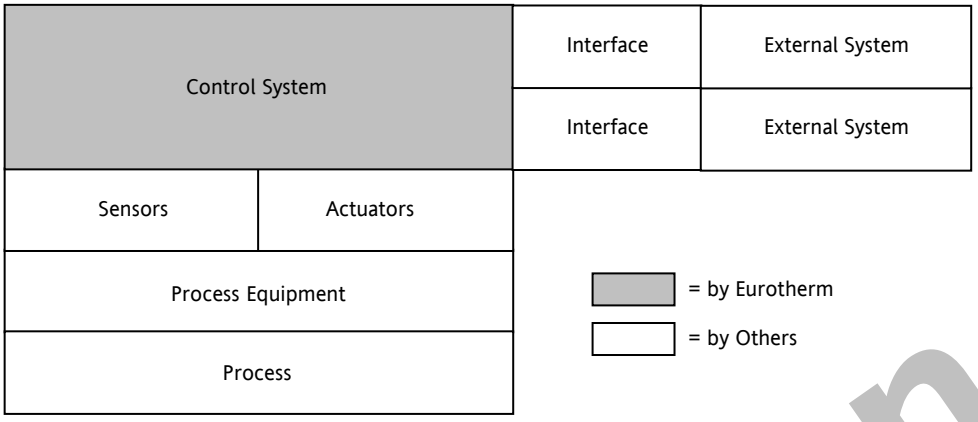
The example (here and for the remainder of the document) assumes typical Eurotherm scope when supplying a stand alone control system.

- *If sensors are also part of the validation scope then associated activities will need to be added into all sections (eg loop calibration, verification of any certification (eg certificates of conformity, ATEX ratings), control of any configurations from smart transmitters, etc)*
- *If actuators are also part of the validation scope then associated activities will need to be added into all sections (eg verification of any certification (eg certificates of conformity, ATEX ratings), control of any configurations, etc)*
- *WARNING: If process equipment is also part of the validation scope then specialist assistance will be required and associated activities will need to be added into all sections (eg verification of product contact materials, surface finish, cleaning validation, verification of appropriate certification (eg welding, pressure testing), etc)*
- *WARNING: If process is also part of the validation scope then specialist assistance will be required and associated activities will need to be added into all sections (eg validation to demonstrate capability of process against original design space)*

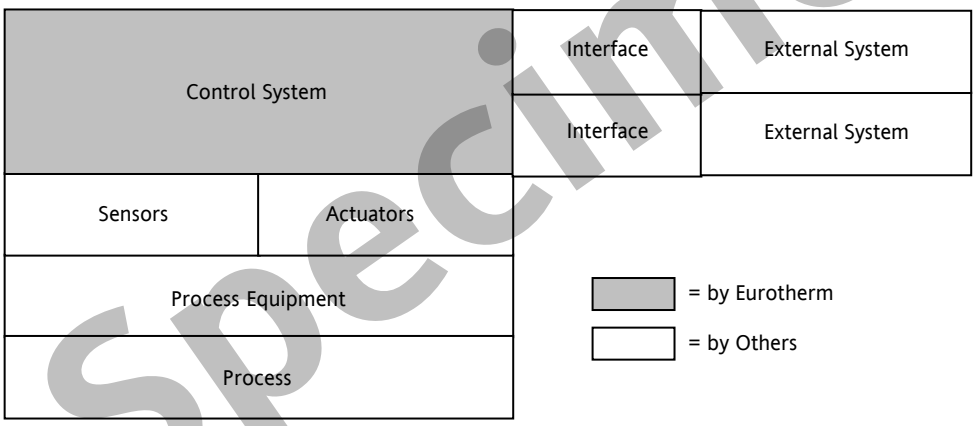
Specimen

Project Boundaries are as follows:

Scope of Supply



Scope of Validation



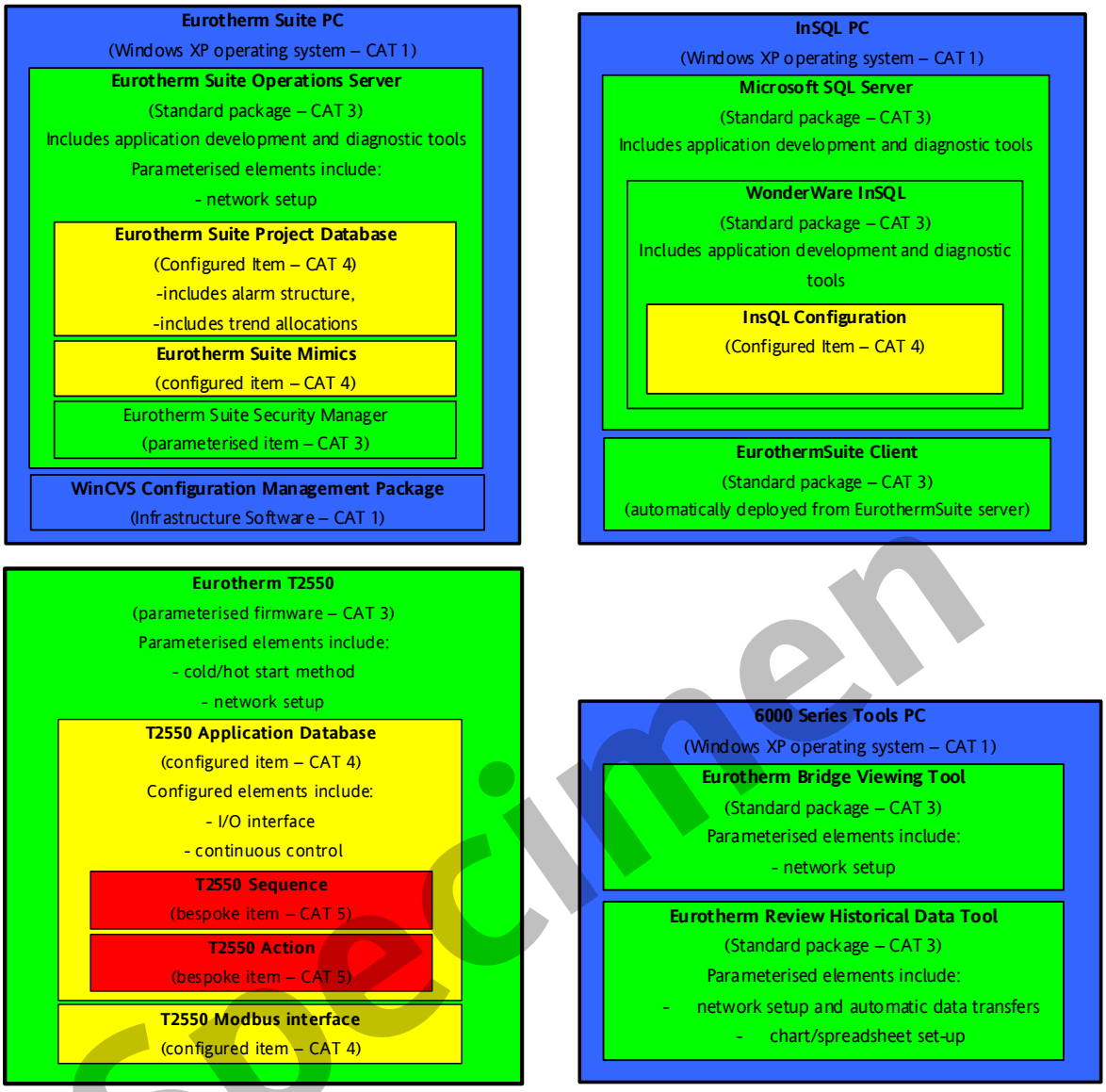
Specimen

3.3 System Overview – Hardware Architecture

The following diagram provides an overview of the control system hardware.
TBA: Explanatory note (delete this before publication): - hardware architecture summary (diagram is probably available from quote, if not then create one)
TBA: Explanatory note (delete this before publication): state whether there is any hardware which is not classified as GAMP5 category 1 (standard hardware)

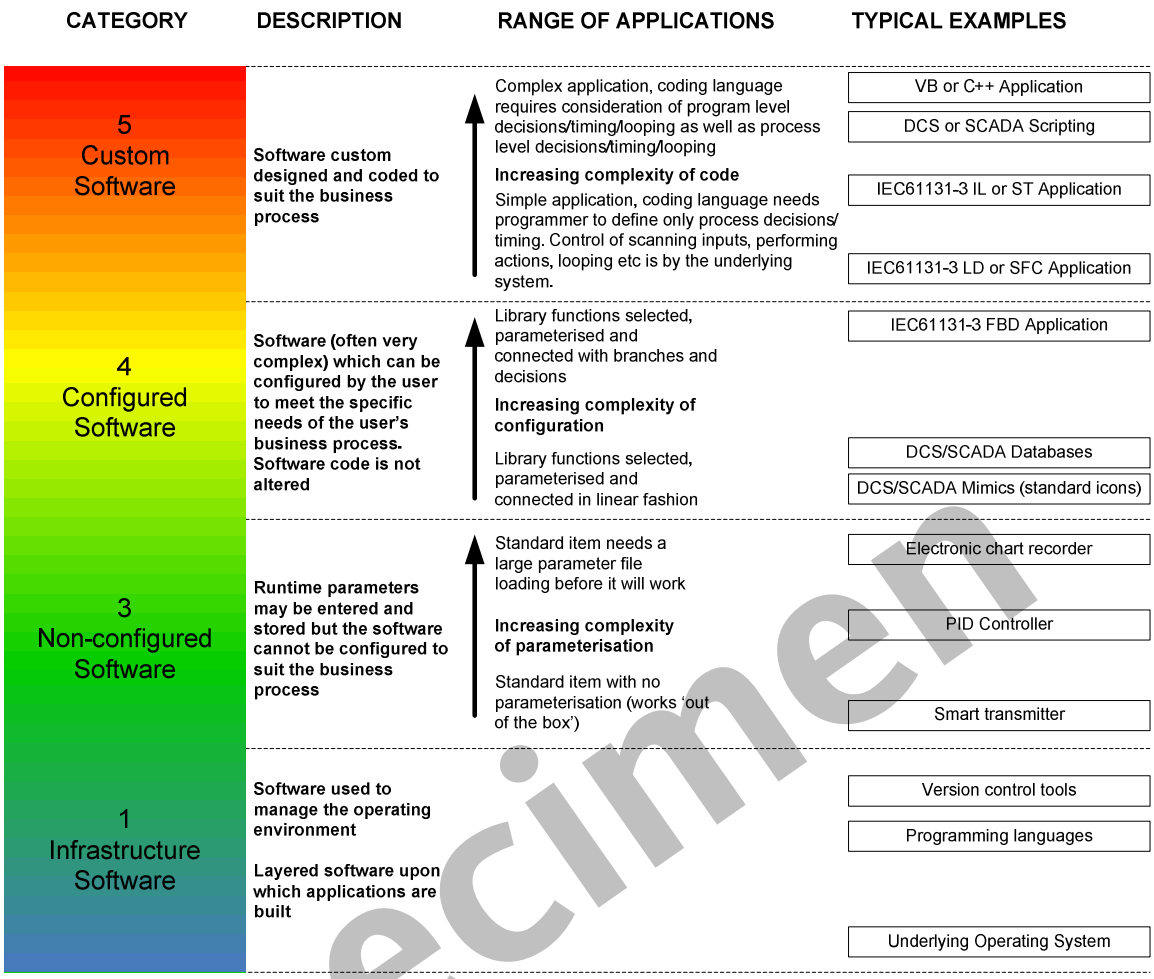
3.4 System Overview – Software Architecture

The following diagram provides an overview of the control system software giving GAMP5 classifications:
TBA: Explanatory note (delete this before publication): software architecture summary should show categorisation of the various elements – do not necessarily need to know exact detail on sequences, actions etc at this stage; just include an example. The following diagram can be used as a starting point:


Eurotherm Suite PC
(Windows XP operating system – CAT 1)
Eurotherm Suite Operations Server
(Standard package – CAT 3)
Includes application development and diagnostic tools
Parameterised elements include:
- network setup
Eurotherm Suite Project Database
(Configured Item – CAT 4)
-includes alarm structure,
-includes trend allocations
Eurotherm Suite Mimics
(configured item – CAT 4)
Eurotherm Suite Security Manager
(parameterised item – CAT 3)
WinCVS Configuration Management Package
(Infrastructure Software – CAT 1)
InSQL PC
(Windows XP operating system – CAT 1)
Microsoft SQL Server
(Standard package – CAT 3)
Includes application development and diagnostic tools
WonderWare InSQL
(Standard package – CAT 3)
Includes application development and diagnostic tools
InsQL Configuration
(Configured Item – CAT 4)
EurothermSuite Client
(Standard package – CAT 3)
(automatically deployed from EurothermSuite server)
Eurotherm T2550
(parameterised firmware – CAT 3)
Parameterised elements include:
- cold/hot start method
- network setup
T2550 Application Database
(configured item – CAT 4)
Configured elements include:
- I/O interface
- continuous control
T2550 Sequence
(bespoke item – CAT 5)
T2550 Action
(bespoke item – CAT 5)
T2550 Modbus interface
(configured item – CAT 4)
6000 Series Tools PC
(Windows XP operating system – CAT 1)
Eurotherm Bridge Viewing Tool
(Standard package – CAT 3)
Parameterised elements include:
- network setup
Eurotherm Review Historical Data Tool
(Standard package – CAT 3)
Parameterised elements include:
- network setup and automatic data transfers
- chart/spreadsheet set-up

Specimen

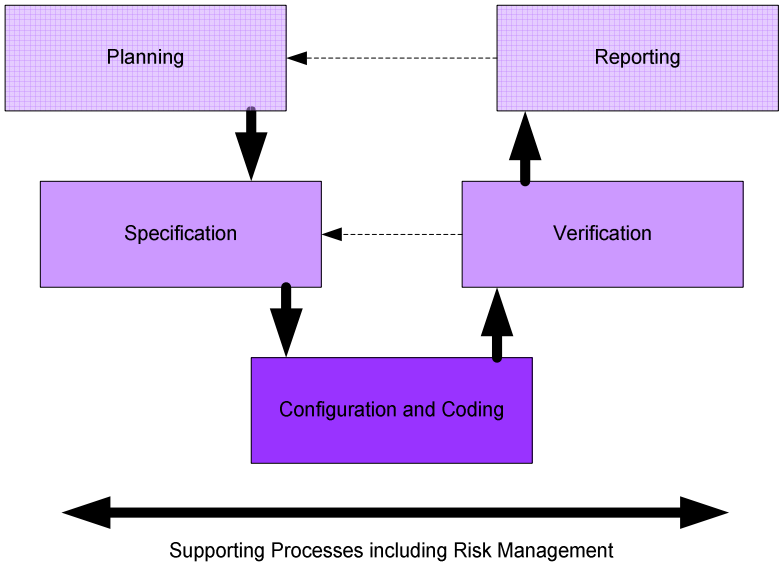
GAMP5 software categorisation in the above diagram is as follows:



Specimen

3.5 Project Lifecycle Overview

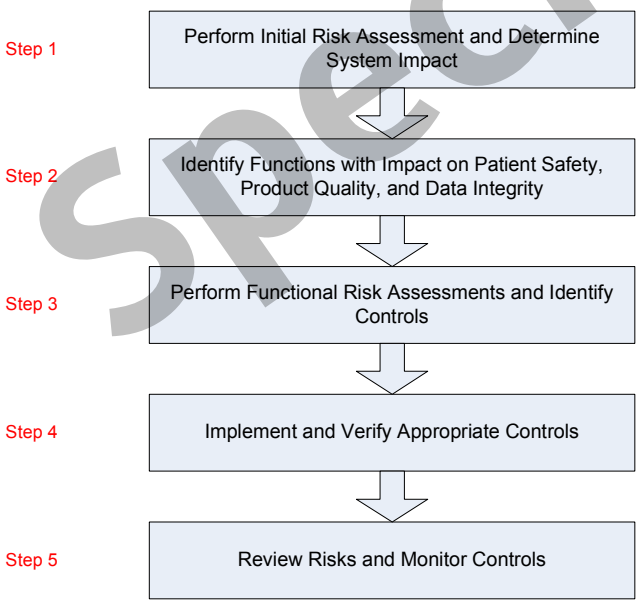
The Project lifecycle can be summarised as follows:



Specific activity requirements for this project are set out in section 4 below.

3.6 Risk Management Overview

Risk management follows the 5 step process as detailed in GAMP5:



3.6.1 Step 1 – Initial Risk Assessment & Determination of System Impact

This step has already been performed by the end user resulting in the system classification as detailed above in section 3.1.4.

3.6.2 Step 2 – Identify Functions with Impact on Patient Safety/Product Quality/Data Integrity

Specimen

The impact on patient safety, product quality and data integrity of each functional and data requirement for the system is detailed by the end user in the following document:

TBA: Explanatory note (delete this before publication): - update this table as relevant to the project

Some customers will provide categorisation of requirements within their URS. Others will supply a separate risk assessment document. If a customer has no suitable risk assessment procedures in place, Eurotherm has a risk assessment template which can be used but the activity should remain the responsibility of the end user as Eurotherm can have no way of knowing the impact on patient safety/product quality of the various requirements .

Project / Document Ref	
Title	
Issue	

3.6.3 Step 3 – Perform Functional Risk Assessment and Identify Controls

On completion of the functional specification, those functions previously identified as having impact on patient safety, product quality and data integrity will undergo risk assessment (jointly by Eurotherm and the end user) as follows:

LOW impact functions	No further assessment required – scale lifecycle activities as detailed in the table under step 4
MEDIUM impact functions	Risk assessment considers generic hazards with functions assessed against a generic list of scenarios/controls. Combining scores for severity, likelihood and probability of detection results in a risk priority for each function which is used to decide upon appropriate controls.
HIGH impact functions	Risk assessment considers specific hazards. Combining scores for severity, likelihood and probability of detection results in a risk priority for each function which is used to decide upon appropriate controls.

3.6.4 Step 4 – Implement and Verify Appropriate Controls

The output of the risk assessment process is used to decide upon appropriate controls. A range of options is available to provide the required control depending on the identified risk. These include, but are not limited to:

- Modification of process design or system design
- Application of external procedures
- Increasing the detail or formality of specifications
- Increasing the number and level of detail of design reviews
- Increasing the extent or rigor of verification activities

For purposes of validation planning, each software or hardware element inherits the highest risk priority of any function it performs. The risk priority is then used to decide on appropriate scaling of validation activities as detailed in the following table:

Specimen

<table>
<tr><th>Lifecycle Phase / Supporting Activity</th><th>Infrastructure software element</th><th>Non-configured software element</th><th>Configured software element</th><th>Bespoke software element</th></tr>
<tr><td>Planning</td><td colspan="4">Quality plan</td></tr>
<tr><td rowspan="5">Specification</td><td colspan="4">Functional Specification (may also detail design and configuration on a simple / low risk system)</td></tr>
<tr><td colspan="2"></td><td colspan="2">Hardware Design and Configuration Specification if justified by HIGH/MEDIUM risk priority or by the complexity of the hardware</td></tr>
<tr><td colspan="2" rowspan="2"></td><td colspan="2">Software Design and Configuration Specification if justified by HIGH/MEDIUM risk priority or by the complexity of the software</td></tr>
<tr><td></td><td>Software Module Specification if justified by HIGH/MEDIUM risk priority or by the complexity of the software</td></tr>
<tr><td colspan="4">For all categories of software, settings and parameters which are critical to meeting user requirements are detailed within the documentation. All other settings and parameters are controlled electronically via baselines of the software taken prior to each verification phase and at project handover. The ‘as handed over’ settings and parameters are supplied to the end user within the software baseline on CD/DVD. Subsequent modifications made on-line are controlled via the audit trail. Subsequent modifications made off-line are controlled via the configuration management system and result in a new baseline being taken.</td></tr>
<tr><td>Configuration and coding</td><td colspan="2">Parameter entry</td><td>Configuration</td><td>Coding</td></tr>
<tr><td rowspan="5">Configuration Management</td><td colspan="2">Parameter file saved to project repository.</td><td>Configuration file saved to project repository.</td><td>Software source file saved to project repository.</td></tr>
<tr><td colspan="2">Control (baselining) starts prior to first formal test activity involving the item.</td><td>Control (baselining) starts prior to first formal test activity involving the item</td><td>Control (baselining) starts prior to code review.</td></tr>
<tr><td colspan="2"></td><td>Where permitted by editing tools and where justified by risk/complexity, files contain text header which identifies version and change history.</td><td>Files contain text header which identifies version and change history.</td></tr>
<tr><td colspan="3">Blocks of parameter or configuration files may be controlled together as a single item where they combine to provide an identifiable function (eg operator interface screens).</td><td>Bespoke items are separately controlled; if necessary exporting them from within a configured item (eg exporting scripts from within a display) to allow separate control.</td></tr>
<tr><td colspan="4">Where settings or parameters cannot be saved to a file (e.g. dip switches used to set up a communications address or initialisation parameters which would need to be entered via the front panel if an instrument was replaced), the required settings are detailed in the Configuration Environment Schedule</td></tr>
</table>

Specimen

<table>
<tr><th>Phase</th><th>Infrastructure software element</th><th>Non-configured software element</th><th>Configured software element</th><th>Bespoke software element</th></tr>
<tr><td rowspan="5">Verification</td><td rowspan="4">Assume infrastructure elements are adequately challenged by functional testing of the application</td><td></td><td></td><td>Code review</td></tr>
<tr><td></td><td></td><td>Structural (module) testing if justified by HIGH/MEDIUM risk priority or by the complexity of the software</td></tr>
<tr><td></td><td colspan="2">Factory acceptance (functional) testing including challenge testing for HIGH risk functionality</td></tr>
<tr><td colspan="3">Factory acceptance (functional) testing against user requirements</td></tr>
<tr><td colspan="4">Site acceptance test – phase 1 (installation checks)</td></tr>
<tr><td></td><td colspan="4">Site acceptance test – phase 2 (operational checks – covers those functions which may be affected by the change from factory test environment to final environment plus any functions which could not be adequately tested in the factory test environment)</td></tr>
<tr><td>Reporting</td><td colspan="4">Final Quality Report and Handover Checklist</td></tr>
</table>

Specific activity requirements for this project are set out in section 4 below.

3.6.5 Step 4 – Review Risks and Verify Controls

Once controls have been identified and implemented, the risk assessment is re-visited (again, jointly by Eurotherm and the end user) in order to confirm that risk levels have been appropriately reduced.

Specimen

4. QUALITY PLANNING - PROJECT LIFECYCLE PHASES

TBA: Explanatory note (delete this before publication): This section allows the controlling procedure for each activity to be agreed (is it Eurotherm's, the customers or an external guideline / procedure such as GAMP?) ***MAKE SURE IT MATCHES THE PURCHASED LIST OF ACTIVITIES FOR THE PROJECTAND THAT THE SPLIT OF ACTIVITIES BETWEEN EUROTHERM AND THE CUSTOMER IS AS PER THE CUSTOMER'S ORDER***
Note that the references in the left hand columns are to allow activities on the project Gantt to be cross-referenced to this document – if not all activities are required then re-number to make consecutive again, if an activity (eg produce software) splits into lots of tasks on the Gantt then give each Gantt task a sub-number (eg C2.2.1, C2.2.2…). Any unplanned tasks or variations as the project progresses can also be added to the Gantt as new sub numbers of existing tasks – assuming they are covered by the relevant procedures listed here.
Note local controlling procedures should be substituted by Group companies if the UK SEP's are not in use.

The following sections define the responsibility and controlling procedures for activities within each phase of the project.

Responsibilities are coded as follows in each table:

PM = project manager QM = quality manager LE = Lead Engineer
PE = project engineer SE = service engineer DO = drawing office
R = Independent Reviewer (at least senior engineer status and not the author of the item under review)

4.1 Planning Phase

TBA: Explanatory note (delete this before publication): -
1) Since GAMP5 makes it clear that risk assessment is an activity belonging to the end user, the activity list below assumes that the customer has suitable risk assessment procedures in place. If they do not, Eurotherm has a risk assessment template which can be used but the activity should remain the responsibility of the end user as Eurotherm can have no way of knowing the impact on patient safety/product quality of the various requirements .

Ref	Activity	Responsibility	Controlling Procedure	Verifying Document
A1	Review customers URS and initial risk assessment	PM	Eurotherm SEP109	(appropriate inclusion of requirements / risk assessment is reviewed within each documentation deliverable)
A2	Generate Project Plan (Gantt)	PM	Eurotherm SEP102	Project Gantt submitted to repository
A3.1	Generate Quality Plan	PM	Eurotherm SEP109 (meets GAMP5 App M6)	Approved Quality Plan
A3.2	Review Quality Plan	QM	Eurotherm SEP109 (meets GAMP5 App M9)	Signed Review Sheets
A3.3	Approve Quality Plan	(customer)	(customer)	Approved Quality Plan

Specimen

4.2 Specification Phase

TBA: Explanatory note (delete this before publication): -
1) For smaller / simpler jobs it may be acceptable to include hardware and software design within the functional specification. In this case a single acceptance test specification usually covers hardware and software and a single witnessed factory test is held.
2) Module specifications, module test specifications, code review and module test are not generally required unless there are category 5 elements (though occasionally a category 4 item may be deemed critical enough to demand them).
3) The traceability matrix is, as a minimum, contained within each document (eg FS cross-referenced to URS, TS cross-referenced to FS…) If this is acceptable to the customer and an overall matrix has not been purchased then delete the activities relating to overall traceability matrix (B6, D9).
4) Since GAMP5 makes it clear that risk assessment is an activity belonging to the end user, the activity list below assumes that the customer has suitable risk assessment procedures in place. If they do not, Eurotherm has a risk assessment template which can be used but the activity should remain the responsibility of the end user as Eurotherm can have no way of knowing the impact on patient safety/product quality of the various requirements .

Ref	Activity	Responsibility	Controlling Procedure	Verifying Document
B1.1	Generate Functional Specification (FS)	PM, LE	Eurotherm SEP109 (meets GAMP5 App D2)	Approved FS
B1.2	Review FS	R	Eurotherm SEP109 (meets GAMP5 App M9)	Signed Review Sheets
B1.3	Approve FS	(customer)	(customer)	Approved FS
B2.1	Generate Hardware Design and Configuration Specification (HDS) including drawing package for any custom hardware	PM, LE, DO	Eurotherm SEP109 (meets GAMP5 App D3)	Approved HDS
B2.2	Review HDS	R	Eurotherm SEP109 (meets GAMP5 App M9)	Signed Review Sheets
B2.3	Approve HDS	(customer)	(customer)	Approved HDS
B3.1	Generate Software Design and Configuration Specification (SDS)	PM, LE	Eurotherm SEP109 (meets GAMP5 App D3)	Approved SDS
B3.2	Review SDS	R	Eurotherm SEP109 (meets GAMP5 App M9)	Signed Review Sheets
B3.3	Approve SDS	(customer)	(customer)	Approved SDS
B4.1	Generate Software Module Specifications (SMS) for bespoke items	PM, LE	Eurotherm SEP109 (meets GAMP5 App D3)	Approved SMS
B4.2	Review SMS	R	Eurotherm SEP109 (meets GAMP5 App M9)	Signed Review Sheets
B4.3	Approve SMS	(customer)	(customer)	Approved SMS
B5	Assist customer with functional risk assessment	PM/LE	(customer)	(customer risk assessment documentation)
B6.1	Generation of overall traceability matrix (TM) - Phase 1 (Design coverage)	PM	Eurotherm SEP109 (meets GAMP5 App M5)	Approved TM
B6.2	Review TM	R	Eurotherm SEP109 (meets GAMP5 App M9)	Signed Review Sheets
B6.3	Approve TM	(customer)	(customer)	Approved TM

Specimen

4.3 Configuration and Coding Phase

TBA: Explanatory note (delete this before publication): If replacing a system, additional data migration activities may need to be added. The controlling procedure may be a standard upgrade path (eg from one version of Review to another) or it might involve writing a separate procedure either as an extra section of the quality plan or as a separate document – if a separate document, make sure it is added to 4.3 and 5.4.2.

Ref	Activity	Responsibility	Controlling Procedure	Verifying Document
C1.1	Order Hardware	PM/LE	Eurotherm SEP104, local purchasing.	Signed Equipment Schedule
C1.2	Build Eurotherm Product	Eurotherm Production	Eurotherm Production Procedures	(none - signed off in verification activities)
C1.3	Receive bought-in product	LE	Eurotherm SEP104, local goods inward procedures.	(none - signed off in verification activities)
C1.4	Build Bespoke hardware (e.g. cubicles)	LE + sub contract supplier	Eurotherm SEP104	Check-sheet from SEP104 completed by supplier.
C2.1	Produce configuration management schedules	LE/PE	Approved quality plan	Schedules completed
C2.2	Produce Software	LE/PE	Eurotherm SEP105/SEP106 (meets GAMP5 App D5)	(none - signed off in verification activities)

4.4 Verification Phase

TBA: Explanatory note (delete this before publication): Site testing and how it fits with IQ/OQ needs to be sorted out during the bid process. The approach given here seems to be most common: Eurotherm site acceptance phases 1 and 2 form part of the customer IQ and OQ respectively (most customers have pre-set IQ/OQ protocols which can reference a Eurotherm test alongside other 'non-Eurotherm' activities such as their own in-house calibrations, checking of SOP's, correct archiving of the project documentation, etc)

TBA: Explanatory note (delete this before publication): for projects which involve enclosures, the panel builder will have to conduct some tests (such as earthing, etc.) as listed in SEP107 and supply test results which can be referred to during FAT and/or SAT.

Ref	Activity	Responsibility	Controlling Procedure	Verifying Document
D1	Code Review (standard Eurotherm review proforma)	R	Eurotherm SEP106 (meets GAMP5 App D4)	Signed Review Report
D2.1	Generate Software Module Test Specifications (SMTS) for bespoke items	PM, LE	Eurotherm SEP109 (meets GAMP5 App D5)	Approved SMTS
D2.2	Review SMTS	R	Eurotherm SEP109 (meets GAMP5 App M9)	Signed Review Sheets
D2.3	Approve SMTS	(customer)	(customer)	Approved SMTS
D2.4	Execute Software Module Test against SMTS	PM/LE	Approved Test Specification	Signed test records
D2.5	Review Software Module Test Results	R	Approved Test Specification	Reviewed test records
D3	System Integration	PE	Manufacturer's instructions and manuals	(none - signed off in FAT phase 1)

Specimen

Ref	Activity	Responsibility	Controlling Procedure	Verifying Document
D4.1	Generate Factory Acceptance Test Specification (FATS) - Phase 1 (hardware tests) - Phase 2 (functional tests)	PM, LE	Eurotherm SEP109 (meets GAMP5 App D5)	Approved FATS
D4.2	Review FATS	R	Eurotherm SEP109 (meets GAMP5 App M9)	Signed Review Sheets
D4.3	Approve FATS	(customer)	(customer)	Approved FATS
D4.4	Integrated Test (Internal) against FATS	PM/LE	Approved Test Specification	Signed test records
D4.5	Review Integrated Test Results	R	Approved Test Specification	Reviewed test records
D4.6	Factory Acceptance Test against FATS - Phase 1 (installation tests) - Phase 2 (functional tests)	PM, LE, customer witness	Approved Test Specification	Signed test records
D4.7	Review Factory Acceptance Test Results	Customer reviewer	Approved Test Specification	Reviewed test records
D5	Ship to site	LE	Eurotherm SEP104	Signed Shipment Request
D6	Installation	(customer)	Manufacturer's instructions and manuals	(none - signed off in SAT phase 1)
D7.1	Generate Site Acceptance Test Specification (SATS) - Phase 1 (installation tests) - Phase 2 (functional tests)	PM, LE	Eurotherm SEP109 (meets GAMP5 App D5)	Approved SATS
D7.2	Review SATS	R	Eurotherm SEP109 (meets GAMP5 App M9)	Signed Review Sheets
D7.3	Approve SATS	(customer)	(customer)	Approved SATS
D7.4	Site Acceptance Test against SATS - Phase 1 (installation tests) - Phase 2 (functional tests)	SE + customer witness	Approved Test Specification	Signed test records
D7.5	Review Site Acceptance Test Results	Customer reviewer	Approved Test Specification	Reviewed test records
D8	Loop Calibration	(customer)	(customer)	(calibration certificates)
D9.1	Generation of overall traceability matrix (TM) - Phase 2 (Test coverage)	PM	Eurotherm SEP109 (meets GAMP5 App M5)	Approved TM
D9.2	Review TM	R	Eurotherm SEP109 (meets GAMP5 App M9)	Signed Review Sheets
D9.3	Approve TM	(customer)	(customer)	Approved TM

4.5 Reporting Phase

Ref	Activity	Responsibility	Controlling Procedure	Verifying Document

Specimen

Ref	Activity	Responsibility	Controlling Procedure	Verifying Document
E1.1	Generate system final documentation - 'as built' design documents - technical manual containing bill of materials, 'as built' configuration management schedules	PM, LE	Eurotherm SEP109	Approved 'as built' documentation
E1.2	Review 'as built' documentation	R	Eurotherm SEP109 (meets GAMP5 App M9)	Signed Review Sheets
E1.3	Approve 'as built' documentation	(customer)	(customer)	Approved 'as built' documentation
E2	Provide training	Eurotherm training officer	As defined in customer order	Training certificates issued
E3.1	Generate final quality report and handover checklist	PM	Eurotherm SEP109 (meets GAMP5 App M7)	Approved final quality report handover checklist
E3.2	Review final quality report handover checklist	QM	Eurotherm SEP109 (meets GAMP5 App M9)	Signed Review Sheets
E3.3	Approve final quality report handover checklist	(customer)	(customer)	Approved final quality report handover checklist
E4	Assist customer with review of residual risks	PM/LE	(customer)	(customer risk assessment documentation)
E5	Archive documentation and configurations	LE	Eurotherm SEP108	Signed Project Closure Checksheet

4.6 Ongoing Operation Phase

TBA: Explanatory note (delete this before publication)
Include detail on any of the following which form part of the user requirements:

Any maintenance contract purchased as part of the project
Warranty period
Obsolescence policy

An example follows:

Eurotherm Limited can offer a variety of maintenance, support, parts management and call-out agreements. A support contract is not included in the scope of supply for this project and is to be negotiated separately.

All equipment shipped under the contract is subject to a parts and workmanship warranty for a minimum of 12 months from the date of shipment. The Eurotherm warranty conditions are available on request.
Upgrades are only supplied if they are mandatory or are required to remedy faults found under the warranty.

Eurotherm obsolescence policy is available on request or from the Eurotherm internet site

Specimen

Specimen

5. QUALITY PLANNING - SUPPORTING ACTIVITIES

5.1 Design review and traceability

Design review and traceability is in accordance with GAMP5 Appendix M5.

5.1.1 Design Review

As each design document is issued it is reviewed internally by an appropriate Eurotherm reviewer (subject matter expert) prior to issue for customer approval. The appropriate internal reviewer(s) for each document are defined in the tables in section 4 above.
All design documents are then issued for independent review and approval by the customer.

5.1.2 Traceability

Traceability is achieved through cross-reference tables in the appendix of each document.

Each design document contains a table cross-referencing its own contents to those of the controlling specification at the next highest level. For example, the functional specification would contain tables cross referencing to and from the URS.

Each test protocol contains a table cross-referencing its own contents to those of the controlling specification. For example, the factory acceptance test specification would contain tables cross referencing to and from the functional specification.

TBA: Explanatory note (delete this before publication): If customer is buying an overall traceability matrix then include the following paragraph – otherwise delete it!
In addition, an overall traceability matrix is produced in two phases:

1) Design coverage (demonstrates coverage of all user requirements within quality plan and design documents)
2) Test coverage (demonstrates coverage of all functional user requirements within test documents)

Specimen

5.2 Project change management

5.2.1 Method for Controlling Changes

Change control is in accordance with GAMP5 Appendix M8. The method for controlling changes depends on the stage at which the change is required (before / after configuration is placed under control) and on whether the change is major (involves contract variation) or minor:

	Before control of documents / configurations	After control of documents / configurations
Minor change with no impact on cost or schedule	Design specification(s) re-issued with source of change listed in document records. Any test specifications affected are also re-issued. Configuration (as yet uncontrolled) is updated to match. No contract variation required	Change is indexed and documented on a change report and this is the controlling document to ensure change is made in all necessary files and documents and agree any retest requirements. No contract variation required
Major change with impact on cost or schedule	Design specification(s) re-issued with source of change listed in document records. Any test specifications affected are also re-issued. Configuration (as yet uncontrolled) is updated to match. Contract variation must be agreed before change can proceed	Change is indexed and documented on a change report and this is the controlling document to ensure change is made in all necessary files and documents and agree any retest requirements. Contract variation must be agreed before change can proceed

A sample change report is shown below.

Specimen

5.2.2 Example change report

CHANGE REPORT

invensys EUROTHERM

Project *Eg Pxxxxx*	**Change Report Number** **(page of)**	**Source of change:** *Eg customer correspondence references*

Change Description

(details of the required change)

Raised By: ..... **Date:** ..... / ..... / .....

CHANGE REVIEW

Modification Agreed *(details of the modification agreed – or detail of why the change was rejected)*	**Modification and retest requirements reviewed and authorised:** *(customer representative)* **Date:**

Details of Items Requiring Modification		**IMPLEMENTATION**	
Software Affected *(list of affected software items)*	Original version	Modified version	**Implemented By:** *(usually Eurotherm engineer)* **Date:**
Documents Affected *(list of affected documents)*			**Implemented By:** *(usually Eurotherm engineer)* **Date:**
Hardware Affected *(list of affected hardware items)*			**Implemented By:** *(usually Eurotherm engineer)* **Date:**

Retest Requirements *(list of required retests if changes affect items which have already been tested – eg Re-run FAT-001A steps 1-5)*	**RETEST** **Test Passed By:** *(usually Eurotherm engineer)* **Date:**

CLOSURE following changes and successful re-test or agreement to abort test
(usually Eurotherm project manager if change made before start of witnessed testing, customer representative thereafter)
Fault Closed By: ..... **Date:** ..... / ..... / .....

Specimen

5.3 Project configuration management

TBA: Explanatory note (delete this before publication): - some customers ask for a separate configuration management plan. If so, this section can be taken out into a separate document with an introduction section (purpose, scope, contractual status, relationship to other documents) similar to that for the Quality Plan. Don't forget to include the extra document in the documentation deliverables above.

Configuration management is in accordance with GAMP5 Appendix M8 / O6.

5.3.1 Configuration Identification

TBA: Explanatory note (delete this before publication): - this section defines WHAT we are going to control. For a very small system it may be possible to list software items here but it is normally easiest to keep a separate schedule which can be updated without the need to up-issue the quality plan.

Project software is categorised in line with the guidance in GAMP5 Appendix M4 as detailed in section 3.4 above.

Configuration Environment

A Configuration Environment Schedule consisting of a list of infrastructure and non-configured software items is issued separately for ease of update. All category 1 and 3 items are listed along with installed version numbers.

Where parameters cannot be saved to a file (e.g. dip switches used to set up a communications address or initialisation parameters which would need to be entered via the front panel if an instrument was replaced), the required settings are detailed in the Configuration Environment Schedule.

Configuration Items to be Controlled

A Configuration Management Schedule consisting of a list of software items to be controlled is issued separately for ease of update. All category 4 and 5 items are listed along with parameter files for any category 1 or 3 items where appropriate.

Blocks of parameter or configuration files may be controlled together as a single item where they combine to provide an identifiable function (eg operator interface screens). Bespoke items are always separately controlled; if necessary exporting them from within a configured item (eg exporting scripts from within a display) to allow separate control.

5.3.2 Configuration Control

TBA: Explanatory note (delete this before publication): - this section defines HOW we are going to control it.

- How is the version identified within the configuration management system?

- Can the version be identified from within the application development tool? – eg by a text header – this will definitely be required for bespoke coded items but may not be possible for many configured items such as Wonderware mimics for example.

- Can the version in use be identified from within the runtime environment? – for example EYCON and T2550 show checksums when viewed via Eurotherm network explorer the in use version can be positively confirmed, 6000 series instruments maintain an automatic version number which is automatically incremented on each save.

Example below assumes use of a WinCVS repository as on projects in the UK.

Configuration management is via **WinCVS (Concurrent Versions System)**; a widely used version control tool for tracking all modifications to project source code files

Specimen

Version Control

Each configuration item to be controlled is placed into a project repository. Formal control commences at the following stages:

Item Type	Stage For Control
Parameter files for Category 1, 3 items	Before first formal test activity involving the item (normally integrated test)
Configurations for Category 4 items	Before first formal test activity involving the item (normally integrated test)
Code for Category 5 items	Before code review

Formal configuration control is applied via baselines taken at critical stages of the project. A baseline is created using the 'tagging' facility within WinCVS to label all files involved in a particular activity (eg a tag 'ForCodeReview_ModuleX' might be applied to all files involved in ModuleX before code review commences; a tag 'ForFAT' might be applied across all files prior to start of factory acceptance test)

Baselines of the configuration items will be taken at the following critical project milestones (as a minimum).

TBA: Explanatory note (delete this before publication): - update this table as relevant to the project. Example below can be reduced if no cat5 software or if the customer takes control of configurations as soon as they reach site – the minimum on any job should be each formal test stage plus AsHandover.

Milestone	Tag
Prior to code review	ForCodeReview_(module name)
Prior to module test	ForModTest_(module name)
Prior to in-house system acceptance test	ForIntTest
Prior to witnessed system acceptance test at suppliers factory	ForFAT
As accepted / shipped	AsShipped
Prior to witnessed system acceptance test at customer site	ForSAT
As final acceptance / handover to site	AsHandover

Specimen

Version identification from within the application development tools:

Source files for bespoke software items (all category 5 items) and configurations (where editing tools permit and where justified by risk/complexity) will have a text header containing the following information:

- Module name
- Details of other source or compilation files (eg map files for generic sequences)
- Project name and number
- Brief description of the module
- Change history including version number, date, person making change, details of change (including reference to fault/change report)

Where a editing tools do not allow text header information (various category 3 and 4 items e.g. mimic definitions), the version will be taken entirely from the project repository within the configuration management tool.

Version identification from within the runtime environment:

On this system the following runtime version information will be available:

TBA: Explanatory note (delete this before publication): - update this table as relevant to the project

6000 Series Recorder	Automatically generated configuration and security versions are visible

	from the 'about' menu.
EYCON Visual Supervisor	Checksum visible in Eurotherm Network
T2550 Unit Supervisor	Checksum visible in Eurotherm Network

Version identification from within the configuration management tool:
Version information available in the runtime environment and versions recorded in file headers will be linked to the project repository by using the note which is entered a file is committed to the repository. For example, if following module test actions, a T2550 sequence file is at version 3 in its own file header and shows a checksum of ABC123 in Eurotherm Network, the note entered as it is committed to the repository would record:

File header version: 3
Checksum: ABC123
Reason for change: Module test actions 1,2,3,4 completed.

Change Control

Change control as defined in section 5.2 of the Quality and Project Plan is applied to all configuration items.

Configuration Item Storage

TBA: Explanatory note (delete this before publication): - this section needs to detail:

- *How do we protect items from unauthorised changes?*
- *How do we back up and, if necessary, recover items?*
- *Are suitable anti-virus precautions in place?*

The examples below describe the situation in the UK. Please alter as appropriate for use elsewhere if DP009 not in use.

During the development phase of the project, all configuration items are stored in the project repository in the project directory on a Eurotherm fileserver. Access control, backup, maintenance and virus protection are then to Eurotherm procedure DP009 – Information Technology Department.

On delivery to the customer, the master copy of the repository can be transferred if required or the controlled files can be transferred to the customer's configuration management system. Responsibility for configuration management and adequate backup passes to the customer.

Release Management and Delivery

TBA: Explanatory note (delete this before publication): - this section needs to detail:

- *How do we control release of files to the customer?*
- *How does the customer know what has changed since the last release?*
- *How does the customer know of any known errors, workarounds, pending change requests?*
- *How does the customer know if there is a dependency between versions or a dependency on a particular hardware or software platform?*
- *How does the customer know how to install a new version of a delivered item?*

The example below assumes use of a WinCVS repository

Handover of configuration files to the customer is controlled as follows:

- A check is carried out that all items have been returned to the master copy of the repository.
- The current configuration is tagged for release.
- A release documentation package is prepared consisting of the following:

Specimen

- Up-to-date configuration environment schedule
- Up-to date configuration management schedule
- Details of baseline applied for the release
- Copy on CD or DVD of all controlled files
- Listing of any known errors / workarounds / pending change requests.

- If the master copy of the repository has been transferred to the customer, a check is made that an up-to-date copy of all controlled files has been retained at Eurotherm.

5.3.3 Configuration Status Accounting

TBA: Explanatory note (delete this before publication): - this section needs to detail:

- *How do we know what are the current versions?*
- *Can we find out the history of a particular file?*

The example assumes WinCVS is in use

Configuration status (including version, up-to-date / modified status for the working directory) and history (version numbers, change references, baselines) is maintained automatically by the WinCVS configuration management tool and can be printed at any time.

5.3.4 Configuration Evaluation

TBA: Explanatory note (delete this before publication): - this section needs to detail:

- *How to verify the control*
- *How is the above documentation controlled, reviewed, approved?*
- *For manually controlled configurations (ie no automatic status/history as in 3.3 above) this section would also need to address how you ensure the configuration status is up-to-date.*

Configuration Status is automatically generated and therefore requires no manual checking.
The Configuration Management Plan is subject to review and approval as part of this Quality Plan.
Release documentation is subject to review and approval as part of the final Quality Report and Handover Checklist.

Specimen

5.4 Document management

5.4.1 Method for Controlling Documents

Documentation delivered to the customer is controlled in accordance with Eurotherm SEP109 (written to conform to GAMP5 Appendix M9).
The document history, document approval record and document controlled circulation list are embedded within the document. A master document index is updated on each issue of a document.

Documents are stored to a file server. File identification for documents is of the form ProjectRef_DocumentName_x where x is the issue number of the document. The issue is a numeric for formal issues and has an alpha character added for draft versions (e.g. version 1a is a draft which becomes version 1 following inclusion of internal review comments).

Document change tracking commences with the first formal issue at version 1. Following this, if an update to a document is needed, a new version of a document is created and issued as follows:

1. The previous version is saved with the new version identifier plus an ‘a’ in the filename (e.g. ‘2a’) so that draft status can be identified immediately from the file name.
2. The document is opened and a printed watermark saying ‘DRAFT’ is added to ensure that draft status can be identified immediately on any printed copy.
3. All previously tracked changes are accepted.
4. The version information on the front sheet is updated to the new version identifier (e.g. ‘2’) and date.
5. The required changes are made with change tracking enabled. If sections are removed, the section heading is left with a comment that it has been removed so as to maintain traceability cross-references.
6. The document history is updated detailing the changes made (including section reference and reason for change).
7. The draft document is reviewed internally (this may be done in either electronic or paper format).
8. The draft is saved with the new version identifier (e.g. ‘2’) in the filename.
9. Any changes resulting from the internal review are made with change tracking enabled.
10. The document history and issue date (front sheet and history) are updated if appropriate.
11. The reviewer confirms that the required changes have been made and signs off the review.
12. The ‘DRAFT’ watermark is removed.
13. Tracked changes are hidden and the document printed.
14. The preparer and reviewer both sign the document front sheet.
15. The master document index is updated.
16. The document is issued to each recipient on the controlled circulation list.

Specimen

5.4.2 Documentation Deliverables

TBA: Explanatory note (delete this before publication): - The table below should be updated to reflect the lifecycle given in section 4. Items which are not required should be deleted. Additional items (eg if calibration or training are part of the scope) can be added. Items should be split if necessary (eg separate SDS requested for Eycon and ESuite, separate module spec for each sequence).
If the customer has not requested their own document references, the first column may be deleted.

The following table details the documentation deliverables. Documents designated 'Live' will be updated to 'as built' status as part of the final documentation package. Other documents represent a snapshot of the system at a point in time and will not be updated.

Customer Doc Ref	Deliverable Item	Live?	Identification	Format of file	Format for Approval	Format for Final Issue
	Quality Plan	No	Double-click HERE and type Eurotherm Reference_QualityPlan_x.doc	MS Word	Electronic submission	Signed paper master
	Functional Specification	Yes	Double-click HERE and type Eurotherm Reference_FunctionalSpec_x.doc	MS Word	Electronic submission	Signed paper master
	Hardware Design Specification	Yes	Double-click HERE and type Eurotherm Reference_HDS_x.doc	MS Word	Electronic submission	Signed paper master
	Drawings Package associated with hardware design	Yes	Double-click HERE and type Eurotherm Reference_DrawingNumber_Sheet_x.dwg	AutoCad	Electronic submission	Paper copy
	Software Design and Configuration Specification	Yes	Double-click HERE and type Eurotherm Reference_SDS_x.doc	MS Word	Electronic submission	Signed paper master
	Software Module Specification	Yes	Double-click HERE and type Eurotherm Reference_SMS_ModuleName_x.doc	MS Word	Electronic submission	Signed paper master
	Software Code Review Report	No	Double-click HERE and type Eurotherm Reference_CodeReview_ModuleName_x.doc	MS Word	Not required (standard pro-forma)	Signed paper master
	Software Module Test Specification	No	Double-click HERE and type Eurotherm Reference_SMTS_ModuleName_x.doc	MS Word	Electronic submission	Signed paper master
	Factory Acceptance Test Specification	No	Double-click HERE and type Eurotherm Reference_FATS_x.doc	MS Word	Electronic submission	Signed paper master
	Site Acceptance Test Specification	No	Double-click HERE and type Eurotherm Reference_SATS_ x.doc	MS Word	Electronic submission	Signed paper master
	Software Module Test results files	No	(hand written test result collated into file)	Paper master	Not required	Paper master
	FAT results files	No	(hand written test result collated into file)	Paper master	Not required	Paper master
	SAT results files	No	(hand written test result collated into file)	Paper master	Not required	Paper master

Specimen

Customer Doc Ref	Deliverable Item	Live?	Identification	Format of file	Format for Approval	Format for Final Issue
	Overall Traceability Matrix	Yes	Double-click HERE and type Eurotherm Reference_TM_ x.xls	MS Excel	Electronic submission	Signed paper master
	Final Quality Report and Handover Checklist	Yes	Double-click HERE and type Eurotherm Reference_QualityReport_ x.doc	MS Word	Not required	Signed paper master
	Standard Manuals	Yes	(supplied on Eurotherm Suite CD)	Online books	N/A	Online books
	Technical Manual	Yes	(collated into Technical Manual file)	(note 1)	Not required	Paper master

TBA: Explanatory note (delete this before publication): - An example of setting out the requirements for a Technical Manual is included here. Thisshould be changed to reflect the deliverables appropriate to the project and may be added to if, for example, SOPs or loop calibration has been sold as part of the project.

Note 1 – The following contents are collated into the Technical Manual file:

Technical Manual Item
IOM Manual Index
Bill of Materials with serial numbers and software licence details
Manufacturer's Calibration Certificates
Hardware Specification Sheets
Configuration Environment Schedule
Configuration Management Schedule

Specimen

5.5 Sub-contractor Control

Sub-contractors who work to their own procedures to produce a standard product are controlled through Eurotherm's local purchasing procedures.

TBA: Explanatory note (delete this before publication): - If any sub-contractors are to be used, how is quality ensured? Do they work to Eurotherm procedures or their own? Is their quality system externally accredited? What certification/ evidence will be supplied for filing as part of the project? Some possible examples are included.

The following sub-contractors are to be used to provide bespoke products or services as part of this project:

Company	Type of Supply	External Accreditation	Certification / Control requirements
(example panel builder 1)	Design and manufacture of control enclosures	ISO9001	Copy of ISO9001 certificate Copy of Eurotherm's supplier qualification sheet
(example panel builder 2)	Manufacture of control enclosures to Eurotherm design working to Eurotherm procedure SEP104	None	Copy of Eurotherm's supplier qualification sheet Copy of SEP104 check sheet filled in by panel builder
(example validation consultant)	Project Management and Validation Services	None	Copy of Eurotherm's supplier qualification sheet Copy of consultant's training / competence records

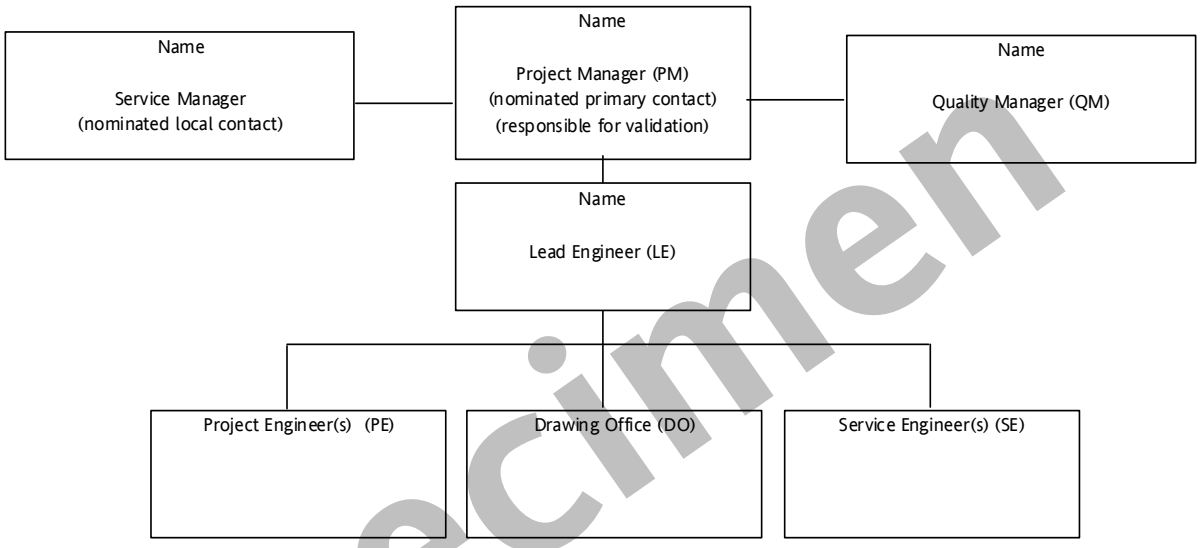
Specimen

6. PROJECT PLANNING

6.1 Project Organisation

TBA: Explanatory note (delete this before publication): - Organisational chart is required giving names and job titles for responsible personnel.

- *Nominated primary contact should be shown*
- *Person with responsibility for validation should be shown*
- *Interface to quality department should be shown*
- *If people show on the project Gantt by initials rather than name, then initials should also be included for ease of cross referencing.*



TBA: Explanatory note (delete this before publication): Also note the nominated point of contact for the customer.

The nominated point of contact for Double-click HERE and type Customer Name is:

Specimen

6.2 Activities

TBA: Explanatory note (delete this before publication): - The project plan needs to define milestones and activities. The start and end dates of each activity should be clear, as should the personnel allocated to the activity. A separate project Gantt chart is usually the easiest way to manage this as the quality plan does not then need re-issuing on every change to the project plan. Note that the activities should normally be cross-referenced between this document and the Gantt (eg by activity reference as given in section 4 above)

A Project plan in Gantt chart format is issued separately for ease of update. The project plan shows the following:

- Project milestones
- Project activities (as listed in section 4 above)
- Personnel allocated to activities
- Planned start and end dates for each activity

The project plan is controlled by the Eurotherm Project Manager.
The plan is version controlled, with any change in milestone dates or timescales resulting in a new version.

6.3 Progress Reporting

TBA: Explanatory note (delete this before publication): - Enter details of how/when project progress is to be reviewed and reported – the example below is from a large project where we were required to submit formal fortnightly progress reports, on smaller projects the customer is often happy just to get Gantt updates if there is a change in milestone / delivery dates:

Progress against the project plan is reviewed fortnightly and reported to the customer within a fortnightly report. The fortnightly report covers the following items:

- Progress Summary (Progress against project plan, current areas of concern)
- Project Team Status (Current team members, project team issues)
- Changes/Modifications (Variations, minor changes)
- Outstanding Issues (Actions from meetings, technical queries, other issues)

The project plan is re-issued to the customer following any change in project milestone dates or timescales.

Specimen

7. GLOSSARY

TBA: Explanatory note (delete this before publication): - add any other abbreviations or project-specific terms

ATEX	The abbreviation ATEX is derived from the French term "Atmospheres Explosibles" and covers two European Union Directives: 94/9/EC and 1999/92/EC.
FAT	Factory Acceptance Test
GAMP	GAMP 5 A Risk Based Approach to Compliant GxP Computerized Systems
GxP Compliance	Meeting all applicable pharmaceutical and associated life-science regulatory requirements
IQ	Installation Qualification at customer's premises
OQ	Operational Qualification at customer's premises
PQ	Performance Qualification at customer's premises
SAT	Site Acceptance Test
SEP	Eurotherm Systems Engineering Procedure
SOP	Standard Operating Procedure
URS	User Requirements Specification

Specimen

APPENDIX A – CROSS-REFERENCE TO CUSTOMER QUALITY REQUIREMENTS

TBA: Explanatory note (delete this before publication): - the following tables need to be completed in order to demonstrate that the customer's quality requirements (from URS or VP as appropriate) have been met.
Any non-compliance should be highlighted in the table
Where a section includes no relevant requirements, this should be made clear

An example is shown below

(The easiest way to create these tables is via a Microsoft Access database – create separate tables for each document and then create additional tables containing just a list of links between two documents. A query can then be used to export the data in the appropriate order)

URS Ref	URS Heading	Quality Plan Ref
1.	DOCUMENTATION RECORDS	(no quality requirements listed)
2.	INTRODUCTION	(no quality requirements listed)
3.	OVERVIEW	(no quality requirements listed)
4.	FUNCTIONS	(no quality requirements listed)
5.	DATA HANDLING	(no quality requirements listed)
6.	INTERFACES	(no quality requirements listed)
7.	VALIDATION REQUIREMENTS	(no quality requirements listed)
7.1	Project Lifecycle Phases	(no quality requirements listed)
7.1.1	Planning	4.1
7.1.2	Specification	4.2
7.1.3	Configuration and Coding	4.3
7.1.4	Verification	4.4
7.1.5	Reporting	4.5
7.2	Supporting Activities	(no quality requirements listed)
7.2.1	Risk management	5.1
etc	etc	etc

QPlan Ref	Quality Plan Heading	URS or VP Ref

Specimen

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F +44 (0)1903 265982
E info@eurotherm.co.uk
www.eurotherm.co.uk

Title	Double-click HERE and type Project Title
Customer	Double-click HERE and type Customer Name
Eurotherm Reference	Double-click HERE and type Eurotherm Reference
Customer Reference	Double-click HERE and type Customer Reference

Explanatory note (delete this before publication):
1) enter all fields above plus date and issue number below
2) search for 'TBA' to find items which need entering on a per-project basis.
3) if not based in the UK, replace the header with the appropriate one from your local letterhead

Specimen

RISK MANAGEMENT REPORT

Prepared by	.....	.....	.....
	Sign / Date	Printed Name	Title
Technical Review by (Eurotherm)	.....	.....	.....
	Sign / Date	Printed Name	Title
Technical Approval by (Customer)	.....	.....	.....
Approved for use as Basis for Project Activities	Sign / Date	Printed Name	Title
Quality Approval by (Customer)	.....	.....	.....
Approved for use as Basis for Project Activities	Sign / Date	Printed Name	Title
Issue	Enter Issue No		
Date	Enter Date		

CONTROLLED CIRCULATION		
Copy	Issued to	**This Copy**
Master	Double-click HERE and type Customer Name	
Copy 1	Project File	

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Registered in England and Wales No 853008

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1. DOCUMENTATION RECORDS

TEMPLATE DETAILS			
HISTORY:			
T1	Template document created to cover GAMP5 5 step approach to risk management		19 Jun 2008
APPROVAL DETAILS FOR CURRENT TEMPLATE			
Template prepared by	Karen Ashworth	Validation Officer	19 Jun 2008
Template reviewed for Technical Content	Malek Madani	Technical Manager	19 Jun 2008
Template reviewed for Quality Assurance	Martin Greenhalgh	Global Quality Manager	19 Jun 2008

DOCUMENT REVISION HISTORY		
Issue	Detail	Issue Date
1a	Project version 1 developed from template T1 and issued for internal review	TBA Enter Issue Date

TBA Explanatory note (delete this before publication):
Once internal review is complete, an additional entry needs to be made for version 1 saying something like 'Internal review comments included. Document issued for customer approval'
All subsequent issues (eg version 2) need to detail the changes which have been made including the section reference and the reason for the change (eg ref to customer comment). When creating a new version: accept all previously tracked comments; make changes with change tracking enabled; hide mark-up (in the VIEW menu) before printing or issuing the document.

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2. INTRODUCTION

TBA: Explanatory note (delete this before publication):
Within GAMP5, it is made quite clear that the risk management process has to be owned by the end user – after all, only they can know the impact of each function on product quality / patient safety. A customer SHOULD, therefore, already have the risk management process underway and have completed steps 1 and 2 before the order is placed. Such customers are therefore likely to have their own risk assessment methodologies and documentation and will want Eurotherm's assistance to complete steps 3,4,5 rather than needing to use this template. This template is provided for completeness and for use with 'novice' customers who need assistance in documenting their risk management process.

TBA: Explanatory note (delete this before publication):
This document would normally be issued several times as each step of the risk management process is completed. Typically, the issues would be

1) *With steps 1 and 2 complete – alongside the Quality Plan and before the FS is written*
2) *With step 3 complete following design review / risk assessment meeting after FS is issued*
3) *With steps 4 and 5 complete prior to system handover*

2.1 Purpose

A Risk Management report details the risk assessment and mitigation process throughout the project lifecycle.

2.2 Scope

This document documents the risk management methodology on the control system required by Double-click HERE and type Customer Name for their Double-click HERE and type Project Title Project.

2.3 Contractual Status

Although documented using a Eurotherm template, the risk assessment process remains the responsibility of the end user.
This document has a phased issue, following the steps of the risk management process. The initial phase, once approved, provides the basis functional design of the system. The second phase reflects the functional risk assessment carried out alongside design review and details the necessary controls. This issue of the document provides the basis for scaling of detailed design documentation and validation effort. The final phase details the review and verification of required control prior to project handover. On project completion, this document passes to the customer for archiving.

2.4 Relationship to Other Documents

2.4.1 Applicable Standards

This document has been written to meet the guideline for science-based quality risk management contained in GAMP5 A Risk-Based Approach to Compliant GxP Computerized Systems Appendix M3.

2.4.2 Definition of User Requirements

TBA: Explanatory note (delete this before publication): The requirements come primarily from the URS but may also include other documents referenced by the URS (which should also be listed here if this is the case)
It is normal to include version numbers for these base documents for contractual reasons, though this may be worth exploring with the customer as it means an update of this document if the customer issues a new URS in order to keep it up to date with changes resulting from design reviews or risk assessments.

The following user requirement documents have been referenced during completion of steps 1 and 2 of the risk management process:

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Project / Document Ref	
Title	
Issue	

The risk assessment tables provide traceability to these user requirements.

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3. OVERVIEW

3.1 Project Background

3.1.1 Process to be Controlled

TBA: Explanatory note (delete this before publication):
This should already exist in Quality Plan section 3.1.1 – cut and paste it from there and elaborate if necessary
Note that if this is a large batch control project which follows the S88.01 physical and process models then the split into process cells and units will also need to be covered here.

3.1.2 Key Benefits

TBA: Explanatory note (delete this before publication):
This should already exist in Quality Plan section 3.1.2 – cut and paste it from there and elaborate if necessary

3.1.3 Relevant GxP Regulations

TBA: Explanatory note (delete this before publication):
This should already exist in Quality Plan section 3.1.3 – cut and paste it from there and elaborate if necessary

3.2 Project Boundaries and Interfaces

TBA: Explanatory note (delete this before publication):
This should already exist in Quality Plan section 3.2 – cut and paste it from there (just the system bit – the validation scope is not relevant to this document) and elaborate if necessary

3.3 System Overview – Hardware Architecture

TBA: Explanatory note (delete this before publication):
This should already exist in Quality Plan section 3.3 – cut and paste it from there and elaborate if necessary

3.4 System Overview – Software Architecture

TBA: Explanatory note (delete this before publication):
This should already exist in Quality Plan section 3.4 – cut and paste it from there and elaborate if necessary (just the project specific part – no need to include the detail on GAMP5 classification of software)

3.5 Risk Management Overview

Risk management follows the 5 step process as detailed in GAMP5:

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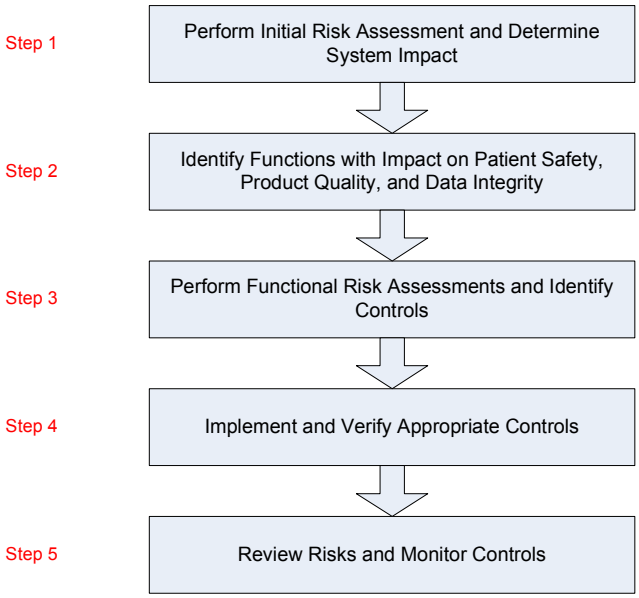
Step 1
Perform Initial Risk Assessment and Determine System Impact
Step 2
Identify Functions with Impact on Patient Safety, Product Quality, and Data Integrity
Step 3
Perform Functional Risk Assessments and Identify Controls
Step 4
Implement and Verify Appropriate Controls
Step 5
Review Risks and Monitor Controls

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4. STEP 1 – INITIAL RISK ASSESSMENT & DETERMINATION OF SYSTEM IMPACT

4.1 Process to be followed

TBA: Explanatory note (delete this before publication):
The end user quality department will have to be involved in providing the information for this section

GAMP5 now stresses science based risk management. End users are encouraged to:

1) *Identify **Critical Quality Attributes (CQAs)** for their product during drug development. These are attributes like purity, potency, stability which are intrinsic to the product.*
2) *Classify these CQAs in terms of their effect on patient safety*
3) *Identify material attributes and process parameters which might affect any of the CQAs (eg purity might be affected by: purity of the input materials; temperature of processing; cleanliness of equipment…).*
4) *Identify the **Design Space** for those material attributes and process parameters (ie determine how they can vary whilst still giving good quality product) in order to determine which are Critical Material Attributes or **Critical Process Parameters (CPPs)** and to give each an impact rating*
5) *Use that information to propose a **control strategy** for the process which will guarantee operation within the design space and also guarantee that any necessary data to prove this is collected.*
6) *Create a URS which splits that control strategy into individual functions (related to critical process parameters) and classified according to their impact on product quality / patient safety / data integrity.*

The initial risk assessment and determination of system impact are based on the answers to a set of standard questions:

4.1.1 GxP Classification

Does the system generate, manipulate or control data supporting regulatory safety and efficacy submissions?	*TBA Yes / No*
Does the system control critical parameters and data in preclinical, clinical, development, or manufacturing?	*TBA Yes / No*
Does the system control or provide data or information for product release?	*TBA Yes / No*
Does the system control data or information required in case of product recall?	*TBA Yes / No*
Does the system control adverse event or compliant recording or reporting?	*TBA Yes / No*
Does the system support pharmacovigilance?	*TBA Yes / No*

4.1.2 System Impact Classification

Worst case impact on patient safety	*TBA (select one)* *High = potential for serious injury or death* *Medium = potential for minor injury* *Low = potential for patient dissatisfaction but not injury*
Worst case impact on product quality	*TBA (select one)* *High = potential for release of product which would cause serious injury to a patient* *Medium = potential for release of product which would cause minor injury to a patient* *Low = potential for poor quality product which would not be released or would not cause harm to patient*
Worst case impact on data integrity	*TBA (select one)* *High = loss of data integrity such that product recall could not be carried out or release could be made of product which would cause serious injury to a patient* *Medium = loss of data integrity such that release could be made*

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	of product which would cause minor injury to a patient *Low = loss of data integrity such that product would need to be scrapped or data records not essential to product release or recall might be lost or impaired*

4.2 Resulting system classification

This system has been classified as:

GxP Critical	*TBA Yes / No*
Impact Level	*TBA High / Medium / Low*

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5. STEP 2 – IDENTIFY FUNCTIONS WITH IMPACT ON PATIENT SAFETY / PRODUCT QUALITY / DATA INTEGRITY

5.1 Process to be followed

TBA: Explanatory note (delete this before publication):
The end user quality department will have to be involved in providing the information for this section
If the system splits into identifiable sub-systems, some of which are not GxP critical based on the classification questions in section 0, the critical and non-critical functions are identified.

Each GxP critical function described within the User Requirements Specification is then considered for impact on patient safety / product quality / data integrity and classified as follows:

Worst case impact on patient safety	High = potential for serious injury or death Medium = potential for minor injury Low = potential for patient dissatisfaction but not injury
Worst case impact on product quality	High = potential for release of product which would cause serious injury to a patient Medium = potential for release of product which would cause minor injury to a patient Low = potential for poor quality product which would not be released or would not cause harm to patient
Worst case impact on data integrity	High = loss of data integrity such that product recall could not be carried out or release could be made of product which would cause serious injury to a patient Medium = loss of data integrity such that release could be made of product which would cause minor injury to a patient Low = loss of data integrity such that product would need to be scrapped or data records not essential to product release or recall might be lost or impaired

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5.2 Resulting impact classification for functions

The resulting GxP is entered into the 'GxP Critical' column of the table in appendix A.
The resulting impact classification is entered into the 'IMPACT' column of the table in appendix A.

Note that where function Y is defined as a control for a risk identified on function X (e.g. an automatic inspection stage after dispensing or an independent interlock at the boundary of the permitted temperature range), this function should inherit the impact level of the risk it is designed to mitigate.

6. STEP 3 – PERFORM FUNCTIONAL RISK ASSESSMENT AND IDENTIFY CONTROLS

6.1 Process to be followed

6.1.1 Functional Risk Assessment

On completion of the functional specification, those functions previously identified as having impact on patient safety, product quality and data integrity undergo risk assessment (jointly by Eurotherm and the end user) as follows:

LOW impact functions	No further assessment required – scale lifecycle activities as detailed in the table under step 4
MEDIUM impact functions	Risk assessment considers generic hazards with functions assessed against a generic list of scenarios/controls.
HIGH impact functions	Risk assessment considers specific hazards.

The risk assessment process follows the GAMP5 model with impact, likelihood and probability of detection graded as follows:

IMPACT takes the highest rating from the following:

Impact on patient safety	High = potential for serious injury or death Medium = potential for minor injury Low = potential for patient dissatisfaction but not injury
Impact on product quality	High = potential for release of product which would cause serious injury to a patient Medium = potential for release of product which would cause minor injury to a patient Low = potential for poor quality product which would not be released or would not cause harm to patient
Impact on data integrity	High = loss of data integrity such that product recall could not be carried out or release could be made of product which would cause serious injury to a patient Medium = loss of data integrity such that release could be made of product which would cause minor injury to a patient Low = loss of data integrity such that product would need to be scrapped or data records not essential to product release or recall might be lost or impaired

LIKELIHOOD is rated according to the type of system component performing the function:

Likelihood	High = function performed by bespoke software Medium = function performed by configured software or bespoke hardware Low = function performed by standard software or hardware

PROBABILITY OF DETECTION is rated as follows:

Probability of Detection	High = automatically detected via an independent / interlock or subject to 100% external check Medium = easily identified by an operator or has an alarm which is not independent of the controls or subject to a sample check Low = unlikely to be identified by an operator or by external checks

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These ratings are combined as follows:

First the impact (severity) and likelihood are combined to give a risk class:

High Impact	Risk Class 2	Risk Class 1	Risk Class 1
Medium Impact	Risk Class 3	Risk Class 2	Risk Class 1
Low Impact	Risk Class 3	Risk Class 3	Risk Class 2
	Low Likelihood	Medium Likelihood	High Likelihood

Then the risk class and probability of detection are combined to give the overall risk priority:

Risk Class 1	High Risk Priority	High Risk Priority	Medium Risk Priority
Risk Class 2	High Risk Priority	Medium Risk Priority	Low Risk Priority
Risk Class 3	Medium Risk Priority	Low Risk Priority	Low Risk Priority
	Low Probability of Detection	Medium Probability of Detection	High Probability of Detection

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6.1.2 Identification of Controls

The output of the risk assessment process (risk priority) is used to decide upon appropriate controls. A range of options is available to provide the required control depending on the identified risk. These include, but are not limited to:

- Modification of process design or system design
- Application of external procedures
- Increasing the detail or formality of specifications
- Increasing the number and level of detail of design reviews
- Increasing the extent or rigour of verification activities

For purposes of validation planning, each software or hardware element inherits the highest risk priority of any function it performs. The risk priority is then used to decide on appropriate scaling of validation activities as detailed in the table in step 4.

6.2 Resulting impact classification for functions

The generic risk assessment applicable to medium impact functions is detailed in appendix B.

Risk assessment for high impact functions considering specific hazards is detailed in appendix C.
Note that where function Y is defined as a control for a risk identified on function X (e.g. an automatic inspection stage after dispensing or an independent interlock at the boundary of the permitted temperature range), it will be appropriate to consider the two functions in a single assessment (fill in function Y as a 'current control' in the table).

7. STEP 4 – IMPLEMENT AND VERIFY APPROPRIATE CONTROLS

7.1 Process to be followed

The identified controls are implemented as follows:

Type of control	Method of implementation
Modification of process design or system design	Functional specification re-issued with changes. Risk assessment updated to reflect new design.
Application of external procedures	(by end user)
Increasing the detail or formality of specifications	Refer to table below
Increasing the number and level of detail of design reviews	Follows detail/formality of specifications – see table below
Increasing the extent or rigour of verification activities	Refer to table below

For purposes of validation planning, each software or hardware element inherits the highest risk priority of any function it performs. The risk priority is then used to decide on appropriate scaling of validation activities as detailed in the following table:

<table>
<tr><th>Lifecycle Phase / Supporting Activity</th><th>Infrastructure software element</th><th>Non-configured software element</th><th>Configured software element</th><th>Bespoke software element</th></tr>
<tr><td>Planning</td><td colspan="4">Quality plan</td></tr>
<tr><td rowspan="5">Specification</td><td colspan="4">Functional Specification (may also detail design and configuration on a simple / low risk system)</td></tr>
<tr><td colspan="2" rowspan="3"></td><td colspan="2">Hardware Design and Configuration Specification if justified by HIGH/MEDIUM risk priority or by the complexity of the hardware</td></tr>
<tr><td colspan="2">Software Design and Configuration Specification if justified by HIGH/MEDIUM risk priority or by the complexity of the software</td></tr>
<tr><td></td><td>Software Module Specification if justified by HIGH/MEDIUM risk priority or by the complexity of the software</td></tr>
<tr><td colspan="4">For all categories of software, settings and parameters which are critical to meeting user requirements are detailed within the documentation. All other settings and parameters are controlled electronically via baselines of the software taken prior to each verification phase and at project handover. The ‘as handed over’ settings and parameters are supplied to the end user within the software baseline on CD/DVD. Subsequent modifications made on-line are controlled via the audit trail. Subsequent modifications made off-line are controlled via the configuration management system and result in a new baseline being taken.</td></tr>
<tr><td>Configuration and coding</td><td colspan="2">Parameter entry</td><td>Configuration</td><td>Coding</td></tr>
</table>

Specimen

<table>
<tr><th>Lifecycle Phase / Supporting Activity</th><th>Infrastructure software element</th><th>Non-configured software element</th><th>Configured software element</th><th>Bespoke software element</th></tr>
<tr><td rowspan="6">Configuration Management</td><td colspan="2">Parameter file saved to project repository.</td><td>Configuration file saved to project repository.</td><td>Software source file saved to project repository.</td></tr>
<tr><td colspan="2">Control (baselining) starts prior to first formal test activity involving the item.</td><td>Control (baselining) starts prior to first formal test activity involving the item</td><td>Control (baselining) starts prior to code review.</td></tr>
<tr><td colspan="2"></td><td>Where permitted by editing tools and where justified by risk/complexity, files contain text header which identifies version and change history.</td><td>Files contain text header which identifies version and change history.</td></tr>
<tr><td colspan="3">Blocks of parameter or configuration files may be controlled together as a single item where they combine to provide an identifiable function (eg operator interface screens).</td><td>Bespoke items are separately controlled; if necessary exporting them from within a configured item (eg exporting scripts from within a display) to allow separate control.</td></tr>
<tr><td colspan="4">Where settings or parameters cannot be saved to a file (e.g. dip switches used to set up a communications address or initialisation parameters which would need to be entered via the front panel if an instrument was replaced), the required settings are detailed in the Configuration Environment Schedule</td></tr>
<tr><td rowspan="5">Verification</td><td rowspan="4">Assume infrastructure elements are adequately challenged by functional testing of the application</td><td></td><td></td><td>Code review</td></tr>
<tr><td rowspan="2"></td><td rowspan="2"></td><td>Structural (module) testing if justified by HIGH/MEDIUM risk priority or by the complexity of the software</td></tr>
<tr><td>Factory acceptance (functional) testing including challenge testing for HIGH risk functionality</td></tr>
<tr><td colspan="2">Factory acceptance (functional) testing against user requirements</td></tr>
<tr><td colspan="4">Site acceptance test – phase 1 (installation checks)</td></tr>
<tr><td colspan="4">Site acceptance test – phase 2 (operational checks – covers those functions which may be affected by the change from factory test environment to final environment plus any functions which could not be adequately tested in the factory test environment)</td></tr>
<tr><td>Reporting</td><td colspan="4">Final Quality Report and Handover Checklist</td></tr>
</table>

Specimen

8. STEP 5 – REVIEW RISKS AND VERIFY CONTROLS

8.1 Process to be followed

Once controls have been identified and implemented, the risk assessment is re-visited (again, jointly by Eurotherm and the end user) in order to confirm that risk levels have been appropriately reduced.

8.2 Resulting confirmation of final risk levels

The revised impact / likelihood / probability of detection figured are filled into the risk assessment tables in appendices B and C and the completion of the recommended actions is confirmed

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9. GLOSSARY

TBA: Explanatory note (delete this before publication): - add any other abbreviations or project-specific terms

FAT	Factory Acceptance Test
GAMP	GAMP 5 A Risk Based Approach to Compliant GxP Computerized Systems
GxP Compliance	Meeting all applicable pharmaceutical and associated life-science regulatory requirements
IQ	Installation Qualification at customer's premises
OQ	Operational Qualification at customer's premises
PQ	Performance Qualification at customer's premises
SAT	Site Acceptance Test
SEP	Eurotherm Systems Engineering Procedure
SOP	Standard Operating Procedure
URS	User Requirements Specification

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APPENDIX A – STEP 2 OUTPUT –- FUNCTIONS RATED FOR IMPACT ON PATIENT SAFETY / PRODUCT QUALITY / DATA INTEGRITY

URS Ref	GxP?	Impact Rating	URS Heading

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APPENDIX B – STEPS 3,4,5 OUTPUT –- GENERIC RISK ASSESSMENT FOR SYSTEM AS A WHOLE AND MEDIUM RISK FUNCTIONS

TBA: Explanatory note (delete this before publication):
The risk priority column is automatically evaluated once impact/likelihood/probability of detection have been entered

WHOLE SYSTEM FUNCTIONS – DISASTER RECOVERY

FS Ref	Event	Worst case effect	Current controls	Impact	Likeli-hood	Prob of Detectn	Risk Priority	Recommended controls	Revised Risk Priority	Revised Risk Priority	Revised Risk Priority	Revised Risk Priority	Verification of Controls
10.2.1	Power failure						#N/A					#N/A	
7, 10.2.2	Component failure - Network						#N/A					#N/A	
10.2.2	Component failure - PC						#N/A					#N/A	
10.2.2	Component failure - Controller						#N/A					#N/A	
10.2.2	Component failure - I/O module						#N/A					#N/A	
10.2.2	Component failure - Sensor						#N/A					#N/A	
10.2.2	Component failure - Communications Link						#N/A					#N/A	
10.2.2	Component failure - Printer						#N/A					#N/A	
10.2.3	Backup and restore						#N/A					#N/A	

WHOLE SYSTEM FUNCTIONS – DATA HANDLING

FS Ref	Event	Worst case effect	Current controls	Impact	Likeli-hood	Prob of Detectn	Risk Priority	Recommended controls	Revised Risk Priority	Revised Risk Priority	Revised Risk Priority	Revised Risk Priority	Verification of Controls
5.1	Data capacity exceded						#N/A					#N/A	
5.1	Data archive / restore failure						#N/A					#N/A	
5.5	Failure of 21CFR11 supporting functions						#N/A					#N/A	
5.6	Incorrect data migration from previous system						#N/A					#N/A	

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WHOLE SYSTEM FUNCTIONS – I/O INTERFACE

FS Ref	Event	Worst case effect	Current controls	Impact	Likeli-hood	Prob of Detectn	Risk Priority	Recommended controls	Revised Risk Priority	Revised Risk Priority	Revised Risk Priority	Revised Risk Priority	Verification of Controls
6	I/O interface - Disconnection						#N/A					#N/A	
6	I/O interface - Incorrect Calibration						#N/A					#N/A	
6	I/O interface - Incorrect operation due to software failure						#N/A					#N/A	

WHOLE SYSTEM FUNCTIONS – OPERATOR INTERFACE

FS Ref	Event	Worst case effect	Current controls	Impact	Likeli-hood	Prob of Detectn	Risk Priority	Recommended controls	Revised Risk Priority	Revised Risk Priority	Revised Risk Priority	Revised Risk Priority	Verification of Controls
9.1	Operator interface function - Incorrect alarm setup						#N/A					#N/A	
9.2	Operator interface function - Incorrect display setup						#N/A					#N/A	
9.3	Operator interface function - Incorrect security setup						#N/A					#N/A	

MEDIUM RISK PROCESS CONTROL FUNCTION - *TBA Name of application specific function from FS (repeat for each medium priority function)*

FS Ref	Event	Worst case effect	Controls external to the system	Impact	Likeli-hood	Prob of Detectn	Risk Priority	Recommended controls	Revised Risk Priority	Revised Risk Priority	Revised Risk Priority	Revised Risk Priority	Verification of Controls
	Process control function - Incorrect Input Data						#N/A					#N/A	
	Process control function - incorrect operation due to software failure						#N/A					#N/A	

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MEDIUM RISK DATA HANDLING FUNCTION - *TBA Name of application specific function from FS (repeat for each medium priority function)*

FS Ref	Event	Worst case effect	Controls external to the system	Impact	Likeli-hood	Prob of Detectn	Risk Priority	Recommended controls	Revised Risk Priority	Revised Risk Priority	Revised Risk Priority	Revised Risk Priority	Verification of Controls
	Data handling function - Incorrect Input Data						#N/A					#N/A	
	Data handling function - incorrect operation due to software failure						#N/A					#N/A	

MEDIUM RISK 3rd PARTY INTERFACE FUNCTION - *TBA Name of application specific function from FS (repeat for each medium priority function)*

FS Ref	Event	Worst case effect	Controls external to the system	Impact	Likeli-hood	Prob of Detectn	Risk Priority	Recommended controls	Revised Risk Priority	Revised Risk Priority	Revised Risk Priority	Revised Risk Priority	Verification of Controls
	Interface function - Disconnection or misconnection						#N/A					#N/A	
	Interface function - Incorrect Input Data						#N/A					#N/A	
	Interface function - Incorrect timing or handshaking						#N/A					#N/A	
	Interface function - incorrect operation due to software failure						#N/A					#N/A	

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APPENDIX C – STEPS 3,4,5 OUTPUT — SPECIFIC RISK ASSESSMENT FOR HIGH RISK FUNCTIONS

HIGH RISK PROCESS CONTROL FUNCTION - *TBA Name of application specific function from FS (repeat for each high priority function – add any other process- or system- specific events that may be appropriate)*

FS Ref	Event	Worst case effect	Controls external to the system	Impact	Likeli-hood	Prob of Detectn	Risk Priority	Recommended controls	Revised Risk Priority	Revised Risk Priority	Revised Risk Priority	Revised Risk Priority	Verification of Controls
	Incorrect input data from operator						#N/A					#N/A	
	Incorrect input data from I/O system						#N/A					#N/A	
	Incorrect input data from 3rd party interface						#N/A					#N/A	
	Incorrect operation due to software failure						#N/A					#N/A	
	Process perturbation outside ability of system to control						#N/A					#N/A	

Specimen

HIGH RISK DATA HANDLING FUNCTION - *TBA Name of application specific function from FS (repeat for each high priority function – add any other process- or system- specific events that may be appropriate)*

FS Ref	Event	Worst case effect	Controls external to the system	Impact	Likeli-hood	Prob of Detectn	Risk Priority	Recommended controls	Revised Risk Priority	Revised Risk Priority	Revised Risk Priority	Revised Risk Priority	Verification of Controls
	Incorrect input data from operator						#N/A					#N/A	
	Incorrect input data from I/O system						#N/A					#N/A	
	Incorrect input data from 3rd party interface						#N/A					#N/A	
	Incorrect operation due to software failure						#N/A					#N/A	
	Output media unavailable or capacity exceeded						#N/A					#N/A	
	Data security compromised						#N/A					#N/A	
	Data integrity compromised						#N/A					#N/A	
	Data confidentiality compromised						#N/A					#N/A	

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HIGH RISK 3rd PARTY INTERFACE FUNCTION - *TBA Name of application specific function from FS (repeat for each high priority function – add any other process- or system- specific events that may be appropriate))*

FS Ref	Event	Worst case effect	Controls external to the system	Impact	Likeli-hood	Prob of Detectn	Risk Priority	Recommended controls	Revised Risk Priority	Revised Risk Priority	Revised Risk Priority	Revised Risk Priority	Verification of Controls
	Physical disconnection						#N/A					#N/A	
	Physical misconnection						#N/A					#N/A	
	Fault reported from 3rd party device						#N/A					#N/A	
	Incorrect input data from 3rd party device						#N/A					#N/A	
	Incorrect timing or handshaking						#N/A					#N/A	
	Incorrect operation due to software failure						#N/A					#N/A	

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Title	Double-click HERE and type Project Title
Customer	Double-click HERE and type Customer Name
Eurotherm Reference	Double-click HERE and type Eurotherm Reference
Customer Reference	Double-click HERE and type Customer Reference

Explanatory note (delete this before publication):
1) enter all fields above plus date and issue number below
2) search for 'TBA' to find items which need entering on a per-project basis.
3) if not based in the UK, replace the header with the appropriate one from your local letterhead

FUNCTIONAL SPECIFICATION

Specimen

Prepared by	.....	.....	.....
	Sign / Date	Printed Name	Title
Technical Review by (Eurotherm)	.....	.....	.....
	Sign / Date	Printed Name	Title
Technical Approval by (Customer)	.....	.....	.....
Approved for use as Basis for Project Activities	Sign / Date	Printed Name	Title
Quality Approval by (Customer)	.....	.....	.....
Approved for use as Basis for Project Activities	Sign / Date	Printed Name	Title
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1. DOCUMENTATION RECORDS

TEMPLATE DETAILS		
HISTORY:		
T1	Template document written to accompany Eurotherm systems engineering procedure SEP013 issue 1. Explanatory notes added in italics.	03 Jul 2003
T2	Template updated following re-issue of Eurotherm System Engineering Procedures in form suitable for use across all group companies. SEP013 now SEP109.	20 Feb 2006
T3	Template updated for GAMP5	27 May 2008

APPROVAL DETAILS FOR CURRENT TEMPLATE			
Template prepared by	Karen Ashworth	Validation Officer	27 May 2008
Template reviewed for Technical Content	Malek Madani	Technical Manager	27 May 2008
Template reviewed for Quality Assurance	Martin Greenhalgh	Global Quality Manager	27 May 2008

DOCUMENT REVISION HISTORY		
Issue	Detail	Issue Date
1a	Project version 1 developed from template T3 and issued for internal review	TBA Enter Issue Date

TBA Explanatory note (delete this before publication):
Once internal review is complete, an additional entry needs to be made for version 1 saying something like 'Internal review comments included. Document issued for customer approval'
All subsequent issues (eg version 2) need to detail the changes which have been made including the section reference and the reason for the change (eg ref to customer comment). When creating a new version: accept all previously tracked comments; make changes with change tracking enabled; hide mark-up (in the VIEW menu) before printing or issuing the document.

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2. INTRODUCTION

2.1 Purpose

A Functional Specification is a key document in defining how the customer functional requirements, as defined in the user requirements specification, are to be met.

2.2 Scope

This document defines the method for meeting customer functional requirements on the control system required by Double-click HERE and type Customer Name for their Double-click HERE and type Project Title Project.

2.3 Contractual Status

This document, once approved, provides the basis for system build and configuration and for the definition of functional tests to be carried out. On project completion, this document passes to the customer for archiving and maintenance as appropriate under their validation plan.

2.4 Relationship to Other Documents

2.4.1 Applicable Standards

This document has been written to meet the procedure for production of a Functional Specification contained in GAMP5 A Risk-Based Approach to Compliant GxP Computerized Systems Appendix D2.

2.4.2 Definition of User Requirements

TBA: Explanatory note (delete this before publication): The requirements come primarily from the URS but may also include other documents referenced by the URS (which should also be listed here if this is the case)
It is normal to include version numbers for these base documents for contractual reasons, though this may be worth exploring with the customer as it means an update of the FS if the customer issues a new URS in order to keep it up to date with changes resulting from design reviews or risk assessments.

The following user requirement documents have been referenced in the production of this specification:

Project / Document Ref	
Title	
Issue	

A cross-reference table linking the sections of the user requirement specification to the sections of this document is provided in appendix A.
The functionality described in this document can be cross referenced to functional tests in the accompanying test specifications by use of the cross reference table in the relevant test specification.

2.4.3 Non-Conformances with User Requirements

TBA: Explanatory note (delete this before publication):
List out any non-conformances
The following non-conformances exist between this document and the User Requirement Specification:

Requirement Ref	Requirement	Comment

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3. OVERVIEW

3.1 Project Background

3.1.1 Process to be Controlled

TBA: Explanatory note (delete this before publication):
This should already exist in Quality Plan section 3.1.1 – cut and paste it from there and elaborate if necessary
Note that if this is a large batch control project which follows the S88.01 physical and process models then the split into process cells and units will also need to be covered here.

3.1.2 Key Benefits

TBA: Explanatory note (delete this before publication):
This should already exist in Quality Plan section 3.1.2 – cut and paste it from there and elaborate if necessary

3.1.3 Relevant GxP Regulations

TBA: Explanatory note (delete this before publication):
This should already exist in Quality Plan section 3.1.3 – cut and paste it from there and elaborate if necessary

3.1.4 Impact on Patient Safety, Product Quality and Data Integrity

TBA: Explanatory note (delete this before publication):
This should already exist in Quality Plan section 3.1.4 – cut and paste it from there and elaborate if necessary

3.2 Project Boundaries and Interfaces

TBA: Explanatory note (delete this before publication):
This should already exist in Quality Plan section 3.2 – cut and paste it from there (just the system bit – the validation scope is not relevant to this document) and elaborate if necessary

3.3 System Overview – Hardware Architecture

TBA: Explanatory note (delete this before publication):
This should already exist in Quality Plan section 3.3 – cut and paste it from there and elaborate if necessary

3.4 System Overview – Software Architecture

TBA: Explanatory note (delete this before publication):
This should already exist in Quality Plan section 3.4 – cut and paste it from there and elaborate if necessary (just the project specific part – no need to include the detail on GAMP5 classification of software)
Include details of specific software types in use – example follows:

Further detail on configured and bespoke software elements are as follows:

Software Type	*Description*
T2550 application database	*IEC 61131 Function Block Diagram implemented within Eurotherm LINtools. Configuration is by pasting down library functions ('blocks') then making connections between their fields.*
T2550 sequence	*IEC 61131 Sequence Function Chart implemented within Eurotherm LINtools. States ('steps') and transitions between them are implemented in IEC 61131 structured text programming language.*
T2550 action	*Logic runs within an action block and can access only the fields of that block. Logic is written in IEC 61131 Structured Text.*

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3.5 System Overview – Assumptions and Restrictions

TBA: Explanatory note (delete this before publication):
Describe any assumptions or limitations (use of particular packages, operating systems, hardware; requirements to interface to or have the same 'look and feel' as existing equipment; compatibility issues, etc)

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4. PROCESS CONTROL FUNCTIONS

TBA: Explanatory note (delete this before publication):
This section assumes low enough risk that only a functional specification is being produced. If further levels of design documentation are being produced then items marked (SDS/SMS) or (HDS) might appropriately be discussed in these documents.

TBA: Explanatory note (delete this before publication):
GAMP5 now stresses science based risk management. End users are encouraged to:

1) *Identify **Critical Quality Attributes (CQAs)** for their product during drug development. These are attributes like purity, potency, stability which are intrinsic to the product.*
2) *Classify these CQAs in terms of their effect on patient safety*
3) *Identify material attributes and process parameters which might affect any of the CQAs (eg purity might be affected by: purity of the input materials; temperature of processing; cleanliness of equipment…).*
4) *Identify the **Design Space** for those material attributes and process parameters (ie determine how they can vary whilst still giving good quality product) in order to determine which are Critical Material Attributes or **Critical Process Parameters (CPPs)** and to give each an impact rating*
5) *Use that information to propose a **control strategy** for the process which will guarantee operation within the design space and also guarantee that any necessary data to prove this is collected.*
6) *Create a URS which splits that control strategy into individual functions (related to critical process parameters) and classified according to their impact on product quality / patient safety / data integrity.*

TBA: Explanatory note (delete this before publication):
Within this FS, the traceability table in the appendix should include these impact ratings from the URS. Space has also been provided in sections dealing with bespoke/configured functionality specific to the business process (4.1, 4.2, 5.2, 5.3, 5.4, 8.1) to make the document easier to read without constant flicking to and from the appendix.

TBA: Explanatory note (delete this before publication):
The example in section 4.1 shows a function which relates to a single critical process parameter. If the URS details functions as part of a design space which includes more than one interacting parameter (eg temperature and humidity) then it is recommended that the relevant part of the functional specification is structured 'by design space' rather than 'by function' in order to reflect the multivariate nature of the control.

4.1 Continuous Control

TBA: Explanatory note (delete this before publication):
EITHER state that there is no requirement for continuous control functions OR take out a subsection for each continuous control function and rename it appropriately:
Since these functions are typically configured rather than coded, for simple/low risk applications it is appropriate for the function to be defined in the FS. For more complex / higher risk applications, it would be appropriate to have a separate software configuration and design specification.

4.1.1 TBA Continuous Control Function 1

TBA: Explanatory note (delete this before publication)

- *Purpose of function*
- *Critical process parameters involved*
- *GxP criticality / impact rating of the function (from URS)*
- *What equipment it controls*
- *Category of software used / module configuration / coding environment (at the FS level this might be just the GAMP software category; at the SDS level it would define the configuration tools)*
- *Interfaces to other modules*
- *Error handling and data checking*

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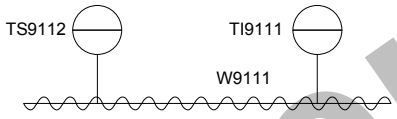
- *Module operation / implementation (at the FS level this might be a description of the required control; at the SDS level this would define the exact configuration)*
- *Note that it is often efficient to cut and paste from a LINtools database worksheet if this is how the control is implemented and then include some words to describe it. This allows future document updates without having to re-draw anything.*
- *Software module data (at the FS level this may just be generic information about what data is accessed; at the SMS level it would typically list all inputs outputs and parameters / flags)*
- *An example follows:*

Purpose of function	*To control distillation column feed trace heating*
Critical process parameters	*Solvent temperature within the feed pipework is a critical process parameter and must be controlled to within 5 degC of the setpoint.*
GxP Critical?	*Yes*
Impact rating from URS	*Medium*
Related plant equipment	*There is a single instance of this module on the trace heating for distillation column 9111.* 
Category of software used	*4 – Configured module*
Interfaces to other modules	*None*
Module operation	*Trace heating temperature controller TC9111 accepts a setpoint from the operator and provides a time proportioned output to heater W9111 to maintain the required temperature.* *W9111 is interlocked off if either TS9112 is high or if feed flow FI9111 is below a cut-off value.*
Error handling and data checking	*The controller TC9111 is forced to manual if an I/O fault is detected.* *Temperature switch TS9112 provides an independent shutdown on controller error*

TBA: Explanatory note (delete this before publication) the following sections may be more appropriate in an SDS if one is being produced – and may not be required at all for very simple / low risk functions..

Module configuration / coding environment
The module is configured as a separate compound within the T2550_10 application database. *The configuration tool is Eurotherm LINtools.*
Module implementation

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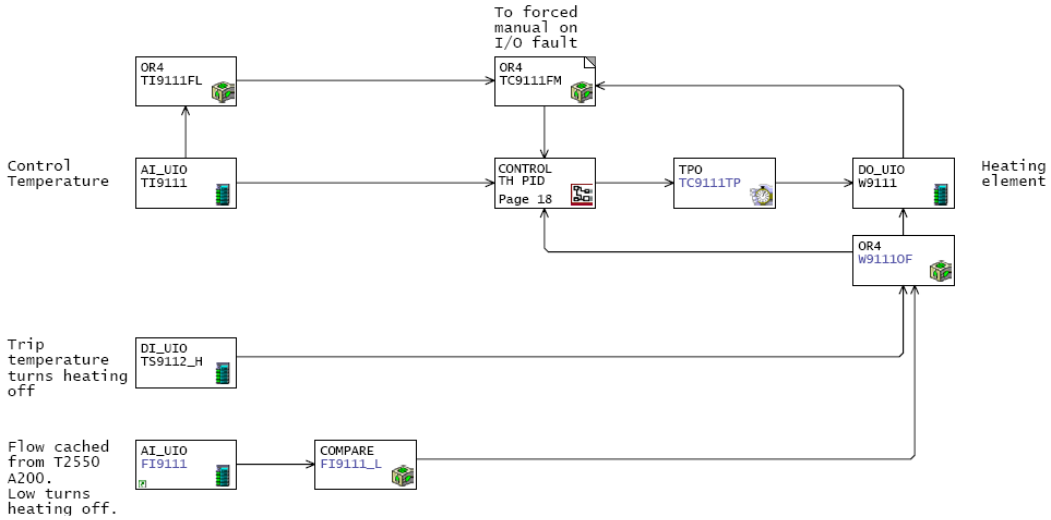

Module data

There is a single instance of this module using signals and tags as in the diagram above.

Configurability

PID coefficients are configurable at engineer level through EurothermSuite point pages

The flow low cut-off threshold can be set via the product recipe.

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4.2 Sequential / Procedural Control

TBA: Explanatory note (delete this before publication):
EITHER state that there is no requirement for sequential / Procedural control OR take out a subsection for each sequential / procedural control function and rename it appropriately:
If this is a large batch project which follows S88.01 it may be appropriate to have different levels of subsection for procedures, unit procedures, unit operations – on such a system detail of individual phases would normally be in further levels of documentation.
For a small system which implements the state machine to control a single equipment module, for a simple / low risk application it may be appropriate to describe the whole thing in this document. For more complex or higher risk systems, further levels of documentation would be appropriate.

4.2.1 TBA Sequential / Procedural Control Function 1

TBA: Explanatory note (delete this before publication)
- *Purpose of function*
- *Critical process parameters involved*
- *GxP criticality / impact rating of the function (from URS)*
- *What equipment it controls*
- *Category of software used / module configuration / coding environment (at the FS level this might be just the GAMP software category; at the SMS level it would define the coding tools and coding standard)*
- *Interfaces to other modules*
- *Error handling and data checking*
- *Module operation / implementation (at the FS level this might be a state transition diagram with labelled transitions and a brief description of the actions carried out in each state; at the SMS level this would define each action and transition using pseudo code)*
- *Note that it is often efficient to cut and paste from a LINtools sequence layout if this is how the control is implemented and then include some words to describe it. This allows future document updates without having to re-draw anything.*
- *Software module data (at the FS level this may just be generic information about what data is accessed; at the SMS level it would typically list all inputs outputs and parameters / flags)*
- *An example follows:*

Purpose of function	*To control filling of a rotary evaporator evaporation vessel*
Critical process parameters	*None*
GxP Critical?	*No*
Impact rating from URS	*Low*

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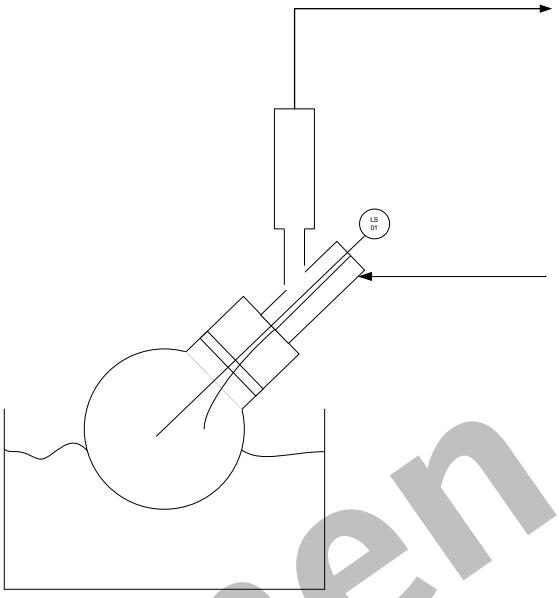
Related plant equipment	*Instances of the sequence are required for each of the following plant units:* - *Rotavapor 01-1234* - *Rotavapor 01-5678* 
Category of software used	*5 - Bespoke coded sequence* *Implemented as a generic LINTools sequence with separate map files for each of the plant units.*
Interfaces to other modules	*The filling sub-sequence is initiated from the overall mode control sequence and returns control to that sequence on completion.*
Module operation	*The module opens the evaporation flask fill valve until high level is detected in the flask, when the fill valve is closed.*
Error handling and data checking	*The following errors are monitored by the overall mode control sequence and result in a fill stop condition:* *- emergency stop / fire alarm* *- condenser level high* *- system pressure hihi* *- receiver full timer expires (receiver at high level > y minutes)* *- system pressure high* *- stop button pressed* *- Not filled timer expires (fill valve open > x minutes)*

TBA: Explanatory note (delete this before publication) the following sections may be more appropriate in an SDS/SMS if these are being produced.

Module configuration / coding environment
The module is configured as a generic sequence with separate map files for each of the plant units. *The coding tool is Eurotherm LINtools.* *The coding standard in use is Eurotherm SEP106.*
Module implementation

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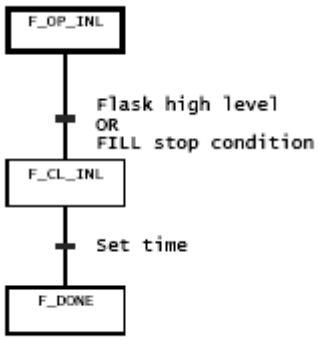
The FILLING sequence starts in state F_OP_INL and proceeds as follows:



Actions within each state are as follows:

State	Actions carried out
F_OP_INL	Opens the flask fill control valve
F_CL_INL	Closes the flask fill control valve
F_DONE	Allows transfer back to FILLWAIT state

Module Data (SDS)

The instances of the filling sequence use data as follows:

Description	Type	Rotavapor 01-1234	Rotavapor 01-5678
Flask High Level	Read	1234LS1H.In	5678LS1H.In
Fill control valve	Write	1234XV1.Demand	5678XV1.Demand
FILL stop condition flag	Read	1234FLAG.W Field1.Bit0	5678FLAG.W Field1.Bit0
Valve close time	Read(initially 5s)	1234DATA.PV1	5678DATA.PV1

Configurability

There is no requirement for configurability outside that provided to engineer level users through the Eurotherm LINtools package.

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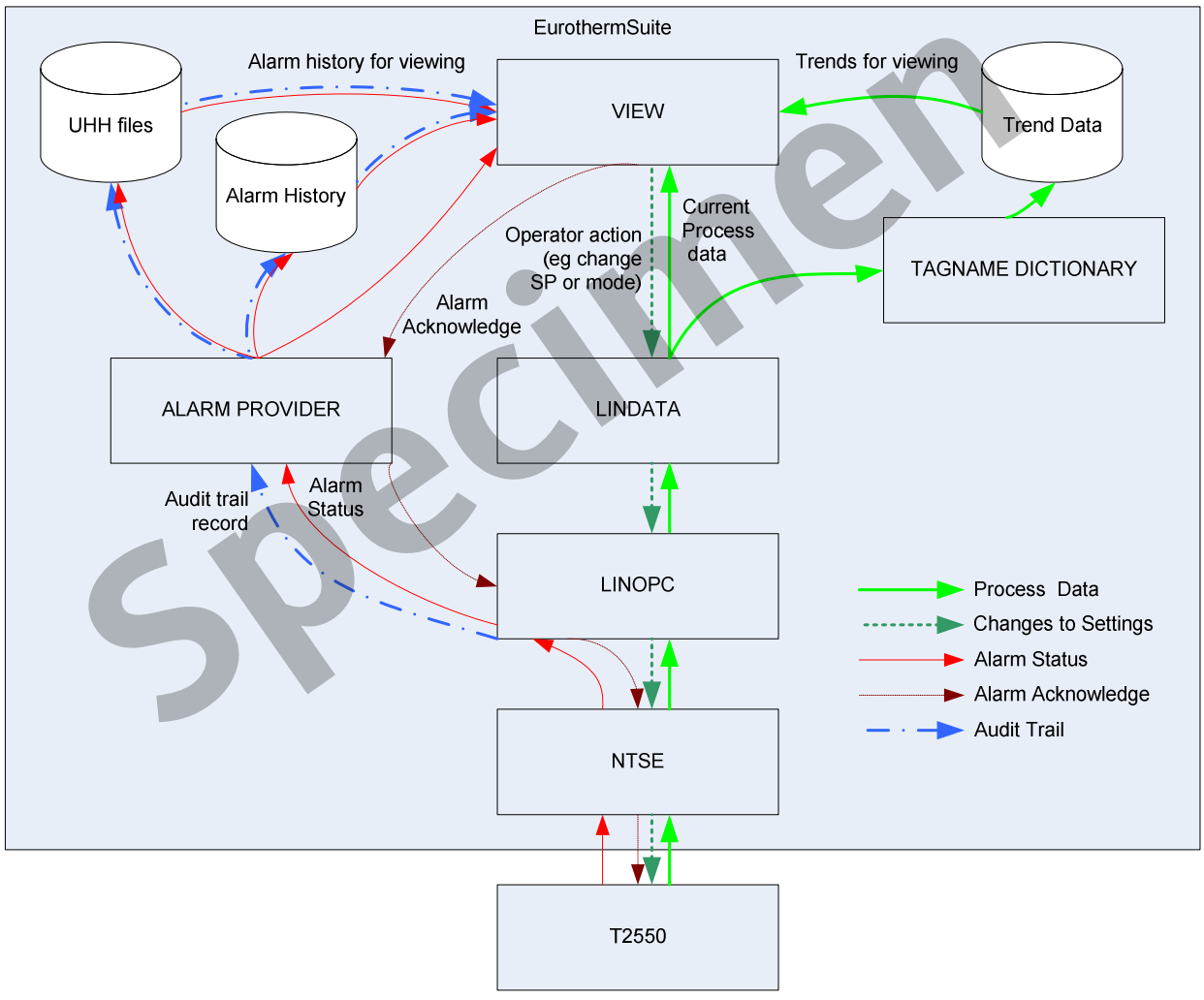
5. DATA HANDLING FUNCTIONS

TBA: Explanatory note (delete this before publication):
This section assumes low enough risk that only a functional specification is being produced. If further levels of design documentation are being produced then items marked (SDS/SMS) or (HDS) might appropriately be discussed in these documents.

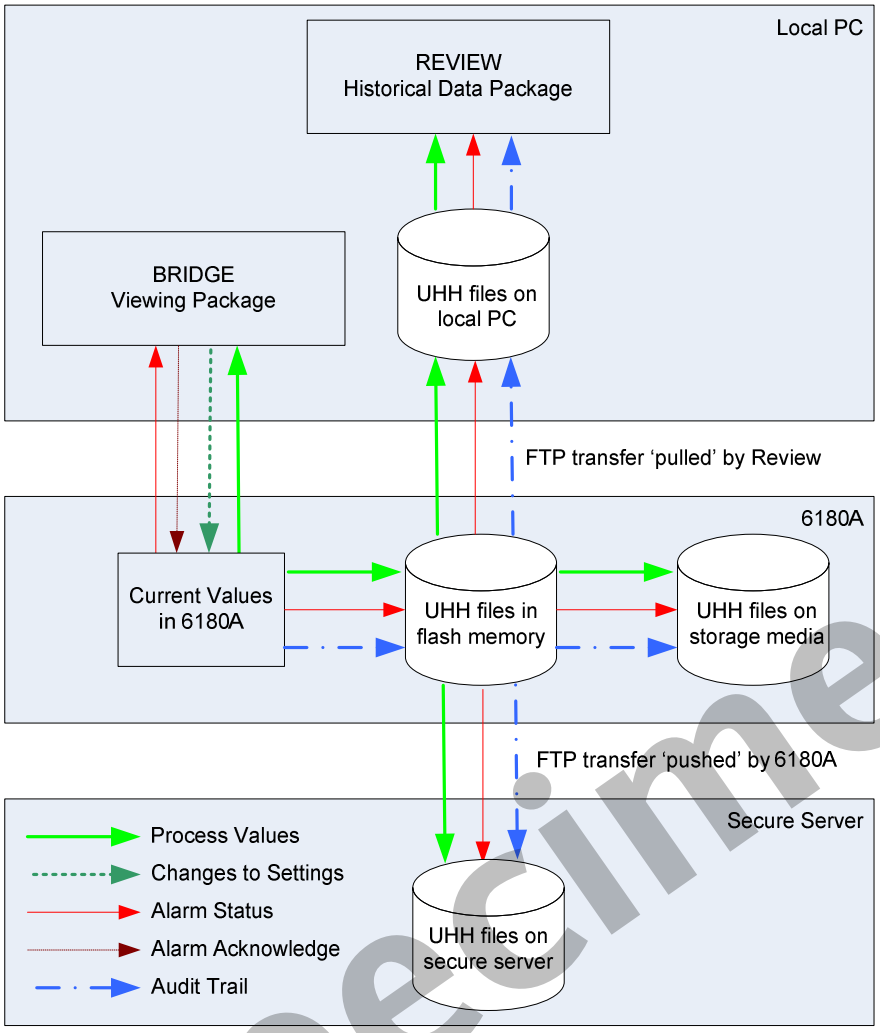
5.1 Internal Data Structures and Data Flows

The following diagram summarises the data structures and interfaces provided as standard by the control system package. Configurable and bespoke elements are discussed in the subsequent sections.
TBA: Explanatory note (delete this before publication):
Include enough information on standard data structures and interfaces for the customer to understand how the system works when reading the following sections. Some example diagrams follow:
TBA: Explanatory note (delete this before publication): This is an example taken from a EurothermSuite system using EurothermSuite trends (not InSQL trends). Delete or modify as appropriate.



Specimen

TBA: Explanatory note (delete this before publication): This is an example taken from a 6000 series system. Delete or modify as appropriate.



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5.1.1 Process Data

TBA: Explanatory note (delete this before publication)
Describe the INPUTS
- *Where does the data originate (eg hardwired I/O, Modbus from another device, etc) ?*
- *What quality checking is carried out? (eg alarms on faulty I/O or comms links)*

TBA: Explanatory note (delete this before publication)
Describe the DATA STRUCTURES
- *how is historical process data stored (what information – eg timestamped values, how often / what threshold on signal change, what format – eg binary tamper resistant file)*
- *where is it stored? (file path,file naming conventions)*
- *what capacity is available?*
- *does it get automatically overwritten?*
- *how does it get archived?*
- *what set-up or configuration is needed? (SDS)*

TBA: Explanatory note (delete this before publication)
Describe the DATA ACCESS
- *how are current process values made available to the operator?*
- *how is historical process data accessed?*

TBA: Explanatory note (delete this before publication) an example follows:

Data inputs	*I/O data values are brought into the system through 4-20mA inputs at the T2550s. The following I/O fault conditions are checked for and alarmed:* • *Hardware (module missing or faulty)* • *Open circuit* • *Out of range*
Data structures	*Historical trend data is stored independently by the Engineers workstation and the Operator workstation in tamper resistant binary files. Two logged data files are created each day and are named following the format YYMMDD00.LGH and YYMMDD00.IDX. The logged data files are stored in a dedicated directory.* *Signals are configured for logging on an 'on change' basis with the system 2 second scan rate. This means data values are stored every 2 seconds if the value has changed by more than the configured deadband (initially set at 0.5% of range).*
Data capacity	*An estimate of the EurothermSuite data storage requirement can be made as follows: Assuming that, on average, signals move by more than the deadband once in 10 seconds and assuming all analogue inputs (142) are trended, a worst case disk usage can be calculated:* *Historical Data file size (per year)* *= 50bytes x no.of tags x samples per year* *= 50 x 142 x (365 x 24 x 60 x 60 / 10)* *= 22GByte* *The available feature to automatically purge trend data older than a specified time will not be set up. Purging of data will be a manual operation once successful archive has been checked.*

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Data archive and restore	*Historical data can be archived by taking a copy of the YYMMDD00.LGH and YYMMDD00.IDX files to a secure medium or location.* *These archive files can be manually restored for viewing by returning the files to the original location.* *It is recommended that the data from both EurothermSuite servers should be kept to avoid loss of data from a period where one of the servers was not on line.*
Data access	*Current process values can be viewed via the EurothermSuite mimics on either the Engineers workstation or the operator workstation.* *Historical process data (trends) can be viewed on either the Engineers workstation or the operator workstation.* *Trends can be either pre-configured or set up on-line by the operator.* *Pre-configured trends are supplied for each room, showing temperature and humidity values for the room.* *A trend allows up to 8 colour coded trend pens to be viewed. On-screen controls allow the operator to do the following operations:* • *Move backwards / forwards in time* • *Zoom in / out on time axis* • *Zoom in / out on y-axis* • *Position a cursor to read off time / value* • *Print a hard copy of the trend* • *Export data in comma separated variable format*

5.1.2 Alarm Data

TBA: Explanatory note (delete this before publication)
Describe the INPUTS
- *Where does the data originate?*
- *Where is it timestamped?*

TBA: Explanatory note (delete this before publication)
Describe the DATA STRUCTURES
- *how is historical alarm data stored (what information – eg timestamped messages, what format – eg binary tamper resistant file / relational database table)*
- *where is it stored? (file path,file naming conventions)*
- *what capacity is available?*
- *does it get automatically overwritten?*
- *how does it get archived?*
- *what set-up or configuration is needed? (SDS)*

TBA: Explanatory note (delete this before publication)
Describe the DATA ACCESS
- *how are current alarm statuses made available to the operator?*
- *how is historical alarm data accessed?*

TBA: Explanatory note (delete this before publication) an example follows:

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Data inputs	*Alarm occurrence and alarm clear messages originate in the T2550 instruments and are timestamped at source (the T2550s synchronise time to the EurothermSuite servers in order to facilitate this).* *Alarm acknowledgement messages originate at the EurothermSuite workstation from which the acknowledgement takes place, and are treated as any other audit trail message. A confirmation of acknowledgement message is also provided, originating at the T2550.*
Data structures	*Alarms and audit trail messages are stored independently by the Engineers workstation and the Operator workstation in tamper resistant binary files (*.UHH)* *For ease of viewing the alarm messages are also stored on a cyclic basis in a single non-redundant relational database table located on the Operator workstation. In the event of this failing, the Engineers workstation buffers 10,000 messages which are automatically transferred to the database when it comes back online.* *Alarm messages, including timestamp and alarm details, are recorded by the system on:* • *Alarm occurrence* • *Alarm clear* • *Alarm acknowledge* *Alarm messages are recorded to local Eurotherm Suite alarm history and tamper resistant binary format (.uhh) files and include the following information:* • *Date* • *Time* • *Tag* • *Description* • *Event Type (ALM = alarm)* • *Alarm State (Acknowledged / Unacknowledged / Return to normal)* • *Alarm Type (eg High, Low)* • *Alarm Group* • *Limit (the alarm threshold)* • *Value at the time of the alarm* • *EurothermSuite PC recording the alarm*
Data capacity	*The size of .UHH files (which contain both alarm and audit trail data) is dependent on the number of alarms but is typically in the region of 100kByte/day.* *The relational database table is purged automatically to remove data older than 31 days.*
Data archive and restore	*Historical data can be archived by taking a copy of the *.UHH files to a secure medium or location.* *These archive files can be manually restored for viewing by returning the files to the original location and transferring them to the Review database.* *It is recommended that the data from both EurothermSuite servers should be kept to avoid loss of data from a period where one of the servers was not on line.*

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Data access	*The alarm history based on the (Operator workstation) relational database can be viewed on either the Engineers workstation or the Operator workstation.* *The alarm history page allows messages to be filtered and sorted by timestamp, alarm group or customised filters.* *The alarm history based on the tamper resistant (.uhh) files can also be viewed on either the Engineers workstation or the Operator workstation by opening the Review package (engineer level function) and loading in the files covering the required time period. The alarm messages are then available to view from within the 'tamperproof alarm history' page. This allows messages to be filtered and sorted by time or alarm group but has more limited customised filtering available.* *To view a complete history for a period regardless of any outages of one EurothermSuite workstation, .uhh files from both servers should be transferred to the Review package. The relevant alarm history page automatically copes with filtering any messages which are repeated in both files (eg alarm messages stored by both servers).*

5.1.3 Audit Trail Data

TBA: Explanatory note (delete this before publication)
Describe the INPUTS
- *Where does the data originate? ESuite? Eycon? 6000 series?*
- *What quality checking is carried out (eg for format of operator entries, source of data)?*
- *What actions are audit trailed?*

TBA: Explanatory note (delete this before publication)
Describe the DATA STRUCTURES
- *how is audit trail data stored (what information – eg timestamped messages, what format – eg binary tamper resistant file / relational database table)*
- *where is it stored? (file path,file naming conventions)*
- *what capacity is available?*
- *does it get automatically overwritten?*
- *how does it get archived?*
- *what set-up or configuration is needed? (eg for things like getting EYCON audit trail into EurothermSuite) (SDS)*

TBA: Explanatory note (delete this before publication)
Describe the DATA ACCESS
- *how is audit trail data accessed?*

TBA: Explanatory note (delete this before publication) an example follows:

Data inputs	*Audit trail messages result from operator entries at EurothemSuite workstations.* *Entered data values are written over the ELIN to the remote block in the T2550, where validation is performed. If the entered data is of an incorrect form (e.g. contains non-numeric data), the write request is rejected by the remote block, and the original value is retained until a new valid value is entered. An alarm is generated at the Operations Server to indicate a LIN write failure. Note that in some instances entering an out of limits value causes the value to limit rather than be rejected.*

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Data structures	*The audit option on the Eurotherm Suite PC provides a secure, computer-generated, time-stamped audit trail to record independently the date and time of operator entries and actions that create, modify, or delete electronic records as well as the user identity. The audit trail does not obscure previously recorded information.* *The audit trail messages are stored in exactly the same way as alarm messages.* *The following details are stored:* • *Date* • *Time* • *Tag and description if action relates to a specific tag* • *Alarm group (if the action relates to a specific tag)* • *Event Type (e.g. ACK = acknowledgement)* • *Previous and new value (if action involved a change)* • *EurothermSuite PC recording the action* • *Name of the current user* • *Any reason or comment entered by the user as a note.* *The following operator actions are recorded to the audit trail:* • *Setpoint entries* • *Parameter or setting changes* • *Alarm acknowledgements* • *Eurotherm Suite startup / shutdown* • *Eurotherm Suite security configuration changes*
Data capacity	*The size of .UHH files (which contain both alarm and audit trail data) is dependent on the number of alarms but is typically in the region of 100kByte/day.* *The relational database table is purged automatically to remove data older than 31 days.*
Data archive and restore	*Archive and restore of historical audit trail data is identical to that for alarm data*
Data access	*Access to historical audit trail data is identical to that for alarm data*

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5.2 Data Input Functions Specific to the Business Process

TBA: Explanatory note (delete this before publication)
Either state that there is no requirement for process-specific data input functions or take out a subsection for each function and rename it appropriately. Typical things that might appear here include

- *recipes*
- *batch data entry*

Example follows (see discussion in section 4.1 for more detail of the items to be described at FS/SDS/SMS level):

5.2.1 TBA Input Function 1 – Example for Recipes

Purpose of function	*To allow reactor configuration data to be saved to file, for later re-loading and re-use*
Critical process parameters	*Solvent temperature alarms*
GxP Critical?	*Yes*
Impact rating from URS	*Medium*
Related plant equipment	*The EYCON recipes used on this system consist of individual files that relate to a single 'product' which can be run on distillation column 9100*
Category of software used	*4 – Configured module*
Interfaces to other modules	*None*
Module operation	*The EYCON recipe management system provides the following facilities as part of the standard functionality:* • *Recipe file load / save as / delete* • *Recipe download (write contents of selected file to the EYCON parameter set)* • *Recipe status (displays status of current download plus time/date of last download)* • *Recipe monitor (shows recipe settings alongside live values and allows those live values to be captured to file)*
Error handling and data checking	*File format is automatically checked by the EYCON recipe management system and incorrect or corrupt files are rejected with an alarm being raised.*
Module configuration / coding environment	
The recipe format can be either comma separated text or tab separated text. Recipes are edited: • *offline in a text editor* • *offline using the recipe editor tool* • *online via the standard EYCON recipe editor* • *online by changing the values in the column setup mimic and then storing the values back to a named recipe. (It is expected that this will be the normal method on this project as it is laid out in an easily understood manner and ranges are limited by the entry point on the mimic)*	
Module implementation	

Each recipe consists of header information plus a list of tags with their associated settings. For example:
`UYR 1`
`1 07/11/2007 11:35:23 UserName`
`30`
`Setpoint:1 COLUMN`
`Feed control mode 91PAR1A.PV1 1.00`
`Calibration flow 91PAR1A.HR1 2.10`
etc	

Module data	
The following tags are included in the recipe: *(list of recipe tags here)*	
Configurability	
Recipe configuration through the column set-up mimic is limited to Supervisor level users. Other methods of	

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configuration are restricted to engineer access.

5.2.2 TBA Input Function 1 – Example for Batch Data

Purpose of function	*To allow batch details to be entered and*
Critical process parameters	*Batch number*
GxP Critical?	*Yes*
Impact rating from URS	*Medium*
Related plant equipment	*The steriliser 6180A is used to capture batch data for each sterilisation cycle*
Category of software used	*3 – Non-configured (Parameterised)*
Interfaces to other modules	*None*
Module operation	*The 6180A provides the following facilities as part of the standard functionality:* • *Batch fields to be entered by the operator* • *Batch start/stop* • *Naming of files by batch for ease of retrieval within Eurotherm Review*
Error handling and data checking	*The batch field entry is free format text*
Module configuration / coding environment	
Not applicable – parameterisation of standard functionality	
Module implementation	
Not applicable – parameterisation of standard functionality	
Module data	
Batch fields to be entered by the operator are parameterised to appear as follows on the screen and in the historical data file: *'batch number'* *'customer'* *'cycle type'*	
Configurability	
Operators can enter batch fields but all other parameterisation is restricted to engineer level users.	

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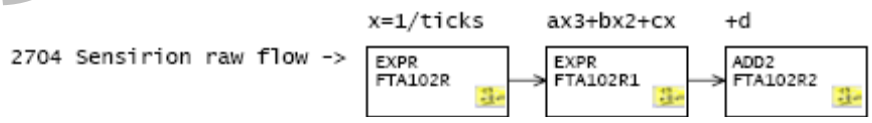
5.3 Data Transformation Functions Specific to the Business Process

TBA: Explanatory note (delete this before publication)
Either state that there is no requirement for bespoke calculations or take out a subsection for each calculation and rename it appropriately.
Example follows (see discussion in section 4.1 for more detail of the items to be described at FS/SDS/SMS level):

5.3.1 TBA Calculation/Algorithm 1

Purpose of function	*To calibrate the raw flow ('ticks') value received from the Sensirion flowmeter*
Critical process parameters	*Solvent flow*
GxP Critical?	*Yes*
Impact rating from URS	*Medium*
Related plant equipment	*There is a single instance of this module relating to Sensirion flowmeter P02FT01*
Category of software used	*4 – Configured module*
Interfaces to other modules	*None*
Module operation	*To achieve the calibration, the operator enters the polynomial coefficients a,b,c,d from their Sensirion flow calibration spreadsheet into the following fields:* *a = FTA102R1.A* *b = FTA102R1.B* *c = FTA102R1.C* *d = FTA102R2.PV_2* *The flowrate is then calculated as follows* *x = 1/ticks* *flow in mg/s = $ax^3 + bx^2 + cx + d$* *flow in g/min = (flow in mg/s) x (60/1000)*
Error handling and data checking	*Operator calibration factor inputs are forced to be a real number between -1000 and +1000.* *There is no quality checking built into the algorithm as poor quality raw flow signal is already alarmed separately.*
Module configuration / coding environment	
The module is configured as a separate compound within the T2550_34 application database. *The configuration tool is Eurotherm LINtools.*	
Module implementation	
	
Module data	
There is a single instance of this module using signals and tags as in the diagram above.	
Configurability	
The calibration inputs are available at operator level. There is no other configurability required.	

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5.4 Data Output Functions Specific to the Business Process

TBA: Explanatory note (delete this before publication)
Either state that there is no requirement for trending or reporting or take out a subsection for each calculation and rename it appropriately.
Example follows (see discussion in section 4.1 for more detail of the items to be described at FS/SDS/SMS level):

5.4.1 TBA Output Function 1 – Example for Eurotherm Suite Trending

Purpose of function	*To provide trends showing historical process data*
Critical process parameters	*Refer to the I/O list in section 6.2 for critical process signals.* *All critical process values are enabled for trending*
GxP Critical?	*Yes*
Impact rating from URS	*Low*
Related plant equipment	*All critical process values are enabled for trending*
Category of software used	*3 – Non-configured (Parameterised)*
Interfaces to other modules	*None*
Module operation	*Once a tag is selected for trending within the EurothermSuite project database, new samples are automatically stored every 2 seconds provided the value changes by more than the preset hysteresis value (smaller of 0.5% range or 1.0).* *The tag automatically becomes available as a trend 'pen' which can be pre-configured onto trend charts or allocated on-line.* *Pre-configured charts are created and saved from within the EurothermSuite runtime environment, which also offers standard functionality to change time-base, zoom in/out, print and export data in .csv format.*
Error handling and data checking	*Trends are stored to tamper resistant binary files and the EurothermSuite package checks format and rejects incorrect or corrupted files.*
Module configuration / coding environment	
Not applicable – parameterisation of standard functionality	
Module implementation	
Not applicable – parameterisation of standard functionality	
Module data	
Preconfigured trends are as follows:	

Chart name	*Pen tag*	*Pen description*

Configurability
All users have the ability to configure their own trend charts online. Changes to the preconfigured trends are limited to supervisor access level and above.

5.4.2 TBA Output Function 1 – Example for 6000 Series / Review Trending

Purpose of function	*To provide trends showing historical process data*
Critical process parameters	*Refer to the I/O list in section 6.2 for critical process signals.* *All critical process values are enabled for trending*
GxP Critical?	*Yes*
Impact rating from URS	*Low*
Related plant equipment	*All critical process values are enabled for trending*
Category of software used	*3 – Non-configured (Parameterised)*
Interfaces to other modules	*None*

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Module operation	*Once a tag is selected for trending within the 6000 series recorder, data values are automatically stored to tamper resistant .uhh history files at the configured rate.* *Pens are allocated to charts ('groups') for viewing on the recorder screen and the .uhh files are stored on a per group basis.* *These .uhh files can be loaded into Eurothem Review for viewing. Within Review, charts can be created with any combination of pens. The package offers standard functionality to change time-base, zoom in/out, print and export data in .csv format.*
Error handling and data checking	*Trends are stored to tamper resistant binary files and the Review package checks format and rejects incorrect or corrupted files.*
Module configuration / coding environment	
Not applicable – parameterisation of standard functionality	
Module implementation	
Not applicable – parameterisation of standard functionality	
Module data	
Preconfigured trends are as follows:	

Chart name	*Pen tag*	*Pen description*

Configurability
Operators can pan forwards and backwards in time on the history view provided at the 6000 series screen but all other configuration parameters are limited to engineer access. *Operators can create charts with any combination of pens within Review and can change time-base, zoom in/out, print and export data in .csv format.*

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5.4.3 TBA Output Function 2 – Example for Reports

Purpose of function	*To provide a report showing mean kinetic temperature for any selected stability room temperature sensor*
Critical process parameters	*Room temperatures*
GxP Critical?	*Yes*
Impact rating from URS	*Medium*
Related plant equipment	*The report covers any temperature sensor within the European stability Rooms*
Category of software used	*4 – Configured module*
Interfaces to other modules	*Data for this report is extracted from the Review database to an Excel spreadsheet using the standard functions provided by the Eurotherm Uhistory package.*
Module operation	*The Excel report template is opened manually by the operator and a tag is selected using drop-down menus for instrument, group and tag. The required start and end times are entered together with the desired averaging period (hour or day).* *The report selects the appropriate data from the Review database and calculates the mean kinetic temperature, the arithmetic mean temperature, and the difference between the two.* *The report is manually printed and a handwritten signature applied.*
Error handling and data checking	*The report flags the following error conditions:* - *Invalid entry made for instrument, group, tag, start date, end date or averaging period.* - *Selected period involves too many samples.* - *Incomplete data available for selected period.*
Module configuration / coding environment	
The module is configured as an Excel spreadsheet	
Module implementation	

Report Layout	*Detail on MKT report worksheet*	*Detail on channel selection worksheet*	*Detail on MKT calculations worksheet*
Report Header (Excel header)	*"3M Healthcare Stability Facility MKT Report"* *Page x of y* *Date of printing*		
Report Header (worksheet rows repeated on each page)	*Selected instrument, group, tag (operator data entry from pick lists)*	*The hidden worksheet retrieves instrument names (using UH_GetInstrumentCount, UH_GetInstrumentName)* *Group names (using UH_GetGroupCount, UH_GetGroupName)* *Tag names (using UH_GetTagCount, UH_GetTagName)*	

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Report Header (worksheet rows repeated on each page)	*Selected start time* *Selected end time (operator data entry to cells formatted "10 Jul 2004 10:00:00")* *Selected averaging period (operator data entry from pick list "hour" / "day")*		
Signature Section	*Space for comments* *Space for signature and date*		
Data section (item 1)	*MKT for period of report based on average*		*MKT calculated for selected sensor as follows:* $T_k = \frac{\frac{-\Delta H}{R}}{\ln\left(\frac{e^{\frac{-\Delta H}{RT_1}} + \cdots + e^{\frac{-\Delta H}{RT_n}}}{n}\right)}$ *ΔH/R = 10,000* *T_n = avg temp (K) sample period n* *n = total sample periods in the calculation.*
Data section (item 2)	*Arithmetic mean for period (using UH_GetChannelValue with mode set to 1=avg)*		
Data section (item 3)	*Difference between MKT and arithmetic mean*		
Data section (item 4)	*Indication of completeness of data (number of available samples / number of possible samples)*		*Number of valid samples is calculated using UH_GetRawSampleCount for the selected tag.* *Number of possible samples is calculated as the number of minutes in the report period.*

Module data
The module reads data from within the Review database. *Any temperature sensor available in that database is available for selection onto the report.*
Configurability
The operator has access to select tag, start time, end time and averaging period. The report is password protected to prevent access to any other spreadsheet cells.

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5.5 Electronic Records and Signatures

5.5.1 Applicable Records

The following records are required under FDA predicate rules and are to be stored electronically:
TBA: Explanatory note (delete this before publication)
Include list of records (should be available in URS – typically includes historical process data for critical values and alarm history) or state that there are no electronic records which are in scope for 21 CFR part 11.

TBA: Explanatory note (delete this before publication) – example follows:

Stored data values for room temperature and humidity
Stored alarm history (tamper resistant .uhh format)

5.5.2 Applicable Signatures

The following signatures are required under FDA predicate rules and are to be made electronically:
TBA: Explanatory note (delete this before publication)
Include list of signatures (should be available in URS) or state that there are no electronic signatures which are in scope for 21 CFR part 11.

TBA: Explanatory note (delete this before publication) – example follows (EYCON):

SECURITY ACCESS	
Save	*Sign & Authorise*
Account Properties	*Sign & Authorise*
Account Maintenance	*Sign & Authorise*
User Password Change	*Sign*
Retire	*Sign & Authorise*
Disable	*Sign & Authorise*
Enable	*Sign & Authorise*
Reinstate	*Sign & Authorise*
Deploy	*Function Disabled*
APPLICATION MANAGER	
Load	*Sign*
Load/Run	*Sign*
Unload	*Sign*
Stop	*Sign*
Start	*Sign*
Save	*Sign*
Save As	*Sign*
Delete	*Sign*
DIAGNOSTICS	
Reset	*Sign*
FUNCTION BLOCK MANAGER	
Save	*Sign & Authorise*
Field Changes	*Sign & Authorise*
Alarm Priority Change	*Sign & Authorise*
SETUP	
Start Strategy Save	*Sign*
COMMS SETUP	
Save	*Sign*

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Hardware	*Sign*
Modbus/M / TCP save	*Sign*
CLOCK SETUP	
Set	*Sign*
Hour +1	*Sign*
Hour -1	*Sign*
INTERNATIONALISE	
Language/Time Format	*Sign*
PANEL SETUP	
Save	*Sign*
SELF TESTS	
Health Relay Test	*Sign*
Run Relay Test	*Sign*
Reset Instrument	*Sign*
CLONING	
Import	*Function Disabled*
Export	*Confirm Only*
FILE MANAGER	
Copy	*Sign*
Delete	*Disable*
ADMINISTRATION	
Network Audit Trail Save	*Sign & Authorise*
Signature Configuration Save	*Sign & Authorise*
ALARMS	
Acknowledge (Low Severity)	*Sign*
Acknowledge (High Severity)	*Sign*
Acknowledge (All)	*Sign*
Archive	*Sign*
Note	*Sign*
OVERVIEW	
Field Changes	*Sign & Authorise*
RECIPE	
Load	*Sign*
Download	*Sign*
Abort	*Sign*
Save	*Sign & Authorise*
Save As	*Sign & Authorise*
Delete	*Function Disabled*
Recipe Monitor SP (Live)	*Sign*
LOGGING	
Offline	*Confirm Only*
Manage	*Confirm Only*
Logging Monitor	*Sign*
Logging Groups – Logging	*Sign*
Logging Groups – Save	*Sign & Authorise*
Logging Groups – Log Now	*No Confirmation*
Archive Manage - Delete	*Sign & Authorise*

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5.5.3 Method of Compliance with 21 CFR Part 11

The method of compliance with 21 CFR part 11 is as follows:
TBA: Explanatory note (delete this before publication)

Complete the table by reference to the generic statements for the equipment being used plus any project specifics (eg whether signing is required, how reports are dealt with). An example is provided (EurothermSuite as configured for a specific customer application – note that if there are no electronic signatures needed then everything from 11.50 onwards is not applicable).

Sub Part B – Electronic Records	
11.10 Controls for closed systems	
(a) Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records	*Validation is described in the project Quality Plan.* *Invalid records are discerned and rejected by both the trend viewing package and the Review package used to view tamper resistant alarm and event history.* *The system does not provide the facility to modify the trend data or alarm records.* *The binary file formats are not published. It is therefore highly unlikely that a user could alter a record externally to the system without making it invalid.*
(b) The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency. Persons should contact the agency if there are any questions regarding the ability of the agency to perform such review and copying of the electronic records.	*Complete and accurate copies on screen or printed out are available through the use of the trend viewing package and the Review package.* *Complete and accurate electronic copies are available by copying the raw data files or by export in CSV format.*
(c) Protection of records to enable their accurate and ready retrieval throughout the records retention period.	*Archiving of data files is assumed to be by the customer to a secure location.* *Once data has left the system, the media that it is stored on and backup strategy are the responsibility of the user*
(d) Limiting system access to authorized individuals.	*Individual password protected user accounts are set up in the security configuration*
(e) Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying.	*The system provides secure (embedded in the binary history file), computer generated, time stamped runtime audit trail of alarms, alarm acknowledgements, logins, signature details, configuration changes.* *Record changes do not obscure previous data.* *Retention of audit trail data alongside process data is the responsibility if the end user.*
(f) Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.	*There is no sequential control required on this system.* *All changes parameter changes made via point pages require confirmation*
(g) Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.	*Individual password protected user accounts are set up in Security Manager.* *Each user belongs to a group from which they inherit permissions or privileges to customise what that user may do to the product.*
(h) Use of device (e.g., terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.	*There is no requirement to limit particular actions to a specific workstation.*

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(i) Determination that persons who develop, maintain, or use electronic record/ electronic signature systems have the education, training, and experience to perform their assigned tasks.	*Procedural*
(j) The establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification.	*Procedural*
(k) Use of appropriate controls over systems documentation including: *(1) Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance.* *(2) Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.*	*Procedural*
11.30 Controls for open systems	*Not Required – the equipment to be supplied is to be used as part of a closed system.*
11.50 Signature Manifestations	
(a) Signed electronic records shall contain information associated with the signing that clearly indicates all of the following: *(1) The printed name of the signer;* *(2) The date and time when the signature was executed; and* *(3) The meaning (such as review, approval, responsibility, or authorship) associated with the signature.*	*Printed name, time/date and meaning are all stored to the audit trail when a signature is executed.*
(b) The items identified in paragraphs (a)(1), (a)(2), and (a)(3) of this section shall be subject to the same controls as for electronic records and shall be included as part of any human readable form of the electronic record (such as electronic display or printout).	*The audit trail is stored as a tamper resistant file. It is available in human readable form by loading into Review. It can be exported in csv format from the viewer within Eurotherm Suite.*
11.70 Signature / Record Linking	
Electronic signatures and handwritten signatures executed to electronic records shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record by ordinary means.	*The electronic signature is stored to a tamper resistant file and cannot therefore be excised / copied / otherwise transferred.*
Sub Part C – Electronic Signatures	
11.100 General requirements	
(a) Each electronic signature shall be unique to one individual and shall not be reused by, or reassigned to, anyone else.	*Uniqueness of user ID is enforced among both current and retired users.*
(b) Before an organization establishes, assigns, certifies, or otherwise sanctions an individual's electronic signature, or any element of such electronic signature, the organization shall verify the identity of the individual.	*Procedural*

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(c) Persons using electronic signatures shall, prior to or at the time of such use, certify to the agency that the electronic signatures in their system, used on or after August 20, 1997, are intended to be the legally binding equivalent of traditional handwritten signatures. *(1)The certification shall be submitted in paper form and signed with a traditional handwritten signature, to the Office of Regional Operations (HFC-100), 5600 Fishers Lane, Rockville, MD 20857.* *(2)Persons using electronic signatures shall, upon agency request, provide additional certification or testimony that a specific electronic signature is the legally binding equivalent of the signer's handwritten signature.*	*Procedural*
11.200 Electronic signature components and controls	
(a) Electronic signatures that are not based upon biometrics shall:	
(1) Employ at least two distinct identification components such as an identification code and password. *(i)When an individual executes a series of signings during a single, continuous period of controlled system access, the first signing shall be executed using all electronic signature components; subsequent signings shall be executed using at least one electronic signature component that is only executable by, and designed to be used only by, the individual.* *(ii)When an individual executes one or more signings not performed during a single, continuous period of controlled system access, each signing shall be executed using all of the electronic signature components.*	*Both ID and password are required in order to execute a signature.*
(2) Be used only by their genuine owners; and	*Passwords are never visible to any user.* *Users are automatically logged out after a period of inactivity.* *Password minimum length and expiry times are configurable.*
(3) Be administered and executed to ensure that attempted use of an individual's electronic signature by anyone other than its genuine owner requires collaboration of two or more individuals.	*Eurotherm Suite security manager allows 'force change of password' to be set when a new password is granted.* *If required, Eurotherm Suite security manager also allows a double signature (sign + authorise) to be enforced on any security change in order to ensure that two individuals must collaborate to make a change.*
(b) Electronic signatures based upon biometrics shall be designed to ensure that they cannot be used by anyone other than their genuine owners.	*(not applicable)*
11.300 Controls for identification codes/passwords	
Persons who use electronic signatures based upon use of identification codes in combination with passwords shall employ controls to ensure their security and integrity. Such controls shall include:	

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(a) Maintaining the uniqueness of each combined identification code and password, such that no two individuals have the same combination of identification code and password.	*Uniqueness of user ID is enforced among both current and retired users.*
(b) Ensuring that identification code and password issuances are periodically checked, recalled, or revised (e.g., to cover such events as password aging).	*Password expiry times are configurable.*
(c) Following loss management procedures to electronically deauthorize lost, stolen, missing, or otherwise potentially compromised tokens, cards, and other devices that bear or generate identification code or password information, and to issue temporary or permanent replacements using suitable, rigorous controls.	*Potentially compromised accounts can be disabled by the Administrator*
(d) Use of transaction safeguards to prevent unauthorized use of passwords and/or identification codes, and to detect and report in an immediate and urgent manner any attempts at their unauthorized use to the system security unit, and, as appropriate, to organizational management.	*Accounts can be automatically disabled on repeated failed logins*
(e) Initial and periodic testing of devices, such as tokens or cards, that bear or generate identification code or password information to ensure that they function properly and have not been altered in an unauthorized manner.	*(Not applicable)*

5.6 Data Migration

TBA: Explanatory note (delete this before publication)
If there is no previous data to be considered, state this.
Otherwise, describe how existing data will be migrated onto the system or (if not being migrated) how it will be accessed after the system is installed

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6. INTERFACES - TO PROCESS EQUIPMENT

TBA: Explanatory note (delete this before publication):
This section can be done either for the system as a whole or for individual plant cells or units if this is more appropriate because of the way the control is split up. If doing it on a plant cell / unit basis, take out a subheading for each cell / unit within the sections
This section assumes low enough risk that only a functional specification is being produced. If further levels of design documentation are being produced then items marked (SDS/SMS) or (HDS) might appropriately be discussed in these documents.

6.1 Input and Output Types

TBA: Explanatory note (delete this before publication):
Take out a subsection for each hardwired input or output type in use and detail

- *Any signal conversion equipment being used*
- *I/O card types being used*

6.2 Input and Output Signals

TBA: Explanatory note (delete this before publication):
Either provide an I/O list or give a cross reference to a separate document which contains it.
I/O list should include:

- *Tags*
- *Types*
- *Channel allocations*
- *Descriptions*
- *Ranges*
- *Required display format*

It may also include:

- *Termination details*
- *GxP criticality of each signal (if available from end user)*
- *Impact or risk rating of each signal (if available from end user)*
- *Alarms*

Tag	*Signal Type*	*Transmitter Range*	*Working Range*	*Channel Allocation*	*Decimal places*	*Description*	*GxP Critical?*	*Impact Rating*
T_P001	*4-20mA*	*0-100%RH*	*10-50 °C*	*10-1-1*	*1*	*P001 ROOM Temperature*	*Yes*	*MEDIUM*

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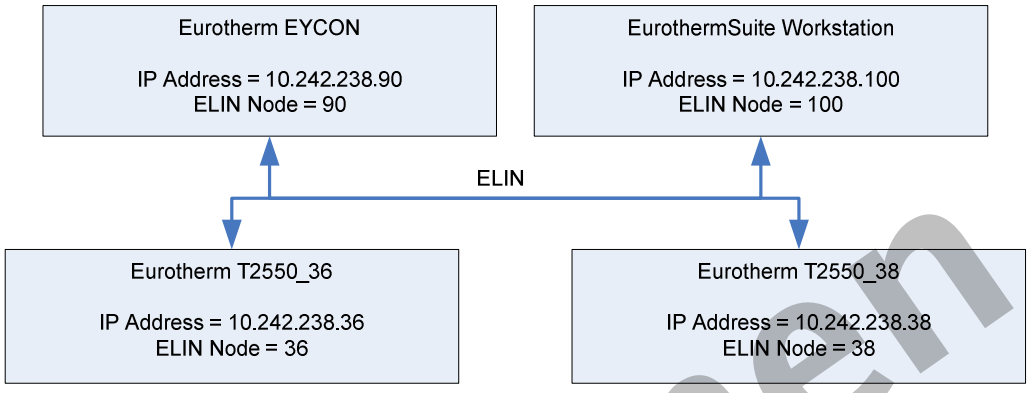
7. INTERFACES - INTERNAL

TBA: Explanatory note (delete this before publication):
Take out a subheading for each interface and rename it appropriately.
Example follows for a standard ELIN interface. Configured or bespoke interfaces need to be treated the same way as for external interfaces in section 8 .

7.1 TBA Example for ELIN

The following devices communicate via the Eurotherm ELIN network:



7.1.1 Physical Connections

ELIN uses Ethernet as the physical transport medium.
Connections are made via an Ethernet switch using Cat5 cable with RJ45 terminals.
The maximum length of each cable does not exceed 100 metres.

7.1.2 Protocol Details

The ELIN communication interface is provided as a standard interface by the EYCON and T2550 firmware and the EurothermSuite package.
The interface allows database blocks to be 'cached' from one application database to another. For example, an analogue input block cached from T2550 to EYCON makes all values and alarms associated with that input available in the EYCON database and thus for connection to EYCON mimics and recipes. Poor data quality is automatically indicated as a 'Software' alarm.

IP addresses (see diagram above) are set in the NETWORK.UNH file within each instrument and within the Windows XP local area connection properties on the PC.
ELIN node addresses (see diagram above) are set in the _SYSTEM.OPT file for the EYCON and via dipswitches on the T2550. ELIN address on the PC is set up via the port configuration options within the EurothermSuite Project Organiser.

7.1.3 Data to be Transferred

All blocks containing values required for display or alarms at the EYCON are cached from the T2550.
The EYCON header block is cached to the T2550 to allow shutdown actions to be triggered if a communications failure occurs.
All blocks are cached from T2550s and EYCON to the EurothermSuite PC (the list is created automatically when the project is built) but only those with connections on mimics, trends, or alarm group allocations are scanned constantly as 'VIEW blocks'.

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8. INTERFACES - EXTERNAL SYSTEMS

TBA: Explanatory note (delete this before publication):
Take out a subheading for each interface and rename it appropriately.
This section assumes low enough risk that only a functional specification is being produced. If further levels of design documentation are being produced then items marked (SDS/SMS) or (HDS) might appropriately be discussed in these documents.

8.1 Interface to TBA External System 1

TBA: Explanatory note (delete this before publication): it is probably easiest to treat a whole communications link in one section (eg T2550 to KD485 to external ASCII device) with separate sections for each protocol in use.

8.1.1 Physical Connections

TBA: Explanatory note (delete this before publication): Give detail of:
- *any protocol conversion devices in use*
- *the physical connection (eg RS422)*
- *the termination details (HDS)*
- *any jumper or switch settings (HDS)*

A drawing can be very helpful

8.1.2 TBA Example Protocol Details – Modbus

TBA: Explanatory note (delete this before publication): Give detail of:
- *the protocol to be used (e.g. ' Modbus RTU' or 'ASCII protocol used by Milligat Pump'*
- *protocol configuration (e.g. baud rate, slave addresses)*
- *the signals (tags) which are to be transferred*
- *signal configuration (e.g. register numbers, data formats, read/write) (SDS/SMS)*
- *Error handling (SDS/SMS)*

For a bespoke interface (e.g. ASCII link to a 3rd party device) this will also need to cover:
- *Command and data formats (SDS/SMS)*
- *Initialisation routine (SDS/SMS)*
- *Timings / handshaking (SDS/SMS)*
- *Data rates (SDS/SMS)*
- *Access and security (SDS/SMS)*

Purpose of function	*To set up the T2550 to read/write data to/from the KD485 protocol convertor on the MZR pump communications link*
Critical process parameters	*None (independent flow reading is defined as critical)*
GxP Critical?	*No*
Impact rating from URS	*Low*
Related plant equipment	*MZR pump 1111PP01*
Category of software used	*4 - Configured*
Interfaces to other modules	*Data is transferred between Modbus tables in the KD485 protocol convertor and the T2550.*
Module operation	*Data is transferred using the following protocol.* *Protocol: RS485 MODBUS RTU* *Master: T2550* *Slave: KD485 (address = 4)* *Baud rate: 9600* *Data bits: 8* *Stop bits: 1* *Parity: None*

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Error handling and data checking	*Alarms on Modbus gateway configuration error and on Modbus table off line are enabled in the GW_CON block within the T2550 application database.*
Module configuration / coding environment	
Serial port parameters are set up in the Eurotherm LIN Instrument Options Editor (within the LINTools package) and are saved within the _SYSTEM.OPT file. *Data values to be transferred are set up in the T2550 Modbus gateway file MBUS_MZR.gwf. This is created and modified using the Modbus tools within Eurotherm LINTools.*	
Module implementation	
Each data item to be transferred is entered within a Modbus table in the T2550 gateway file. *For each data item, the source ('slave') instrument, Modbus register within that instrument ('offset'), field within the T2550, data format and direction of transfer are defined*	
Module data	
The data to be transferred is detailed in the following section.	
Configurability	
The interface is configurable at engineer level only via the Modbus tools within Eurotherm LINTools	

8.1.3 Data to be Transferred

The following data is to be transferred:
TBA: Explanatory note (delete this before publication):
Detail the data which needs to be transferred – example (Modbus) follows

Parameter Name	*Slave Number*	*Offset*	*Field in T2550*	*Format*	*DP*	*Direction*
Speed Setpoint	*4*	*40002*	*TIC9151.SP*	*32 bit*	*N/A*	*M→S*
Heartbeat	*4*	*40004*	*MZR9161X.PV2*	*16 bit*	*0*	*M→S*
Pump Status	*4*	*40005*	*MZR9161X.PV_1*	*16 bit*	*0*	*S→M*
Write Quality	*4*	*40006*	*MZR9161Y.PV_1*	*16 bit*	*0*	*S→M*
Read Quality	*4*	*40007*	*MZR9161Z.PV_1*	*16 bit*	*0*	*S→M*

Specimen

9. INTERFACE FUNCTIONS - OPERATOR INTERFACE

9.1 Alarm and Event Strategy

9.1.1 Alarm Priority Structure

TBA: Explanatory note (delete this before publication):
How are alarms grouped according to priority?
How are the different priorities annunciated (colour/flash, horn, requirement for acknowledgement)

Example for T2550/EurothermSuite follows:
The system allows alarms to be prioritised and alarm indication (e.g. colour, audible annunciation, requirement for acknowledgement) and alarm action to be based on that priority level.
All alarms are initiated at the T2550. Priorities are set in the T2550 and map onto alarm priorities at EurothermSuite as follows:

T2550 Priority	Eurotherm Suite Priority	Alarm Type	Alarm Indication	Alarm Sound	Acknowledge required
0	Disabled	(disabled)	None	No	No
1	999	(unused)	Cyan	Yes	No
2	900	(unused)	Cyan	Yes	No
3	850	(unused)	Cyan	Yes	No
4	800	System Alarm	Cyan	Yes	No
5	750	(unused)	Orange	Yes	No
6	700	Pilot Plant Non-Critical Alarm	Orange	Yes	Yes
7	650	(unused)	Orange	Yes	Yes
8	600	Main Plant Non-Critical Alarm	Orange	Yes	Yes
9	550	(unused)	Yellow	Yes	Yes
10	500	(unused)	Yellow	Yes	Yes
11	450	(unused)	Yellow	Yes	Yes
12	400	Pilot Plant Critical Alarm	Red	Yes	Yes
13	350	(unused)	Red	Yes	Yes
14	300	Main Plant Critical Alarm	Red	Yes	Yes
15	250	(unused)	Red	Yes	Yes

Specimen

9.1.2 Alarm Area Structure

TBA: Explanatory note (delete this before publication):
How are alarms divided by plant area?
What difference does the plant area make to where/how they are acknowledged?
What difference does the plant area make to who can acknowledge them?

Example for T2550/EurothermSuite follows:
An alarm group is created for each room and the temperature and humidity alarms for the room are allocated to that group. This allows alarm summary and alarm history information to be filtered by room if desired.
A separate 'General' alarm group is used for all system alarms.

9.1.3 Alarm Display and Acknowledgement

TBA: Explanatory note (delete this before publication):
How and where are alarms displayed and acknowledged?

What filtering is possible?
It is often helpful to define the sequence of actions on alarm active, alarm acknowledge, alarm clear.

Example for T2550/EurothermSuite follows:
When an alarm condition occurs, this is indicated by flashing of the alarm banner, colour change on mimics and an alarm sound.
All alarms above LIN priority 5 require acknowledgement by the operator before they will clear. Alarms can be acknowledged from the alarm banner or from the alarm summary page. The alarm summary can be filtered by alarm group and by acknowledged/unacknowledged status.
Once an alarm has cleared and been acknowledged, it is automatically removed from the alarm banner and alarm list.

9.1.4 Process Alarms

TBA: Explanatory note (delete this before publication):
Do one of the following:

- *provide generic rules about hwo alarms will be set (eg "All temperature sensors will have a deviation alarm at ±2degC of the stability room setpoint")*
- *provide an alarm list (consider threshold, priority, area, hysteresis, delay, masking, GxP criticality / impact rating)*
- *give a cross reference to a separate document which contains the alarm list.*

9.1.5 System Alarms

TBA: Explanatory note (delete this before publication):
Do one of the following:

- *provide an alarm list (consider threshold, priority, area, hysteresis, delay, masking, GxP criticality / impact rating)*
- *give a cross reference to a separate document which contains the alarm list.*

9.1.6 Events and Messages

TBA: Explanatory note (delete this before publication):
What provision is made for other (non-alarm) events being brought to the attention of the operator?
If correct sequencing of operator actions is required, how is this enforced?
How are messages to the operator and their responses managed?

Specimen

9.2 Displays

9.2.1 Standard Displays – Alarms

TBA: Explanatory note (delete this before publication):
Include detail on alarm banners, alarm summaries, alarm history

Example for T2550/EurothermSuite follows:
Eurotherm Suite provides standard alarm displays as follows:

- *The alarm summary shows current alarms in order of occurrence and colour coded by priority. Alarms are identified by tag, description and type and show the time of the last change of state of the alarm entry. Alarm status (Ack / Unack), value at alarm are shown. Alarm summaries can be filtered to show only unacknowledged alarms and can also be accessed by alarm group.*

- *The alarm history shows all alarms, events and messages in order of occurrence. Alarms and events are identified by tag, description and type. Entries can be filtered by time/date, area, message type (eg alarm, acknowledge, event, security) or a custom query used.*

- *All displays include an alarm banner where the two most recent alarms and any alarm groups with active alarms are shown.*

9.2.2 Standard Displays – Trends

TBA: Explanatory note (delete this before publication):
Include detail on trend displays (historical, runtime, pre-configured/operator selected)

Example for T2550/EurothermSuite follows:
On EurothermSuite Operations servers and viewers, all items have a real time trend available on their point display for tuning / fault finding purposes.

Historical trends are pulled up by selecting the desired trend group from the list provided by the 'Trend' softkey.

The required trend opens up within the EurothermSuite screen. The package allows the operator to carry out the following operations on a trend which is currently being viewed:

- *move forward and backward in time*
- *zoom in on a particular area of the trend*
- *select a particular pen (the engineering units range of this pen is then displayed)*
- *position a hairline cursor to read off values and timestamp*
- *print display charts*
- *export data in csv format*

9.2.3 Standard Displays – Point Information and Faceplates

TBA: Explanatory note (delete this before publication):
Include detail on how information on individual tags is accessed
Include detail on pop-up or other pre-configured faceplates

Example for T2550/EurothermSuite follows:
Point displays are available for all tag items. They present to the operator full text/data associated with any plant item together with a real time trend and a faceplate. These displays enables all tuning parameters to be viewed and (subject to user authorisation level) adjusted.

Specimen

9.2.4 Display Navigation

TBA: Explanatory note (delete this before publication):
Include an overview (diagram?) of how the navigation will be set-up (menus? up/down/prev/next? on-screen navigation elements?)

9.2.5 Display Icons

TBA: Explanatory note (delete this before publication):
Include detail on standard icons which are to be used across all custom built displays (screenshot if possible, description of dynamic movement or colouring, error indications, etc)

TBA: Explanatory note (delete this before publication)
If an SDS is being produced, then a detailed navigation diagram in 8.2.4 may suffice for high level FS detail, with individual displays being defined in the SDS.
If displays are being defined here, take out a subsection to describe each custom display (or display type if there are many similar displays)

9.2.6 TBA Example Plant Overview Mimic

Layout
Distillation column shown diagrammatically

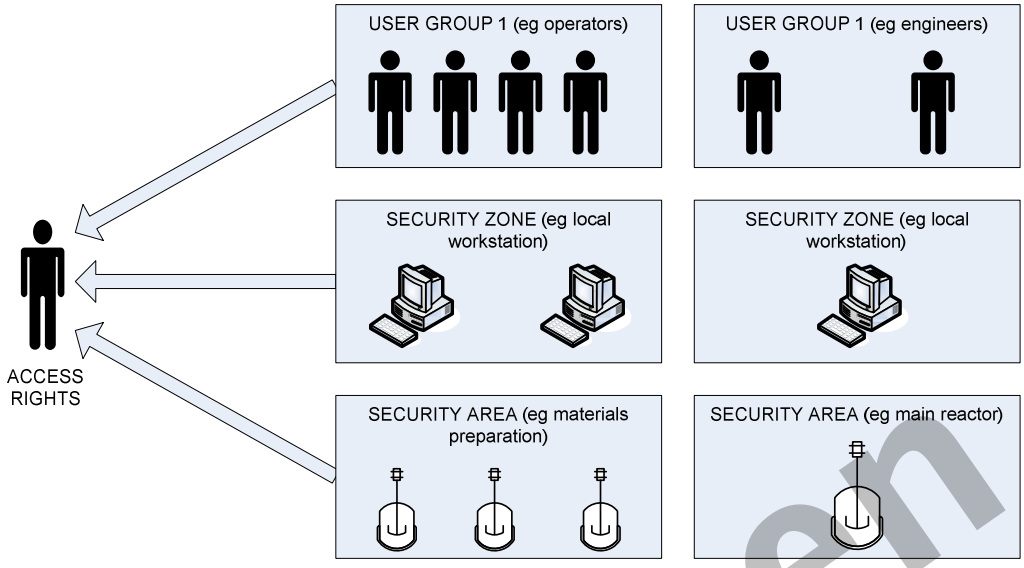
Dynamic Data
Mass flow rates
Temperatures
Pressures
Valve positions
Reflux ratio
Liquid levels
Composition

Operator Controls
Pushbutton for each control scheme gives access to the relevant control pop-up mimic.
Navigation pushbutton allows access to the Recipe / Parameter Entry Mimic.

Specimen

9.3 System Access Control

Throughout this section, the following diagram is used to summarise the way access rights are inherited by a user dependent on their user group, the security zone through which they are currently acting and the area of plant they are attempting to control:



9.3.1 Physical Security

TBA: Explanatory note (delete this before publication)
Is there any physical security surrounding the system?

9.3.2 Global Security Settings

The end user security policy requires the following settings globally throughout the system:
TBA: Explanatory note (delete this before publication)
Fill in any of the following required to meet the user's standard policy

Parameter	*Setting*
Max login attempts	
Password expiry period	
Password re-use period	
Minimum user ID length	
Maximum user ID length	
Minimum password length	
Maximum password length	

The following global settings are used to ensure that end user security policy is met:
TBA: Explanatory note (delete this before publication)
The level of detail in the following would be more appropriate in the SDS if one is being produced.
Example follows for EurothermSuite security manager – note that the example uses a single zone and a single item type. Required fields for other item types can be easily identified from a Security manager export.

Options settings

Parameter	*Setting*
Import users from active directory	*No*
PC Configuration	*Only the EurothermSuite PC configured*
Master UNC path	*Set to be \EuroPS\LCPS on the EurothermSuite PC*
Regulation	*Default*
Deployable	*Yes*

Specimen

Enable Security on EurothermSuite PCs	*Yes*

User Global settings

Parameter	*Setting*
Login dialogue timeout	*30s*
Max login attempts	*99*
Keep retired user IDs	*Yes*
Minimum user ID length	*3*
Maximum user ID length	*8*
Minimum password length	*3*
Maximum password length	*8*
Password re-use period	*180 days*

Settings for Security Manager access

Parameter	*Setting*
Audit trail	*Enabled*
Signing	*Not required*
Authorisation	*Not required*
Recovery user	*Enabled (allows Eurotherm to provide a temporary password to enable a recover user if no other administrator is available)*
User timeout	*99 mins (entered on a per user group basis for each zone)*

Settings for EurothermSuite PC access

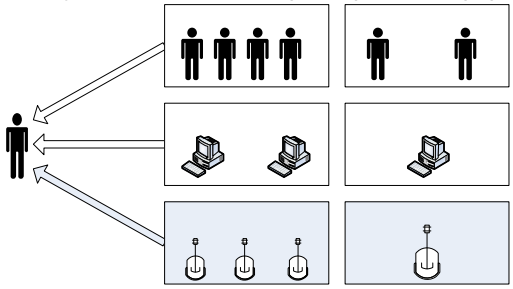
Parameter	*Setting*
Audit trail	*Enabled*
Signing	*Enabled (Signing follows configuration for the user/zone)*
Authorisation	*Enabled (Authorisation follows configuration for the user/zone)*
Alarm Signing	*0 (Disabled)*
Alarm Authorisation	*0 (Disabled)*
Confirmation	*Enabled (Confirmation follows configuration for the user/zone)*
Notes	*Enabled (Enforcement of note entry follows configuration for the user/zone)*
Auto Logon User ID	*Logged Out*
Log Invalid Times	*Yes (makes time synchronisation problems visible in log)*
Audit Ports	*None required (no EYCONs reporting audit trail data)*
Lockout level	*None (can still navigate to all areas within EurothermSuite)*

Specimen

On logging into Security Manager, an ordinary user has access only to change their password. An administrator level user has access to all security setup parameters.

9.3.3 Security Areas

A security are defines the scope of process equipment over which a user has the same access rights.



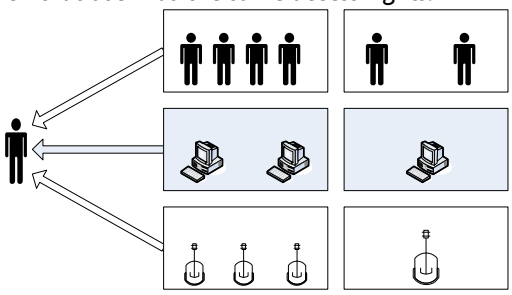
The following security areas are configured.

TBA: Explanatory note (delete this before publication). Example follows for EurothermSuite security manager

Security Area	Description
Eg REACTOR A	All equipment associated with reactor A
Eg COLUMN	All equipment associated with the distillation column

9.3.4 Security Zones and Items

A security zone defines a set of devices through which a user may gain access to the system and through which that user has the same access rights.

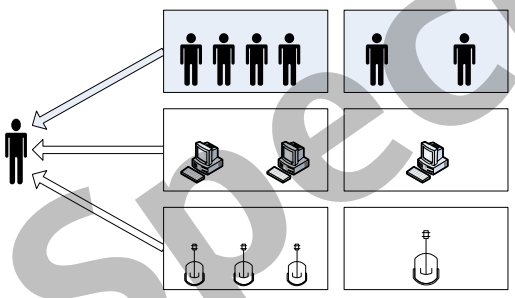


The following security zones are initially configured:

TBA: Explanatory note (delete this before publication). Example follows for EurothermSuite security manager

Security Zone	PCs in zone	Other devices in zone
Security Manager	(special zone for security manager tool)	none
Eg ControlRoom	Eurotherm Suite PC	
Eg Laboratory 1		EYCON 1

9.3.5 Security Groups



A security group is used to define the access rights applicable to a particular type of user.
The following security groups are initially configured:

Security Group	Type of User in group
SecurityAdmin	System owner
Engineers	Control system engineers
Operators	Plant operators

9.3.6 Resulting Access Rights

Access rights relating to the security zone / operator interface item being used are allocated as follows:

TBA: Explanatory note (delete this before publication)

Example follows for EurothermSuite security manager assuming a single zone

Security Zone / Item Type	Access Right	Security Administrators	Engineers	Operators
Security Manager	Sign	True	False	False
Security Manager	Authorise	True	False	False
Security Manager	Inactivity timeout (mins)	99	99	99
Security Manager	View security data	True	False	False
Security Manager	Change own password	True	True	True
Security Manager	Change own expired password	True	True	True
Security Manager	Edit user global data	True	False	False

Specimen

Security Manager	Edit user data	True	False	False
Security Manager	Edit user group data	True	False	False
Security Manager	Edit security item data	True	False	False
Security Manager	Edit zone configuration	True	False	False
Security Manager	Edit zone management data	True	False	False
Security Manager	Edit zone access rights	True	False	False
Security Manager	Edit Security Manager setup	True	False	False
Security Manager	Edit Deployable flag	True	False	False
Security Manager	Deploy security	True	True	True
Zone1 / EurothermSuite	Sign	True	True	True
Zone1 / EurothermSuite	Authorise	True	True	False
Zone1 / EurothermSuite	Inactivity timeout (mins)	99	99	99
Zone1 / EurothermSuite	Task Switch	Confirm	Confirm	Disabled
Zone1 / EurothermSuite	Operator group global	Confirm	Confirm	Disabled
Zone1 / EurothermSuite	Operator groups	Confirm	Confirm	Confirm
Zone1 / EurothermSuite	Trend global	Confirm	Confirm	Disabled
Zone1 / EurothermSuite	Trends	Confirm	Confirm	Confirm
Zone1 / EurothermSuite	Display access level	0 (all available)	0 (all available)	0 (all available)
Zone1 / EurothermSuite	Recipes (system user to use for recipe operations)	ESDataSrv	ESDataSrv	ESDataSrv
Zone1 / EurothermSuite	Change Language	Confirm	Confirm	Disabled
Zone1 / EurothermSuite	Synchronise Files	Confirm	Confirm	Disabled
Zone1 / EurothermSuite	Override Server Redundancy	Confirm	Confirm	Disabled
Zone1 / EurothermSuite	Faceplate Configurator	True	True	False
Zone1 / EurothermSuite	Print	True	True	True
Zone1 / EurothermSuite	Debug	Confirm	Confirm	Disabled
Zone1 / EurothermSuite	TagEdit	True	True	False
Zone1 / EurothermSuite	Operator Point Display	True	True	True
Zone1 / EurothermSuite	Export Historical Trend	True	True	True
Zone1 / EurothermSuite	AlarmHistMaxItems	Confirm	Confirm	Disabled
Zone1 / EurothermSuite	Recipe Download	Confirm	Confirm	Confirm
Zone1 / EurothermSuite	Global Alarm Acknowledge	Confirm	Confirm	Confirm
Zone1 / EurothermSuite	Faceplate Modify	Confirm	Confirm	Disabled
Zone1 / EurothermSuite	Offline data writes	Confirm	Confirm	Disabled
Zone1 / EurothermSuite	IO data writes	Confirm	Confirm	Disabled
Zone1 / EurothermSuite	System User writes	Log All	Log All	Log All

Access rights relating to the area of plant being operated are allocated as follows:

Security Zone / Area	Tag area access level	Security Administrators	Engineers	Operators
Zone1 / Reactor A	Field Security	Engineer	Engineer	Operator
Zone1 / Column	Field Security	Engineer	Engineer	Operator

Where the tag area access level is defined to give access to fields up to the following security thresholds (e.g. 'Operator' access level gives access to all parameters set as 'Public', 'AlarmAck', 'CtrlModReset' and 'Operator')

Field Security Threshold	Description of use
Public	Fields which are read only and cannot be altered
AlarmAck	Fields which may be written to only by users whose accounts contain 'AlarmAck' rights or higher to the selected tag (for example alarm acknowledges)
CtrlModReset	(Unused on this project) Fields which may be written to only by users whose accounts contain 'CrtlModReset' rights or higher to the selected tag (for example control module resets)
Operator	Used for fields which may be written to only by users whose accounts contain 'Operator' rights or higher to the selected tag (for example control loop setpoints)
Engineer	Used for fields which may be written to only by users whose accounts contain 'Engineer' rights or higher to the selected tag (for example ranges or tuning parameters or alarm priorities)

Specimen

9.3.7 User Accounts

A user account inherits permissions from the groups to which it belongs and defines the access rights associated with an individual user.
The following user accounts are initially configured as examples that can be copied by the customer's system keeper when setting up individual accounts for site personnel.
TBA: Explanatory note (delete this before publication)
Example follows for EurothermSuite security manager assuming a single zone

User ID	Full Name	Password	Security Group Membership
Admin	Example Administrator	EPAEPA0	SecurityAdmin
Eng	Example Engineer	ENGENG0	Engineers
Oper	Example Operator	OPEOPE0	Operators
ESDataSrv	ESDataSrv	(system user)	(not applicable)

The EurothermSuite package starts up with no user logged in.

9.3.8 Underlying PC Security

TBA: Explanatory note (delete this before publication)
This section can be deleted if there are no PC-based workstations
Example follows for EurothermSuite security manager

The PC is set to boot straight into EurothermSuite and only privileged users can escape from the EurothermSuite environment to the underlying PC desktop.

The EurothermSuite package offers its own security system on top of a single Windows XP security account. The PCs have the following Windows XP accounts initially configured:

1. *EPA - configured to provide user only access. This account is logged in automatically on start-up and used beneath the EurothermSuite package. The initial password is EPA205277*
2. *EPAAdmin - configured to provide administrator access and required if additional software is installed in future. The initial password is EPABN148NN*
3. *Administrator – default administrator access account. The initial password is EPAEPA*

As these accounts are 'hidden' beneath the EurothermSuite security, their passwords are not set to expire after a pre-determined time. It is strongly recommended that the initial passwords should be changed and controlled by the customer to prevent access via any other networked PC.

Note that any user with access to the Windows XP environment is able to run the LINtools package. LINTools security is provided by LINOPC. The current Windows XP user must be registered in the DEFACCESS.CSV file stored on the server or in the project database with read/write access in order to be able to change data from the LINTools online packages (for example to force values for test purposes).

Specimen

10. SYSTEM TECHNICAL DETAIL

10.1 Hardware Design

TBA: Explanatory note (delete this before publication)
EITHER refer the reader to the HDS or fill in hardware details here

10.1.1 Computerised System Components

TBA: Explanatory note (delete this before publication)
Include detail on equipment (PC's, EYCON's, T2550s, 5000 series, etc) to be supplied including storage devices, printers and other peripherals

Description	Model Number	Supply by	No
T2550 (Reactor Skid) 	*T2550S/8S/NONE/L40/MB-TCPM/SERIAL/RJ45/ AI2-DC/AI2-DC/AI2-DC/AI2-DC/AI2-DC/AI2-MA/ RLY4-FUSE/DI424/NONE/NONE/NONE/NONE/ NONE/NONE/NONE/NONE/NONE/CDM/XXXXX/ XXXXXX*	*Eurotherm*	*5*

10.1.2 Interconnections

TBA: Explanatory note (delete this before publication)
Include detail on all interconnections. Standard cables can be defined by type. Bespoke cables should give drawing reference if appropriate.

From / To	Type	Supply by	No
LAN switch to T2550	*Shielded CAT5 RJ45 – RJ45, 5m*	*Eurotherm*	*5*

10.1.3 Inputs and Outputs

TBA: Explanatory note (delete this before publication)
Include detail on I/O types.

- *I/O card specifications (e.g. for accuracy, load, isolation, etc)*
- *Termination details*
- *Powering of signals*

10.1.4 Environment

The equipment is suitable for operation in the following environment:
TBA: Explanatory note (delete this before publication)
Include detail on the relevant environmental performance of the equipment.

Operating temperatures	
Operating humidity	
IP rating	
Shock / Vibration	
Altitude	
EMC emissions / immunity	

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10.1.5 Services

The equipment is requires the following service connections:
TBA: Explanatory note (delete this before publication)
Detail electrical supply requirements (voltage, frequency, power consumption, filtering, earthing)
Detail any UPS requirements if appropriate
Detail any pneumatic air requirements if appropriate

10.1.6 Physical Details

TBA: Explanatory note (delete this before publication)
If instrumentation or other equipment is being supplied for installation by others, provide detail on sizes and mounting.
If instrumentation is being supplied in panels, give a brief description of the panels (size, material, IP rating, wall mounting or floor standing, top or bottom entry, etc) and reference panel GA drawings.

10.2 Disaster Recovery

10.2.1 Power Outage

TBA: Explanatory note (delete this before publication)
What happens to outputs on loss of power?
What happens to programs / configurations on loss of power?

What happens on restart – cold / warm / tepid?
What happens to outputs on restart?
What happens to run-time data on restart?

10.2.2 Equipment Failure and Redundancy

TBA: Explanatory note (delete this before publication)
Is there any redundancy supplied?
Complete the following table for failure of each type of equipment item in turn (don't forget to include communications equipment such as Ethernet switches)

Equipment Item	Indication of failure	Effect on control	Effect on process visibility

10.2.3 Backup and Restore

TBA: Explanatory note (delete this before publication)
Describe how each type of equipment is backed up.
What would the end user need to do to return to the operational state if a spare was fitted.

Equipment Item	Method of backup	Method of restore

Specimen

10.3 Performance

TBA: Explanatory note (delete this before publication)
Give detail relating to any performance requirements in the URS and/or any known restrictions on performance

- *Speed of specific functions*
- *Speed of data access*
- *Data capacity*
- *etc*

Specimen

11. NON-FUNCTIONAL ATTRIBUTES

11.1 Availability

The system is designed to be suitable for use in an environment which operates 24 hours per day 7 days per week provided that appropriate maintenance activities are carried out.
MTBF figures are available from Eurotherm on demand.
Recommended maintenance activities are detailed in the user manuals for each device.

TBA: Explanatory note (delete this before publication)
If customer URS specifically requests MTBF figures, include these TOGETHER WITH the explanation of how they are derived.

11.2 Maintainability

11.2.1 Diagnostic Facilities

TBA: Explanatory note (delete this before publication)
Include detail on built in diagnostic / self-test facilities

11.2.2 Expansion Capability

TBA: Explanatory note (delete this before publication)
Fitted spare capacity?
Expansion possibilities?
Licensing issues?

Specimen

12. GLOSSARY

TBA: Explanatory note (delete this before publication): - add any other abbreviations or project-specific terms (including Eurotherm instrument names, comms protocol names,etc)

DCS	Distributed Control System
GAMP	GAMP 5 A Risk Based Approach to Compliant GxP Computerized Systems
GxP Compliance	Meeting all applicable pharmaceutical and associated life-science regulatory requirements
I/O	Inputs and Outputs

Specimen

APPENDIX A – CROSS REFERENCE TO CUSTOMER REQUIREMENTS

TBA: Explanatory note (delete this before publication): - the following tables need to be completed in order to demonstrate that the customer's technical requirements (from the URS) have been met.
Any non-compliance should be highlighted in the table
Where a section includes no relevant requirements, this should be made clear
If all subsections of an FS statement relate to a single requirement, it is acceptable to cross reference at the section level rather than the subsection level.

The GxP and Impact rating columns may need modifying according to the way this information is represented in the URS. If the URS does not include this information then issue 1 of the FS to the customer should include the blank columns and be accompanied by a request to the customer to provide the information.

(The easiest way to create these tables is via a Microsoft Access database – create separate tables for each document and then create additional tables containing just a list of links between two documents. A query can then be used to export the data in the appropriate order)

URS Ref	GxP?	Impact Rating	URS Heading	FS Ref

FS Ref	FS Heading	URS Ref	GxP?	Impact Rating

Specimen

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Title	Double-click HERE and type Project Title
Customer	Double-click HERE and type Customer Name
Eurotherm Reference	Double-click HERE and type Eurotherm Reference
Customer Reference	Double-click HERE and type Customer Reference

Explanatory note (delete this before publication):
1) enter all fields above plus date and issue number below
2) search for 'TBA' to find items which need entering on a per-project basis.
3) if not based in the UK, replace the header with the appropriate one from your local letterhead

CONFIGURATION MANAGEMENT SCHEDULE

Prepared by	.....	.....	.....
	Sign / Date	Printed Name	Title
Issue	Enter Issue No		
Date	Enter Date		

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1. DOCUMENTATION RECORDS

TEMPLATE DETAILS			
HISTORY:			
T1	Template document written for GAMP5 based on requirements in Quality Plan template T3.		01 Jul 2008
APPROVAL DETAILS FOR CURRENT TEMPLATE			
Template prepared by	Karen Ashworth	Validation Officer	01 Jul 2008
Template reviewed for Technical Content	Malek Madani	Technical Manager	01 Jul 2008
Template reviewed for Quality Assurance	Martin Greenhalgh	Global Quality Manager	01 Jul 2008

DOCUMENT REVISION HISTORY		
Issue	Detail	Issue Date
1	Project version 1 developed from template T1	TBA Enter Issue Date

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2. NOTES ON FILE TYPES CONTROLLED

TBA Explanatory note (delete this before publication):
This section identifies, for each node type in the system, the types of software items to be controlled
Note that any test data, simulations, etc should also be included
This document is normally issued at around the point where module specs are approved -since it details which items need to be controlled prior to code review, it needs to be issued before code review starts. It is then updated if necessary for the start of testing, for shipment and for final handover.
The example below shows Eurotherm Suite with the Wonderware factory suite part of the configuration controlled as a single item (we have discussed this with many customers and found that it is generally acceptable to control the whole factory suite directory and apply tags to everything within it at once – Wonderware is very difficult to do otherwise with as the many internal cross references can lead to many 'changed' files when a mimic is modified. WinCVS is clever enough to put only changed files back into the repository at a new version so the history of individual files within the directory can still be tracked).
Expand on / Delete from the items listed below to match the architecture to be supplied:

2.1 6180A

File Type	Tool used for editing	Notes
**.uhz*	*Via front panel or Bridge5000*	*Provides a complete definition of the 6180A configuration (note that 5000 series off-line configuration tool is also available but not installed for this application as it does not provide an audit trail of changes)*

2.2 Recorders Tools PC

File Type	Tool used for editing	Notes
**.cgp*	*Review*	*Chart group set up for review*
**.xls*	*Microsoft Excel*	*Excel spreadsheet*
Secmandb.ujx	*Security Manager*	*Security management settings*

2.3 EYCON

File Type	Tool used for editing	Notes
_system.opt	*Text editor (or via EYCON panel)*	*System configuration settings.*
Network.unh	*Text editor (or via EYCON panel)*	*System network settings.*

Specimen

File Type	Tool used for editing	Notes
*.dbf *.dtf *.grf	Eurotherm LINtools	.dbf, .dtf, .grf together make up a LINtools database definition Only the .dbf file needs to be downloaded
*.uxg	Eurotherm LINtools	.uxg files are created automatically for any LINtools database which includes recording functions. This file needs to be downloaded before recording can take place.
*.uqd *.uqg *.uqt *.uqm *.sdb, *.sdt, *.sgx	Eurotherm LINtools	.uqd, .uqg, .uqt together make up a LINtools generic sequence definition .uqm defines the mappings used for a particular instance of the sequence. Together these can be used to generate a specific instance of the sequence (.sdb, .sdt, .sgx) of which only the .sdb file needs to be downloaded
*.stx *.sto	Eurotherm LINtools	.stx is the source and .stx the object code for a LINtools action Only the .sto needs to be downloaded
*.ujg *.gwf	Eurotherm LINtools Modbus tools	.ujg is the source and .gwf the object code for a LINtools Modbus gateway file. Only the .gwf file needs to be downloaded
*.uxm	Eurotherm LINtools Modbus tools	A .uxm file defines the mapping of Modbus address to IP address when Modbus TCP is used
*.upm *.gwf	Eurotherm LINtools Profibus tools	.upm and .gwf together make up a LINtools Profibus gateway file. Only the .gwf file needs to be downloaded
*.upb	Eurotherm LINtools Profibus tools	A .upb file defines the profibus network configuration. It must be downloaded.
*.gsd	Eurotherm LINtools Profibus tools	.gsd files define communications to a profibus device. One must be downloaded for each profibus device type.
*.cpf	Text editor	Defines the coldstart state for an instrument. Needs to be downloaded.
*.uxp *.ofl	User Screen Editor	Defines the user screens. .uxp is used to generate a .ofl file which needs to be downloaded
*.uys	Setpoint Programmer	Defines a setpoint program. Needs to be downloaded
_user.uyl	Text editor	Dictionary for system text / messages. Needs to be downloaded.
*.uyn	Text editor	Dictionary for user text / messages (eg aliases for block names). Needs to be downloaded.
*.ubl	Text editor	List of layer databases to be built into target database (ready for download) when 'build' is selected
List.ujd	Text editor	List of files to be downloaded to instrument when 'download' is selected

Specimen

2.4 T2550

File Type	Tool used for editing	Notes
_system.opt	*Text editor (or via T800 panel)*	*System configuration settings.*
Network.unh	*Text editor (or via EYCON panel)*	*System network settings.*
**.dbf* **.dtf* **.grf*	*Eurotherm LINtools*	*.dbf, .dtf, .grf together make up a LINtools database definition* *Only the .dbf file needs to be downloaded*
**.uxg*	*Eurotherm LINtools*	*.uxg files are created automatically for any LINtools database which includes recording functions. This file needs to be downloaded before recording can take place.*
**.uqd* **.uqg* **.uqt* **.uqm*	*Eurotherm LINtools*	*.uqd, .uqg, .uqt together make up a LINtools generic sequence definition* *.uqm defines the mappings used for a particular instance of the sequence.* *Together these can be used to generate a specific instance of the sequence (.sdb, .sdt, .sgx) of which only the .sdb file needs to be downloaded*
**.stx* **.sto*	*Eurotherm LINtools*	*.stx is the source and .stx the object code for a LINtools action* *Only the .sto needs to be downloaded*
**.ujg* **.gwf*	*Eurotherm LINtools Modbus tools*	*.ujg is the source and .gwf the object code for a LINtools Modbus gateway file. Only the .gwf file needs to be downloaded*
**.uxm*	*Eurotherm LINtools Modbus tools*	*A .uxm file defines the mapping of Modbus address to IP address when Modbus TCP is used*
**.upm* **.gwf*	*Eurotherm LINtools Profibus tools*	*.upm and .gwf together make up a LINtools Profibus gateway file. Only the .gwf file needs to be downloaded*
**.upb*	*Eurotherm LINtools Profibus tools*	*A .upb file defines the profibus network configuration. It must be downloaded.*
**.gsd*	*Eurotherm LINtools Profibus tools*	*.gsd files define communications to a profibus device. One must be downloaded for each profibus device type.*
**.cpf*	*Text editor*	*Defines the coldstart state for an instrument. Needs to be downloaded.*
**.ubl*	*Text editor*	*List of layer databases to be built into target database (ready for download) when 'build' is selected*
List.ujd	*Text editor*	*List of files to be downloaded to instrument when 'download' is selected*

2.5 EurothermSuite

File Type	Tool used for editing	Notes

Specimen

File Type	Tool used for editing	Notes
Project.mdb	*Eurotherm Suite*	*Project database used during Eurotherm Suite run time* *Contains data entered via Eurotherm Suite tools (Eurotherm Suite Configurator, Eurotherm Suite Manager, Plant Model editor, IO Allocation editor, Tag editor, Data Security editor, Standard Navigation editor)*
SecManDb.ujx	*Eurotherm Suite*	*Eurotherm Suite security database*
(Factory Suite directory)	*Wonderware Windowmaker*	*Eurotherm Suite operator interface* *Entire directory is controlled as a single block since Wonderware cross-referencing potentially results in changes to many files for a single edit.*
Linopc.ini	*Text editor*	*Configuration file for LINOPC which determines what conditions cause data to show as 'unavailable' on mimics.*
Ufolder.ini	*(automatically created)*	*Folder configuration details – eg device type, what commands are available from the folder, etc. (this file exists and is controlled for every folder within the project directory – these have not been listed individually in section 2 below)*

2.6 Test Software

File Type	Tool used for editing	Notes
**.dbf* **.dtf* **.grf*	*Eurotherm LINtools*	*.dbf, .dtf, .grf together make up a LINtools database definition* *Only the .dbf file needs to be downloaded*
**.sdb* **.sdt* **.sgx*	*Eurotherm LINtools*	*.sdb, .sdt, .sgx together make up a LINtools specific sequence definition* *Only the .sdb file needs to be downloaded*

2.7 BespokeTools

File Type	Tool used for editing	Notes

Specimen

3. CONFIGURATION SCHEDULE

TBA Explanatory note (delete this before publication):
This section gives a full list of items to be controlled (instances of the item types listed above).

3.1 6180A

File	Description	GAMP category	Point for control

3.2 Recorders Tools PC

File	Description	GAMP category	Point for control

3.3 EYCON

File	Description	GAMP category	Point for control

3.4 T2550

File	Description	GAMP category	Point for control

3.5 EurothermSuite

File	Description	GAMP category	Point for control

3.6 Test Software Requiring Control

File	Description	GAMP category	Point for control

3.7 Bespoke Tools Requiring Control

File	Description	GAMP category	Point for control

Specimen

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Specimen

Title	Double-click HERE and type Project Title
Customer	Double-click HERE and type Customer Name
Eurotherm Reference	Double-click HERE and type Eurotherm Reference
Customer Reference	Double-click HERE and type Customer Reference

Explanatory note (delete this before publication):
1) enter all fields above plus date and issue number below
2) search for 'TBA' to find items which need entering on a per-project basis.
3) if not based in the UK, replace the header with the appropriate one from your local letterhead

CONFIGURATION ENVIRONMENT SCHEDULE

Prepared by	.....	.....	.....
	Sign / Date	Printed Name	Title
Issue	Enter Issue No		
Date	Enter Date		

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CONTENTS

Specimen

1. DOCUMENTATION RECORDS

TEMPLATE DETAILS			
HISTORY:			
T1	Template document written for GAMP5 based on requirements in Quality Plan template T3.		01 Jul 2008
APPROVAL DETAILS FOR CURRENT TEMPLATE			
Template prepared by	Karen Ashworth	Validation Officer	01 Jul 2008
Template reviewed for Technical Content	Malek Madani	Technical Manager	01 Jul 2008
Template reviewed for Quality Assurance	Martin Greenhalgh	Global Quality Manager	01 Jul 2008

DOCUMENT REVISION HISTORY		
Issue	Detail	Issue Date
1	Project version 1 developed from template T1	TBA Enter Issue Date

Specimen

2. SCHEDULE OF STANDARD PACKAGE / FIRMWARE VERSIONS

TBA Explanatory note (delete this before publication):
This section identifies, for each node in the system, the manufacturer's unique name and version number of any operating system, firmware or standard packages. Note that application development tools should be included if appropriate
We normally make a preliminary issue of this document very early on (alongside the configuration management plan and quality plan) so that the end-user can use it in registering his system for validation. It is then formally issued for start of testing and updated if any upgrades are applied.
Expand on / Delete from the items listed below to match the architecture to be supplied:

Node	Type	Standard Software item	Function	Version	GAMP category
Engineers Station	*Eurotherm Suite DS-300*	*Windows XP*	*Operating System*		*1*
Engineers Station	*Eurotherm Suite DS-300*	*Eurotherm Suite Operations Server*	*Control System Operator Workstation (Server) and Configuration Tools Package*		*3*
Engineers Station	*Eurotherm Suite DS-300*	*WinCVS*	*Configuration Management*		*3*
Operator Station	*Eurotherm Suite RT-300*	*Windows XP*	*Operating System*		*1*
Operator Station	*Eurotherm Suite RT-300*	*Eurotherm Suite Operations Server*	*Control System Operator Workstation (Server) and Configuration Tools Package*		*3*
Client Station	*Eurotherm Suite OP*	*Windows XP*	*Operating System*		*1*
Client Station	*Eurotherm Suite OP*	*Eurotherm Suite Operations Client*	*Control System Operator Workstation Package (Client)*		*3*
EYCON_10	*EYCON10*	*EYCON Firmware*	*Distillation column control*		*3*
T2550_12	*T2550*	*T2550 Firmware*	*Distillation column control*		*3*
Review PC	*Review PC*	*Windows XP*	*Operating System*		*1*
Review PC	*Review PC*	*Microsoft Excel*	*Spreadsheet package*		*3*
Review PC	*Review PC*	*Bridge*	*Remote viewing package for 5180V recorders*		*3*
Review PC	*Review PC*	*Review (Full)*	*Historical data viewing package for 5180V recorders*		*3*
Review PC	*Review PC*	*Report*	*Excel add-in to allow retrieval of data from Review*		*3*
Stability1	*6180A*	*6180A Firmware*	*Stability room monitoring (rooms 1-4)*		*3*

Specimen

3. ENVIRONMENT SET-UP PARAMETERS

TBA Explanatory note (delete this before publication):
This section is used for any parameters which are outside the standard package / controlled configuration but are required to be set up – for example on replacing an instrument. The example below was extended at the customers request to cover PC set-up details.
Expand on / Delete from the items listed below to match the architecture to be supplied:

This section is used to list any non-default set-up parameters which are not part of a controlled configuration file and which would therefore need to be re-applied to a newly installed system hardware element, for example following a fault.

3.1 EYCON

Most system set-up parameters are exported and controlled as a configuration file (_system.opt plus the ELIN communication setup NETWORK.UNH)

Security setup can be exported from an EYCON unit for import into a new unit (remaining valid for 1 hour from the export). As a 'last resort' it can be manually re-configured as follows:

- *Electronic signatures DISABLED.*
- *Network audit trail ISOLATED*
- *User based security is ENABLED with parameters are set as follows:*

Section	Parameter	Value
Account maintenance	*Recovery Account*	*YES*
	Master Access	*YES*
	Edit Own Expired Password	*YES*
Account Properties	*Min User ID Length*	*3 characters*
	Min Password Length	*3 characters*
	Max Login Attempts	*99*
	Password Expiry	*180 days*
	User Timeout	*99 minutes*

Specimen

3.2 T2550

Most system set-up parameters are exported and controlled as a configuration file (_system.opt plus the ELIN communication setup NETWORK.UNH)
ELIN node number and hot/cold start are determined by switch bank SW1 under the T2550 processor

SWITCH BANK SW1	T2550_10	T2550_12
HS	*OFF*	*OFF*
CS	*ON*	*ON*
Address bit 7 (MSB = 128)	*OFF*	*OFF*
Address bit 6 (64)	*OFF*	*ON*
Address bit 5 (32)	*ON*	*OFF*
Address bit 4 (16)	*ON*	*OFF*
Address bit 3 (8)	*ON*	*OFF*
Address bit 2 (4)	*OFF*	*OFF*
Address bit 1 (2)	*OFF*	*OFF*
Unused	*OFF*	*OFF*

3.3 Eurotherm Suite

This section assumes that EurothermSuite has been installed in accordance with the instructions in the EurothermSuite Installation & Setup Guide (RM 028 188). Parameters set during that procedure are not repeated here.

Parameter	Set from	ESuite DS	ESuite RT	ESuite OP
WINDOWS XP				
Network Setup	*Control Panel, System, Network Identification* ***Full Computer Name*** ***Workgroup*** *Local Area Connection <properties>* *Internet Protocol (TCP/IP) <properties>* ***IP address*** ***Subnet Mask*** ***Default Gateway***	 *ENGINEER* *X_LABS*	 *SERVER* *X_LABS*	 *LAB1 / LAB2* *X_LABS*
Regional Settings	*By double clicking time on toolbar* ***Time zone*** ***Automatically adjust clock for daylight saving changes?***	 *GMT* *No*	 *GMT* *No*	 *GMT* *No*

Specimen

Parameter	Set from	ESuite DS	ESuite RT	ESuite OP
	(must be an Administrator to see this)			
Power Save Options	*Display Properties, Screen Saver, Power*			
	Power Scheme	*Always On*	*Always On*	*Always On*
	Turn Off Monitor	*Never*	*Never*	*Never*
	Turn Off Hard Disks	*Never*	*Never*	*Never*
	System Standby	*Never*	*Never*	*Never*
Accessibility Options	*Control Panel, Accessibility Options*			
	Keyboard>StickyKeys>Settings>UseShortcut	*Off*	*Off*	*Off*
	Keyboard>FilterKeys>Settings>UseShortcut	*Off*	*Off*	*Off*
	Keyboard>ToggleKeys>Settings>UseShortcut	*Off*	*Off*	*Off*
	Display>HighContrast>Settings>UseShortcut	*Off*	*Off*	*Off*
	Mouse>MouseKeys>Settings>UseShortcut	*Off*	*Off*	*Off*
EurothermSuite Trends				
Historical trend configuration	*Start, Programs, Wonderware Factory Suite, WindowMaker, Configuration, Historical logging*			
	Overwrite	*N/A (deployed)*	*31 days*	*N/A (deployed)*
	Location	*N/A (deployed)*	*D:\EuroPS\Pxxxxx\History\Trends*	*N/A (deployed)*
EurothermSuite ALARMS				
Alarm Logger Filtering	*Start, Programs, Wonderware Factory Suite, Alarm Suite, Alarm Logger Configuration 'Filtering' Tab*			
	High Priority Range	*999*	*999*	*999*
	Low Priority Range	*1*	*1*	*1*
Alarm Logger Logging	*Start, Programs, Wonderware Factory Suite, Alarm Suite, Alarm Logger Configuration 'Logging' Tab*			
	Enable Alarm Logging System	*YES*	*YES*	*YES*
	Enable History	*YES*	*YES*	*YES*
	Enable Summary	*NO*	*NO*	*NO*
	Discard oldest when full	*YES*	*YES*	*YES*
	Show Alarm Logger monitor window	*YES*	*YES*	*YES*
	Use External Suitelink Timestamps	*NO*	*NO*	*NO*

Specimen

Parameter	Set from	ESuite DS	ESuite RT	ESuite OP
	Use Extended Messages for String Events	*YES*	*YES*	*YES*
Alarm Logger Advanced	*Start, Programs, Wonderware Factory Suite, Alarm Suite, Alarm Logger Configuration 'Advanced' Tab* ***Enable Write-Back***	*NO*	*NO*	*NO*
Alarm Logger Database	*Alarm Logger Configuration 'Database' Tab* ***Connection timeout (s)*** ***Retry interval (s)*** ***Data Source Name*** ***User Identification*** *Set from Automatic Configuration Wizard* ***Server Location*** ***Database Name*** ***Connection Protocol*** ***(NOTE THAT THESE SETTINGS CAN ONLY BE CHECKED BY USING ADMINISTRATIVE TOOLS, ODBC SETTINGS, SYSTEM DSN, ALARMSUITEDSN, CONFIGURE, CLIENT CONFIG. THIS REQUIRES AN ADMINISTRATOR TO BE LOGGED IN)***	*15* *60* *AlarmSuiteDSN* *sa* *LOCAL* *MASTER* *Named Pipes*	*15* *60* *AlarmSuiteDSN* *sa* *REMOTE (Name = SERVER)* *MASTER* *Named Pipes*	*15* *60* *AlarmSuiteDSN* *sa* *REMOTE (Name = SERVER)* *MASTER* *Named Pipes*
Alarm Purge Utility	*Windows 2000* ***Startup*** *list* ***Enable History Auto Purge*** ***Days Online*** ***Enable summary Auto Purge*** ***Enable Archive*** ***Row Deletion Block Size***	*Add D:\Program Files\FactorySuite\InTouch\AlarmSuitePurge.exe* *Yes* *31* *No* *No* *500*	*N/A*	*N/A*
TIME SYNCHRONISATION				
W32Time SNTP server	*Registry HKEY_LOCAL_MACHINE \ SYSTEM \ CurrentControlSet \ Services \ W32Time \ Paramters* ***LocalNTP value***	*1*	*0*	*0*
Windows Time Service	*Control Panel, Administrative Tools, Services,*			

Specimen

Parameter	Set from	ESuite DS	ESuite RT	ESuite OP
Startup Type	***Windows Time Service***	*Startup AUTOMATIC*	*N/A*	*Startup AUTOMATIC*
Windows Time Service SNTP Server to use	*Typed from MS-DOS prompt* *Viewed from registry HKEY_LOCAL_MACHINE \ SYSTEM \ CurrentControlSet \ Services \ W32Time \ Paramters \ ntpserver*	*Net time /setsntp:xxx.xxx.xxx.xxx*	*Net time /setsntp:xxx.xxx.xxx.xxx*	*Net time /setsntp:xxx.xxx.xxx.xxx*
LINOPC time synchronisation	*Control Panel LINOPC applet* ***LINOPC Sync Time***	*Selected*	*Selected*	*N/A*

Specimen

3.4 6180A

All system set-up parameters are exported and controlled as a configuration file except for the locale settings which need to be reset as follows if a spare is installed:

Language	*English*
Country	*United Kingdom*
Time Zone	*GMT*
Use Summertime (DST)	*Yes*
Start At	*02:00:00*
On the	*Last*
(day)	*Sunday*
In (month)	*March*
End at	*02:00:00*
On the	*Last*
(day)	*Sunday*
In (month)	*October*

3.5 Recorder Tools PC

The recorder tools PC is by others.

In addition to installing Review, Bridge, Security Manager and Report, the following will be necessary:

3.5.1 Review

The review chart groups can controlled as configuration files.

The review database instrument set-up needs configuring to communicate with each recorder:

Identifier	
TCP/IP Address or Host Name	
Connection Timeout (s)	
Transaction Logging	
Use proxy for FTP	

Specimen

Use passive FTP	

The review database automatic backup and transfer needs configuring as follows for each recorder:

User Name for Login	
Backup Enabled?	
Files to Back Up	
Destination	
Transfer Enabled?	
Files to Transfer	
Tag	
Period for Auto Backup/Transfer	
Also run when new file detected?	
Run as a service?	

3.5.2 Bridge

There are no set-up parameters to configure for Bridge

3.5.3 Security Manager

All set-up parameters are controlled as a configuration file.
The security manager auto deploy is set up via a shortcut in the startup folder - **SecMan /AutoDeploy 60 C:\Security Manager\SecManDb.ujx** must be entered in the target field of the shortcut properties dialog box.

3.5.4 Report

There are no set-up parameters to configure for Report5000.
If a new PC user is added then Microsoft Excel will need to be opened by that user and 'UHistory' checked under Tools > Add-Ins.

Specimen

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Title	Double-click HERE and type Project Title
Customer	Double-click HERE and type Customer Name
Eurotherm Reference	Double-click HERE and type Eurotherm Reference
Customer Reference	Double-click HERE and type Customer Reference

Explanatory note (delete this before publication):
1) enter all fields above plus date and issue number below
2) search for 'TBA' to find items which need entering on a per-project basis.
3) if not based in the UK, replace the header with the appropriate one from your local letterhead

HARDWARE DESIGN AND CONFIGURATION SPECIFICATION

Specimen

Prepared by	..... Sign / Date	..... Printed Name	..... Title
Tehnical Review by (Eurotherm)	..... Sign / Date	..... Printed Name	..... Title
Technical Approval by (Customer) Approved for use as Basis for Project Activities	..... Sign / Date	..... Printed Name	..... Title
Quality Approval by (Customer) Approved for use as Basis for Project Activities	..... Sign / Date	..... Printed Name	..... Title
Issue	Enter Issue No		
Date	Enter Date		

CONTROLLED CIRCULATION		
Copy	Issued to	**This Copy**
Master	Double-click HERE and type Customer Name	
Copy 1	Project File	

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CONTENTS

Specimen

1. DOCUMENTATION RECORDS

TEMPLATE DETAILS			
HISTORY:			
T1	Template document written to accompany Eurotherm systems engineering procedure SEP013 issue 1. Explanatory notes added in italics.		03 Jul 2003
T2	Template updated following re-issue of Eurotherm System Engineering Procedures in form suitable for use across all group companies. SEP013 now SEP109.		20 Feb 2006
T3	Template updated for GAMP5		02 Jun 2008
APPROVAL DETAILS FOR CURRENT TEMPLATE			
Template prepared by	Karen Ashworth	Validation Officer	02 Jun 2008
Template reviewed for Technical Content	Malek Madani	Technical Manager	02 Jun 2008
Template reviewed for Quality Assurance	Martin Greenhalgh	Global Quality Manager	02 Jun 2008

DOCUMENT REVISION HISTORY		
Issue	Detail	Issue Date
1a	Project version 1 developed from template T3 and issued for internal review	TBA Enter Issue Date

TBA Explanatory note (delete this before publication):
Once internal review is complete, an additional entry needs to be made for version 1 saying something like 'Internal review comments included. Document issued for customer approval'
All subsequent issues (eg version 2) need to detail the changes which have been made including the section reference and the reason for the change (eg ref to customer comment). When creating a new version: accept all previously tracked comments; make changes with change tracking enabled; hide mark-up (in the VIEW menu) before printing or issuing the document.

Specimen

2. INTRODUCTION

2.1 Purpose

A Hardware Design Specification defines how the system hardware is designed in order to meet the functional requirements of the system.

2.2 Scope

This document defines the hardware design on the control system required by Double-click HERE and type Customer Name for their Double-click HERE and type Project Title Project.

2.3 Contractual Status

This document, once approved, provides the basis for hardware supply and for the definition of hardware tests to be carried out. On project completion, this document passes to the customer for archiving and maintenance as appropriate under their validation plan.

2.4 Relationship to Other Documents

2.4.1 Applicable Standards

This document has been written to meet the guidelines for defining system design and configuration contained in GAMP5 A Risk-Based Approach to Compliant GxP Computerized Systems Appendix D3.

2.4.2 Definition of Functionality

TBA: Explanatory note (delete this before publication): The HDS is generally linked back to the functions described in the project functional specification. Fill in the table below. Note that issue number is not normally included so as to avoid getting caught in a circle of 'updating one document means updating another…'
The system functionality is defined in the following document:

Project / Document Ref	
Title	

A cross-reference table linking the sections of the functional specification to the sections of this document is provided in appendix A.
The functionality described in this document can be cross-referenced to functional tests in the accompanying test specifications by use of the cross-reference table in the relevant test specification.

2.4.3 Drawings

TBA: Explanatory note (delete this before publication):
Include a schedule of associated drawings.
The minimum is probably a communications schematic.
For projects involving bespoke panels, it will also need to include GA drawings, power distribution and earthing, and signal wiring if there is sufficient complexity to require this (eg wiring is via terminals or conditioning devices and therefore not completely covered by a termination schedule).

Drawing number	Title

Specimen

3. OVERVIEW

3.1 Process to be Controlled

TBA: Explanatory note (delete this before publication):
This should already exist in FS section 3.1.1 – cut and paste a brief description to here.
Make sure that the scope of process control covered by this document is suitably highlighted.

3.2 Overall System Hardware Architecture

TBA: Explanatory note (delete this before publication):
This should already exist in FS section 3.2 – cut and paste diagram plus a brief description to here.
Make sure that the scope of hardware covered by this document and by other documents / drawings is suitably highlighted.

Specimen

4. HARDWARE

4.1 Computerised System Components

TBA: Explanatory note (delete this before publication)
Include detail on equipment (PCs, EYCONs, T2550s, 5000 series, etc) to be supplied including storage devices (including capacities), printers and other peripherals

Description	Model Number	Supply by	No
T2550 (Reactor Skid) 	*T2550S/8S/NONE/L40/MB-TCPM/SERIAL/RJ45/ AI2-DC/AI2-DC/AI2-DC/AI2-DC/AI2-DC/AI2-MA/ RLY4-FUSE/DI424/NONE/NONE/NONE/NONE/ NONE/NONE/NONE/NONE/NONE/CDM/XXXXX/ XXXXXX*	*Eurotherm*	*5*

4.2 Interconnections

TBA: Explanatory note (delete this before publication)
Include detail on all interconnections. Standard cables can be defined by type. Bespoke cables should give drawing reference if appropriate.

From / To	Type	Supply by	No
LAN switch to T2550	*Shielded CAT5 RJ45 – RJ45, 5m*	*Eurotherm*	*5*

4.3 Inputs and Outputs

TBA: Explanatory note (delete this before publication)
Include detail on I/O types.

- *I/O card specifications (e.g. for accuracy, load, isolation, etc)*
- *Termination details*
- *Powering of signals*

4.4 Environment

The equipment is suitable for operation in the following environment:
TBA: Explanatory note (delete this before publication)
Include detail on the relevant environmental performance of the equipment.

Operating temperatures	
Operating humidity	
IP rating	
Shock / Vibration	
Altitude	
EMC emissions / immunity	

4.5 Services

The equipment is requires the following service connections:
TBA: Explanatory note (delete this before publication)
Detail electrical supply requirements (voltage, frequency, power consumption, filtering, earthing)

Specimen

Detail any UPS requirements if appropriate
Detail any pneumatic air requirements if appropriate

4.6 Physical Details

TBA: Explanatory note (delete this before publication)
If instrumentation or other equipment is being supplied for installation by others, provide detail on sizes and mounting.
If instrumentation is being supplied in panels, give a brief description of the panels (size, material, IP rating, wall mounting or floor standing, top or bottom entry, etc) and reference panel GA drawings.

Specimen

5. GLOSSARY

TBA: Explanatory note (delete this before publication): - add any other abbreviations or project-specific terms (including Eurotherm instrument names, comms protocol names,etc)

DCS	Distributed Control System
GAMP	GAMP 5 A Risk Based Approach to Compliant GxP Computerized Systems
GxP Compliance	Meeting all applicable pharmaceutical and associated life-science regulatory requirements
I/O	Inputs and Outputs

Specimen

APPENDIX A CROSS-REFERENCE TO FUNCTIONAL REQUIREMENTS

TBA: Explanatory note (delete this before publication):
It is normal to cross-reference to the functional specification sections. Any which contain no hardware requirement should be noted as such.
Note that if any detailed user output has been referenced(eg room layouts) and these are not already taken care of by the FS/URS cross referencing in the FS, they will also need to be cross-referenced to here.

(The easiest way to create these tables is via a Microsoft Access database – create separate tables for each document and then create additional tables containing just a list of links between two documents. A query can then be used to export the data in the appropriate order)

FS Ref	Risk Priority	FS Heading	HDS Ref

HDS Ref	HDS Heading	FS Ref	Risk Priority

TBA: Explanatory note (delete this before publication):
Risk priority is the overall risk level output from the functional risk assessment (step 3) process.
If the customer's risk assessment procedures do not do the step 3 functional risk assessment until all the design documents are complete, this should be replaced with impact rating (output from step 2 of the risk assessment process) as in the FS

TBA: Explanatory note (delete this before publication): Some examples of how to deal with headings, cross-references and sections with no hardware requirement follows
1) heading or high level section which does not need cross referencing

FS Ref	Risk Priority	FS Heading	HDS Ref
1.	N/A	DOCUMENTATION RECORDS	
2.	N/A	INTRODUCTION	
3.	N/A	OVERVIEW	(covered in greater detail later in document)
4.	N/A	PROCESS CONTROL FUNCTIONS	

2) function with a valid cross-reference to hardware design

FS Ref	Risk Priority	FS Heading	HDS Ref
6.	N/A	INTERFACES - TO PROCESS EQUIPMENT	
6.1	MEDIUM	Input and Output Types	4.3

3) function with no effect on hardware design

FS Ref	Risk Priority	FS Heading	HDS Ref
4.	N/A	PROCESS CONTROL FUNCTIONS	
4.1	N/A	Continuous Control	
4.1.1	MEDIUM	TBA Continuous Control Function 1	(no impact on hardware design)

Specimen

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Title	Double-click HERE and type Project Title
Customer	Double-click HERE and type Customer Name
Eurotherm Reference	Double-click HERE and type Eurotherm Reference
Customer Reference	Double-click HERE and type Customer Reference

Explanatory note (delete this before publication):
1) enter all fields above plus date and issue number below
2) search for 'TBA' to find items which need entering on a per-project basis.
3) if not based in the UK, replace the header with the appropriate one from your local letterhead

Specimen

SOFTWARE DESIGN AND CONFIGURATION SPECIFICATION

Double-click here and type name of system element if more than one SDS is being produced

Prepared by	..... Sign / Date	..... Printed Name	..... Title
Tehnical Review by (Eurotherm)	..... Sign / Date	..... Printed Name	..... Title
Technical Approval by (Customer) Approved for use as Basis for Project Activities	..... Sign / Date	..... Printed Name	..... Title
Quality Approval by (Customer) Approved for use as Basis for Project Activities	..... Sign / Date	..... Printed Name	..... Title
Issue	Enter Issue No		
Date	Enter Date		

CONTROLLED CIRCULATION		
Copy	Issued to	**This Copy**
Master	Double-click HERE and type Customer Name	
Copy 1	Project File	

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CONTENTS

Specimen

1. DOCUMENTATION RECORDS

TEMPLATE DETAILS			
HISTORY:			
T1	Template document written to accompany Eurotherm systems engineering procedure SEP013 issue 1. Explanatory notes added in italics.		03 Jul 2003
T2	Template updated following re-issue of Eurotherm System Engineering Procedures in form suitable for use across all group companies. SEP013 now SEP109.		20 Feb 2006
T3	Template updated for GAMP5		02 Jun 2008
APPROVAL DETAILS FOR CURRENT TEMPLATE			
Template prepared by	Karen Ashworth	Validation Officer	02 Jun 2008
Template reviewed for Technical Content	Malek Madani	Technical Manager	02 Jun 2008
Template reviewed for Quality Assurance	Martin Greenhalgh	Global Quality Manager	02 Jun 2008

DOCUMENT REVISION HISTORY		
Issue	Detail	Issue Date
1a	Project version 1 developed from template T3 and issued for internal review	TBA Enter Issue Date

TBA Explanatory note (delete this before publication):
Once internal review is complete, an additional entry needs to be made for version 1 saying something like 'Internal review comments included. Document issued for customer approval'
All subsequent issues (eg version 2) need to detail the changes which have been made including the section reference and the reason for the change (eg ref to customer comment). When creating a new version: accept all previously tracked comments; make changes with change tracking enabled; hide mark-up (in the VIEW menu) before printing or issuing the document.

Specimen

2. INTRODUCTION

TBA Explanatory note (delete this before publication):
Depending on the size and complexity of a project, the software design may be contained either within the functional specification or within a single SDS or within multiple SDS volumes relating to different parts of the system. This template assumes a single SDS for the system – it can be split out into multiple volumes if desired.

2.1 Purpose

A Software Design and Configuration Specification defines how the software is designed and configured in order to meet the functional requirements of the system.

2.2 Scope

This document defines the software design and configuration of the Double-click here and type name of system element if more than one SDS is being produced module for the control system required by Double-click HERE and type Customer Name for their Double-click HERE and type Project Title Project.

2.3 Contractual Status

This document, once approved, provides the basis for configuration and for the definition of functional tests to be carried out. On project completion, this document passes to the customer for archiving and maintenance as appropriate under their validation plan.

2.4 Relationship to Other Documents

2.4.1 Applicable Standards

This document has been written to meet the guidelines for defining system design and configuration contained in GAMP5 A Risk-Based Approach to Compliant GxP Computerized Systems Appendix D3.

2.4.2 Definition of Functionality

TBA: Explanatory note (delete this before publication): The SDS is generally linked back to the functions described in the project functional specification. Fill in the table below. Note that issue number is not normally included so as to avoid getting caught in a circle of 'updating one document means updating another…'
The software functionality is defined in the following document:

Project / Document Ref	
Title	

A cross-reference table linking the sections of the functional specification to the sections of this document is provided in appendix A.
The functionality described in this document can be cross referenced to functional tests in the accompanying test specifications by use of the cross reference table in the relevant test specification.

TBA: Explanatory note (delete this before publication): if the SDS is being produced in several volumes, list these and make it clear how this one fits with the rest.

Specimen

3. OVERVIEW

3.1 Process to be Controlled

TBA: Explanatory note (delete this before publication):
This should already exist in FS section 3.1.1 – cut and paste a brief description to here.
Make sure that the scope of process control covered by this document is suitably highlighted.

3.2 Overall System Software Architecture

TBA: Explanatory note (delete this before publication):
This should already exist in FS section 3.2 – cut and paste diagram plus a brief description to here.
The version in the FS will need expanding to show actual modules rather than just a 'sample sequence for showing the classification'
Make sure that the scope of software covered by this document is suitably highlighted.

3.3 Modules Covered by this Specification

TBA: Explanatory note (delete this before publication):
List out all of the configured and bespoke modules and say where they are described in more detail. Note that the rest of the document is normally divided up following the software architecture.
Parameterised, configured and bespoke coded software covered by this specification is as follows:

Module	Software Type	Reference for module description
Example parameterised item (eg T2550 network setup)	*2 (Non-configured)*	*Give section reference*
Example configured item (eg T2550 database)	*3 (Configured)*	*Give section reference*
Example bespoke coded item (eg T2550 database)	*3 (Bespoke)*	*Give section or SMS reference*

Specimen

3.4 Standard Data Structures and Interfaces

TBA: Explanatory note (delete this before publication):
This section needs to define the standard structures and interfaces within the system. Bespoke data handling functions will be dealt with in the modules where they are configured.

TBA: Explanatory note (delete this before publication):
The necessary information can be pasted in from FS 5.1 and subsections and elaborated if necessary.

4. TBA EXAMPLE DEVICE OR PACKAGE 1

TBA: Explanatory note (delete this before publication)
Take out a section for each device or package which contains software (eg T2550, Eurotherm Suite, EYCON etc) and name them appropriately.
Now create subsections for each module within the device based on the list in 4.3 and divide these into non-configured (parameterised), configured, coded and take out subsections for each module.

A section describing a T2550 might typically be structured like this:

- *Non-Configured Software Module – T2550 network setup*
- *Non-Configured Software Module – T2550 options setup*
- *Non-Configured Software Module – T2550 cold start parameters*
- *Configured Software Module – T2550 application database*
  - *Subsection for header and diagnostic blocks*
  - *Subsection for I/O interface*
  - *Subsection for alarm handling logic*
  - *Subsection for each control function configured in the database*
  - *Subsection for each data handling function configured in the database*
  - *Subsection for each interface function configured in the database*
- *Configured Software Module – T2550 Modbus gateway*
- *Bespoke Coded Software Module – T2550 action 1*
- *Bespoke Coded Software Module – T2550 action 2*
- *Bespoke Coded Software Module – T2550 sequence 1*
- *Bespoke Coded Software Module – T2550 sequence 2*
- *etc*

A section describing an EYCON might typically be structured like this:

- *Non-Configured Software Module – EYCON network setup*
- *Non-Configured Software Module – EYCON options setup*
- *Non-Configured Software Module – EYCON cold start parameters*
- *Non-Configured Software Module – EYCON user dictionary*
- *Non-Configured Software Module – EYCON database change audit trail file*
- *Non-Configured Software Module – EYCON security setup*
- *Non-Configured Software Module – EYCON signing and authorisation setup*
- *Non-Configured Software Module – EYCON network audit trail setup*
- *Configured Software Module – EYCON application database*
  - *Subsection for header and diagnostic blocks*
  - *Subsection for I/O interface*
  - *Subsection for alarm handling logic*
  - *Subsection for each control function configured in the database*
  - *Subsection for each data handling function configured in the database*
  - *Subsection for each interface function configured in the database*
- *Configured Software Module – EYCON Mimics*
  - *Subsection for each mimic*
- *Configured Software Module – EYCON Recipes*
  - *Subsection for each recipe type*
- *Bespoke Coded Software Module – EYCON action 1*
- *Bespoke Coded Software Module – EYCON action 2*
- *Bespoke Coded Software Module – EYCON sequence 1*
- *Bespoke Coded Software Module – EYCON sequence 2*
- *etc*

Specimen

A section describing EurothermSuite might typically be structured like this:

- *Non-Configured Software Module – PC network setup*
- *Non-Configured Software Module – PC security setup*
- *Configured Software Module – EurothermSuite project database*
  - *Subsection for networks*
  - *Subsection for plant model*
  - *Subsection for alarm groups and alarm group sets*
  - *Subsection for tag security areas*
  - *Subsection for computers setup*
  - *Subsection for display blocks and navigation*
  - *Subsection for trended tags*
  - *Subsection for tag editor*
  - *Subsection for tag profiles*
- *Configured Software Module – EurothermSuite Mimics*
  - *Subsection for each mimic*
- *Configured Software Module – EurothermSuite Trends*
- *Configured Software Module – EurothermSuite Recipes*
  - *Subsection for each recipe type*
- *Configured Software Module – EurothermSuite Security*
  - *Subsection for global settings*
  - *Subsection for security areas*
  - *Subsection for zones and items*
  - *Subsection for security groups*
  - *Subsection for security rights*
  - *Subsection for user accounts*
- *Bespoke Coded Software Module – EurothermSuite Script 1*
- *Bespoke Coded Software Module – EurothermSuite Script 2*
- *etc*

A section describing a KD485 protocol converter might typically be structured like this:

- *Bespoke Coded Software Module – Protocol Conversion Program*

TBA: Explanatory note (delete this before publication). An example of each level of module follows based on some of the examples in the template functional specification:

4.1 Non-Configured Software Module – TBA Example T2550 Network Setup

Function of Module
To set up the ELIN protocol and Ethernet networking in the T2550
Module configuration / coding environment
Ethernet Address and ELIN protocol details are set up in the Eurotherm LIN Instrument Options Editor (within the LINTools package) and are saved as a NETWORK.UNH file
Parameters and Settings Critical to Meeting the User Requirement

Parameter	*Function*	*Required value*
[LIN] ProtocolName AllSubnet	ELIN protocol setup	 LCPS on
[IP] IPaddress Subnet DefaultGateway	Ethernet setup	 10.242.238.90 255.255.255.0 10.242.238.254

Specimen

4.2 Configured Software Module – TBA Example T2550 Application Database

4.2.1 TBA Example control function within the database

Function of Module

To control feed trace heating:
Trace heating temperature controller TC9111 accepts a setpoint from the operator and provides a time proportioned output to heater W9111 to maintain the required temperature.
W9111 is interlocked off if either TS9112 is high or if feed flow FI9111 is below a cut-off value.

Module Interfaces

None

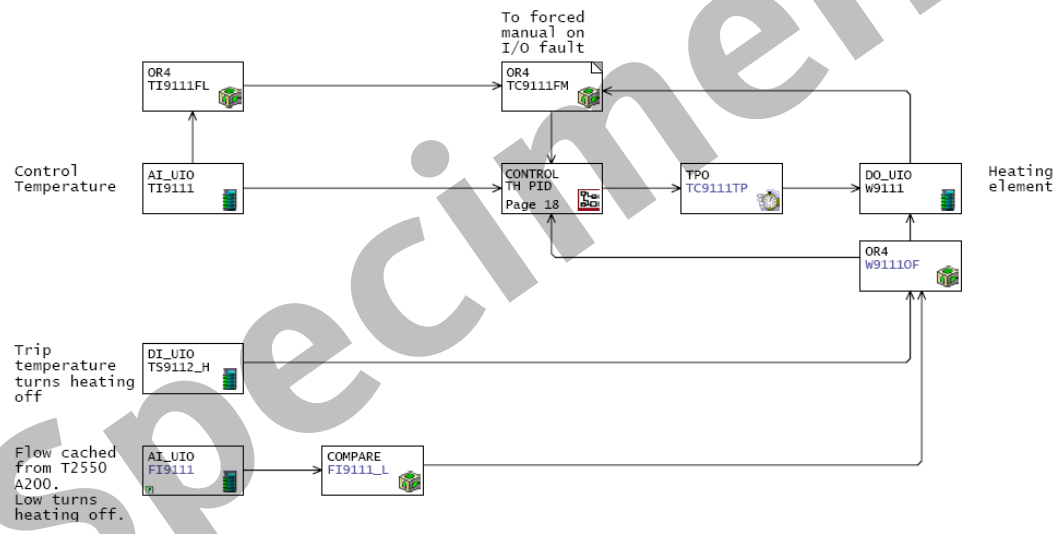
Module Error Handling

The controller TC9111 is forced to manual if an I/O fault is detected.
Temperature switch TS9112 provides an independent shutdown on controller error

Module configuration / coding environment

The module is configured as a separate compound within the T2550_10 application database.
The configuration tool is Eurotherm LINtools.

Module implementation



Module data

There is a single instance of this module using signals and tags as in the diagram above.

Parameters and Settings Critical to Meeting the User Requirement

Parameter	*Function*	*Required value*
TI9111.LR	*Low range on control temperature*	*0degC*
TI9111.HR	*High range on control temperature*	*100degC*
etc		

Configurability

PID coefficients are configurable at engineer level through EurothermSuite point pages
The flow low cut-off threshold can be set via the product recipe.

Specimen

4.2.2 TBA Example data handling function within the database

Function of Module
To calibrate the raw flow ('ticks') value received from the Sensirion flowmeter: *To achieve the calibration, the operator enters the polynomial coefficients a,b,c,d from their Sensirion flow calibration spreadsheet into the following fields:* *a = FTA102R1.A* *b = FTA102R1.B* *c = FTA102R1.C* *d = FTA102R2.PV_2* *The flowrate is then calculated as follows* *x = 1/ticks* *flow in mg/s = $ax^3 + bx^2 + cx + d$* *flow in g/min = (flow in mg/s) x (60/1000)*
Module Interfaces
None
Module Error Handling
Operator calibration factor inputs are forced to be a real number between -1000 and +1000. *There is no quality checking built into the algorithm as poor quality raw flow signal is already alarmed separately*
Module configuration / coding environment
The module is configured as a separate compound within the T2550_34 application database. *The configuration tool is Eurotherm LINtools.*
Module implementation

Module data
There is a single instance of this module using signals and tags as in the diagram above.
Parameters and Settings Critical to Meeting the User Requirement
None required - parameters are all entered by the operator
Configurability
The calibration inputs are available at operator level. There is no other configurability required.

Specimen

4.3 Configured Software Module – TBA Example T2550 Modbus Gateway

Function of Module

To set up the T2550 to read/write data to/from the KD485 protocol convertor on the MZR pump 1111PP01 communications link

Data is transferred using the following protocol.

Protocol: RS485 MODBUS RTU
Master: T2550
Slave: KD485 (address = 4)
Baud rate: 9600
Data bits: 8
Stop bits: 1
Parity: None

Module Interfaces

Data is transferred between Modbus tables in the KD485 protocol convertor and the T2550.

Module Error Handling

Alarms on Modbus gateway configuration error and on Modbus table off line are enabled in the GW_CON block within the T2550 application database.

Module configuration / coding environment

Serial port parameters are set up in the Eurotherm LIN Instrument Options Editor (within the LINTools package) and are saved within the _SYSTEM.OPT file.

Data values to be transferred are set up in the T2550 Modbus gateway file MBUS_MZR.gwf. This is created and modified using the Modbus tools within Eurotherm LINTools.

Module implementation

Each data item to be transferred is entered within a Modbus table in the T2550 gateway file.

For each data item, the source ('slave') instrument, Modbus register within that instrument ('offset'), field within the T2550, data format and direction of transfer are defined

Module data

The data to be transferred is detailed in the following section.

Parameters and Settings Critical to Meeting the User Requirement

The following parameters are to be brought across via Modbus and must be set up as follows:

Parameter Name	*Slave Number*	*Offset*	*Field in T2550*	*Format*	*DP*	*Direction*
Speed Setpoint	*4*	*40002*	*TIC9151.SP*	*32 bit*	*N/A*	*M→S*
Heartbeat	*4*	*40004*	*MZR9161X.PV2*	*16 bit*	*0*	*M→S*
Pump Status	*4*	*40005*	*MZR9161X.PV_1*	*16 bit*	*0*	*S→M*
Write Quality	*4*	*40006*	*MZR9161Y.PV_1*	*16 bit*	*0*	*S→M*
Read Quality	*4*	*40007*	*MZR9161Z.PV_1*	*16 bit*	*0*	*S→M*

Configurability

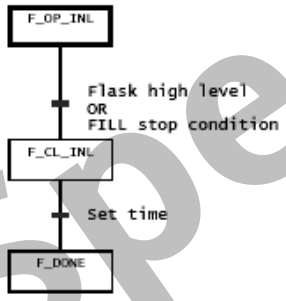
The interface is configurable at engineer level only via the Modbus tools within Eurotherm LINTools

Specimen

4.4 Bespoke Coded Software Module – TBA Example T2550 Sequence

TBA: Explanatory note (delete this before publication):
If separate software module specifications are being produced for bespoke items then the module function can be described and then the software module specification referenced for the rest of the details.

Function of Module
To control filling of a rotary evaporator evaporation vessel. The module opens the evaporation flask fill valve until high level is detected in the flask, when the fill valve is closed.
Module Interfaces
The filling sub-sequence is initiated from the overall mode control sequence and returns control to that sequence on completion.
Module Error Handling
The following errors are monitored by the overall mode control sequence and result in a fill stop condition: *- emergency stop / fire alarm* *- condenser level high* *- system pressure high or hihi* *- receiver full timer expires (receiver at high level > y minutes)* *- stop button pressed* *- Not filled timer expires (fill valve open > x minutes)*
Module configuration / coding environment
The module is configured as a generic sequence with separate map files for each of the plant units. *The coding tool is Eurotherm LINtools. The coding standard in use is Eurotherm SEP106.*
Module implementation
The FILLING sequence starts in state F_OP_INL and proceeds as follows:



Actions within each state are as follows:

State	*Actions carried out*
F_OP_INL	*Opens the flask fill control valve*
F_CL_INL	*Closes the flask fill control valve*
F_DONE	*Allows transfer back to FILLWAIT state*

Module Data (SDS)

The instances of the filling sequence use data as follows:

Description	*Type*	*Rotavapor 01-1234*	*Rotavapor 01-5678*
Flask High Level	*Read*	*1234LS1H.In*	*5678LS1H.In*
Fill control valve	*Write*	*1234XV1.Demand*	*5678XV1.Demand*
FILL stop condition flag	*Read*	*1234FLAG.W Field1.Bit0*	*5678FLAG.W Field1.Bit0*
Valve close time	*Read(initially 5s)*	*1234DATA.PV1*	*5678DATA.PV1*

Parameters and Settings Critical to Meeting the User Requirement

Specimen

Parameter	*Function*	*Required value*
Valve close time	*High range on control temperature*	*100degC*

Configurability
There is no requirement for configurability outside that provided to engineer level users through the Eurotherm LINtools package.

Specimen

5. GLOSSARY

TBA: Explanatory note (delete this before publication): - add any other abbreviations or project-specific terms (including Eurotherm instrument names, comms protocol names,etc)

DCS	Distributed Control System
GxP Compliance	Meeting all applicable pharmaceutical and associated life-science regulatory requirements
GAMP	GAMP 5 A Risk Based Approach to Compliant GxP Computerized Systems
I/O	Inputs and Outputs

Specimen

APPENDIX A – CROSS REFERENCE TO FUNCTIONAL REQUIREMENTS

TBA: Explanatory note (delete this before publication):
It is normal to cross reference to the functional specification sections. Any which contain no software requirement should be noted as such.
Note that if any detailed user output has been referenced(eg control schematics) and these are not already taken care of by the FS/URS cross referencing in the FS, they will also need to be cross referenced to here.

(The easiest way to create these tables is via a Microsoft Access database – create separate tables for each document and then create additional tables containing just a list of links between two documents. A query can then be used to export the data in the appropriate order)

FS Ref	Risk Priority	FS Heading	SDS Ref

SDS Ref	SDS Heading	FS Ref	Risk Priority

TBA: Explanatory note (delete this before publication):
Risk priority is the overall risk level output from the functional risk assessment (step 3) process.
If the customer's risk assessment procedures do not do the step 3 functional risk assessment until all the design documents are complete, this should be replaced with impact rating (output from step 2 of the risk assessment process) as in the FS

TBA: Explanatory note (delete this before publication): Some examples of how to deal with headings, cross-references and sections with no software requirement follows
1) heading or high level section which does not need cross referencing

FS Ref	*Risk Priority*	*FS Heading*	*SDS Ref*
1.	*N/A*	*DOCUMENTATION RECORDS*	
2.	*N/A*	*INTRODUCTION*	
3.	*N/A*	*OVERVIEW*	*(covered in greater detail later in document)*
4.	*N/A*	*PROCESS CONTROL FUNCTIONS*	

2) function with a valid cross-reference to software design

FS Ref	*Risk Priority*	*FS Heading*	*SDS Ref*
4.	*N/A*	*PROCESS CONTROL FUNCTIONS*	
4.1	*N/A*	*Continuous Control*	
4.1.1	*MEDIUM*	*TBA Continuous Control Function 1*	*4.2.1*

3) function with no effect on software design

FS Ref	*Risk Priority*	*FS Heading*	*SDS Ref*
6.	*N/A*	*INTERFACES - TO PROCESS EQUIPMENT*	
6.1	*MEDIUM*	*Input and Output Types*	*(no impact on software design)*

Specimen

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Title	Double-click HERE and type Project Title
Customer	Double-click HERE and type Customer Name
Eurotherm Reference	Double-click HERE and type Eurotherm Reference
Customer Reference	Double-click HERE and type Customer Reference

Explanatory note (delete this before publication):
1) enter all fields above plus date and issue number below
2) search for 'TBA' to find items which need entering on a per-project basis.
3) if not based in the UK, replace the header with the appropriate one from your local letterhead

SOFTWARE MODULE SPECIFICATION
Double-click here and type name of module

Specimen

Prepared by	..... Sign / Date	..... Printed Name	..... Title
Tehnical Review by (Eurotherm)	..... Sign / Date	..... Printed Name	..... Title
Technical Approval by (Customer) Approved for use as Basis for Project Activities	..... Sign / Date	..... Printed Name	..... Title
Quality Approval by (Customer) Approved for use as Basis for Project Activities	..... Sign / Date	..... Printed Name	..... Title
Issue	Enter Issue No		
Date	Enter Date		

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Registered in England and Wales No 853008

CONTENTS

Specimen

1. DOCUMENTATION RECORDS

TEMPLATE DETAILS			
HISTORY:			
T1	Template document written to accompany Eurotherm systems engineering procedure SEP013 issue 1. Explanatory notes added in italics.		03 Jul 2003
T2	Template updated following re-issue of Eurotherm System Engineering Procedures in form suitable for use across all group companies. SEP013 now SEP109.		20 Feb 2006
T3	Template updated for GAMP5		02 Jun 2008
APPROVAL DETAILS FOR CURRENT TEMPLATE			
Template prepared by	Karen Ashworth	Validation Officer	02 Jun 2008
Template reviewed for Technical Content	Malek Madani	Technical Manager	02 Jun 2008
Template reviewed for Quality Assurance	Martin Greenhalgh	Global Quality Manager	02 Jun 2008

DOCUMENT REVISION HISTORY		
Issue	Detail	Issue Date
1a	Project version 1 developed from template T3 and issued for internal review	TBA Enter Issue Date

TBA Explanatory note (delete this before publication):
Once internal review is complete, an additional entry needs to be made for version 1 saying something like 'Internal review comments included. Document issued for customer approval'
All subsequent issues (eg version 2) need to detail the changes which have been made including the section reference and the reason for the change (eg ref to customer comment). When creating a new version: accept all previously tracked comments; make changes with change tracking enabled; hide mark-up (in the VIEW menu) before printing or issuing the document.

Specimen

2. INTRODUCTION

TBA Explanatory note (delete this before publication):
Depending on the size and complexity of a project, the software module design may be contained either within the functional specification or within the SDS. This template assumes bespoke coded items are being split out for separate module design.

2.1 Purpose

A Software Module Specification defines how a bespoke software module is designed and configured in order to meet the functional requirements of the system.

2.2 Scope

This document defines the software design and configuration of the Double-click here and type name of module module for the control system required by Double-click HERE and type Customer Name for their Double-click HERE and type Project Title Project.

2.3 Contractual Status

This document, once approved, provides the basis for module coding and for the definition of structural tests to be carried out. On project completion, this document passes to the customer for archiving and maintenance as appropriate under their validation plan.

2.4 Relationship to Other Documents

2.4.1 Applicable Standards

This document has been written to meet the guidelines for defining system design and configuration contained in GAMP5 A Risk-Based Approach to Compliant GxP Computerized Systems Appendix D3.

2.4.2 Definition of Functionality

TBA: Explanatory note (delete this before publication): The SMS is generally linked back to the functions described in the SDS. Fill in the table below. Note that issue number is not normally included so as to avoid getting caught in a circle of 'updating one document means updating another…'
The software design for the system as a whole is defined in the following document:

Project / Document Ref	
Title	

A cross-reference table linking the sections of the software design and configuration specification to the sections of this document is provided in appendix A.
The functionality described in this document can be cross referenced to structural tests in the accompanying module test specifications by use of the cross reference table in the relevant test specification.

Specimen

3. OVERVIEW

3.1 Process to be Controlled

TBA: Explanatory note (delete this before publication):
This should already exist in SDS section 3.1.1 – cut and paste a brief description to here.
Make sure that the scope of process control covered by this document is suitably highlighted.

3.2 Overall System Software Architecture

TBA: Explanatory note (delete this before publication):
This should already exist in SDS section 3.2 – cut and paste diagram plus a brief description to here.
Make sure that the scope of software covered by this document is suitably highlighted.

3.3 Modules Covered by this Specification

Software covered by this specification is as follows:

Module	Software Type	Reference for module description
Example bespoke coded item (eg T2550 database)	*3 (Bespoke)*	*Give section*

Specimen

4. TBA EXAMPLE MODULE 1

TBA: Explanatory note (delete this before publication)
Take out a section for each bespoke module. Normally only one would be dealt with per SMS but if there are, for example, heavily interlinked modules or modules which are variations on a common theme it may well make sense to group them together in one document.

4.1 Function of Module

TBA: Explanatory note (delete this before publication)
Explain briefly what the module is supposed to achieve.

e.g. The FILLING sub-sequence controls filling of a rotary evaporator vessel. The module opens the evaporation flask fill valve until high level is detected in the flask, when the fill valve is closed.

4.2 Module Interfaces

TBA: Explanatory note (delete this before publication)
Define the interfaces with other modules (what data or commands are transferred in which direction). A picture may be helpful.
Define any timing or handshaking requirements
Define any operator interface requirements (commands, feedback)

For a protocol conversion module, the details of both protocols need to be given in detail in subsections.

e.g. The FILLING sub-sequence is initiated from the overall mode control sequence and returns control to that sequence on completion.
The FILLING sub-sequence has no direct operator interface as all operator commands and feedback are dealt with by the overall mode control sequence.

4.3 Module Error Handling

TBA: Explanatory note (delete this before publication)
List out the errors that the module checks for (e.g. validation of operator data entry, checks on signal quality, checks that devices respond correctly to commands, checks on process conditions)

e.g. The following errors are monitored by the overall mode control sequence and result in a fill stop condition:
- emergency stop / fire alarm
- condenser level high
- system pressure high or hihi
- receiver full timer expires (receiver at high level > y minutes)
- stop button pressed
- Not filled timer expires (fill valve open > x minutes)

4.4 Module configuration / coding environment

TBA: Explanatory note (delete this before publication)
What package(s) are used to configure the module?
What coding standards apply?
What source code is compiled into what target file and how?
If the module is generic, how is it mapped onto different plant items?

e.g. The module is configured as a generic sequence with separate map files for each of the plant units.
The coding tool is Eurotherm LINtools.
The coding standard in use is Eurotherm SEP106.

Specimen

4.5 Module Data

TBA: Explanatory note (delete this before publication)
List the inputs, outputs and parameters accessed by the module (all of them, not just those critical to meeting the customer's requirements)

e.g. for a generic sequence

Alias used in generic sequence	*Database tag mapped in Rotavapor 01-1234*	*Database tag mapped Rotavapor 01-5678*	*Detail*	*Data Type*	*Read / Write*	*Initial Value*
FlaskHighLevel	*1234LS1H.In*	*5678LS1H.In*	*Flask High Level*	*Boolean*	*Read*	*From database*
FillControlValve	*1234XV1.Demand*	*5678XV1.Demand*	*Fill control valve*	*Boolean*	*Write*	*N/A*
FillStopCondition	*1234FLAG.W Field1.Bit0*	*5678FLAG.W Field1.Bit0*	*FILL stop condition flag*	*Boolean*	*Read*	*From database*
ValveCloseTime	*1234DATA.PV1*	*5678DATA.PV1*	*Valve close time*	*Real*	*Read*	*5s*

Specimen

4.6 Module Configurability

TBA: Explanatory note (delete this before publication)
Is there any requirement for online configurability of the module (eg parameters the operator can change, options which can be selected or deselected, etc)

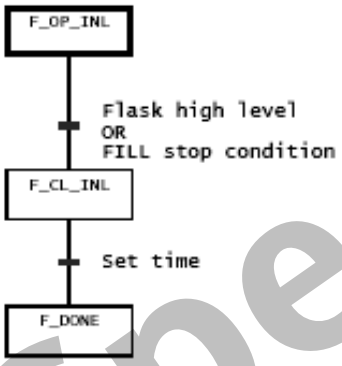
e.g. There is no requirement for configurability outside that provided to engineer level users through the Eurotherm LINtools package.

4.7 Module implementation

TBA: Explanatory note (delete this before publication)
Detail the operation of the overall program including any split into sub-programs.
Use pseudo-code, flowcharts or state transition diagrams as appropriate to the module type.

For LINtools control applications a state transition diagram may be helpful as it can then be followed by a list of states against actions in each state and a list of states against events which cause transitions to other states. This can be cut and pasted from LINtools to save re-drawing time on future document up-issues.
Make it clear what state the program adopts on startup.

e.g. The FILLING sequence starts in state F_OP_INL and proceeds as follows:



Actions within each state are as follows:

State	Actions carried out
F_OP_INL	Opens FillControlValve
F_CL_INL	Closes FillControlValve
F_DONE	Allows transfer back to the calling sequence

Transitions between states are as follows:

Initial State	Event	Resulting State
F_OP_INL	FlaskHighLevel OR FillStopCondition	F_CL_INL
F_CL_INL	Time in step > ValveCloseTime	F_DONE
F_DONE	(Allows transfer back to the calling sequence)	N/A

Specimen

5. GLOSSARY

TBA: Explanatory note (delete this before publication): - add any other abbreviations or project-specific terms (including Eurotherm instrument names, comms protocol names,etc)

DCS	Distributed Control System
GAMP	GAMP 5 A Risk Based Approach to Compliant GxP Computerized Systems
GxP Compliance	Meeting all applicable pharmaceutical and associated life-science regulatory requirements
I/O	Inputs and Outputs

Specimen

APPENDIX A – CROSS REFERENCE TO SOFTWARE DESIGN

TBA: Explanatory note (delete this before publication):
It is normal to cross reference to the SDS sections. Any which are not relevant to the modules in this document should be noted as such.

(The easiest way to create these tables is via a Microsoft Access database – create separate tables for each document and then create additional tables containing just a list of links between two documents. A query can then be used to export the data in the appropriate order)

SDS Ref	Risk Priority	SDS Heading	SMS Ref

SMS Ref	SMS Heading	SDS Ref	Risk Priority

TBA: Explanatory note (delete this before publication):
Risk priority is the overall risk level output from the functional risk assessment (step 3) process.
If the customer's risk assessment procedures do not do the step 3 functional risk assessment until all the design documents are complete, this should be replaced with impact rating (output from step 2 of the risk assessment process) as in the FS

TBA: Explanatory note (delete this before publication): Some examples of how to deal with headings, cross references and sections with no software requirement for this module follows
1) heading or high level section which does not need cross referencing

SDS Ref	*Risk Priority*	*SDS Heading*	*SMS Ref*
1.		*DOCUMENTATION RECORDS*	
2.		*INTRODUCTION*	
3.		*OVERVIEW*	*(covered in greater detail later in document)*

2) function with a valid cross reference to software

SDS Ref	*Risk Priority*	*SDS Heading*	*SMS Ref*
5.2.1	*HIGH*	*TBA Sequential Control Function 1*	*4*

3) function with no software required

SDS Ref	*Risk Priority*	*SDS Heading*	*SMS Ref*
4.2.1	*MEDIUM*	*TBA Continuous Control Function 1*	*(no relevance to modules in this document)*

Specimen

CODE REVIEW sheet of .

CUSTOMER NAME : .....
PROJECT TITLE : .....
FILENAME : .....
VERSION .....
GAMP CATEGORY : .....

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SECTION 1 - GENERIC CODING STANDARD

Coding Standard: SEP106 / Other (please give title)
Issue Level:

Identification and Traceability	**Pass / Fail / N/A**	**Action Ref.**
When configuration tools permit, modules should have a text header including: - Module name and brief description - Project reference plus cross reference to controlling specification - Names of all source files which constitute the module (including variable mappings etc) - Details of any specific command files needed to compile or build the module - Change history - version, date, initials, details of code affected, reference to source of change (eg testing fault report, change request)		
Any changes made since the code was put under control should be identified within the code by comments including date, initials and reference to the source of change.		
Static Analysis Checks - Dead Code Removal / Use of Variables	**Pass / Fail / N/A**	**Action Ref.**
Variable names should be meaningful if the language allows		
All variables should be declared		
All declared variables should be used		
All variables should be initialised or set before they are used		
Each variable should be used for only one purpose		
There should be no potential confusion between global and local variables		
All procedures should be called somewhere within the code		
Code made redundant by changes should be removed		
DEBUG statements should be removed		
Code required for test purposes only should be clearly identified and documented		
Code where different options are selected or configured for different projects should have the correct options enabled or disabled		
Reliability and Error Recovery	**Pass / Fail / N/A**	**Action Ref.**
Failure path should be provided where appropriate		
Operator inputs should be checked for format and range (and source device if appropriate)		
Operator inputs which occur when they are not applicable should be reset		
Plant input status should be checked where appropriate (eg out-of-range, known hardware fault)		
Plant device status should be checked where appropriate (eg valve / motor status)		
Appropriate checks should be made for the success of requested operations (eg writes to remote devices)		

Specimen

CODE REVIEW sheet of .

CUSTOMER NAME : .....
PROJECT TITLE : .....
FILENAME : .....
VERSION .....
GAMP CATEGORY : .....

Maintainability	Pass / Fail / N/A	Action Ref.
Code should be broken down into logically distinct blocks		
Code should be clearly laid out - There should be only one action per line of code - Indentation should be used to indicate different levels of nesting for If..Then..Else, Do..Until, etc - Code should be aligned for ease of reading (eg declarations, '=' signs, trailing comments lined up) - Brackets should be used if they add clarity even if not strictly necessary for the logic / arithmetic - Blank lines should be used to separate blocks of code		
Code should be adequately commented - a general comment should be present at the beginning of each module explaining the purpose of this module. - variable declarations should include sufficient comments to make clear the function of the variable - each step / function / procedure should have a comment explaining the action of the step (eg: applying vacuum to the tank). - In each section more comments should be present in such detail that a maintenance technician could easily understand the purpose of the section without having to analyse the code (eg. "logic to determine pass/fail condition for pressure test"). - In the common sections, each part of logic should be well described. - For every module interfacing with other packages, detailed instructions should be present. - If code blocks extend beyond about 20 lines it is recommended that the terminating delimiter (eg END_IF) is commented to clarify the function of the block		
Code should be structured for ease of maintenance - 'Constants' should be parameters not hard coded values - Where languages allow, parameters should be formally passed to procedures / subroutines rather than using shared variables - Path names should not be hardcoded into any application. All paths should use the Universal Naming Convention (UNC) for shared drives. Mapped drive letters should be avoided unless provided as input from the user.		

Specimen

CODE REVIEW sheet of .

CUSTOMER NAME : .....
PROJECT TITLE : .....
FILENAME : .....
VERSION .....
GAMP CATEGORY : .....

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Modular Structure	**Pass / Fail / N/A**	**Action Ref.**
Modules should perform a single easily identified function		
The split into modules should maximise functional cohesion and minimise data coupling		
Generic structures should be used where appropriate		
Independent modules should be saved as separate files for ease of change control		
Switches / Cases / Branches (textual programming languages)	**Pass / Fail / N/A**	**Action Ref.**
Code should use structured programming techniques wherever possible		
Use of labels should be minimised		
Where labels remain, they should be declared and have meaningful names		
Branches should be forward through the code as far as is possible		
Branches into 'do..while' loops, 'if..then' or 'case' blocks should be avoided		
Branches out of loops (eg for exception handling) should be minimised and carefully defined		
Data integrity (eg counter, timer, pointer values) should be taken into account when branching		
Multiple options should include a default for all values outside the expected range		
Multiple options should each exit to the next step (or if designed to run on into the next option should be commented to explain why)		
All exits from a procedure should be from a single exit point (normally at the end)		
States / Transitions / Actions (SFC)	**Pass / Fail / N/A**	**Action Ref.**
Where coding implements a 'state machine', indication of current state should be provided		
Where a choice of action types (start / continuous / final) is available, choice should be is correct for the function carried out		
Where actions can be set to run continuously, care should be taken that these do not interfere with other actions		
Care should be taken that actions cannot be set to run twice (eg on a loop back)		
Only one transition from a state should be capable of being active at once		
Where necessary, a default transition should be provided for values outside the expected range, timeout, or other fault conditions		
Account should be taken of the fact that sub-code stops when a step completes		
Comparing Values	**Pass / Fail / N/A**	**Action Ref.**
Comparison of plant input values (or other floating point values where appropriate) should be to within a tolerance		
Error-Prone Language Features	**Pass / Fail / N/A**	**Action Ref.**
Uses of any of the following error-prone language features should be fully documented and particular attention given during code review: GOTO / GOSUB Manipulation / conversion of floating-point numbers Pointers Parallel paths Recursion of routines / actions Interrupts Dynamic allocation of memory		
Compiler Switches	**Pass / Fail / N/A**	**Action Ref.**
Compile time checks should always be enabled		
Run time checks should be enabled during development and preferably through to final testing and operation if size / speed limitations allow		

Specimen

CODE REVIEW sheet of .

CUSTOMER NAME : .....
PROJECT TITLE : .....
FILENAME : .....
VERSION .....
GAMP CATEGORY : .....

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SECTION 2 – REVIEW AGAINST DESIGN REQUIREMENTS

Design Specification Title:
Issue Level:

Function/Purpose of Module	**Design Spec Section Ref**	**Pass / Fail / N/A**	**Action Ref.**
Does the function description in the module header correspond to (or summarise) that in the design specification?			
Module Interfaces	**Design Spec Section Ref**	**Pass / Fail / N/A**	**Action Ref.**
Are the module interfaces as defined in the design specification?			
Module Error Handling	**Design Spec Section Ref**	**Pass / Fail / N/A**	**Action Ref.**
Is the module error handling as defined in the design specification?			
Module coding environment	**Design Spec Section Ref**	**Pass / Fail / N/A**	**Action Ref.**
Is the module coding environment as defined in the design specification?			
Module Data	**Design Spec Section Ref**	**Pass / Fail / N/A**	**Action Ref.**
Is the module data as defined in the design specification?			
Module Configurability	**Design Spec Section Ref**	**Pass / Fail / N/A**	**Action Ref.**
Is the module configurability as defined in the design specification?			
Module Implementation	**Design Spec Section Ref**	**Pass / Fail / N/A**	**Action Ref.**
Is the module implementation as defined in the design specification?			

Specimen

CODE REVIEW sheet of .

CUSTOMER NAME : ……
PROJECT TITLE : ……
FILENAME : ……
VERSION ……
GAMP CATEGORY : ……

SECTION 3 – COMMENTS AND SIGN-OFF

REVIEW COMMENTS

Action Ref.	Comment	Action By	Completed

Specimen

REVIEWED BY:

SIGNED	PRINTED NAME	TITLE	DATE

CORRECTIVE ACTIONS CHECKED AS COMPLETE:

SIGNED	PRINTED NAME	TITLE	DATE

CODE REVIEW sheet of .

CUSTOMER NAME : ……
PROJECT TITLE : ……
FILENAME : ……
VERSION ……
GAMP CATEGORY : ……

Action Ref.	Comment	Action By	Completed

Specimen

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Title	Double-click HERE and type Project Title
Customer	Double-click HERE and type Customer Name
Eurotherm Reference	Double-click HERE and type Eurotherm Reference
Customer Reference	Double-click HERE and type Customer Reference

Explanatory note (delete this before publication):
1) enter all fields above plus date and issue number below
2) search for 'TBA' to find items which need entering on a per-project basis.
3) if not based in the UK, replace the header with the appropriate one from your local letterhead
4) Give the document the appropriate name for the test phase and save it as the appropriate file name

DOUBLE-CLICK HERE AND TYPE TEST PHASE
DOUBLE-CLICK HERE AND TYPE 'PROTOCOL' OR 'SPECIFICATION'

Specimen

Prepared by	..... Sign / Date	..... Printed Name	..... Title
Tehnical Review by (Eurotherm)	..... Sign / Date	..... Printed Name	..... Title
Technical Approval by (Customer) Approved for use as Basis for Test Activities	..... Sign / Date	..... Printed Name	..... Title
Quality Approval by (Customer) Approved for use as Basis for Test Activities	..... Sign / Date	..... Printed Name	..... Title
Issue	Enter Issue No		
Date	Enter Date		

CONTROLLED CIRCULATION		
Copy	Issued to	**This Copy**
Master	Double-click HERE and type Customer Name	
Copy 1	Project File	

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Specimen

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1. DOCUMENTATION RECORDS

TEMPLATE DETAILS			
HISTORY:			
T1	Template document written to accompany Eurotherm systems engineering procedure SEP013 issue 1. Explanatory notes added in italics.		03 Jul 2003
T2	Template updated following Eurotherm involvement in GAMP Shared Interest Group on the Testing of GxP Critical Systems		28 Sep 2005
T3	Template updated following re-issue of Eurotherm System Engineering Procedures in form suitable for use across all group companies. SEP013 now SEP109.		20 Feb 2006
T4	Template updated for GAMP5		19 Jun 2008
APPROVAL DETAILS FOR CURRENT TEMPLATE			
Template prepared by	Karen Ashworth	Validation Officer	19 Jun 2008
Template reviewed for Technical Content	Malek Madani	Technical Manager	19 Jun 2008
Template reviewed for Quality Assurance	Martin Greenhalgh	Global Quality Manager	19 Jun 2008

DOCUMENT REVISION HISTORY		
Issue	Detail	Issue Date
1a	Project version 1 developed from template T4 and issued for internal review	TBA Enter Issue Date

TBA Explanatory note (delete this before publication):
Once internal review is complete, an additional entry needs to be made for version 1 saying something like 'Internal review comments included. Document issued for customer approval'
All subsequent issues (eg version 2) need to detail the changes which have been made including the section reference and the reason for the change (eg ref to customer comment). When creating a new version: accept all previously tracked comments; make changes with change tracking enabled; hide mark-up (in the VIEW menu) before printing or issuing the document.

Specimen

2. INTRODUCTION

TBA Explanatory note (delete this before publication):
This test protocol template can be used for any test phase (eg software module test, factory acceptance test, etc)
Which test phases are required depends on the lifecycle and documentation deliverables agreed in the approved quality plan. Typically, a small, simple project might have a single 'system acceptance' test protocol covering all test stages (hardware, system integration, factory acceptance, site hardware, site system acceptance). A more complex project is likely to include separate module test protocols for each bespoke module, factory acceptance test protocol (used for internal integrated testing plus witnessed factory test) and a site acceptance protocol in separate volumes.
Some customers prefer to have the site test split into volumes called 'installation qualification' and 'operational qualification' because this fits better with their procedures.
It is also reasonably common to split the system acceptance test protocols into an 'overall system' volume plus a volume for each major sub-system defined by a separate software design specification.

2.1 Purpose

A test double-click here and type 'protocol' or 'specification' defines the testing to be carried out to verify that the system (or its individual elements) meets pre-defined requirements.

2.2 Scope

This double-click here and type 'protocol' or 'specification' sets out the testing to be carried out during the Double-Click Here And **Type Test Phase** on the control system required by Double-click HERE and type Customer Name for their Double-click HERE and type Project Title Project. It covers the following test phases:
TBA Explanatory note (delete this before publication):
List the test phases covered – see the explanatory note above. For example:

1) *Eurotherm Internal Integrated Testing*
2) *Witnessed Factory System Acceptance Testing*

2.3 Contractual Status

This document, once approved, provides the basis for Double-Click Here And **Type Test Phase**. On project completion, this document passes to the customer for archiving and maintenance as appropriate under their validation plan.

2.4 Relationship to Other Documents

2.4.1 Applicable Standards

This document has been written to meet the guidance on Testing of Computerized Systems contained in GAMP5 A Risk-Based Approach to Compliant GxP Computerized Systems Appendix D5.

2.4.2 Definition of Functionality Under Test

TBA: Explanatory note (delete this before publication):
Each test protocol is generally linked back to the functions described in the appropriate design specification (FAT/SAT link to FS (and possibly also to SDS/HDS), SMTS links to SMS, etc.
Fill in the table below – adding an entry for each document. Note that issue number is not normally included so as to avoid getting caught in a circle of 'updating one document means updating another…'
The functionality to be tested is defined in the following document:

Project / Document Ref	
Title	

Specimen

Each test script includes a cross-reference to the relevant section of the relevant design document. A cross-reference table summarising test coverage is also provided in appendix A.

TBA: Explanatory note (delete this before publication): if the test protocol is being produced in several volumes for different plat areas or control system devices, list these and make it clear how this one fits with the rest.

Specimen

3. VERIFICATION STRATEGY

3.1 Risk-Based Scaling of Verification Activities

The risk priority associated with each function to be tested is included in the cross-reference table in appendix A.

Verification activities are scaled according to this risk priority and the type of software involved:
TBA: Explanatory note (delete this before publication): modify the table if the agreement with the end user differs from this (eg if the end user has risk priority as a number not high/medium/low or if, for example, or if module testing is only needed for high risk modules on this particular project)

<table>
<tr><th></th><th>Infrastructure software element</th><th>Non-configured software element</th><th>Configured software element</th><th>Bespoke software element</th></tr>
<tr><td>High Risk</td><td rowspan="3">Assume infrastructure elements are adequately challenged by functional testing of the application</td><td rowspan="3">Functional testing</td><td>Functional testing
Challenge testing</td><td>Code review
Structural (module) testing
Functional testing
Challenge testing</td></tr>
<tr><td>Medium Risk</td><td rowspan="2">Functional testing</td><td>Code review
Structural (module) testing
Functional testing</td></tr>
<tr><td>Low Risk</td><td>Code review
Functional testing</td></tr>
</table>

Specimen

3.2 Types and Phasing of Verification Activities

The overall validation involves the following phases.
Phases covered by this double-click here and type 'protocol' or 'specification' are highlighted in bold with additional detail given below. Where a double-click here and type 'protocol' or 'specification' is to be used for more than one phase, results for each phase are recorded onto a separate copy of the double-click here and type 'protocol' or 'specification'.
TBA: Explanatory note (delete this before publication):
Modify the table if the agreement with the end user differs from this (eg if the end user insists on IQ/OQ terminology or if there are no separate code review or module test activities either because there is no coded software or because the system is simple enough for the structural testing to be contained within the witnessed FAT)
Highlight the test phase(s) covered by this document in bold

Activity	Description
Code review	Code review of bespoke software elements against both coding standards and software design documentation
Module testing	Structural (module) testing of high / medium risk bespoke software elements against the software design documentation
Eurotherm Internal Integration Testing	**Unwitnessed Eurotherm tests using the FAT double-click here and type 'protocol' or 'specification' to check correct system integration prior to inviting the customer to witness FAT.**
Factory Acceptance Testing **- phase 1 (hardware tests)** **- phase 2 (functional tests)**	**Witnessed functional and challenge testing of the system in a test environment at Eurotherm's premises**
Site Acceptance Testing - phase 1 (hardware tests) - phase 2 (functional tests)	Witnessed functional and challenge testing of those aspects of the system which may be affected by the move to the production environment or which could not be adequately tested in the test environment.

TBA: Explanatory note (delete this before publication):
Take out a sub-heading for each phase covered by this protocol. Examples follow

3.2.1 TBA Example Module Testing – Module X

Test Coverage:	*Structural testing of module X against the software design documentation*
Location:	*At Eurotherm's premises.*
Timing:	*Before integration of software and hardware*
Testing:	*By a Eurotherm representative*
Witnessing:	*Not witnessed.*
Reviewing:	*By Eurotherm project manager*
Test Hardware Environment:	*Performed on a T2550 of the same version as the target instrument with a test PC running LINTools connected via the ELIN network.*
Test Software Environment:	*The software under test is the sequence MODULEX.SDB which will be loaded onto the test T2550. The source files (listed below) for MODULEX.SDB will be committed to the WinCVS repository and a configuration management baseline taken prior to the start of module test.* • *MODULEX.UQD* • *MODULEX.UQT* • *MODULEX.UQG* • *INSTANCE1.UQM* *In order to test the sequence, all database blocks referenced by the sequence will need to be available. This will be achieved by creating a test version of the database T2550_38.DBF in which all blocks run locally. The source files (listed below) will be committed to the WinCVS repository and a configuration management baseline taken prior to the start of module test.*

Specimen

	• *T2550_38.DBF* • *T2550_38.DTF* • *T2550_38.GRF*
Test Data:	*No test data is required*
Test User Accounts:	*No test user accounts are required*

3.2.2 TBA Example Eurotherm Internal Integration Testing

Test Coverage:	*Phase 1 – Hardware tests* *Hardware checks against hardware design* *Process equipment interface (input and output signals)* *Internal interfaces (communication / data checks)* *Phase 2 – Functional tests* *Process control functions (continuous / sequential)* *Data handling functions (internal data structures and data flows, data input functions, data transformation functions, data output functions, electronic records and signatures, data migration from previous system)* *Interfaces to external systems (communications / data checks)* *Operator interface (alarm and event strategy, displays, access control)* *System technical detail (disaster recovery, performance)*
Location:	*At Eurotherm's premises.*
Timing:	*After integration of software and hardware and before FAT*
Testing:	*By a Eurotherm representative*
Witnessing:	*Not witnessed.*
Reviewing:	*By Eurotherm project manager*
Test Hardware Environment:	*Performed with all customer equipment present but networks connected using 5m patch cables in place of the site cable runs and without customer network infrastructure.*
Test Software Environment:	*Performed with all application software loaded.* *All source files will be committed to the WinCVS repository and a configuration management baseline taken prior to the start of integrated test.* *Once I/O testing is completed, simulation sequences running in a test instrument attached to the ELIN network will be used to provide motor running / valve position inputs during sequence tests. Source files for this will also be committed to the WinCVS repository and a configuration management baseline taken prior to the start of integrated test*
Test Data:	*Test recipes will be used as full detail of the actual recipes is not yet available. The test recipes used will be committed to the WinCVS repository*
Test User Accounts:	*Test user accounts corresponding to each access level will be used*

3.2.3 TBA Example Factory Acceptance Testing

Test Coverage:	*Phase 1 – Hardware tests* *Hardware checks against hardware design* *Process equipment interface (input and output signals) – 10% random check* *Internal interfaces (communication / data checks)* *Phase 2 – Functional tests* *Process control functions (continuous / sequential)* *Data handling functions (internal data structures and data flows, data input functions, data transformation functions, data output functions, electronic records and signatures, data migration from previous system)* *Interfaces to external systems (communications / data checks)* *Operator interface (alarm and event strategy, displays, access control)* *System technical detail (disaster recovery, performance)*

Specimen

Location:	*At Eurotherm's premises.*
Timing:	*After completion of internal integration tests and before release of system for shipment to site*
Testing:	*By a Eurotherm representative*
Witnessing:	*By a customer representative*
Reviewing:	*By a customer representative*
Test Hardware Environment:	*Performed with all customer equipment present but networks connected using 5m patch cables in place of the site cable runs and without customer network infrastructure.*
Test Software Environment:	*Performed with all application software loaded.* *All source files will be committed to the WinCVS repository and a configuration management baseline taken prior to the start of integrated test.* *Once I/O testing is completed, simulation sequences running in a test instrument attached to the ELIN network will be used to provide motor running / valve position inputs during sequence tests. Source files for this will also be committed to the WinCVS repository and a configuration management baseline taken prior to the start of integrated test*
Test Data:	*Test recipes will be used as full detail of the actual recipes is not yet available. The test recipes used will be committed to the WinCVS repository*
Test User Accounts:	*Test user accounts corresponding to each access level will be used*

3.2.4 TBA Example Site Acceptance Testing

Test Coverage:	*Phase 1 – Hardware tests* *Hardware checks against hardware design* *Operating environment checks* *Process equipment interface (input and output signals) – 10% random check* *Internal interfaces (communication / data checks)* *Phase 2 – Functional tests* *Process control functions which may be affected by the move to the site environment (eg because of timing considerations)* *Data handling functions (data input functions, data output functions,, data migration from previous system)* *Interfaces to external systems (communications / data checks)*
Location:	*At Customer's premises.*
Timing:	*After installation of the system on site and prior to final system handover*
Testing:	*By a Eurotherm representative*
Witnessing:	*By a customer representative*
Reviewing:	*By a customer representative*
Test Hardware Environment:	*Performed with the system installed in its final production environment.*
Test Software Environment:	*Performed with all application software loaded.* *All source files will be committed to the WinCVS repository and a configuration management baseline taken prior to the start of integrated test.*
Test Data:	*No test data is required as all required data will be collected during the tests.*
Test User Accounts:	*Test user accounts corresponding to each access level will be used*

3.2.5 Specific Areas Excluded From Tests

TBA: Explanatory note (delete this before publication):
Detail any areas which cannot be tested in this phase – for example, statements such as:
- Calibration checking of inputs is excluded since calibration certificates traceable to national standards are supplied separately.

Specimen

- Tests requiring the customer's network infrastructure (DNS servers, Email servers or default gateways) are excluded from tests carried out at Eurotherm's premises
- Note that the site tests are designed to prove correct operation of the system itself. Excluded are any qualification activities required to prove correct operation of the equipment being monitored or to cover checks that suitable customer procedures are in place.

3.2.6 Order of Tests

TBA: Explanatory note (delete this before publication):
If there is a specific order required then state this. Otherwise state that tests are most efficiently carried out in the order stated but can be carried out in any order except where the pre-requisites state that a particular test must have been completed.

3.2.7 Format of Test References

TBA: Explanatory note (delete this before publication):
Sometimes a format is specified by the customer. Otherwise, the approach below should be followed (the table includes examples for different test phases – modify it to include only the relevant ones:

Test references are made up of the following elements which appear on each test script. Elements are pre-filled onto the test script unless a script is used for more than one test phase or more than one item:

	Phase	Item	Area	Number	Identifier
	Initials for the test phase	The item under test (where tests cover multiple items)	The test area (usually relating back to the design specification sections)	Unique 3 digit test number	Optional identifier to distinguish multiple tests on a single item
Module test script	MOD	(module name)	IFACE (interfaces) ERROR (error handling) DATA (data) CONFIG (configurability tests) FUNC (functionality and module implementation)	Nnn	(A,B,C…)
Script used for Integrated test and factory acceptance tests	INT FAT	(often N/A on a simple system) (can be pre-filled to distinguish different volumes of protocol if these exist) (can be hand-filled to distinguish different instances of a test which applies to multiple items)	HW(hardware) IO (process I/O interface) COMMS (internal interfaces) FUNC (functions) DATA (data handling) EXT (external interfaces) OPER (operator interface) TECH (technical requirements)	Nnn	(A,B,C…)

Specimen

	Phase	*Item*	*Area*	*Number*	*Identifier*
Site acceptance tests	*SAT*	*(often N/A on a simple system)* *(can be pre-filled to distinguish different volumes of protocol if these exist)* *(can be hand-filled to distinguish different instances of a test which applies to multiple items)*	*HW(hardware)* *ENV (environment)* *IO (process I/O interface)* *COMMS (internal interfaces)* *FUNC (functions)* *DATA (data handling)* *EXT (external interfaces)*	*Nnn*	*(A,B,C…)*

Incident reports take sequential numbers within each test phase and item

	Phase	*Item*	*Number*
	Initials for the test phase	*The item under test (where tests cover multiple items)*	*Unique 3 digit test number*
Module test incident report	*MOD*	*(module name)*	*nnn*
Integrated test incident report	*INT*	*(fill in N/A or test volume or instance of test as appropriate to the specific system)*	*nnn*
Factory acceptance test incident report	*FAT*	*(fill in N/A or test volume or instance of test as appropriate to the specific system)*	*nnn*
Site acceptance test incident report	*SAT*	*(fill in N/A or test volume or instance of test as appropriate to the specific system)*	*nnn*

Specimen

3.3 Procedures for Verification Activities

3.3.1 Procedure for Test Execution

Prior to start of testing:

1. A copy of the signed paper master of this document becomes the test results file onto which test results are recorded by hand as testing progresses. If additional copies of any sheets are required (e.g. for recording re-runs of tests after an incident) these may be photocopied from the signed paper master or printed from the electronic master version.
2. Each person involved in testing, witnessing or reviewing tests provides a sample signature into the table in section 4.1
3. Details of the test environment are recorded into section 4.2 to 4.7
4. Supporting data for the test environment (eg calibration certificates, software baseline details) are included in Appendix C

Each test is run as follows, filling in the results directly in ink onto the test scripts:

1. The run number is filled in.
2. A check is made that any necessary pre-requisites have been completed.
3. The actions associated with each test step in turn are carried out and the required data recorded.
4. Any associated raw data (print-outs, etc) described in the test script is signed and dated by the tester or witness on each page and marked with the full test reference (including phase/item reference as appropriate) and run number. It is then inserted behind the Test Results Sheet.
5. The actual results are compared to the expected results and PASS or FAIL for the step is recorded into the right hand column.
6. If the step passes then testing proceeds to the next step.
7. If a step fails then the tester (together with the witness if this is a witnessed test) decides whether the failure is serious enough to halt the test at that point or whether the remaining steps can proceed independently once an incident report has been raised.
8. In the event of a documentation error, an incident report is raised and recorded on the results sheet and the documentation is hand marked with the required change, signed and dated. The test step can then be confirmed as a pass against the marked up version.
9. At the end of the test, any required post test actions are carried out.
10. The total number of pages of appended test evidence is filled in onto the test results sheet.
11. Any incident reports raised are noted in the 'Incident Report Reference' box on the test results sheet.
12. The tester (together with the witness if this is a witnessed test phase) then decides whether the overall acceptance criteria are met and the test can be passed. The test script is completed as PASS or FAIL. In either case the test results are then signed and dated.
13. The tester updates the Test Result Summary in the Test Report (section 6.1). This sheet is used to record a summary of test results in tabular form. It also serves as the record of the final post-test review.

3.3.2 Procedure for Control of test incidents

1. Where a test incident report is raised, this is cross-referenced to the test and indexed in the Test Incident Summary in the Test Report (section 6.2).The incident report itself is inserted into Appendix B
2. The incident report originator completes the first section of the incident report with a description of the fault / incident.
3. The second section of the report is then completed with details of the proposed modification, the files/documents/hardware affected and the proposed scope of retest.
4. An independent reviewer (customer representative during a witnessed test phase) then reviews and approves the proposed modification and scope of retest.
5. The person implementing the change signs the appropriate box for software, hardware and documentation changes.

Specimen

6. The required retests are performed and the results sheets appended to the incident report and the test progress sheet completed.
7. The scope of retest will normally include the step which previously failed and possibly other steps from the original test. These are recorded on a copy of the test script with a new run number (any steps which passed previously and are not required to be repeated, being clearly marked 'Pass on run X'). If the scope of modification requires that other existing tests are also re-run, these are also recorded on copies of the relevant test script with a new run number. The fact that the test follows correction of the fault is noted in the comments section of the sheet. If the scope of retest requires new test scripts to be generated then these are appended to the incident report.
8. If the retest is successful, the retest section is signed by the tester (or witness for a witnessed test stage).
9. If the retest is unsuccessful, a new incident report is raised to control any subsequent modifications and retest.
10. The incident report sheet final closure is signed by the independent reviewer during the post test review.

3.3.3 Procedure for Test Review and Reporting

1. On completion of testing, the results for each test are independently reviewed to check that sufficient data has been recorded to confirm that the acceptance criteria were met. If the reviewer accepts the test results, the 'reviewed' column of the Test Result Summary in the Test Report (section 6.1) is initialled. If the reviewer rejects the test results, the final test status is changed from PASS to FAIL and the test must be re-run to the reviewer's satisfaction.
2. Any incident reports raised are also independently reviewed to check that the required work to close the test incident has been completed. If the reviewer accepts the closure, the 'closed by' section of the incident report is signed and the Test Incident Summary in the Test Report (section 6.1) completed. If the reviewer rejects the closure, a further incident report must be raised to cover any resulting modifications or retests.
3. On completion of each of the test phase, the Acceptance Certificate in the Test Report (section 6.3) will be signed by the lead tester and the reviewer. Acceptance may also be granted in the event that problems of a minor nature exist (such that they can be rectified promptly before shipment and tested as part of site tests). In this case, a list of remedial actions is appended to the certificate. In the event that the session has not been successful, a certificate is not awarded. A schedule for re-work is drawn up with the customer reserving the right to call a re-test involving as much testing as is reasonable in order to prove that the short fall has been remedied.

Specimen

4. TEST ENVIRONMENT

TBA: Explanatory note (delete this before publication):
The template below assumes that the document covers a single test phase or two phases (eg INT and FAT) which will be carried out in the same environment and recorded onto separate copies of the protocol. If this is not true, it may be necessary to divide each section below into subsections for each test phase.
In all sections, if there are no such items, the heading should be left in and a statement added saying that there are none required

4.1 Record of Test Personnel

All personnel involved in testing, witnessing or reviewing results at any test phase should record sample signatures and initials in the following table:

Test Phase		Item Reference		
Signature	Initials	Printed Name	Position	Function *

* Function within test team (eg Tester or Witness or Reviewer)

Specimen

4.2 Hardware Environment

TBA: Explanatory note (delete this before publication):
Repeat the description of the hardware environment from section 3.2 and elaborate if necessaryto explain:
What project equipment will be present?
What will be used to represent equipment which is not present?
How will removal of additional non-project equipment be confirmed?
How will the equipment be networked together?
Include a diagram of the test rig architecture if necessary to clarify.

4.2.1 Project Hardware

TBA: Explanatory note (delete this before publication):
List all purchased/ free issued computerised system items in the table below(eg T2550s, EYCONs, EurothermSuite PCs)

Test Phase			Item Reference		
Item	Type	Serial Number		Initials	Date

OR (for a large system) ask for the bill of materials (including serial numbers) to be appended to the Supporting Data in Appendix C and each item initialled on the list when confirmed as correct.

Test Phase		Item Reference		
	Version	Number of Pages	Initials	Date
Bill of materials appended				

4.2.2 Test Hardware

TBA: Explanatory note (delete this before publication):
List all test rig items being used to represent existing or 3rd party equipment (eg test PC used to test Review, T2550 running simulation, test Modbus slave device, etc).
Note that when putting test items into the production environment, their removal will need signing for – otherwise the 'removed by' can be pre-filled as 'N/A – not in production environment'

Test Phase			Item Reference			
Item	Type	Serial Number	Initials	Date	Removed by Initials	Date

Specimen

4.3 Test Equipment

4.3.1 Services

TBA: Explanatory note (delete this before publication):
Give details of services required (eg 230V 50Hz mains power, oil free air at 6 bar)

4.3.2 Consumables

TBA: Explanatory note (delete this before publication):
Give details of any consumables required (eg suitably formatted storage media)

4.3.3 Test Equipment

TBA: Explanatory note (delete this before publication):
Give details of any test equipment required (eg Process multimeter capable of injecting 4-20mA signals)
List all items in the table. For those which do not need to be calibrated (eg because they are used only for functional test with calcerts for I/O supplied separately) state this in the Calibration Date column.

Test Phase			Item Reference		
Test Equipment	Type	Serial Number	Calibration Date	Initials	Date

Specimen

4.4 Software Environment

TBA: Explanatory note (delete this before publication):
Repeat the description of the software environment from section 3.2 and elaborate if necessary to explain:

- *What project software will be installed?*
- *How will the software set-up be recorded (eg baseline to be taken)?*
- *What test software is needed?*
- *Where will it run?*
- *How will its removal be confirmed?*
- *How will the software set-up be recorded (eg baseline to be taken)?*

Include a diagram of the test rig software architecture if necessary to clarify.

4.4.1 Infrastructure and Standard Software

TBA: Explanatory note (delete this before publication):
List all GAMP cat 1 & 3 items

Test Phase			Item Reference				
Standard Software Item		Version at start	Initials	Date	Version at end	Initials	Date

4.4.2 Application-Specific Software

TBA: Explanatory note (delete this before publication):
List all GAMP cat 4 & 5 items plus any parameter files associated with Cat 1&3 items (may be appropriate for a small recorders job or an upgrade where software is in customers CM system not Eurotherm's)

Test Phase			Item Reference				
Project Software Item	Filename(s)	Version at start	Initials	Date	Version at end	Initials	Date

Specimen

OR ask for a print of the software baseline to be appended to the Supporting Data in Appendix C and signed/dated when confirmed as correct.

Test Phase		Item Reference			
		Baseline Name	Number of pages	Initials	Date
Print of software baseline appended at start of test					
Print of software baseline appended at end of test					

4.4.3 Test Software

TBA: Explanatory note (delete this before publication):
List all test software items (eg simulation sequences) being used.
Note that when putting test software items onto project hardware or onto any hardware in the production environment their removal will need signing for – otherwise the 'removed by' can be pre-filled as 'N/A' and the reason given

Test Phase			Item Reference			
Item	Filename(s)	Version	Initials	Date	Removed by Initials	Date

OR ask for a print of the software baseline to be appended to the Supporting Data in Appendix C and signed/dated when confirmed as correct.

Test Phase		Item Reference				
	Baseline Name	Number of pages	Initials	Date	Removed by Initials	Date
Print of baseline for test software appended at start of test						

Specimen

4.5 Test Data

TBA: Explanatory note (delete this before publication):
Repeat the description of the software environment from section 3.2 and elaborate if necessary to explain:
What test data is needed? (eg test recipes, sample data from pre-upgrade system, sample outputs such as reports or trends from pre-upgrade system)
How will it be generated?
How will it be included on the system?
Does it need removing and if so how will its removal be confirmed?
How will the test data set be recorded (eg electronic data put into repository and baseline to be taken, sample reports signed by customer to confirm status)?

4.5.1 Test Data Held Electronically

TBA: Explanatory note (delete this before publication):
List all test data items (eg recipes, sample data from previous system) being used in electronic format.
Note that when putting test software items onto project hardware or onto any hardware in the production environment their removal will need signing for – otherwise the 'removed by' can be pre-filled as 'N/A' and the reason given

Test Phase		Item Reference				
Item	Filename(s)	Version	Initials	Date	Removed by Initials	Date

4.5.2 Test Data Held as Paper Copies

TBA: Explanatory note (delete this before publication):
List all test data items (eg sample reports from previous system) being used in paper format.

Test Phase		Item Reference	
Item Description		Initials	Date

Specimen

4.6 Test User Accounts

TBA: Explanatory note (delete this before publication):
Repeat the description of the software environment from section 3.2 and elaborate if necessary to explain:
What user accounts are needed?
Do they need removing and if so how will removal be confirmed?

Test Phase		Item Reference			
User Name	User Group	Initials	Date	Removed by Initials	Date

Specimen

4.7 Reference Documents

TBA: Explanatory note (delete this before publication):
List all the design documentation required from reference during the test including any with cross references in the traceability table in the appendix plus any other which are directly referenced in tests (eg drawings) :

Test Phase		Item Reference			
Document Title			Version	Initials	Date

Specimen

4.8 Temporary Modifications for Test Purposes

Any temporary modifications to the system made during testing are recorded so that removal of these modifications can be checked and signed off at the end of testing.

Test Phase			Item Reference			
Mod. No.	Test Reference	Description of Modification	Made by (signed)	Date	Removed by (signed)	Date

Specimen

5. TESTS TO BE PERFORMED

See Appendix A for cross-reference of design specification detail to test number.

TBA: Explanatory note (delete this before publication):
Make sure the test groupings and test references match those in section 3.2.7
Take out a second level heading for each test grouping (typical groupings are listed below:

Phase	*Area*
Module test	*IFACE (interfaces – this may be combined with 'DATA' if all values are via a standard interface – for example a T2550 sequence picking up values from a T2550 database)* *ERROR (error handling – this may be combined with 'FUNC' if error handling is simple and fully defined within the implementation details)* *DATA (data – typically checks that all inputs / outputs / parameters / flags are as per the SDS and any map file compiles without error)* *CONFIG (configurability tests – checks any configurability set out in the SMS)* *FUNC (functionality and module implementation – typically a separate script for each function in the SMS).*
Integrated test and factory acceptance tests	*HW(hardware – typically separate scripts for Components Checks (specification, condition, certification where appropriate), Cold wire interconnection and wiring checks, Panel and physical details, service connection and power up)* *IO (process I/O interface – typically checks each input an output by signal injection; may well be just a sample check at FAT)* *COMMS (internal interfaces – typically checks all internal interfaces are correctly set up (eg Node no / IP address) and showing live data – ELIN, Modbus, etc)* *FUNC (functions – typically one script per function defined in the FS)* *DATA (data handling – typically scripts for standard process data / alarms / audit trail plus one script per data handling function in the FS plus scripts for electronic records and signatures)* *EXT (external interfaces) – typically one script per interface to check correct data being transferred successfully* *OPER (operator interface) – typically one or more scripts for alarm strategy, one or more scripts for displays, one or more scripts for security)* *TECH (technical requirements) – typically scripts covering disaster recovery and performance*
Site acceptance tests	*HW(hardware) – typically checks for condition of system, service connection and power up* *ENV (environment) – typically one script to check operating environment suitable for equipment* *IO (process I/O interface) – typically sample checks (one I/O per card)* *COMMS (internal interfaces) – typically checks all internal interfaces are showing live data* *FUNC (functions) – typically limited to those functions or aspects which may have been affected by the move to site (eg timing or tuning issues)* *DATA (data handling) – typically limited to ensuring sample inputs (eg recipes) can be used and sample outputs (eg reports) produced* *EXT (external interfaces) – typically one script per interface to check correct data being transferred successfully*

Specimen

TBA: Explanatory note (delete this before publication):
Take out a third level heading for each separate test script and make sure that both the test reference and the test title appear in the heading so that the contents page shows both.
All test scripts should be in the format shown below

Note - it is acceptable for scripts to ask for design document pages to be appended and each Input/Output or alarm or data item or state/transition to be initialled when checked)

5.1 TBA Enter Test Group Heading

5.1.1 AREA-nnnA TBA Enter Test Script Reference and Heading

TEST SCRIPT AND RESULTS SHEET											
Test Phase		Item Ref		Test Ref		Title			Run number:	
Objective									Pages in script:	
Acceptance criteria									Pages appended:	
Requirement Ref										
Pre-requisites										
Record any changes to the recorded the test environment										
Test step	Action			Data to be Recorded			Actual Result / Incident Record		Expected Result	Pass / Fail
Post Test Actions										
Comments										
Overall Test Result	Incident Report Reference			Tester Signature			Date		Witness Signature	Date

Specimen

TBA: Explanatory note (delete this before publication):
The test script fields are filled in as follows:

Field	*Detail to be pre-filled*	*Detail to be hand written at time of test*
Test Phase	*Pre-fill only if test protocol applies to one phase only* *e.g. MOD / INT / FAT / SAT as defined in 3.2.7*	*Hand write phase initials if not pre-filled*
Item Ref	*Pre-fill only if test protocol applies to one item only or if item ref is 'N/A' in this case* *e.g. module name as defined in 3.2.7*	*Hand write item reference if not pre-filled*
Test Ref	*Pre-fill as defined in 3.2.7*	*None*
Title	*Pre-fill, preferably with titles that link clearly to the design documentation*	*None*
Run number:	*None*	*Hand write run number*
Objective	*Pre-fill with the high level objective for the whole script*	*None*
Pages in script:	*Pre-fill with the number of pages the script takes*	*None*
Acceptance criteria	*Pre-fill with the high level acceptance criteria for the whole script (often very repetitive of the objective but various end user validation managers have insisted on it because it allows them to confirm a test as a pass even if a documentation error is present)*	*None*
Pages appended:	*None*	*Hand write the number of sheets appended*
Requirement Ref	*Pre-fill with cross reference to the design document section being tested*	*None*
Pre-requisites	*Pre-fill with any pre-requisites for the test*	*None*
Record any changes to the recorded the test environment	*None*	*Hand write any changes to the recorded test environment (eg because a run 2 is being carried out an a different version of software)*
Test step	*Pre-fill with sequential step numbers*	*None*
Action	*Pre-fill with instructions for what the tester needs to do* *Make sure that structural test and challenge test elements are covered as appropriate to the type and risk level of the software(see 3.1).* *- Structural testing, where each possible branch in the software is considered, may already be in a separate module test specification (in which case there is no need to repeat it at later phases)* *- Challenge testing, depending on the type of function, may include things like invalid cases, cases which check the boundaries of the function, repeatability, testing under high load conditions.*	*None*

Specimen

Field	*Detail to be pre-filled*	*Detail to be hand written at time of test*
Data to be Recorded	*Pre-fill with what the tester needs to record or append*	*None*
Actual Result / Incident Record	*None*	*Hand write actual result of test*
Expected Result	*Pre-fill with what the tester should expect to see*	*None*
Pass / Fail	*None*	*Hand write 'PASS' or 'FAIL' for the step*
Post Test Actions	*Pre-fill with any actions the tester must take to return the system to a known safe state*	*None*
Comments	*None*	*Hand write any comments about the method of testing and/or note to say this test is a re-run after a particular incident report*
Overall Test Result	*None*	*Hand write 'PASS' or 'FAIL' for the script as a whole*
Incident Report Reference	*None*	*Hand write reference of any incident report raised*
Tester Signature and date	*None*	*Tester signature and date*
Witness Signature and date	*None*	*Witness signature and date (or tester writes 'N/A' if this is not a witnessed test phase*

Some examples follow.

Specimen

5.1.2 HW-001 TBA Example Hardware Component Checks at INT/ FAT

TEST SCRIPT AND RESULTS SHEET									
Test Phase		Item Ref	N/A	Test Ref	HW-001	Title	Component Checks	Run number:	
Objective	To check the specification and condition of the hardware and confirm that all necessary certification is present.							Pages in script:	1
Acceptance criteria	Hardware matches required specification and is in good condition. All necessary certification is present							Pages appended:	
Requirement Ref	FS 10.1								
Pre-requisites	Test environment as in section 4 above								
Record any changes to the recorded the test environment									

Test step	Action	Data to be Recorded	Actual Result / Incident Record	Expected Result	Pass / Fail
1	Check that the 6180A is free from damage. (note that serial number is already recorded in the test pre-requisites)	Free from visible damage? Tools CD available? Panel clamps available? Panel seal available?		No visible damage Tools CD available Panel clamps available Panel seal available	
2	Check that the hardware options match the order codes	Order code from product label		Product code matches customer requirement.	
3	Check that the 6180 Certificate of Conformity is available	Location of certificate of conformity		Certificate in system Technical Manual	

Post Test Actions	None Required
Comments	

Overall Test Result	Incident Report Reference	Tester Signature	Date	Witness Signature	Date

Specimen

5.1.3 FUNC-001 TBA Example Implementation / Functionality Checks at Software Module Test

TEST SCRIPT AND RESULTS SHEET									
Test Phase	MOD	Item Ref	ModuleX	Test Ref	FUNC-001	Title	Implementation and Functionality – Vent Sequence	Run number:	
Objective	To check the implementation of the Vent Sequence							Pages in script:	1
Acceptance criteria	Vent Sequence functions as defined in the software module specification							Pages appended:	
Requirement Ref	SMS 4.7								
Pre-requisites	Test environment as in section 4 above								
Record any changes to the recorded the test environment									

Test step	Action	Data to be Recorded	Actual Result / Incident Record	Expected Result	Pass / Fail
1	Move the sequence through each state shown in their normal order and for each state check that: • the correct actions are carried out in the step • the current mode is indicated correctly	Append a copy of module specification section 4.7 Individual actions should be initialled once checked for correct operation. Steps should be initialled once all associated actions have been checked		Actions are carried out in each step as per module specification Each step gives correct mode indication.	
2	For each normal operation transition, check that • the sequence does not move on to the next state unless all of the correct conditions are met • the sequence does move on when the correct conditions are met	Individual normal operation transitions should be initialled once they have been checked for correct operation		Normal operation transitions are made as per module specification	
3	For each fault transition, check that the sequence moves on to the correct failure state when each possible failure conditions is present	Individual failure transitions should be initialled once they have been checked for correct operation		Failure transitions are made as per module specification	

Post Test Actions	None Required
Comments	

Overall Test Result	Incident Report Reference	Tester Signature	Date	Witness Signature	Date

Specimen

6. TEST REPORT AND POST-EXECUTION REVIEW

TBA: Explanatory note (delete this before publication):
Pre-fill the table below with all the test references in the left hand column. The remainder is hand filled at the end of test.

6.1 Test Result Summary

Test Phase						Item Reference									
Test Reference	Initial run					Second run					Third run				
	Result	Incident cross ref	Tester Initials/ Date	Witness Initials / Date	Review Initials / Date	Result	Incident cross ref	Tester Initials/ Date	Witness Initials / Date	Review Initials / Date	Result	Incident cross ref	Tester Initials/ Date	Witness Initials / Date	Review Initials / Date

Specimen

6.2 Test Incident Summary

Test Phase		Item Reference	

Report No.	Fault (Yes/No)	Change (Yes/No)	Brief Description	Closed (signature)	Date

Specimen

6.3 Test Acceptance Certificate

Title	**Double-click HERE and type Project Title**
Customer	**Double-click HERE and type Customer Name**
Eurotherm Reference	**Double-click HERE and type Eurotherm Reference**
Customer Reference	**Double-click HERE and type Customer Reference**
Test Phase	
Item Reference	

We hereby confirm that the test phase has been completed to our satisfaction subject to the completion of the outstanding items listed below

Specimen

Signed (Eurotherm Lead Tester)	.....	.....	.....
	Sign / Date	**Printed Name**	**Title**
Signed (Reviewer)	.....	.....	.....
	Sign / Date	**Printed Name**	**Title**

7. GLOSSARY

TBA: Explanatory note (delete this before publication): - add any other abbreviations or project-specific terms (including Eurotherm instrument names, comms protocol names,etc)

DCS	Distributed Control System
GAMP	GAMP 5 A Risk Based Approach to Compliant GxP Computerized Systems
GxP Compliance	Meeting all applicable pharmaceutical and associated life-science regulatory requirements
I/O	Inputs and Outputs

Specimen

APPENDIX A CROSS REFERENCE TO DESIGN SPECIFICATION

TBA: Explanatory note (delete this before publication): - the following tables need to be completed in order to demonstrate that the appropriate design requirements have been tested.

The design spec reference and test spec reference in the table headings should be modified to reflect the actual documents (eg SMS/SMTS or FS/FAT etc)
Risk priority is the overall risk level output from the functional risk assessment (step 3) process.

(The easiest way to create these tables is via a Microsoft Access database – create separate tables for each document and then create additional tables containing just a list of links between two documents. A query can then be used to export the data in the appropriate order)

TBA Design Spec Ref	Risk Priority	*TBA Design Spec* Heading	*TBA Test Spec* Ref

TBA Test Spec Ref	*TBA Test Spec* Heading	*TBA Design Spec* Ref	Risk Priority

TBA: Explanatory note (delete this before publication): Some examples of how to deal with headings, cross-references and sections with no test requirement follows
1) heading or high level section which does not need cross referencing

FS Ref	*Risk Priority*	*FS Heading*	*FAT Ref*
1.	*N/A*	*DOCUMENTATION RECORDS*	
2.	*N/A*	*INTRODUCTION*	
3.	*N/A*	*OVERVIEW*	*(covered in greater detail later in document)*
4.	*N/A*	*PROCESS CONTROL FUNCTIONS*	

2) function with a valid cross-reference to test

FS Ref	*Risk Priority*	*FS Heading*	*FAT Ref*
4.	*N/A*	*PROCESS CONTROL FUNCTIONS*	
4.1	*N/A*	*Continuous Control*	
4.1.1	*MEDIUM*	*TBA Continuous Control Function 1*	*FUNC-001*

3) function with no relevance for this test phase

FS Ref	*Risk Priority*	*FS Heading*	*FAT Ref*
11.	*N/A*	*NON-FUNCTIONAL ATTRIBUTES*	
11.1	*MEDIUM*	*Availability*	*(no relevance to test phase – non functional attribute)*

Specimen

APPENDIX B INCIDENT REPORTS

Each Incident Report is indexed in the index within the test report section of this document.
Individual reports (together with any associated test scripts and test evidence from re-test) are inserted into the test results file at this point.

Incident report sections are completed as follows:

INCIDENT REPORT

invensys EUROTHERM

Project *(Eurotherm Project Ref)*	**Incident Report Number** *(Number as defined in section 3.2.7)* **(page of)**	**Source of change:** **Test Reference** *(test ref on which incident was observed)* **Run number** *(run number on which incident was observed)* **Other** *(e.g source for customer instigated change)*

Incident Description
(Description of the symptoms observed)

Raised By: *(person observing the incident)* **Date:** .....

INCIDENT REVIEW

Modification Agreed *(Description of the agreed change OR a statement that no change is required)*	**Modification and retest requirements reviewed and authorised:** *(Eurotherm reviewer for internal tests)* *(Customer representative for witnessed tests)* **Date:**

Details of Items Requiring Modification		**IMPLEMENTATION**	
Files Affected *(list affected files)* *(versions will normally be from file header for cat5 items or from baseline reference for all others)*	Original version	Modified version	**Implemented By:** *(Implementing engineer)* **Date:**
Documents Affected *(list affected documents)*			**Implemented By:** *(Implementing engineer)* **Date:**
Hardware or Standard Software Items Affected *(list affected hardware or standard software items)*			**Implemented By:** *(Implementing engineer)* **Date:**

Retest Requirements *(list required retests by test reference and step number – see 3.3.2 for guidance)* *(if any tests require hand marking with changes prior to retest, detail that here)* *(if any new test scripts are required, give them references related to the incident report reference and append a suitable script)*	**RETEST** **Test Passed By:** *(Tester or witness may sign here)* **Date:**

CLOSURE following changes and successful re-test or agreement to abort test
(Eurotherm reviewer for internal test; customer representative for witnessed tests)
Incident Closed By: ..... **Date:** .....

Specimen

INCIDENT REPORT

invensys EUROTHERM

Project	**Incident Report Number** **(page of)**	**Source of change:** **Test Reference** **Run number** **Other**

Incident Description

Raised By: ..... **Date:** .....

INCIDENT REVIEW

Modification Agreed	**Modification and retest requirements reviewed and authorised:** **Date:**

Details of Items Requiring Modification		**IMPLEMENTATION**	
Files Affected	Original version	Modified version	**Implemented By:** **Date:**
Documents Affected			**Implemented By:** **Date:**
Hardware Affected			**Implemented By:** **Date:**

Retest Requirements	**RETEST** **Test Passed By:** **Date:**

CLOSURE following changes and successful re-test or agreement to abort test

Incident Closed By: ..... **Date:** .....

Specimen

APPENDIX C SUPPORTING DATA

Supporting data appended to the test specification should be indexed in the table below:

Item number	Pages	Brief Description

Specimen

Eurotherm Ltd.
Faraday Close
Durrington
Worthing BN13 3PL
United Kingdom

T +44 (0)1903 268500
F +44 (0)1903 265982
E info@eurotherm.co.uk
www.eurotherm.co.uk

Title	Double-click HERE and type Project Title
Customer	Double-click HERE and type Customer Name
Eurotherm Reference	Double-click HERE and type Eurotherm Reference
Customer Reference	Double-click HERE and type Customer Reference

Explanatory note (delete this before publication):
1) enter all fields above plus date and issue number below
2) search for 'TBA' to find items which need entering on a per-project basis.
3) if not based in the UK, replace the header with the appropriate one from your local letterhead

OVERALL TRACEABILITY MATRIX

Specimen

Prepared by	.....	.....	.....
	Sign / Date	Printed Name	Title
Tehnical Review by (Eurotherm)	.....	.....	.....
	Sign / Date	Printed Name	Title
Technical Approval by (Customer) Approved as a true reflection of project design and test coverage	.....	.....	.....
	Sign / Date	Printed Name	Title
Quality Approval by (Customer) Approved as a true reflection of project design and test coverage	.....	.....	.....
	Sign / Date	Printed Name	Title
Issue	Enter Issue No		
Date	Enter Date		

CONTROLLED CIRCULATION		
Copy	Issued to	**This Copy**
Master	Double-click HERE and type Customer Name	
Copy 1	Project File	

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Registered Office
Portland House Bressenden Place London SW1E 5BF
Registered in England and Wales No 853008

CONTENTS

Specimen

1. DOCUMENTATION RECORDS

TEMPLATE DETAILS			
HISTORY:			
T1	Template document created to cover GAMP5 overall traceability requirements		19 Jun 2008
APPROVAL DETAILS FOR CURRENT TEMPLATE			
Template prepared by	Karen Ashworth	Validation Officer	19 Jun 2008
Template reviewed for Technical Content	Malek Madani	Technical Manager	19 Jun 2008
Template reviewed for Quality Assurance	Martin Greenhalgh	Global Quality Manager	19 Jun 2008

DOCUMENT REVISION HISTORY		
Issue	Detail	Issue Date
1a	Project version 1 developed from template T1 and issued for internal review	TBA Enter Issue Date

TBA Explanatory note (delete this before publication):
Once internal review is complete, an additional entry needs to be made for version 1 saying something like 'Internal review comments included. Document issued for customer approval'
All subsequent issues (eg version 2) need to detail the changes which have been made including the section reference and the reason for the change (eg ref to customer comment). When creating a new version: accept all previously tracked comments; make changes with change tracking enabled; hide mark-up (in the VIEW menu) before printing or issuing the document.

Specimen

2. INTRODUCTION

TBA Explanatory note (delete this before publication):
*This document is produced in addition to the traceability tables within individual documents **only** if required by the customer (refer to Quality Plan for project traceability requirements)*
It is usual to issue the document as two separate phases – the first with the design traceability matrix complete for use in design reviews and the second with the test traceability matrix complete for use in test reviews.

2.1 Purpose

A Traceability Matrix sets out traceability between requirements, design and testing. The matrix in this document is set out to demonstrate full coverage of requirements in both design and verification activities.

2.2 Scope

This document defines the traceability of customer requirements on the control system required by Double-click HERE and type Customer Name for their Double-click HERE and type Project Title Project.

2.3 Contractual Status

This document forms an input to design and test reviews and is used, when reviewing proposed changes, to decide on the scope of documentation update and scope of re-test.
On project completion, this document passes to the customer for archiving and maintenance as appropriate under their validation plan.

2.4 Relationship to Other Documents

2.4.1 Applicable Standards

This document has been written to meet the guidelines for project traceability in GAMP5 A Risk-Based Approach to Compliant GxP Computerized Systems Appendix M5.

2.4.2 Documents Included in the Traceability Tables

TBA Explanatory note (delete this before publication):
Complete the table below to include:

- *URS*
- *FS + any other design documents*
- *Test specifications*

Discuss with the end user whether they want issue numbers including (they are going to have to maintain this for any future upgrades!)
The following documents are included within these traceability tables:

Document Ref	Document Title	Issue

Specimen

3. DESIGN TRACEABILITY

TBA Explanatory note (delete this before publication):
Table needs to end up showing traceability between all design documents. This can be done manually but an automated method is suggested below:

URS ref	FS ref	HDS Ref	SDS Ref	SMS Ref (module X)	SMS Ref (module Y)

Specimen

TBA Explanatory note (delete this before publication):
If the individual traceability tables within documents have been produced via a Microsoft Access database, the starting point for this table is that database, which should contain separate tables for each document and then additional tables containing lists of links between each pair of documents.
Otherwise, you can always cut and paste the tables from the individual documents into Access to get to that starting point (note that you are likely to need to add a column to give the required sort order for each document)

Problems likely to be encountered:

- *Creating a simple query in Access to trace URS to every design document results in multiple entries because it treats every combination of entries as unique. This is likely to produce a table which is thousands of entries long, even on a fairly simple project, and be unacceptable to the end user because (although technically correct) it is extremely difficult to use*
- *Where, in previous tables between documents, a whole section has been traced to rather than every subsection listed individually, traceability will hit a dead end.*

The most efficient method for creating the table automatically is probably as follows:

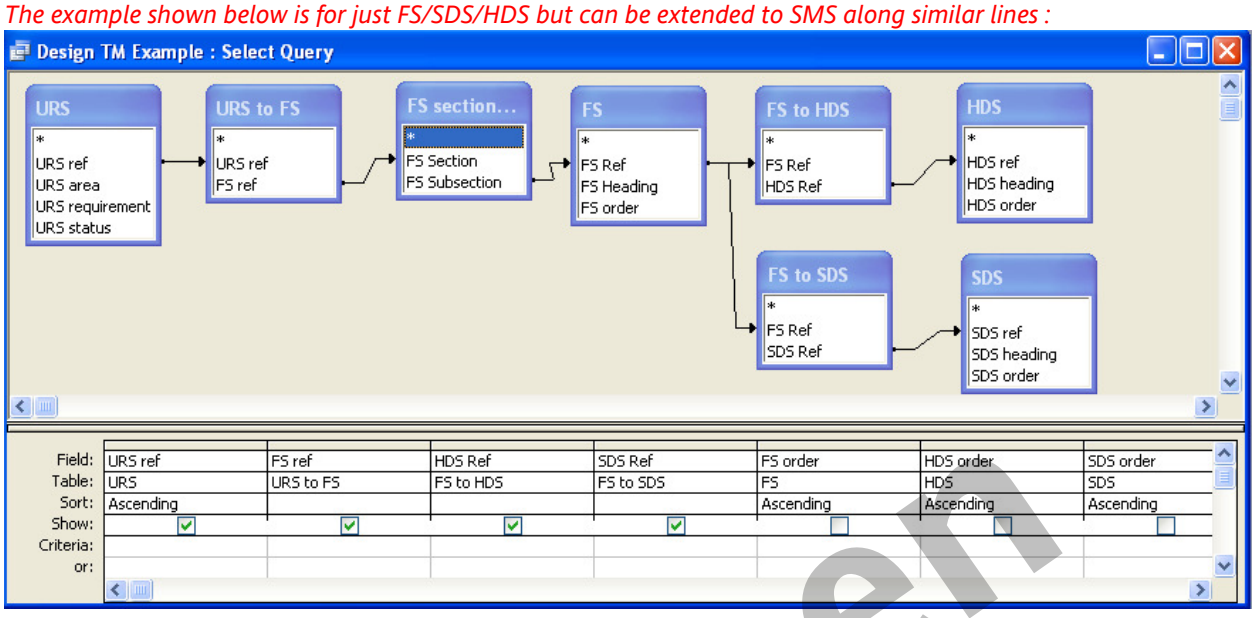
STEP 1) Check for section level traces which might result in 'dead ends' in the traceability and create an additional table linking the section numbers to every subsection – for example if a URS references traces to 'the whole of FS4.1' part of the table might look like this:

FS Section	FS Subsection
4	4
4.1	4.1
4.1	4.1.1
4.1	4.1.2
4.1	4.1.3
4.1	4.1.4
4.1	4.1.5
4.1.1	4.1.1
4.1.2	4.1.2
4.1.3	4.1.3
4.1.4	4.1.4
4.1.5	4.1.5
4.2	4.2
etc	

The query to generate the TM will then connect the URS tables to 'FS section' and the FS tables to 'FS subsection'.

Specimen

STEP 2) Create an overall traceability query from URS to each design document
The example shown below is for just FS/SDS/HDS but can be extended to SMS along similar lines :



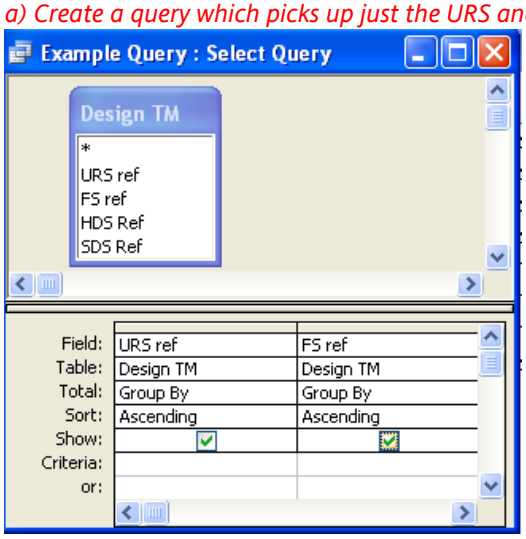
This will give a correct but difficult to use table with lots of repeat entries – for example:

URS ref	FS ref	HDS Ref	SDS Ref
UR-DCCS-005	5.1.7	4.3.1.	6.4.1
UR-DCCS-005	5.1.7	4.3.1.	6.4.2
UR-DCCS-005	5.1.7	4.3.1.	7.2.4
UR-DCCS-005	5.1.7	4.3.1.	7.2.5
UR-DCCS-005	5.1.7	4.3.2.	6.4.1
UR-DCCS-005	5.1.7	4.3.2.	6.4.2
UR-DCCS-005	5.1.7	4.3.2.	7.2.4
UR-DCCS-005	5.1.7	4.3.2.	7.2.5
UR-DCCS-005	5.1.8	4.3.2.	6.4.1
UR-DCCS-005	5.1.8	4.3.2.	6.4.2
UR-DCCS-005	5.1.8	4.3.2.	7.2.4
UR-DCCS-005	5.1.8	4.3.2.	7.2.5
UR-DCCS-005	5.1.9	4.3.2.	6.4.1
UR-DCCS-005	5.1.9	4.3.2.	6.4.2
UR-DCCS-005	5.1.9	4.3.2.	7.2.4
UR-DCCS-005	5.1.9	4.3.2.	7.2.5
etc			

Specimen

STEP 3) Manually editing the table is a non-starter as it is likely to have thousands of entries!
If it is unacceptable to the customer in this form, the following is somewhat time-consuming but will produce a more easily read table.

a) Create a query which picks up just the URS and FS columns of the table.



URS ref	FS ref
UR-DCCS-002	4.1.2
UR-DCCS-002	5.1.3
UR-DCCS-003	4.1.4
UR-DCCS-004	5.1.3
UR-DCCS-005	5.1.7
UR-DCCS-005	5.1.8
UR-DCCS-005	5.1.9
UR-DCCS-005	5.4
etc	

b) Manually edit this by merging cells to give just one row per URS ref

URS ref	FS ref
UR-DCCS-002	4.1.2 5.1.3
UR-DCCS-003	4.1.4
UR-DCCS-004	5.1.3
UR-DCCS-005	5.1.7 5.1.8 5.1.9 5.4
etc	

Specimen

c) repeat the process for URS/HDS, URS/SDS etc

URS ref	HDS Ref
UR-DCCS-002	
UR-DCCS-003	
UR-DCCS-004	
UR-DCCS-005	4.3.1. 4.3.2.

URS ref	SDS Ref
UR-DCCS-002	6.1.4
UR-DCCS-002	7.4
UR-DCCS-002	8.2.4
UR-DCCS-002	8.3
UR-DCCS-003	8.2.4
UR-DCCS-003	8.3
UR-DCCS-004	6.1.4
UR-DCCS-004	7.4
UR-DCCS-005	6.4.1
UR-DCCS-005	6.4.2
UR-DCCS-005	7.2.4
UR-DCCS-005	7.2.5

d) you will then be able to cut and paste columns to create a more readable overall matrix like this:

URS ref	FS ref	HDS Ref	SDS Ref
UR-DCCS-002	4.1.2 5.1.3		6.1.4 7.4 8.2.4 8.3
UR-DCCS-003	4.1.4		8.2.4 8.3
UR-DCCS-004	5.1.3		6.1.4 7.4
UR-DCCS-005	5.1.7 5.1.8 5.1.9 5.4	4.3.1. 4.3.2.	6.4.1 6.4.2 7.2.4 7.2.5
etc			

Specimen

4. TEST TRACEABILITY

TBA Explanatory note (delete this before publication):
Table needs to end up showing traceability between all test protocols.
This can be done manually but the automated method suggested in the explanatory notes for section 3 will be more efficient.

URS ref	SMTS ref (Module X)	SMTS ref (Module Y)	FAT ref	SAT Ref

Specimen

5. GLOSSARY

TBA: Explanatory note (delete this before publication): - add any other abbreviations or project-specific terms (including Eurotherm instrument names, comms protocol names,etc)

DCS	Distributed Control System
GAMP	GAMP 5 A Risk Based Approach to Compliant GxP Computerized Systems
GxP Compliance	Meeting all applicable pharmaceutical and associated life-science regulatory requirements
I/O	Inputs and Outputs

Specimen

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Title	Double-click HERE and type Project Title
Customer	Double-click HERE and type Customer Name
Eurotherm Reference	Double-click HERE and type Eurotherm Reference
Customer Reference	Double-click HERE and type Customer Reference

Explanatory note (delete this before publication):
1) enter all fields above plus date and issue number below
2) search for 'TBA' to find items which need entering on a per-project basis.
3) if not based in the UK, replace the header with the appropriate one from your local letterhead

FINAL QUALITY REPORT AND HANDOVER CHECKLIST

Specimen

Prepared by	..... Sign / Date	..... Printed Name	..... Title
Quality Review by (Eurotherm)	..... Sign / Date	..... Printed Name	..... Title
Quality Approval by (Customer) Approved for use as Basis for Project Activities	..... Sign / Date	..... Printed Name	..... Title
Issue	Enter Issue No		
Date	Enter Date		

CONTROLLED CIRCULATION		
Copy	Issued to	**This Copy**
Master	Double-click HERE and type Customer Name	
Copy 1	Project File	

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Registered Office
Portland House Bressenden Place London SW1E 5BF
Registered in England and Wales No 853008

CONTENTS

Specimen

Specimen

1. DOCUMENTATION RECORDS

TEMPLATE DETAILS			
HISTORY:			
T1	Template document created to cover GAMP5 5 step approach to risk management		19 Jun 2008
APPROVAL DETAILS FOR CURRENT TEMPLATE			
Template prepared by	Karen Ashworth	Validation Officer	19 Jun 2008
Template reviewed for Technical Content	Malek Madani	Technical Manager	19 Jun 2008
Template reviewed for Quality Assurance	Martin Greenhalgh	Global Quality Manager	19 Jun 2008

DOCUMENT REVISION HISTORY		
Issue	Detail	Issue Date
1a	Project version 1 developed from template T1 and issued for internal review	TBA Enter Issue Date

TBA Explanatory note (delete this before publication):
Once internal review is complete, an additional entry needs to be made for version 1 saying something like 'Internal review comments included. Document issued for customer approval'
All subsequent issues (eg version 2) need to detail the changes which have been made including the section reference and the reason for the change (eg ref to customer comment). When creating a new version: accept all previously tracked comments; make changes with change tracking enabled; hide mark-up (in the VIEW menu) before printing or issuing the document.

Specimen

2. INTRODUCTION

2.1 Purpose

The Quality Report and Handover Checklist summarises the fitness for intended use of the system. It lists the activities performed together with any deviations from the original Quality Plan and any outstanding and corrective actions.

2.2 Scope

This document summarises the fitness for handover of the control system required by Double-click HERE and type Customer Name for their Double-click HERE and type Project Title Project.

2.3 Contractual Status

This document, once approved, provides the basis for project handover. On project completion, this document passes to the customer for archiving.

2.4 Relationship to Other Documents

2.4.1 Applicable Standards

This document has been written to meet the guideline for validation reporting contained in GAMP5 A Risk-Based Approach to Compliant GxP Computerized Systems Appendix M7 and the guideline on handover contained in GAMP5 A Risk-Based Approach to Compliant GxP Computerized Systems Appendix O1.

2.4.2 Quality Plan Reported Against

TBA: Explanatory note (delete this before publication):
Fill in the quality plan details in the table below.
The original Quality Plan is as follows:

Project / Document Ref	
Title	
Issue	

Specimen

3. PROJECT OVERVIEW

TBA: Explanatory note (delete this before publication): -
Fill in each item as either 'no significant changes' or the detail (including change request / variation request numbers if appropriate) of what has changed

Ref	Items to be considered	Status
3.1.1	Have there been any significant changes to the process to be controlled?	
3.1.2	Have there been any significant changes to the key benefits requested by the end user?	
3.1.3	Have there been any significant changes to the GxP regulations relevant to the project?	
3.1.4 3.6.1	Have there been any significant changes to the project GxP or impact ratings?	
3.2	Have there been any significant changes to the project boundaries and interfaces?	
3.3	Have there been any significant changes to the project hardware architecture?	
3.4	Have there been any significant changes to the project software architecture?	
3.5	Have there been any significant changes to the project lifecycle requirements as specified by the end user?	
3.6.2	Have there been any significant changes to the initial impact ratings given for individual functions in the URS?	
3.6.3	Was the functional risk assessment completed?	
3.6.4	Have all identified controls been implemented?	
3.6.5	Has the risk assessment been revisited to confirm that risk levels have been appropriately managed?	

Specimen

4. PROJECT LIFECYCLE PHASES

TBA: Explanatory note (delete this before publication): -
Copy the tables from Quality Plan section 4, delete the contents of the final column and re-label it as 'Status'
Fill in as either 'Completed as per Quality Plan' or detail any deviations from that plan - typically things like:

- *the customer changing his mind about who will sign documents or witness / review tests*
- *procedures being updated during the project (did you carry on against the original or do what the new version said?)*

4.1 Planning Phase

Ref	Activity	Responsibility	Controlling Procedure	Status
A1	Review customers URS and initial risk assessment	PM	Eurotherm SEP109	
A2	Generate Project Plan (Gantt)	PM	Eurotherm SEP102	
A3.1	Generate Quality Plan	PM	Eurotherm SEP109 (meets GAMP5 App M6)	
A3.2	Review Quality Plan	QM	Eurotherm SEP109 (meets GAMP5 App M9)	
A3.3	Approve Quality Plan	(customer)	(customer)	

4.2 Specification Phase

Ref	Activity	Responsibility	Controlling Procedure	Status
B1.1	Generate Functional Specification (FS)	PM, LE	Eurotherm SEP109 (meets GAMP5 App D2)	
B1.2	Review FS	R	Eurotherm SEP109 (meets GAMP5 App M9)	
B1.3	Approve FS	(customer)	(customer)	
B2.1	Generate Hardware Design and Configuration Specification (HDS) including drawing package for any custom hardware	PM, LE, DO	Eurotherm SEP109 (meets GAMP5 App D3)	
B2.2	Review HDS	R	Eurotherm SEP109 (meets GAMP5 App M9)	
B2.3	Approve HDS	(customer)	(customer)	
B3.1	Generate Software Design and Configuration Specification (SDS)	PM, LE	Eurotherm SEP109 (meets GAMP5 App D3)	
B3.2	Review SDS	R	Eurotherm SEP109 (meets GAMP5 App M9)	
B3.3	Approve SDS	(customer)	(customer)	
B4.1	Generate Software Module Specifications (SMS) for bespoke items	PM, LE	Eurotherm SEP109 (meets GAMP5 App D3)	
B4.2	Review SMS	R	Eurotherm SEP109 (meets GAMP5 App M9)	

Specimen

Ref	Activity	Responsibility	Controlling Procedure	Status
B4.3	Approve SMS	(customer)	(customer)	
B5	Assist customer with functional risk assessment	PM/LE	(customer)	
B6.1	Generation of overall traceability matrix (TM) - Phase 1 (Design coverage)	PM	Eurotherm SEP109 (meets GAMP5 App M5)	
B6.2	Review TM	R	Eurotherm SEP109 (meets GAMP5 App M9)	
B6.3	Approve TM	(customer)	(customer)	

4.3 Configuration and Coding Phase

Ref	Activity	Responsibility	Controlling Procedure	Status
C1.1	Order Hardware	PM/LE	Eurotherm SEP104, local purchasing.	
C1.2	Build Eurotherm Product	Eurotherm Production	Eurotherm Production Procedures	
C1.3	Receive bought-in product	LE	Eurotherm SEP104, local goods inward procedures.	
C1.4	Build Bespoke hardware (e.g. cubicles)	LE + sub contract supplier	Eurotherm SEP104	
C2.1	Produce configuration management schedules	LE/PE	Approved quality plan	
C2.2	Produce Software	LE/PE	Eurotherm SEP105/SEP106 (meets GAMP5 App D5)	

4.4 Verification Phase

Ref	Activity	Responsibility	Controlling Procedure	Ststus
D1	Code Review (standard Eurotherm review proforma)	R	Eurotherm SEP106 (meets GAMP5 App D4)	
D2.1	Generate Software Module Test Specifications (SMTS) for bespoke items	PM, LE	Eurotherm SEP109 (meets GAMP5 App D5)	
D2.2	Review SMTS	R	Eurotherm SEP109 (meets GAMP5 App M9)	
D2.3	Approve SMTS	(customer)	(customer)	
D2.4	Execute Software Module Test against SMTS	PM/LE	Approved Test Specification	
D2.5	Review Software Module Test Results	R	Approved Test Specification	
D3	System Integration	PE	Manufacturer's instructions and manuals	
D4.1	Generate Factory Acceptance Test Specification (FATS) - Phase 1 (hardware tests) - Phase 2 (functional tests)	PM, LE	Eurotherm SEP109 (meets GAMP5 App D5)	

Specimen

Ref	Activity	Responsibility	Controlling Procedure	Ststus
D4.2	Review FATS	R	Eurotherm SEP109 (meets GAMP5 App M9)	
D4.3	Approve FATS	(customer)	(customer)	
D4.4	Integrated Test (Internal) against FATS	PM/LE	Approved Test Specification	
D4.5	Review Integrated Test Results	R	Approved Test Specification	
D4.6	Factory Acceptance Test against FATS - Phase 1 (installation tests) - Phase 2 (functional tests)	PM, LE, customer witness	Approved Test Specification	
D4.7	Review Factory Acceptance Test Results	Customer reviewer	Approved Test Specification	
D5	Ship to site	LE	Eurotherm SEP104	
D6	Installation	(customer)	Manufacturer's instructions and manuals	
D7.1	Generate Site Acceptance Test Specification (SATS) - Phase 1 (installation tests) - Phase 2 (functional tests)	PM, LE	Eurotherm SEP109 (meets GAMP5 App D5)	
D7.2	Review SATS	R	Eurotherm SEP109 (meets GAMP5 App M9)	
D7.3	Approve SATS	(customer)	(customer)	
D7.4	Site Acceptance Test against SATS - Phase 1 (installation tests) - Phase 2 (functional tests)	SE + customer witness	Approved Test Specification	
D7.5	Review Site Acceptance Test Results	Customer reviewer	Approved Test Specification	
D8	Loop Calibration	(customer)	(customer)	
D9.1	Generation of overall traceability matrix (TM) - Phase 2 (Test coverage)	PM	Eurotherm SEP109 (meets GAMP5 App M5)	
D9.2	Review TM	R	Eurotherm SEP109 (meets GAMP5 App M9)	
D9.3	Approve TM	(customer)	(customer)	

4.5 Reporting Phase

Ref	Activity	Responsibility	Controlling Procedure	Status
E1.1	Generate system final documentation - 'as built' design documents - technical manual containing bill of materials, 'as built' configuration management schedules	PM, LE	Eurotherm SEP109	
E1.2	Review 'as built' documentation	R	Eurotherm SEP109 (meets GAMP5 App M9)	
E1.3	Approve 'as built' documentation	(customer)	(customer)	

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Ref	Activity	Responsibility	Controlling Procedure	Status
E2	Provide training	Eurotherm training officer	As defined in customer order	
E3.1	Generate final quality report and handover checklist	PM	Eurotherm SEP109 (meets GAMP5 App M7)	
E3.2	Review final quality report handover checklist	QM	Eurotherm SEP109 (meets GAMP5 App M9)	
E3.3	Approve final quality report handover checklist	(customer)	(customer)	
E4	Assist customer with review of residual risks	PM/LE	(customer)	
E5	Archive documentation and configurations	LE	Eurotherm SEP108	

4.6 Ongoing Operation Phase

TBA: Explanatory note (delete this before publication): -
Fill in as either 'Completed' or 'None Required' or detail of current status

Ref	Items to be considered	Status
4.6	Have spares been ordered and delivered?	
4.6	Has a maintenance contract been purchased	

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5. SUPPORTING ACTIVITIES

TBA: Explanatory note (delete this before publication): -
Fill in as either 'Completed as per Quality Plan' or detail any deviations from that plan:

Ref	Items to be considered	Status
5.1.1	Design Review	
5.1.2	Traceability	
5.2	Change management	
5.3	Configuration management	
5.4.1	Document management	
5.4.2	Documentation deliverables	
5.5	Subcontractor control	

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6. CLOSURE OF VERIFICATION ACTIVITIES

6.1 Code Review

TBA: Explanatory note (delete this before publication): -
List all category 5 (bespoke) modules and complete the table
Status should be completed as either 'Accepted' or 'Not Accepted' and give details of outstanding actions

Bespoke Module	Code review required?	Code review completed?	Number of actions raised?	All actions closed down?	Status / Outstanding Actions

6.2 Structural Testing Phases

TBA: Explanatory note (delete this before publication): -
List all category 5 (bespoke) modules and complete the table
Status should be completed as either 'Accepted' or 'Not Accepted' and give details of outstanding actions

Bespoke Module	Module test required?	Module test completed?	Number of incidents raised?	All incidents closed down?	Status / Outstanding Actions

6.3 Functional Testing Phases

TBA: Explanatory note (delete this before publication): -
List all functional test phases (Integrated, FAT, SAT, etc) and complete the table
Status should be completed as either 'Accepted' or 'Not Accepted' and give details of outstanding actions

Test Phase	Test phase completed?	Number of incidents raised?	All incidents closed down?	Status / Outstanding Actions

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7. HANDOVER CHECKLIST

7.1 Deliverables

Items to be considered	Status
Has all system hardware been shipped / installed?	
Has all hardware certification (CE certificates, calibration certificates, etc) been supplied?	
Have manufacturer's manuals and instruction sheets for all hardware been supplied?	
Have spares been ordered and delivered?	
Has a maintenance contract been purchased?	
Has any training purchased as part of the contract been carried out?	
Have all live documents been issued at 'as built' status?	
Have all standard software package installation media been supplied?	
Have all appropriate software licences been supplied?	
Have all application-specific software modules been returned to the master repository and tagged for release?	
Has an up-to-date configuration environment schedule been supplied?	
Has an up-to-date configuration management schedule been supplied?	
Has a copy of the 'as released' baseline details been supplied?	
Has a copy of all controlled files been supplied on CD or DVD?	
Has a copy of all controlled files been retained at Eurotherm?	

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7.2 Known Errors

(insert details of any outstanding test incident reports or other known problems)

7.3 Work-Arounds Applied

(insert details of any work-arounds currently applied)

7.4 Pending Change Requests

(insert details of any outstanding change requests)

8. GLOSSARY

TBA: Explanatory note (delete this before publication): - add any other abbreviations or project-specific terms

ATEX	The abbreviation ATEX is derived from the French term "Atmospheres Explosibles" and covers two European Union Directives: 94/9/EC and 1999/92/EC.
FAT	Factory Acceptance Test
GAMP	GAMP 5 A Risk Based Approach to Compliant GxP Computerized Systems
GxP Compliance	Meeting all applicable pharmaceutical and associated life-science regulatory requirements
IQ	Installation Qualification at customer's premises
OQ	Operational Qualification at customer's premises
PQ	Performance Qualification at customer's premises
SAT	Site Acceptance Test
SEP	Eurotherm Systems Engineering Procedure
SOP	Standard Operating Procedure
URS	User Requirements Specification

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Title	Double-click HERE and type Project Title
Customer	Double-click HERE and type Customer Name
Eurotherm Reference	Double-click HERE and type Eurotherm Reference
Customer Reference	Double-click HERE and type Customer Reference
Original Project Reference	Double-click HERE and type Original Project Reference(s)

Explanatory note (delete this before publication):
1) enter all fields above plus date and issue number below
2) search for 'TBA' to find items which need entering on a per-project basis.
3) if not based in the UK, replace the header with the appropriate one from your local letterhead

SCOPE OF UPGRADE

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Prepared by	..... Sign / Date	..... Printed Name	..... Title
Technical Review by (Eurotherm)	..... Sign / Date	..... Printed Name	..... Title
Technical Approval by (Customer) Approved for use as Basis for Upgrade Activities	..... Sign / Date	..... Printed Name	..... Title
Quality Approval by (Customer) Approved for use as Basis for Upgrade Activities	..... Sign / Date	..... Printed Name	..... Title
Issue	Enter Issue No		
Date	Enter Date		

CONTROLLED CIRCULATION		
Copy	Issued to	**This Copy**
Master	Double-click HERE and type Customer Name	
Copy 1	Project File	

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CONTENTS

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1. DOCUMENTATION RECORDS

TEMPLATE DETAILS			
HISTORY:			
T1	Template document created to cover GAMP5 5 approach to operational change management		19 Jun 2008
APPROVAL DETAILS FOR CURRENT TEMPLATE			
Template prepared by	Karen Ashworth	Validation Officer	19 Jun 2008
Template reviewed for Technical Content	Malek Madani	Technical Manager	19 Jun 2008
Template reviewed for Quality Assurance	Martin Greenhalgh	Global Quality Manager	19 Jun 2008

DOCUMENT REVISION HISTORY		
Issue	Detail	Issue Date
1a	Project version 1 developed from template T1 and issued for internal review	TBA Enter Issue Date

TBA Explanatory note (delete this before publication):
Once internal review is complete, an additional entry needs to be made for version 1 saying something like 'Internal review comments included. Document issued for customer approval'
All subsequent issues (eg version 2) need to detail the changes which have been made including the section reference and the reason for the change (eg ref to customer comment). When creating a new version: accept all previously tracked comments; make changes with change tracking enabled; hide mark-up (in the VIEW menu) before printing or issuing the document.

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2. INTRODUCTION

TBA: Explanatory note (delete this before publication): this document is designed for the sort of minor upgrades often done by field service engineers or as a small project – upgrading firmware, adding an I/O card for example.

It is not suitable for major system changes involving additions or changes to bespoke functionality. These should be treated as projects in their own right with the full GAMP lifecycle to be followed set out in a Quality Plan.

2.1 Purpose

A Scope of Upgrade document seeks to set out the necessary information to allow an end user to accept or reject a proposed change to an operational system.

2.2 Scope

This document defines the scope of upgrade on the control system required by Double-click HERE and type Customer Name for their Double-click HERE and type Project Title Project.

2.3 Contractual Status

Although documented using a Eurotherm template, the risk assessment process in section 4 remains the responsibility of the end user.
This document, once approved, provides the basis for upgrade activities. On project completion, this document passes to the customer for archiving.

2.4 Relationship to Other Documents

2.4.1 Applicable Standards

This document has been written to meet the guideline for operational change management contained in GAMP5 A Risk-Based Approach to Compliant GxP Computerized Systems Appendix O6.

2.4.2 Relationship to Original System Documentation

The project references for the original system are Double-click HERE and type Original Project Reference(s). Documentation requiring updating as a result of the upgrade is detailed in section 3.3.

2.4.3 Definition of Requirements for Upgrade

TBA: Explanatory note (delete this before publication):
If the upgrade is a bug fix, there should be some sort of a fault or incident report which can be referenced rather than a requirements document
Customer requirements for the upgrade are listed in the following documents:

Project / Document Ref	
Title	
Issue	

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3. UPGRADE SCOPE

3.1 Justification for Upgrade

TBA: Explanatory note (delete this before publication):
Explain why the upgrade is needed (to get new functionality? to fix a bug?)

3.2 Scope of Changes to System

3.2.1 Changes to System Hardware Architecture

TBA: Explanatory note (delete this before publication):
Include hardware architecture drawings if appropriate (probably available in the original system documentation) highlighting the items which will be modified

3.2.2 Changes to System Software Architecture

TBA: Explanatory note (delete this before publication):
Include software architecture drawings if appropriate (probably available in the original system documentation) highlighting the items which will be modified

3.2.3 New or Changed Functionality

TBA: Explanatory note (delete this before publication):
Detail the changes to the functionality taking out subheadings if required

3.3 Scope of Documentation Changes

3.3.1 Design and System Documentation

TBA: Explanatory note (delete this before publication):
List the document updates which will be needed
Consider
- *Design docs such as FS/SDS/SMS*
- *Standard manuals for upgraded firmware / packages*
- *System documentation such as configuration schedule / configuration environment / bill of materials*

Document Title	Initial Version	Detail of Changes	Responsibility

3.3.2 Test Documentation

TBA: Explanatory note (delete this before publication):
Normally this will be against a new test protocol created for the upgrade (if so state this and give document details)
If it is regression tests only and therefore against previously defined tests, give details of the test protocols which are to be used)

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4. RISK ASSESSMENT AND RESULTING RETEST REQUIREMENTS

TBA: Explanatory note (delete this before publication):
Within GAMP5, it is made quite clear that the risk management process has to be owned by the end user – after all, only they can know the impact of each function on product quality / patient safety. A customer SHOULD, therefore, already have the risk management process underway and be able to provide impact ratings for affected system functions (if the original project was done to GAMP5 then this information for existing functions should already be in available) .

4.1 Risk Assessment Methodology

The risk assessment process follows the GAMP5 model with impact, likelihood and probability of detection graded as follows:

IMPACT takes the highest rating from the following:

Impact on patient safety	High = potential for serious injury / health effect or death Medium = potential for minor injury / health effect Low = potential for customer dissatisfaction
Impact on product quality	High = potential for release of product which would cause serious injury to a patient Medium = potential for release of product which would cause minor injury to a patient Low = potential for poor quality product which would not be released or would not cause harm to patient
Impact on data integrity	High = loss of data integrity such that product recall could not be carried out or release could be made of product which would cause serious injury to a patient Medium = loss of data integrity such that release could be made of product which would cause minor injury to a patient Low = loss of data integrity such that product would need to be scrapped or data records not essential to product release or recall might be lost or impaired

LIKELIHOOD is rated according to the type of system component performing the function:

Likelihood	High = function performed by bespoke software Medium = function performed by configured software or bespoke hardware Low = function performed by standard software or hardware

PROBABILITY OF DETECTION is rated as follows:

Probability of Detection	High = automatically detected via an independent / interlock or subject to 100% external check Medium = easily identified by an operator or has an alarm which is not independent of the controls or subject to a sample check Low = unlikely to be identified by an operator or by external checks

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These ratings are combined as follows:

First the impact (severity) and likelihood are combined to give a risk class:

High Impact	Risk Class 2	Risk Class 1	Risk Class 1
Medium Impact	Risk Class 3	Risk Class 2	Risk Class 1
Low Impact	Risk Class 3	Risk Class 3	Risk Class 2
	Low Likelihood	Medium Likelihood	High Likelihood

Then the risk class and probability of detection are combined to give the overall risk priority:

Risk Class 1	High Risk Priority	High Risk Priority	Medium Risk Priority
Risk Class 2	High Risk Priority	Medium Risk Priority	Low Risk Priority
Risk Class 3	Medium Risk Priority	Low Risk Priority	Low Risk Priority
	Low Probability of Detection	Medium Probability of Detection	High Probability of Detection

The output of the risk assessment process (risk priority) is used to decide upon appropriate controls, in the case of an upgrade these will normally be an appropriate level of verification activities after the upgrade is complete.

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4.2 Risk Assessment Results

TBA: Explanatory note (delete this before publication):
The end user quality department will have to be involved in providing the information for this section

TBA: Explanatory note (delete this before publication):
Note that the embedded excel table doesn't split across pages very well. Cut and paste it to create a new table for each new page.
Consider things like

- *Loop no longer in calibration*
- *Ethernet or other communications wiring not connected or wrongly connected*
- *Incorrect installation of new hardware item*
- *Incomplete or failed upgrade of any standard packages or firmware*
- *New version of firmware or package has unexpected deleterious effect on current functionality*
- *Incorrect setup parameters entered*
- *Incorrect configuration of new or changed configured function*
- *Incorrect coding of new or changed bespoke function*
- *Failure of data migration*

Risk Ref	Scenario	Worst case effect	Current controls	Impact	Likeli-hood	Prob of Detectn	Risk Priority	Recommended controls
							#N/A	
							#N/A	
							#N/A	
							#N/A	
							#N/A	
							#N/A	
							#N/A	
							#N/A	
							#N/A	

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5. METHOD OF IMPLEMENTATION

5.1 Preparation of Upgrade

5.1.1 Pre-Work (Hardware)

TBA: Explanatory note (delete this before publication):
Consider:

- *Is any project hardware being provided by the customer (eg free issue PCs, use of spares belonging to the customer, etc)?*
- *Do any items need to be free issued to make up a test rig?*
- *New items of project hardware to be purchased (do versions need to match existing?)*
- *Items needed to make up a test rig (what versions are needed?)*
- *What test equipment needs to be supplied and by whom? (calibrated?)*
- *What consumables need to be supplied and by whom?*
- *Wiring in of new equipment or signals?*
-

Ref	Activity	Detail	Responsibility

5.1.2 Pre-Work (Software)

TBA: Explanatory note (delete this before publication):
Consider:

- *Does the customer need to supply any project software? If so, how are configurations controlled by the customer? How will they be handed over such that Eurotherm own the master copy whilst modifications are done? How will these configurations be controlled whilst in Eurotherm's possession? How will they be handed back?*
- *What test software / simulations are to be provided and by whom?*
- *What programming tools are to be provided and by whom?*
- *What new firmware / standard packages (or versions) are to be provided and by whom?*
- *Are any licences needed and who is providing them?*
- *What items of project software need modifying or creating?*

Ref	Activity	Detail	Responsibility

5.1.3 Pre-Work (Data)

TBA: Explanatory note (delete this before publication):
Consider:

- *Does customer need to provide sample data for testing migration paths*
- *Does customer need to provide samples of reports / trends / alarm prints / audit trail prints from before upgrade to allow comparison afterwards*

Ref	Activity	Detail	Responsibility

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5.1.4 Pre-Work (User Accounts)

TBA: Explanatory note (delete this before publication):
Consider:
- *How Eurotherm engineer is going to get access to the system on site*
- *How Eurotherm engineer is going to get access to any PC hardware brought away for modification*
- *How Eurotherm engineer is going to get access to any configurations brought away for modification*

Ref	Activity	Detail	Responsibility

5.1.5 Pre-Work (Documentation)

TBA: Explanatory note (delete this before publication):
Consider:
- *Who currently owns masters of documents?*
- *Which documents need updating and by whom?*

Ref	Activity	Detail	Responsibility

5.1.6 Pre-Work (Testing outside the Production Environment)

TBA: Explanatory note (delete this before publication):
What testing is going to be done in advance of installation? (This can be quite high level and reference a test protocol document for the details)
- *Testing on a test rig? Witnessed?*
- *Will it create any data that needs to be removed before transferring to the production environment?*
- *Will it involve any temporary modifications that need to be removed before transferring to the production environment?*

Ref	Activity	Detail	Responsibility

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5.2 Installation of Upgrade

5.2.1 Pre-Requisites for Installation

TBA: Explanatory note (delete this before publication):
- *What state does the plant need to be in?*
- *How long for?*
- *Who is responsible for ensuring backups are available?*
- *Who is responsible for ensuring data is archived?*
- *Are there any other (conventional) safety precautions needed*

Ref	Activity	Detail	Responsibility

5.2.2 Installation Method

TBA: Explanatory note (delete this before publication):
This should be a step by step list suitable for an engineer to follow on site.
Don't forget that it may need to start by ensuring that backups are in place and data has been archived.

Ref	Activity	Detail	Responsibility

5.2.3 Post-Installation Testing

TBA: Explanatory note (delete this before publication):
What is going to be done after installation? (This can be quite high level and reference a test protocol document for the details)
- *Witnessed?*
- *Will it create any data that needs to be removed before handover?*
- *Will it involve any temporary modifications that need to be removed before handover?*

Ref	Activity	Detail	Responsibility

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5.3 Back-Out and Disaster Recovery

TBA: Explanatory note (delete this before publication):
What is the 'plan B' if the upgrade doesn't work?

Specimen

6. GLOSSARY

TBA: Explanatory note (delete this before publication): - add any other abbreviations or project-specific terms

GAMP	GAMP 5 A Risk Based Approach to Compliant GxP Computerized Systems
GxP Compliance	Meeting all applicable pharmaceutical and associated life-science regulatory requirements

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APPENDIX A – CROSS-REFERENCE TO CUSTOMER UPGRADE REQUIREMENTS DOCUMENTATION

TBA: Explanatory note (delete this before publication): -
THIS CAN BE REMOVED IF THIS IS A BUG FIX AND THERE IS THEREFORE NO CUSTOMER REQUIREMENT DOCUMENT.
Otherwise, the following tables need to be completed in order to demonstrate that the customer's requirements have been met.
Any non-compliance should be highlighted in the table
Where a section includes no relevant requirements, this should be made clear

An example is shown below

(The easiest way to create these tables is via a Microsoft Access database – create separate tables for each document and then create additional tables containing just a list of links between two documents. A query can then be used to export the data in the appropriate order)

URS Ref	GxP?	Impact Rating	URS Heading	Scope of Upgrade Ref

Scope of Upgrade Ref	Scope of Upgrade Heading	URS Ref	GxP?	Impact Rating

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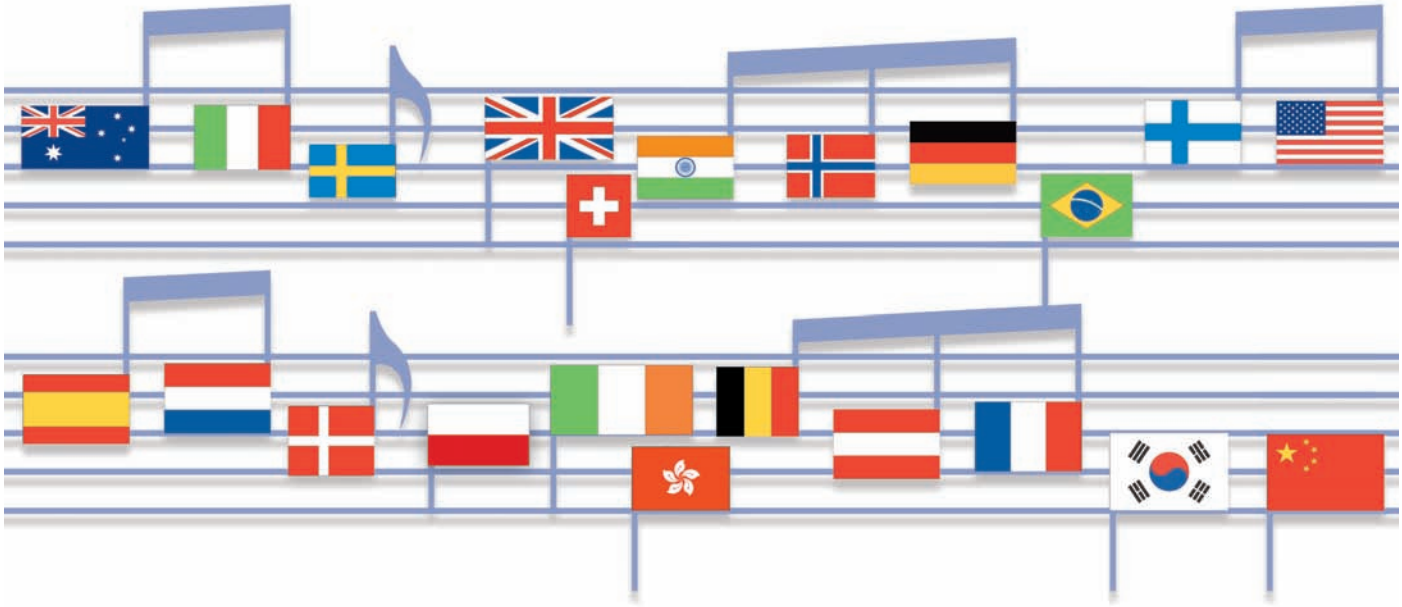
Understanding and providing local support is a key part of Eurotherm business. Complementing worldwide Eurotherm offices are a whole range of partners and a comprehensive technical support team, to ensure you get a service you will want to go back to.



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ED57

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