Software Product: F26 Temperature According to ITS-90

References and annexes

All external documents (if any) must be dated and signed.

	Document Name	*Filename*
1	Risk Analysis	*Risk_Analysis_F26_Temperature*
2	Validation Plan	*Validation_plan_F26_Temperature*
3	Software Requirement Specification	*SRS_F26_Temperature*
4	Software Design Specification	*SDS_F26_Temperature*
5	System test Plan/Report	*System_test_F26_Temperature*
6	System test – Error reports	*Error_report_1, 2 and 3*
7	Acceptance test Plan/Report	*Acceptance_test_F26_Temperatue*
8	System Documentation	*System_documentation_F26_Temperature*
9	Validation Report	*Validation_report_F26_Temperature*
10	Software Design Document - Note 1)	*SDD_F26_Temperature*

Note 1) The Software Design Document is not entirely included (too large).

In order to to make the Appendices easier accessible, they are copied into this document, which is the primary appendix to the main validation report file:

Gambro Nordtest – F26 ITS90 1.0 Report.doc

In a local environment it could be easier to retain the original document files as dynamic links.

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Appendix 1 Risk analysis

Risk analysis

for

F26 Temperature According to ITS-90

Prepared by

Name:	*Project function:*	*Date:*	*Signature:*
Carl Tillman	Validation Manager		

Reviewed by

Name:	*Project function:*	*Date:*	*Signature:*
	Project Manager		

Approved by

Name:	*Project function:*	*Date:*	*Signature:*
Evert Håkansson	System Owner		
Name:	*Project function:*	*Date:*	*Signature:*
Christer Magnusson	Quality Assurance		

Revision History

Version:	*Date:*	*Revised by:*	*Comments:*
1		Carl Tillman	First issue.
Version:	*Date:*	*Revised by:*	*Comments:*
Version:	*Date:*	*Revised by:*	*Comments:*

1 Categorizing the software

Category 1 ☐ (1 p) Category 2 ☐ (3p) Category 3 ☒ (5p)

Comments: *Software is developed by Gambro Lundia AB.*

2 Interaction with other Software

2.1 Input from other software

None ☐ (1p) Some ☒ (2p) Large ☐ (3p)

2.2 Output to other software

None ☒ (1p) Some ☐ (2p) Large ☐ (3p)

Comments: *Input from operator and from the measuring device. Output to operator only.*

3 Impact

3.1 Product quality

	High probability	Medium probability	Low probability
High impact	☐9p	☐6p	☒4p
Medium impact	☐6p	☐4p	☐2p
Low impact	☐3p	☐2p	☐1p

Comments: *It is considered to be low probability for the software to calculate temperatures wrongly, although the impact is high since instrument will then not be correctly calibrated.*

3.2 Regulatory impact

	High probability	Medium probability	Low probability
High impact	☐9p	☐6p	☐4p
Medium impact	☐6p	☐4p	☐2p
Low impact	☐3p	☐2p	☒1p

Comments: *This is a technical system with limited regulatory impact.*

4 Possibility to detect error

High ☐(1p) Medium ☒(2p) Low ☐(3p)

Comments: *The software contains some error handling, although it cannot determine whether correct temperatures are displayed.*

5 Total risk

Use the formula: 1. + 2.1 + 2.2 + (3.1 + 3.2) × 4. to calculate the risk

We have: 5 + 2 + 1 + (4 + 1) × 2 = **18**

5	**X**	**65**

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Appendix 2 Validation Plan

Validation plan

for

F26 Temperature According to ITS-90

Prepared by

Name:	*Project function:*	*Date:*	*Signature:*
Carl Tillman	Validation Manager		

Reviewed by

Name:	*Project function:*	*Date:*	*Signature:*
	Project Manager		

Approved by

Name:	*Project function:*	*Date:*	*Signature:*
Evert Håkansson	System owner		
Christer Magnusson	Quality assurance		

Revision History

Version:	Date:	Revised by:	Comments:
1		Carl Tillman	First issue.
Version:	Date:	Revised by:	Comments:
Version:	Date:	Revised by:	Comments:

Table of contents

1 Introduction

The software “F26 Temperature According to ITS-90” version 1.0 displays values of temperatures measured with a platinum resistance thermometer attached to a resistance bridge. This system forms the primary temperature standard at Gambro Lundia AB.

The software is developed (custom made) and used by personnel from the Calibration Group. Therefore no Supplier Qualification will be made.

2 Roles and responsibilities

2.1 Validation Team

Role	Name	Abbreviation
System Owner	Evert Håkansson	seevha
Quality Assurance	Christer Magnusson	sechma
Validation Manager	Carl Tillman	secati

Validation Team	Lars-Göran Andersson, Kenneth Bengtsson	selran, sekebe
Development Manager	Lars-Göran Andersson	selran
Development Team	N/A	
Project Manager	N/A	

2.2 Responsibilities of the Validation Group members

The individual roles responsibilities are defined in SOP 1540 “Validation of administrative and technical software”. The Validation Team members are also responsible for the following:

- Attending Validation Team meetings.
- Contributing to/creating and reviewing/approving computer validation documentation.
- Ensuring compliance with the Validation Plan, throughout the validation process.
- Communicating go/no go recommendations.

3 Validation Approach

3.1 Assumptions

It is assumed that the ASL F26 and the Pt-25 comply with their technical specifications.

It is assumed that the latest Pt-25 calibration report from SP is technically correct.

3.2 Scope

The purpose of the validation effort is to ensure that the software is validated in accordance with SOP-1540.

3.3 Dependencies

The validation is dependent on that the hardware is functioning, as some tests can only be made on the system as a whole.

4 Test

4.1 System Test Plan / Report

The system test will be conducted against the *Software Design Specification for F26 Temperature According To ITS-90*.
The results of system testing will be documented in the *System test Plan / Report for F26 Temperature According To ITS-90*.

4.2 Acceptance Test Plan / Report

The system test will be conducted against the *Software Requirements Specification for F26 Temperature According To ITS-90*.

The results of acceptance testing will be documented in the *Acceptance test Plan / Report for F26 Temperature According To ITS-90*.

5 System Acceptance Criteria

The system will be considered as validated when all criteria in the SRS and the SDS are fulfilled and all validation documents have been approved.

6 Validation Documents

Phase	Documents	Responsibility			
		N/A	Prepared by	Reviewed by	Approved by
Concept	Risk Analysis		secati	PM	SO /QA
	Validation Plan		secati	PM	SO /QA
Requirement	System Requirement Specification		secati	PM	SO
	Acceptance Test *Plan* / Report		secati	PM	SO
Design and/or	System Design Specification		secati	PM	Dev
Purchase	System test *Plan* /Report		secati	PM	Dev
Implementation	System Documentation		secati	PM	Dev
	System test Plan / *Report*		secati	PM	Dev
	Error report (System)		secati	PM	Dev
	Installation Manual	N/A		PM	Dev
	User Manual	N/A		PM	Dev
Test	Acceptance Test Plan / *Report*		secati	PM	SO
	Error report (Acceptance)		secati	PM	SO
Preparation for Maintenance	Validation Report		secati	PM	SO /QA

Table 1 - Validation documents and roles responsibility
SO System Owner *QA Quality Assurance*
PM Project Manager *Dev Development Manager*

No separate Installation Manual will be produced. Instructions for installation will be included in the *System Documentation for F26 Temperature According to ITS-90*.

No separate User Manual will be produced. The software contains some help texts and users are assumed to be able to operate the software without specific instructions, see section 8 below.

7 Validation Report

The validation report is the summary of all test results. The Validation Group will also provide recommendations to accept/reject the software, based on the acceptance criteria.

8 Training and Rollout Strategy

All users will be staff at the Calibration Group, assumed to have adequate computer knowledge
to install and use the software without any formal training.

The software and hardware are expected to be retired together. Any future replacement system is likely not to have any need for external ITS-90 computations.

9 System Maintenance

The software F26 Temperature will be covered by the Change control described in POP-1771 .

10 Document Maintenance

The Validation documents will be stored and version controlled according to SOP-1540.

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Appendix 3 **Software Requirement Specification**

Software Requirement Specification

for

F26 Temperature According to ITS-90

Prepared by

Name:	*Project function:*	*Date:*	*Signature:*
Carl Tillman	Validation Manager		

Reviewed by

Name:	*Project function:*	*Date:*	*Signature:*
	Project Manager		

Approved by

Name:	*Project function:*	*Date:*	*Signature:*
Evert Håkansson	System owner		

Revision History

Version:	Date:	Revised by:	Comments:
1		Carl Tillman	First issue.
Version:	Date:	Revised by:	Comments:
Version:	Date:	Revised by:	Comments:

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1 Introduction

This document is divided into two primary sections, the Overview section and the User and Functional Requirements section. The Overview section describes the Product Perspective, General Constraints, and Assumptions and Dependencies. The User and Functional Requirements section describes the User Requirements and the Functional Requirements for the system. It also describes External Interface Requirements, Performance Requirements, Design Constraints, Attributes and Other Requirements.

The references and definitions are described in SOP-1540.

2 Overview

2.1 System Perspective

The software “F26 Temperature According to ITS-90” version 1.0 displays momentary values of temperature measured with a platinum resistance thermometer attached to a resistance bridge. This system forms the primary temperature standard at Gambro Lundia AB.

The software is developed and used by personnel from the Calibration Group.

Definitions and acronyms
The following definitions and acronyms are used in the validation documents for this software:

F26
A resistance measuring bridge, manufactured by Automatic Systems Laboratories, ASL.
The F26 is equipped with a GPIB interface.

GPIB, General Purpose Interface Bus
The standard bus used for controlling electronic instruments with a computer. Also called
IEEE 488 bus, defined by ANSI/IEEE Standards 488-1978, 488.1-1987 and 488.2-1992.

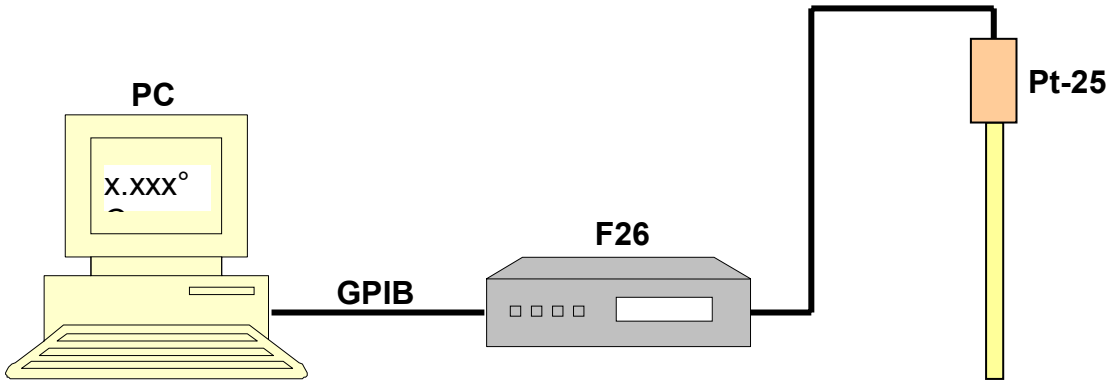
ITS-90, The International Temperature Scale of 1990
Defines procedures by which certain specified practical thermometers can be calibrated in such a way that the values of temperature obtained by them can be precise and reproducible.
Platinum resistance thermometers are specified for use from 13,8033 K up to 962,78°C.

LabVIEW, Laboratory Virtual Instrument Engineering Workbench
A graphical programming language using icons instead of lines of text as source code.

Pt-25
A platinum resistance thermometer of the highest quality. A Pt-25 has a nominal resistance of
25 ohm at 0°C.

2.1.1 General architecture

Pt-25 resistance values are read via GPIB from a F26. The ITS-90 temperature corresponding to the resistance is calculated and displayed on screen.



The formula for calculating temperatures is depending on two coefficients **a** and **b**. These coefficients have different values for temperatures <0.01 °C and >0.01 °C respectively.

2.1.2 General Constraints

If ITS-90 is replaced or updated the software must be examined for agreement with the new standard. Any discrepancy has to be resolved by update of the software.

2.2 Assumptions and Dependencies

It is assumed that the users are familiar with the Windows operating system.
It is assumed that the GPIB hardware and software is properly functioning.
It is assumed that all original user data and probe data is recorded on paper, and hence there is no need for backup of any electronic information handled by the software.
It is assumed that for the acceptance test of correct calculation of temperatures it is sufficient with two test points; one for a temperatures <0.01 °C and the other for a temperature >0.01 °C

3 User and Function Requirements

3.1 Interface

The software shall be possible to run on a PC with the following configuration:

- Pentium compatible PC
  - 100 MHz or higher
  - 32 MB RAM or more
  - 100 MB free space on hard drives or more
- Windows 95
- Pre-installed GPIB hardware and software from National Instruments.
- Pre-installed LabVIEW Run-TIME Engine 6.1 or higher versions.

User interface

- The user shall be able to work with the software through a graphical user interface.
- Help texts shall be displayed when the mouse pointer is above input and output objects in the interface.

3.1.1 Input

Pt-25 data

The following information shall be stored for registered Pt-25 thermometers:

Label	***Description***	***Type / format***	***Length / precision***	***Interval***
ID number	Gambro's internal ID-number.	Text	>= 4	
Calibration date	Date for last calibration.	Date YYYY, MM, DD		YYYY: 2000-2040 MM: 1-12 DD: 1-31
Certificate number	Latest certificate number from SP.	Text	10	
R0.01	Resistance at the triple point for water, 0.01°C.	Numeric / Float	5 decimals	
a(t>0.01°C)	ITS-90 coefficient	Numeric / Scientific	5 decimals	
b(t>0.01°C)	ITS-90 coefficient	Numeric / Scientific	5 decimals	
a(t<0.01°C)	ITS-90 coefficient	Numeric / Scientific	5 decimals	
b(t<0.01°C)	ITS-90 coefficient	Numeric / Scientific	5 decimals	

For the numeric data, the value range covered by standard variables in LabView is more than enough. Hence there are no further requirements with respect to value range.

User profile

The following information shall be stored for a registered user:

Label	***Description***	***Type / format***	***Length / precision***	***Other***
Name in full	First name and family name.	Text	>= 20	
User name	Unique user code.	Text	>= 10	
Password	User password.	Text	>= 12	
Operator level	Pre-defined user levels that can be chosen from a list.	List		Pre-defined levels: - Administrator - Technician - Operator

GPIB data

The software shall be able to read resistance data from the F26.

3.1.2 Output

The software shall present the following data:

- Temperature
  - The software shall present calculated temperatures with 4 decimals.
- Resistance
- User's first name and family name
- Pt-25 data
  - The software shall present calibration data for chosen Pt-25 thermometer.
- User guidance
  - 'Tip strips' (help texts displayed when hovering the mouse over objects) shall be used where appropriate.

3.2 Functions

The software shall support the following functionality:

1. Manage data for user profiles
2. Manage data for Pt-25 thermometers.
3. Calculate temperatures according to ITS-90

The software shall be able to calculate temperatures correctly in the range -40°C to +290° C.

3.3 Performance / Constraints

3.3.1 Performance Requirements

The software shall have the capacity to manage simultaneously:

- Calibration data for up to 3 Pt-25 thermometers
- User data for up to 5 user accounts

The software shall be able to calculate:

- Temperatures with a repetition rate of 1 Hz or higher

3.3.2 Limitations

N/A

3.3.3 Design Constraints

The software shall be developed with LabVIEW 6.1.

3.4 Security

- The software shall be password protected.
- Users shall be able to log in at 3 different user levels, with access rights at each level according to:

Operator level	*Access to Pt-25 data*	*Access to User profiles*
Operator	Read	No access
Technician	Read/Write	No access
Administrator	Read/Write	Read/Write

- User ID and passwords must not be stored in a format directly readable for humans, e.g. unencrypted text files.

3.5 Alarms

N/A The system is not designed to include any Alarm functions.

3.6 Errors

The software shall communicate errors and warning messages to the user. Situations that shall trigger such messages are:

Errors

- Error in the communication with the F26
- Read / write error for configuration data

Warnings

- Calibration date for chosen Pt-25 has expired
- Calibration date not the latest (there is another Pt-25 with a newer calibration date)

3.7 Other Requirements

N/A

4 Documentation

4.1 User Manuals

No separate User Manual is produced. User Instructions are included in the *System Documentation for F26 Temperature According to ITS-90*.

GAMBRO Renal Products

Appendix 4 **Software Design Specification**

Software Design Specification

for

F26 Temperature According to ITS-90

Prepared by

Name:	*Project function:*	*Date:*	*Signature:*
Carl Tillman	Validation Manager		

Reviewed by

Name:	*Project function:*	*Date:*	*Signature:*
	Project Manager		

Approved by

Name:	*Project function:*	*Date:*	*Signature:*
Lars-Göran Andersson	Development Manager		

Revision History

Version:	Date:	Revised by:	Comments:
1		Carl Tillman	First issue.
Version:	Date:	Revised by:	Comments:
Version:	Date:	Revised by:	Comments:

Table of contents

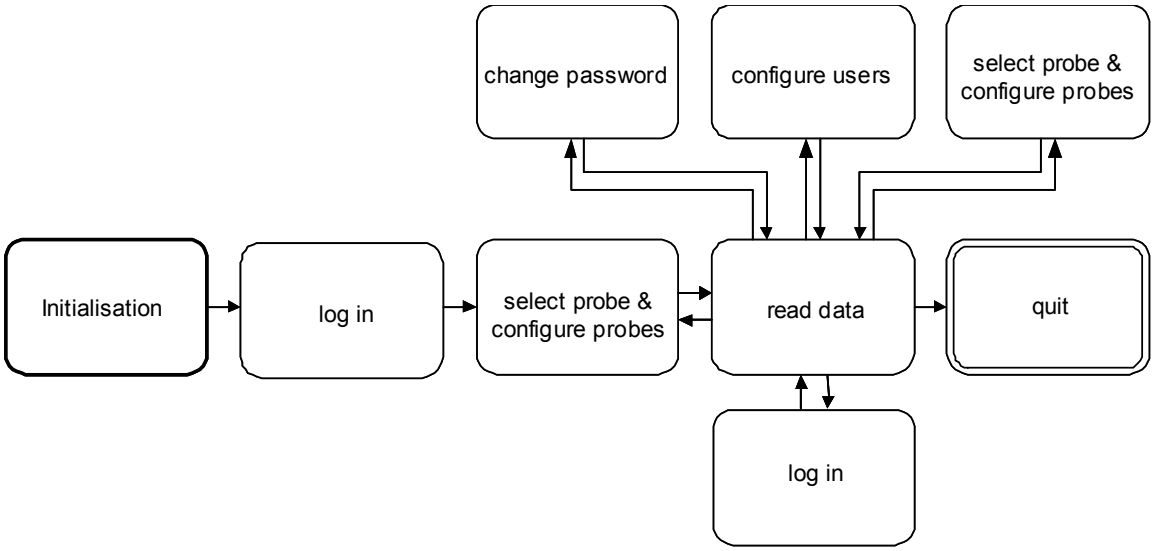
1 Introduction

The software displays momentary values of temperature measured with a platinum resistance thermometer attached to a resistance bridge. This system forms the primary temperature standard at Gambro Lundia AB.

The software is developed and used by personnel from the Calibration Group.

2 Architecture / Interface

The software is based on a program flow as illustrated in the figures below.



Interface

User requirements for input and output data is listed in *SRS for F26 Temperature According to ITS-90*.

Additional design requirements for user communication:

Label	***Input / Output***	***Font / size***	***Colours***
ID number	Input	Arial, 35 points	Black text, light yellow background
Temperature	Output	Arial, 50 points	

The user interface is consists of a main windows always shown in the background, and two further windows that can be activated; a “Select or Edit Pt-25 Probe Data” window and a “Configure Users” window. Each of these windows contains one or more buttons for activation of functionality. In addition to these windows a number of dialog boxes will be shown for e.g. input of passwords or display of warning messages.

References
For further information about the system design and interface see the document *Software Design Document for F26 Temperature According to ITS-90*. This document is an auto generated design description based on the code input in the LabView development environment.

3 Functions

The software shall support the following high-level functionality:

4. Manage data for user profiles
5. Manage data for Pt-25 thermometers.
6. Calculate temperatures according to ITS-90

These functions are further detailed below.

Login / Manage data for user profiles

- At log in the user shall be prompted to enter user name and password in a dialog box.
- If not correct name and password are entered the software shall display an appropriate message and display the login dialog box once again.
- When a user has logged in with Administrator access right he/she shall be able to active “Manage data for user profiles” by clicking a button labelled “Users”.
- When a user has logged in with Operator or Technician access right the button “Users” shall be deactivated, so as he/she shall be able to active.
- Administrator shall be able to create new user accounts.
- Administrator shall be able to delete users registered in the user list.
- Administrator shall be able to update data for any user. This includes all fields; “name in full”, user name”, “password” and “level”.
- It shall not be possible all to erase all users at administrator level, or change the level of the last Administrator to another level. At least one administrator must be left.

- All users shall be able to change password by clicking the button “Password”.
- When changing password the user shall be prompted to enter a new password twice in a dialog box.
- If the two passwords being entered are not identical, or if the password is less than 4 characters in length the software shall display an appropriate message and display the change password dialog box once again.

Manage data for Pt-25 thermometers

- All users shall be able to activate “select probe” by clicking the button “Probe” in the main window.
- All users shall be able to select a probe from the list of registered probes in the “Select or Edit Pt-25 Probe Data” window. When a probe is selected the corresponding data for that probe shall be displayed.
- If a probe is selected the software shall display a warning if the calibration date is expired, see section 7 below.
- If a probe is selected and any other probe is registered with a later calibration data the software shall display a warning, see section 7 below.
- Administrators and technicians shall be able to edit data for any probe. This includes the following data;
  - The calibration date for the latest calibration certificate.
  - Calibration certificate number.
  - The resistance at the triple point of water, R0.01
  - The coefficients a and b for temperatures >0.01°C
  - The coefficients a and b for temperatures <0.01°C
- Administrators and technicians shall be able to create records for new probes by clicking the button “Create”.
- After a new record is created empty data fields shall be displayed and the user shall be able to edit data as above.
- Administrators and technicians shall be able to delete registered probes by clicking the button “Erase”.
- Administrators and technicians shall be able to reset changes by clicking the button “Reset”. This will reset any changes made before confirmation by clicking “OK”.
- Pressing the OK button will save all changes and the software proceeds to the main screen. It is then not possible to Reset any changes.
- When a user is logged in as Operator both buttons “Create” or “Erase” shall be deactivated, and thus not allow new records to be created or old ones to be erased.

Calculate temperatures according to ITS-90

- When no other windows are displayed, other than the main window, the software shall continuously read, calculate temperatures and display temperatures. This is the default mode of the software. For repetition rate see section 3.3.1 in the SRS.
- When the software is executing in default mode (as defined above) any users with a high enough access right shall be able to activate the other functions as described above.

- The software shall calculate temperatures according to the ITS-90. This shall be done by reading resistance values from the F26 and converting them to ITS-90 temperatures by using the inverse reference functions 9b and 10b as well as the deviation functions 12 and 13 defined in ITS-90.

4 Data Architecture / Data Structure

All registered data used by the software shall be stored as an ini-file. This includes all data as specified in section 3.1.1 of the SRS.

User data shall be encrypted so that no login information can be read directly by an individual, i.e. without manipulating the data.

As stated in section 2.2 Assumption in the SRS there is no requirements for any data backup.

5 Security

All requirement for security functionality has been specified in the section 3 Functions above.

6 Alarms

N/A The software does not support any Alarm functions.

7 Error Handling

Error and warning messages shall be presented for the user as messages in dialog boxes. Definition of errors and warnings are as follows:

Cause	***Message***	***Type (Error / Warning)***
Error in the communication with the F26	This is handled by standard functionality in LabView. Therefore no specific requirements for which message to be shown.	E
Problem in reading or writing to configuration file	This is handled by standard functionality in LabView. Therefore no specific requirements for which message to be shown.	E
A Pt-25 is selected with a calibration date that has expired	“Probe is due for calibration”	W
A Pt-25 is selected with a calibration date that isn't the latest among the registered probes.	“Another probe has a later calibration date”	W

The user is required to accept each displayed error/warning message.

8 Installation instructions

See *System Documentation for F26 Temperature According to ITS-90* for installation instructions.

GAMBRO Renal Products

Appendix 5 **System test Plan/Report**

System test Plan/Report

for

F26 Temperature According to ITS-90

Prepared by

Name:	*Project function:*	*Date:*	*Signature:*
Carl Tillman	Validation Manager		

Plan reviewed by

Name:	*Project function:*	*Date:*	*Signature:*
	Project Manager		

Report reviewed by

Name:	*Project function:*	*Date:*	*Signature:*
	Project Manager		

Plan approved by

Name:	*Project function:*	*Date:*	*Signature:*
Lars-Göran Andersson	Development Manager		

Report approved by

Name:	*Project function:*	*Date:*	*Signature:*
Lars-Göran Andersson	Development Manager		

Revision History

Version:	Date:	Revised by:	Comments:
1		Carl Tillman	First issue.
Version:	Date:	Revised by:	Comments:
Version:	Date:	Revised by:	Comments:

Table of contents

1 Introduction

This document is used for the system test of the F26 Temperature and will include both test plan and test results. The requirements from the Software Design Specification have been converted to test cases and test criteria.

The references and definitions are described in SOP-1540.

2 Test environment

The tests were conducted on a PC meeting the requirements stated in the *SRS for F26 Temperature According To ITS-90*, section *User and Function Requirements*.

3 Test results

When the tests are finished, the errors will be reviewed and decision will be taken for actions. Use Error report, Template-1551, for error registrations.

4 Tests

4.1 Installation

Purpose and descriptions
The purpose of this test case is to verify that the software can be installed according to the Installation Manual.

ID	Test description	Expected results	Result (Pass or Fail)	Error Report ID	Date	Sign
4.1.1	Installation of the software on PC running Windows 95.	Installation successful and it is possible to start the program.				

4.2 Architecture / Interface

Purpose and descriptions
The purpose of this test case is to verify that the software meets the requirements for input/output.

ID	Test description	Expected results	Result (Pass or Fail)	Error Report ID	Date	Sign
4.2.1	Verify that all requirements in the SRS 3.1.1 are met for each data field of the user data; name in full, user name, password and operator level.	All data types are correct with regard to; type, length and list items.				

ID	Test description	Expected results	Result (Pass or Fail)	Error Report ID	Date	Sign
4.2.2	Verify that all requirements in the SRS 3.1.1 are met for each data field of the Pt-25 data; ID number, calibration number, R0.01, a(t>0.01°), b(t>0.01°), a(t<0.01°) and b(t<0.01°).	All data types are correct with regard to; type, format, number of decimals and interval.				
4.2.3	Verify that ID number is displayed with large fonts. Font size cannot be determined from screen.	ID number is displayed in a large font and is easy to read.				
4.2.4	Verify that temperature is displayed with large fonts and 4 decimals. Font size cannot be determined from screen.	Temperature is displayed in a large font and is easy to read.				
4.2.5	Graphic user interface	The software has a graphic user interface.				

4.3 Functions

Purpose and descriptions

The purpose of this test case is to verify that all specified functionality is contained in the software.

ID	Test description	Expected results	Result (Pass or Fail)	Error Report ID	Date	Sign
4.3.1	At log in the user shall be prompted to enter user name and password in a dialog box.	A dialog box is displayed where user name and password can be entered.				
4.3.2	Entered user name and/or password that is not correct.	The software displays an appropriate message and displays the login dialog box once again.				
4.3.3	Log in as Administrator. Click button “Users”.	It is possible to active “Manage data for user profiles” by clicking a button labelled “Users”.				
4.3.4	Log in as Operator and as Technician. Try click button “Users”.	Button “Users” is deactivated.				
4.3.5	Log in as Administrator. Click button “Users”, select a user in the list of registered users and then click “Erase”.	It is possible to erase users registered in the user list.				
4.3.6	Log in as Administrator. Try to erase all administrators.	It is only possible to erase all but one administrator.				

ID	Test description	Expected results	Result (Pass or Fail)	Error Report ID	Date	Sign
4.3.7	Log in as Administrator. Click button “Users” and then select a user in the list of registered users and try to edit user data.	Data for any user can be updated. This includes all fields; “name in full”, user name”, “password” and “level”.				
4.3.8	Log in as Administrator. Erase all users but one. Try to change the level from Administrator to other level.	OK to change the last Administrator to other level.				
4.3.9	Log in as Administrator, Technician and Operator. Click “Password”.	OK at all levels to reach the password dialog box.				
4.3.10	Change password and enter the same password, with at least 4 characters, twice (in the two field).	The software accepts the new password.				
4.3.11	Change password and enter passwords with at least 4 characters, but be sure the password are not identical.	The software detects a mismatch and displays message and a cleared password dialog box once again				
4.3.12	Log in as Administrator, Technician and Operator. Click “Probe”.	OK for users at all levels to click button “Probe”.				
4.3.13	Following 4.3.12, select a probe in the list. Try for Administrator, Technician and Operator.	The corresponding data for the chosen probe is shown at all user levels.				

ID	Test description	Expected results	Result (Pass or Fail)	Error Report ID	Date	Sign
4.3.14	Log in as Administrator, Technician and Operator. Click “Probe” and select a probe with an expired calibration date.	The software detects the expired date and displays the warning message “Probe is due for calibration”.				
4.3.15	Log in as Administrator, Technician and Operator. Click “Probe” and select a probe with a calibration date that is not the latest among the registered probes. Requires at least probes being registered.	The software detects another probe with a later calibration date and displays the warning message “Another probe has a later calibration date”.				
4.3.16	Log in as Administrator and as Technician. Click “Probe”, select a probe and edit data for that probe.	OK as Administrator or Technician to edit any data for a probe.				
4.3.17	Log in as Administrator and as Technician. Click “Probe” and then click “Create”.	OK to create new probe data as Administrator or Technician. All data fields shall be clear, apart from ID number.				
4.3.18	When a new record has been created try to edit data directly.	OK to edit data for new probe as Administrator or Technician.				
4.3.19	Log in as Administrator and as Technician. Click “Probe”, select a probe and click “Erase”.	OK to erase probe data as Administrator and Technician.				

ID	Test description	Expected results	Result (Pass or Fail)	Error Report ID	Date	Sign
4.3.20	Log in as Administrator and as Technician. Click “Probe” and edit, create or erase any record. Click button “Reset” before confirming by clicking “OK”.	OK to “Reset” changes made before any confirmation (“OK” button).				
4.3.21	Log in as Administrator and as Technician. Click “Probe” and edit, create or erase any record. Click button “OK”. Click ”Probe” again to verify that changes have been stored.	The software stores changes in probe data after button “OK” is pressed.				
4.3.22	Log in as Operator. Click “Probe” and verify that neither “Create” nor “Erase” can be pressed.	Operator cannot create new records or erase old ones. Buttons are deactivated.				
4.3.23	Log in as Administrator, Technician and Operator, select a probe and click “OK”. Verify that the software runs in its normal mode showing temperature values.	OK for all users to enter normal mode.				
4.3.24	Continue from 4.3.23 and verify that any user from any level Administrator, Technician and Operator can press the “Probe” button in normal mode.	OK for all user levels to press button “Probe”.				

ID	Test description	Expected results	Result (Pass or Fail)	Error Report ID	Date	Sign
4.3.25	Continue from 4.3.23 and verify that any user from any level Administrator, Technician and Operator can press the “Password” button in normal mode.	OK for all user levels to press button “Password”.				
4.3.26	Continue from 4.3.23 and verify that any user from any level Administrator, Technician and Operator can press the “Log in” button in normal mode.	OK for all user levels to press button “Log in” and execute a new log in.				
4.3.27	Run the software in normal operation. Note all data for the selected probe and try to freeze a value for both the resistance and the temperature shown in the main window. Verify the calculation according ITS-90. Probe ID: _____ Read resistance: _____Ω Read temperature: _____°C	Manual calculation confirms that the displayed temperature is correctly shown with at least two decimals. Manually calculated temperature: _____°C				
4.3.28	Log in as Administrator. Click button “Users” and then click “Create”.	It is possible to create a new user account.				

4.4 Data Architecture / Data Structure

Purpose and descriptions

The purpose of this test case is to verify that user data is encrypted.

ID	Test description	Expected results	Result (Pass or Fail)	Error Report ID	Date	Sign
4.4.1	Verify that at least three users are registered. Close down the software open the ini-file in an editor. Verify that no user names nor passwords can be read without data manipulation.	Neither user names nor passwords can be read directly in an editor.				

4.5 Security

All tests of security functionality is integrated in the functions test. See section 4.3 above.

4.6 Alarm

N/A

4.7 Error Handling

Purpose and descriptions

The purpose of this test case is to verify that the software can handle error. Warnings are tested in section 4.3 above.

ID	Test description	Expected results	Result (Pass or Fail)	Error Report ID	Date	Sign
4.7.1	Enter normal operation (measuring mode). Break the communication between the PC and the F26 by shutting dow3n the F26.	Error message is shown indicating a broken communication with the measuring unit.				
4.7.2	Create a backup copy of the ini-file. Start the software and enter into normal mode. Erase the original ini-file. Try to create a new user.	Error message shown (unknown since depen-dence on LabView).				

4.8 Back up / Restore

N/A

4.9 Stress / Worst case test

Purpose and descriptions

The purpose of this test case is to verify that the software is not limited to the number of users and probes specified in the SRS.

ID	Test description	Expected results	Result (Pass or Fail)	Error Report ID	Date	Sign
4.9.1	Create data for 10 probes.	The software is not limited to the number of probes specified in the SRS (3 probes), but can handle a larger amount of probe data.				
4.9.2	Create 10 user accounts.	The software is not limited to the number of user accounts specified in the SRS (5 accounts), but can handle a larger number of users.				

4.10 Other

N/A

5 Errors during the test

The errors that occurred during the tests are described in the table below. Actions that need to be taken will be described in the Error report. If changes in the software will be necessary, the software or parts of the software need to be retested.

Errors

ID	Test description	Expected results	Actual Result	Error Report ID	Date	Sign

Appendix 6 System test – Error Reports

Error report

for

Error ID #1
System: F26 Temperature According to ITS-90

Prepared by

Name:	*Project function:*	*Date:*	*Signature:*
Carl Tillman	Validation Manager		

Reviewed by

Name:	*Project function:*	*Date:*	*Signature:*
	Project Manager		

Approved by

Name:	*Project function:*	*Date:*	*Signature:*
Lars-Göran Andersson	Development manager		

Revision History

Version:	*Date:*	*Revised by:*	*Comments:*
1		Carl Tillman	First issue.
Version:	*Date:*	*Revised by:*	*Comments:*
Version:	*Date:*	*Revised by:*	*Comments:*

1 Description

1.1 Test

Test case 4.3.5 and 4.3.6

Log in as Administrator. Try to erase all but one Administrator.

1.2 Expected result

All but one Administrator can be erased.

Undefined whether it should be possible to erase the user account that is presently logged on.

1.3 Actual result

All but one Administrator can be erased.

It is possible to delete the user account which is logged in (when logged in as an Administrator).

Resulting anomalies/errors:

1. When clicking “OK” the main Windows is displayed again. Despite having erased the user account used for login, the same account is still shown as being the current user.
2. If now clicking “Password” the software tries to read information about the user account that has just been erased. This causes the software to display an error dialog.

2 Extent

This is not a critical error, and the outcome was never clearly specified.

3 Decision

No need of re-test.

It is recommended to update the software at the next release so that the currently logged in user account cannot be erased

GAMBRO Renal Products

Error report

for

Error ID #2
System: F26 Temperature According to ITS-90

Prepared by

Name:	*Project function:*	*Date:*	*Signature:*
Carl Tillman	Validation Manager		

Reviewed by

Name:	*Project function:*	*Date:*	*Signature:*
	Project Manager		

Approved by

Name:	*Project function:*	*Date:*	*Signature:*
Lars-Göran Andersson	Development manager		

Revision History

Version:	*Date:*	*Revised by:*	*Comments:*
1		Carl Tillman	First issue.
Version:	*Date:*	*Revised by:*	*Comments:*
Version:	*Date:*	*Revised by:*	*Comments:*

1 Description

1.1 Test

Test case 4.3.17

Log in as Administrator and as Technician. Click “Probe” and the click “Create”.

1.2 Expected result

OK to create new probe data as Administrator or Technician. All data fields shall be clear, apart from ID number.

Undefined whether it should be possible to create more than one probe with the same ID, or whether ID can be left blank.

1.3 Actual result

OK to create new probe data as Administrator or Technician. All data fields are then clear, apart from ID number (if any was entered).

Resulting anomalies/errors:

3. It is possible to create more than one probe with the same ID.
4. It is possible to create a probe but leaving probe ID blank.

2 Extent

This is not a critical error, and the outcome was never clearly specified.

3 Decision

No need of re-test.

It is recommended to update the software at the next release so that a check is made that the probe ID is unique and must not be left blank.

GAMBRO Renal Products

Error report

for

Error ID #3
System: F26 Temperature According to ITS-90

Prepared by

Name:	*Project function:*	*Date:*	*Signature:*
Carl Tillman	Validation Manager		

Reviewed by

Name:	*Project function:*	*Date:*	*Signature:*
	Project Manager		

Approved by

Name:	*Project function:*	*Date:*	*Signature:*
Lars-Göran Andersson	Development manager		

Revision History

Version:	*Date:*	*Revised by:*	*Comments:*
1		Carl Tillman	First issue.
Version:	*Date:*	*Revised by:*	*Comments:*
Version:	*Date:*	*Revised by:*	*Comments:*

1 Description

1.1 Test

Test case 4.3.28

Log in as Administrator. Click button “Users” and then click “Create”.

1.2 Expected result

It is possible to create a new user account.

Undefined whether it should be possible to create more than one user with the same user name, and whether user name can be left blank.

1.3 Actual result

It is possible to create a new user account.

It is possible to create multiple users with the same user name and a user with no user name.

Resulting anomalies/errors:

5. If more than one user is created some of the users that have the same name will not be able to login.
6. A no-name user will not not leave any name in the main window.

2 Extent

This is not a critical error, and the outcome was never clearly specified.

3 Decision

No need of re-test.

It is recommended to update the software at the next release so that user name must be unique and must not be left blank.

Appendix 7 Acceptance test Plan/Report

Acceptance test Plan/Report

for

F26 Temperature According to ITS-90

Prepared by

Name:	*Project function:*	*Date:*	*Signature:*
Carl Tillman	Validation Manager		

Plan reviewed by

Name:	*Project function:*	*Date:*	*Signature:*
	Project Manager		

Report reviewed by

Name:	*Project function:*	*Date:*	*Signature:*
	Project Manager		

Plan approved by

Name:	*Project function:*	*Date:*	*Signature:*
Evert Håkansson	System owner		

Report approved by

Name:	*Project function:*	*Date:*	*Signature:*
Evert Håkansson	System owner		

Revision History

Version:	Date:	Revised by:	Comments:
1		Carl Tillman	First issue.
Version:	Date:	Revised by:	Comments:
Version:	Date:	Revised by:	Comments:

Table of contents

1 Introduction

This document is used for the acceptance test of the software *F26 Temperature According to ITS-90* and will include both test plan and test results. The requirements from the Software Requirement Specification have been converted to test cases and test criteria.

The references and definitions are described in SOP-1540.

2 Test environment

The tests were conducted on a PC meeting the requirements as stated in the *SRS for F26 Temperature According To ITS-90*, section *User and Function Requirements*.

The test environment also included the following equipment:

- F26 ID-number 28
- Pt-25 ID-number 71 or 80

3 Test results

When the tests are finished, the errors will be reviewed and decision will be taken for actions. Use Error report, Template-1551, for error registrations.

4 Tests

4.1 Interface

Purpose and descriptions
The purpose of this test case is to verify that the software can be run on a PC as specified in the SRS.

ID	Test description	Expected results	Result (Pass or Fail)	Error Report ID	Date	Sign
4.1.1	Test that the software can be run on a PC as specified in the SRS. Only start up is tested.	The software can be started.				

4.2 Input

Purpose and descriptions
The purpose of this test case is to verify that the software handle input according to specifications. Test of requirements for data type, format and length and intervals will be tested in the System test.

ID	Test description	Expected results	Result (Pass or Fail)	Error Report ID	Date	Sign
4.2.1	Enter data in data fields using the PCs keyboard.	Data can be entered in data fields.				
4.2.2	Start the software and verify that data from the F26 can be read.	Displayed temperatures on the F26 and in the software are identical.				

4.3 Output

Purpose and descriptions

Syftet med dessa tester är att verifiera att programvaran visar önskad information**.**

ID	Test description	Expected results	Result (Pass or Fail)	Error Report ID	Date	Sign
4.3.1	Verify that temperature is displayed with at least 4 decimals.	Temperature is displayed with at least 4 decimals. Nr of decimals shown: ____				
4.3.2	Verify that temperature is displayed with large fonts. Font size cannot easily be determined from screen.	Temperature is displayed in a large font and is easy to read.				
4.3.3	Verify that resistance can be shown on screen.	The resistance is displayed.				
4.3.4	Verify that user data can be displayed on the screen.	User data can be displayed.				
4.3.5	Verify that probe data can be displayed.	Probe data can be displayed.				
4.3.6	Verify that “Tip strips” can be shown.	Tip strips shown when pointing with mouse on objects on the screen.				

4.4 Functions

Purpose and descriptions

The purpose of this test case is to verify that all specified functionality is contained in the software.

ID	Test description	Expected results	Result (Pass or Fail)	Error Report ID	Date	Sign
4.4.1	Verify that the software can manage user data.	User data can be managed.				
4.4.2	Verify that the software can manage Pt-25 probe data.	User data can be managed.				
4.4.3	Verify that the software can correctly calculate a temperature <0.01 °C. Verify the calculation according to ITS-90. Note all values from screen below. Probe ID: _____ Read resistance: _____Ω Read temperature: _____°C	Manual calculation confirms that the displayed temperature is correctly shown with at least two decimals. Manually calculated temperature: _____°C				
4.4.4	Verify that the software can correctly calculate a temperature >0.01 °C. Verify the calculation according to ITS-90. Note all values from screen below. Probe ID: _____	Manual calculation confirms that the displayed temperature is correctly shown with at least two decimals. Manually calculated temperature:				

ID	Test description	Expected results	Result (Pass or Fail)	Error Report ID	Date	Sign
	Read resistance: _____Ω Read temperature: _____°C	_____°C				

4.5 Performance Requirements

The purpose of this test case is to verify that all performance constraints are fulfilled.

ID	Test description	Expected results	Result (Pass or Fail)	Error Report ID	Date	Sign
4.5.1	Verify that temperature values can be updated on the screen at least with a rate of 1 Hz.	Updating frequency >1 Hz.				
4.5.2	Verify that at least 5 users can be registered.	Data for at least five users can be registered.				
4.5.3	Verify that at least 3 probes can be registered.	Probe data for at least five probes can be registered.				

4.6 Limitations

N/A

4.7 Design Constraints

N/A

4.8 Security

Purpose and descriptions

The purpose of this test case is to verify that all security requirements are fulfilled.

ID	Test description	Expected results	Result (Pass or Fail)	Error Report ID	Date	Sign
4.8.1	Verify that the software is password protected.	The software can not be used for any measurements or management of data without a login using user ID and password.				
4.8.2	Verify that the software supports three different access levels.	The software supports the access levels: Administrator, Technician and Operator.				
4.8.3	Verify that only Administrators can manage user data.	Only Administrators can manage user data. For other access levels the “Users” button is deactivated.				
4.8.4	Verify that only Administrators and Technicians can manage probe data.	Only Administrators and Technicians can manage probe data. For Operator access level the “Erase” and “Create” buttons are deactivated.				

ID	Test description	Expected results	Result (Pass or Fail)	Error Report ID	Date	Sign
4.8.5	Verify that neither user names nor passwords can be read without data manipulation in the ini-file.	Neither user names nor passwords can be read directly in an editor.				

4.9 Alarms

N/A

4.10 Errors

Test of Error handling is done as a part of the system test. See System tests 4.3.14, 4.3.15, 4.7.1 and 4.7.2.

ID	Test description	Expected results	Result (Pass or Fail)	Error Report ID	Date	Sign
4.10.1	Verify that the software has functionality for error handling.	The software can handle errors.				

4.11 Other Requirements

N/A

5 Errors during the test

The errors that occurred during the tests are described in the table below. Actions that need to be taken will be described in the Error report. If changes in the software will be necessary, the software or parts of the software need to be retested.

Errors

ID	Test description	Expected results	Actual Result	Error Report ID	Date	Sign

Appendix 8 **System Documentation**

System documentation

for

F26 Temperature According to ITS-90

Prepared by

Name:	*Project function:*	*Date:*	*Signature:*
Carl Tillman	Validation Manager		

Reviewed by

Name:	*Project function:*	*Date:*	*Signature:*
	Project Manager		

Approved by

Name:	*Project function:*	*Date:*	*Signature:*
Lars-Göran Andersson	Development Manager		

Revision History

Version:	Date:	Revised by:	Comments:
1		Carl Tillman	First issue
Version:	Date:	Revised by:	Comments:
Version:	Date:	Revised by:	Comments:

Table of contents

1 Introduction

The software “F26 Temperature According to ITS-90” version 1.0 displays values of temperatures measured with a platinum resistance thermometer attached to a resistance bridge. This system forms the primary temperature standard at Gambro Lundia AB.

The software is developed (custom made) and used by personnel from the Calibration Group. Therefore no Supplier Qualification will be made.

Definitions and acronyms

The following definitions and acronyms are used in the validation documents for this software:

F26
A resistance measuring bridge, manufactured by Automatic Systems Laboratories, ASL. The F26 is equipped with a GPIB interface.

GPIB, General Purpose Interface Bus
The standard bus used for controlling electronic instruments with a computer. Also called
IEEE 488 bus, defined by ANSI/IEEE Standards 488-1978, 488.1-1987 and 488.2-1992.

ITS-90, The International Temperature Scale of 1990

Defines procedures by which certain specified practical thermometers can be calibrated in such a way that the values of temperature obtained by them can be precise and reproducible.
Platinum resistance thermometers are specified for use from 13,8033 K up to 962,78°C.

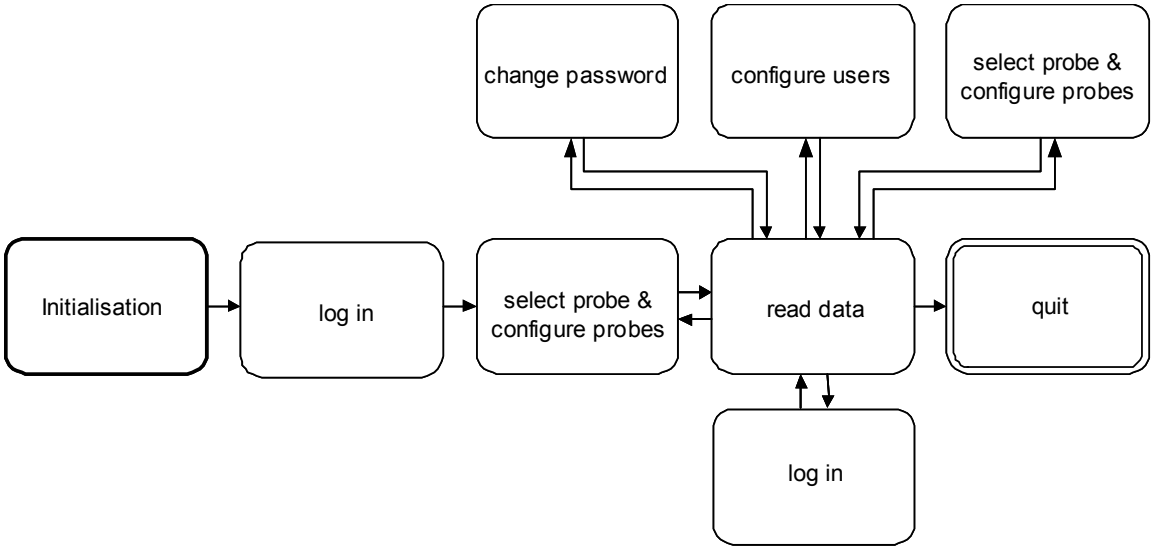
LabVIEW, Laboratory Virtual Instrument Engineering Workbench
A graphical programming language using icons instead of lines of text as source code.

Pt-25
A platinum resistance thermometer of the highest quality. A Pt-25 has a nominal resistance of
25 ohm at 0°C.

2 System Architecture

The software is based on a program flow as illustrated in the figures below.

2.1 Graphic Overview



3 Functions

The purpose of the software is to automate the conversion of measured resistance values into temperatures. Pt-25 resistance values are read via GPIB from a F26. The ITS-90 temperature corresponding to the resistance is calculated and displayed on screen.

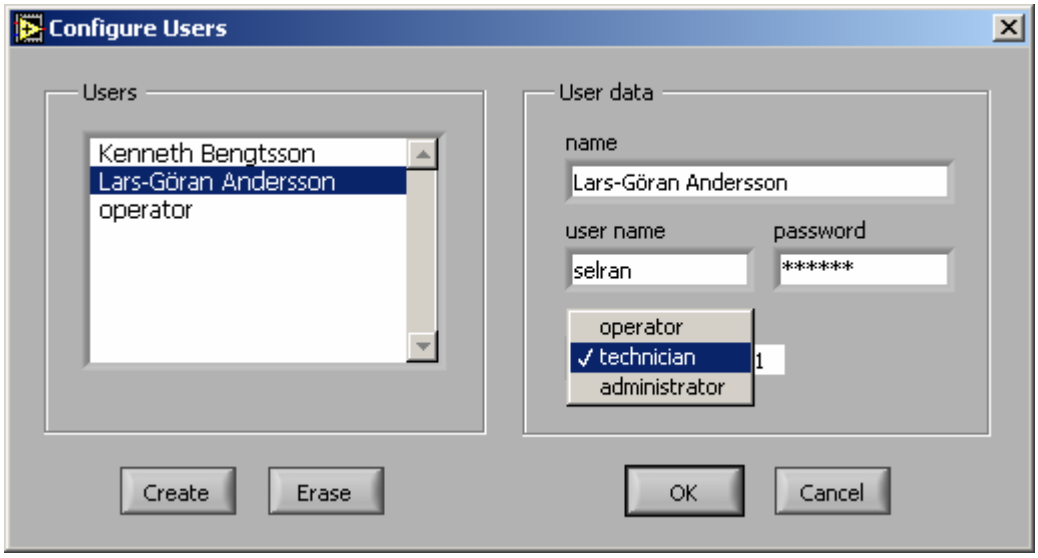
The formula for calculating temperatures is depending on two coefficients **a** and **b**. These coefficients have different values for temperatures <0.01 °C and >0.01 °C respectively. The software can calculate temperatures correctly in the range -40°C to +290° C (limited by ITS-90 conversion formulas).

The main functionality of the software is:

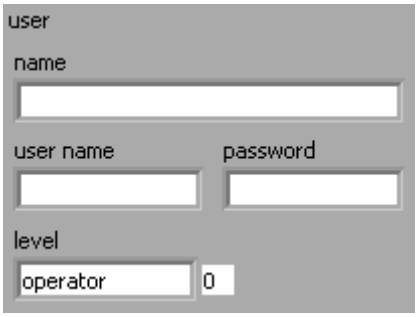
7. Login / Manage data for user profiles
8. Manage data for Pt-25 thermometers.
9. Calculate temperatures according to ITS-90

Login / Manage data for user profiles

- At log in the user shall be prompted to enter user name and password in a dialog box.
- If not correct name and password are entered the software shall display an appropriate message and display the login dialog box once again.
- When a user has logged in with Administrator access right he/she shall be able to active “Manage data for user profiles” by clicking a button labelled “Users”.



- When a user has logged in with Operator or Technician access right the button “Users” shall be deactivated, so as he/she shall be able to active.
- Administrator shall be able to create new user accounts.
- Administrator shall be able to delete users registered in the user list.
- Administrator shall be able to update data for any user. This includes all fields; “name in full”, user name”, “password” and “level”.



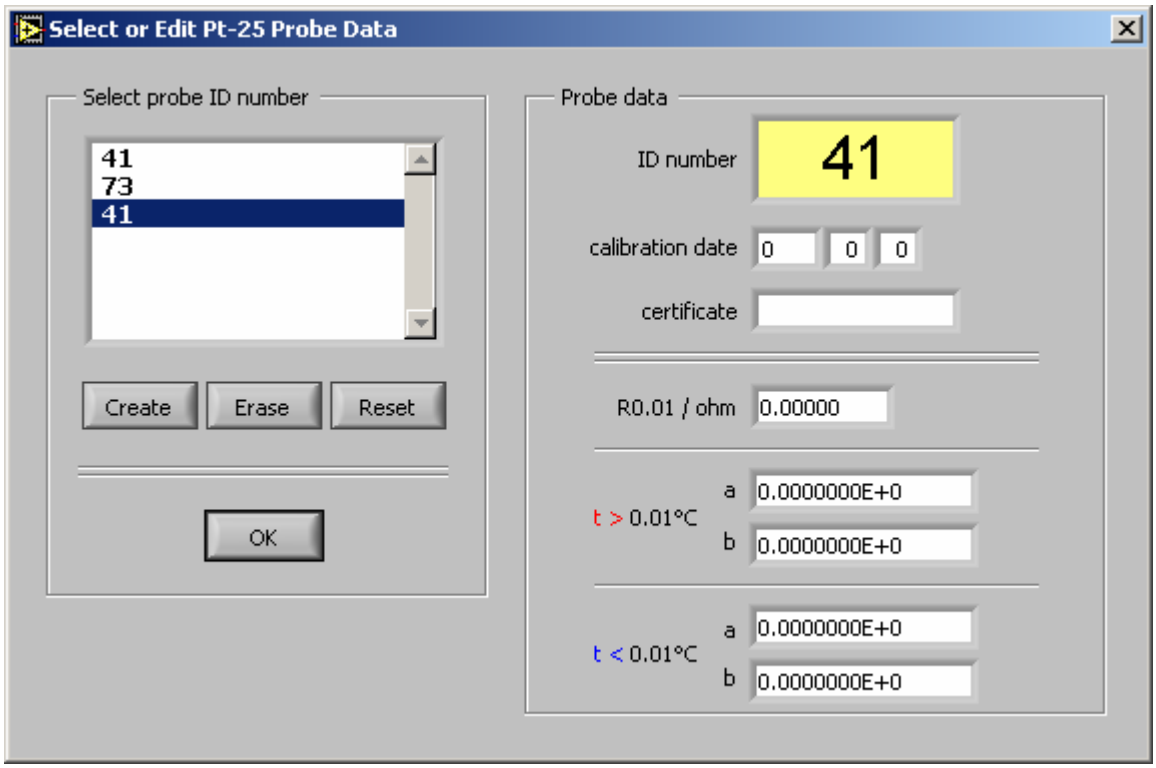
- It shall not be possible all to erase all users at administrator level, or change the level of the last Administrator to another level. At least one administrator must be left.

- All users shall be able to change password by clicking the button “Password”.

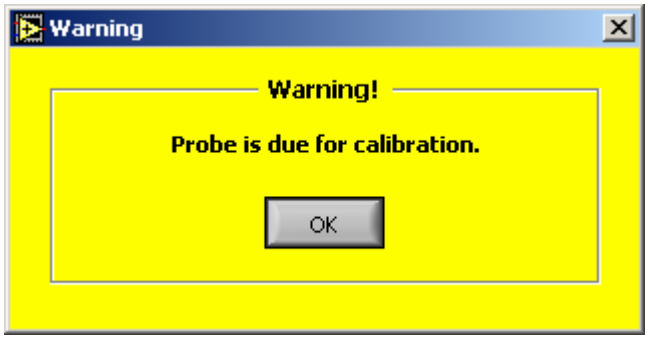
- When changing password the user shall be prompted to enter a new password twice in a dialog box.
- If the two passwords being entered are not identical, or if the password is less than 4 characters in length the software shall display an appropriate message and display the change password dialog box once again.

Manage data for Pt-25 thermometers

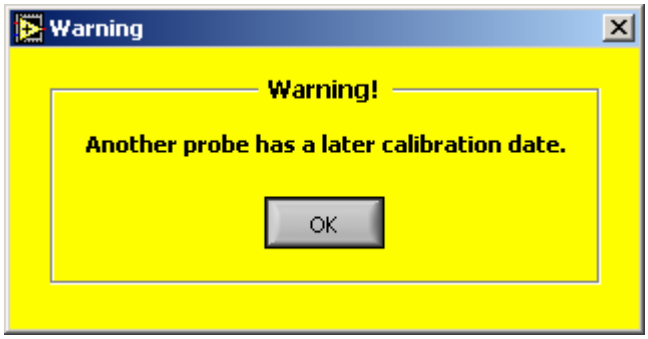
- All users shall be able to activate “select probe” by clicking the button “Probe” in the main window.
- All users shall be able to select a probe from the list of registered probes in the “Select or Edit Pt-25 Probe Data” window. When a probe is selected the corresponding data for that probe shall be displayed.



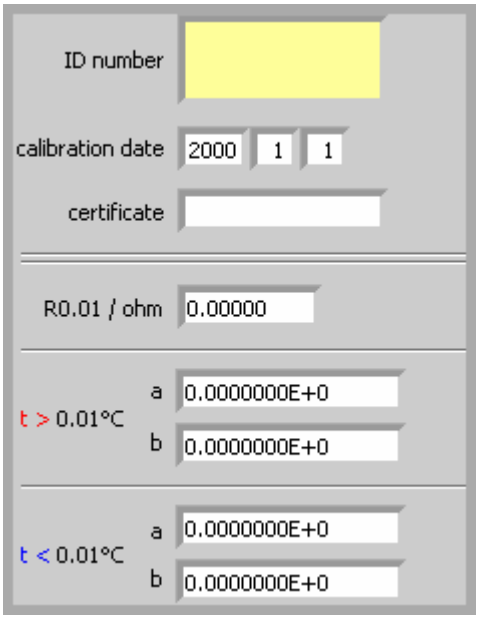
- If a probe is selected the software shall display a warning if the calibration date is expired, see section 7 below.



- If a probe is selected and any other probe is registered with a later calibration data the software shall display a warning, see section 7 below.



- Administrators and technicians shall be able to edit data for any probe. This includes the following data;
  - The calibration date for the latest calibration certificate.
  - Calibration certificate number.
  - The resistance at the triple point of water, R0.01
  - The coefficients a and b for temperatures >0.01°C
  - The coefficients a and b for temperatures <0.01°C

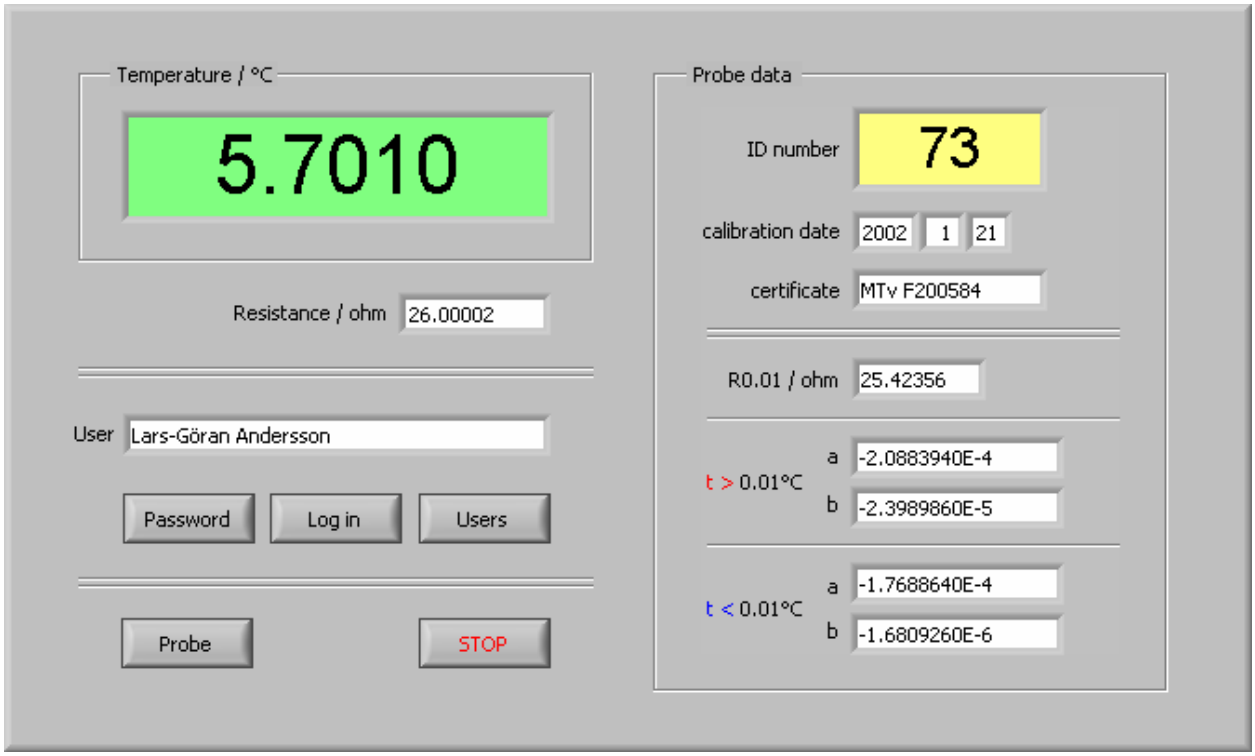


- Administrators and technicians shall be able to create records for new probes by clicking the button “Create”.
- After a new record is created empty data fields shall be displayed and the user shall be able to edit data as above.
- Administrators and technicians shall be able to delete registered probes by clicking the button “Erase”.
- Administrators and technicians shall be able to reset changes by clicking the button “Reset”. This will reset any changes made before confirmation by clicking “OK”.
- Pressing the OK button will save all changes and the software proceeds to the main screen. It is then not possible to Reset any changes.

- When a user is logged in as Operator both buttons “Create” or “Erase” shall be deactivated, and thus not allow new records to be created or old ones to be erased.

Calculate temperatures according to ITS-90

- When no other windows are displayed, other than the main window, the software shall continuously read, calculate temperatures and display temperatures. This is the default mode of the software. For repetition rate see section 3.3.1 in the SRS.



- When the software is executing in default mode (as defined above) any users with a high enough access right shall be able to activate the other functions as described above.
- The software shall calculate temperatures according to the ITS-90. This shall be done by reading resistance values from the F26 and converting them to ITS-90 temperatures by using the inverse reference functions 9b and 10b as well as the deviation functions 12 and 13 defined in ITS-90.

4 Data Architecture / Data Structure

The software is not based on any database, but rather a number of defined variables.

For specification of input and output data see the *Software Requirement Specification for F26 Temperature According to ITS-90*. For specification of internal variables see the *System Design Document for F26 Temperature According to ITS-90*.

5 Client – Server

N/A, the software is not developed according to Client-Server principles.

6 Security

- The software shall be password protected.
- Users shall be able to log in at 3 different user levels, with access rights at each level according to:

Operator level	*Access to Pt-25 data*	*Access to User profiles*
Operator	Read	No access
Technician	Read/Write	No access
Administrator	Read/Write	Read/Write

- User ID and passwords must not be stored in a format directly readable for humans, e.g. unencrypted text files.
-

7 Alarm

N/A, The software does not support any alarm functions.

8 Error handling

The software shall communicate errors and warning messages to the user. Situations that shall trigger such messages are:

Errors

- Error in the communication with the F26
- Read / write error for configuration data

Warnings

- Calibration date for chosen Pt-25 has expired
- Calibration date not the latest (there is another Pt-25 with a newer calibration date)

See warning messages in section 0
Functions above.

9 Installation

This software is designed for installation on a PC as specified in section 3.1 of the SRS.

The installation package includes the following files:

- install.msi
- InstMsi.exe
- InstMsiW.exe
- setup.exe
- setup.ini

Run the setup.exe file. That will start an Installation Wizard. Follow the instructions on the screen in order to complete the installation.

10 Third party components

Component	Description
LabView Run-Time Engine 6.1	The system is developed using LabView 6.1. In order to run the software the LabView Run-Time Engine has to be installed prior to the F26 Temperature software.

Appendix 9 **Validation Report**

Validation report

for

F26 Temperature According to ITS-90

Prepared by

Name:	*Project function:*	*Date:*	*Signature:*
Carl Tillman	Validation Manager		

Reviewed by

Name:	*Project function:*	*Date:*	*Signature:*
	Project Manager		

Approved by

Name:	*Project function:*	*Date:*	*Signature:*
Evert Håkansson	System Owner		
Name:	*Project function:*	*Date:*	*Signature:*
Christer Magnusson	Quality Assurance		

Revision History

Version:	Date:	Revised by:	Comments:
1		Carl Tillman	First issue.
Version:	Date:	Revised by:	Comments:
Version:	Date:	Revised by:	Comments:

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1 Concept and Planning Phase

The software was developed internally by the Calibration Group (Monitor Division).

1.1 Risk Analysis

A risk analysis was conducted in accordance with SOP-1540. The risk analysis gave a total risk of 18 points (on scale 5 to 65 points). See document *Risk Analysis for F26 Temperature According to ITS-90*.

1.2 Validation Plan

A validation plan was documented in accordance with SOP-1540, and was subseqeuntly followed during the validation work. See document *Validation Plan for F26 Temperature According to ITS-90*.

2 Requirement Phase

No problems during this phase.

2.1 Software Requirement Specification

A software requirement specification was documented, including both user requirements and functional requirements. See document *Software Requirement Specification for F26 Temperature According to ITS-90*.

3 Design and/or Purchase

No problems during this phase.

3.1 Software Design Specification

The basic requirements from the SRS were further detailed in a software design specification. See document *Software Design Specification for F26 Temperature According to ITS-90*.

3.2 Supplier Qualification

N/A. The system has been developed in-house.

4 Implementation

4.1 System documentation

See document *System Documentation for F26 Temperature According to ITS-90*.

4.2 System test report

See document *System test Plan / Report for F26 Temperature According to ITS-90*. 3 error reports were generated. None of these generated any critical errors, but the reports should be used as an input for the next release of the software.

5 Test

No problems during this phase, and no faults were detected acceptance tests.

5.1 Acceptance test report

See document *System test Plan / Report for F26 Temperature According to ITS-90*. No error reports were generated.

6 Preparation for Maintenance

6.1 User Manual

No separate User Manual has been produced. User instructions are included in the *System Documentation for F26 Temperature According to ITS-90*.

6.2 Installation / Training documentation

Installation instructions are included in the *System Documentation for F26 Temperature According to ITS-90*.

No training material has been produced. Users are assumed to have the adequate computer knowledge to in stall and use the system without any formal training, see *Validation Plan for F26 Temperature According to ITS-90*.

7 Change control

The software follows change control POP-1771.

8 Retirement

The software follows the general Retirement plan. For further information see Change control POP-1771.

9 Conclusions

The recommendation is that the software *F26 Temperature According to ITS-90* version 1.0 is approved from a validation point of view.

It is also recommended that the error reports #1-3 from the system tests are used as an input for code correction in the next release of the software.

Appendix 10 Software Design Document

Software Design Document

for

F26 Temperature According to ITS-90

Prepared by

Name:	*Project function:*	*Date:*	*Signature:*
Lars-Göran Andersson	Development Manager		

Revision History

Version:	*Date:*	*Revised by:*	*Comments:*
1		Lars-Göran Andersson	First issue.
Version:	*Date:*	*Revised by:*	*Comments:*
Version:	*Date:*	*Revised by:*	*Comments:*

1 Introduction

This document has been auto generated from the source code in LabView. The text is stored in its raw text format and has not been formatted or styled. The program modules developed in LabView are called VIs. Identification of the different modules can be done by searching for stext strings ending with ".vi:".

2 Design Documentation

F26 Temperature According To ITS-90.vi:
VI Path: I:\Records\Confidential\Mjukvara\F26 Temperature According To ITS-90\F26 ITS-90 version 1.0\F26 Temperature According To ITS-90.llb\F26 Temperature According To ITS-90.vi
Last Modified: 2002-09-02 16:18
Version: 121

VI Description:
Code by:
Lars-Göran Andersson
Calibration Group
Gambro Lundia AB---

Controls and Indicators:
Control #1:password
Data Type: boolean (TRUE or FALSE)
Description:
Change password for the current user.---
Control #2:log in
Data Type: boolean (TRUE or FALSE)
Description:
Log in as new user.---
Control #3:users
Data Type: boolean (TRUE or FALSE)
Description:
Edit user information.---
Control #4:new probe
Data Type: boolean (TRUE or FALSE)
Description:
Select or edit probe.---
Control #5:stop
Data Type: boolean (TRUE or FALSE)
Description:
Indicator #1:temperature
Data Type: double [64-bit real (~15 digit precision)]
Description:
Temperature / °C.---
Indicator #2:resistance
Data Type: double [64-bit real (~15 digit precision)]
Description:
Resistance / ohm.---
Indicator #3:user
Data Type: string
Description:
User's name in full.---
Indicator #4:probe
Data Type: cluster of 8 elements
Description:
Probe data.---
Indicator #4.1:name
Data Type: string
Description:
Gambro ID number.---
Indicator #4.2:calibration date
Data Type: cluster of 3 elements
Description:
Latest calibration date.---
Indicator #4.2.1:year
Data Type: unsigned long [32-bit integer (0 to 4,294,967,295)]
Description:
Year.
Range: [2000...2040]---
Indicator #4.2.2:month
Data Type: unsigned long [32-bit integer (0 to 4,294,967,295)]
Description:
Month.
Range: [1...12]---
Indicator #4.2.3:day
Data Type: unsigned long [32-bit integer (0 to 4,294,967,295)]
Description:
Day.
Range: [1...31]---
Indicator #4.3:certificat
Data Type: string
Description:
Calibration certificate number.---
Indicator #4.4:R0.01 / ohm
Data Type: double [64-bit real (~15 digit precision)]
Description:
Probe resistance at 0.01°C.---
Indicator #4.5:a (t>0.01°C)
Data Type: double [64-bit real (~15 digit precision)]
Description:
ITS-90 coefficient for t > 0.01°C.---
Indicator #4.6:b (t>0.01°C)
Data Type: double [64-bit real (~15 digit precision)]
Description:
ITS-90 coefficient for t > 0.01°C.---