Software Product: F26 Temperature According to ITS-90

Preface

This software validation method, described in the document "Nordtest Method of Software Validation", is basically developed to assist accredited laboratories in validation of software for calibration and testing. The actual report is provided via a Word 2000 template "Nordtest Software Validation Report.dot" which is organized in accordance with the life cycle model used in the validation method. There are two main tasks associated with each life cycle phase:

- *Preliminary work*. To specify/summarize the requirements (forward/reverse engineering for prospective/retrospective validation), to manage the design and development process, make the validation test plan, document precautions (if any), prepare the installation procedure, and to plan the service and maintenance phase.
- *Peer review and test*. To review all documents and papers concerning the validation process and conduct and approve the planned tests and installation procedures.

The report template contains 5 sections:

1. *Objectives and scope of application.* Tables to describe the software product, to list the involved persons, and to specify the type of software in order to determine the extent of the validation.
2. *Software life cycle overview.* Tables to specify date and signature for the tasks of preliminary work and the peer reviews assigned to each life cycle phase as described above.
3. *Software life cycle activities.* Tables to specify information that is relevant for the validation. It is the intention that having all topics outlined, it should be easier to write the report.
4. *Conclusion.* Table for the persons responsible to conclude and sign the validation report.
5. *References and annexes.* Table of references and annexes.

Even if possible, it is recommended not to delete irrelevant topics but instead mark them as excluded from the validation by a "not relevant" or "not applicable" (n/a) note – preferably with an argument – so it is evident that they are not forgotten but are deliberately skipped.

It is the intention that the validation report shall be a "dynamic" document, which is used to keep track on all changes and all additional information that currently may become relevant for the software product and its validation. Such current updating can, however, make the document more difficult to read, but never mind – it is the *contents*, not the *format*, which is important.

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1 Objectives and scope of application

This section describes the software product in general terms. It includes objectives and scope of application and, if relevant, overall requirements to be met (such as standards and regulations).

All persons who are involved in the validation process and are authorized to sign parts of this report should be listed in the Role / Responsibility table. The report could hereafter be signed electronically with date and initials of those persons at suitable stages of the validation process.

The type of the software is outlined in order to determine the extent of validation and testing.

1.1 Objectives and scope of application	
General description	The software visually presents momentary values of temperature measured with a platinum resistance thermometer.
Scope of application	Resistance values are read from an *Automatic Systems Laboratories, ASL F26* resistance bridge. The corresponding temperature values are derived using procedures described in *The International Temperature Scale of 1990, ITS-90*.
Product information	The software and hardware together form the primary temperature standard at Gambro Lundia AB.
Overall requirements	According to the validation procedure used at Gambro Lundia AB, validation documents are signed manually and stored at a safe place. By filling in parts of this validation report it is intented to confirm that this validation method can encompass external validation documents as well. Thus, the information stated in this validation report is also stated in the documents listed in the reference table in section 5.

1.2 Role / Responsibility	*Title and Name*	*Initials*
System owner	Evert Håkansson	seevha
System administrator	Lars-Göran Andersson	selran
Application administrator	Lars-Göran Andersson	selran
System user	Kenneth Bengtsson	sekebe
Quality responsible	Christer Magnsson	sechma
Requirements team...	Kenneth Bengtsson Lars-Göran Andersson Evert Håkansson Peter Lindblad Inge Åberg Nicolaus Malmgren	seevha selran sekebe septli seinab senima
Development team...	Lars-Göran Andersson Kenneth Bengtsson	selran sekebe
Peer review team...	Kenneth Bengtsson Carl Tillman	sekebe secati
Testing team...	Kenneth Bengtsson Carl Tillman	sekebe secati

1.3 Type of software	
Purchased Software:	Self-developed software:
☐ Configurable software package	☑ Compiled executable program (e.g. C/C++)
☐ Commercial off-the-shelf software	☐ Spreadsheet (macro code, Add-In, etc.)
☐ Tool to assist in the software development	☐ Simple spreadsheet (no macro code)
☐ Subcontracted software development	☐ Tool to assist in development or testing
☐ Source code available and known	☐ Includes purchased software components
☐ Only partial validation	☐ Subcontracted software validation
Comments:	Comments:

2 Software life cycle overview

This section outlines the activities related to the phases in the life cycle model used in the validation process. The numbers refer to the corresponding subsections in section 3. Each activity contains a field for the preliminary task to be performed, a field for the validation method, and fields to specify the date and signature when the work is done.

Activity	**2.1 Requirements and system acceptance test specification**	*Date / Initials*
Task	3.1.1 Requirements specification (Appendix 3 and 8)	2002-11-01 secati
Method	3.1.1 Peer review	n/a
Check	3.1.1 Requirements specification approved	2002-11-08 sevha
Task	3.1.2 System acceptance test specification (Appendix 7)	2002-11-01 secati
Method	3.1.2 Peer review	n/a
Check	3.1.2 System acceptance test specification approved	2002-11-08 sevha

Activity	**2.2 Design and implementation process**	*Date / Initials*
Task	3.2.1 Design and development planning (Appendix 4)	2002-11-01 secati
Method	3.2.1 Peer review	n/a
Task	3.2.2 Design input (Appendix 4)	2002-11-01 secati
Method	3.2.2 Peer review	n/a
Task	3.2.3 Design output (Appendix 4)	2002-11-01 secati
Method	3.2.3 Peer review	n/a
Task	3.2.4 Design verification	n/a
Method	3.2.4 Peer review	n/a
Task	3.2.5 Design changes 1. Description: 2. Description: 3. ...	n/a

Activity	**2.2 Design and implementation process**	*Date / Initials*
Method	3.2.5 Peer review 1. Action: 2. Action: 3. ...	n/a

Activity	**2.3 Inspection and testing**	*Date / Initials*
Task	3.3.1 Inspection plan	2002-11-01 secati
Method	3.3.1 Inspection	2002-11-08 selran
Check	3.3.1 Inspection approved	2002-11-11 selran
Task	3.3.2 Test plan (Appendix 5)	2002-11-01 secati
Method	3.3.2 Test performance	n/a
Check	3.3.2 Test approved	n/a

Activity	**2.4 Precautions**	*Date / Initials*
Task	3.4.1 Registered anomalies	n/a
Method	3.4.1 Peer review	n/a
Task	3.4.2 Precautionary steps taken	n/a
Method	3.4.2 Verification of measures	n/a

Activity	**2.5 Installation and system acceptance test**	*Date / Initials*
Task	3.5.1 Installation summary	2002-11-01 secati
Method	3.5.1 Peer review	n/a
Task	3.5.2 Installation procedure (Appendix 8)	2002-11-01 secati
Method	3.5.2 Verification and test of installation	2002-11-08 selran
Task	3.5.3 System acceptance test preparation (Appendix 7)	2002-11-01 secati
Method	3.5.3 System acceptance test	2002-11-11 selran
Check	3.5.3 System acceptance test approved	2002-11-11 selran

Activity	**2.6 Performance, servicing, maintenance, and phase out**	*Date / Initials*
Task	3.6.1 Performance and maintenance	n/a
Method	3.6.1 Peer review	n/a
Task	3.6.2 New versions 1. Version: 2. Version: 3. ...	n/a

Activity	**2.6 Performance, servicing, maintenance, and phase out**	*Date / Initials*
Method	3.6.2 Peer review 1. Action: 2. Action: 3. ...	n/a
Task	3.6.3 Phase out	n/a
Method	3.6.3 Peer review	n/a

3 Software life cycle activities

This section contains tables for documentation of the software validation activities. Each subsection is numbered in accordance with the overview scheme above. The tables are filled in with information about the tasks to be performed, methods to be used, criteria for acceptance, input and output required for each task, required documentation, the persons that are responsible for the validation, and any other information relevant for the validation process. Topics excluded from being validated are explicitly marked as such.

3.1 Requirements and system acceptance test specification

The requirements describe and specify the software product completely and are basis for the development and validation process. A set of requirements can always be specified. In case of retrospective validation (where the development phase is irrelevant) it can at least be specified what the software is purported to do based on actual and historical facts. The requirements should encompass everything concerning the use of the software.

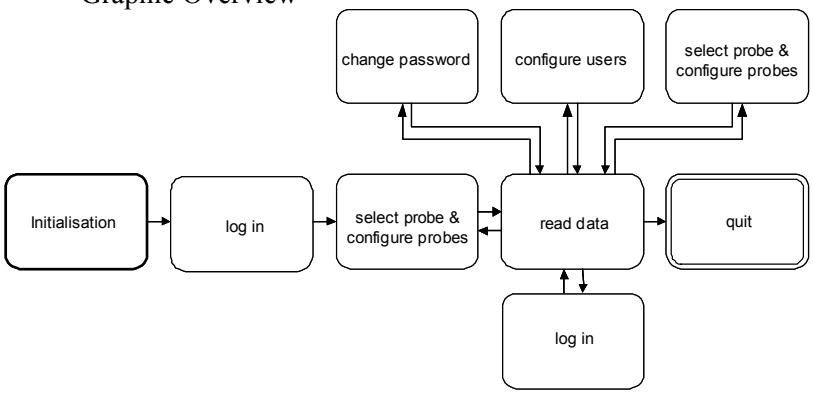
Topics	**3.1.1 Requirements specification**
Objectives *Description of the software product to the extent needed for design, implementation, testing, and validation.*	The software "F26 Temperature According to ITS-90" version 1.0 displays values of temperatures measured with a platinum resistance thermometer attached to a resistance bridge. This system forms the primary temperature standard at Gambro Lundia AB.
Version of requirements *Version of, and changes applied to, the requirements specification.*	1.0 Initial version

Topics	**3.1.1 Requirements specification**
Input *All inputs the software product will receive. Includes ranges, limits, defaults, response to illegal inputs, etc.*	***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.
Output *All outputs the software product will produce. Includes data formats, screen presentations, data storage media, printouts, automated generation of documents, etc.*	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.
Functionality *All functions the software product will provide. Includes performance requirements, such as data throughput, reliability, timing, user interface features, etc.*	The software uses the inverse reference functions 9b and 10b as well as the deviation functions 12 and 13 defined in ITS-90. The resistance at the triple point of water, *R0.01* and the coefficients *a* and *b* are stored in a configuration file. 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.

Topics	**3.1.1 Requirements specification**
	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.

Topics	**3.1.1 Requirements specification**
	- 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.
Traceability *Measures taken to ensure that critical user events are recorded and traceable (when, where, whom, why).*	n/a

Topics	**3.1.1 Requirements specification**
Hardware control *All device interfaces and equipments to be supported.*	GPIB interface ASL F26
Limitations *All acceptable and stated limitations in the software product.*	The software is only used by personnel within the Calibration Group. 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.
Safety *All precautions taken to prevent overflow and malfunction due to incorrect input or use.*	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)
Default settings *All settings applied after power-up such as default input values, default instrument or program control settings, and options selected by default. Includes information on how to manage and maintain the default settings.*	The GPIB-address for the ASL F26 is permanently set to 10, as the F26 is not expected to change its address
Version control *How to identify different versions of the software product and to distinguish output from the individual versions.*	The version number is part of the software name.
Dedicated platform *The hardware and software operating environment in which to use the software product. E.g. laboratory or office computer, the actual operating system, network, third-party executables such as Microsoft® Excel and Word, the actual version of the platform, etc.*	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.

Topics	**3.1.1 Requirements specification**
Installation *Installation requirements, e.g. installation kit, support, media, uninstall options, etc.*	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.
How to upgrade *How to upgrade to new versions of e.g. service packs, Microsoft® Excel and Word, etc...*	Upgrades will be done by an uninstall process followed by a new installation.
Special requirements *Requirements the laboratory is committed to, security, confidentiality, change control and back-up of records, protection of code and data, precautions, risks in case of errors in the software product, etc.*	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 <u>not</u> be stored in a format directly readable for humans, e.g. unencrypted text files.
Documentation *Description of the modes of operation and other relevant information about the software product.*	Graphic Overview  **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.

Topics	**3.1.1 Requirements specification**

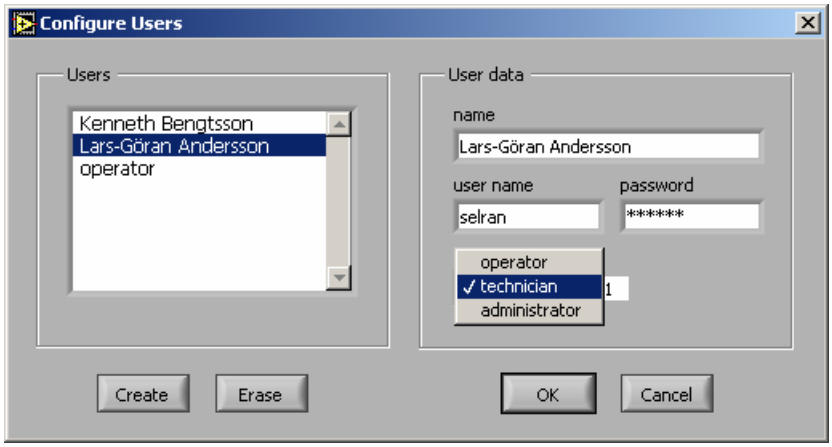
The formula for calculating temperatures is depending on two coefficients a and b. These coefficients have different values for temperatures <0.01 °C and >0.01 °C respectively. The software can calculate temperatures correctly in the range -40°C to +290° C (limited by ITS-90 conversion formulas).

The main functionality of the software is:
Login / Manage data for user profiles
Manage data for Pt-25 thermometers.
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.

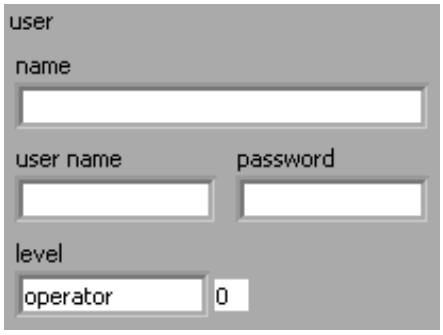
If not correct name and password are entered the software shall display an appropriate message and display the login dialog box once again.

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”.

Topics	**3.1.1 Requirements specification**

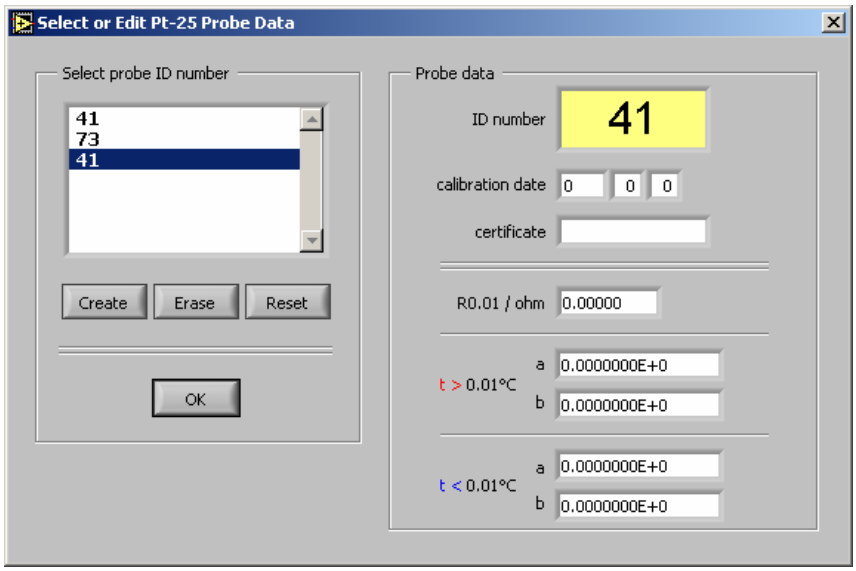


It shall not be possible all to erase all users at administrator level, or change the level of the last Administrator to another level. At least one administrator must be left.
All users shall be able to change password by clicking the button "Password".

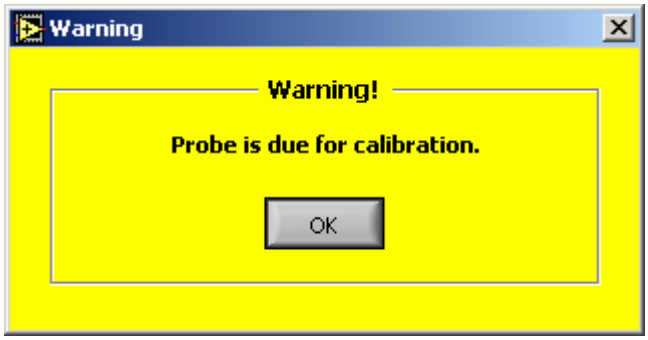
When changing password the user shall be prompted to enter a new password twice in a dialog box.
If the two passwords being entered are not identical, or if the password is less than 4 characters in length the software shall display an appropriate message and display the change password dialog box once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

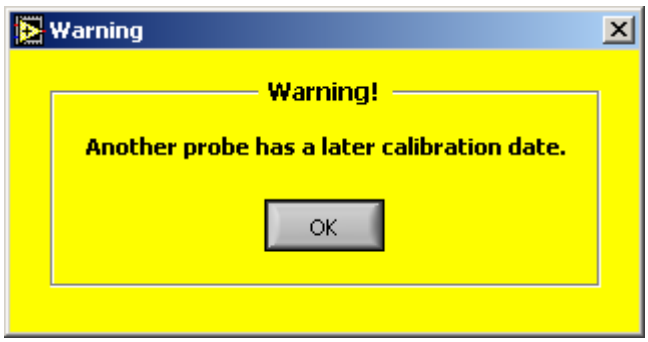
Topics	**3.1.1 Requirements specification**



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

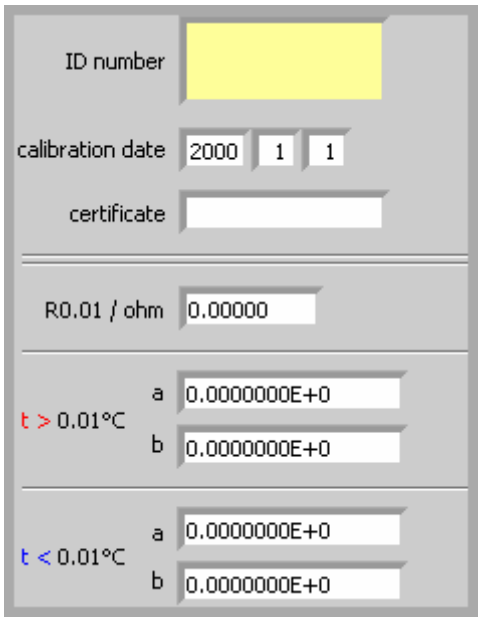


If a probe is selected and any other probe is registered with a later calibration data the software shall display a warning, see below.



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

Topics	**3.1.1 Requirements specification**



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”.

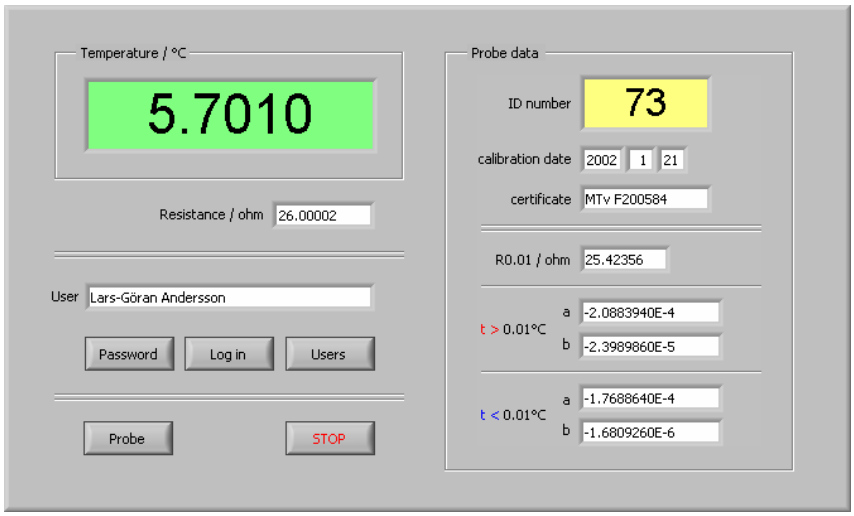
Administrators and technicians shall be able to reset changes by clicking the button “Reset”. This will reset any changes made before confirmation by clicking “OK”.

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.

Topics	**3.1.1 Requirements specification**
	 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.
User manual *User instructions on how to use the software product.*	No separate User Manual is produced. User Instructions are included in the *System Documentation for F26 Temperature According to ITS-90*.
On-line help *On-line Help provided by Windows programs.*	All front panel items will have tip-strips.
Validation report *Additional documentation stating that the software product has been validated to the extent required for its application.*	See Appendix 9 Validation Report for F26 Temperature According to ITS-90
Service and maintenance *Documentation of service and support concerning maintenance, future updates, problem solutions, requested modifications, etc.*	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.

Topics	**3.1.1 Requirements specification**
Special agreements *Agreements between the supplier and the end-user concerning the software product where such agreements may influence the software product development and use. E.g. special editions, special analysis, extended validation, etc.*	n/a
Phase out *Documentation on how (and when) to discontinue the use of the software product, how to avoid impact on existing systems and data, and how to recover data.*	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.
Errors and alarms *How to handle errors and alarms.*	n/a - The system is not designed to include any Alarm functions.

The system acceptance test specification contains objective criteria on how the software product should be tested to ensure that the requirements are fulfilled and that the software product performs as required in the environment in which it will be used. The system acceptance test is performed after the software product has been properly installed and thus is ready for the final acceptance test and approval for use.

Topics	**3.1.2 System acceptance test specification**
Objectives *Description of the operating environment(s) in which the software product will be tested and used.*	See Appendix 7 Acceptance test Plan/Report for F26 Temperature According to ITS-90
Scope *Scope of the acceptance test. E.g. installation and version, startup and shutdown, common, selected, and critical requirements, and areas not tested.*	See Appendix 7 Acceptance test Plan/Report for F26 Temperature According to ITS-90
Input *Selected inputs the software product must receive and handle as specified.*	See Appendix 7 Acceptance test Plan/Report for F26 Temperature According to ITS-90

Topics	**3.1.2 System acceptance test specification**
Output *Selected outputs the software product must produce as specified.*	See Appendix 7 Acceptance test Plan/Report for F26 Temperature According to ITS-90
Functionality *Selected functions the software product must perform as specified.*	See Appendix 7 Acceptance test Plan/Report for F26 Temperature According to ITS-90
Personnel *Description of operations the actual user(s) shall perform in order to make evident that the software product can be operated correctly as specified and documented.*	See Appendix 7 Acceptance test Plan/Report for F26 Temperature According to ITS-90
Errors and alarms *How to handle errors and alarms.*	See Appendix 7 Acceptance test Plan/Report for F26 Temperature According to ITS-90

3.2 Design and implementation process

The design and implementation process is relevant when developing new software and when handling changes subjected to existing software. The output from this life cycle phase is a program approved and accepted for the subsequent inspection and testing phase. Anomalies found and circumvented in the design and implementation process should be described in section 3.4, Precautions.

Topics	**3.2.1 Design and development planning**
Objectives *Expected design outcome, time schedule, milestones, special considerations, etc.*	See Appendix 4 Software Design Specification for F26 Temperature According to ITS-90
Design plan *Description of the software product e.g. in form of flow-charts, diagrams, notes, etc.*	See Appendix 4 Software Design Specification for F26 Temperature According to ITS-90
Development plan *Development tools, manpower, and methods.*	See Appendix 4 Software Design Specification for F26 Temperature According to ITS-90
Review and acceptance *How to review, test, and approve the design plan.*	See Appendix 4 Software Design Specification for F26 Temperature According to ITS-90

The design input phase establishes that the requirements can be implemented. Incomplete, ambiguous, or conflicting requirements are resolved with those responsible for imposing these requirements. The input design may be presented as a detailed specification, e.g. by means of flow charts, diagrams, module definitions etc.

Topics	**3.2.2 Design input**
Requirements analysis *Examinations done to ensure that the requirements can be implemented.*	See Appendix 4 Software Design Specification for F26 Temperature According to ITS-90
Software modules *Description of the software modules to be implemented.*	See Appendix 4 Software Design Specification for F26 Temperature According to ITS-90
Review and acceptance *How to review, test, and approve the Design Input section.*	See Appendix 4 Software Design Specification for F26 Temperature According to ITS-90

The design output must meet the design input requirements, contain or make references to acceptance criteria, and identify those characteristics of the design that are crucial to the safe and proper functioning of the product. The design output should be validated prior to releasing the software product for final inspection and testing.

Topics	**3.2.3 Design output**	
Implementation (coding and compilation) *Development tools used to implement the software, notes on anomalies, plan for module and integration test, etc.*	Development environment is LabVIEW 6.1	
Version identification *How to identify versions on screen, printouts, etc. Example "Version 1.0.0".*	Version number is part of the program name, e.g. F26 Temperature According To ITS-90 version 1.0	
Good programming practice *Efforts made to meet the recommendations for good programming practice...*	Source code is... ☑ Modulized ☑ Encapsulated ☑ Functionally divided ☑ Strictly compiled ☑ Fail-safe (handling errors)	Source code contains... ☐ Revision notes ☑ Comments ☑ Meaningfull names ☑ Readable source code ☑ Printable source code

Topics	**3.2.3 Design output**
Windows programming *If implementing Windows applications...*	☐ Interface implemented using standard Windows elements ☑ Interface implemented using self-developed Windows elements ☐ Application manages single/multiple running instances Comments:
Dynamic testing *Step-by-step testing made dynamically during the implementation...*	☑ All statements have been executed at least once ☑ All functions have been executed at least once ☑ All case segments have been executed at least once ☑ All loops have been executed to their boundaries ☐ Some parts were not subject to dynamic test Comments:
Utilities for validation and testing *Utilities implemented to assist in validation and testing and specification of the test environment.*	See Appendix 4 Software Design Specification for F26 Temperature According to ITS-90
Inactive code *Inactive (dead) code left for special purposes.*	No dead code exists.
Documentation *Documentation provided as output from the Design Output section.*	See Appendix 4 Software Design Specification for F26 Temperature According to ITS-90
Review and acceptance *How to review, test, and approve the Design Output section.*	See Appendix 4 Software Design Specification for F26 Temperature According to ITS-90

At appropriate stages of design, formal documented reviews and/or verifications of the design should take place before proceeding with the next step of the development process. The main purpose of such actions is to ensure that the design process proceeds as planned.

Topics	**3.2.4 Design verification**
Review *Review current development stage according to the design and development plan.*	See Appendix 4 Software Design Specification for F26 Temperature According to ITS-90

Topics	**3.2.4 Design verification**
Change of plans *Steps taken to adjust the development process.*	See Appendix 4 Software Design Specification for F26 Temperature According to ITS-90

The Design Change section serves as an entry for all changes applied to the software product, also software products being subjected to retrospective validation. Minor corrections, updates, and enhancements that do not impact other modules of the program are regarded as changes that do not require an entire revalidation. Major changes are reviewed in order to decide the degree of necessary revalidation or updating of the requirements and system acceptance test specification.

Topics	**3.2.5 Design changes**	*Date / Initials*
Justification *Documentation and justification of the change.*	1. Description: 2. Description: 3. ...	n/a
Evaluation *Evaluation of the consequences of the change.*	1. Description: 2. Description: 3. ...	n/a
Review and approving *Review and approving the change.*	1. Description: 2. Description: 3. ...	n/a
Implementing *Implementing and verifying the change.*	1. Action: 2. Action: 3. ...	n/a
Validation *The degree of revalidation or updating of requirements.*	1. Action: 2. Action: 3. ...	n/a

3.3 Inspection and testing

The inspection and testing of the software product is planned and documented in a test plan. The extent of the testing is in compliance with the requirements, the system acceptance test specification, the approach, complexity, risks, and the intended and expected use of the software product.

Topics	**3.3.1 Inspection plan and performance**	*Date / Initials*
Design output *Results from the Design Output section inspected...*	☑ Program coding structure and source code ☑ Evidence of good programming practice ☑ Design verification and documented reviews ☑ Change-control reviews and reports Comments:	2002-11-01 sechma

Topics	**3.3.1 Inspection plan and performance**	*Date / Initials*
Documentation *Documentation inspected...*	☑ Program documentation, flow charts, etc. ☑ Test results ☑ User manuals, On-line help, Notes, etc. ☐ Contents of user manuals approved Comments:	2002-11-01 selran
Software development environment *Environment elements inspected...*	☐ Data integrety ☑ File storage ☑ Access rights ☑ Code protection ☑ Installation kit, replication and distribution Comments:	2002-11-01 seevha
Result of inspection *Approval of inspection.*	☑ Inspection approved Comments:	2002-11-08 seevha

The test plan is created during the development or reverse engineering phase and identify all elements that are about to be tested. The test plan should explicitly describe what to test, what to expect, and how to do the testing. Subsequently it should be confirmed what was done, what was the result, and if the result was approved.

Topics	**3.3.2 Test plan and performance**	*Date / Initials*
Test objectives *Description of the test in terms of what, why, and how.*	See appendix 5 System test Plan/Report for F26 Temperature According to ITS-90	n/a
Relevancy of tests *Relative to objectives and required operational use.*	See appendix 5 System test Plan/Report for F26 Temperature According to ITS-90	n/a
Scope of tests *In terms of coverage, volumes, and system complexity.*	See appendix 5 System test Plan/Report for F26 Temperature According to ITS-90	n/a
Levels of tests *Module test, integration test, and system acceptance test.*	See appendix 5 System test Plan/Report for F26 Temperature According to ITS-90	n/a
Types of tests *E.g. input, functionality, boundaries, performance, and usability.*	See appendix 5 System test Plan/Report for F26 Temperature According to ITS-90	n/a

Topics	**3.3.2 Test plan and performance**	*Date / Initials*
Sequence of tests *Test cases, test procedures, test data and expected results.*	See appendix 5 System test Plan/Report for F26 Temperature According to ITS-90	n/a
Configuration tests *Platform, network, and integration with other systems.*	See appendix 5 System test Plan/Report for F26 Temperature According to ITS-90	n/a
Calculation tests *To confirm that known inputs lead to specified outputs.*	See appendix 5 System test Plan/Report for F26 Temperature According to ITS-90	n/a
Regression tests *To ensure that changes do not cause new errors.*	See appendix 5 System test Plan/Report for F26 Temperature According to ITS-90	n/a
Traceability tests *To ensure that critical events during use are recorded and traceable as required.*	See appendix 5 System test Plan/Report for F26 Temperature According to ITS-90	n/a
Special concerns *Testability, analysis, stress, reproducibility, and safety.*	See appendix 5 System test Plan/Report for F26 Temperature According to ITS-90	n/a
Acceptance criteria *When the testing is completed and accepted.*	See appendix 5 System test Plan/Report for F26 Temperature According to ITS-90	n/a
Action if errors *What to do if errors are observed.*	See appendix 5 System test Plan/Report for F26 Temperature According to ITS-90	n/a
Follow-up of tests *How to follow-up the testing.*	See appendix 5 System test Plan/Report for F26 Temperature According to ITS-90	n/a
Result of testing *Approval of performed tests.*	☑ Testing approved Comments: See appendix 9 Validation Report for F26 Temperature According to ITS-90	n/a

3.4 Precautions

When operating in a third-party software environment, such as Microsoft® Windows and Office, some undesirable, inappropriate, or anomalous operating conditions may exist. A discrepancy between the description of the way an instrument should operate, and the way it actually does, may be regarded as

an anomaly as well. Minor errors in a software product may sometimes be acceptable if they are documented and/or properly circumvented.

Topics	**3.4.1 Registered anomalies**
Operative system *Anomalous operating conditions in e.g. Windows.*	n/a
Spreadsheet *Anomalous operating conditions in e.g. Excel.*	n/a
Instruments *Anomalous operating conditions in the used instruments.*	n/a
General precautions *Anomalous operating conditions associated with the software product itself.*	n/a

The steps taken to workaround anomalous, inappropriate, or undesired operating conditions are verified and tested.

Topics	**3.4.2 Precautionary steps taken**	*Date / Initials*
Operative system *Precautionary steps taken in e.g. Windows settings.*	n/a	n/a
Spreadsheet *Precautionary steps taken to workaround problems using e.g. Excel.*	n/a	n/a
Instruments *Precautionary steps taken to workaround problems with the used instruments.*	n/a	n/a
General precautions *Precautionary steps taken to workaround problems with the software product itself.*	n/a	n/a

3.5 Installation and system acceptance test

The validation of the installation process ensures that all software elements are properly installed on the host computer and that the user obtains a safe copy of the software product.

Topics	**3.5.1 Installation summary**
Installation method *Automatic or manual installation...*	☑ Automatic - installation kit located on the installation media ☐ Manual - Copy & Paste from the installation media Comments:
Installation media *Media containing the installation files...*	☐ Diskette(s) ☑ CD-ROM ☐ Source disk folder (PC or network) ☐ Download from the Internet Comments:
Input files *List of (relevant) files on the installation media.*	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.
Installed files *List of (relevant) installed files, e.g. EXE- and DLL-files, spreadsheet Add-ins and Templates, On-line Help, etc.*	F26 Temperature According To ITS-90.exe F26 Temperature According To ITS-90.ini
Supplementary files *Readme files, License agreements, examples, etc.*	

The program is tested after installation to the extent depending on the use of the product and the actual requirements, e.g. an adequate test following the validation test plan. Sometimes it is recommendable to carry out the installation testing in a copy of the true environment in order to protect original data from possible fatal errors due to using a new program.

Topics	**3.5.2 Installation procedure**	*Date / Initials*
Authorization *Approval of installation in actual environment.*	Person responsible: secati	2002-11-02 secati
Installation test *The following installations have been performed and approved...*	☐ Tested and approved in a test environment ☑ Tested and approved in actual environment ☑ Completely tested according to test plan ☐ Partly tested (known extent of update) Comments:	2002-11-02 secati

The system acceptance test is carried out in accordance with the system acceptance test specifications after installation. The software product may subsequently be approved for use.

Topics	**3.5.3 System acceptance test**	*Date / Initials*
Test environment *The environment in which the system acceptance test has been performed...*	☑ The actual operating environment (site test) ☐ A true copy of the actual environment ☐ External environment (supplier factory test) Comments:	2002-11-02 secati
Test performance *Areas, which have been tested and approved...*	☑ Installation and version ☑ Startup and shutdown ☑ Selected or critical requirements ☑ Selected inputs ☑ Selected outputs ☑ Selected functionality ☑ Performance vs. user instructions Comments:	2002-11-02 secati
User level test *Test if users of various skills can use the software product...*	☐ Tested on beginner user level ☐ Tested on experienced user level ☐ Tested on professional user level Comments:	n/a
Result of testing *Approval for use.*	☑ Testing approved Comments:	2002-11-08 seevha

3.6 Performance, servicing, maintenance, and phase out

In this phase the software product is in use and subject to the requirements for service, maintenance, performance, and support. This phase is where all activities during performance reside and where decisions about changes, upgrades, revalidation, and phase out are made.

Topics	**3.6.1 Performance and maintenance**	*Date / Initials*
Problem / solution *Detection of software problems causing operating troubles. A first step could be to suggest or set up a well-documented temporary solution or workaround.*	1. Problem / solution: 2. Problem / solution: 3. ...	n/a

Topics	**3.6.1 Performance and maintenance**	*Date / Initials*
Functional maintenance *E.g. if the software product is based on international standards, and these standards are changed, the software product, or the way it is used, should be updated accordingly.*	1. Function / action: 2. Function / action: 3. ...	n/a
Functional expansion and performance improvement *List of suggestions and requests, which can improve the performance of the software product.*		n/a

When a new version of the software product is taken into use, the effect on the existing system is carefully analyzed and the degree of revalidation decided. Special attention is paid to the effect on old spreadsheets when upgrading the spreadsheet package.

Topics	**3.6.2 New versions**	*Date / Initials*
Description *Description of the new version to the extent needed to decide whether or not to upgrade.*	1. Version: Initial version. 2. Version: 3. ...	n/a
Action *Action to be taken if upgrade is decided. See also the Design Changes section.*	1. Action: 2. Action: 3. ...	n/a

It is taken into consideration how (and when) to discontinue the use of the software product. The potential impact on existing systems and data are examined prior to withdrawal.

Topics	**3.6.3 Phase out**	*Date / Initials*
How and when *To discontinue the use of the software product.*	n/a	n/a
Consequences *Assumed impact on existing systems and data and how to avoid or reduce the harm.*	n/a	n/a

4 Conclusion

By the subsequent signatures it becomes evident that all validation activities are documented and approved.

Final approval for use	
Laboratory Identification:	F26 Temperature According to ITS-90 version 1.0
Responsible for validation:	System Owner, seevha
Remarks:	
Date: 2002-11-08	Signature: seevha

Conclusion	
☑ All check boxes are locked for editing (to avoid inadvertent change of settings)	
Comments:	
Date: 2002-11-08	Signature: seevha

5 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	*SDD_F26_Temperature*

All documents related to validation tasks are normally stored as signed documents in a safe place. However, to make the access easier the documents listed above are copied into a single document file named:

Gambro Nordtest – F26 ITS90 1.0 Appendix.doc

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