

ValSuite® Software



*The world's
leading validation,
qualification and
calibration
software*

ValSuite® - introduction

The Ultimate Time-saving Software Solution

ValSuite is our reputable validation and calibration software. This intuitive software combines all our equipment systems into a single platform. Thereby opening the door to a vast amount of new possibilities by allowing you to combine data loggers with the traditional thermocouple systems.

We offer multiple versions of ValSuite to meet your exact needs. Most notably ValSuite Pro, our FDA 21 CFR Part 11 compliant software that ensures full data integrity.

ValSuite offers features like customized reports with clear pass/fail criteria, test templates, data analysis, monitoring, live data and much more.

ValSuite is developed according to GAMP principles and is available in multiple languages for Windows 7, 8 and 10 (32/64-Bit).

Detailed Control of Validation Studies

ValSuite guides you through the complete thermal validation process. The database structure within the software provides you with complete documentation and procedural control for complete peace of mind.

Test Setup

The report function allows you to program detailed test criteria into the software. Information on sensor placement, operator, test, vessel, required temperature limits, start and stop times, monitoring interval and specific calculations can all be saved in templates, uploaded and repeated. This ensures accurate documentation and correct implementation of the required procedures for consistent and repeatable tests.

Software Data Analysis Features

- The data analysis tools greatly reduce the time required to locate critical data
- The ability to zoom in the graphs and display multiple windows at a time, simplifies the process of identifying important data
- Multiple calculations, such as min/max, standard deviation, average, delta T and lethality can be calculated using any block of the displayed data - eliminating the need for exporting data and compromising data security

ValSuite collects and presents validation data from both the [E-Val™ Pro](#) and [TrackSense® Pro](#) data logging systems. The data from both systems can be presented and analyzed in the same session. The software can run up to 160 TrackSense channels or 120 E-Val Pro channels at a time, all of which can be identified and displayed in different groups, such as penetration and distribution. Any grouping or specific channels can be displayed in a separate data block and analyzed. It is also possible to merge individual sessions and run analysis for comparison purposes.

Your Choice:

ValSuite Basic - for your small or mid-sized food company

- ✓ Basic set of analytical tools and reports including lethality calculations
- ✓ Manual calibration
- ✓ Database back-up and restore

ValSuite Medical - for your hospital or medical company

- ✓ All **ValSuite Basic** features
- + Unit report with pictures
- + Bowie Dick Test for routine control of autoclaves

ValSuite Plus - for your large food company or hospital

- ✓ All **ValSuite Medical** features
- + Automatic calibration with optional OEM configuration
- + Moderate set of analytical tools and reports, including Heat Factors/Ball Simulation
- + Access Manager/Individual User Profiles
- + Server Solution

ValSuite Pro - for your Pharmaceutical company

- ✓ All **ValSuite Plus** features
- + Complete set of analytical tools and reports, including Advanced Phase Statistics
- + FDA 21 CFR Part 11 Compliant (Audit Trail/Electronic Signature/Access Point)
- + Validated according to GAMP 5



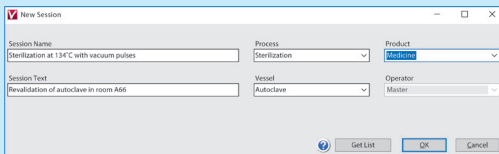
ValSuite's data integrity is demonstrated through evaluations made by Quality Compliance Partners Inc.



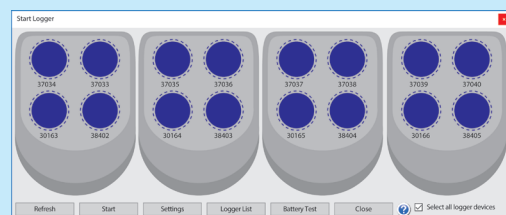
Intuitive and User-friendly Software

How to easily run the ValSuite software:

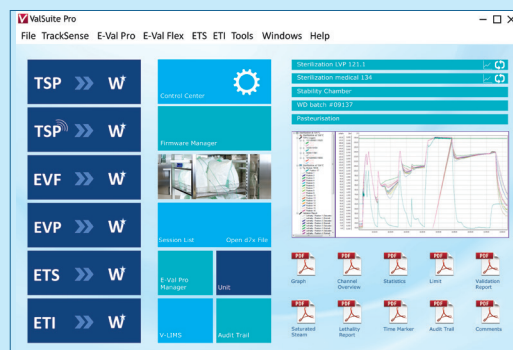
- 1 Login, program and start the measuring equipment using the Repeat function. This function includes a unit configuration and report selection.
Place the measuring equipment in the load or process and run the cycle.



- 2 Read the equipment. The data analysis will run and reports will be generated automatically.



- 3 Review the report and check the result.



ValSuite® - introduction

Highlighted Features

- One software platform for all Ellab equipment
- Combine TrackSense data loggers and the E-Val Pro wired thermocouple system in the same session
- Automatic PDF report generation with clear pass/fail indication
- Can run from a stand-alone PC or networked

GAMP Guidelines and ISO 9001:2015

All documentation and development of the ValSuite software is in accordance with the guidelines specified in GAMP and includes all the appropriate documentation. Ellab's quality system is in compliance with ISO 9001:2015.

Compliant to FDA Guidelines

- SQL database that ensures that complete sessions and individual data cannot be deleted or manipulated
- Serial number sensor ID's for complete traceability
- Customizable report generator that eliminates the need for exporting data into a different program

Validated Software - Documentation

The structure of the validation documentation behind the software complies with guidelines set by the following authorities:

- Good Automated Manufacturing Practice (GAMP 5), written by the International Society for Pharmaceutical Engineering (ISPE)
- FDA 21 CFR Part 11, subpart B & C, written by the U.S. Food & Drug Administration (FDA)

The following documents are either included or available upon request:

- User Requirement Specification (URS)
- Project Master Plan (PMP)
- Project Plan (CC) (RD system On-track)
- Critical Parameters (CP)
- Change Control (CC)
- Risk Based Code Review (RBCR)
- FDA 21 CFR Part 11 Compliance (21 CFR Part 11)
- IQ - Installation Qualification (protocol/report)
- OQ - Operational Qualification (protocol/report)

The following pages offer a small selection of the features that ValSuite offers...

Monitoring

Options

ValSuite offers several monitoring features, including on-screen statistical calculations, limit alarms, alarms via internet and notifications via e-mail. In addition to this, a "transport logger" function allows you to start and read a logger from two different databases/PC's. This feature enables the logger to monitor parameters during transportation over long distances.

Web Link Support

The ValSuite user manual is embedded in the software and can be accessed from relevant software positions marked with a ?. Hardware and software support is accessible within the ValSuite desktop through a direct link to the Ellab website. For E-service (hardware support) and calibration inquiries, a link is also available directly on the ValSuite desktop.



Remote Access & Data Monitoring

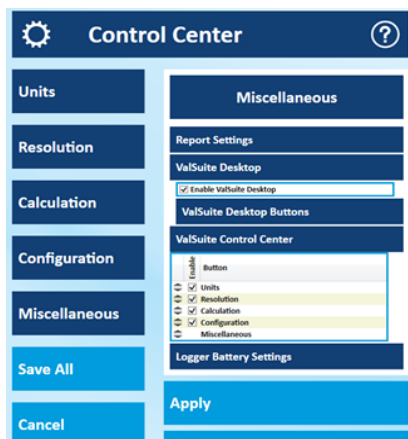
You can connect directly to the ValSuite SQL database by using an iPhone with the ValSuite App. An intuitive tool to monitor online data from ETS, E-Val Pro and TrackSense SKY sessions. This functionality is available through an IP address setup via a PC. The online alarm limit system for the basic parameters of temperature, pressure and relative humidity can be activated through a relay. Thereby providing an input to a SCADA system or any other external, or PC, alarm system. The gathered data is then either presented in a table or graph.

ValSuite® Basic

General Setup

Setting up and Programming via the Control Center

The Control Center is the main interface used to operate the hardware and ValSuite software settings. The Control Center collects and saves individual basic settings, such as parameter and unit definitions, calculations and resolution settings and database management. It also manages the design and configuration of the desktop's functionalities.



Super Quick Start

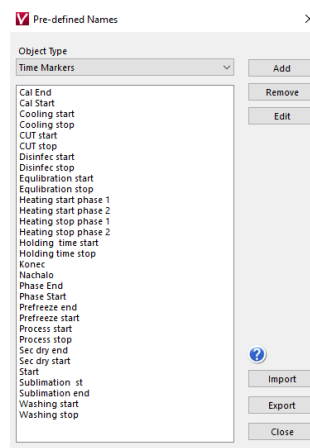
To quickly begin collecting data, ValSuite has a 'Super Quick Start' function. This feature creates a default session with a sequential name that can easily be changed later. Once data has been collected, the standard tools can be used to add reports, time markers, etc. Thereby reducing the setup time to an absolute minimum.

Repeat Session Feature

Additionally, it is possible to repeat an executed session's settings directly from the ValSuite desktop. This is done through a single click of the repeat session icon (dynamic).

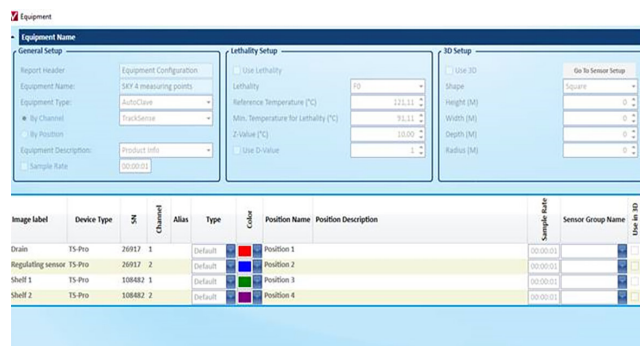
Sensor Grouping Function

ValSuite supports a special grouping facility for sensors. By adding sensors to a specific group, it is possible to analyze the performance of individual sensors as well as sensor groups. This is a major advantage for e.g. statistical analysis, in which multiple sensors are placed in a specific location and then compared to sensors in another area. For example, during shelf mapping in a freeze dryer, where the criteria performance is evaluated for both cross shelves and between shelves.



Predefined Names

Using Predefined Names ensures consistency, which is ideal for database search functionalities. By creating simple lookup tables by object type, position, time markers, process, vessel, operator, sensor group, equipment type or equipment description, you can quickly execute new studies. ValSuite also supports the ability to import/export existing namelists between databases, which is ideal for large organizations that need to share information between multiple users.



Unit Configuration

The Unit Configuration is the ideal choice for increasing the efficiency of studies that repeat the same sensor configuration and receive documentation that is in accordance with GMP. The functionality provides a quick layout of the sensors being used, including their position and ID. Thereby fully documenting the study. By implementing the use of Units, the startup process becomes much easier, and even safer, as it reduces the risk of human error. The Unit Configuration option works perfectly with Predefined Names.

ValSuite® Basic

The screenshot shows the 'Sessions' window in ValSuite. On the left is a tree view with categories like 'Philippine seminar', 'PIA', 'PMEC', 'SII Singapore', 'SKY test', 'Stability Chamber', 'Sterilization 121', 'Sterilization 134', 'SteriSense', 'Trash', 'Washers Disinfectors', 'Web sessions', 'Inactive', and 'Master Sessions'. The main area is a table with columns: ID, Name, Date/Time, User, Process, Product, Vessel, Operator, and Session Type. Below the table is a search interface with a 'Category' dropdown set to 'Process', a 'Search Sessions' field containing '38376', and date range filters for 'From' (01-01-2004) and 'To' (10-09-2019). A 'Preview' checkbox is checked, and a graph shows multiple data series over time with highlighted regions in yellow, red, and blue. Buttons for 'Transfer', 'Auto Transfer', 'OK', and 'Cancel' are visible.

ID	Name	Date/Time	User	Process	Product	Vessel	Operator	Session Type
4184	TSP standard calibration @0-60-90-120-140	12-07-2019 13:05	JER				Jan S Eriksen	TSP / ETS
4183	TSP manual PRS calibration	12-07-2019 13:05	JER				Jan S Eriksen	TSP / ETS
4182	TSP calibration @ 60-90-120-140 with adjust	12-07-2019 13:04	JER				Jan S Eriksen	TSP / ETS
4181	TSP 0-100°C calibration w. adjustment	12-07-2019 13:04	JER	Calibration	TSP loggers	LiquiCal SM	Jan Eriksen	TSP / ETS
4180	EVF Precalibration @ 60-90-120-140	12-07-2019 13:04	JER	Calibration	STC probes	LiquiCal HM	Jan Eriksen	EVF
4179	EVF Postcalibration @ 60-90-120-140	12-07-2019 13:04	JER	Calibration	EVF probes	LiquiCal HM	Master	EVF
4178	EVF calibration with increasing temperatures	12-07-2019 13:04	JER	Calibration	EVF probes	LiquiCal HM	Jan Eriksen	EVF
4177	EVF calibration with decending temperatures	12-07-2019 13:02	JER	Calibration	EVF probes	LiquiCal HM	Jan Eriksen	EVF
4176	TrackSense 4176	10-07-2019 15:58	JER				Jan S Eriksen	TSP / ETS
4175	TrackSense 4175	10-07-2019 15:52	JER				Jan S Eriksen	TSP / ETS
4174	10-07-2019- 8 (4138) B1 134 Electronic Bow	10-07-2019 14:48	JER	B1_100kPa/min	SteriSense	330-035 P	Jan S Eriksen	TSP / ETS
4173	TrackSense 4173	10-07-2019 13:58	JER				Jan S Eriksen	TSP / ETS
4172	10-07-2019- 7 (4138) B1 134 Electronic Bow	10-07-2019 12:50	JER	B1_100kPa/min	SteriSense	330-035 P	Jan S Eriksen	TSP / ETS
4171	10-07-2019- 6 (4138) B1 134 Electronic Bow	10-07-2019 12:48	JER	B1_100kPa/min	SteriSense	330-035 P	Jan S Eriksen	TSP / ETS
4170	10-07-2019- 5 (4138) B1 134 Electronic Bow	10-07-2019 10:49	JER	B1_100kPa/min	SteriSense	330-035 P	Jan S Eriksen	TSP / ETS
4169	TrackSense 4169	10-07-2019 10:44	JER				Jan S Eriksen	TSP / ETS
4168	TrackSense 4168	10-07-2019 10:43	JER				Jan S Eriksen	TSP / ETS
4167	Repeat Tracksense (4106) 10-07-2019 5	10-07-2019 10:31	JER				Jan S Eriksen	TSP / ETS
4166	TrackSense 4166	10-07-2019 10:28	JER				Jan S Eriksen	TSP / ETS
4165	TrackSense 4164c	10-07-2019 10:23	JER				Jan S Eriksen	TSP / ETS
4164	TrackSense 4164	10-07-2019 10:22	JER				Jan S Eriksen	TSP / ETS

Database Architecture

Database and Installation Modes

ValSuite uses a Microsoft SQL Server (MSQL) database that administrates the hardware and data. The database maintains complete and secure data integrity, while eliminating the risk of data manipulation. The SQL server solution manages user profiles, password security, electronic signatures, audit trails and file log. The database structure offers an advanced session search tool, allowing you to search for exact sensor serial numbers used during sessions.

The database is installed along with ValSuite, either directly on the PC or remotely on a server. The database can also be installed both ways as a Dual Dynamic Database.

A Dual Dynamic Database allows you to create sessions on a PC while disconnected from the company network (LAN). And then have them automatically synchronize once the PC is reconnected to the network.

Backup and Restore

ValSuite uses the Microsoft SQL Server's 10 GB database to backup data. Database backups can either be scheduled automatically (hourly, daily or weekly) or you can backup the database manually whenever necessary.

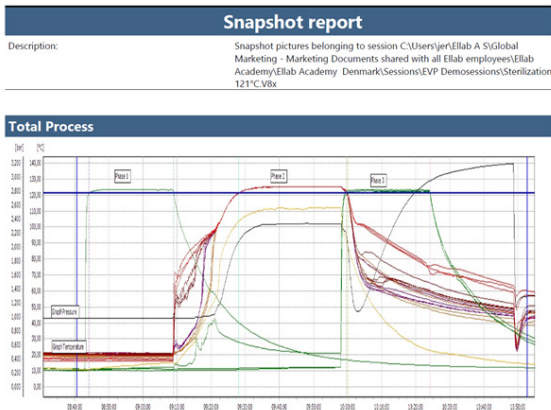
Alarms

Custom Alarms/General Online Alarms

General and custom alarms can be setup in ValSuite to notify you of any divergence. General alarms apply to all sensors of a given type (temperature, pressure, etc.). Whereas custom alarms are applied per sensor ID. It is also possible to create lethality alarms. Alarm notifications can be sent through email or an ethernet relay box (iTach). A relay box can be used in conjunction with PLC equipment or provide input to SCADA systems. Alarms include a ripple time by default, which prevents repeated alarms during the specified time period.

The screenshot shows the 'Alarm Configuration' dialog box. It has several sections: 'Temperature' with 'Upper Limit' at 140 °C and 'Lower Limit' at 80 °C; 'Pressure'; 'Relative Humidity'; 'Lethality' with 'Send or show alarm when lethality is' set to 12.00; 'E-Mail Configuration' with 'Send e-mail on alarm' checked, 'Use Outlook 2007 settings' checked, 'Max no. of e-mails pc. session' set to 5, 'E-mail Receiver' as jerr@ellab.com, 'E-mail Sender', 'SMTP Server', and 'Port' fields; a 'Test' button; 'Alarm Over Ethernet'; 'Ripple Time'; and 'Custom Alarms'.

ValSuite® Basic



Lethality

Predefined

Predefined F0 ▾

Current Values

Reference Temperature (°C)	121,11
Min. Temperature for Lethality (°C)	91,11
Z-Value (°C)	10,00

Use D-Value

Use D-Value 1

Add Custom Lethality

Graphical User Interface (GUI)

Graph Features

ValSuite graphs have an adjustable zoom feature that identifies target temperatures and times. The zoom feature can also take a snapshot of the data for documentation, which can then be saved to a photo library in the database.

Phase Analyzer

The Phase Analyzer function allows names and colors to be added to defined phases in validation and qualification reports. Each phase can be adjusted individually for a better overview of the process. The Phase Analyzer is ideal for reports like EN17665, EN13060 and EN285 for autoclaves and EN15883 for washer disinfectors.

Calculations

Lethality Calculations

ValSuite also offers default lethality calculations on temperature sensors for A0 (Washer Disinfectors), F0 (Sterilizers), P0 (Pasteurizers), C0 (Cookers), and FH/FD (Dry Heat Sterilization/Depyrogenation). You can even create custom lethality values and save them as a template for future use.

Lethality is represented on a graph, from which you can select specific temperature channels to view or to view them all. You can also select lethality calculations for the entire process or simply for specific parts of the process. For a more advanced analysis, lethality can be linked to the presence of saturated steam.

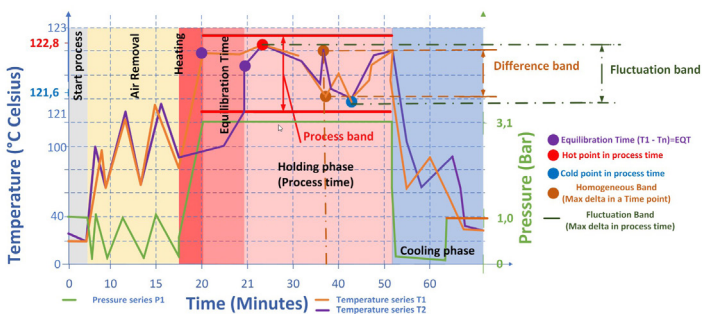
For automatic control of e.g. sterilizers, a digital output sensor can be set according to a user defined state (open – or closed contact). This state is based on the real-time lethality calculation on any given temperature sensor.

RH Dry/Wet Calculations

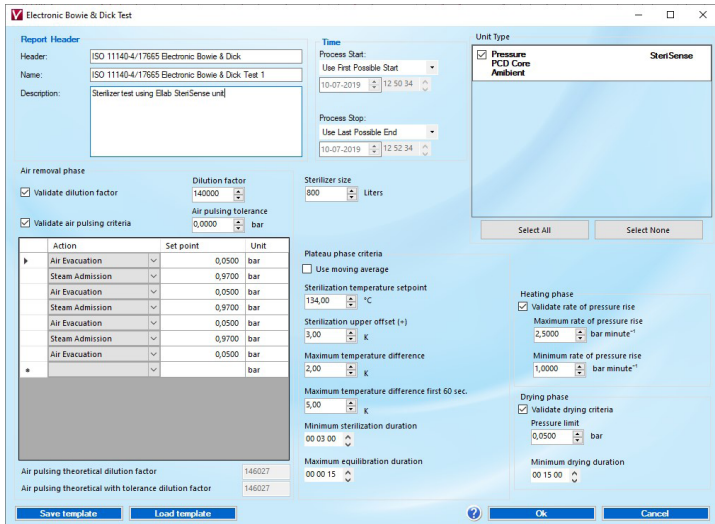
ValSuite supports RH% calculation, using wet and dry temperature values through the psychrometric method. This calculation is typically used when a standard RH sensor is unable to be used in a session due to the risk of clogging.

Manual Calibration

ValSuite Basic is also a calibration software, allowing you to perform manual calibrations. All sensors can be user calibrated at predefined intervals and have their offset values linked to the sensor serial number. These offsets will then be taken into account whenever a sensor is used in future studies.



ValSuite[®] Medical - includes all ValSuite Basic features and more

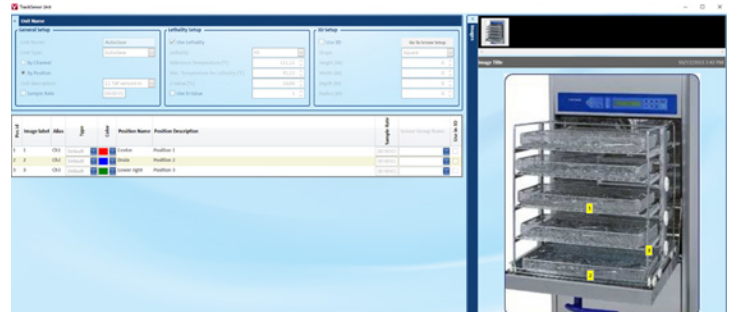


Bowie Dick Test

Following the EN 17665 and EN 285 standards, autoclaves in the medical device sector must routinely be tested for their steam penetration and air removal systems. To do this, Ellab has developed an electronic measuring device that provides measurements used to evaluate critical physical parameters of the sterilization process. Thereby providing more accurate results and eliminating the guesswork typically associated with chemical indicators - by clearly highlighting the pass or fail result directly in the automatically generated report. The Bowie Dick test in ValSuite allows you to store the results electronically in the database, opposed to keeping them physically.

Theoretical Saturated Steam Temperature Calculations

The theoretical steam temperature function converts a pressure series to a temperature series. The conversion is performed according to the steam table and is used to identify if the saturated steam condition was achieved. It does this by simply comparing the calculated values to real temperature measurements.



Units with Pictures

ValSuite provides you with the option to document the sensor number in relation to its position by adding a unit with a picture. Multiple pictures or graphical schematics can be added that clearly shows where a sensor is located, complying with the demands of certain authorities. You can define the sensor placements through the sensor serial numbers (the same sensor in the same location for every study) or by sensor position (any sensor can go into the position).



ValSuite® Plus - includes all ValSuite Basic features and more

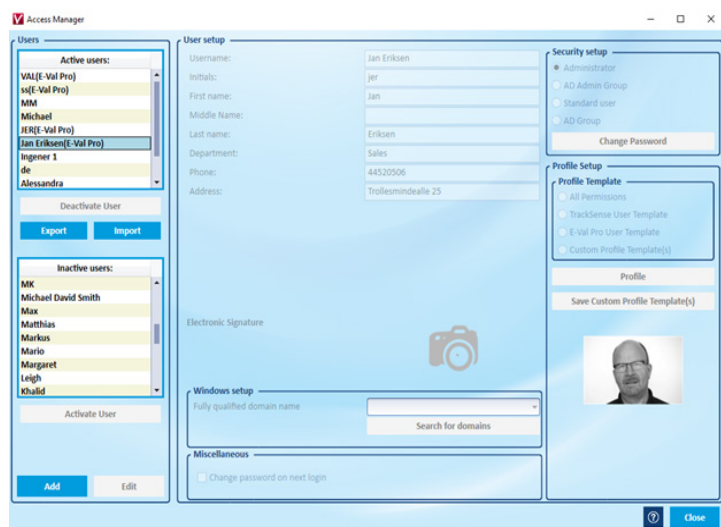
Security Modes and Access Manager with AD Groups

ValSuite Security uses an advanced access manager function to define users and configure their rights. It defines, lists and controls the access to application setups, session execution, file handling, report generation and equipment access.

ValSuite's individual profiles can allow or restrict the software's functionalities depending on the profile that is selected. These profiles, or operator levels, consist of Administrator, Standard User, Active Directory (AD) Member or AD Admin Group User. The software interface shown on the desktop changes when each user profile is configured. This means that only the approved functionalities or available instrumentation is activated, making the software even more intuitive to use.

The access manager can also be linked to Windows Login, where users are part of a domain AD group. Administrators will be connected to an AD Admin Group while standard users will be sorted into a regular AD Group. This way, all handling of passwords is performed by Windows, providing a major advantage for larger organizations.

Furthermore, it can be defined whether passwords should be used at startup (login) – or be prompted at predefined points.

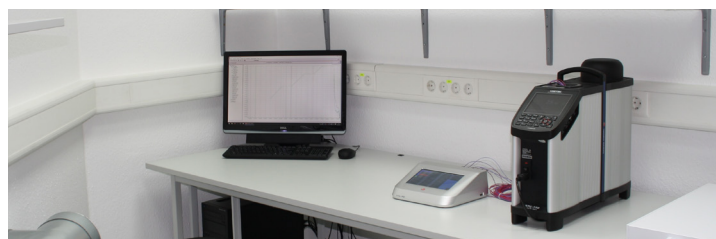


Profile Features

The Profile session is a high level template that offers increased efficiency for repetitive studies and analyses. When using a unit, the predefined sensors/positions can be defined and numerous reports, comments and time markers can be added to preprogram a complete study. This study setup can then be reused at a later date, ensuring repeatability and reduced setup times.

Automatic Calibration

Fully automatic calibrations can be performed by connecting the Ellab Temperature Standard (ETS) and appropriate calibration bath or dry block to a PC. You simply input the calibration criteria and walk away until the calibration is complete.



Heat Penetration Study

ValSuite supports the Heat Penetration method known as "Ball", which refers to a formula in the "Thermal Process Time for Canned Food". The purpose of the heat penetration analysis is to obtain a model of a specific process based on the following constants: Fh, Jh, Fc and Jc.

The model can be used to answer these typical questions:

- If a process runs for 30 minutes instead of 25 minutes, what effect does that have on the lethality value?
- If the lethality value must be 15, how long should the process time be?

Instead of performing additional time-consuming tests to answer these questions, ValSuite allows you to run a Ball Simulation that calculates the heating factors and provides clear-cut answers.

Dew Point Calculation

ValSuite supports Dew Point calculations made from two temperatures - one wet and one dry. By using this psychrometric principle, the two temperatures can easily be defined to perform rather advanced calculations and generate individual reports.

Client/Server Solution

The Client/Server solution is used for organisations with many ValSuite installations that wish to store all of their sessions in one database. This way, several PC's/clients can be connected to the same server, providing access to all the data at the same time.

For example, a PC environment that uses the Client/Server feature can be configured by a number of portable ValSuite PC's (clients). The PC's are used remotely and are therefore disconnected from the server during data acquisition - a rather normal scenario for validation consultant companies.

During operation, the data is consequently stored locally, however, when the portable PC's are reconnected to the server, the auto transfer tool is used to copy and send all new sessions to the server.

ValSuite® Pro - includes all ValSuite Plus features and more

FDA 21 CFR Part 11 Compliance

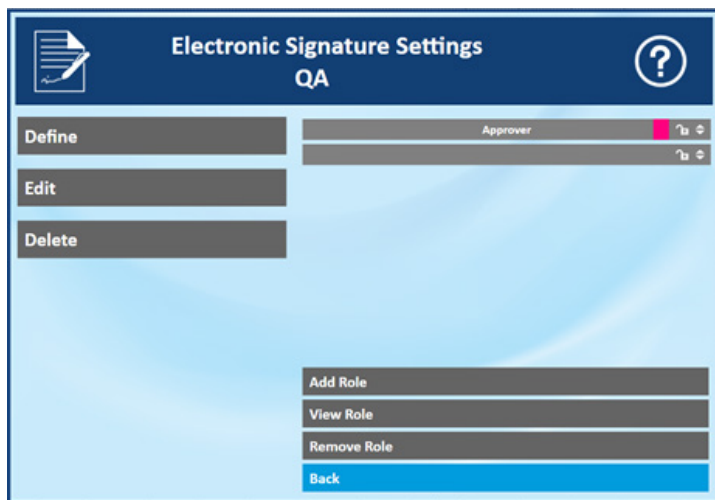


Compliant with FDA Guidelines

- SQL database that protects sessions and individual data from being deleted or manipulated
- Audit trail report
- Electronic signature
- Access manager with password control and user ID settings
- Complete traceability by Sensor ID
- Customized report generator that eliminates the need to export data

Electronic Signatures

In addition to password login requirements, audit trails and controlled user permissions, the electronic signature feature is a cornerstone of FDA 21 CFR Part 11 compliance. By utilizing a workflow function where individual users are defined by the “roles” of Operator, Reviewer or Approver, it is possible to control and trace every session. This ultimately approves and locks sessions with time stamps and user ID’s. Sessions with the electronic signature feature activated are clearly marked by color in the session list for easy identification, tracking and retrieval.



Electronic Master Report

The Electronic Master Report feature allows you to automatically apply an electronic (digital) signature to report pages. This FDA compliant feature determines how signatures are managed and is far more efficient than manually printing, signing and scanning documents.

Audit Trail Report

ID	Text	Time stamp	User	Import Date Time	Import User
240548	Create Session:TrackSense cal 1(ID:4119) By User: JER PC: LENOVO-X1-JER-Operator;Jan S Eriksen'	21-02-2019 08:27:52 (UTC+01:00) Romance Standard Time	JER	N/A	N/A
240550	Start Logger(s) in Session(ID:4119) ValSuite Version: 5.2.0.13 [Logger SN:413718 Sensor SN:390569]	21-02-2019 08:28:29 (UTC+01:00) Romance Standard Time	JER	N/A	N/A

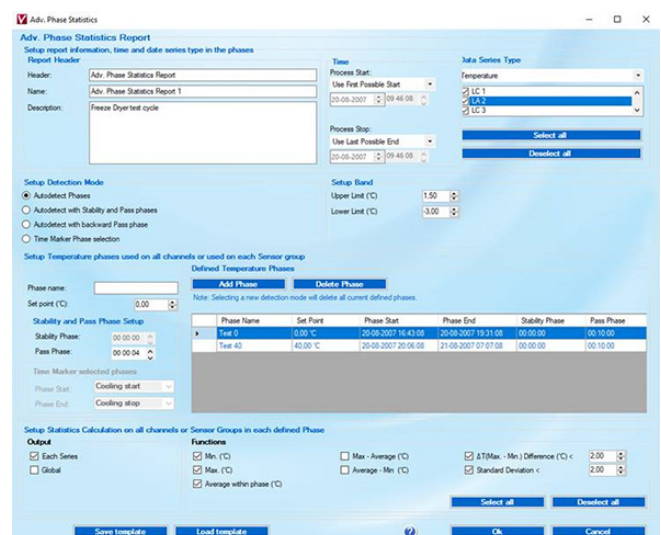
Audit Trail

The audit trail in ValSuite is a record that shows who has accessed the software and what actions particular users have performed during a given time period. It presents a unique ID number, a text explaining the action according to the access points, a category definition, a user field showing the operator initials and a time stamp. Due to the database structure, it is possible to facilitate convenient searches on strings of text, like user ID's or dates. Every single session has an individual audit trail that covers the entire scope of activities and actions in chronological order.

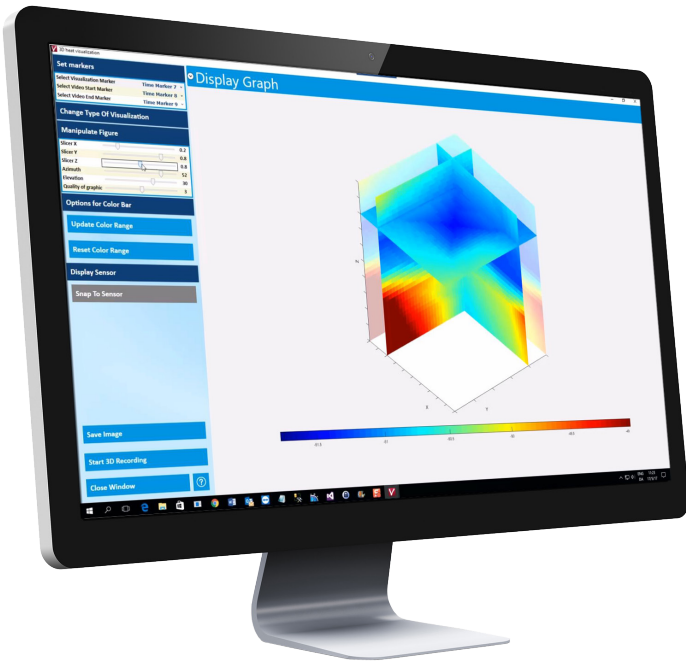
Advanced Phase Statistic report

The Advanced Phase Statistics is a multi-flexible analyze tool that performs statistics (min/max, standard deviation, average, delta T and lethality) and limit tests. It does so on either manually defined phases (by time markers) or automatically detected phases in the process. A global pass/fail report can then be generated in addition to the wide range of test modes.

The Advanced Phase Statistics works perfectly in combination with sensor groups, which allocates the sensors into groups that represent areas or temperatures of an application. For example, a shelf in a freeze dryer or a specific temperature zone within a tunnel.



ValSuite® - options



3D Heat Analysis

The optional 3D Analysis tool allows you to visualize the temperature, humidity or lethality gradients in a 3-dimensional environment, indicated by a change in color. The ideal tool for mapping. The data can also be documented and presented as a video that shows the variations over time. All custom settings can be saved and stored in a template for later use.

The ValSuite SCADA Version

Supervisory Control and Data Acquisition (SCADA) installation offers you the option to import online data generated by E-Val Pro or TrackSense Sky sessions from the SQL database and send it to the control process machinery's PLC (Programmable Logic Control). This is achieved by creating a parallel database to extract data from in order to merge ValSuite studies with process data from equipment. Ultimately providing a comparison and analysis of the collective data. This has proven to be highly useful for process monitoring and batch control applications.

Large-Scale IT System Integration

Integrate into Simple or Advanced Setups

ValSuite can be operated from a singular laptop or be integrated into large-scale IT systems:

- Client server solution with a central server database
- Citrix solution
- Virtual servers and remote desktop
- Cloud solutions in the Amazon Web Service

ValSuite is designed to integrate into any modern IT Architecture, providing a safe and compliant solution.

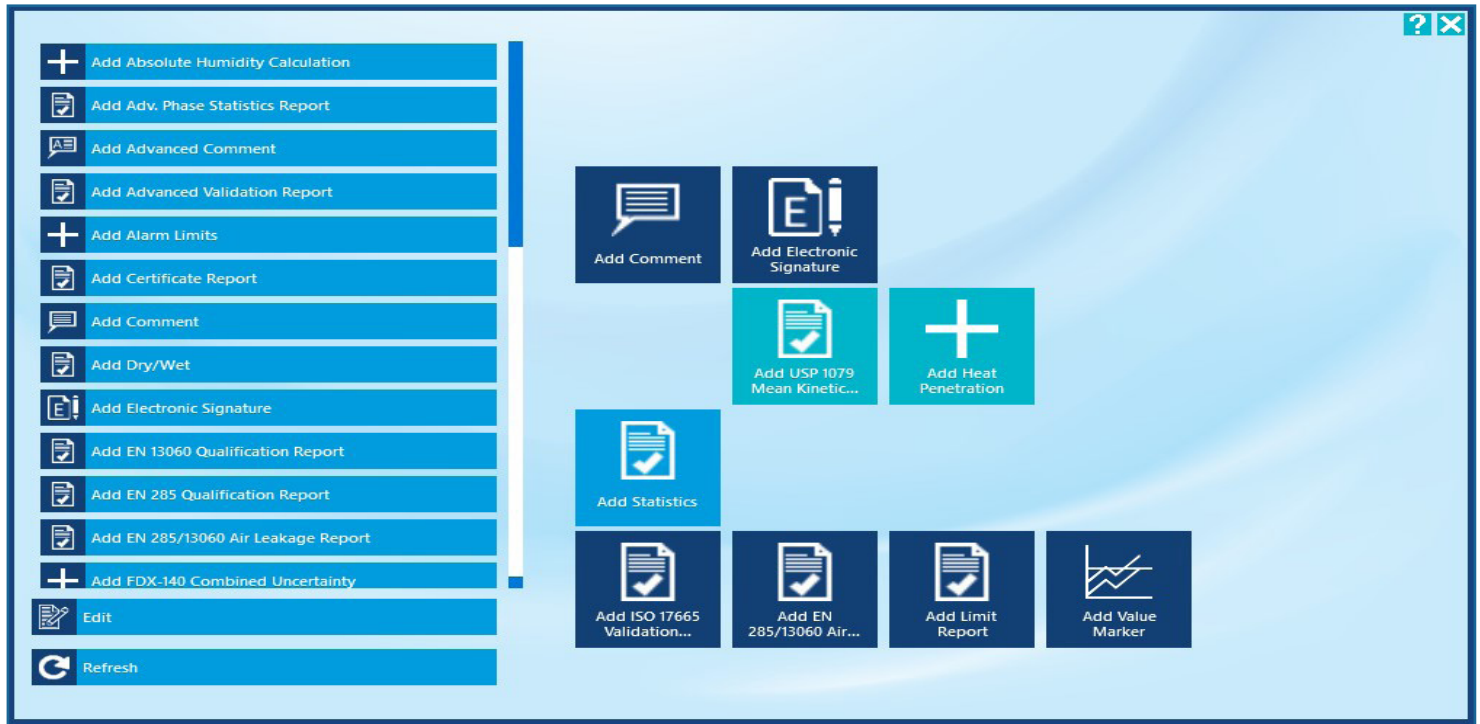
Citrix Ready

ValSuite can support a remote/virtual desktop Citrix application delivery setup, where applications and resources are hosted on central servers. The Citrix XenApp, then isolates these applications from the underlying OS and streams them into an isolated environment on the targeted device so that they may be used. By choosing a Citrix solution, applications and software no longer have to be installed locally on client devices.

Integrates into Active Directory

The Active Directory interface and support provides improved user management tools for large-scale IT systems.





Reporting

ValSuite offers an outstanding Datapoint Process Report Generator (DPRG), which produces fully compliant user reports in accordance with current norms and standards related to validation processes and equipment qualifications.

ValSuite also maintains templates for reports designed to meet specific requirements of tests, such as:

- EN 13060 Qualification Report
- EN 285 Qualification Report (incl. special templates for different sizes)
- EN 285/13060 Air Leakage Report
- EN17665 (EN554) Report for evaluating the sterilization processes of healthcare products
- FDX-140 Combined Uncertainty for a statistical analysis of the stability in a chamber
- ISO 15883 Basic and Advanced Washer Disinfectant Evaluation Report
- USP 1079 Mean Kinetic Temperature Report for evaluating the products contained in pharmaceutical warehouses
- ISO 11140-4/17665 Electronic Bowie Dick Test

The user designed templates can be customized to organize data and perform calculations to match exact criteria.

This feature greatly reduces the time required for the data analysis process. Reports can be reviewed with the print preview feature and saved in a PDF file format.

Custom Logo

By using the Configuration facility in the Control Center, a company logo can be embedded into reports for clear origin documentation. Using no logo or the default Ellab logo is also an option. Logos are automatically formatted to fit the report heading.

ValSuite® - producing reports

Table of Contents

Report name	Page
Front Page	1
Table of Contents	2
General Description	3
Snapshot report	4
Time Marker Report	6
Unit Configuration	7
Time ≥ 121 °C (Bioreactor) Passed	17
Time ≥ 121 °C (Condensate drain) Failed	18
Lethality	19
Statistics - Sterilisation Phase 1	20
Statistics - Sterilisation Phase 2	21
Statistics - Sterilisation Phase 3	23
Statistics - P Sterilisation Bioreactor	24
Statistics - T Sterilisation Bioreactor	25
Summary of results - Bioreactor	26
Summary of results - Condensate Drain	27

Table of Contents

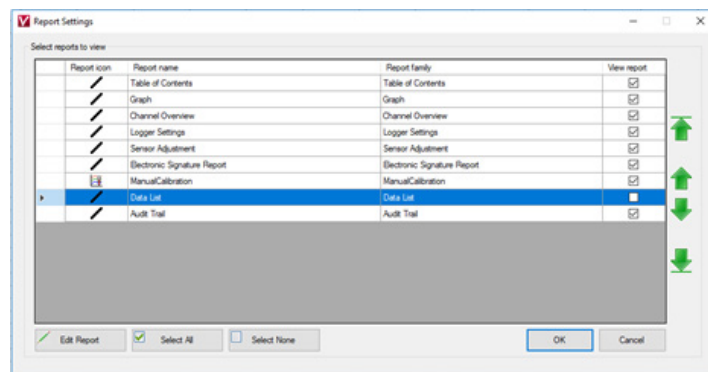
This feature automatically generates an index containing all the parts of the study that you select. The pages are numbered to provide an easy overview and the pass/fail results for each analysis are shown directly on the list.

Front Page Report

A simple and easy front page setup that includes a description of the study, acceptance criteria, final result and an identification of the operator/vendor.

Report Order Selection

This control center feature allows you to decide the exact order or sequence in which the different reports are shown and eventually printed. This setup can be saved as a template for repeatability and conformance.

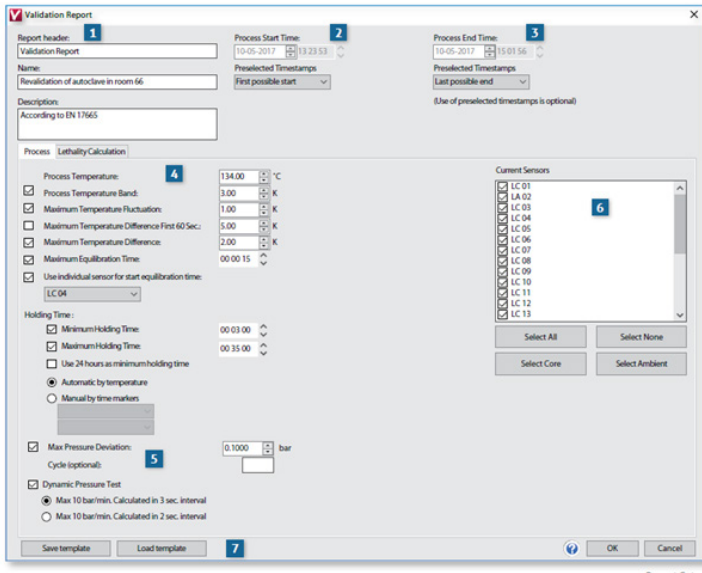


Add Comments

Additional information can be added by using the Comment, Advanced Comment or Word document attachment features. The Comment setup works as a text editor with an option to copy/paste from MS Word or other similar programs. All comments are then stored along with the session/files in the database.

The Advanced Comment feature uses the Report Builder SQL 2016 tools for more intensive documentation. Advanced Comments can also be saved in the database.

Finally, a complete Word document, i.e a SOP, can be added. Once uploaded, the document is locked and saved in the database. If the related session is later shared or exported from the database, the Word document is automatically attached.



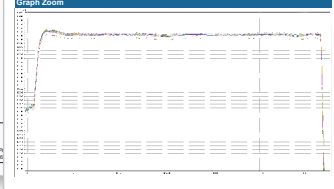
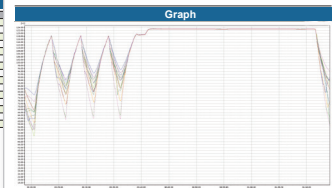
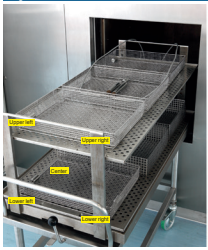
Step-by-Step Programming

1. Input a report header, report name and a detailed description.
2. Input a process start time and optional timestamps.
3. Input a process end time and optional timestamps.
4. Input the desired values in the process fields and select the process parameters in accordance with the appropriate standard.
5. Fill out the additional fields and select the process parameters in accordance with the appropriate standard.
6. Define the measuring points (sensors) that should be included in the report.
7. Save and upload preconfigured report templates.
8. The result of the analysis is presented in a clear format that is ready to be printed, saved or distributed electronically.

A non-successful validation process will, in addition to being marked failed, also indicate which part of the process failed, making it easier to diagnose and correct the issue.

Report Setup

All reports are designed to provide maximum flexibility and usability by using templates that are easy to program and execute.



ValSuite® - user calibration



ValSuite is not only a validation software, but also a calibration software. This means that all sensors and probes can be user-calibrated at predefined intervals. Their offset values can also easily be stored in either the software and/or hardware. A report is then automatically generated with the overall calibration results.

Depending on the ValSuite version, you can set the calibration setup to either Manual, Semi-Automatic or Full Automatic calibrations. Various templates can be stored and uploaded at any given time. The identified offset values are linked directly to the sensor ID number, and will be taken into account whenever the sensor is used in future measurements.

Calibration Certificates/Factory Calibration

To secure overall product quality, all equipment manufactured by Ellab is either factory calibrated optionally or by default. We also recommend that sensors receive annual factory calibrations.

During factory calibration, the sensor-under-test is compared to reference equipment with full traceability to national and international standards. The data is then saved in the sensor and presented in a calibration certificate.

For several years, the Ellab factory calibration certificates for TrackSense have been available via our Cloud solution. These can easily be accessed through V-LIMS or directly from ValSuite by using the sensor ID number. All certificates are digitally signed and saved in a database which fully complies with FDA 21 CFR Part 11.

Calibration Setup

Operation Type

- Full-Automatic Calibration
- Semi-Automatic Calibration
- Manual Calibration

Calibration Type

- Calibration
- Verification
- Verification custom

Device Type

- E-Val Pro
- E-Val Flex Module
- TS Pro Logger
- ETI
- ETS

Temperature Standard Info

Serial Number: 110001

Stability Criteria

Fluctuation Band: 0,20 °C

Fluctuation Time: 00 03 00

Holding Time: 00 05 00

Pass Criteria

Temperature Standard Fluctuation Band: 0,10 °C

Channel Temperature Deviation Before Adjustment (+/-): 0,15 °C

Channel Temperature Deviation After Adjustment (+/-): 0,05 °C

Calibration Points

°C 0,00

Temp	Adj. Point
0	<input checked="" type="checkbox"/>
60	<input checked="" type="checkbox"/>
90	<input checked="" type="checkbox"/>
120	<input checked="" type="checkbox"/>
140	<input checked="" type="checkbox"/>
0	<input type="checkbox"/>

Set Point Tolerance (+/-): 1,00 °C

Ellab



Ellab has been your validation and monitoring partner since 1949, offering wireless data loggers and thermocouple systems for thermal validation processes as well as environmental wireless monitoring solutions.

We serve both small and large companies within the Life Science and Food industries and have solutions for almost all applications such as sterilization, freeze drying, environmental chamber testing, depyrogenation, warehouse mapping, pasteurization and many more.

Ellab develops unique and innovative solutions based on input from close interactions and dialogues with our customers. Our goal is to help our customers overcome challenges and increase their productivity by providing reliable and efficient solutions.

Ellab also offers complete turn-key or supplemental rental solutions, equipment qualification and validation services and our specialized training courses within Ellab Academy.

Ellab has a long tradition and dedication for delivering the highest performance and quality in our industry. Our user friendly and flexible validation and monitoring solutions are recognized and used by thousands of customers worldwide.

Ellab A/S is ISO 9001 & ATEX IEC 80079-34 certified. Our calibration laboratories in DK are accredited according to ISO/IEC 17025:2005 by DANAK under registration no. 520 and our German laboratory has a DAkkS ISO/IEC 17025:2005 accreditation. We also have a UKAS ISO/IEC 17025:2005 accreditation at our monitoring manufacturing site in UK.



Validation & Monitoring
Solutions

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