



Electronic Test System



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Remark: The term “ETS Sensing Unit” in this document always includes ETS Sensing Unit 4108, ETS Sensing Unit 4208 and ETS Sensing Unit 4308. The term “ETS USB Data Reader” always includes ETS Data Reader 4109 and ETS Data Reader 4309



1 Preface

1.1 General System Description

The Electronic Test System (ETS) is an easy to use electronic test system that provides the user with comprehensive objective information on the physical variables of a steam sterilizer.

In addition to providing an alternative to the Bowie and Dick test, a number of other important functions and tests can be performed by the device.

Its performance is highly reproducible and equivalent in terms of the performance of a standard Bowie and Dick test pack as described in EN 285 and EN ISO 11140-3. It is tested in accordance with the methods described in EN ISO 11140-4.

It therefore satisfies the requirements for a daily steam penetration test as prescribed in EN ISO 17665-1.

An "Early Warning" indication is given to further qualify the pass result of a Bowie and Dick test cycle.

A "Fail" result is indicated if there is sufficient residual air within the chamber to create a Bowie and Dick test failure as described in EN 285. A "Fail" result will also be indicated if the fundamental sterilization parameters defined in EN 285 and by the WHO (134°C / 3 min) are not met.

The main component is the ETS Sensing Unit which functions as a stand-alone measurement system, providing clear "Pass" or "Fail" results and, if applicable, the "Early Warning" indication.

The system can be further enhanced by using the optional ETS USB Data Reader. The ETS USB Data Reader enables data transfer from the ETS Sensing Unit to a computer.

In combination with the optional ETS PC Software 4110, additional information on the sterilizer's performance can be obtained, such as the Leak Rate Test (EN 285), Dilution factor, F_0 Integration and Sterilization Parameter Indication (according to EN 285 and WHO 134°C for 3 min). The software also offers diagnostic functions such as a cycle comparison. This important function helps to identify process variations and supports finding causes of failure(s) and recommendations for possible remedial action.

Additionally, the ETS PC Software 4110 provides a secure and easy to use digital archive in which all relevant information is stored required for full trace ability.

Note: To facilitate the installation process for the entire system it is recommended to install and start the ETS PC Software 4110 first. The installation (connection) of the ETS USB Data Reader shall be the second step.

This procedure provides also the benefit of access to the full documentation available in the on-line help of the software package. The ETS Sensing Unit requires no installation.

1.1.1 Intended Use

The primary function of the ETS Sensing Unit is to monitor the air removal stage and the sterilization phase of a steam sterilization cycle as required by EN ISO 17665-1.

The ETS Sensing Unit can be used as alternative to the Bowie and Dick test as described in EN 285. Furthermore, data logged by the ETS Sensing Unit can be used for calculation of a Leak Rate in accordance to EN 285.

The ETS Sensing Unit can also be set in Data Logging Mode for use in steam sterilization cycles operating at temperatures other than 134°C for 3 minutes. When used in this mode the software allows individual interpretation of sampled data. No Bowie and Dick result will be available then.



The ETS Sensing Unit offers the following functions and features:

- Daily steam penetration test (Bowie and Dick test)
- Early Warning (as part of steam penetration test result)
- SPI (Sterilization Parameter Indication)

In combination with the ETS USB Data Reader and the ETS PC Software 4110:

All of the above plus:

- Complete trace ability information
- 21 CFR part 11 compliance
- Dilution factor / Residual air calculation
- Master Overlay evaluation
- Multiple test comparison
- Pressure control points detection
- Superheated steam detection (via theoretical temperature curve calculation)
- Sterilization period evaluation
- SPI evaluation
- F_0 Integration
- Calibration check
- Data logging
- Leak Rate test
- Pressure change rate test
- Intelligent data handling, logbook, sorting and filtering

1.1.2 Compatibility

The Electronic Test System contains a number of technical upgrades. These upgrades are implemented in the ETS Sensing Unit, the ETS USB Data Reader and the ETS PC Software 4110 latest revision. All three components are fully compatible with each other.

ETS Sensing Unit

All ETS Sensing Units (4108 (old) / 4208 (current) / 4308 (new)) can be used in combination with the ETS PC Software 4110 latest revision and ETS USB Data Reader 4109 / 4309.

Note: The user can keep using the ETS Sensing Units 4108 and 4208 until the 400 uses are reached.

ETS USB Data Reader

The ETS USB Data Reader is compatible with computers that have a free USB port and operating system Microsoft Windows 10 and previous versions.

The ETS USB Data Reader is a Human Interface Device and requires no additional USB driver installation. The required driver is available in Windows.



ETS PC Software 4110

The ETS PC Software 4110 is compatible with operating system Microsoft Windows 10 and previous versions.

New or special operating systems must be tested and validated before.

Files from a previous ETS PC Software version:

All historical ETS files can be imported into the ETS PC Software 4110 data base.

New ETS data records generated with the new system can be exported to original ETS files (*.ets).

1.1.3 Safety

The ETS Sensing Unit is only to be used according to the User Manual.

Only those parts which are listed and described in [Section 2.3 Instructions for Use on Page 12](#) shall be used.

Caution: After usage in a sterilizer cycle, the ETS Sensing Unit will be hot. Protective gloves shall be worn when handling the ETS Sensing Unit.

After activation the switch will return to its start position. If for whatever reason, the switch stays in the pulled position the ETS Sensing Unit should not be used.

The product was tested under EN 61010-1 and EN 50081-1.

After switching on, do not use compressed air etc. to e.g. dry the ETS Sensing Unit.

The ETS Sensing Unit shall only be used in the environment as described in the [Section 2.2 Technical Data on Page 11](#).

1.1.4 Warranty

This product has a warranty of two years or 400 uses, whichever is earlier.

In case of a legitimate complaint, 3M's sole obligation as regards warranties shall be to either replace the defective product or refund the purchase price.

1.1.5 Service

The ETS Sensing Unit does not require any dedicated or routine service, e.g. no battery change. In case of any malfunction, please contact your local 3M representative.

1.1.6 Approvals

The product meets the basic requirements of the RoHS directive 2011/65/EU and is therefore CE marked.

1.1.7 Disposal



WEEE (Waste Electrical and Electronic Equipment) symbol

Do NOT dispose your products as unsorted municipal waste! The crossed-out wheeled bin symbol indicates that all EEE (Electrical and Electronic Equipment), batteries and accumulators must be disposed of according to local law by the use of available return and collection systems.

By separating a marked item from household waste, you will help reduce the volume of waste sent to incinerators or land-fill and minimize any potential negative impact on human health and the environment.

Thank you for your assistance in complying with this regulation and contributing to environmental stewardship. If you have further questions, please contact your local 3M subsidiary or sales rep.

1.2 Conditions for Sale

1.2.1 Disclaimer

ETS PC Software 4110 Copyright © 2007, 3M Company. All Rights Reserved.

You shall carefully read the following terms and conditions before using this software.

Your use of this software indicates your acceptance of the limitations and disclaimers detailed below.

ETS PC Software 4110 is supplied as is. 3M Company disclaims all warranties, expressed or implied, including, without limitation, the warranties of merchantability and of fitness for any purpose. 3M Company assumes no liability for damages, direct or consequential, which may result from the use of ETS PC Software 4110.

Any liability of 3M Company will be limited exclusively to product replacement or refund of the purchase price.

1.2.2 Intellectual Property

This program is owned by 3M Company and is protected by U.S. and international copyright laws. Violation of copyright is an offense.

1.2.3 Distribution

The ETS PC Software 4110 shall not be distributed without the expressed prior written permission of 3M Company.

1.2.4 No Copy, Disassembly and Decryption

You may not copy, disassemble, decompile or decrypt the software without the expressed prior written permission of 3M Company.

2 ETS Sensing Unit

2.1 General Description

The ETS Sensing Unit ([Figure 1](#)) is a battery powered, stand-alone measurement system for the physical parameters of a steam sterilizer. It can be used as an alternative to the Bowie and Dick test. It consists of a data logger for time, temperature, pressure and air removal efficiency. It contains embedded evaluation software which provides a simple "Pass / Fail" decision based on the measured and recorded data.

The configuration has defined thermal characteristics in order to simulate the standard steam penetration tests, described in EN 285, EN ISO 11140-3 and EN ISO 11140-4.

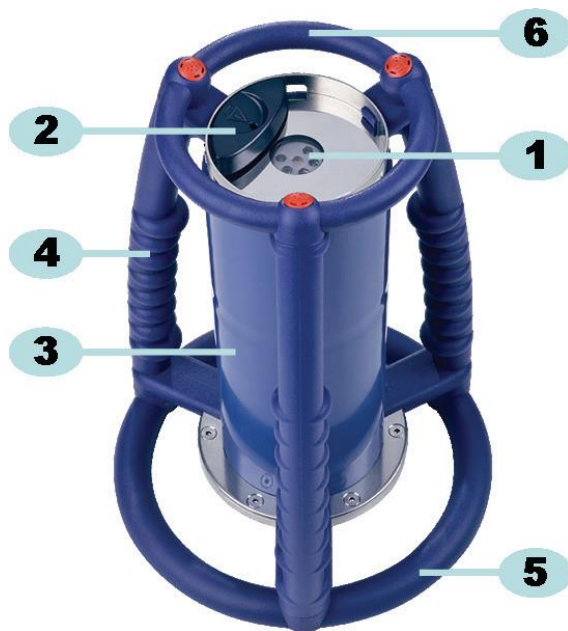


Figure 1: ETS Sensing Unit

1 – Data transfer LEDs (Light Emmiting Diodes)

2 – Switch

3 – Sensing Unit core

4 – Handle

5 – Bottom ring

6 – Top ring

The design of the ETS Sensing Unit consists of an outer handle arrangement ([Figure 1 – # 4, 5 and 6](#)) with the ETS Sensing Unit core ([Figure 1 – #3](#)) placed in the centre. On top of the ETS Sensing Unit is a switch ([Figure 1 - #2](#)) and indicator LED's ([Figure 1 - #1](#)) are located. The indicator LEDs provide result and status information. Data transfer is achieved via the transmitter and receiver LEDs and the optional ETS USB Data Reader using infra-red technology.

The ETS Sensing Unit is a reusable device capable of 400 test cycles. A LED code will indicate when 20 test cycles remain. This allows the operator to re-order a new ETS Sensing Unit to ensure uninterrupted usage.



2.2 Technical Data

Dimensions:

Height:	268 mm
Diameter:	200 mm
Weight:	~2900 g
Life cycle:	400 test cycles
Power supply:	build-in battery

Technical specification of pressure sensor:

Scale range:	0 mbar to 4000 mbar (0 kPa-400 kPa absolute)
Resolution:	1 mbar (100 Pa)
Accuracy:	+/- 20 mbar / 0.5% (FS) @ 20°C +/- 20 mbar /@ 121°C at 2.1 bar -10/+ 30 mbar /@ 134°C at 3.1 bar Accuracy includes temperature drift and long-term drift.

Technical specification of temperature sensors (3x Pt1000):

Scale range:	0°C to 150°C
Resolution:	0.01°C
Accuracy:	+/- 0.2°C (at operating temperature) Accuracy includes temperature drift and long-term drift.

Technical specification of time measurement (crystal oscillator):

Scale range:	1 second to 60 minutes
Resolution:	1 second
Accuracy:	+/- 0.2% FSD (Full Scale Deflection) (at operating temperature) Accuracy includes temperature drift and long-term drift.

Environmental operation limitations:

Temperature:	Maximum 140°C for 60 minutes
Pressure:	Maximum 4000 mbar

Environmental storage limitations:

Temperature:	0 - 50°C
Humidity:	20 - 80% RH

Note: The ETS Sensing Unit will only provide a Bowie and Dick test result when the internal starting temperature is below 35°C. If the unit is stored above 35°C or when the unit is still hot due to a recently conducted test the unit has to be cooled down below 35°C before use in the Bowie and Dick Test Mode.

2.3 Instructions for Use

2.3.1 Identification System

You may want to dedicate an ETS Sensing Unit to a specific sterilizer. A tag can be attached to one of the handle bars or the upper ring of the ETS Sensing Unit. The adherence of labels to the silicon material of the ETS Sensing Unit may be poor. This may cause loss of identification.

2.3.2 Operation

2.3.2.1 Bowie and Dick Test Mode

- The Bowie and Dick Test Mode is activated by pulling the switch on top of the ETS Sensing Unit once in the indicated direction ([Figure 2](#)). Ensure that the switch returns to its original position. The status of the unit is shown.



Figure 2: Actuation of the ETS Sensing Unit switch

- Check status before use. See [Section 5 LED Guides on Page 19](#).
- When a single flashing yellow LED is shown place the ETS Sensing Unit in the centre of the steam sterilizer at a height of about 10 cm above the base.
- Start the Bowie and Dick test cycle on your sterilizer. Ensure that the cycle starts within 5 minutes after switching on the ETS Sensing Unit otherwise it will switch off automatically to save energy.
- After the Bowie and Dick test cycle is completed remove the ETS Sensing Unit from the sterilizer, holding it by the handles.

Caution: Wear protective gloves, as the ETS Sensing Unit will still be hot.

- Check the LEDs on top of the ETS Sensing Unit: if a single yellow flashing LED ([Figure 3 - #3](#)) is seen, the unit is still logging. Pull the switch ([Figure 2](#)) to stop the unit. All LED's shall be off. Wait 15 seconds for the unit to calculate the result and pull the switch once again to see the result. If no LED is on or flashing after removal from the sterilizer, pull the switch once. If no immediate result indication occurs, wait 15 seconds and pull switch again.

The result is shown and held for 30 seconds. See [Section 5 LED Guides on Page 19](#).

Note: Allow the ETS Sensing Unit to cool down at room conditions for at least 2 hours (preferably longer) before re-use in a Bowie and Dick test cycle. The ETS Sensing Unit will indicate if the temperature is low enough when the black switch is pulled. See [Section 5 LED Guides on Page 19](#).

2.3.2.2 Data Logger Mode

The following applications can only be enabled by using the ETS PC Software 4110.

This mode allows the ETS Sensing Unit to be used in the following applications:

- Leak Rate Test
- Testing steam sterilization cycles other than those operating at 134°C for 3 minutes or longer.
- A number of special functions.

Procedure:

- Set the ETS Sensing Unit in Data Logger Mode using the procedure described in [Section 10.2 Data Logger Mode on Page 68](#). Data logging will continue for a maximum of 60 minutes.

Note: Do not activate the switch or put the ETS USB Data Reader on top of the ETS Sensing Unit before you are sure data logging shall be stopped.

- Check status before use. See [Section 5 LED Guides on Page 19](#).
- Place the ETS Sensing Unit in the steam sterilizer chamber.
- Operate the cycle to be tested.
- Remove the ETS Sensing Unit from the sterilizer after completion of the cycle.

Caution: Wear protective gloves, as the ETS Sensing Unit will still be hot.

- Activate the black switch to stop data logging (the ETS Sensing Unit will automatically stop data logging after 60 minutes).
- Transfer data to the PC using the ETS USB Data Reader. See [Section 7.8.1 Typical Procedure on Page 45](#).

Note: A Bowie and Dick test result is not available in the Data Logger Mode.

2.3.3 Results and Status

The result of a Bowie and Dick test and the status of the ETS Sensing Unit are indicated by four coloured LEDs (Light Emitting Diodes).

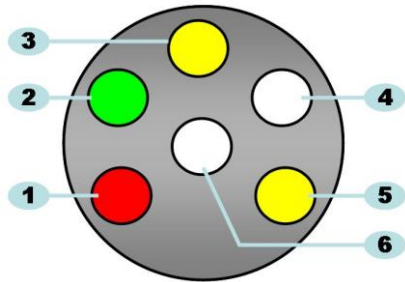


Figure 3: Light Emmiting Diods (LEDs)

- 1: Red LED
- 2: Green LED
- 3: Yellow 1 LED
- 4: Infrared receiver LED
- 5: Yellow 2 LED
- 6: Infrared transmitter LED

2.3.3.1 Retrieval of Results and Status

The ETS Sensing Unit will always contain the result of the latest test cycle. The result only changes potentially when a new test cycle is performed.



Figure 4: Actuation of the ETS Sensing Unit switch

To retrieve the test result and status:

- Pull the switch once ([Figure 4](#)) for result read-out after a Bowie and Dick test cycle. The result will be indicated for 30 seconds maximum.
- Pull the switch ([Figure 4](#)) once more for status read-out. The status will be indicated for 10 seconds maximum. Status indication can be read-out any time during or after result indication.
- The status indication is shown every time the switch is pulled once towards the centre of the top plate.
- The previous result indication can be recalled at any time by pulling the switch ([Figure 4](#)) three times within three seconds.

See also [Section 5 LED Guides on Page 19](#).

3 ETS USB Data Reader

3.1 General Description

The ETS USB Data Reader enables data transfer from the ETS Sensing Unit to a computer. It consists of a reader and a special (RJ12) / Standard (A-B) USB cable ([Figure 5a and 5b](#)).



Figure 5a: Special USB Cable for 4109



Figure 5b:
Standard USB Cable for 4309

The ETS USB Data Reader is designed to fit exactly into the top ring of the ETS Sensing Unit. This ensures good alignment of the infrared transmitter and receiver LEDs.

The data set logged by the ETS Sensing Unit is transferred by the ETS USB Data Reader to the computer using infrared technology.

Note: The ETS USB Data Reader contains a magnet. Do not place disks or other magnetic storage media on or near the ETS USB Data Reader. Stored data may become corrupted. Also keep the ETS USB Data Reader away from the computer display since it may have a distorting effect.

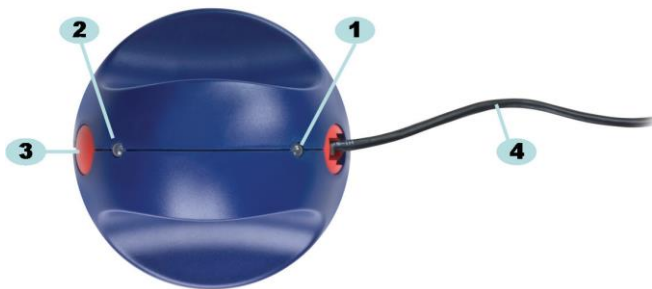


Figure 6a: ETS USB Data Reader 4109



Figure 6b: ETS USB Data Reader 4309

- 1: LED 1
- 2: LED 2
- 3: Switch to start data transfer
- 4: Special (RJ12) USB cable (4109) / Standard (A-B) USB cable (4309)

The two LEDs on the ETS USB Data Reader indicate its status:

- LED 1 shows the status of the connection to the PC.
- LED 2 shows the status of connection to the ETS Sensing Unit.



To perform data transfer, the ETS PC Software 4110 is required. This software package controls the data communication between the ETS Sensing Unit, ETS USB Data Reader and the computer.

3.2 Technical Data

Dimensions Reader:

Height: 55 mm
Diameter: 93 mm

USB Cable:

Length: 1,8 - 2.0 m

Environmental conditions:

Temperature: 0 - 50°C
Humidity: 20 - 80% RH

3.3 Installation

The ETS USB Data Reader is a HID (Human Interface Device) type. Therefore, it requires no installation of a specific USB driver on the Microsoft™ Windows™ operating system. Other typical HID devices are a computer keyboard, computer mouse and display devices.

Note: As soon as the ETS USB Data Reader is connected to the computer text balloons will appear in the windows taskbar indicating that new hardware has been found. This happens only when a connection is made on a USB port which has not been used before to connect the ETS USB Data Reader. These balloons will automatically disappear. Alternatively, the balloons can be closed by clicking the cross in the upper right corner. Either way the USB driver installation is handled completely by windows and requires no user interaction.

Procedure:

- Connect the special connector (RJ12) or the Standard (A-B) USB-plug of the supplied cable to the ETS USB Data Reader. When the connector snaps into place it is properly connected.
- Locate a free USB port on the computer and plug-in the other side of the supplied cable.
- For the first installation on a selected USB port of the computer, MS Windows will automatically install the standard HID USB driver for the ETS USB Data Reader. User interaction is **not** required.
- Check the status of the LED. See [Section 5.5 ETS USB Data Reader on Page 23](#).
- Verify if the LED indication matches the connection status of your system.
- Data transfer is only possible when the ETS PC Software 4110 is running.
- When LED 1 is GREEN and LED 2 is RED the ETS USB Data Reader is ready to be used.

For a complete overview of the ETS USB Data Reader LED indications and their significance see [Section 5.5 ETS USB Data Reader on Page 23](#).



4 ETS PC Software 4110

4.1 General Description

The ETS PC Software 4110 package enables data transfer from the ETS Sensing Unit via ETS USB Data Reader to your computer. The stored data provides the possibility for further analysis, graphical representation and structured digital archiving of data on your computer or server.

4.2 Technical Data

Minimum system requirements

Operating System:	Windows
RAM:	512Mb
Required Hard Disk Space:	50Mb
CD ROM drive:	6 speed
Screen Resolution:	1024 x 768, 65536 colours (16 Bit)
USB Interface:	USB 1.1, 2.0, 3.0

The typical file size per test is 33 Kilobyte. (exported file).

4.3 Installation

The PC Software is provided on a CD (compact disc). It contains an automated installation program. If your computer is setup to automatically play the CD the installation program starts automatically. If not locate the setup file (setup.exe) in the root directory of the CD and run it.

The installation requires a minimum of user interaction. The installation program guides you through the steps necessary for a successful installation of the software. See [Section 9.1 Installing the Software on Page 63.](#)

Note: The users of the software need appropriate access rights to run the software and to save, open and add information to data records. You may wish to consult your IT department to assure alignment with your local IT policy.

4.4 Starting the Software

To start the software:

- Click the desktop **Application Icon for ETS PC Software 4110.**
- Click **Start - All Programs - Application line for ETS PC Software 4110.**



4.5 Logging on

As soon as the software has started the *Logon* window opens:

1 - First time logon

A default administrator is available in the software

To start using the software:

- Enter **Admin** in the *User Name* field.
- Enter **Admin** as *Password*.
- Click **OK** to confirm.

A second logon window opens that requests to a change the password. See [Section 11.7 Change Password on Page 72](#).

Note: The administrator shall now complete the configuration described in [Section 9.2 Configuration the Software on Page 63](#).

To provide access to the software for other administrators and / or users the administrator shall add the required accounts in the User Administration tool. See [Section 11.2 Creating a New User Account on Page 69](#).

2 - First time Logon for users and additional administrators

To start using the software:

- Enter your **User Name**. (provided by administrator).
- Enter your preliminary **Password**. (provided by administrator).
- Click **OK** to confirm.

A second logon window opens in which requests to a change the password. See [Section 11.7 Change Password on Page 72](#).

3 - Normal Logon

- Enter your **User Name**.
- Enter your **Password**.
- Click **OK** to confirm.







4.6 Configuration

See [Section 9.2 Configuring the Software on Page 63](#).

5 LED Guides

5.1 Appearance of Coloured LEDs

ETS Sensing Unit - Appearance of the Coloured LEDs

A		Off	No illumination
B		On	Continuous illumination
C		Flash	Intermittent illumination
D		Double flash	Intermittent illumination, two flashes in quick succession
E		Small flash (slow)	Intermittent illumination, but dimmed (1 flash per second)
F		Small flash (fast)	Intermittent illumination, but dimmed (3 flashes per 2 seconds)

5.2 Result

ETS Sensing Unit - Result (30 seconds visible)

Code	Meaning	Display	Green	Red	Yellow 1	Yellow 2
S1	Pass					
S2	Pass, Early Warning					
S3	Fail					
S4	No pass or fail result available Internal temperature too high or battery low during the Bowie and Dick test					
S5	No pass or fail result available Leak Rate Test mode or Data Logger mode					

5.3 Status

ETS Sensing Unit - Status (10 seconds visible)

Code	Meaning	Display	Green	Red	Yellow 1	Yellow 2
S6	Ready for use Data <u>not</u> transferred					
S7	Ready for use Data <u>not</u> transferred 20 or less Bowie and Dick tests left Battery low, re-order Sensing Unit					
S8	Not Ready for use Data <u>not</u> transferred Internal temperature too high					
S9	Ready for use Data transferred					
S10	Ready for use Data transferred 20 or less Bowie and Dick tests left Battery low, re-order Sensing Unit					
S11	Not Ready for use Data not transferred Internal temperature too high					

5.4 Special

ETS Sensing Unit – Special

Code	Meaning	Display	Green	Red	Yellow 1	Yellow 2
S12	Awaiting cycle start (stand by, max 10 minutes) In Bowie & Dick test mode!					
S13	Logging data (max 60 minutes) In Data Logger mode!					
S14	Unit is calculating (max 15 seconds) or unit is defect when LEDs are off					
S15	Sensing Unit can not be started Battery problem					

5.5 ETS USB Data Reader

Code	Indication on Reader		Status System		Status Software	
	LED1	LED2				
R1	○	○	Software:	Not running		
			Data Reader:	Not connected	Data Reader	
			Sensing Unit:	Not connected	Sensing Unit	
			DR switch:	----	Data transfer	
R2	●	●	Software:	Not running		
			Data Reader:	Connected	Data Reader	
			Sensing Unit:	Not connected	Sensing Unit	
			DR switch:	----	Data transfer	
R3	●	●	Software:	Not running		
			Data Reader:	Connected	Data Reader	
			Sensing Unit:	Connected	Sensing Unit	
			DR switch:	----	Data transfer	
R4	○	○	Software:	Running		
			Data Reader:	Not connected	Data Reader	Not connected
			Sensing Unit:	Not connected	Sensing Unit	Not accessible
			DR switch:	Not activated	Data transfer	Idle
R5	●	●	Software:	Running		
			Data Reader:	Connected	Data Reader	Connected
			Sensing Unit:	Not connected	Sensing Unit	Not accessible
			DR switch:	Not activated	Data transfer	Idle
R6	●	●	Software:	Running		
			Data Reader:	Connected	Data Reader	Connected
			Sensing Unit:	Connected	Sensing Unit	Accessible
			DR switch:	Not activated	Data transfer	Idle
R7	●	●	Software:	Running	Message box	Start download?
			Data Reader:	Connected	Data Reader	Connected
			Sensing Unit:	Connected	Sensing Unit	Accessible
			DR switch:	Activated	Data transfer	Idle
R8	●	●	Software:	Running	Message box	Yes
			Data Reader:	Connected	Data Reader	Connected
			Sensing Unit:	Connected	Sensing Unit	Accessible
			DR switch:	Activated	Data transfer	In progress
R9	●	●	Software:	Running	Window	Test identification open
			Data Reader:	Connected	Data Reader	Connected
			Sensing Unit:	Connected	Sensing Unit	Not accessible
			DR switch:	Activated	Data transfer	Successful
R10	●	●	Software:	Running	Window	Test identification saved
			Data Reader:	Connected	Data Reader	Connected
			Sensing Unit:	Connected	Sensing Unit	Not accessible
			DR switch:	Activated	Data transfer	Successful
R11	●	●	Software:	Running		
			Data Reader:	Not connected	Data Reader	Not connected
			Sensing Unit:	Connected	Sensing Unit	Not accessible
			DR switch:	----	Data transfer	Idle
R12	●	●	Software:	Running		
			Data Reader:	Connected	Data Reader	Not connected
			Sensing Unit:	Connected	Sensing Unit	Not accessible
			DR switch:	----	Data transfer	Not successful

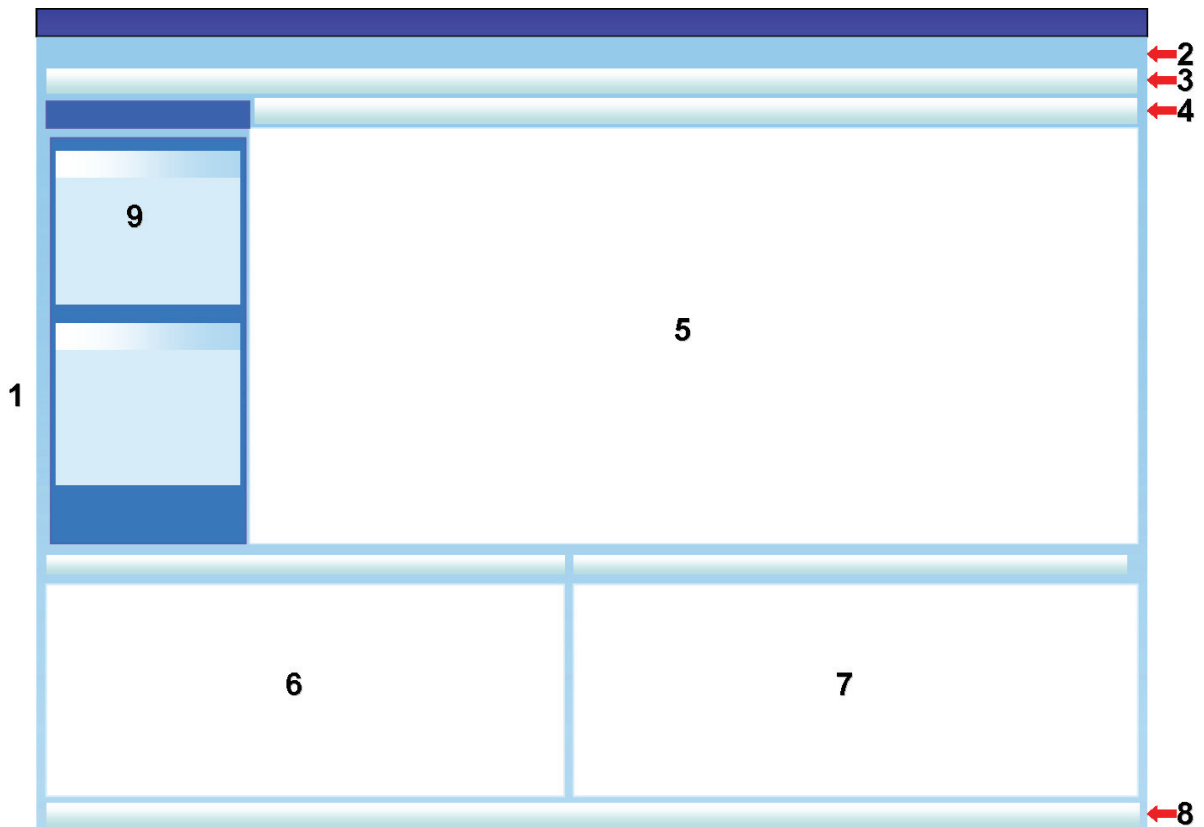
6 Graphical User Interface

6.1 Screen Layout

After a successful logon the software displays the *MAIN SCREEN*. Within the *main screen* all windows providing information are available. The *main screen* provides a Navigation, a Main, a File, a Data and a Status bar window. You can hide or show all windows except the main window and the status bar. See [Section 6.1.1 Customizing the Layout on Page 24](#).

Screen layout:

- 1: Main Screen
- 2: Menu Bar
- 3: Icon Bar
- 4: Icon Bar (Graph)
- 5: Main Window
- 6: File Window
- 7: Data Window
- 8: Status Bar
- 9: Navigation





6.1.1 Customizing the Layout

When the software is started the default layout appears. Each user can change the layout. However, the changes will only be active for the duration of the session. Once a new user logs on the default layout is restored.


6.1.1.1 Resizing Windows

To resize a window:


- Position the cursor on the border of the window you want to resize
- If this  or this  figure appears hold down the left mouse key and drag it in the direction you want the window to resize.
- Release the left mouse key


Note: All windows will always be completely visible. When a window is re-sized the adjacent window is automatically adapted. Overlapping the windows is not possible.

6.1.1.2 Fixing and Auto Hiding Windows

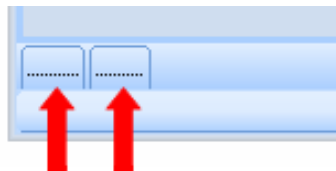
In the upper right corner of the *Navigation*, *File* information and *Data* window a push-pin  is visible.

When you click on the push-pin its orientation changes.

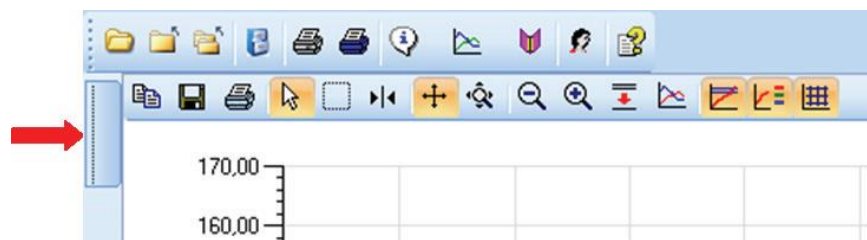
 : means that the window is fixed in position (**Fixed mode**). The window is always visible regardless of where the cursor is located.

 : means that the window disappears as soon as the cursor is moved off of the window (**Auto hide mode**). You can make the window reappear by positioning the cursor over its tab.

The *Files* and the *Data* tabs are located at the bottom left corner of the main screen.




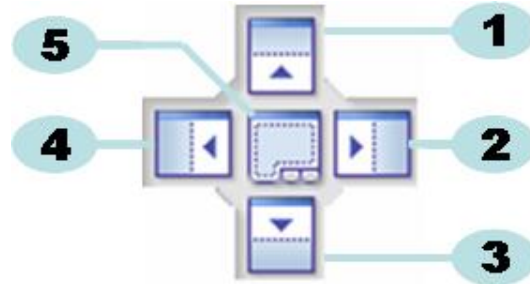
The *Navigation* tab is located at the upper left corner of the main screen.



6.1.1.3 Repositioning Windows

To reposition the windows:

- Position the cursor on the title bar of the window.
- Hold down the left mouse key. The cursor changes to .
- Drag the cursor into the other window.
- Position the cursor on one of the five areas:



- 1: **The source window is positioned above the target window.**
- 2: **The source window is positioned right from the target window.**
- 3: **The source window is positioned below the target window.**
- 4: **The source window is positioned left from the target window.**
- 5: **The source window is positioned on top of the target window.**

- A transparent dark blue area indicates where the dragged window will be positioned.
- Release the left mouse key.

When windows are positioned on top of each other in **fixed mode** you can show them again by clicking the relevant tab at the lower left corner of the main screen.

When windows are positioned on top of each other in **auto hide mode** you can show them again by moving the cursor over the relevant tab at the lower left corner of the main screen.

See [Section 6.1.1.2 Fixing and Auto Hiding Windows on Page 25.](#)

- To restore the windows next to each other you shall drag the **TAB** (Files or Data) and drop it onto **6** or **7**.

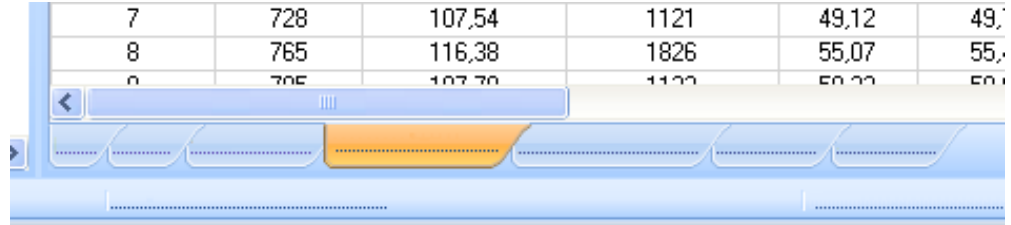


- 6: **The source window is positioned above the target window.**
- 7: **The source window is positioned below the target window.**

- Now perform the steps described at the top of this paragraph.

6.1.1.4 Selecting Data Tabs

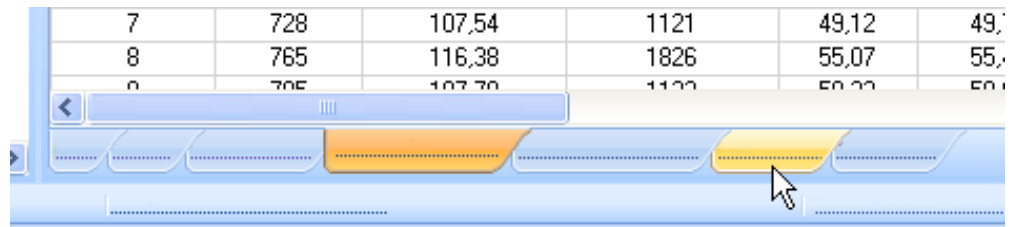
In the *Data* window you can select from a number of data information views. The active window is indicated by an orange background.



7	728	107,54	1121	49,12	49,
8	765	116,38	1826	55,07	55,
9	705	107,70	1122	50,22	50,

To select a different tab:

- Move the cursor onto the desired tab. The background colour changes to light orange.
- Click the left mouse key once to confirm your choice.



7	728	107,54	1121	49,12	49,
8	765	116,38	1826	55,07	55,
9	705	107,70	1122	50,22	50,

In case the Data Window is not wide enough to display all tabs, a scroll bar will automatically appear. By clicking the triangle at the right lower corner of the window you can navigate to the tab you desire.



6.2 Navigation

The *Navigation* window provide access to all available sections of the software. The **Menu bar** and **Icon bar** provide only a "most used" selection.

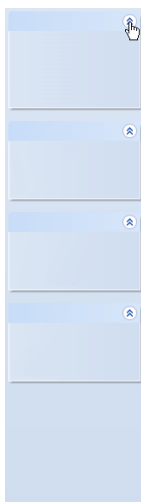
6.2.1 Open and Close Sub Sections

Sub sections can individually be opened and closed by clicking once in the title area of a section.

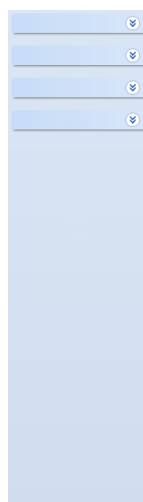
A double chevron pointing downward indicates that the section can be opened.

- A single click on the double chevron opens or closes the individual sections.

All sections opened



All sections closed



6.2.2 Auto Hide Navigation

See [Section 6.1.1.2 Fixing and Auto Hiding Windows on Page 25.](#)

6.2.3 Selecting Functions from the Navigation Bar

To select items from the **Navigation bar**:

- Position the finger pointing hand on the item.
- When the item is underlined and displayed in a lighter shade of blue click the left mouse key.



6.3 Menu Bar

The **Menu bar** located at the top of the *Main Screen* provides a selection of most used functions.

To select an item from the menu bar:

- Click with the left mouse key on the item

In case sub items are available a pull-down window will open.

- Select the sub item by clicking with the left mouse key on the item

6.4 Icon Bar

The **Icon bar** located directly below the Menu bar at the top of the *Main Screen* provides a selection of most used functions.

To select an item from the **Icon bar**:

- Click with the left mouse key on the item.

6.5 View Data

There are three different ways to view the data in the *Main window*.

1 - Test information

- Click: *Navigation - View Data - Test Information*

This window shows information which uniquely identifies the test by:

- Test and data transfer date and time
- ETS Sensing Unit identification
- User information
- File information
- Comments and approvals

See [Section 6.5.2 Test information on Page 34.](#)

2 - Graph

- Click: *Navigation - View Data - Graph*

The display shows measurement data as well as calculated data as curves.

See [Section 6.5.1 Graph on Page 30.](#)

3 - Logbook

- Click: *Navigation - Main - Open Logbook*

The logbook provides a complete overview of all tests that are transferred from the sensing unit to the computer. The log book is the primary tool to open ETS records.

See [Section 6.5.3 Logbook on Page 35.](#)

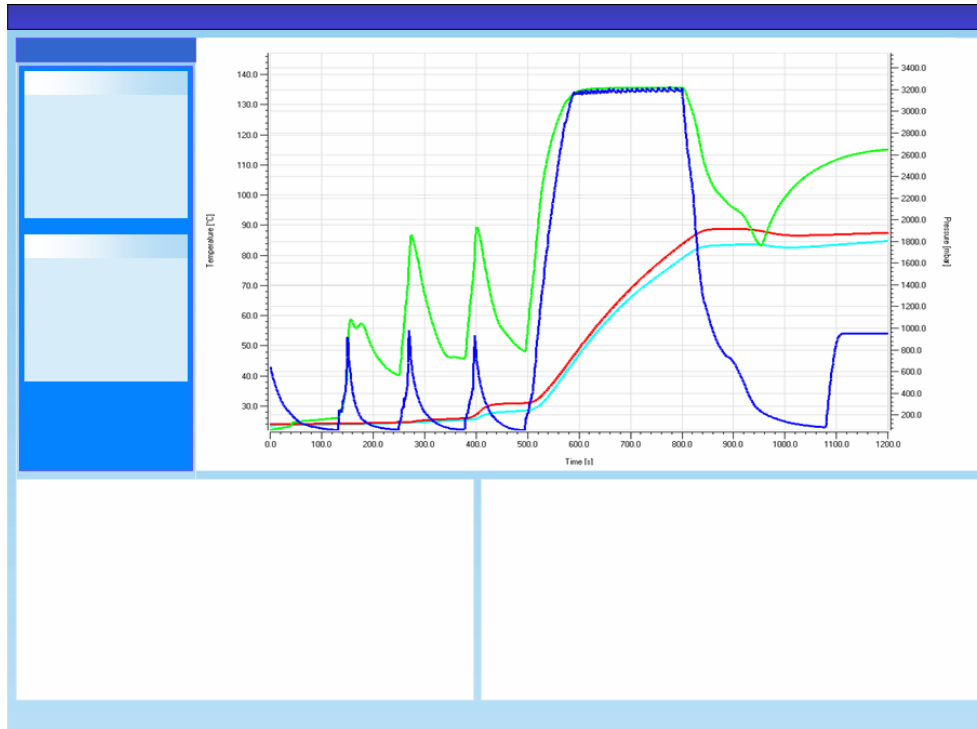
There is an additional way to view the data in the *Datawindow*

The available tabs provide the option to explore the measurement data.

See [Section 8 Data Analysis on Page 49.](#)

6.5.1 Graph

The graph is displayed in the *Main Window*.



From any view the *graph* can be displayed in three different ways:

- from the *Navigation* section **View** Data
- from the **View** menu on the Menu bar
- from the **Graph** icon on the Icon bar

6.5.1.1 Modifying the Graph

A record that is opened is always displayed first in a predefined way. Predefining the first view of the graph is typically done by the administrator during configuration of the software.

You can change the appearance of the graph when this is appropriate for your diagnostic activities.

The aspects of the graph which can be modified are:

- the number of displayed data records
- scaling of the Y-axis and X-axis
- positioning of the curves
- number of curves visible
- availability of the legend
- availability of the Sterilization Temperature Band
- availability of grid

6.5.1.1.1 Showing and Hiding Data Records

Opened data records are displayed in list in the *Files* window.

1	2	3	4	5	6	7
10	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		051207_1007_03168_0189pa	07.12.2005 10:07:56
11	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		051207_1012_03179_0188pa	07.12.2005 10:12:43
12	<input checked="" type="checkbox"/>			0.5	050303_1117_02454_0012pf	03.03.2005 11:17:51
13	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		051208_0842_03179_0189pa	08.12.2005 08:42:50
14	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		051209_1249_02155_0025fa	09.12.2005 12:49:33
15	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		051122_1157_02155_0024fa	22.11.2005 11:57:11
16	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		051212_0925_03179_0190pa	12.12.2005 09:25:32
17	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		051212_1602_03179_0191fa	12.12.2005 16:02:36
18	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	3.2	051212_1612_03179_0191pa	12.12.2005 16:12:33
19	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		051213_0922_03168_0193pa	13.12.2005 09:22:03

Column	Description
1	Identification of data records assigned in chronological order.
2	Indicates if data records are displayed in the graph
3	Indicated Bowie and Dick result
4	Indicates SPI result
5	Indicates leak rate result (if available)
6	Unique data record name
7	Date and time of test

To show or hide a data record in the graph:

- Check or uncheck the box in column 2 (Graph)

To show or hide related information (test information, table, control points etc.):

- Click once on the line in the *Files* window showing the data record you want to explore.

The line is highlighted

The line width of all curves in the graph doubles compared with other visible graphs. This indicates which curves belong to the active (high- lighted) file.

6.5.1.1.2 Showing and Hiding Curves

To hide or show a function / curve during a session:

- Select **Functions** from the *Navigation* window
- Check or uncheck the desired function
- Click **OK** to confirm the selection

or


- Click **Cancel** to close the window leaving the settings unchanged.

Curves representing the chamber pressure and temperature are always automatically displayed and can not be hidden.

Curves that shall be displayed by default can be preset in **Preferences - Diagnostics**. See [Section 9.2.2 Showing and Hiding Diagnostic Data on Page 64](#).

6.5.1.1.3 Showing and Hiding the Legend


To hide or show the legend

- Click  on the icon bar in the graph.

The icon is highlighted to indicate that the function is active 

6.5.1.1.4 Showing and Hiding Sterilization Temperature Band


To hide or show the Sterilization Temperature Band

- Click  on the icon bar in the graph.

The icon is highlighted to indicate that the function is active 

6.5.1.1.5 Showing and Hiding the Grid

To hide or show the grid

- Click  on the icon bar in the graph.

The icon is highlighted to indicate that the function is active 


Activating or deactivating this function has an effect for ALL grids in case multiple Y-axis are used.

6.5.1.1.6 Zooming the Graph

A selected part of the graph can be zoomed. The following tools are available:

1 - The Zoom Box

The Zoom Box  enlarges the part of the graph enclosed in the box.


- Click the tool icon 

the cursor  adopts this shape: 

- Hold down the left mouse key and move the cursor in any direction. A rectangle box (dotted lines) indicates the area of interest.
- Release the left mouse key


The graph is rebuilt enlarging the defined box to full scale.



2 - Zoom out / in

The Zoom out / in tool  changes the scale of a selected axis stepwise.

- Click with cursor on the axis that shall be zoomed.

The selected Y-axis text is black and boxed.


As soon as the cursor is over the axis it adopts this shape: 

- Click the tool icon  or 


The selected axis increases or decreases the scale stepwise by 50%. The center of the axis is fixed.

3 - Fit all

The Fit all tool reverts all zooming to full scale.


- Click the Fit all tool icon 


4 - Zoom SPI



The Zoom SPI tool  displays the sterilization temperature band.

- Click the Zoom SPI tool icon 

5 - Zoom Axis

The Zoom axis tool  changes the scale of a selected axis gradually

- Click the Zoom Axis tool icon 
- Click with cursor on the axis that shall be zoomed.

As soon as the cursor is over the axis it adopts this shape:  (Y-axis),  (X-axis)

The selected axis text turns black and boxed.

Method 1

- On the selected axis hold down the left mouse key.
- Move the cursor up to zoom in or down to zoom out (Y- axis).
- Move the cursor right to zoom in or left to zoom out (X- axis).

The zoom factor depends on the distance the cursor is moved. The center of the axis is fixed.

Method 2

- Move the scroll wheel of the mouse up to zoom in or down to zoom out.


Note: The tools **Zoom Axis** and **Scroll Axis** can not be active simultaneously. One of both is always active. Switching very fast between the two modes can be achieved by using the control **[CTRL]** key.


While in one mode, holding the **[CTRL]** key down switches to the other function. Releasing the **[CTRL]** key switches back to the original function.


6.5.1.1.7 Moving the Graph

When a graph is zoomed, selected axis (curves) can be scrolled within its fullscale range.

Scroll Axis

The Scroll axis tool  changes the range of the scale of a selected axis.

- Click the Scroll Axis tool icon 
- Click with cursor on the axis that shall be scrolled.

As soon as the cursor is over the axis it adopts this shape: 

The selected axis text turns black and boxed.

Method 1

- On the selected axis hold down the left mouse key.
- Move the cursor up to scroll up in or down to scroll down (Y-axis).
- Move the cursor right to scroll right or left to scroll left (X-axis).

The scroll factor depends on the distance the cursor is moved.

Method 2

- Move the scroll wheel of the mouse up to scroll up in or down to scroll down (Y-axis).
- Move the scroll wheel of the mouse up to scroll right or down to scroll left (X-axis).

Note: The tools **Zoom Axis** and **Scroll Axis** can not be active simultaneously. One of both is always active. Switching very fast between the two modes can be achieved by using the control **[CTRL]** key.

While in one mode, holding the **[CTRL]** key down switches to the other function. Releasing the **[CTRL]** key switches back to the original function.

6.5.2 Test Information

From any view *Test Information* can be displayed in three different ways:

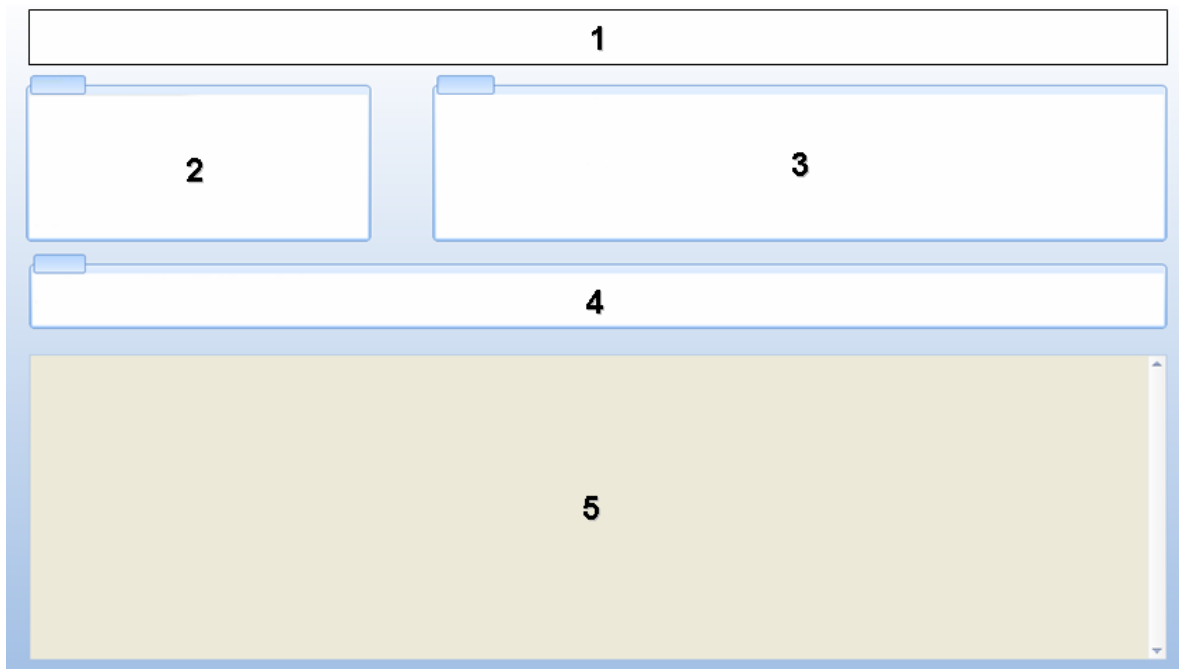
- from the **Navigation bar**
- from the **Menu bar**
- from the **Icon bar**

Test Information is displayed in the *Main Window*.

It contains all information required for full trace ability of the test results to the tested equipment, test equipment, test type, test person, times, dates, file identity, comments and approvals.

The information originates from:

- User entries made completing the data transfer process
- User entries made it in subsequent sessions
- administrator defined settings in **Preferences**
- the PC's operating system
- the ETS Sensing Unit



- 1: Result (Pass, Early Warning, Fail, No Result)
- 2: Test information
- 3: User information
- 4: File information
- 5: Comments

The information displayed in *Test Info* and *User Info* can not be changed. This ensures the authenticity of the test.

See also [Section 7.8.3 Test Identification on Page 46](#).

6.5.3 Logbook

See [Section 7.3 Logbook on Page 39](#).

6.5.4 Evaluating Data

The software provides a wide variety of data analysis tools. Most of the calculations required for data analysis is performed automatically as soon as a data record is opened. Some tests can be manually controlled. The analysis data can be evaluated graphically ([Section 6.5.1 Graph on Page 30](#)) and numerically. The numeric data is displayed in the control window.

See [Section 6.1 Screen Layout on Page 24.](#)

For detail on the various data analysis tools.

See [Section 8 Data Analysis on Page 49.](#)


6.5.5 Print

6.5.5.1 Printing Graph and Information

To print the graph and the information identifying the test:

- Compose the graph as desired (in/exclude curves, legend, axis, grid, etc ...). See [Section 6.5.1.1 Modifying the Graph on Page 30.](#)
- Click **File** on the menu bar.
- Select **Print** from the menu.
- Select **Graph and Info.**
- Change the printer settings if required.
- Click **OK** to print.

or


- Click the **Print Graph and Info** icon .
- Change the printer settings if required.
- Click **OK** to print.

Note: All that is currently visible in the graph is printed.

6.5.5.2 Printing the Graph only

To quickly printout of the graph only:


Note: All that is currently visible in the graph is printed.

- Compose the graph as desired (in / exclude curves, legend, axis, grid, etc ...) See [Section 6.5.1.1 Modifying the Graph on Page 30.](#)
- Click the print icon  on the graph icon bar
- Change the printer settings if required
- Click **OK** to print

6.5.5.3 Printing the Logbook

To print the contents of the log book:

Note: All information that is currently visible in the logbook is printed.

- Use the filter setting to display what shall be printed.
See [Section 7.3.6 Setting a Filter for Specific Data Record Properties on Page 41.](#)
 - Click **File** on the menu bar
 - Select **Print** from the menu
 - Select **Log book**
 - Change the printer settings if required
 - Click **OK** to print.
- or
- Click the **Print Log book** icon 
 - Change the printer settings if required
 - Click **OK** to print

6.6 Status Bar

The status bar is located at the bottom of the Main Screen



The *Status Bar* presents the status of the various components and activities of the ETS system.

Communication Status (1)

Data Reader (2)

- *Connected*
The ETS USB Data Reader is plugged into the USB port of the computer. The device is properly recognized by MS Windows.
- *Not Connected*
The ETS USB Data Reader is not plugged into the USB port of the computer or the device is properly recognized by MS Windows.

Sensing Unit (3)

- *Accessible*
The ETS USB Data Reader is properly positioned on the ETS Sensing Unit. Communication between the ETS USB Data Reader and the ETS Sensing Unit is possible.
- *Not Accessible*
The ETS USB Data Reader is not or not properly positioned on the ETS Sensing Unit or the ETS Sensing Unit is unable to respond.

Data Transfer (4)

- *Idle*
No data transfer activity.
- *In progress (5)*
Data is being transferred (the progress indicator shows what percentage of the data transfer is already completed)
- *Successful*
Data Transfer is completed successfully
- *Not Successful*
Data Transfer is not completed successfully



7 Data Management

The measurement and calculated data are transferred from the ETS Sensing Unit to the Computer

Data is defined as:

ETS Data Set:	Data stored in the ETS Sensing Unit memory
ETS Data Record:	Data transferred to the PC and stored in the ETS database
ETS Data File:	Data transferred for the ETS Sensing Unit and stored as a file on a file system (e.g. Hard disk or network drive (recommended)) Data records from the ETS Database exported to the file system.

7.1 File System

By default, the installation folder for the ETS software 4110 is **C:\Program Files\3M\3M 4110 ETS Software**

The Drive (**C:**) will be different in case you prefer to install the software on a different drive.

Caution: Do not delete the application folder nor its sub-folder.

7.2 IT consideration

7.2.1 Access Rights

Administrator rights are required for installing the software on the computer. The installation shall preferably be for *All Users*. When the software is installed using the default paths all access rights are allocated correctly.

Note: When the default path is changed it is important to check that users have *read, write* and *delete* rights (*full control*) for the new folder and related sub folders.

7.2.2 Shares on Servers

The location of the ETS log book database file and the exported ETS files can be changed.

Note: When the default path is changed it is important to check that users have *read, write* and *delete* rights (*full control*) for the new folder and related sub folders on the network share.

To change the file location see [Section 9.2.4 File Locations on Page 64](#).

7.3 Logbook

The Logbook can be started in three different ways:

1 - From the *Navigation* bar

- Click Main - **Open Logbook**

2 - From the *Menu* bar

- Click View - Logbook

3 - From the *Icon* bar

- Click **Logbook** 

7.3.1 Logbook File Location

To change the file location see [Section 9.2.4 File Locations on Page 64](#).

7.3.2 Data Records

A data record is a package that contains specific information related to one test and is available in the ETS PC Software 4110 database.

The format of the record name is:

YYMMDD_HHMM_#####_9999xx

YYMMDD:	Year - Month – Day	(Date of test)
HHMM:	Hours – Minutes	(Time of test)
#####:	5 digits	(ETS serial Number)
9999:	4 digits	(ETS counter)
xx:	2 characters	(Result indicator)

7.3.3 Opening Data Records

To open a single data record from the logbook:

- Double click a row in the logbook

To open multiple data records from the logbook:


Method 1

- Click once on a row to select the first data record
- Hold down the **[Shift]** key and click once on the **last** data record (All data records in between the selected first and last data record are now selected)

Method 2

- Hold down the [CTRL] key and click once on the rows you want to add to your selection

Method 3

- Click once on the first row and hold down the left mouse key
- Drag the mouse down until the last row of your selection.
- Click in the *File* menu **Open...** to open all data records
- Or click the Open Record Icon 

7.3.4 Sorting Columns

To sort a column:

- Click once on the header of the column you want to sort.

Subsequent clicks on the header changes the sorting direction between ascending and descending.

7.3.5 Importing ETS Files to Data Records

The Import function provides the possibility to integrate ETS files e.g. generated with a previous version of the software into a new or different database.

Note: A function for copying of files is not available in the ETS PC Software 4110. Use Microsoft Windows Explorer or an equivalent tool.

Files can be imported individually or as a batch. The files shall be **copied** to the designated import folder.

See [Section 9.2.4 File Locations on Page xx](#).

The default file location is C:\Users\Public\Documents\3M ETS 4110\Import.

It is possible to copy a complete folder including sub folders with ETS files into the Import folder.

Note: Copy the folders / files to the import folder. **Do not move** the folders / files into the import folder. The import folder will be empty after successful completion of the import process. Moving the files can lead to loss of data.

To import the file(s):

- Assure that the files/folders are available in the designated import folder
- In the **File** menu click **Import**

The duration of the import process depends on the amount of files to import.

Note: To reduce the probability of errors in the import process the database is not accessible for other activity.

When the process is completed the files are integrated into the database. Folders and files are removed from the import folder.

- Excluded from integration are:
- Corrupted files
- Incompatible files
- Duplicates
- Files with modified file names
- Files with incomplete file names

These files are moved to the folder **C:\Users\Public\Documents\3M ETS 4110\No_Import**.

Note: Files generated with previous versions of the ETS PC Software 4110 may contain less information compared to data records generated with the latest version. Data fields for which no information is available show "- - -".

7.3.6 Setting a Filter for Specific Data Record Properties


The logbook contains all data records that have been entered. A selection of filters is available to reduce the displayed list to data records containing only specific information.

To set the filter:


Date of test

1. Select start date **From**
2. Select end date **To**
3. Or click the Today button to show only today's data records

Organization, Department, Operator, Sterilizer, ETS serial number, Approver.

1. Click  to open the selection box
2. Make a selection

Result (pass, fail, etc..) and Approval Status

- Click the radial button  in front of the preferred selection

Note: The logbook list is updated as soon as a filter is set.

7.3.7 Recovery and Synchronising of Data

To view logbook data from networked computers the ETS database can be located on a network share.

To define the network location. See [Section 9.2.4 File Locations on Page 64](#).

When the administrator has defined a network share for storage of the ETS data base it can happen that data is not available for use due to network connectivity problems.

The logbook will not be available!

Data from ETS Sensing Units can still be transferred. The data sets from the ETS Sensing Unit will be stored temporarily as data files in the recovery folder on the workstation.

To view the transferred data:

- Click the File Open Icon 


Note: All information including the graph is available. Comments, approvals or leak rate test results can NOT be included.

As soon as the network connectivity is re-established the ETS software will automatically update the contents of the network database with that of the local recovery folder. No user activity is required.

Note: Comments, approvals and leak rate test results can now be included again.


7.4 Saving the Graph

To save the graph of an opened ETS record:

- Click on the icon Save 
- The save as dialog window opens
- Select the folder location
- Enter the filename
- Select graphic format
- Click on **Save**

7.5 Copying the Graph

To copy the graph of an opened ETS record:

- Click on the icon **Copy** 
- The image data is copied to the MS Windows clipboard
- Use the **Paste** function to include the graph in another application



7.6 Saving Comments and Approvals

Comments and approvals are saved to the ETS data record as soon as the function is closed. They can not be modified or removed.

7.7 Exporting

7.7.1 Exporting the Table

To export the table of an active ETS data record

- In the File menu click **Export - Table**
- Click the preferred data format (Excel or ASCII)

The file name is extended by "_TB" to indicate that the file concerns the complete data table (YYMMDD_HHMM_#####_9999xx_**TB**.ext)

The file is located in the designated export folder. See [Section 9.2.4 File Locations on Page 64](#).

7.7.2 Exporting the Control Points

To export the Control Points of an active ETS data record:

- In the File menu click **Export - Control Points**
- Click the preferred data format (Excel or ASCII)

The file name is extended by "_CP" to indicate that the file concerns a table with control points (YYMMDD_HHMM_#####_9999xx_**CP**.ext)

The file is located in the designated export folder. See [Section 9.2.4 File Locations on Page 64](#).

7.7.3 Exporting Data Records to Files

To select a single data record to export:

- Click once on a row in the logbook

To select multiple data records from the logbook:

Method 1

- Click once on a row to select the first data record
- Hold down the **[Shift]** key and click once on the **last** data record (All data records in between the selected first and last data record are now selected)

Method 2

- Hold down the **[CTRL]** key and click once on the rows you want to add to your selection

Method 3

- Click once on the first row and hold down the left mouse key
- Drag the mouse down until the last row of your selection.

To select multiple data record using a filter:

- Set the filter(s). See [Section 7.3.6 Setting a Filter for Specific Data Record Properties on Page 41.](#)
- To export:

Select all displayed Data Records press **[CTRL A]**

- In the **File** menu click **Export - As ETS file**

Data records exported to ETS files are located in the designated *Export* folder. See [Section 9.2.4 File Locations on Page 64.](#)

7.7.4 Exporting the Summary

See [Section 8.13 Generating a Summary on Page 62.](#)

7.7.5 Exporting the Software Settings

To export the Software Settings:

- In the File menu click **Export - Settings**

The file name is *set.bin*

The file is located in the designated export folder. See [Section 9.2.4 File Locations on Page 64.](#)



7.8 Data Transfer

7.8.1 Typical Procedure

The procedure describes a normal data transfer process.

- Remove the ETS Sensing Unit from the sterilizer

Caution: Wear protective gloves, as the ETS Sensing Unit will still be hot.

- Move the black switch on top of the ETS Sensing Unit towards the center of the top plate.
- Read the result. See [Section 5.2 Result on Page 20](#).

The result is shown for 30 seconds.

Check the status of the Sensing Unit. See [Section 5.3 Status on Page 21](#).

The status appears automatically after the 30 seconds or if the switch is activated again.

- Place the ETS Sensing Unit on a stable surface
- Reassure yourself that the ETS PC Software 4110 is running and that you are logged on with your own user name and password.
- Verify the communication status in the status bar of the software on the computer. See [Section 6.6 Status Bar on Page 37](#).
- When the status bar indicates:

ETS USB Data Reader:	Connected
ETS Sensing Unit:	Not Accessible
Data transfer:	Idle
Progress indicator:	0 %

Position the ETS USB Data Reader firmly inside the top ring of the ETS Sensing Unit. The LEDs of the ETS USB Data Reader shall be directed downward facing the LEDs of the ETS Sensing Unit.

- Verify the communication status in the status bar of the software on the computer.
- When the status bar indicates:

ETS USB Data Reader:	Connected
ETS Sensing Unit:	Accessible
Data transfer:	Idle
Progress indicator:	0 %

push the red button on the ETS USB Data Reader.

- A window opens asking if you want to proceed.
- Click **YES** to confirm
- The window closes and the data transfer starts
- Verify the communication status in the status bar of the software on the computer.
- Wait while the status bar indicates:

ETS USB Data Reader:	Connected
ETS Sensing Unit:	Accessible
Data transfer:	In Progress
Progress indicator:	Increasing percentage



- After completion of the data transfer the *Test Identification* window opens.
- The status bar indicates:

ETS USB Data Reader: Connected
ETS Sensing Unit: Not Accessible
Data transfer: Successful
Progress indicator: 100%

- The pre-defined fields are filled automatically
- Fill out the blank field(s)
- Verify the correctness of all entries and make changes if necessary
- Click **Save** to save the information
- The status bar indicates:

ETS USB Data Reader: Connected
ETS Sensing Unit: Not Accessible
Data transfer: Idle
Progress indicator: 0%

- Remove the Data Reader from the Sensing Unit and locate it in a safe place with the LEDs facing down.
- The status bar indicates:

ETS USB Data Reader: Not Connected
ETS Sensing Unit: Not Accessible
Data transfer: Idle
Process indicator: 0%

- The data transfer process is now complete.

After saving the Test Identification window the graph is opened automatically. You can repeat the described process for other ETS Sensing Units. It is possible to transfer data while you are investigating other data. The software will automatically put the data analysis on hold when input is required. After entering the required information, the data analysis will resume.

Note: Besides the information provided in the status bar the two LED on the data reader will indicate also the status of the system. See [Section 9.2.4 File Locations on Page 64.](#)

7.8.2 Status of the System before, during and after Data Transfer

See [Section 5.5 ETS USB Data Reader on Page 23.](#)

7.8.3 Test Identification

Each time a data set is transferred from the ETS Sensing Unit to the PC a window opens in which specific data shall be entered. All fields are mandatory.

All of the information is linked to the test result assuring that each test result can be fully traced to the tested equipment, test equipment, test type, test person, times, dates, file identity and approvals.

**Test Date & Time:**

Description: The date and the time the test is performed.

Source: ETS Sensing Unit timing algorithm

Source: PC system time (ETS Sensing Unit)

Data Transfer Date & Time:

Description: The date and the time the data of a test is transferred to the computer.

Source: PC system time

ETS Serial Number:

Description: The serial number of the ETS Sensing Unit that is used to record the data and to calculate the result.

Source: ETS Sensing Unit

ETS counter:

Description: The number of tests already performed with the ETS Sensing Unit.

Source: ETS Sensing Unit

Sterilizer Name:

Description: The name of the sterilizer in which the test is performed.

Source: Automatically entered from **Preferences** entry by the administrator
Selected from drop down list by the user
Manually entered by user

Sterilizer Cycle Number:

Description: The number of processes carried out by the sterilizer.

Source: Manually entered by the user

Organization:

Description: The name of the organization at which the test is performed.

Source: Automatically entered.
Selected from **Preferences** entry by the administrator
Selected from drop down list by the user
Manually entered by user

Department:

Description: The name of the department at which the test is performed.

Source: Automatically entered. Selected from **Preferences** entry by the administrator.
Selected from drop down list by the user
Manually entered by user

**Operator:**

Description: The name of the person carrying out the test.

Source: Automatically entered. Operator is identified by log on procedure.

Supervisor:

Description: The name of the person the operator reports to.

Source: Automatically entered. Selected from **Preferences** entry by the administrator
Selected from drop down list by the user
Manually entered by user

See also [Section 6.5.2 Test information on Page 34.](#)

7.8.4 Trace ability, Authenticity and Data Integrity

The measurement data as captured by the ETS Sensing Unit can not be accessed in any other way than by transferring the data to a PC using the ETS USB Data Reader and the ETS PC Software 4110. The data stored in the ETS Sensing Unit can therefore not be manipulated.

The transferred data must be identified in a unique manner by completing the window which opens after successful data transfer. Saving the data set to the PC is only possible when all mandatory entries are made.

In case of unsuccessful data transfer the data is NOT lost. It is still available in the ETS Sensing Unit for as long as it is not re-used for a subsequent test. It is therefore important that each time before an ETS Sensing Unit is used for a test, it is verified that the data set is transferred. See [Section 5.3 Status on Page 21.](#)

The data stored on a computer is encrypted. Deliberate manipulation of the file will render it useless.

Note: To achieve a secure level of data security a data back-up procedure shall be established. This is the responsibility of the individual organization.

8 Data Analysis

8.1 Master Overlay (Tab "Master")

The Master Overlay function provides a quick comparison between an active record and the master record for the sterilizer in which the test was performed. Based on the mandatory entry of the sterilizer name in the data transfer process the software identifies automatically the matching master record.

8.1.1 Typical Procedure

- Open a data record (from logbook or data transfer).
- Display the graph.
- Click the **Master** tab.

The master record is opened automatically. The graph opens. The graph contains two X-axis.

- Move the active record left or right to synchronize the pressure profile to the desired control point. See [Section 6.5.1.1.7 Moving the Graph on Page 34](#).

The table displayed on the Master tab shows the values (time, pressure, temperatures) at the control points for both records.

Note: The zoom factors for both records shall be the same for meaningful visual comparison.

8.1.2 Designating a Data Record as Master Record

To designate a record as master record:

- Open the record.
- Click **Options - Master - Designate as master record**.
- Click Yes to confirm the decision.

The name of the master record for the actual sterilizer will appear in *Preferences - Sterilizer*. See [Section 9.2.8 Sterilizers on Page 66](#).

Note: There can only be one master record per sterilizer. Each subsequent record that is promoted to master record will replace the previous master record. The replaced records are not deleted.

8.2 Control Points (Tab "Control Points")

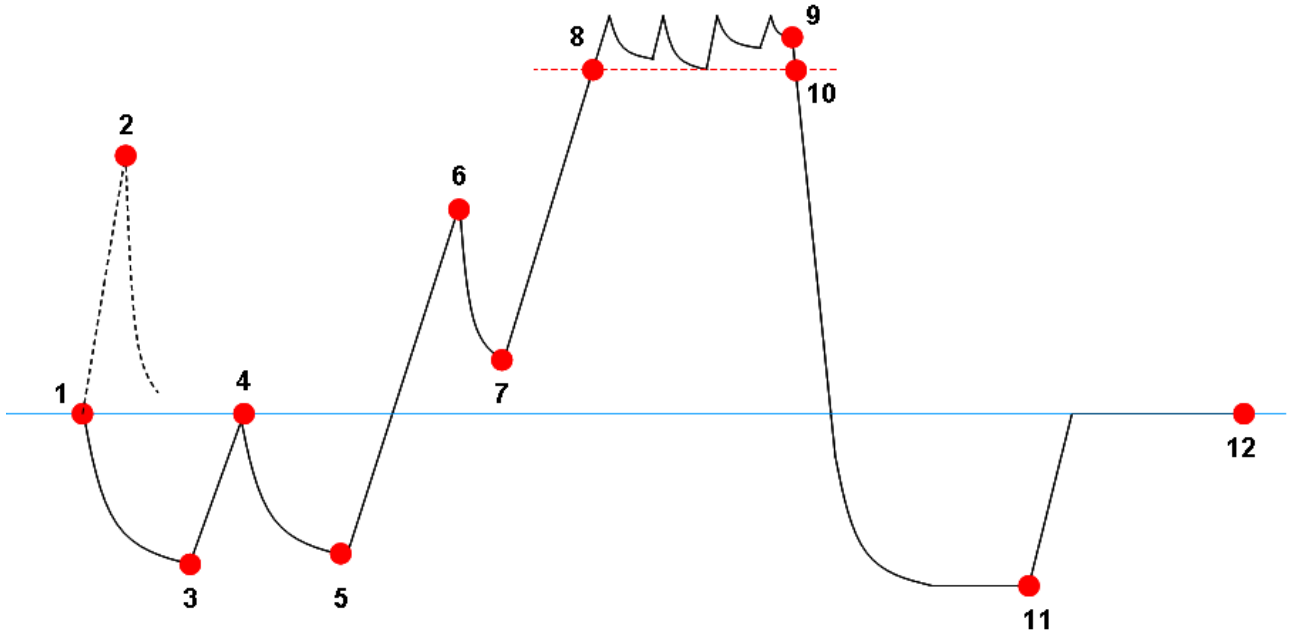
The control points indicate the time and pressure level during the pre-vacuum stage at which the "pressure change direction" of the sterilization cycle changes.

A pressure control points is identified:

- when a vacuum valve is opened (1, 9)
- when a steam valve is opened and vacuum valve is closed (3, 5, 7)
- when a vacuum valve is opened and a steam valve is closed (2, 4, 6)
- when a steam valve is opened (1)
- when the valve for sterile air admission is opened (11)

The pressure control points list is extended with points of interest showing the time and pressure:

- at first measured value after achieving 134.00°C (8)
- at last measured value still above 134.00°C (10)
- when the end of the cycle is reached (12)



The control point list can display more data. This depends on the selected functions to display in the graph. See [Section 6.5.1.1.2 Showing and Hiding Curves on Page 31](#).

For pressure profiles that contain multiple small pulses or pressure control noise a dampening filter is available to define the sensitivity for the designation of control points. See [Section 9.2.9 Preset Values on Page 66](#) - Pressure Control Points.

8.2.1 Condensed List with Control Points

The control points are displayed in a table on the *Control Points* Tab. Each line in the table contains measured and calculated data related to the control point.

The condensed list with control points can be exported for further analysis. See [Section 7.7.2 Exporting the Control Points on Page 43](#).

8.2.2 Control Points in Table

The full data table is displayed on the *Table* Tab. The row that represents a control point is indicated by a chronological numeric label in the column *Control Point*. The row is also high-lighted.

8.2.3 Differences between ETS and Sterilizer

Due to the wide variation in sterilizers and sterilization programs and the dynamic nature of the sterilization process the control points determined by the ETS can deviate from those indicated on your sterilizer documentation.

Fast pressure changes in combination with a 1-per-second measurement interval and pressure sensor inaccuracy are the main reason for this.

It can also happen that the ETS software detects more or less control points. This is caused by the nature of the pressure control of your sterilizer. "Noise" on the pressure curve can be interpreted as real control points. They might, however, be only the result of rapidly opening and closing steam and/or vacuum valves in order to force a controlled pressure increase or decrease.

8.2.3.1 Setting a Filter for Control Point Recognition

The ETS software algorithm can be fine-tuned to match the sterilizer documentation.

Analysis of a large number of pressure control curve show that a vast majority is correctly interpreted by the algorithm using the default settings.

The default values for the filter are:

- Absolute threshold for recognition: 256mbar
- Relative threshold for recognition: 20%

Changing these values increases or decreases the sensitivity of the algorithm to detect control points.

8.3 Table (Tab "Table")

The tab "Table" contains multiple columns with data. The table contents represent measurement data and / or calculated data. Each line in the table shows data that belongs to a single measurement. The sampling rate is fixed at one measurement per second. The number of lines in the table therefore represents the duration of the entire measurement in seconds

The complete table can be exported for further analysis. See [Section 7.7.3 Exporting Data Records to Files on Page 43](#).

8.3.1 Add or Remove Columns

Table columns that shall display calculated data by default can be preset in **Preferences - Diagnostics**. See [Section 9.2.2 Showing and Hiding Diagnostic Data on Page 64](#).

Measurement data is always automatically displayed.

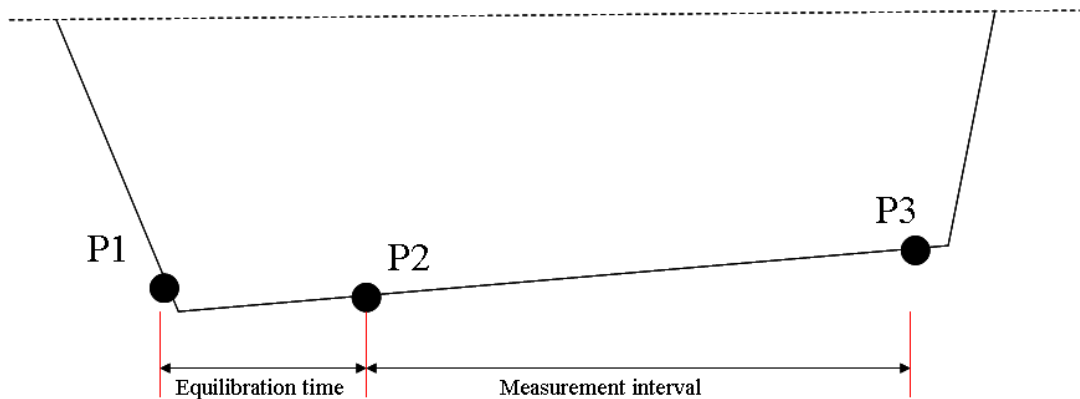
Preset columns can be blended out by using unchecking the functions in the window *Functions*

Calculation data that is not selected to be shown by default can be added by checking the functions in the *Functions* window

8.4 EN 285 Leak Rate Test (Tab "Leak Rate")

8.4.1 Definition of the Test

The Leak Rate test is used to demonstrate that the quantity of air leakage into the sterilizer chamber during the periods of vacuum does not exceed a level that will inhibit the penetration of steam into the sterilizer load and will not be a potential cause of recontamination of the sterilizer load during drying. The test complies with the Air leakage test described in EN 285.



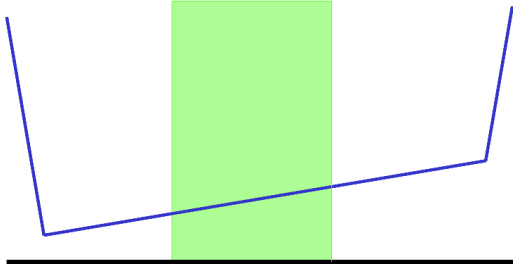
- P1 represents the minimum pressure value required to comply to the standard (70mbar). This is also the start of the equilibrium period.
- P2 is the first pressure measurement after the equilibration period has ended.
- P3 is the pressure measurement after 600 seconds.
- The leak rate is calculated as: $(P3 - P2) / 10 \text{ mbar/min}$

8.4.2 Typical Procedure

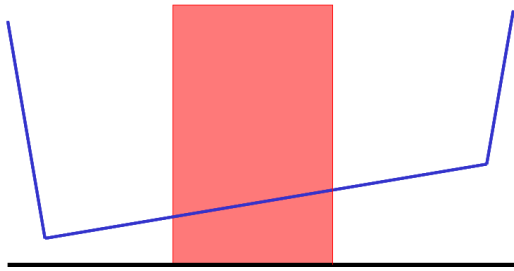
- Activate the ETS Sensing Unit.
- Place an **ETS Sensing Unit** in an empty sterilizer cycle.
- Activate the sterilizer's "EN 285 leak rate" test program.
- Remove the **ETS Sensing Unit** from the sterilizer after completion of the test program.
- Transfer the data to the PC.
- Open the data record and display the graph.
- Click on the Leak Rate tab to open display the leak rate test information.
- The software will automatically look whether or not the data record contains a portion that meets the test criteria.
- The result of the test is displayed graphically (bar in graph) and numerically (values in Leak Rate table).

8.4.3 Leak Rate Test Pass and Fail Criteria

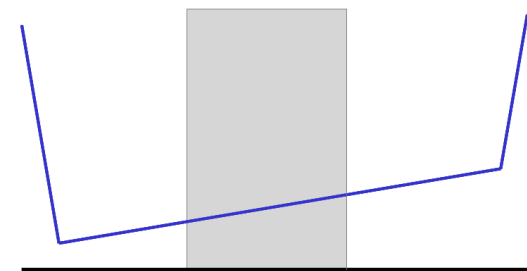
- A portion of in the data record is found that meets the test requirements of EN 285. When the actual leak rate is **equal or smaller then 1.3 mbar/min** the bar in the graph is displayed Green indicating a "pass"
Leak Rate field in the table on the *Leak Rate* tab indicates the actual leak rate value.



- A portion of in the data record is found that meets the test requirements of EN 285. When the actual leak rate **exceeds 1.3 mbar/min** the bar in the graph is displayed Red indicating a "fail"
Leak Rate field in the table on the *Leak Rate* tab indicates the actual leak rate value.



- No portion of in the entire data record could be found that meets the test requirements of EN 285. The bar in the graph is displayed grey.
Leak Rate field in the table on the *Leak Rate* tab is empty (**no result**).




- If there exist more portions in the data record that meet the test requirements of EN 285 the **highest** value for the leak rate will be calculated and displayed graphically and numerically.

8.4.4 Changing the Leak Rate Test Criteria

To change the portion of the data record from which the leak rate is calculated you can change the time at which the start and end measurement of the pressure is taken. The measurement interval is fixed at 600 seconds.

Method 1:

- position the cursor over the coloured bar in the graph.
- The cursor changes to a finger-pointing hand 
- Hold down the left mouse key and drag the coloured bar to in the desired direction (left or right)

All leak rate information is instantly updated as you move the bar

- Release the left mouse key to freeze the results of the modification

Method 2:

- In the table on the Leak Rate tab double click on the value for *First measurement* in column *t[s]*
- Enter a new time
- Confirm with [Enter]

The value for the second measurement is automatically updated (first measurement + 600s)

The leak rate is instantly recalculated

The bar moves to the new position.

8.4.5 Storing the EN 285 Leak Rate Test

Document the result of the leak rate test by clicking the **Save Leak Rate Result** button.

The value will be attached to the original data record. The leak rate value is displayed in the LRT column in the *Files* window and in the *Logbook*.

It is possible to perform a new leak rate calculation on a data record that already has a leak rate value attached to it. The original leak rate result however, can not be overwritten.

Note: If required you can add the results of the new calculation manually as a comment in the *Test Information* window

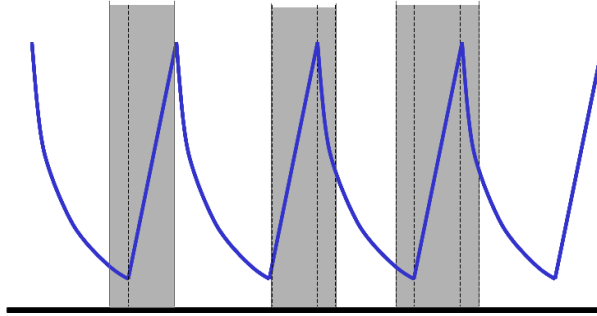
8.5 Pressure Change Rate (Tab "Pressure Change")

8.5.1 Definition of the Test

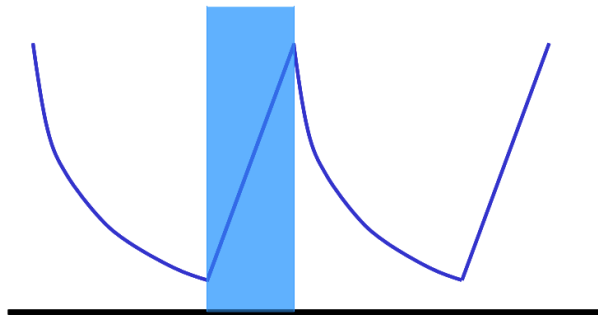
The pressure change rate test is a tool that can be used to determine the rate at which the pressure of a pulse changes.

The result is only meaning full when the entire measurement interval of interest is between two successive control points.

- The measurement interval bar is grey when it includes one or more control points.



- The measurement interval bar is blue when it includes no control points.



- The same applies to evacuation pulses.

8.5.2 Typical Procedure

- Open the data record and display the graph.
- Use the zoom function to display the area of interest (optional).
- Click on the *Pressure Change* tab to display the information.

A coloured bar appears in the graph from 40% to 60% of the visible time range.

The rate at which the pressure of a pulse changes can be measured and calculated in the following manners:

Method 1:

- Enter a time for *First measurement* in column *t[s]*.
- Confirm with [Enter].
- Enter a time for *Second measurement* in column *t[s]*.
- Confirm with [Enter].

The pressure change rate is instantly calculated.

The coloured bar in the graph indicates the measurement interval.

Values for first and/or second measurement can be changed as required.

Method 2:

- Position the cursor over the border of the coloured bar so that the cursor changes to a double-sided arrow

- Hold down the left mouse key and move the cursor to the left or right.

The coloured bar in the graph changes width thus indicating the measurement interval.

All information in the table is instantly updated while moving the cursor

- Release the left mouse key to fix the measurement.

Values for first and/or second measurement can be changed as required using method 1.

Alternatively:

- repositioning the cursor on the right or left border of the coloured bar until it changes to a double-sided arrow
- Hold down the left mouse key and move the cursor to the right or left.
- Release the left mouse key to fix the measurement.

To change the position of the measurement interval leaving the interval itself unchanged:

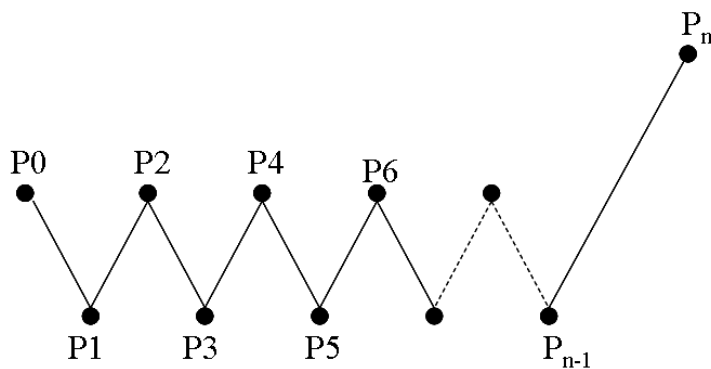
- position the cursor over the coloured bar
- The cursor changes to a finger pointing hand
- Move the entire bar to the left or the right
- Release the left mouse key to fix the measurement.

8.6 Dilution

The theoretical dilution factor is a dimensionless numerical value. It represents the dilution based on the pressure control points detected during the portion of the cycle preceding the start of the sterilization period.

The formula used to calculate the theoretical dilution factor is:

$$P_2/P_1 \times P_4/P_3 \times P_6/P_5 \times \dots \times P_n/P_{n-1}$$



8.6.1 Overall Dilution Factor

The Dilution factor presented as a single value (*Info* tab and *Sterilization* tab) indicates the dilution reached at the start of the sterilization phase.



8.6.2 Continuous Dilution Factor

The Dilution presented as a curve or table represents the actual dilution reached at the indicated time.

8.7 Residual Air

The dilution factor is used to calculate the theoretical amount of residual air in the chamber. The chamber volume of the related sterilizer under test is derived from the entry made in the Sterilizer Name field when the data is transferred from the ETS Sensing Unit to the computer.

The calculation does not consider quantities of air coming from air leakage or poor steam quality (NCG)

8.7.1 Residual Air as Single Value

The Residual Air presented as a single value (*Info* tab and *Sterilization* tab) indicates the amount of air present in the sterilizer at the start of the sterilization phase.

8.7.2 Residual Air as Curve or Table

The Residual Air presented as a curve or table represents the actual (theoretical) amount of air present in the chamber at the indicated time.

8.8 F₀ Lethality

A technique commonly applied to steam sterilization is to integrate the lethality of the process using the familiar F₀ function. This process involves measuring the temperature within the sterilizer and fitting this data into the F₀ equation.

F₀ is the integrated lethality function (the equivalent time of exposure at a specified reference temperature, which for F₀ is 121°C but could also be 134 °C).

Thus, for a sterilization cycle operating at 134°C for 3 minutes the F₀ value would be approximately 60. In other words, exposure at 134°C for 3 minutes is equivalent to an exposure at 121°C for 60 minutes in terms of the microbial lethality of the process.

8.8.1 Formula

The formula used to calculate the F₀:

$$F_0 = 10^{(T-121/z)} dt$$

Where:

- F₀ is the equivalent heating time at 121°C, thus 1 F₀ unit is equal to 1 minute at 121°C.
- T is the temperature at time interval dt (typical 1 second or 0.0166 of a minute).
- z is the z value of the microbial population for which the lethality is being calculated (normally 10)

8.8.2 Change Temperature for Calculation

To change the temperature see [Section 9.2.9 Preset Values on Page 66.](#)

8.9 Sterilization (Tab Sterilization)

The Sterilization tab provides a table with information specific to the sterilization phase.

8.9.1 Sterilization Temperature Band

Lower limit

- User defined temperature as lower limit for the sterilization temperature band. See [Section 9.2.9 Preset Values on Page 66.](#)

Upper limit

- User defined temperature as upper limit for the sterilization temperature band. See [Section 9.2.9 Preset Values on Page 66.](#)

Measured start

- First measured value after the chamber temperature is above the preset temperature for the lower limit of the sterilization temperature band.

Measured end

- Last measured chamber temperature value which is still above the preset temperature for the lower limit of the sterilization temperature band.

Maximum temperature

- Maximum temperature during sterilization temperature band.

Duration

- Total time within sterilization temperature band (from start to end).

8.9.2 Sterilization Parameter Indication

Measured start

- First measured value after the chamber temperature is above 134°C.

Measured end

- Last measured chamber temperature value which is still above 134°C.

Duration

- Total time above 134°C.

8.9.3 Evaluation Period

Exclude from start

- Interval starting at the beginning of the sterilization temperature band which is excluded from the evaluation of the sterilization temperature band.

Exclude from end

- Interval ending at the end of the sterilization temperature band which is excluded from the evaluation of the sterilization temperature band.

Start

- Start of the user defined interval of interest (evaluation period).

End

- End of the user defined interval of interest (evaluation period).

Duration

- Total time of evaluation period.

Average temperature

- Average temperature over evaluation period.

Temperature range

- The difference between the maximum temperature and minimum temperature during evaluation period.

Maximum temperature

- Maximum temperature during evaluation period.

Minimum temperature

- Minimum temperature during evaluation period.

Average pressure

- Average pressure over evaluation period.

Pressure range

- The difference between the maximum pressure and minimum pressure during evaluation period.

Maximum pressure

- Maximum pressure during evaluation period.

Minimum pressure

- Minimum pressure during evaluation period.

8.9.3.1 Typical Procedure

- Click on the *Sterilization* tab to display the information.


A coloured bar appears in the graph from 40% to 60% of the visible time range.

Modify the evaluation range by changing the time to exclude from the start and end of the sterilization phase.

Method 1:

- Enter a time for *Exclude from start* in column *t[s]*
- Confirm with [Enter]
- Enter a time for *Exclude from end* in column *t[s]*

Method 2:

- Position the cursor over the border of the coloured bar so that the cursor changes to a double-sided arrow 
- Hold down the left mouse key and move the cursor to the left or right.

To fix the evaluation range:

- Release the left mouse key.

The values are updated instantaneously.

The coloured bar in the graph indicates the evaluation range.

8.9.4 Residual Air at Start of Sterilization


See [Section 8.7.1 Residual Air as Single Value on Page 57](#).

8.10 Data Scanner

Use the data scanner to show the measured and calculated data at a selected time. The indicated values correspond with the intercept of each individual curve and the vertical slider in the graph.


8.10.1 Selecting a Point of Interest

To select a point of interest:

- Click on the icon bar in the graph on the data cursor icon  to activate the data scanner

A vertical red line appears in the middle of the graph. Also, a table opens automatically. The table is situated at the far-right side of the graph.

- Move the cursor over the red line

The cursor changes to a finger-pointing hand 

- Hold down the left mouse key and move the data cursor to the left or right.

The data belonging to the time indicated by the slider is shown the table.

- Release the left mouse key at the desired time.

Data is also shown on the *Table* tab. This view provides also data directly preceding and succeeding the time indicated by the slider. The data range that is shown depends on the size of the *Data Window*.

8.10.2 Showing / Hiding Data Scanner Information

The table for the data scanner is opened in a window at the right of the graph. Between the table and the graph is a separator.



- Position the cursor over the separator so that the cursor changes to a double-sided arrow and the separator changes from blue to orange.



A single click on the separator closes or opens the data scanner window revealing the table.

- The width of the data scanner window can be adjusted by dragging the separator to the left or the right while holding the left mouse key down.

8.11 Theoretical Temperature

The theoretical temperature is calculated from the pressure measured by the ETS pressure sensor.

Calculated results are conforming the steam table.

Both the pressure sensors and the temperature sensor for the chamber temperature have a defined measurement accuracy. See [Section 2.2 Technical Data on Page 11](#). Taking this accuracy into account the theoretical temperature curve can be used to compare the actual chamber temperature with the theoretical temperature that should be obtained when the pressure results from 100% dry saturated steam.

The function can be displayed by default (See [Section 9.2.2 Showing and Hiding Diagnostic Data on Page 64](#)) or shown / hidden on demand (See [Section 6.5.1.1.2 Showing and Hiding Curves on Page 31](#))

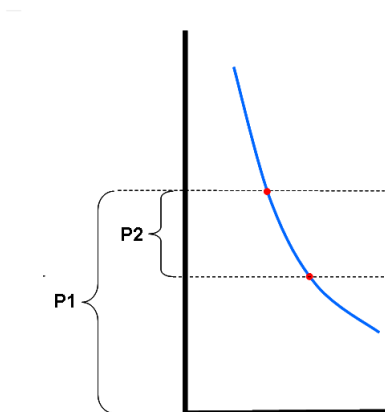
8.12 Vacuum Pump Efficiency

The vacuum pump efficiency provides information on the capacity of the vacuum pump to reduce the pressure.

During a steam admission pulse the vacuum pump efficiency is 0.

The value displayed indicates the pressure reduction in relation to the previous pressure measurement.

The calculation of each value is performed on two consecutive pressure measurements (1 second interval).



The formula for calculating the vacuum pump efficiency is:

$$(P1-P2) / P1 \times 100\%$$

The pressure values are averaged over the interval P - 2 second to P + 2 seconds. (5 measurements)

8.13 Generating a Summary

The summary generator is a tool that generates a file containing a table with information which can be used for further analysis in other data analysis software e.g. Microsoft Excel or statistical software.

A summary table can contain all historical ETS records available in the ETS databank (logbook) or a selection.

Use the logbook to make a selection.

To select the records to summarize:

- Use the filter setting options. See [Section 7.3.6 Setting a Filter for Specific Data Record Properties on Page 41.](#)

To start the generation of the summary file:

- In the File menu click Export – Summary.

The file name is Summary_Date_Time.ext

The file is located in the designated export folder. See [Section 9.2.4 File Locations on Page 64.](#)

9 Setting up the software

9.1 Installing the Software

To install the ETS PC Software 4110 on your computer:

- Insert the CD into your CD-ROM Drive.
- Locate the SETUP.EXE on the CD-ROM.
- Start SETUP.EXE.
- Follow the instructions on the screen.

Note: It is highly recommended to install the software as suggested by the installation program. No changes are required then.

- Click the **Next** button to progress to the next window each time a new dialog window pops up.
- Click the **Close** button after the installation procedure is completed.

9.2 Configuring the Software

The configuration process adapts the ETS PC Software 4110 to the working environment.

9.2.1 First Time

To ensure a maximum easy-to-use software it is important to complete the entire configuration process. In this process the person setting up the software is required to enter specific data that is required for:

- Full trace ability
- Automated calculation
- Minimizing the number of manual entries
- Eliminating as much typing as possible
- Personalizing / Customizing
- Data security and integrity

This process is to be completed by the administrator of the software. Entries made by the administrator are valid for all users. Modifications after completing the initial configuration can only be made by the administrator.

Note: This configuration procedure shall be completed before the software is used. If it is not completed correctly or specific information is missing error messages may appear or certain information will not be calculated and displayed. This, however, will not lead to damage to data or software.

9.2.2 Showing and Hiding Diagnostic Data

The diagnostic information for an ETS file is calculated automatically as soon as the record is opened (exception: Leak Rate Test and Pressure Change Rate Test).

The administrator can define what information shall be displayed by default when the file is opened. Depending on the function the curve in the graph, the numerical data in the table and specific calculated results (single values) can be hidden or shows by default.

To hide / show the available function:

- select from the *Navigation* window: **Options - Preferences**

The *Preference* window opens.

- Select **Diagnostic** from the list on the left side of the window.

All available functions are displayed.

- Check or uncheck the boxes to define your preference.
- Confirm the selection by clicking **OK**.
- or click **Cancel** close the window leaving the settings unchanged.

During a session the information can be shown or hidden as desired by using the **Functions** selection feature. See [Section 6.2.3 Selecting Functions from the Navigation Bar on Page 28](#).

Ending a session resets the visualization of diagnostic information to the default defined by the ETS software administrator.

9.2.3 Language

To select the language of your preference:

- select from the *Navigation* window: **Options – Preferences**.


The *Preference* window opens.

- Select **Language** from the list on the left side of the window.
- Open the selection box and click on the desired language.
- Confirm the selection by clicking **OK**.
- Exit and restart the software.

The selected language is the new default .

9.2.4 File Locations

To change the file location:

- From the Menu bar or Navigation click **Options - Preference - Communication**
- Click  (next to the fields ETS Database location or ETS File Export location).
- Select the desired path/folder from the dialog window.
- Click **OK** to confirm.
- Click **OK** to confirm and close the *Preference* window.



9.2.5 Internet

To Change the Internet settings:

- select from the *Navigation* window: **Options – Preferences.**

The *Preference* window opens.

- Select **Communication** from the list on the left side of the window.

3M Homepage

- Enter the preferred 3M home page.

Contact us

- Enter the e-mail address for the preferred contact at 3M.

9.2.6 Locations

Add the name of the organization and department from which you want to administer the ETS results. The names appear in selection lists for fields that shall uniquely identify test data.

To add an organization and / or department:

- select from the *Navigation* window: **Options – Preferences.**

The *Preference* window opens.

- Select **Location** from the list on the left side of the window.
- Below the entry box for *Organization* click **Add.**
- Enter the name of the new organization.
- Click **Save.**

To add a department:

- select a previously entered organization.
- Below the entry box for *Department* click **Add.**
- Enter the name of the new department.
- Click **Save.**

The departments are linked to the selected organization.

Use **Remove** or **Rename** to modify the list of locations.


9.2.7 21 CFR part 11

The software meets the FDA requirements for validated software and 21 CFR Part 11 electronic signatures. The default setting is *Basic*

Software Features	Low <i>Basic</i>	High <i>21 CFR part 11</i>
Logon procedure	Yes	Yes
User administration	Yes	Yes
Meet User name convention	Yes	Yes

Meet Password convention	Yes	Yes
Audit Trail	Yes	Yes
Comments	Yes	Yes
Approvals	No	Yes
Password Expiry after 3 months	No	Yes
Session Time out after 15 minutes	No	Yes

To change the level of compliance

- Click the radial button  for the desired level of compliance.

Note: It is highly recommended to configure the software with full 21 CFR part 11 compliance.

See [Section 12 Electronic Signature - 21 CFR Part 11 on Page 73.](#)

9.2.8 Sterilizers

Add the name(s) of the sterilizer(s) from which you want to administer the ETS results. The Sterilizer names appear in selection lists when test data shall be designated.

To add a Sterilizer:

- select from the *Navigation* window: **Options – Preferences.**

The *Preference* window opens.

- Select **Sterilizer** from the list on the left side of the window.

Entry fields appear in the window.

- Complete the entries for Sterilizer.
- Click Add Sterilizer.

The entries are automatically saved.

Use **Edit Sterilizer** to modify the entries.

Use **Sterilizer decommissioned** to delete a sterilizer. Information about the deleted sterilizer will still be available. This ensures trace ability.

See also [Section 9.2.10 Assigning an ETS Sensing Unit to a Sterilizer on Page 67.](#)

See also [Section 8.1 Master Overlay \(Tab "Master"\) on Page 49.](#)

9.2.9 Preset Values

In Preset Values all values used for calculation of information displayed on the various tabs are shown. The values are either variables (white background) or constants (grey background).

To change the variables:

- Double click the value that you want to change.
- Enter a new value.
- Click **OK** to confirm.

9.2.10 Assigning an ETS Sensing Unit to a Sterilizer

An ETS Sensing Unit can be assigned to a specific sterilizer in case frequently the same Sensing Unit is used. As soon as the data is transferred from this allocated Sensing Unit the correct field entries for sterilizer department and organization are suggested automatically. In case of exceptions the entry can be changed by selecting a different item from the list.

To allocate an ETS Sensing Unit to a sterilizer:

- select from the *Navigation* window: **Options - Preferences**

The *Preference* window opens


- Select **Sterilizer** from the list on the left side of the window
- Select the sterilizer to which the Sensing Unit shall be assigned or add a sterilizer
- Enter the full **ETS serial number** in the field *Assigned ETS Sensing Unit*
- Click **OK**

9.2.11 Measuring Units

To select the units of your preference

- select from the *Navigation* window: **Options - Preferences**

The *Preference* window opens

- Select **Units** from the list on the left side of the window
- Click the radial button  in front of the preferred unit
- Confirm the selection by clicking **OK**



10 Operating Mode

An ETS Sensing Unit can be operated in two different modes:

- Bowie and Dick Mode
- Data Logger Mode

10.1 Bowie and Dick Mode

The ETS Sensing Unit is a stand-alone device which means that it can be used without an additional computer.

Activating the ETS Sensing Unit by pulling the black switch on top activates the unit in Bowie and Dick Mode by default. See [Section 2.3.2 Operation on Page 12](#).

When the ETS Sensing Unit is exposed to the right conditions the unit will automatically calculate a Result.

10.2 Data Logger Mode

In data logger mode the ETS Sensing Unit merely records all sensor data for temperature and pressure. The maximum logging capacity is 1 hour (3600 seconds: 3600 measurements for each sensor).

No calculation is performed after the logging of data has stopped.

To activate the data logger mode:

- Position the ETS USB Data Reader correctly on top of the ETS Sensing Unit.
- Click on the **Advance** menu or in the *Navigation* section **Advanced**.
- Select **Select Mode**.
- Click **OK** to confirm and activate the ETS Sensing Unit in data logger mode.
- Remove the ETS USB Data Reader from the ETS Sensing Unit

The ETS Sensing Unit starts recording as soon as the OK button is clicked.

To stop the logging

- Pull the black switch on the ETS Sensing Unit once or
- Position the ETS USB Data Reader correctly on top of the ETS Sensing Unit.

After 1 hour the logging stops automatically.

Logging has stopped when no LEDs flash any longer.

11 User Administration

Note: The User Administration function is only available to accounts belonging to the Administrator group.

The User Administration can be started in three different ways.

1 - From the Navigation bar

- Click *Options* - **User administration**.

2 - From the Menu bar

- Click **Options** - **User administration**.

3 - From the Icon bar

- Click **User administration** .

To open the User Administration:

- Select your preferred access to user administration (see above).
- Click on **User Administration**.

A Dialog window *User Administration* opens.

11.1 Logon Password

To ensure full trace ability it is essential to record certain activities that influence authenticity and integrity of the data record.

All relevant activities will be linked to the person who is logged on the ETS software.

When setting up an account a preliminary password will be provide by the administrator. Both user name and preliminary password shall be communicated to the user. The user can log on the fist time using this information.

The option *Password expires after first login* is activated by default. This will force the user to change his / her password during the first logon session.

Password convention:

- Minimum lengths: 8 characters
- Maximum lengths: 64 characters
- A password can not contain the more than four sequential characters from the user name.
- A total of five previously used passwords is blocked for reuse.
- Passwords shall be renewed every three months.

11.2 Creating a New User Account

Note: Only a member of the Administrator Group can create a new user account.

To add a new user account:

- Click **Add Account**.
- Enter a **User Name**.



- Enter the **Full Name** of the new user.
- Enter a preliminary **Password**.
- Re-type the preliminary password in **Confirm Password**.
- Select the appropriate **Group Membership** for the new account.
- Select from scroll list or enter **Supervisor, Organization and Department**.

Note: New entries for Organization and Department will also be added to Locations in *Preferences*

By default, the function **Password expires after first logon** and **Account Enabled** are activated.

To deactivate these functions:

- Uncheck the box.

Note: The **Save** button will become active only when all fields are filled.

- Click **Save** to complete adding the new account.
- Click **Close** to exit and close the User Administration Window.
- Alternatively, click **Cancel** to close the *User Administration Window* without saving any changes.

User name convention:

- Minimum lengths for user name: 6 characters
- Maximum lengths for user name: 16 characters
- The user name can only be assigned once. User names must differ by at least one character.

11.3 Group Membership

Two membership groups are available:

1 - Administrator

2 - User

The table illustrates available functions for the Administrator and User group.

An example of typical members for the group:

Administrator

- IT personal, department managers and designated responsible personal.

User

- Personnel or designated testers involved with day to day testing and data transfer of ETS data records to the PC.

Function	Group	
	Administrator	User
Start application	Yes	Yes
Transfer data from ETS SU to PC	Yes	Yes

Identify test	Yes	Yes
Save downloaded file	Yes	Yes
Open downloaded file	Yes	Yes
Open existing file	Yes	Yes
View graph	Yes	Yes
View all that is preset by admin	Yes	Yes
Add comments to ETS file	Yes	Yes
Turn curves off/on	Yes	Yes
Open logbook	Yes	Yes
Open records from logbook	Yes	Yes
Use logbook filter	Yes	Yes
Print graph & information	Yes	Yes
Print graph	Yes	Yes
Print logbook	Yes	Yes
Designate master record	Yes	No
Export records to files	Yes	No
Export table	Yes	No
Export control points	Yes	No
Import ETS files into database	Yes	No
Start User administration	Yes	No
Add/Delete Users	Yes	No
Change Group membership	Yes	No
Set-up and modify preferences	Yes	No
View audit trail	Yes	No

11.4 Editing an Existing User Account

To edit a user account:

- Click once on the user name in the list *User* to select the user you want to edit.
- Click **Edit Account** to change the actual account data.

Note: The user name can not be changed.

Note: The **Password** can be changed, however the user of this account will be asked to change it at next logon.

11.5 Deleting a User Account

To delete a user account:

- Click once on the user name in the list *User* to select the user you want to delete.
- Click **Delete Account** to delete the account.

Note: Deleted accounts cannot be restored. The deleted user name will be blocked to assure full trace ability. It is no longer available as a user name for a new user account.

11.6 Password Expiry

The Passwords expires every 90 days. A window will open requesting to enter a new password. See [Section 11.7 Change Password on Page 72.](#)

11.7 Change Password

To change the password, select option 1 or 2:

1 - From the **Navigation bar**:

- Click *Options* - **Change Password**.

2 - From the **Menu bar**:

- Click **Options** - **Change Password**.

A Dialog window *Change Password* opens.

- Enter **old password** (Password characters will be shown as black dots).
- Enter **new password**.
- Re-type new password.

Note: Consider password convention.

See [Section 11.1 Logon Password on Page 69.](#)

- Click **OK** to confirm password change and close window.
- or click **Cancel** to exit without any changes and close window.

11.8 Logon Timeout

When the ETS software does not register any activity for 15 minutes it will automatically close the session of the user which was logged on most recently. The software is not closed. As soon as the somebody wants to use the software again a new logon is required.

11.9 Disabling / Enabling an Account

An administrator can disable a user account. The account is not deleted but the user can not log on to the system any longer.

Also, as a result from an incorrect logon procedure an account is automatically disabled (after 4 failing attempts).

The account can be enabled again by the administrator.

See [Section 11.4 Editing an Existing User Account on Page 71.](#)

12 Electronic Signature - 21 CFR Part 11

12.1 Adding Comments

The *Comments* field displays all information related to the file's history. Comment can only be added, not changed or deleted. It can be used as an audit trail of an individual file.

Any information considered relevant by the user can be added to the ETS data record.

To add a comment:

- Click the **Append Comment** button on the *Test Information* window or select **Add Comment** from the *Navigation* window

The *Append Comments* window opens

- Enter the **comment**.
- Click the **Save** button to store the comment and close the window.

The maximum length of a single comment is 256 characters. The comment can be split in several comments in case the comment is longer. The maximum number of comments per data record is 42.

Each comment is preceded by the time, the date and the user name.

12.2 Adding an Electronic Signature

An electronic signature is considered to be the official prove that a responsible person has been informed about the result of a test.

A signature can only be given by an administrator.

To sign:

- Click the **Sign** button on the *Test Information* window or select **Add Signature** from the *Navigation* window.

A window opens requesting a password. This shall be the password of the person that is currently logged on.

- Enter the **Password**.
- Click OK to confirm and close the window.

12.3 Audit Trail

The audit trail independently records the date and time of operator entries and actions that create or modifies electronic records.

The audit trail records only activities related to:

- Logon / off
- Data transfer
- Comments
- Signature
- User administration

The audit trail can be viewed by an administrator only.

The entire contents of the audit trail can be exported.

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