

CELSIUS FDA



USER MANUAL

CELSIUS 10

Control software for MEMMERT appliances – FDA Edition
Validatable in according to 21 CFR Part 11
U. S. Food and Drug Administration

Manufacturer and customer service

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About this manual

Intended use and target group

This user manual describes the installation and use of the MEMMERT control software CELSIUS 10 FDA Edition. It is intended for use by trained personnel of the operating company, who have the task of programming/operating MEMMERT ovens.

If you intend to work with the software, please read this manual carefully before starting. Familiarise yourself with the programme and run several tests before actually controlling an oven. Incorrect use could result in damage to the oven and/or to the chamber load.

If there is something you do not understand, or certain information is missing, ask your superior or get in touch with the manufacturer. Do not do anything without authorisation.

i The representation of the programme windows in this manual is based on the operating system Windows® XP Professional. On computers with other Windows® versions (Vista, 7), the representation may differ.

Explanation of terms

Below, we shall explain a number of terms that are used repeatedly in this manual.

Term	Meaning	Description on/from page
Tempering profile/ramp	a time sequence of physical values/combinations (temperature and – depending on oven type – humidity, vacuum, CO ₂ and O ₂), that the oven should perform	27
Protocol	Recording of the actual physical values/combinations (temperature and – depending on oven type – humidity, vacuum, CO ₂ and O ₂), that the oven should create during the execution of a tempering profile (measuring values)	38
Controller	internal control of an oven	
Electronic Record	Electronic Records are defined as combination of texts, graphics, data or other information which can be generated, edited or stored by a computer system.	
Audit Trail	Any editing of an Electronic Record must be protocolled with time, user name and type of alteration and must be stored independently of the Electronic Record. With the aid of the Audit Trail it is possible to follow the history of any document.	53
Electronic Signature	By means of the Electronic Signature the user confirms that he has edited an Electronic Record. For this it is necessary that the user can be uniquely identified and that his authority can be tested. "Electronic Signatures" are not electronic signatures within the meaning of the German signature laws.	55

Other documents that you must read:

Please also read the user manual for the respective oven to be operated with the software and familiarise yourself with it.

Storage and forwarding

This manual should always be kept in a place where those working with the software have access to it. It is the responsibility of the operator to ensure that persons who work with or will work with the software are informed as to the whereabouts of this user manual. We recommend that it is always stored in a protected location close to the computer on which the software is installed. Make sure that the manual is not damaged by heat or damp.

 An electronic version of this manual in PDF format can be run from the software via the help function (see page 19).

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1. End user licence agreement

NOTE - IMPORTANT - PLEASE READ THE FOLLOWING AGREEMENT TEXT CAREFULLY

This end user licence agreement forms a legally binding agreement between you, whether a natural or a legal person, and MEMMERT GmbH & Co.KG.

This licence agreement bindingly regulates the use of software licences of MEMMERT GmbH & Co.KG. The software licence may include also pertinent media and printed material as well as in online or electronic format ("software licence"). Included are also all updates and supplements to the software product originally supplied. These are also covered by this licence agreement without requiring any separate agreement.

By installing, downloading, copying or otherwise using or accessing this software you declare your legally binding agreement that you accept the conditions of this licence agreement and are bound by it. If you do not agree to the conditions of this licence agreement you are not entitled to instal the software or otherwise use it.

The software is protected by copyright laws, international copyright agreements, as well as by other laws and agreements on intellectual property.

§1 - RESERVED OWNERSHIP

The software product is licenced, not sold. All property and user rights remain with MEMMERT GmbH & Co.KG. The licensee is entitled to its use exclusively within the scope of the agreement and for its duration. The property and the copyright of the software product, of the accompanying printed material and of any copy of the software product are and remain with MEMMERT GmbH & Co.KG. If and in so far as this software product contains documentation provided only in electronic form, you may print a copy of this electronic documentation. You are however not authorised to duplicate or distribute the printed material accompanying the software product.

§2 - LICENCE CONCESSION

The software product is licenced as follows:

MEMMERT GmbH & Co.KG licences you the right to instal and use copies of the software product on computers on your business premises in so far as it is required for the use of the equipment concerned.

As customer you must use the software only for the MEMMERT equipment entered in the licence file. The licence for the particular equipment must not be split or used on other equipment simultaneously. The licence is assigned and limited to the particular equipment. You are obliged to obtain a separate licence for each equipment.

You are not entitled to hire out, lease, loan or otherwise dispose of the software product. You are also not authorised to amend, back-develop, decompile, disassemble etc. the software product unless this is expressly permitted in writing by MEMMERT GmbH & Co.KG.

§3 - WARRANTY

Errors in computer programmes can never be completely excluded in the present state of technological development. The user hereby notes this situation.

All warranty lapses if the user modifies programmes or programme parts or has such changes or extensions carried out by third parties.

MEMMERT GmbH & Co.KG accepts no responsibility for errors, faults or damage which result from incorrect operation, use of unsuitable operating material, or unusual operating conditions.

The user must employ the SOFTWARE PRODUCT only for his own purpose unless expressly agreed otherwise.

The user must notify MEMMERT GmbH & Co.KG without delay of any faults which occur, together with a brief description of the fault.

§4 - RESTRICTED WARRANTY

MEMMERT GmbH & Co.KG warrants for a period of 1 year that the data medium on which the SOFTWARE PRODUCT is supplied, is free from material faults and manufacturing faults.

The software has been carefully developed and tested by MEMMERT GmbH & Co.KG. There is however no warranty that the functions of the software meet all expectations or that the software runs without any interruptions.

MEMMERT GmbH & Co.KG is not liable for any damage, lost profit, loss of confidential or other information, interruption of business, personal damage, loss of privacy, breach of duty, including duties in good faith or duty of care, property or other damage which may arise from the use of this software product or any inability to use this software product.

This applies also in case MEMMERT GmbH & Co.KG has been advised of the possibility of such damage.

This exclusion does not apply to damage which has been wilfully caused by MEMMERT GmbH & Co.KG.

§5 - TERMINATION

Irrespective of other rights MEMMERT GmbH & Co.KG is entitled to terminate this licence agreement if you contravene in any form the terms and conditions of this licence agreement.

In such a case you are obliged to return all originals and copies of the software product to MEMMERT GmbH & Co.KG. Copies in whatever form and on whatever data medium must not be retained. In so far as MEMMERT GmbH & Co.KG waives the obligation to such return, you must destroy all originals and copies and this destruction must be documented and proven.

§6 - DAMAGE LIMITATION OBLIGATION

1) The licensee is expressly advised that he has to produce security copies of the data on his computer regularly and at adequate intervals of time (normally weekly). If he does not do this he defaults on his obligation to limit damage. The licensor is not liable for damage arising from such contravention.

2) The licensee is expressly advised that the software must not be employed in dangerous environments which presume fault-free operation (high-risk activities such as operation of nuclear installations, weapon systems, aircraft navigation or communication systems or life-preserving machines). If he still does so he defaults on his obligation to limit damage. The licensor has not liability for damage arising from such default.

§7 - AGREEMENT ALTERATIONS AND DEFENCE CLAUSE

The agreement is concluded exclusively on the basis of the General Utilization Conditions of MEMMERT GmbH & Co.KG. Other agreements are inapplicable, even if certain regulations are not included in the Utilization Conditions of MEMMERT GmbH & Co.KG.

§8 - CHOICE OF LAW

All legal relations between the parties, including delict law, are subject to the law of the German Republic. The legal domicile is Schwabach, Germany.

§9 - FINAL CLAUSE

- 1) Supplements to this agreement, including this clause, have to be produced in writing.
- 2) If one or several of the above terms should be or become invalid, this does not affect the effectiveness of the other terms. The invalid term is to be replaced by a valid term which as far as possible realizes the intended commercial purpose. This also applies in case of a gap in the agreement.
- 3) This agreement is subject to the law of the German Republic. Legal domicile is the domicile of the licensor. All questions relating to the validity, interpretation and performance of the contents of this agreement should be clarified at the legal domicile of the licensor in the German Republic.

2. Introduction

2.1 Description

2.1.1 Basic programme functions

CELSIUS is a computer programme for the programming, control and logging of MEMMERT ovens with an RS-232, or alternatively RS-485, USB or Ethernet interface.

With CELSIUS, you can

- ▶ Create, change and save tempering profiles on your computer in graphical or tabular form.
- ▶ Control one or more MEMMERT ovens via one or more serial interfaces and log the current values. up to eight ovens can be controlled via RS-232 or USB, and if RS-485 or Ethernet interfaces are used (not for ovens of the E class), you can control up to 16 ovens simultaneously;
- ▶ if your oven is equipped accordingly, you can use the functions of the MEMoryCard XL, i. e. to store a tempering profile on a MEMoryCard XL, as well as load tempering profiles and protocols from a MEMoryCard XL, display this on the monitor and save it to a different data medium (hard drive, USB stick);
- ▶ read out, manage and document the internal ring protocol memory (1024 kB) of the MEMMERT ovens;
- ▶ print out tempering profiles and accompanying protocol data (depending on the oven type, temperature, humidity, vacuum, CO₂, O₂, fan speed, air flap position and switch contacts, see page 7) including GLP data, graphically or numerically.

2.1.2 Advanced FDA Edition functions

Within a closed system this specially developed software meets the FDA requirements. The Food and Drug Administration as the USA regulatory authority is responsible for monitoring manufacturing processes in the food, chemical and pharmaceutical industries.

- ▶ User management in user groups by the administrator
- ▶ Storage of profile and protocol data in file format secure against falsification
- ▶ Monitoring of log on/off procedures, alteration of the raw data with the aid of an audit trail
- ▶ Complete integration into the Windows NT, 2000, or XP Professional security system (authority management, user and password management, user authentication)
- ▶ Facility for data export in generally readable HTML

21 CFR Part 11

The regulation 21 CFR (Code of Federal Regulation) Part 11 came into force in 1997. It describes the requirements of the American health authority FDA (Food and Drug Administration) in respect of electronic data sets and signatures so that they can be used as replacement for extensive paper documents and manual signatures. The initiative for their development came from the pharmaceutical industry. It applies to all enterprises in pharmacy, biotechnology and medical technology which manufacture in the USA or supply to the USA.

Manufacturers of FDA-regulated products, especially of pharmaceutical and chemical products, are subject to strict validation duty. The USA regulatory authority prescribes a continuous documentation and long-term archivation of the process variables.

The regulation applies to all production and quality assurance documents which previously had to be presented on paper and signed. These documents can in future be generated, stored and signed electronically.

They are filed in:

- ▶ Electronic Records
- ▶ Audit Trails
- ▶ electronic signatures (Definitions see page 3)

The FDA conform software "CELSIUS FDA-Edition" meets the requirements for the use of electronically stored data sets and electronic signatures as laid down in the directive 21 CFR Part 11 of the US Food and Drug Administration (FDA) :

- ▶ **Authenticity:** user and administrator of Electronic Records must be uniquely identifiable and authentic.
- ▶ **Integrity:** the data of Electronic Records must permit unique inference to the processes documented. All alterations must be documented long-term over the course of the archivation period.
- ▶ **Undeniability:** the Electronic Signature inseparably linked to the data set must uniquely identify the responsible originator
 - Unique identification of the user
 - User-related access protection for individual system functions
 - Security of data against falsification
 - Automatically operating audit trail with time stamp, signature, and type of alteration on the Electronic Records
 - Facility for human and electronic reading and copying of the Electronic Records
 - Facility for access to the data by inspectors of the regulatory authorities

2.2 System Requirements

Category	Minimum system requirements
Processor	Pentium 1 GHz
Main memory	1 GB
Available free space on hard drive	1 GB
CD-ROM drive	yes
Graphics	VGA graphics and colour monitor
Interfaces	an unused RS-232 or USB interface, if several ovens are being operated, one interface for each oven
Operating system	Windows XP, Vista, 7, Windows 10

For its safety-relevant access control, CELSIUS FDA bases itself deliberately on the existing Windows® NT security concept of software manufacturer Microsoft. The core operating system of Windows NT was successfully tested by NCSC into security level C2 of the orange book (published by US government as standard for computer security). By this means both the security of the user authentication and audit trails, as well as the file protection of electronic records (by the use of NTFS standards) are ensured.

2.3 Supported MEMMERT ovens and parameters

Oven type	Parameters						
	Temperature	Humidity	Vacuum	CO ₂	O ₂	Fan speed	Servo air flap
<u>Incubators</u>							
INE, BE	✓	–	–	–	–	–	–
INP, BP	✓	–	–	–	–	–	✓
IFE	✓	–	–	–	–	✓	–
IFP	✓	–	–	–	–	✓	✓
<u>Universal ovens</u>							
UE	✓	–	–	–	–	–	–
ULE	✓	–	–	–	–	✓	–
UNE	✓	–	–	–	–	–	–
UNP	✓	–	–	–	–	–	✓
UP	✓	–	–	–	–	–	–
UFE	✓	–	–	–	–	✓	–
UFP	✓	–	–	–	–	✓	✓
ULP	✓	–	–	–	–	✓	✓
<u>CO₂ incubator</u>							
INCO ₂	✓	✓*	–	✓*	–	–	–
INCO ₂ + Oxigene	✓	✓*	–	✓*	✓*	–	–
<u>Cooled incubators</u>							
ICP (Min: -12°)	✓	–	–	–	–	✓	–
ICP (Min: 0°)	✓	–	–	–	–	–	–
IPP	✓	–	–	–	–	–	–
<u>Vacuum drying ovens</u>							
VO	✓	–	✓	–	–	–	–
<u>Constant climate and humidity chambers</u>							
HCP	✓	✓	–	–	–	–	–
HPP	✓	✓	–	–	–	–	–
<u>Climatic test chambers</u>							
CTC	✓	✓	–	–	–	✓	–
TTC	✓	–	–	–	–	✓	–
<u>Storage chambers</u>							
IPS	✓	–	–	–	–	–	–

* Parameter is logged by CELSIUS, but cannot be set with CELSIUS.

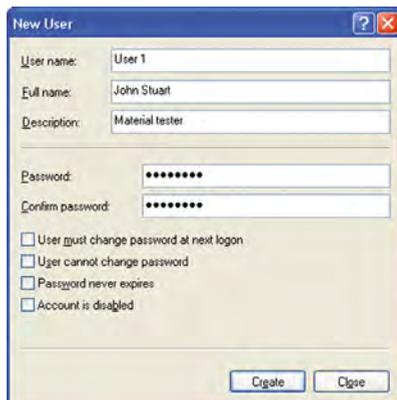
3. Preparation and installation

- Always first install CELSIUS before you connect an oven to your computer.
- 1** The installation of CELSIUS FDA-Edition must be performed by the Windows system administrator.

3.1 Establishing Windows users and assigning user rights

All users of CELSIUS FDA-Edition must be established by the system administrator as Windows users with their own user passwords.

1. Establish a new user (Control Panel → Users):
 - For reasons of data security it is recommended to assign restricted account rights to all users.
2. Assign restricted user rights.
3. Repeat items 1 and 2 for every user who is supposed to work with CELSIUS.



3.2 Installing CELSIUS and device drivers

Start the installation file Celsius.exe from the USB storage medium provided. You are now guided through the installation process step by step.

4. You are first requested to select the language for the installation. Select the desired language and confirm with OK.



5. The installation wizard takes you through the installation procedure. Click on "Next" to continue.



- You are shown the License conditions for the use of the software in German and English. You must accept the license conditions before you can continue with the installation. If you reject the license agreement, the installation procedure is terminated; but it can be restarted at any time. Click on "I accept the terms of the License Agreement" if you agree with the terms of the license, and then click on "Next".

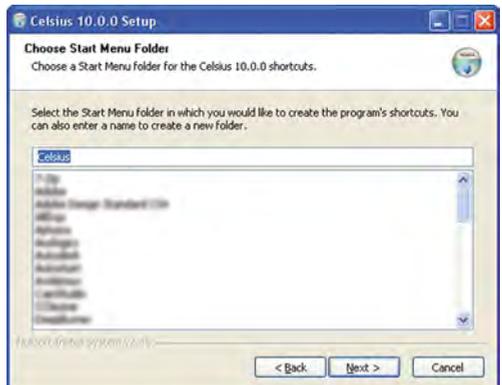


- Then you must choose the target directory where the programme files will be installed. With "Browse", you can change the preset path/folder.

Click on "Next" to continue.



- Choose a Start Menu folder for the programme shortcuts. The default setting is "CELSIUS". You can choose a different directory from the list or enter the name of a folder that should be newly created.

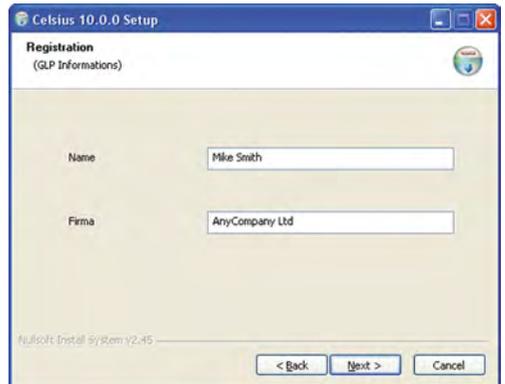


9. In the next window, select the programme components/drivers that should be installed:
- ▶ Select "CELSIUS 10.0" if you only want to install the programme itself.
 - ▶ Also select "USB Device Driver" if you want to connect ovens via the USB interface.
 - ▶ In addition, you should select "Chipcard Driver" if you want to use a MEMoryCard XL in an external card reader device (see page 24).

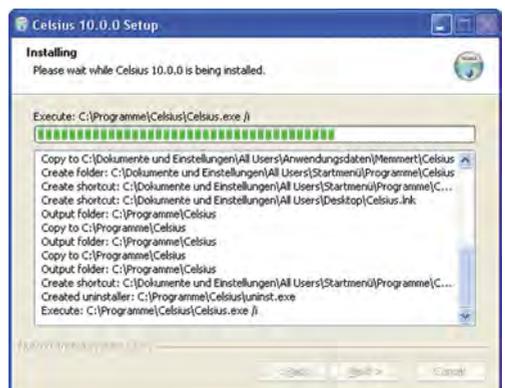
i You can also install USB and chip card drivers later on. To do this, restart the installation and, in the top window, select the components to be installed additionally.



10. You now have the option of registering with GLP data (GLP = good laboratory practice) (name and company). You may also skip this step and enter GLP data at a later date (see page 45).



11. Click on "Install". Each of the installation routines for the selected components are now run one after another. In the same way, carry out steps 2 to 4. Click on "Next" each time to continue the installation or finally to complete it.



12. Click on "Finish" to complete the installation. CELSIUS 10.0 and the selected drivers are now installed on your PC/laptop and can be used.



4. Programme description

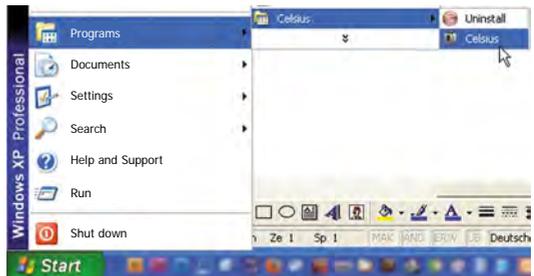
4.1 Starting CELSIUS

CELSIUS can be started in three ways:

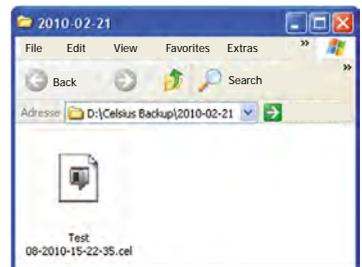
- ▶ by double-clicking on the shortcut created on the desktop:



- ▶ by going to the Start menu:



- ▶ by double-clicking on a profile file generated by CELSIUS (*.cel) or log file (*.pro) (see also pages 36 and 39):



4.2 Start screen and licence file

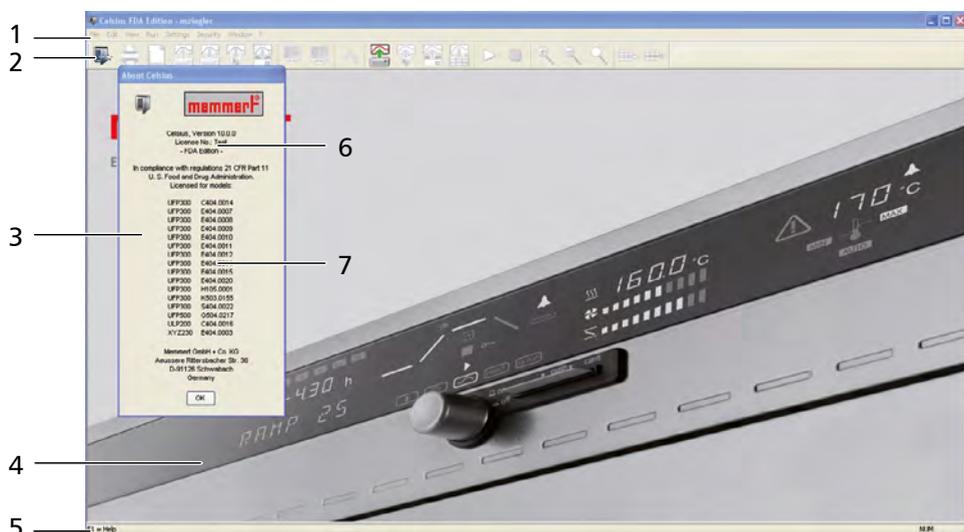
CELSIUS FDA Version can be started only with a valid licence file containing a list of equipment serial numbers which can be accessed with this version. The licence file called "LICENSE.XML" is located in the CELSIUS folder and carries a digital signature; it is thus protected against any alteration.

The licence file contains also a licence number and optionally an entity name which is included in the GLP data. The digital signature on the licence file can be produced only by MEMMERT. The licence number remains unchanged if the entity name is altered or if additional equipment is purchased, so that all data remain readable.

The digital signature ensures that CELSIUS refuses to operate if the licence file has been altered. Without a valid licence file in the CELSIUS base folder CELSIUS operates in the standard version (not FDA-version).

Once the programme has started, the start screen appears. Confirm the infobox (3) with license information by clicking on "OK".

The main programme window of CELSIUS is divided into the following areas:



- 1 Menu bar: The various processing options are given here (description from page 13).
- 2 Toolbar: This contains buttons to quickly access the main functions (for an explanation, see page 19).
- 3 Information box
- 4 Main window: When functions have been run, you can create and edit tempering profiles here (in graphical or tabular form, see page 27 and display logs (see page 38).
- 5 Status line: A help text for the function currently chosen is displayed here, along with various information on the current PC configuration.
- 6 Licence number under which the software is registered
- 7 List of oven types and serial numbers for which this CELSIUS FDA licence can be used

4.2.1 Language

Programme interface and menus can be displayed in five languages (German, English, Spanish, French and Italian). If you want to use a different language than the one currently set, you can change the language via the menu bar:

Preset language	Can be changed via ...
German	Einstellungen→Sprache
English	Settings→Language
Spanish	Ajustes→Lenguaje
French	Réglages→Langue
Italian	Impostazioni→Lingua



Confirm the language selection with OK and restart CELSIUS for the change to take effect.

4.2.2 Menu bar

All programme functions can be run from the menu bar. The most important programme functions can also be run quickly via the icons of the tool bar (see page 19). The individual functions and how they are run are described below.

- As long as no oven is logged in, only general programme parameters can be changed and log files loaded. Functions currently not available are greyed out and cannot be clicked on.

"File" menu

Menu item	Submenu items	Quick call via	Description	See page
New Profile	–		Creates a new tempering profile. A possible existing profile will be deleted. Deleting a profile that has not yet been saved must be confirmed.	27
Load Tempering Profile ▶	From File		Loads a tempering profile from a file	36
	From Device		Loads a tempering profile from the oven	36
	From Internal MemoryCard		loads a tempering profile from the MEMoryCard in the oven	36
	From External MemoryCard (USB/RS 232)		Loads a tempering profile from the MEMoryCard in the external card reader The card reader must be logged in beforehand via the menu item Settings→Options (see page).	36
Save Tempering Profile ▶	To File		Saves the current tempering profile to a file	36
	To Device		Saves the current tempering profile to the internal memory of the oven	36
	To Internal MemoryCard		Saves a tempering profile on the MEMoryCard in the oven if no external card reader is connected	36
	To External MemoryCard (USB/RS 232)		Saves a tempering profile on the MEMoryCard in the external card reader, if connected	36
Load Protocol Data ▶	From File		Opens an existing log file (*.pro)	39
	From File (Ring Protocol Memory *.bin)		Opens an existing log file (*.bin) which has been transferred from the ring protocol memory of the oven	39
	From Device (Ring Protocol Memory)		Loads the log files from the internal ring protocol memory of the oven	39
	From Internal MemoryCard		Loads log files from the MEMory-Card in the oven	39

Menu item	Submenu items	Quick call via	Description	See page
	From External MemoryCard		Loads log files from the MEMORY-Card in the external card reader	39
Save Protocol Data ►	To File (*.pro)		If no log file was specified when a tempering profile was started, the log file can be generated with this after the sequence has been completed.	39
	Report		Print log data as a spreadsheet or save as Excel® format (.xls)	41
Print Profile			The tempering profile in the active window is printed. Depending on the display type currently selected on the screen, the printout is as a graphic (including possible log values) or as a table (without log values). The exact screen contents are printed here. The printout is prefixed with a GLP header if this option has been enabled.	37
Multipage Printout			The printout is done as in Print tempering profile, but the entire tempering profile is printed out – on several pages, if necessary. The time axis is selected according to the current screen display.	37
Preset GLP Data			If a tempering profile is to be printed with GLP data, it must be specified here first.	45
Show GLP Data			Display of GLP data entered	45
Transmit GLP Data to Device			Sends the GLP data to the controller of the oven. The GLP data appear in the GLP header on each printed page.	45
1 Test-11-03-10 2 Test-10-03-10			Most recently saved tempering profiles	

Menu item	Submenu items	Quick call via	Description	See page
Exit			Ends CELSIUS. If the function "Save Settings on Exit" is activated (see page), the assignment of the interfaces to the ovens and their configurations are saved for the next programme start. Other basic settings are always saved when the programme is terminated. If some ovens are still active or if tempering profiles have not yet been saved a prompt appears for security reasons.	

Menu "Edit"

Menu item	Quick call via	Description	See page
Insert Line		Adds a new line to the table. The current ramp is divided.	35
Delete Line		Deletes the current line in the table	35
Undo		Undoes the last action	
Wrap-Up Profile		Allows a tempering profile to be edited after a programme sequence. The values logged for this oven so far are deleted and the tempering profile can now be edited.	

Menu "View"

Menu item	Quick call via	Description	See page
Graphics		Displays the opened tempering profile in graphical form	29
Table		Displays the opened tempering profile in tabular form	34
Zoom In		Zooms into the time range displayed in the graphical view at fixed steps. The smallest display range is one hour.	

Menu item	Quick call via	Description	See page
Zoom Out		Zooms out of the time range displayed in the graphical view. The largest time unit is 10 000 h.	
Zoom all		Displays the standard time range in the graphical view so that all data are displayed	

Menu "Run"

Menu item	Quick call via	Description	See page
Start		Starts the tempering profile displayed in the current window	35
Stop		Ends the sequence of a started tempering profile prematurely. Continuation not possible.	
Pause		Interrupts the sequence of a started tempering profile	
Continue		Continues an interrupted sequence	

Menu "Settings"

Menu item	Quick access via	Description	See page
Log-on Device		Logs on a new oven	25
Log-off Device		Logs off the oven in the current window. If the oven is still active or if the tempering profile has not yet been saved, you are prompted for confirmation.	
Log-off all Devices		Logs off all ovens	
Save Settings		Saves the current assignment of interfaces to ovens, and their configurations. All other basic settings of this menu are saved automatically when the programme ends	44

Menu item	Quick access via	Description	See page
Save Settings on Exit		When this function is enabled, the allocation of interfaces to ovens and their configurations is automatically saved when the programme ends. The next time the programme starts, CELSIUS tries to log on the ovens exactly as before. If an oven that was previously logged on online is no longer available, it is not logged on again.	44
Options		This assigns default settings to the GLP data and enables the GLP header and log to be activated. If an external card reader is used, the relevant interface is specified here.	45, 27
Language		Setting the desired language	13
Show Color Legends		Switches the colour legend in the log window on and off	38
Auto-Update Ring Protocol		Updates the transmitted ring memory of the oven at regular intervals	43
Backup Folder		Selecting a directory in which backup copies are saved automatically	43
Open CELSIUS Working Directory		Opens the working directory in which tempering profiles and logs are saved, in Windows Explorer	43
Open Common CELSIUS Directory		Opens the directory in which tempering profiles and logs are saved for all users, in Windows Explorer	43
Toolbar		Switching toolbar on and off	19

Menu „Security“

Menu item	Description	See page
Manage Rights	Allocate user authorisations for different Windows users	26
Audit Trail	Generate an audit trail file for a particular user	51
Lock CELSIUS	Block the control software against unauthorised operation during absence	54
Signatures ...	Provide thermostating profiles and protocol files with a digital signature	53

"Window" menu

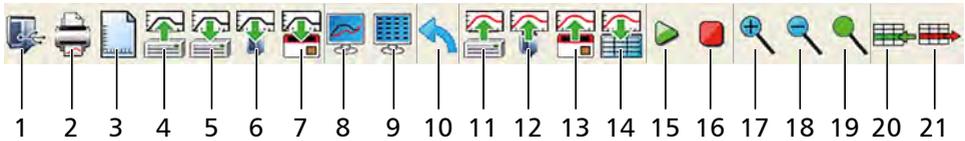
Menu item	Description
Cascade	Arranges windows in overlapping form
Tile	Arranges windows next to each other
Arrange Icons	Re-arranges iconified windows
1, 2 ...	Moves to the corresponding device window

Menu "?"

Menu item	Description
User Manual	Opens this manual in PDF format
Info about CELSIUS	Information on the programme version and registration

4.2.3 Toolbar

Via the toolbar, you have quick access to the most important and most frequently used programme functions. Functions currently not available are greyed out and cannot be clicked on. The toolbar can be switched on and off via the "Settings" menu.



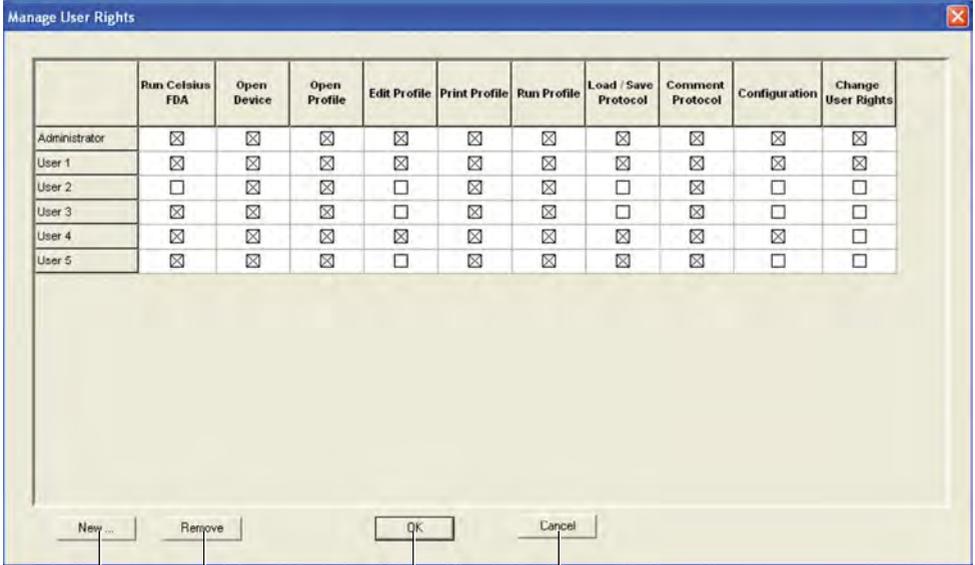
Item	Function	Description	See page
1	Log-on Device	Logs on a new oven	25
2	Print Profile	The tempering profile in the active window is printed. Depending on the display type currently selected on the screen, the printout is as a graphic (including possible measured values) or as a table (without measured values). The exact screen contents are printed here. The printout is prefixed with a GLP header if this option has been enabled.	37
3	New Profile	Creates a new tempering profile. A possible existing tempering profile will be deleted. Deleting a tempering profile that has not yet been saved must be confirmed.	27
4	Load Tempering Profile	Loads a tempering profile from a file	35

Item	Function	Description	See page
5	Save tempering profile to file	Saves the current tempering profile to a file	35
6	Save tempering profile to oven	Saves the current tempering profile to the internal memory of the oven	35
7	Save tempering profile to MEMoRYCard	Saves a tempering profile on the MEMoRYCard in the oven or in an external card reader, if connected	35
8	Graphical View	Displays the opened tempering profile in graphical form	29
9	Tabular View	Displays the opened tempering profile in tabular form	34
10	Undo	Undoes last action	
11	Load the log data from file	Opens an existing log file (*.pro)	39
12	Load the log data from oven	Loads the log files from the internal ring protocol memory of the oven	39
13	Load the log from the MEMoRYCard	Loads log files from the MEMoRYCard in the external card reader	39
14	Report	Print log data as a spreadsheet or save as Excel® format (.xls)	41
15	start profile	Starts the tempering profile displayed in the current window	35
16	Stop	Ends the sequence of a started tempering profile prematurely. Continuation not possible.	
17	Zoom In	Zooms into the time range displayed in the graphical view at fixed steps. The smallest display range is one hour.	
18	Zoom out	Zooms out of the time range displayed in the graphical view. The largest time unit is 10 000 h.	
19	Zoom all	Displays the standard time range so that all data are displayed	
20	insert cell	Adds a new line to the table. The current ramp is divided (only available in tabular view).	35
21	Delete Line	Deletes the current line in the table (only available in tabular view).	35

5. Establish CELSIUS users and manage user rights

The FDA version of CELSIUS has its own user management. CELSIUS users must however already be Windows users. After the installation of CELSIUS-FDA the standard procedure is to designate the installing operator as the CELSIUS administrator. He then has the authority to designate other users and to assign to them CELSIUS-specific rights.

The CELSIUS user administration is called via „Security“→“Manage Rights“:



- Quit User Rights Administration without saving
- Save settings and quit User Rights Administration
- Delete selected Celsius user
- Designate new Celsius user

Every user can have individual rights assigned to him for the use of CELSIUS FDA Edition:

User right	Description
Run CELSIUS FDA	This authorization permits a Windows user to start the CELSIUS programme.
Open device	If this field is marked, the user is authorized to connect up the equipment via the PC port and to exercise control and produce protocols.
Open profile	If this field is marked, the user is authorized to load an existing thermostating profile.
Edit profile	If this field is marked, the user is authorized to prepare a new profile and to edit a new or existing profile.
Print profile	If this field is marked, the user is authorized to print a prepared profile or protocol.
Run profile	If this field is marked, the user is authorized to start a newly prepared or loaded thermostating profile.
Load/save protocol	If this field is marked, the user is authorized to load or to store a protocol.
Comment protocol	If this field is marked, the user is authorized to comment a flash protocol.
Configuration	If this field is marked, the user is authorized to make settings in the Options and Language menu.
Change User Rights	If this field is marked, the user is authorized to configure the authorizations for all CELSIUS users. This authority should be reserved for the administrator of CELSIUS FDA . All other users of CELSIUS FDA are assigned their individual rights by the CELSIUS administrator.

Every unauthorized access attempt is indicated in an information window and logged in the audit trail (see page 50).



6. Connect ovens and external devices

- i** Always install the software and necessary drivers (e.g. USB) first before connecting an oven to the computer.
- i** Only ovens that are listed in the license file and license box (see page 17) can be connected.



When connecting an oven, read the information and notes concerning this in the oven's user manual.

To control an oven from the PC and – if it is equipped accordingly – to be able to access the integrated card reader, the oven must be connected to the PC and switched on. It must be in the "I" operating mode. In addition, the address with which you want to access the oven from the CELSIUS software must be set (see also page 25 and the user manual for the oven).

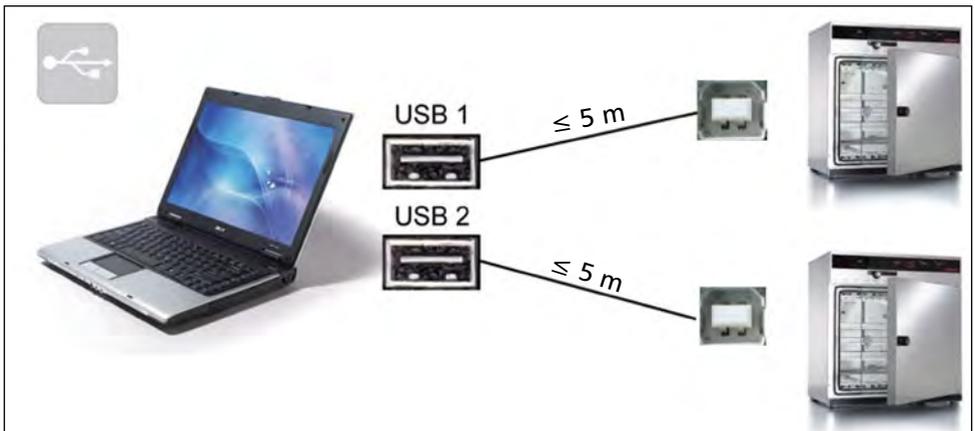
Connecting wires to the ovens with the RS-232 or USB interface (alternatively via RS-485 or Ethernet, for the P class only) is described in the user manual.

The correct installation and configuration of the PC interfaces is in general dependent on the type and manufacturer, which is why we refer you to the appropriate system documentation.

6.1 Connect ovens with a USB interface to a computer with an USB interface

For every oven with a USB interface that is to be connected to the computer, one USB interface must be available on the computer.

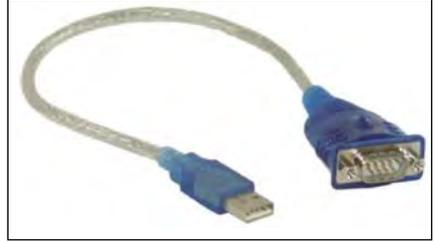
Connect the USB connections of the oven and computer with a standard USB cable (maximum 5 m) and log on the oven in CELSIUS as described on page 25.



6.2 Connect ovens with an RS-232 interface

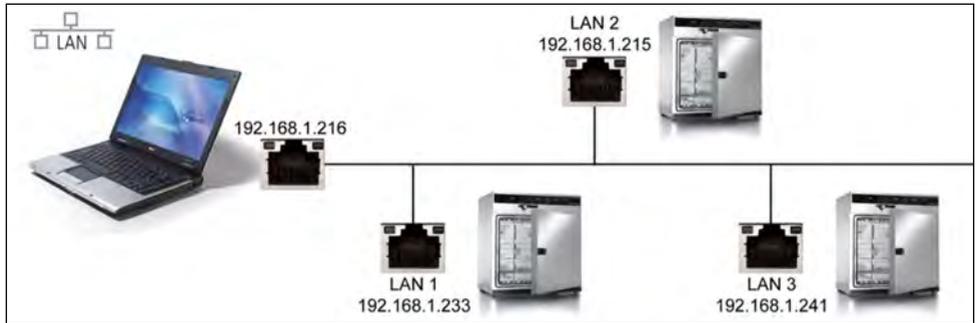
To connect an oven with an RS-232 interface, a twisted RS-232 connection cable in accordance with DIN 12900 part 1 is required (see also page 48). If the computer has no nine-pin RS-232 interface, then a USB–RS-232 adapter is additionally required (available in specialist shops, see figure on the right).

Connect the RS-232 connection of the oven to the RS-232 or USB connection of the computer and log on the oven in CELSIUS as described on page 25.



6.3 Connect ovens with an Ethernet interface to a network (LAN)

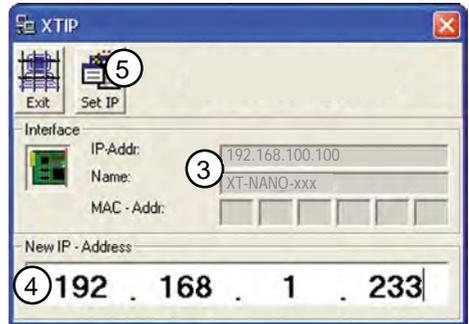
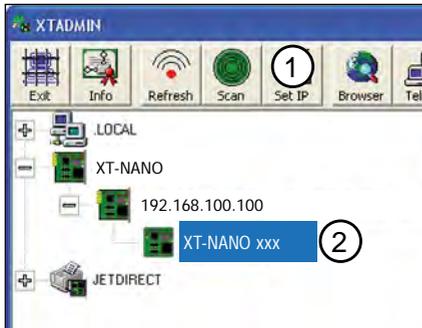
For identification purposes, each oven that is to be connected to a network (LAN) should have its own unique IP or DNS address (e.g. firmxyz.dyndns.org). Schematic example:



Each oven is delivered by default with the IP address 192.168.100.100. The programme "XTADMIN", which can be found on the USB-Stick, can be used to change the IP address of the oven.

6.3.1 Setting the IP address of the oven with XTADMIN

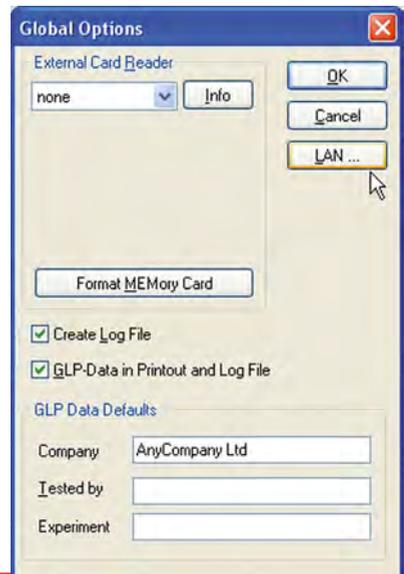
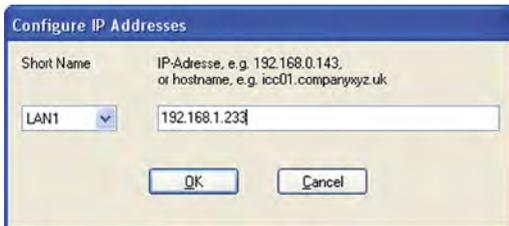
1. Connect the oven whose IP address you want to change with a standard network cable to a free network socket and switch it on.
2. Install and run the programme XTADMIN. The main programme window of XTADMIN appears.
3. Click on "SET IP" (1), a new "XTIP" window opens
4. In the window column to the left, click on the plus sign next to the name of the oven ("XT-NANO") whose IP address you want to change and highlight the lowest entry ("XT-NANO xxx", the name may deviate from this) (2). In the XTIP window, the preset IP address and the name of the oven must now appear (3).
5. Enter the IP address which you want to assign to the oven (4). Make a note of the IP address.
6. Click on "Set IP" (5) in the XTIP window. The oven is now assigned the IP address entered.
7. Close XTADMIN.



Now the IP address of the oven needs to be set in CELSIUS (see next page).

6.3.2 Setting the IP address in CELSIUS

8. Start CELSIUS and in the "Settings" menu, select the item "Options". Click on "LAN".
9. Enter the IP address or DNS of the oven set in XTADMIN and confirm this with "OK":



10. Close the window "Global Options" by clicking on "OK".

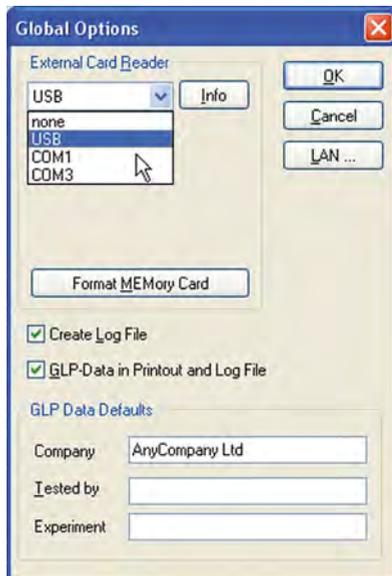
You can now log on the oven in CELSIUS, as described from page 25.

6.4 Connecting an external card reader

If you want to connect an external card reader (can be acquired separately as an accessory) to your computer so that you can store data on a MEMoryCard, the card reader must first be logged on.

1. Connect the card reader to a USB or COM interface of the computer.
2. In the "Settings" menu, click on the menu item "Options".
3. Select the interface to which you have connected the card reader (USB or COM) and close the options and settings windows with "OK". The card reader can now be used.

 If you click on "Format MEMoryCard", the card is re-formatted. All data stored on it is then deleted.



7. Logging on ovens

7.1 Logging on online and offline



When logging an oven on, read the information and notes concerning this in the oven's user manual.

In order to create and edit a tempering profile, an oven must always be logged on. There are basically two ways of doing this:

▶ **Logging on online:**

An oven can be logged on that is switched on and connected to an interface of the PC. Only for an online log-on can the oven be controlled from the PC or the programme be saved on a MEMoryCard (XL) located in the PC.

▶ **Logging on offline:**

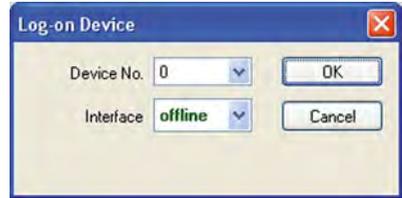
As an alternative to logging on online, a virtual oven can also be logged on, which does not have to be currently connected to the PC. This so-called offline operation is useful, for example, when

- the tempering profile is created initially on a notebook computer that is to be connected to the oven to control it at a later time;
- a new tempering profile is to be created while the oven is controlled from the same PC with a different tempering profile;
- the tempering profile is created on the PC and is to be stored afterwards on a MEMoryCard (XL) using an external card reader.

7.2 Logging on an oven

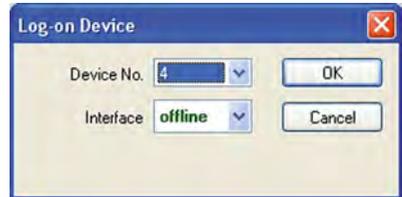
1. In the "Settings" menu, select the menu item "Log-on Device" or click in the toolbar on the icon.

The dialog box "Log-on Device" appears:



2. Each oven by default is given a device address. What device address is preset can be found out in the setup menu for the oven (see accompanying user manual). The device address can also be changed there. Every oven that is or is going to be connected must have its own distinctive device address. No ovens may have an identical device address.

You can adjust the preset or altered device address of the oven (e.g. "4") in the dialog box "Log-on Device" in the drop-down menu "Device No."



3. Select the interface (offline, COM1 or USB) (if you select "LAN", "USB" or "COM", make sure that the oven is in operating mode "I"):

- ▶ "offline", if the oven is (not yet) connected (see above)
- ▶ COM: The oven logged on is connected to the serial RS-232 interface (optionally RS-485). Up to 16 ovens can be connected and controlled via USB ports. In the selection of the interface for logging on the oven, "COM 1...16" is displayed.
- ▶ USB: The oven logged on is connected to the USB port. Up to 16 ovens can be connected and controlled via USB ports. When connecting via a USB port, "USB 1...16" is displayed automatically.
- ▶ LAN: The oven logged on is connected to a LAN (Ethernet) interface. Up to 16 ovens can be connected and controlled via LAN interfaces (for configuration, see page 22). In the selection of the interface for logging on the oven, "LAN 1...16" is displayed.



If an interface was specified and CELSIUS cannot find an oven at this interface, this setting is switched automatically to offline. CELSIUS automatically determines the configuration of ovens connected online.

For ovens logged on offline, the desired device configuration must be specified in another dialog. The configuration dialog appears automatically if an oven was logged on offline.



Select from the list the oven type that you want to simulate or to which you want to transfer a tempering profile, and confirm this with "OK". With optional extras (e.g. additional switching contacts), these must be activated manually for them to be used later on.

Depending on what oven type you set, different, oven-specific setting options (e.g. flap or fan) will be available later when you are creating a tempering profile (see pages 29 and 34).

If an oven has been logged on for the first time, a graphics window is automatically generated so that a new tempering profile can be created. The window can be opened or minimised with a double click.



- If there is more than 30 minutes difference between the oven and computer times, a warning is displayed when the oven is logged on. In this case, you should set the oven to the time displayed by the computer (see user manual for the oven).

8. Working with CELSIUS

8.1 Tempering profiles

8.1.1 Creating a new tempering profile

A new, empty tempering profile can be created in three ways:

- ▶ in the graphics window that is automatically started when a new oven has been logged on (see above)
- ▶ via "File"→"New Profile"
- ▶ by clicking on  in the toolbar

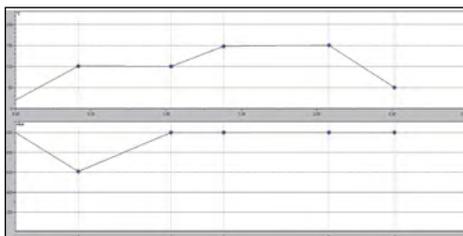
8.1.2 Graphical and tabular view

Tempering profiles can be created and edited in graphical (see page 29) and tabular form (see page 34).

You can switch between the two views at any time:

- ▶ with the icons  (graphical view) and  (tabular view) in the toolbar
- ▶ via "View"→"Graphics" or "View"→"Table"

Example of graphical and tabular presentation of the same tempering profile:



	Time hh:mm	Period hh:mm	Temp °C	Vacuum mBar	Type	a
1	0:30	0:30	100	600	next	<input type="checkbox"/>
2	1:00	0:30	100	1000	next	<input type="checkbox"/>
3	1:30	0:30	150	1000	next	<input type="checkbox"/>
4	2:00	0:30	150	1000	next	<input type="checkbox"/>
5	3:00	1:00	50	1000	end	<input type="checkbox"/>
6						<input type="checkbox"/>

What setting options are available depends on what oven type is used for a tempering profile. The setting options for individual oven types are listed from page 7.

With "Edit"→"Undo" or , the last performed entry / change can be revoked.

8.1.3 Device status line

The device status line is visible at the top of the graphical and tabular views while a tempering profile is being created or run. It shows the following information:

Controller active	COM3	IST: 24.1 °C	40.1 °C	0:02h
1	2	3	4	5

1 *Controller status, e.g.:*

- ▶ Edit Profile The tempering profile can currently be edited.
- ▶ starts at ...: Time at which the controller starts
- ▶ Controller active: The controller is currently controlled by the PC. At the temperature curve, nothing can be changed.
- ▶ Controller passive: The programme sequence was interrupted by a pause in the Run menu.
- ▶ STOP: The programme, and thus the controller, was stopped. To edit the tempering profile, the menu item "Wrap-Up Profile" in the "Edit" menu must be selected.
- ▶ ERROR <Text>: The controller has reported an error state. The corresponding error text is displayed.

2 *COM interface of oven or "offline"*

3 *Actual temperature value*

4 *Physical properties of the oven at the mouse position while a tempering profile is being run (e. g. temperature, humidity, vacuum) or the temperature at the mouse cursor position while the temperature profile is being entered*

5 *Current runtime or the time coordinates at the mouse cursor position while the temperature profile is being entered*

The device status line can be switched on and off in the Settings menu.

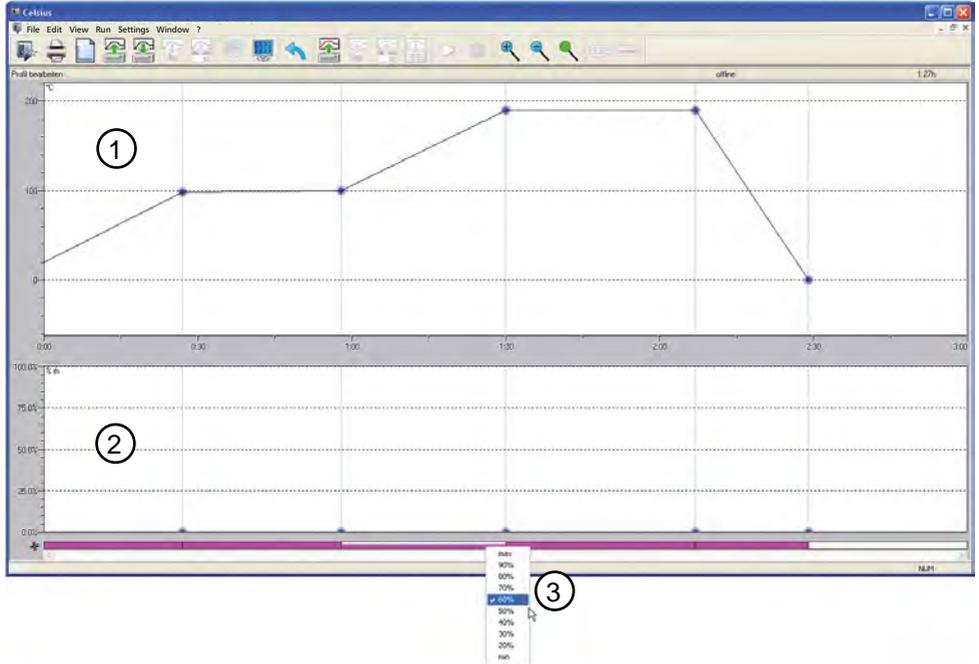
8.1.4 Working in the graphical view

The graphical view of a tempering profile can be displayed

- ▶ with the icon in the toolbar
- ▶ via "View"→"Graphics" in the menu bar

The graphics window is divided into horizontal segments, depending on the oven type. In the top segment (1), a tempering profile can be created, and the temperature is logged when a tempering profile is executed. In the lower segment (2), other oven-specific parameters (e.g. humidity, vacuum) can be programmed and logged. What these are specifically can be seen in the table on page 7.

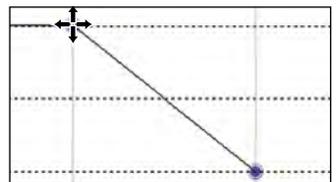
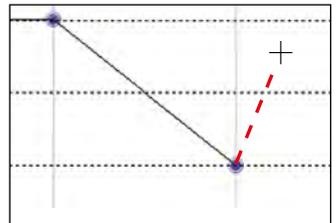
Depending on the oven type, additional oven-specific functions are available at the bottom of the graphics window, such as for adjusting the flaps, controlling the fan speed or for programming the switching contacts (3). They can be enabled and disabled via mouse click or adjusted via drop-down menus. These functions are shown in the tabular view as additional table columns (see page 34).



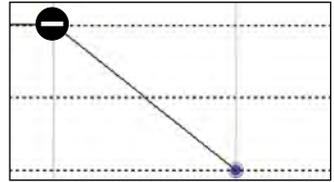
In the graphics window, the mouse cursor is displayed as a cross. With this you can, in the coordinates system portrayed, define and connect various points of the combination of time and temperature or time and air pressure (in the example VO).

To create a new segment, click on where you want the end point to be. It is automatically connected to the end point of the previous segment in the form of a line. The current data of the mouse position are shown at the top right in the status line (see page 28).

If you move the mouse cursor over predefined coordinates (links between two segments), it turns into a cross with four arrows. If you hold the mouse button down, you can then move the respective point on the x and/or y axis.



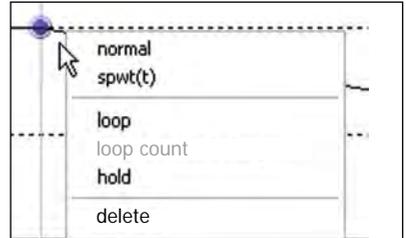
If a coordinate is created in a prohibited area or you want to move it to such an area, the mouse cursor turns into a no-entry sign. The coordinate jumps automatically back to its previous position when you let go.



- Changes to the graphical view are automatically updated when you switch to the tabular view, and vice versa.

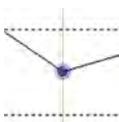
Ramp close statements

Each segment (ramp) of a tempering profile must end with a close statement and be linked to the next segment. These positions are represented by the blue dots.



To run the selection dialog, move the mouse cursor to one of the blue ramp end points and press the right mouse button. The following ramp close statements are available:

▶ normal:



Resets the end point definition back to the standard value. At the end of the ramp segment the oven continues straightaway with the next ramp segment. If this is the final ramp segment, the tempering profile is stopped and the connected oven is reset to its default configuration.

▶ spwt()



(= Setpoint wait). The oven waits for the end of the ramp segment until the required setpoint has approximately been reached. Only then is the next segment processed. This command cannot be applied for the final ramp segment of a tempering profile.

- Which setpoint is involved depends on the oven, and can be seen from the expression in brackets: spwt(t) = Temperature, spwt(h) = Humidity, spwt(p) = Pressure etc.

Temperature for incubators (Ixx, INCO 2, IPP, ICP) and HCP humidity chambers:

If this function is enabled, the next ramp only begins when the setpoint temperature has been reached with a tolerance of $\pm 0.5^\circ \text{C}$.

Temperature for universal ovens, sterilisers and vacuum ovens:

If this function is enabled, the next ramp only begins when the setpoint temperature has been reached with a tolerance of $\pm 2.0^\circ \text{C}$.

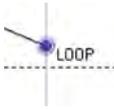
Vacuum for VO vacuum ovens:

If this function is enabled, the next ramp only begins when the setpoint vacuum has been reached with a tolerance of $\pm 3 \text{ mbar}$. For VO vacuum ovens, the SPWT function can be enabled separately for temperature and vacuum.

Humidity for HCP humidity chambers:

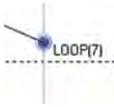
If this function is enabled, the next ramp only begins when the setpoint humidity has been reached with a tolerance of $\pm 2 \% \text{ rh}$. For HCP humidity chambers, the SPWT function can be enabled separately for temperature and humidity.

▶ loop:

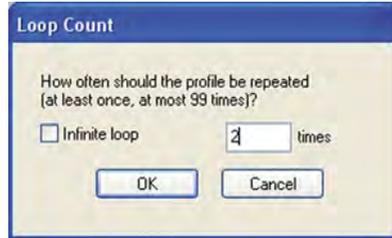


The tempering profile is repeated endlessly from the beginning, until the user ends the tempering profile. This command can only be applied for the final ramp segment of a tempering profile.

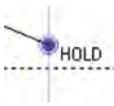
▶ LOOP(n)



The tempering profile is repeated from the beginning n-times (n: 1 ... 99):



▶ HOLD



At the end of the tempering profile, the parameters of the last ramp segment are retained until the user ends the tempering profile. This command can only be applied for the final ramp segment of a tempering profile.

▶ Delete

Deletes the respective ramp segment. If a subsequent ramp segment exists, the end point of this is connected by a ramp to the end point of the previous segment.

1 If no ramp close statement is specified, the command "normal" (see above) is automatically applied.

Zooming

You can zoom in and out of the display in the various graphics windows. There are different ways of doing this:

▶ via the tool and menu bar:

-  extends the time range (menu bar: View→Zoom in)
-  squashes the time range (menu bar: View→Zoom out)
-  displays the time range so that all data are displayed (menu bar: View→Zoom all)

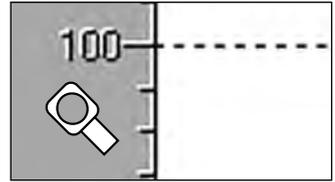
▶ Move the mouse cursor over the time axis. The mouse cursor turns into a magnifying glass. You can now

- expand the time axis at the position of the magnifying glass by clicking the left mouse button
- compress the time axis at the position of the magnifying glass by clicking the right mouse button

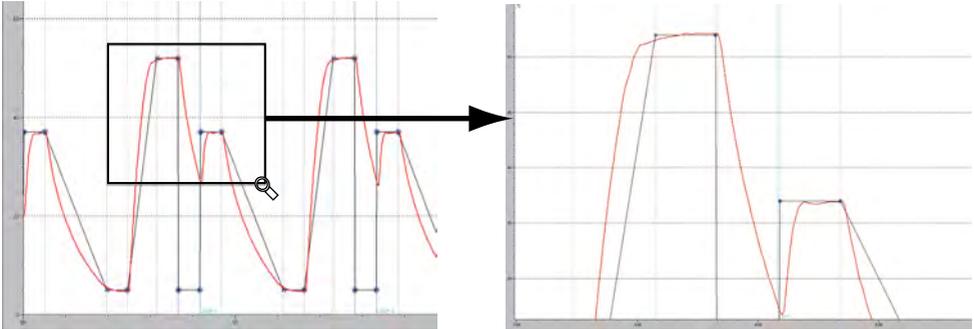


► Move the mouse cursor over the vertical axis in the temperature, humidity, pressure, CO₂ or O₂ windows. The mouse cursor turns into a magnifying glass. You can now

- expand the respective axis at the position of the magnifying glass by clicking the left mouse button
- compress the respective axis at the position of the magnifying glass by clicking the right mouse button

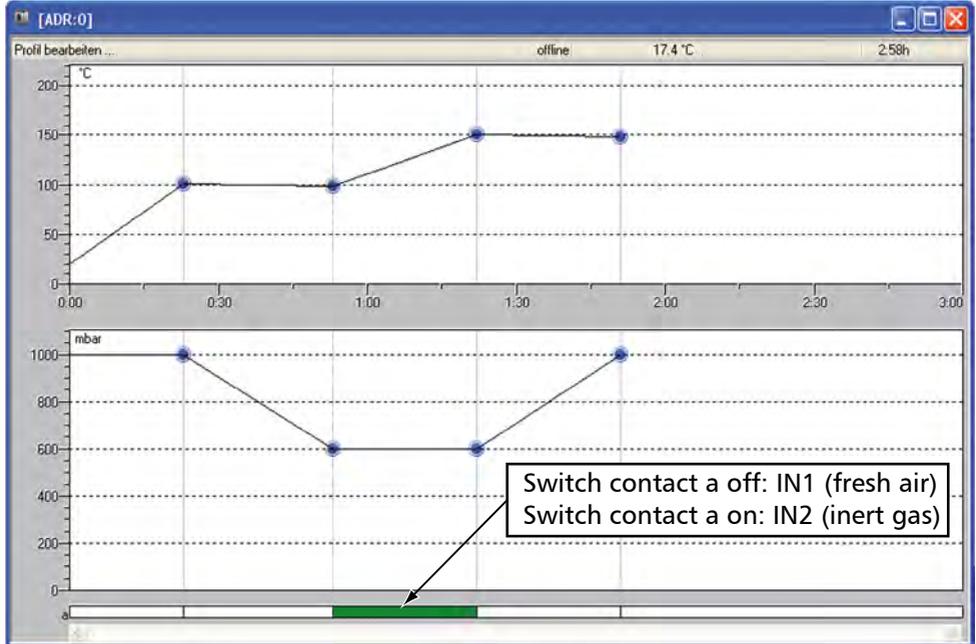


► If the mouse cursor is shown as a magnifying glass: Holding the left mouse button down, select the area into which you want to zoom. Let go of the mouse button. The selected area is now shown in a full window:



Working with vacuum ovens VO in the graphical view

With vacuum ovens VO, the temperature and vacuum profiles are displayed in the graphical window simultaneously. The switching output A of the CELSIUS software offers a choice between IN1 (fresh air) and IN2 (inert gas). To switch over to the respective ramp segment, click on line a:



8.1.5 Working in the tabular view

The tabular view of a tempering profile can be displayed

- ▶ with the  icon in the toolbar
- ▶ via "View"→"Table" in the menu bar

In the table window, the tempering profile is shown as a table. The individual adjustment options are displayed in columns. What columns are displayed depends on the oven and how it is configured. Time, duration and temperature can be entered or modified via the keyboard. Inadmissible entries are simply ignored, with no messages. Settings that are only available in certain predefined values (in the example below, type, flap and fan), can be specified via drop-down menus.

In contrast to the graphical view, protocol values are not shown in the table window.

	1	2	3	4	5	6	7	8	9
	Time hh:mm	Period hh:mm	Temp °C	Type	Flap	Fan	a	b	
1	1:00	1:00	100	NEXT	CLOSE	MAX	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
2	2:00	1:00	100	NEXT	40%	60%	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
3	2:01	0:01	200	SPWT	CLOSE	MAX	<input type="checkbox"/>	<input type="checkbox"/>	
4	3:01	1:00	200	NEXT	CLOSE	OFF	<input type="checkbox"/>	<input type="checkbox"/>	
5	5:16	2:15	150	NEXT	OPEN	50%	<input type="checkbox"/>	<input type="checkbox"/>	
6	5:46	0:30	150	NEXT	50%	OFF	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
7	6:46	1:00	100	END	OPEN	MIN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
8						20%	<input type="checkbox"/>	<input type="checkbox"/>	
						30%	<input type="checkbox"/>	<input type="checkbox"/>	
						40%	<input type="checkbox"/>	<input type="checkbox"/>	
						50%	<input type="checkbox"/>	<input type="checkbox"/>	
						60%	<input type="checkbox"/>	<input type="checkbox"/>	
						70%	<input type="checkbox"/>	<input type="checkbox"/>	
						80%	<input type="checkbox"/>	<input type="checkbox"/>	
						90%	<input type="checkbox"/>	<input type="checkbox"/>	
						MAX	<input type="checkbox"/>	<input type="checkbox"/>	

Tabular View (example)

- 1 Ramp segment No. ...
- 2 Beginning of ramp segment after programme start
- 3 Duration of the ramp segment
- 4 Temperature in the ramp segment
- 5 Ramp close statement (see page 30)
- 6 Flap position
- 7 Fan speed
- 8 Position of switching contact a
- 9 Position of switching contact b

In addition to the ramp segments entered, the table always shows an empty line (in the example: line 8). A further ramp segment can be added here.

Inserting and deleting lines

If the table window is active, the commands for deleting and inserting lines are additionally available in the view menu and toolbar:

- Insert a line at the position marked
- Delete selected line

i If the last ramp segment is deleted, the ramp close statement is automatically transferred to the line above.

8.1.6 Executing a tempering profile

i Before a tempering profile is started, disable the screen saver and the energy-saving mode of your computer, as these could interfere with the programme sequence.

For a tempering profile to be started,

- ▶ it must have previously been saved (see page 36)
- ▶ the relevant oven must be connected and logged on to the computer and be in operating mode "I". If this is not the case, an error message will be displayed. In this case, you should check that the oven is switched on, connected and logged in to CELSIUS.

Every tempering profile can only be run on the oven type for which it was created. The same applies for saving to a MEMory Card (XL).

A tempering profile can be started

- ▶ via the  button in the toolbar
- ▶ via "Run"→"Start" in the menu bar

When a tempering profile is started, the start dialog appears automatically with the following setting options:

- 1 Log and print GLP data (automatically enabled if GLP data were preset, see page 9)
- 2 Select the storage location of the log file if "Create Log File" was clicked
- 3 Click on this if a log file is to be generated
- 4 GLP description of the procedure
- 5 GLP value company
- 6 Starting time; the default is "today" and the current time; both values can be changed. The tempering profile then starts at the set time.
- 7 GLP value tested by
- 8 If "Protocol only" is clicked, no setpoint values are sent to the oven and only the actual values are logged. The setpoint values must be set on the oven. The "Protocol only" operating mode is possible both in the main switch position "I" and in the "clock" position of the oven.
- 9 Starting time
- 10 GLP value sample ID

8.1.7 Saving and loading tempering profiles

1 In order to prevent any alteration of files, CELSIUS FDA encrypts all profile and protocol files. Encryption employs a key which is specified in the licence file. Existing files from a previous CELSIUS version can not be read or exported. If an encrypted file has been altered (except through CELSIUS), access to the data is no longer possible, even for the producer of the software.

A tempering protocol can be saved

▶ To File ( or "File"→"Save Tempering Profile"→"To File"). In the window that opens, you can specify the file name and the storage location. In the preset directory there is a folder each for tempering profiles and for protocols.

With "File"→"Load Tempering Profile"→"From File" or  you can open saved tempering profile files (*.cel) and edit them.

▶ In the oven ( or "File"→"Save Tempering Profile"→"To Device"). The tempering profile is saved in the ring protocol memory of the oven. It can be opened and edited with "File"→"Load Tempering Profile"→"From Device".

▶ To Internal MemoryCard ( or "File"→"Save Tempering Profile"→"To Internal MemoryCard"). With this command, the tempering profile on the MEMoryCard can be stored in the controller of the oven. In this case, the MEMory-Card must be compatible with the oven model. You may enter a name for the tempering profile saved on the card (max. 8 characters, no spaces) or use the name suggested.



If you enable "Write Protection", you ensure that the tempering profile on the MEMory-Card cannot be altered by the controller of the oven. This write protection has no effect on CELSIUS writing data to the MEMoryCard. The default setting for write protection is ON.

1 Only one tempering profile can be written on a MEMoryCard XL. The MEMoryCard XL can be overwritten at any time, however.

▶ To External MemoryCard ("File"→"Save Tempering Profile"→"To External MemoryCard (USB/RS 232)"). This allows you to save a tempering profile of up to 40 ramps on a card in a connected and logged on card reader (see page 45).

With "File"→"Load Tempering Profile"→"From Internal MemoryCard"/"... external" you can open tempering profiles stored internally or externally on the MEMoryCard.

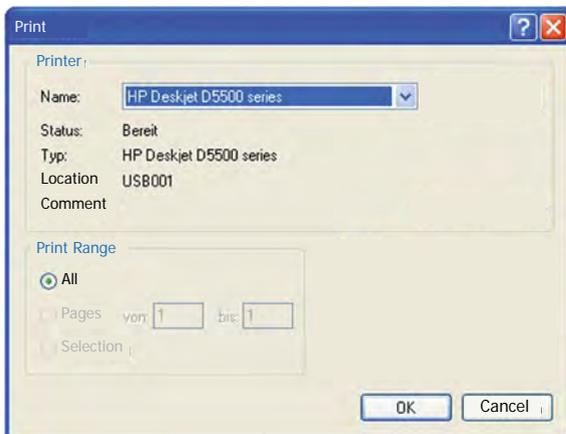
8.1.8 Printing a tempering profile

In order to print a tempering profile, click on  or select "File→Print Profile".

The Windows print dialog appears. The default setting is the standard printer set for Windows. You may select a different printer that is connected.

The print command prints out the content of the active window. The time range displayed on the screen is printed, with or without GLP header data.

If the graphics window is active on the screen, the current tempering profile and the protocol are printed in the graphic mode. If the tempering profile is displayed on screen in tabular form, it will be printed out in tabular form.



 Printing is only possible if the tempering profile is not currently being run in the oven.

Multipage Printout

For the print option "File→Multipage Printout", the printout is done as in "Print Profile", but the entire tempering profile is printed out – on several pages, if necessary. The time axis is selected according to the current screen display.

8.2 Protocol

A protocol is the recording of the actual physical values that prevail in the oven while a tempering profile is running (e.g. temperature, humidity, air pressure and CO₂ content). This allows a comparison to be made between the desired (set) and the actual values.

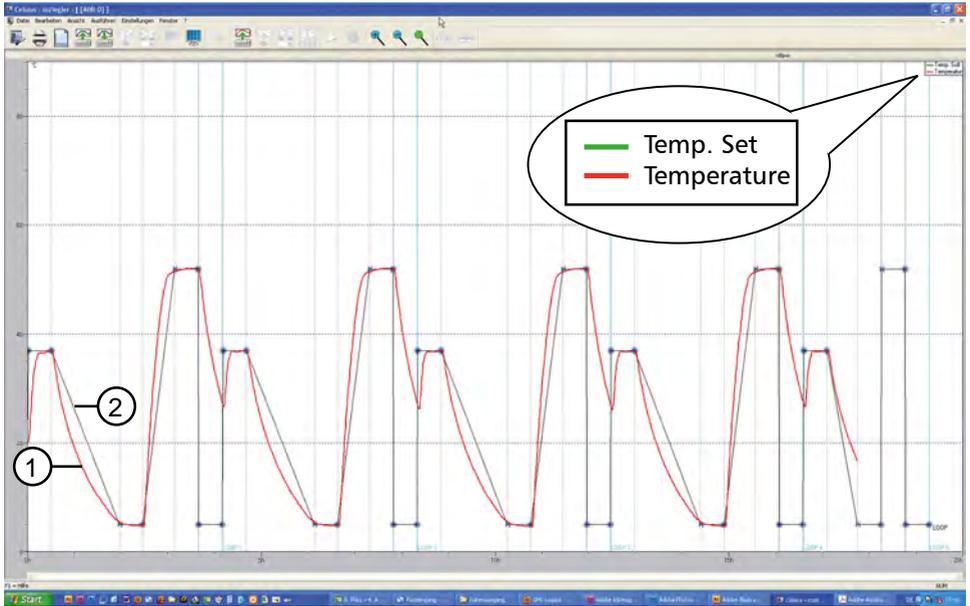
8.2.1 Types of Protocols

Protocol values can be generated and recorded in three ways:

- ▶ in the internal ring protocol memory of the oven. Each oven automatically records all actual values of up to several months. If the memory is full, the oldest entries are overwritten. These protocol data can be read out with CELSIUS, transferred to the PC, saved in *.bin file format or be further processed (see page 39).
- ▶ When a tempering profile is run via CELSIUS, the protocol data (actual values) are displayed as continuous curves in the graphic window and can be saved (file format *.pro) (see next section).
- ▶ Protocol values can be stored on the MEMoRYCard in the oven.

8.2.2 Recording the actual progression

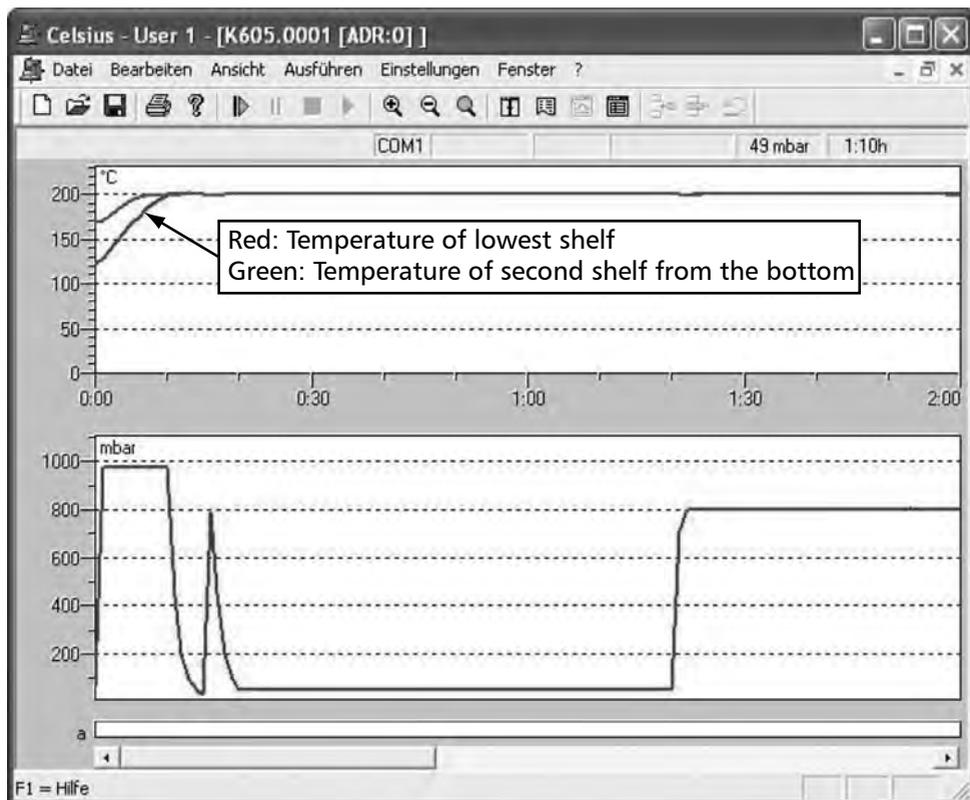
When a tempering profile is run, the actual values of the oven are displayed in the graphical view as colour curves (1) which follow the tempering profile (2). Each colour represents a different value (e.g. temperature, humidity), explained in a colour legend at the top right of the window:



The display of the colour legend can be switched on and off in the in the menu via "Settings"→"Show Color Legends".

Logging with vacuum ovens VO

The logged measured values for temperature and vacuum for vacuum ovens VO are entered as a red curve. In online operation (oven must be registered), the actual temperatures of a maximum of two heating levels are logged by CELSIUS. If there are more than two shelves, only the temperatures of the two lowest heating levels are logged. In operation with a chip card, the value of the lowest heating level is logged.



8.2.3 Saving and loading protocol data (*.pro)

If the option "Create Log File" is enabled when a tempering profile is run (see page 35), the protocol values are saved to the protocol file (*.pro) selected. You may also write the actual value curve with the corresponding tempering profile later on to a protocol file if the protocol option is not enabled in the start dialog of the temperature programme.

- The protocol can only be saved later for as long as it is displayed in the graphics window.

To create a file for the protocol displayed, select "File"→"Save Protocol Data"→"To File (*.pro)". In the window appearing, you can select the protocol file (button "File") and GLP data that are to be recorded. This option is automatically enabled if GLP data have been set (see page 9).

Protocol data saved in this way can be re-opened with "File"→"Load Protocol Data"→"From File" or

The unique device number of the connected MEMMERT equipment is read by CELSIUS FDA and stored with each protocol, with protection against alteration.

- In order to prevent any alteration of files, CELSIUS FDA encrypts all profile and protocol files. Encryption employs a key which is specified in the licence file. Existing files from a previous CELSIUS version can not be read or exported. If an encrypted file has been altered (except through CELSIUS), access to the data is no longer possible, even for the producer of the software.



8.2.4 Loading protocol data from the internal MEMORYCard of the oven

If the oven is equipped with a MEMORYCard, protocol data are stored on it. They can be read in with CELSIUS via "File"→"Load Protocol Data"→"From Internal MemoryCard" or .

8.2.5 Loading protocol data (*.bin) from the ring protocol memory of the oven

The oven saves all values measured over a long period automatically in its internal ring protocol memory. These measured values can be read in with CELSIUS ("File"→"Load Protocol Data"→"From Device (Ring Protocol Memory)" or .

When they are first read out, the entire ring protocol memory is read out and saved as a file in the format *.bin. This file is write-protected. The preset directory for ring protocol files varies according to the operating system. This can be displayed via "Settings"→"Open Common CELSIUS Directory". The ring protocol data are located in the subdirectory of this, "FlashProtocols".

- Reading out the protocol memory for the first time may take some time (up to 15 minutes), depending on the device runtime.

After data have been read in, a selection dialog appears. Here you can select the period of time for which you would like to display a protocol. The protocol is read from the bin file that was previously transferred by the oven, and which is displayed in the entry field "Ring Protocol File".

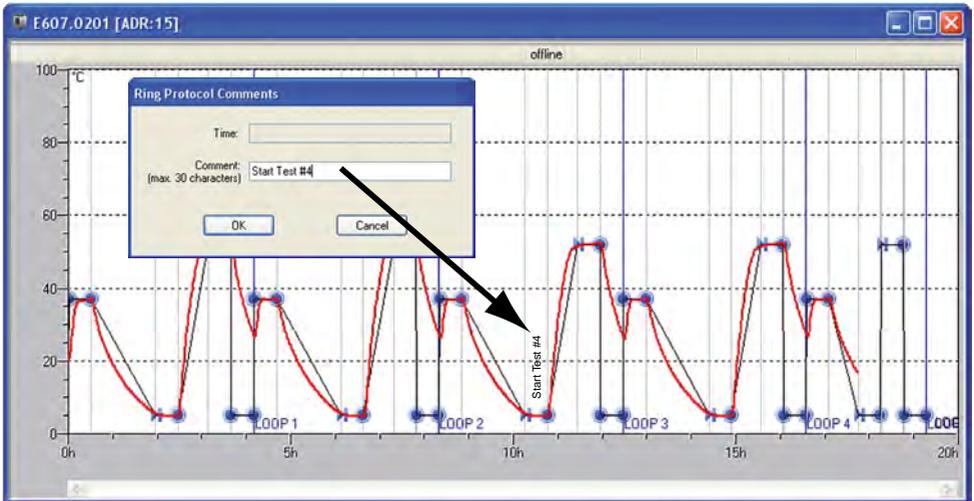


- If the protocol data for the selected period of time need more main memory than is made available by the computer, a warning appears. In this case, you should make the period of time shorter.

With "Browse", you can open protocol files of other ovens that have already been transferred in the format *. No oven needs to be logged on for this. You can also run this function via "File"→"Load Protocol Data"→"From File (Ring Protocol Memory *.bin)"

Adding comments to the ring protocol

You can add comments later on to the ring protocol file. The comment is displayed as text in the protocol window for the corresponding point in time:



Position the mouse cursor in the graphic window at the point at which you would like to add a comment (max. 30 characters). Press the right mouse button. In the window that opens, you can enter the comment and save it with OK.

An added comment can also be changed later. To do this, right click on the comment. It is recommended that you select the highest zoom level so that you can select exactly the same point in time.

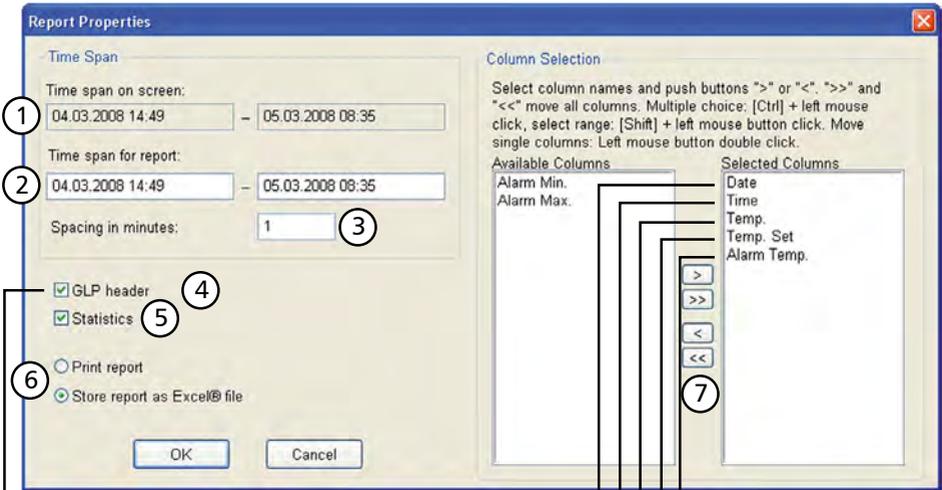
8.2.6 Export log data in tabular form (Report)

With the report function, it is possible to print log data in tabular form or save them as Excel® format (.xls) for processing in a spreadsheet programme and graphically enhance them, for example. This way, ring protocol data can be processed, as well as log data resulting from running a temperature-control profile (see Chapter “Types of Protocols” on page 38). The report function is available if a log or ring protocol is displayed in the window, and this window is active.

You can run the report function

- ▶ via the tool panel 
- ▶ via “File” → “Save protocol data” → “Report”

A dialog window appears in which you can specify what is to be included in the report:



	A	B	C	D	E	F	G
1	Company	Mennert			Tested by	Peter Englisch	
2	Experiment	HPP mit USB über 7-fach-HUB, Port 2			Measuring period	04.03.2008 14:49:00 - 05.03.2008 08:34:00	
3	Exp.No.	E607.0201					
4							
5							
6							
7	Date	Time	Temp. (°C)	Set-Point (°C)	Alarm Temp. (°C)		
8							
9	04.03.2008	14:56	30,6	37,0			
10	04.03.2008	14:57	32,3	36,9			
11	04.03.2008	14:58	33,5	37,0			
12	04.03.2008	14:59	34,3	37,0			
13	04.03.2008	15:00	35,0	37,0			
14	04.03.2008	15:01	35,5	37,0			
15	04.03.2008	15:02	36,0	37,0			
16	04.03.2008	15:03	36,4	37,0			
17	04.03.2008	15:04	36,5	37,0			
18	04.03.2008	15:05	36,5	37,0			
19	04.03.2008	15:06	36,6	37,0			
20	04.03.2008	15:07	36,5	37,0			
21	04.03.2008	15:08	36,5	37,0			

Report options and presentation as spreadsheet

- 1 Period presented in protocol window (can be changed by zooming [see page 32] and/or the horizontal scroll bar)
- 2 Period to be included in the report
- 3 Interval of individual datasets, recordings are taken at one-minute intervals. To reduce the amount of datasets, a larger interval (e.g. 5 minutes) may be chosen.
- 4 GLP data (see page 44) are also included if selected.
- 5 If selected, a short statistic (minimum, maximum and average value of displayed data) is generated at the end of the report for the setting "Print Report".
- 6 Selection whether the report is to be printed or saved as a file in the .xls format.
- 7 Selection of the columns to be included in the report. The left window shows the available device dependent columns, the right window shows the columns that will appear in the report. With > or <, columns can be added or removed, with >> or <<, all columns are included or removed.

8.3 Ending work with CELSIUS

You can end work with CELSIUS

- ▶ via "File"→"Exit"
- ▶ by closing the programme window
- ▶ with the key combination Alt + F4

If an oven is still logged on or an opened tempering profile has not been saved, a warning will appear:



If you confirm the prompt with Yes, open tempering profiles will be closed and not saved. If you want to cancel this, click No. Save open tempering profiles (see page 36) and log off ovens that are currently logged on (see page 45).

● If the option "Save Settings on Exit" (see page 44) is enabled, the assignment of the interfaces to the ovens and their configurations are saved automatically if the programme is ended via "File"→"Exit".

9. Security functions of the CELSIUS FDA Edition

9.1 Traceability through a protected audit trail file

The audit trail data are stored in an encrypted file which can be exported in HTML format and in this way read or printed with any internet browser.

The time period to be exported can be selected. Selection is also possible to indicate the activities of a particular or of all CELSIUS users.

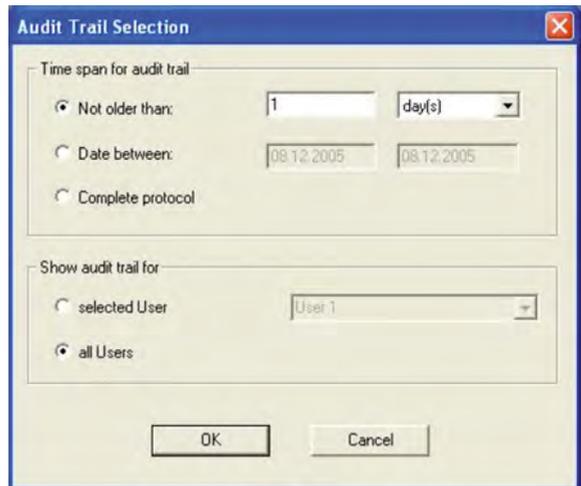
The audit trail function can be called via Menu „Security“→“Audit Trail“:

All essential functions and activities are stored in the audit trail. These include:

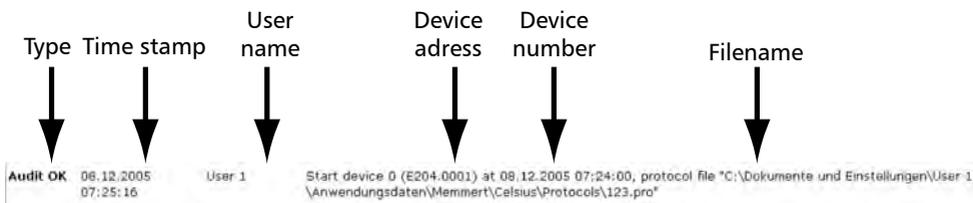
- ▶ Successful and faulty log-on and log-off processes.
- ▶ Preparation and alteration of profile and protocol files.
- ▶ Starting, stopping and closing thermostating profiles.
- ▶ Actions in CELSIUS which must only be performed with assigned authority.
- ▶ Producing electronic signatures.

● Actions performed via the operating system can not be recognised here, such as deleting files if the user has the required authority (e.g. system administrator).

Audit trail files can be exported in HTML format. All generated audit trail displays are stored as copy in the "AuditTrails" folder.



Typical arrangement of an entry in the audit trail file:



Forms of audit trail entries:

Report type	Description
Audit OK	General audit trail entries, e.g. during storing
OK	Audit trail entries of authority tests:
Fehler	User authorized for this action User not authorized for this action
Info	Notes, e.g. on electronic signing of a profile or protocol file.
Warnung	Warnings of certain (uncritical) user activities, e.g. that an alteration of the profile file has not been saved.

Examples of entries during saving and programme run:

Audit OK	08.12.2005 07:27:22	User 1	Continue device No. 0 (E204.0001), profile "C:\Dokumente und Einstellungen\User 1\Anwendungsdaten\Memmert\Celsius\Profiles\10011.cel".
Audit OK	08.12.2005 07:27:22	User 1	Continue device No. 0 (E204.0001), profile "C:\Dokumente und Einstellungen\User 1\Anwendungsdaten\Memmert\Celsius\Profiles\10011.cel".

Examples of info entries:

Info	12.12.2005 07:21:13	User 1	Dialog to register a cabinet cancelled by user.
Info	12.12.2005 07:29:33	User 1	New signature(s): As author; Reviewer in "C:\Dokumente und Einstellungen\User 1\Anwendungsdaten\Memmert\Celsius\Profiles\1011.cel"

Example of warnings:

Warnung	12.12.2005 07:29:33	User 1	Device 0 on COM4: Modified profile discarded by user.
----------------	------------------------	--------	---

Examples of successful authorization tests:

OK	08.12.2005 07:07:59	User 1	Checking rights: "Change User Rights"
OK	08.12.2005 07:12:44	User 1	Checking rights: "Open Device"
OK	08.12.2005	User 1	Device 0 (E2040001) logged on at interface "COM3". Configuration loaded

Examples of denied authorization test and error entries:

Fehler	08.12.2005 07:10:12	User 2	"User 2" is not allowed "Run Celsius FDA".
Fehler	08.12.2005 07:11:26	User 3	Checking rights: "Load / Save Protocol"
Fehler	08.12.2005 07:11:26	User 3	"User 3" is not allowed "Load / Save Protocol".

9.2 Electronic signature

Using the electronic signature, the user of a tempering profile or a protocol file can sign it digitally. The digital signature is saved and encrypted in the particular file. The signature function is called via the menu entry „Security“→“Signatures“.

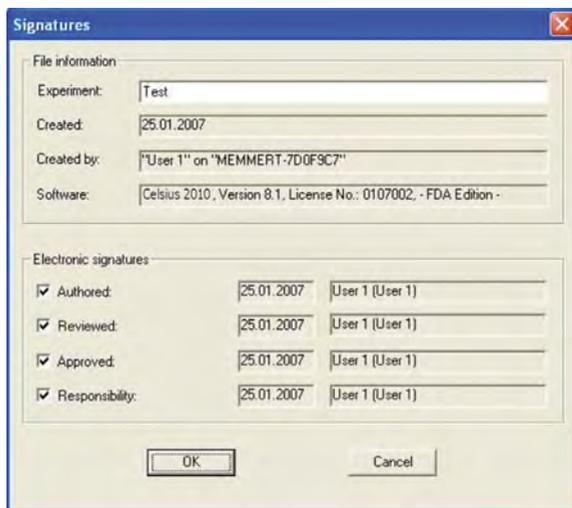
An electronic signature is applied when the reported Windows user clicks on the appropriate field:

- ▶ Authored
- ▶ Reviewed
- ▶ Approved
- ▶ Responsibility

The date and name fields are then automatically completed with the user authenticated in Windows. The digital signature is applied to the file by clicking on the OK button.

Every application of an electronic signature is documented by an entry in the audit trail file.

Example:



Info	06.12.2005 11:16:23	User 1	Neue Signatur(en): Als Verfasser; Gesehen; Genehmigt; Verantwortlich in "C:\Dokumente und Einstellungen\User 1\Anwendungsdaten\Memmert\Celsius\Profiles\10011.cel"
-------------	------------------------	--------	--

- i** Electronic signatures can not be deleted or overwritten as long as the file has not been altered. If a signed profile is altered (menu: Wrap-Up profile) or an existing profile is saved under a different name (menu: save as ...), all digital signatures are deleted.

9.3 Protection against unauthorized intervention

While CELSIUS FDA is running to control a MEMMERT equipment or to produce a protocol, the programme can be protected against unauthorized intervention by the current user through applying a password. The user has to input a password (menu entry: „Security“→“Lock CELSIUS“). CELSIUS FDA can be unlocked by the input of the same password which has been used to lock it.

- i** The password makes a distinction between upper case and lower case characters. It is therefore necessary to note how the password has to be entered.

If the user has forgotten the password used, CELSIUS can be closed only via the taskmanager (key combination CTL+ALT+DEL). Warning: data loss possible.

To protect the MEMMERT equipment against readjustment of the parameters, the equipment can also be locked through the optional User-ID card. The use of the USER-ID card is documented in the internal protocol memory of the controller. On reading the protocol memory the ID number of the particular reported user is documented in the protocol data.



10. Settings and Options

10.1 Working directories

Tempering profile and protocol files are saved in a predetermined directory if no other path is specified when they are saved (see pages 36 and 39). With "Settings"→"Open CELSIUS Working Directory" you can open this directory in Explorer.

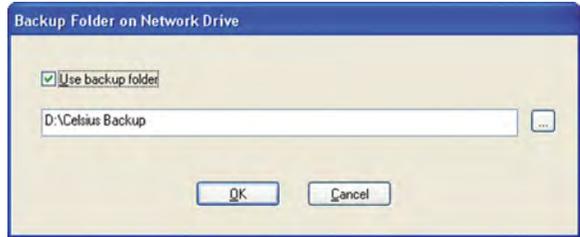
For shared CELSIUS files, there is also a preset directory available to all users. This can be run in Explorer with "Settings"→"Open Common CELSIUS Directory". Ring protocol files (*.bin) are stored in the subdirectory "FlashProtocols".

10.2 Auto-Update Ring Protocol

Via the menu item "Settings"→"Auto-Update Ring Protocol", CELSIUS can reload all online ring protocols at specified intervals, so that any data that has arrived in the meantime is immediately displayed. This function should only be enabled if there is little activity in CELSIUS or in the operating system in general, since it could overload system resources. If the data are not constantly required, for example to observe an experiment, this function should be disabled.

10.3 Backup Folder

If you want verification of all changes to the temperature profiles and protocol files, it is possible to create backup copies with time and date stamp when any change is made and store these in a separate, write-protected backup folder. The backup function can be enabled via "Settings"→"Backup Folder".



If the checkmark "Use backup folder" is set, an existing directory can be entered, or an existing backup directory can be selected via the button.

Backup folder can be located locally on the same computer as CELSIUS or on a network drive with write permission.

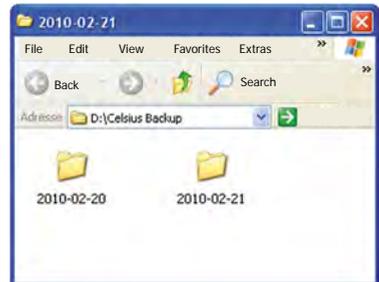
● Only existing folders or network drives may be selected. No new folders may be created.

1 Backup copies in the backup folder can be read, but not deleted or overwritten. If backup files are to be deleted, the "Read only" property of the directory must be changed.

A copy of the following file types is saved automatically in the backup folder:

- ▶ *.cel: CELSIUS tempering profiles
- ▶ *.pro: CELSIUS protocol files
- ▶ *.bin: Protocol files of the internal controller ring protocol memory

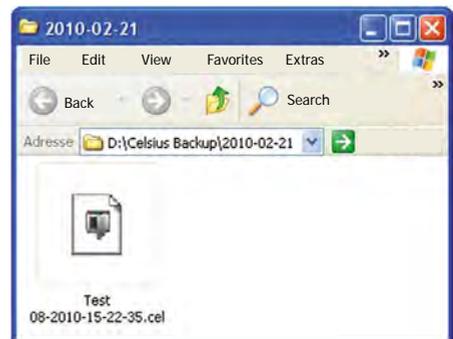
For each day when data is saved, a separate folder with the appropriate date is created. All the backup copies for one day are located in this folder. The current time is added to the file name each time. In this way, it is possible to save several backup copies under the same file name on the same day.



Example:

The tempering profile file "Test 08-2010.cel" is backed up on 21 February 2010 at 15:22:35 in the folder

D:\CELSIUS Backup\2010-02-21 as "Test 08-2010-15-22-35.cel":



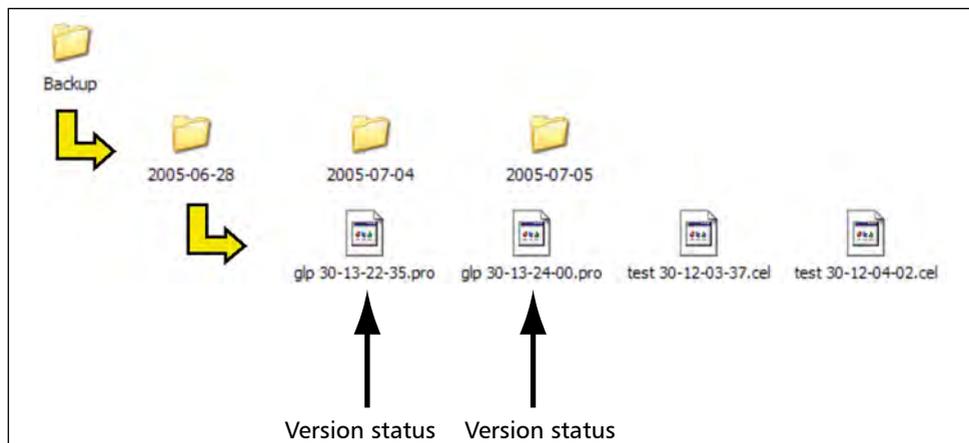
10.3.1 Automatic backup of versions in the backup folder

As evidence for all alterations of temperature profiles and protocol data, CELSIUS FDA-Edition prepares backup copies for each alteration, with date and time stamp, which are saved in a separate backup folder.

A separate folder, marked with the date, is produced for each date. The folder contains all backup copies of a day. The filename is extended by the current clock time. In this way it is possible to save several backup copies on one day under the same filename.

Example:

The protocol file GLP 30.pro was altered twice on 2005-06-28 and saved under the same filename:



Through the automatic generation of backup copies the storage remains transparent to the user, i.e. he can overwrite the file. Backup copies in the backup folder can be read, but not deleted or overwritten.

10.4 Saving Settings

„Settings→Save Settings" saves the current assignment of interfaces to ovens and their configurations. All other basic settings of this menu are saved automatically when the programme ends.

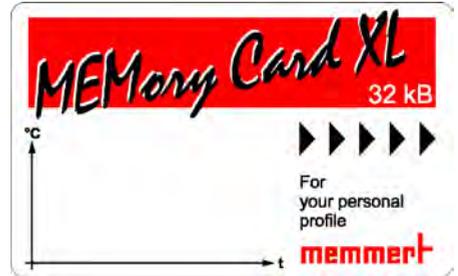
If you enable "Save Settings on Exit" and close CELSIUS via "File"→"Exit", the assignment of the interfaces to the ovens and their configurations are saved automatically when the programme ends. The next time the programme starts, CELSIUS tries to log on the ovens exactly as before. If an oven that was previously logged on online is no longer available, it is not logged on again.

10.5 Logging off ovens

With "Settings→Log-off Device" you can log off the oven that is shown in the current window. If the oven is still active or if the tempering profile has not yet been saved, you are prompted for confirmation. "Log-off all Devices" - logs off all devices.

10.6 Working with MEMoryCard

MEMMERT ovens with P fittings are equipped with an integrated card reader for MEMoryCard XL (32 kB). On each MEMoryCard, a tempering profile with up to 40 ramps can be stored. This tempering profile is then processed by the oven on its own, i.e. without a PC connection. During the profile sequence, the MEMoryCard saves the actual data that are accumulated in electronic form. For vacuum ovens or humidity chambers, the vacuum or humidity actual values are saved on the MEMoryCard. These protocol data can be read out later on from the PC with the help of CELSIUS. The MEMoryCard is therefore a transportable and interchangeable storage medium for tempering profiles and protocols. More information on the MEMoryCard can be found in the user manual for the oven.

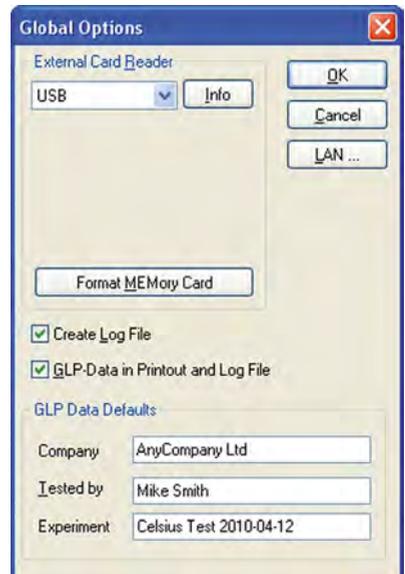


10.7 GLP Data

CELSIUS supports archiving and the printout of GLP data (GLP = "good laboratory practice"). Global data that is always to be used (e.g. company name and Tested by), can be specified via "Settings→Options":

This data can be modified and/or oven-specific details can be added to it:

- ▶ when running a tempering profile in the start dialog (see page 35)
- ▶ if you create a protocol file (see page 39)



- ▶ at any time via "File→Preset GLP Data"
 - Only digits and capital letters are permitted in the field "Sample ID".
- With "File→Show GLP Data" you can have the currently stored GLP data displayed.



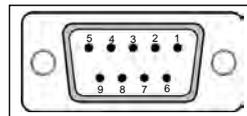
10.8 Programme language

The programme and the menus can be displayed in five different languages. How you can change the languages is described on page 13.

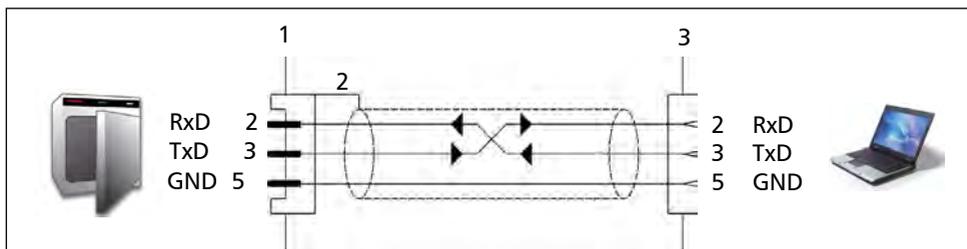
10.9 Connection details

10.9.1 Pin assignment RS-232 and RS-485

		Pin assignment RS-232	Pin assignment RS-485	
1	–	not occupied	–	
2	RxD	Received data	–	
3	TxD	Send data	A	Send and receive data
4	–	not occupied	–	
5	GND	Signal ground	–	
6	–	not occupied	–	
7	–	not occupied	–	
8	–	not occupied	B	Send and receive data
9	–	not occupied	–	



10.9.2 Interface cable for RS-232 in accordance with DIN 12900 part 1



8 Pin contacts (male)

9 Screening

10 Spring contacts (female)

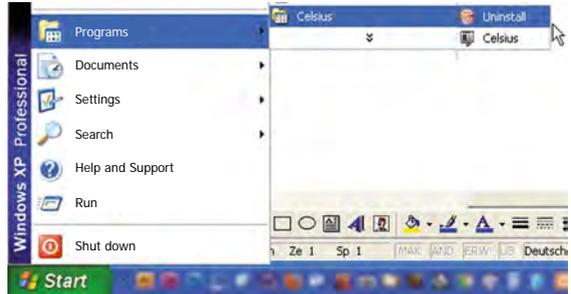
- ▶ Use screened interface cables
- ▶ Connect screening at one end to the plug casing

A standard-compliant connecting cable can be purchased from the company MEMMERT under the name V6. The protocol description of the interface (according to NAMUR) can be requested from MEMMERT customer service.

10.10 Deinstalling CELSIUS

i You must have administrator rights to be able to deinstall CELSIUS.

If you want to remove CELSIUS from your computer, you can run the deinstallation routine via Start→Programs→CELSIUS→Uninstall:



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