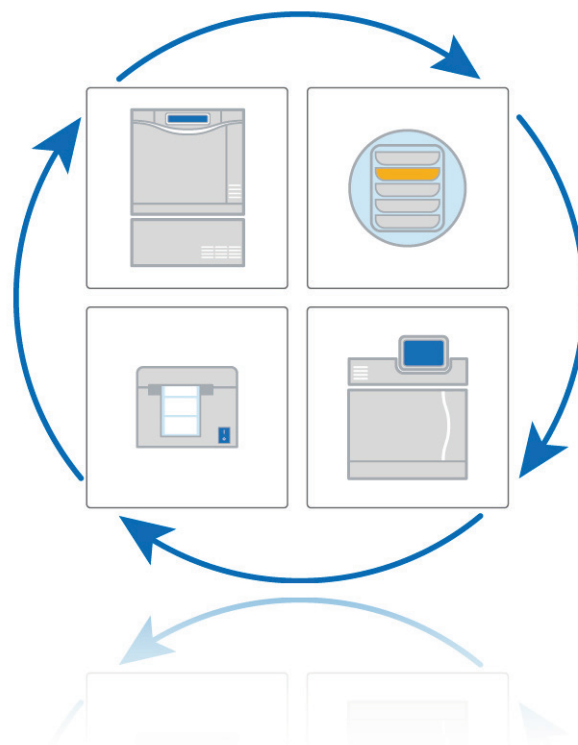


Operating Manual

MELAtrace

Documentation. Load management.
Approval.

Version 3.0.8.1



We thank you for your confidence demonstrated by the purchase of this product.

Since 1951 MELAG, a medium-sized family-run enterprise, has specialised in the sector of hygiene for medical practices. In the meantime our company has grown into one of the world's leading producers of sterilization equipment. World sales of more than 450,000 MELAG devices gives testimony to the quality of our devices, which we manufacture exclusively in Germany.

MELAG – management and employees

General Guidelines

Please read this operating manual carefully before proceeding with the installation and application of this program. Please also read all safety instructions carefully. Please store this operating manual carefully. It represents a component of the product.

User Group

This operating manual is targeted at doctors, medical assistants and customer service.

About these Instructions

Symbols used

Symbol	Explanation
	Draws your attention to a dangerous situation, which if not avoided, could result in damage to the device software, data-loss or network problems.
	Draws your attention to important information.

Formatting rules

Symbol	Explanation
<i>Approval autoclave</i>	Commands are marked by italic and bold print. <i>Autoclave approval</i> refers to, for example, the "Autoclave approval" menu. Parts of dialogue boxes are in bold type, too.
Cleaning	Words or phrases appearing on the display of the device are marked as display text.
see Chapter 2	Reference to another text section or a figure within this manual.

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Chapter 1 – Installation and Licensing

System requirements

Hardware

- At least 1 GHz (x86) or 1.4 GHz (x64) processor, and 2 GHz multi-core processor is recommended
- Windows 8 or 7 SP1, Windows Vista SP2, Windows Server 2012, Windows Server 2008 SP2
- At least 1 GB RAM, and 4 GB RAM is recommended
- At least 7 GB free hard disk space for the installation
- Label printer MELA*print* 60 for printing labels (optional)

Software

- MELA*view* 3 documentation software
- Microsoft .NET Framework 4.5



PLEASE NOTE

Microsoft SQL Desktop Edition should not be installed on the computer.

Installation

There are two installation files on the DVD, one for MELA*trace* and one in which MELA*view* and MELA*trace* are installed together. Carry out the latter only if MELA*view* has not yet been installed on your computer.

Depending on whether you install MELA*trace* together with MELA*view* or separately, the following additional components are installed:

- Microsoft .NET Framework (is installed when installing MELA*view* if .NET Framework has not yet been installed on the computer)
- Microsoft SQL Server 2012 (is installed with MELA*trace* provided that SQL Server has not yet been installed on the computer)

Please observe the following instructions for the installation of MELA*trace*:

- ▶ If you are using a notebook computer, operate it only with a mains adapter unit during installation.
- ▶ Windows should not be operated in safe mode during installation.
- ▶ Check whether you have administrator rights on the computer.
- ▶ Connect the computer to the Internet during installation.
- ▶ Close all open programs prior to installation.

Proceed as follows to start installation from the DVD:

1. Start the relevant installation file. The installation wizard opens.
2. Select your desired language and click on **Next**.
3. Follow the instructions during installation.

Licensing

If you already have a valid MELA*view* 3 licence and install MELA*trace* subsequently, no additional licensing from MELA*trace* is required.

If you are installing MELA*trace* together with MELA*view* 3, licensing is done via MELA*view*.

Chapter 2 – User Interface

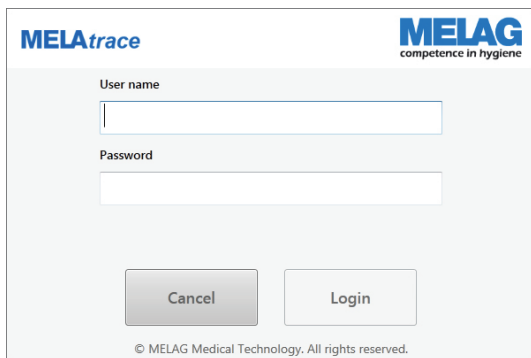
Introduction

MELAtrace is a software for the documentation, load management and approval of instrument treatment. MELAtrace links up the processing steps of cleaning and disinfection with sterilization to ensure comprehensive documentation. The intuitive user interface and the simple licence model guarantee the maximum level of safety and satisfaction.

Logging in

You need to log in every time that you start MELAtrace or every time that you log out and for the authentication processes.

Enter your user name and password into the log-in window for this purpose.

The image shows the MELAtrace login window. It has a light blue header with the 'MELAtrace' logo on the left and the 'MELAG competence in hygiene' logo on the right. Below the header, there are two input fields: 'User name' and 'Password'. Below these fields are two buttons: 'Cancel' and 'Login'. At the bottom of the window, there is a small copyright notice: '© MELAG Medical Technology. All rights reserved.'

Access data for logging in the first time:

User name: MELAGadmin

Password: melag



PLEASE NOTE

It is urgently recommended that you change the pre-selected user name and password after you log in for the first time.

Main view

The main menu of the program opens after you log in successfully.

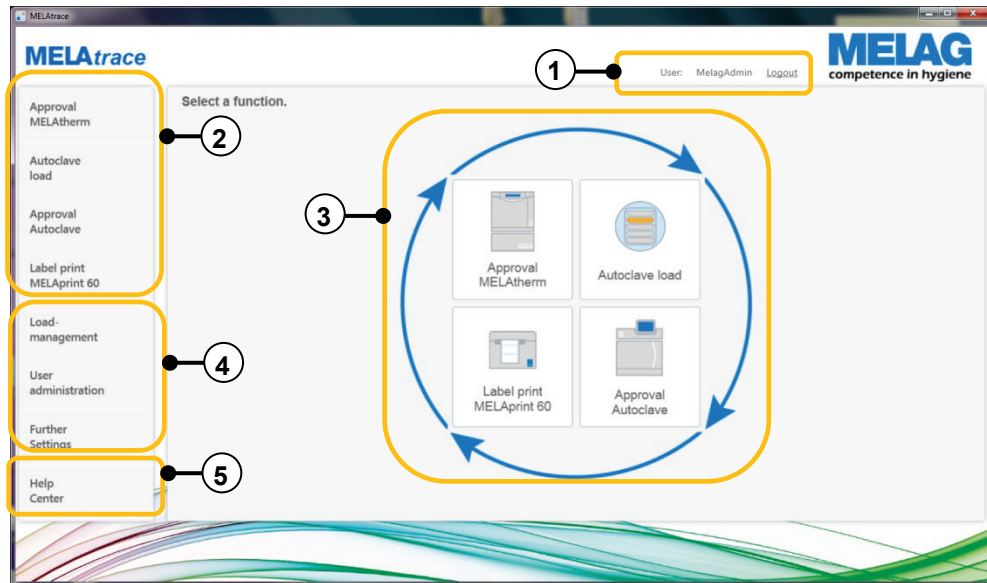


Fig. 1: Main view

- (1) Header with user information
- (2) Menu bar
- (3) Main menu
- (4) Settings (visible only to the administrator)
- (5) Help Center

Header

The user name of the user currently logged in is shown here as well as the time remaining until the user is logged off automatically, if activated (see [Chapter 5 – Administrator Settings](#)).

You can log out the current user via "Log out".

Menu bar

Approval MELAtherm

You can approve MELAtherm logs here and use them subsequently to load the autoclave.

Autoclave load

You can specify the load elements here, e.g. wash trays, sterile containers, individually packed instruments etc., which are used for loading the autoclave.

Approval autoclave

Here, you can approve the logs of sterilized batches completely or have the option of approving only some of the load elements of the batch. Loading elements that have not been approved can be saved with a reason, e.g. not properly packed, residues on the instruments etc. You can prepare a treatment report for batches that have been approved successfully.

Label print MELAprint 60

After approving a sterilized batch, you can print the labels here on the MELAprint 60 label printer in order to enable *traceability* of the load elements.

Main menu

This is where you can find the four main functions **Approval MELAtherm**, **Autoclave load**, **Approval autoclave**, **Label print MELAprint 60**.

Administrator Settings

The following menu options are visible only to users with administrator rights (in MELA*trace*):

Load management

This is where load elements, standard batches and reasons for load elements and batches that have not been approved are created and administered.

User administration

Users are created and administered here, practical information is entered here and settings for authentication and auto logout, i.e. automatic log out for a user in case of inactivity are specified here.

Other settings

Settings for approval and database management are configured here.

Help Center

You can find helpful documentation such as the operating manual and sample loadings here with examples of loading here.

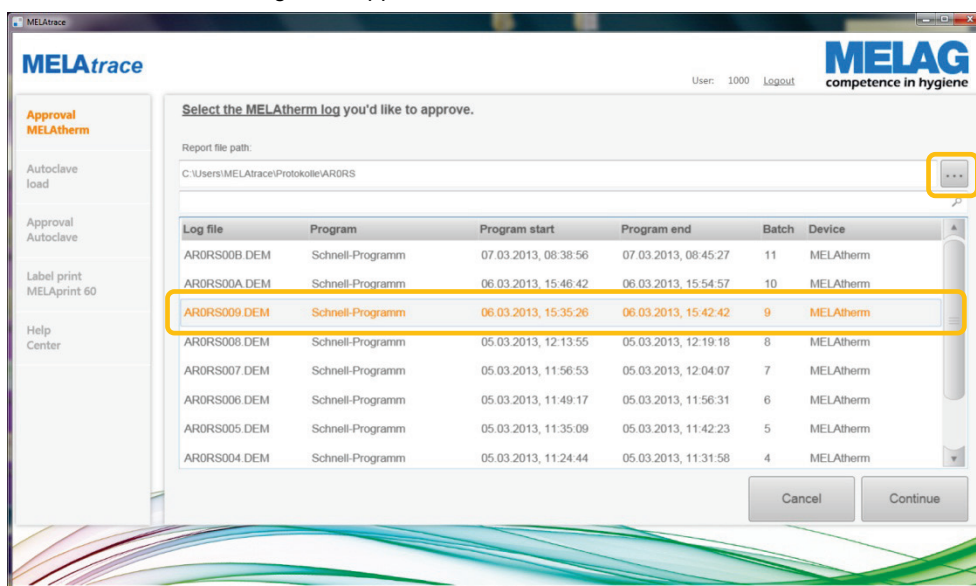
Chapter 3 – Approval Process

Approving MELAtherm-logs

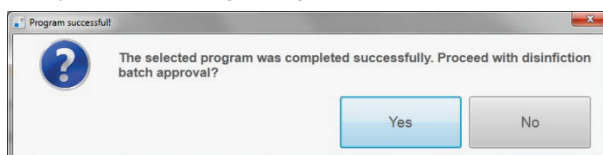
The prerequisite so that a MELAtherm log in MELAtrace can be approved:

- ✓ *The cleaning and disinfection program was completed successfully.*
- ✓ *The MELAtherm log has not yet been approved.*
- ✓ *The contents of the MELAtherm log have not been changed.*
- ✓ *The MELAtherm log is not older than 1 hour or than that configured as the hold-back time specified in the settings.*
- ✓ *The MELAtherm log was generated by a device that is licensed in MELAview.*

1. Select **Approval MELAtherm** in the main menu.
2. By clicking on  choose the directory containing the MELAtherm log. Depending on the depth of search, the directory, and if necessary, sub-directories will be searched for MELAtherm logs that have not yet been approved and shown in the list.
3. Select the MELAtherm log to be approved from the list and click on **Next**.



4. Reply to the following dialogue box with **Yes**.



The MELAtherm batch approved can then be used further for defining the load for the autoclave within 24 hours. The MELAtherm log expires after this period.

**PLEASE NOTE**

The time for holding back MELAtherm logs for subsequent loading definition can be changed under **Further settings** → **Approval**.

**PLEASE NOTE**

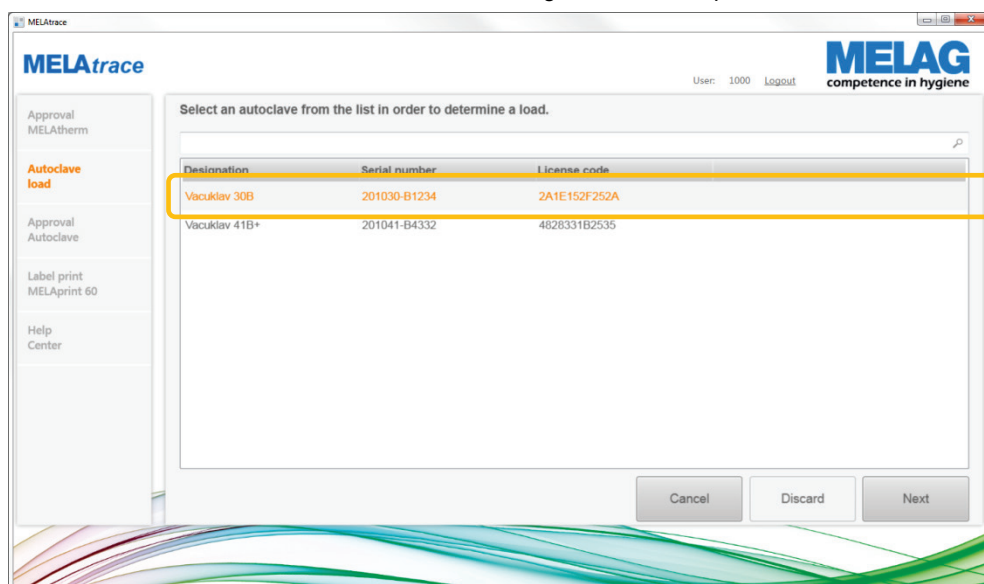
If the dialogue box displays a warning message, please refer to the MELAtherm log for detailed information.

Loading for the Autoclave

Select a device connected to MELAview

This window is displayed only if several autoclaves have been licensed in MELAview.

1. Select **Autoclave load** in the main menu.
2. Select an autoclave from the list for which a loading has to be compiled and click on **Next**.



The loading is compiled in the window that opens.

Compiling the autoclave load

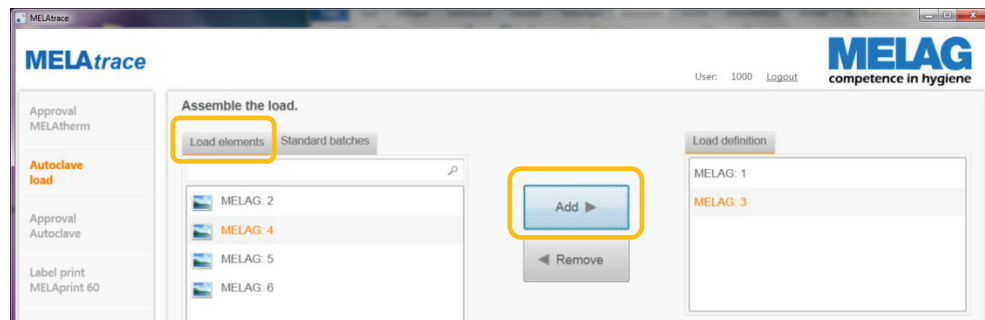
from individual load elements

1. In order to select load elements, choose an element from the list of **Load elements**.

The prerequisite is that the load elements were created in **Load Management**, see **Chapter 5 – Administrator Settings**.

2. Click on **Add** in order to add this to the load.

Alternatively, the element of the loading definition can be added with the help of a double click or double touch

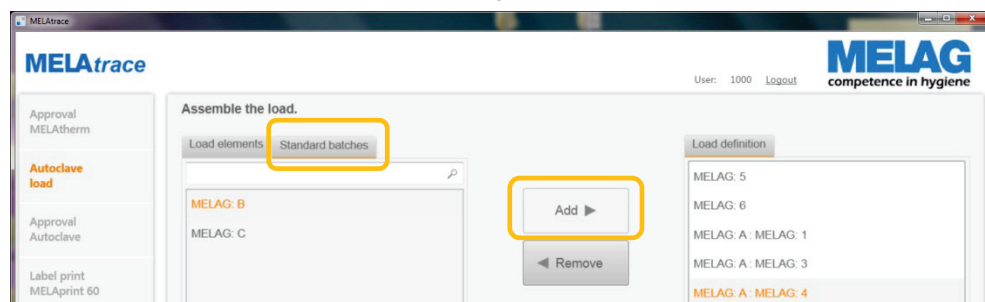


from specific standard batches

1. In order to select a predefined loading (standard batch), select a load from the list **Standard batches**.

The prerequisite is that at least one standard batch was created in [Load Management](#), see [Chapter 5 – Administrator Settings](#).

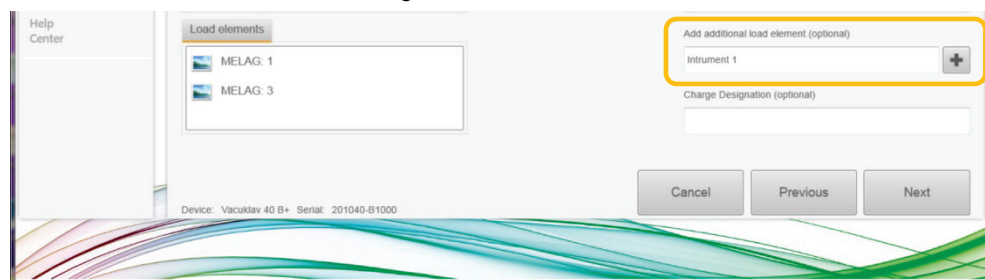
2. Click on **Add** in order to add this to the loading.



from elements not saved in the database

Apart from the selection of predefined load elements and standard batches, you can also add load elements to the batch that have not been saved in the database.

1. Enter the name of another load element in the **Add element** field.
2. Click on **+** to add this to the loading.



PLEASE NOTE

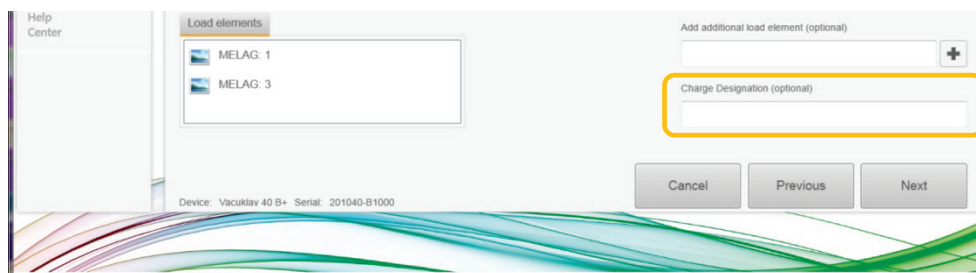
This load element is not automatically saved in the database, but can be used only for the current batch.

Deleting a load element

By clicking on **Delete** the load elements or the standard batches are deleted from the **Load definition** list.

Entering a batch name

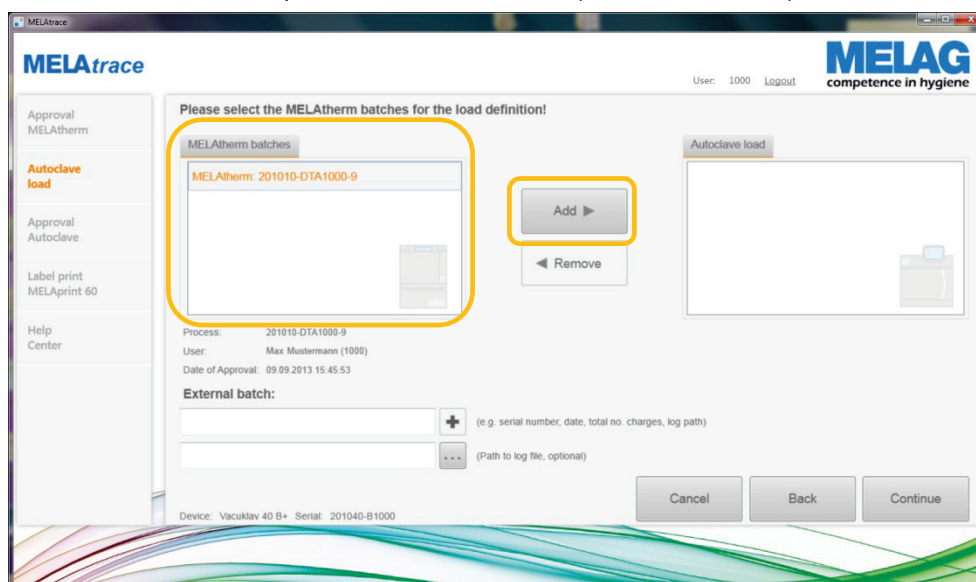
You can assign a name optionally to each batch. To do this, enter a description optionally in the **Batch Name** field. The name is specified at the end of the process on the treatment report.



Connect the autoclave loading with the MELAtherm batches

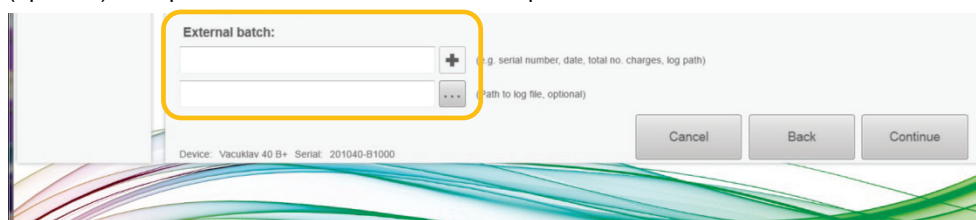
1. After you have specified the loading for the autoclave (see section [Compiling the autoclave load](#)), click on **Next**.

The following window opens. The **MELAtherm batches** list contains all approved MELAtherm batches that lie within the permissible hold-back time (Standard: 24 hours).

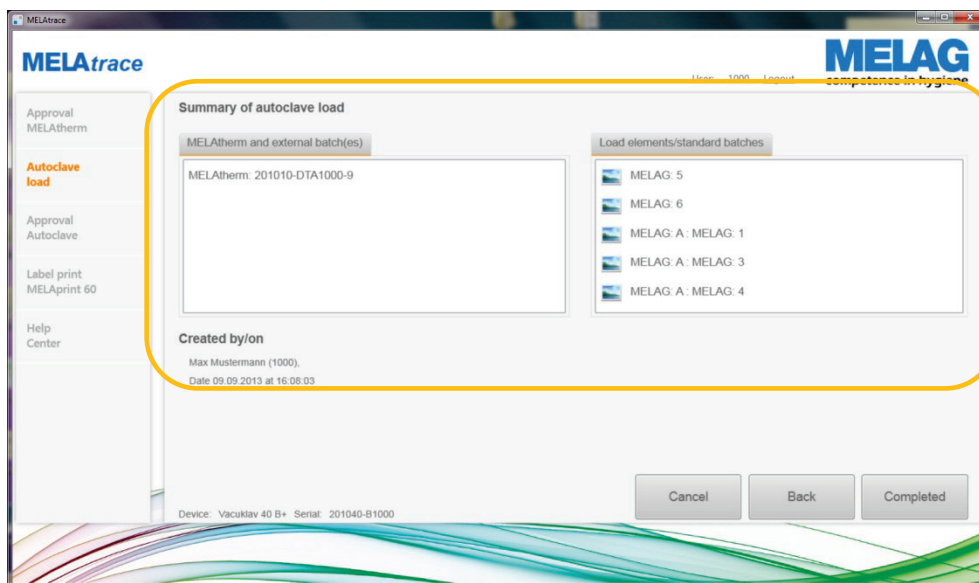


2. Select a batch from the **MELAtherm batches** list and then click on **Add**.
3. If you would like to select an external batch, for example, from a cleaning or disinfection device of another manufacturer, enter a description in the **External batch** field.

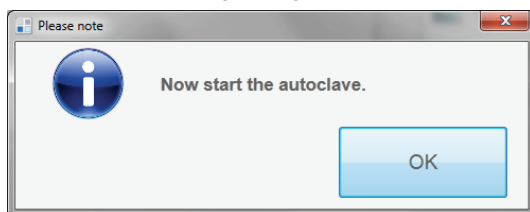
You can still specify the path to the respective log file for the external batch by clicking on  (optional). The path is marked in the treatment report.



4. To continue, click on **Next**.
A summary is displayed.



5. To complete the loading definition, click on **Completed**.
6. Confirm the following dialogue box with OK.

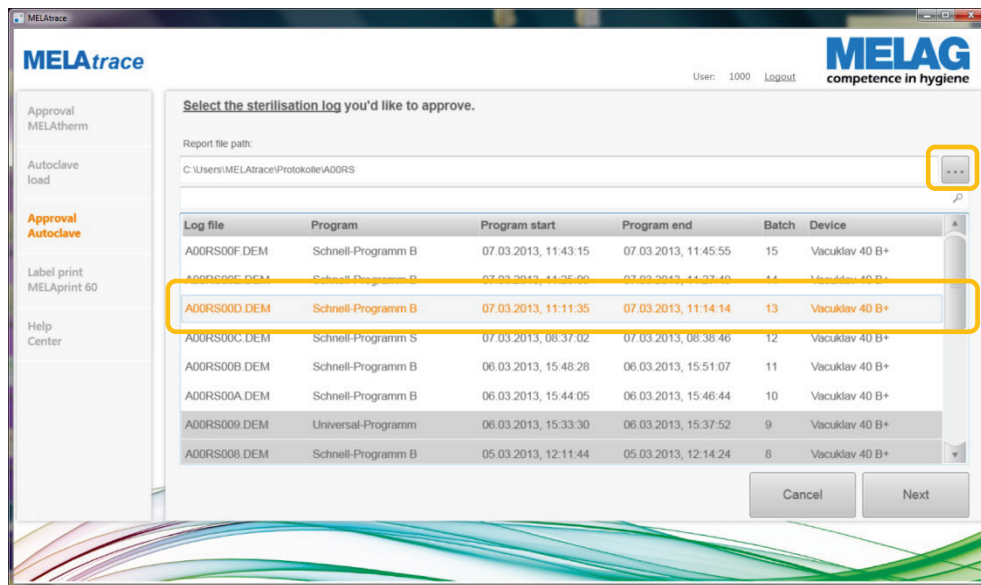


Approval of sterilization logs

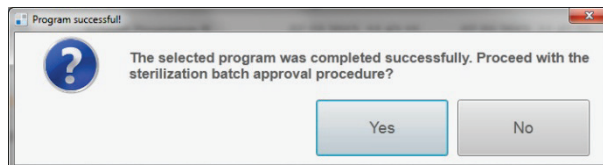
The prerequisite so that a sterilization log can be approved in MELAttrace:

- ✓ *The sterilization program was completed successfully.*
- ✓ *The sterilization log has not yet been approved.*
- ✓ *The contents of the sterilization log have not been changed.*
- ✓ *The sterilization log is not older than 1 hour or than the time configured as the hold-back time in the settings.*
- ✓ *The sterilization log was generated by a device that is licensed in MELAview.*

1. Select **Approval Autoclave** in the main menu.
2. By clicking on  choose the directory containing the particular sterilization log. Depending on the depth of search, the directory, and if necessary, sub-directories will be searched for sterilization logs that have not yet been approved and shown in the list.
3. Select the sterilization log to be approved from the list and click on **Next**.



- If you would like to approve the sterilization log selected, respond to the following dialogue box with **Yes** in order to execute the approval process as described in the following.



NOTE

The time for holding back the sterilization logs for approval can be changed in **Further settings** → **Approval**.

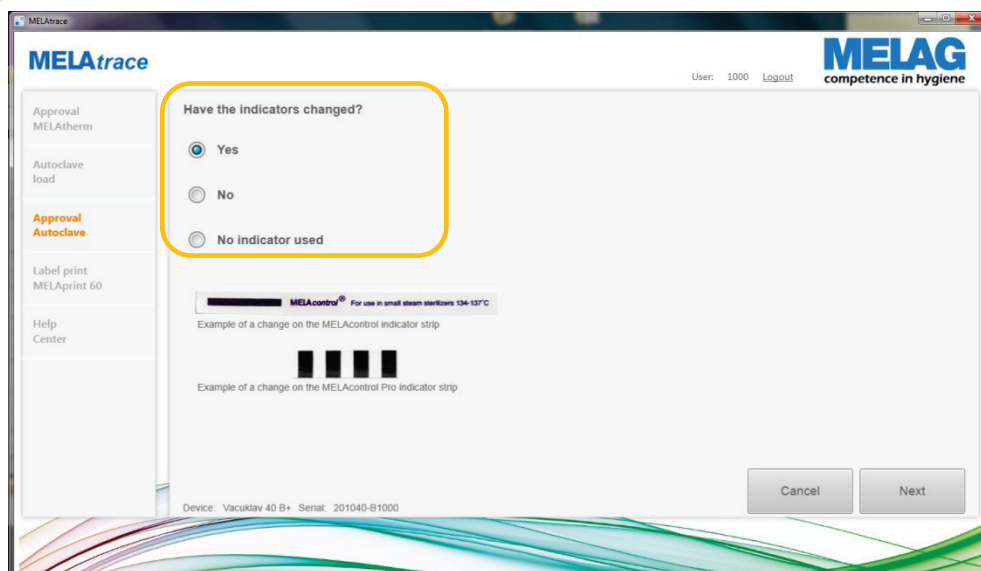


PLEASE NOTE

If the dialogue box displays a warning message, please refer to the sterilization log for detailed information.

Indicator query

If the indicator query is enabled, you can evaluate here whether the indicators included have changed. The following window opens:



1. Evaluate whether the indicator included has changed and then click on **Next**.



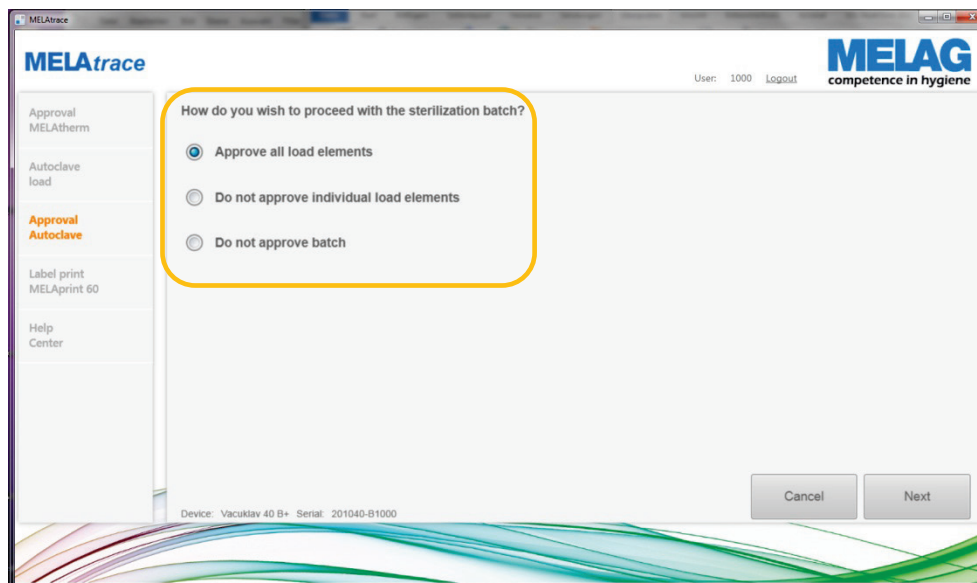
PLEASE NOTE

The indicator query is displayed only if this feature has been enabled in **Further settings** → **Approval** → **Perform indicator checks**. This window is skipped otherwise.

2. To continue, click on **Next**.

Approval options

After the indicator query, the load elements must be approved. There are three options available for this purpose.



Approving the entire sterilization batch

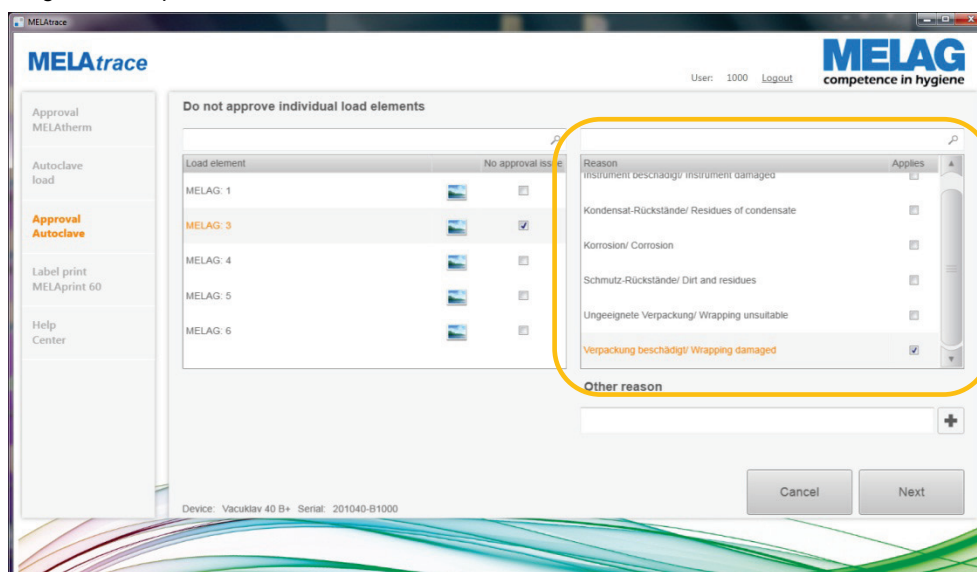
If you would like to approve all load elements of a sterilization batch, select **Approve all load elements** and then click on **Next**.

A preview of the treatment report is displayed, see section [Compiling a treatment report](#).

Do not approve individual load elements

If you would like not to approve one or more load elements of a sterilization batch, select **Do not approve individual load elements** and then click on **Next**.

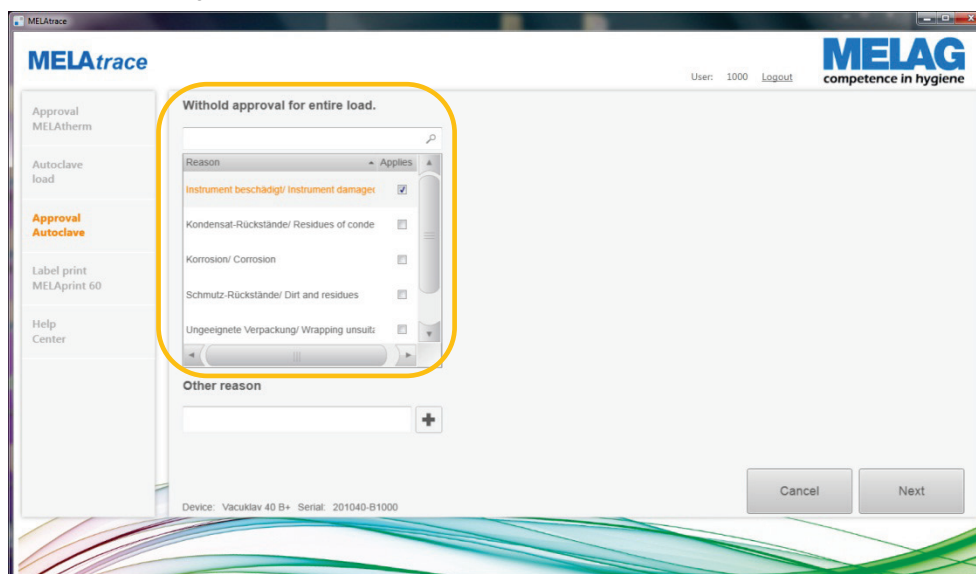
The following window opens:



1. Select the appropriate load element from the **Load element** list on the left and specify at least one reason in the **Reason** list on the right for why the particular element has not been approved. The prerequisite is that the reasons have been created in **Load Management**, see **Chapter 5 – Administrator Settings**.
2. If the relevant reason is not indicated in the list, enter a different reason under **Other reason** and add this by clicking on , see also **Load management** → **Reasons**. Other reasons are not saved in the list of reasons in the database.
3. Proceed in this manner with all load elements that have not been approved.
4. Finally, click on **Next**.

Not approving the entire sterilization batch

If you would like not to approve the entire sterilization batch, select **Do not approve the batch** and then click on **Next**. The following window opens:

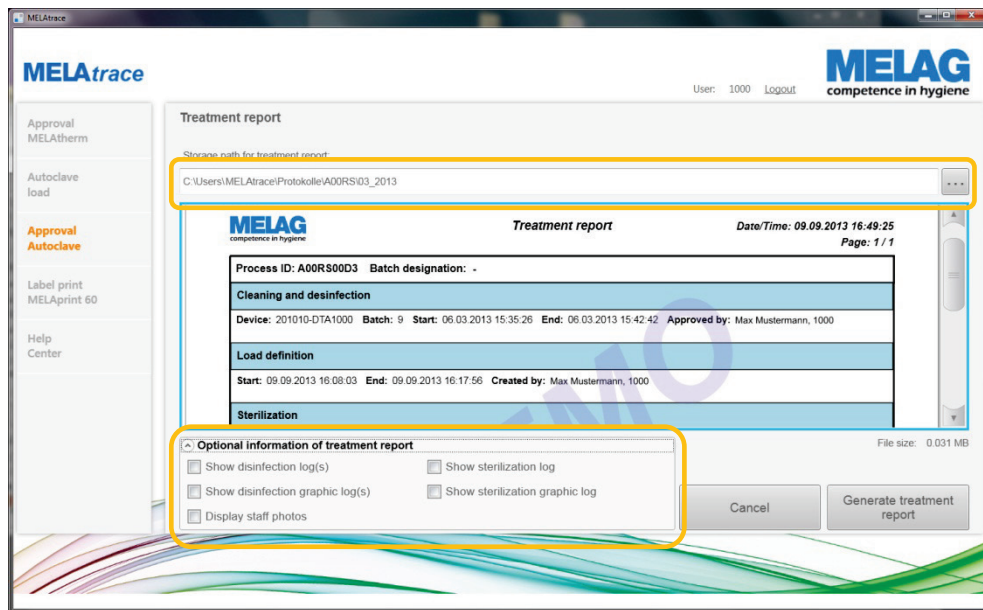


1. Enter one or more reasons in the **Reasons** list for why the concerned sterilization batch has not been approved. The prerequisite is that the reasons have been created in **Load Management**, see **Chapter 5 – Administrator Settings**.
2. If the relevant reason is not indicated in the list, enter a different reason under **Other reason** and add this by clicking on , see also **Load management** → **Reasons**.
3. Finally, click on **Next**.

Compiling a treatment report

A so-called treatment report is compiled after approving the sterilization batch or a part of the batch.

All information about the treatment process of a batch (approval, MELAtherm batch, loading the autoclave, approval of the autoclave) is documented in the treatment report.



A preview is prepared to begin with.

You can also have the following elements displayed in the treatment report under **Optional information**:

Displaying MELAtherm log(s)

The MELAtherm log that has been assigned to the autoclave loading is displayed in the appendix of the treatment report.

Displaying MELAtherm graphic log(s)

The MELAtherm graphic log that has been assigned to the autoclave loading is displayed in the appendix of the treatment report.

Displaying a sterilization log

The sterilization log of the batch approved previously is displayed in the appendix of the treatment report.

Displaying the sterilization graphic log

The log of the sterilization graphic log of the batch approved previously is displayed in the appendix of the treatment report.

To change the saving location of the treatment report, click on  and choose the desired destination folder.



PLEASE NOTE

By default, the treatment report is saved in the directory that has been specified in **Further settings** → **Approval**.

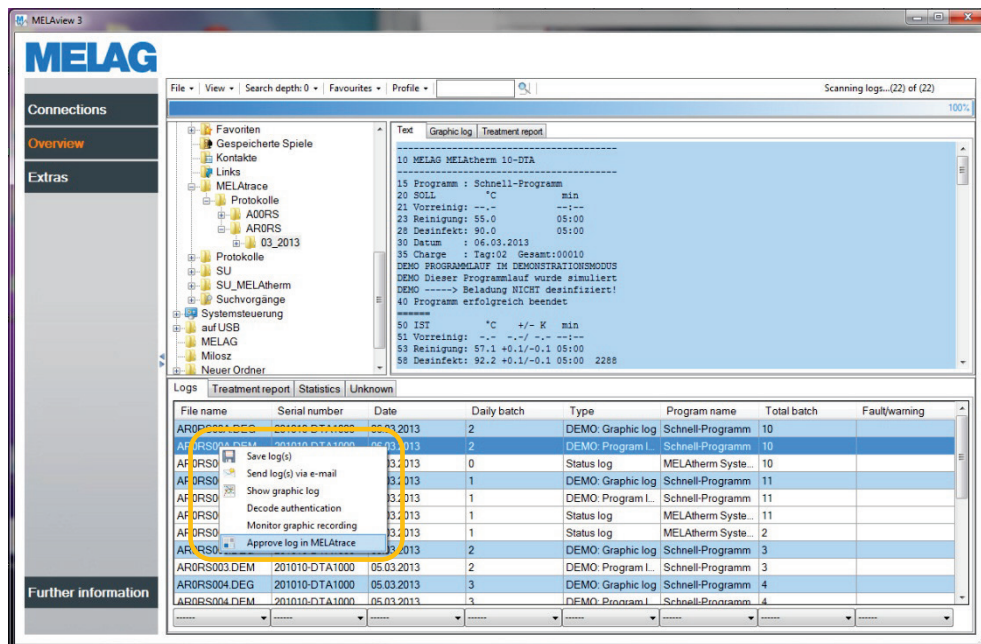
After clicking on **Generate treatment report** the treatment report displayed is saved as a PDF document in the appropriate directory.

Finally, you will learn how to print labels in the next chapter.

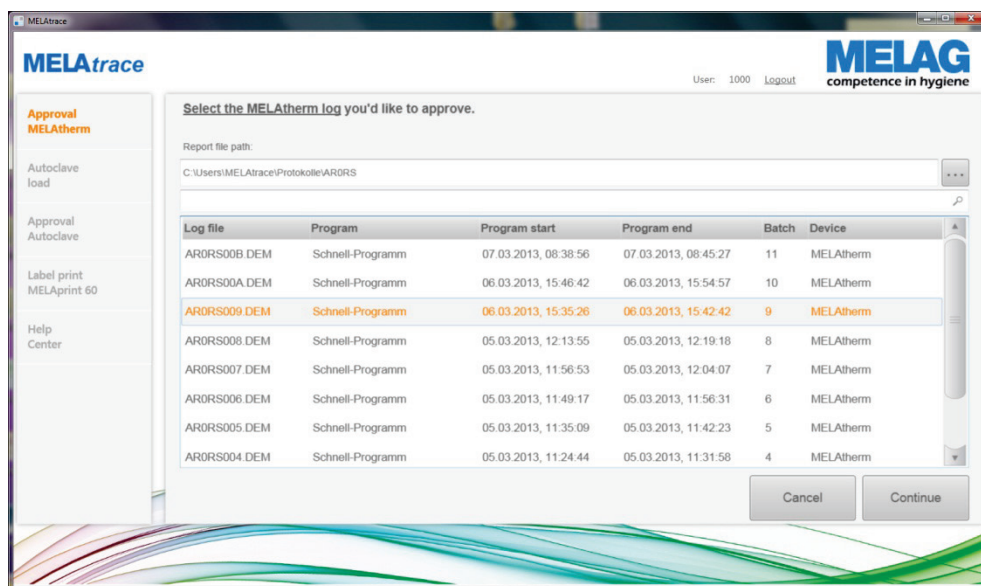
Approving a log from the MELAview

MELAttrace can also be started directly from MELAview:

1. Choose a MELAtherm log or sterilization log from the list of logs in MELAview.
2. Call up the context menu by clicking with the right mouse button on the log selected. With **Approve log in MELAttrace** you can start MELAttrace.



If you, for example, have selected a MELAtace log, then in MELAtace the **Approval MELAtace** menu opens. In this case, only the previously selected MELAtace log is displayed in the list.



- Proceed as described in the section above, **Approving MELAtace-logs** to approve the MELAtace log.

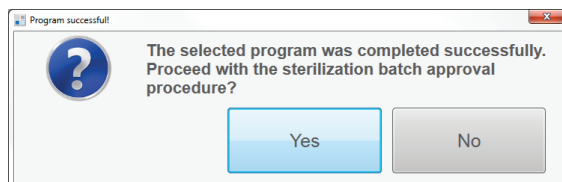
Proceed as described in the section above, **Approval of sterilization logs** to approve a sterilization log.

Receiving a log from MELAview

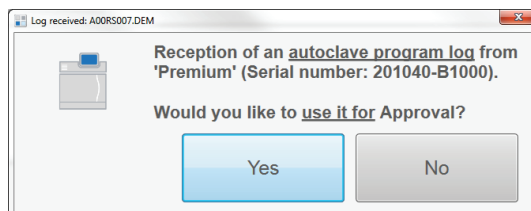
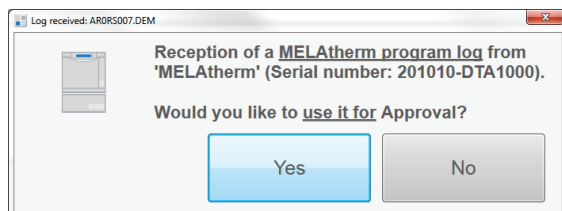
The prerequisite so that a log can be received in MELAtrace:

- ✓ *The device (MELAtherm or autoclave) is connected with MELAview.*
- ✓ *Immediate output has been enabled in the corresponding device.*
- ✓ *The MELAtrace program is executed.*

After the program ends, the MELAtherm log or sterilization log is forwarded directly to MELAtrace and a dialogue box is displayed that a log has been received.



If you would like to approve the log with MELAtrace respond to the associated query in the dialogue box with **Yes**.

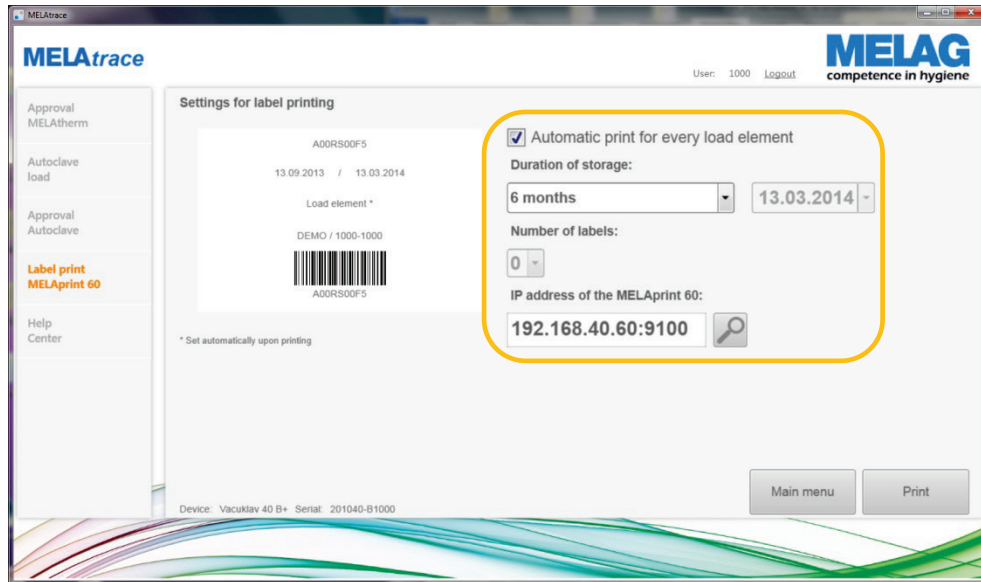


Next, carry out the approval process as described in the previous sections.

Chapter 4 – Printing Labels

Printing labels immediately after approval

If you have completed the approval of a packed sterilization program successfully and then generated a treatment report, the **Label print with MELAprint 60** is displayed automatically.



You specify the following options here:

Automatic printing for all load elements

Active: A label with the relevant name is printed for each load element that has been approved. The number of the labels cannot be changed in this case.

Inactive: The name of the load element is not marked on the label and the number of labels can be determined independently.

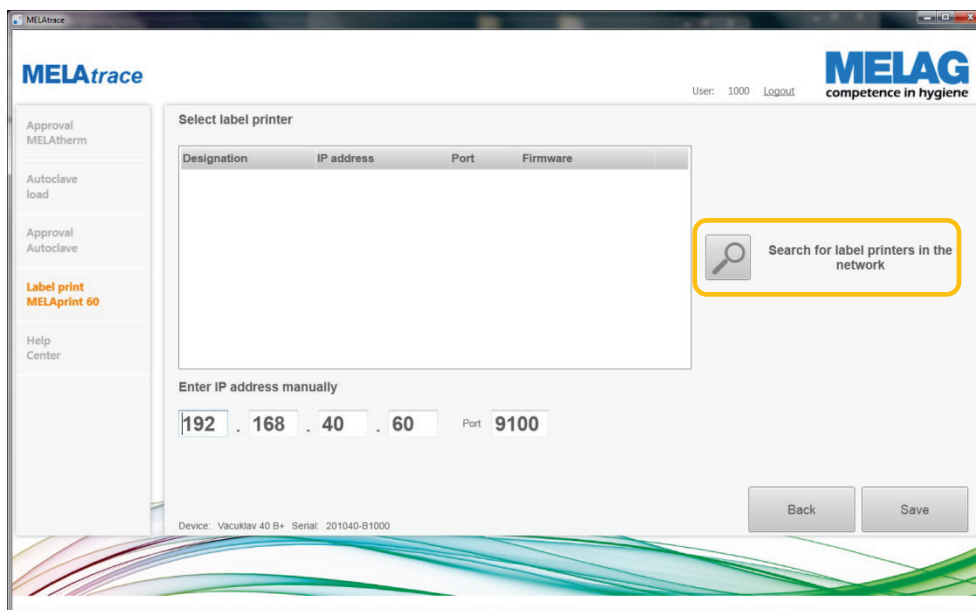
Storage period

You can specify the maximum storage period for the sterilized load elements here, i.e. until when the load elements are considered to be sterile.

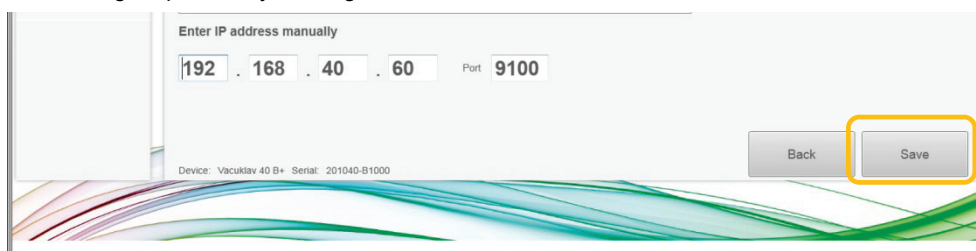
IP address of the MELAprint 60

You select the appropriate label printer here as follows:

1. Enter the IP address of the MELAprint 60 label printer directly.
2. If you would like to use a label printer that is different from the one that is preselected, click on the magnifying glass  icon. The following window opens:



3. Click once again on the magnifying glass  icon to search for all label printers available in the network.
4. Choose the desired label printer from the list and click on **Save** to accept this printer. The IP address of the label printer is saved in MELAttrace.
The window is closed once again.
5. The label gets printed by clicking on the **Print** button.



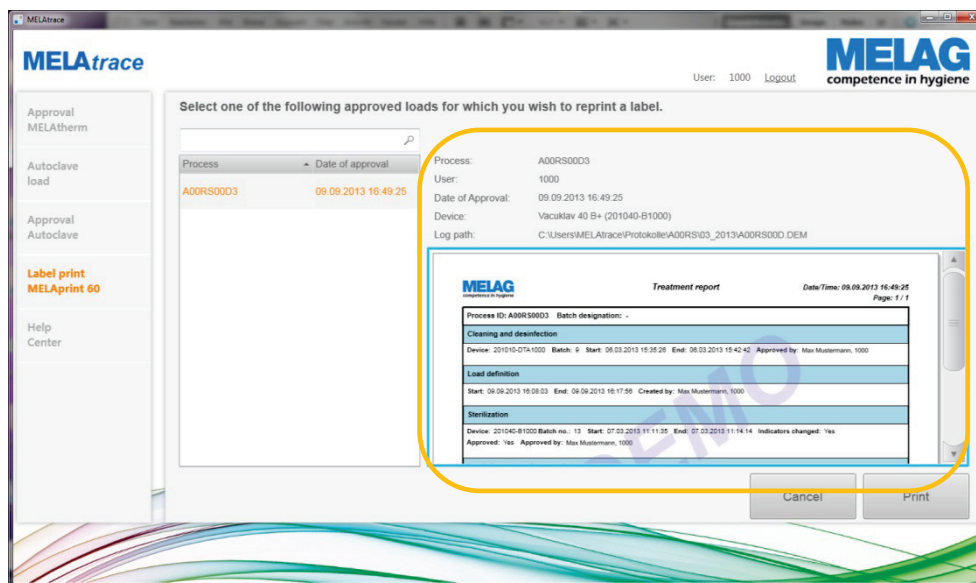
Printing labels subsequently



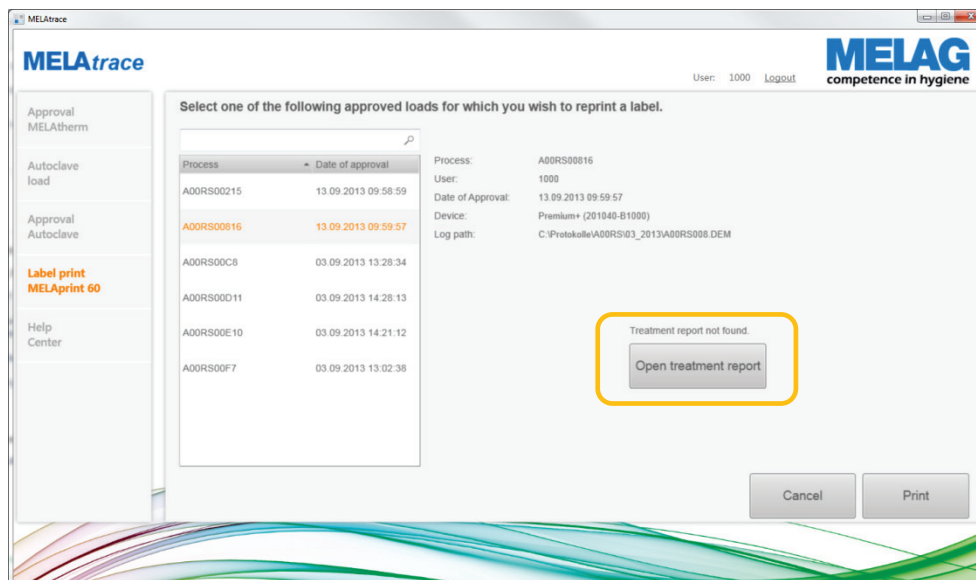
PLEASE NOTE

Only labels for the class B sterilization program can be printed. An appropriate message is displayed otherwise.

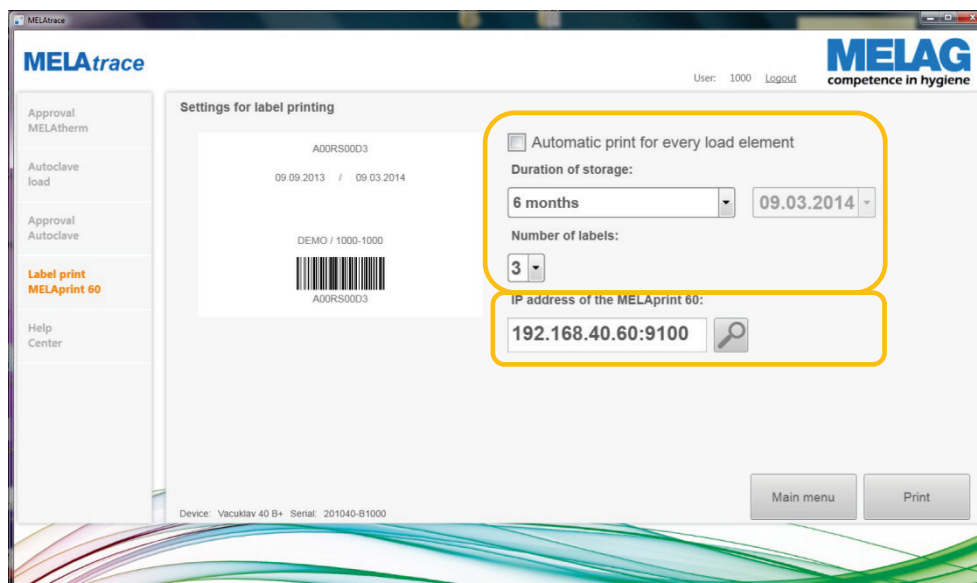
1. Choose **Label print with MELAprint 60** in the main menu.
2. Select the relevant batch from the list of approved sterilization batches. If a treatment report has been created for the batch, this is displayed in the preview, as well information about the person who has approved the batch, date of approval, device used, among others.



If no treatment report can be found for the batch selected, for example, since it has been moved to another directory or it has been renamed, you can search for the directory manually and open the treatment report by clicking on **Open treatment report**.



3. Click on **Next** to display the next window for the settings regarding the number of labels to be printed and the storage period.



4. Specify the number of labels as well as the maximum storage period of the instruments, see page 19, [Printing labels immediately after approval](#).

Chapter 5 – Administrator Settings

The following menus are displayed only if you have logged in as an administrator in MELAtrace.

Load Management

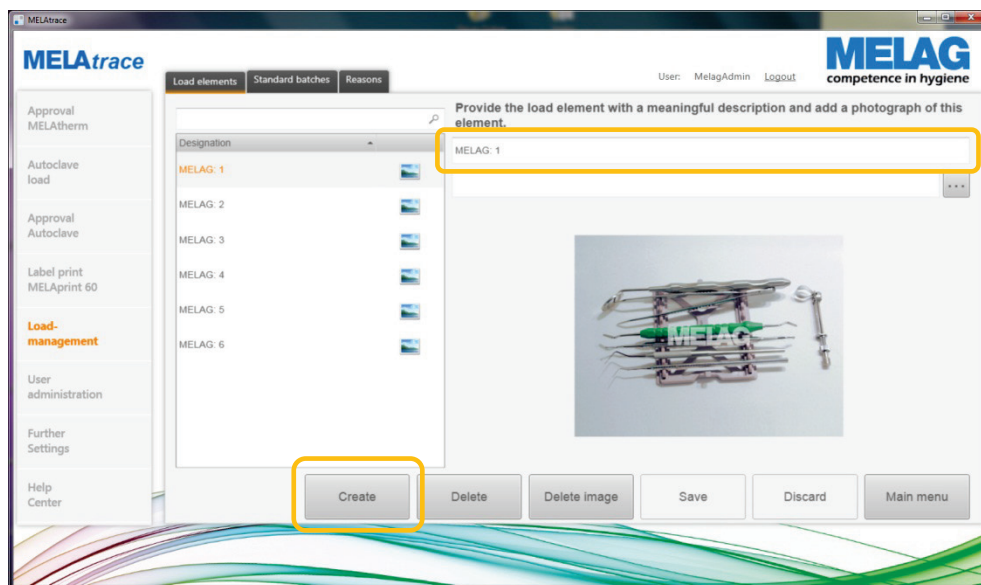
Load elements

Here, you can create, edit or delete the load elements that have been selected for defining the loading.

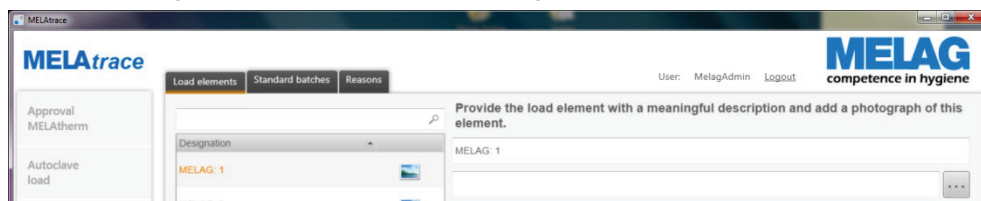
Creating a new load element

1. In the **Load management** → **Load elements** menu click on the **Create** button.

A new load element is created in the list.

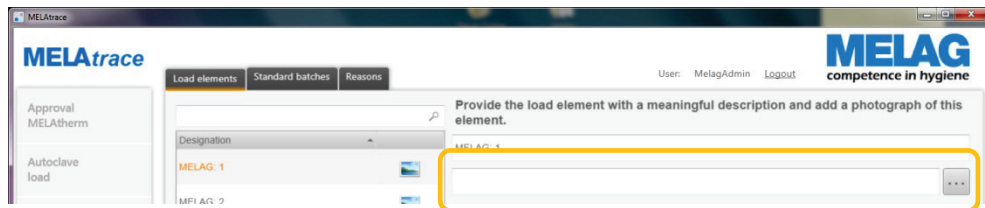


2. Enter a meaningful name in the text field on the right side.



3. If you would like to save an image for the load element, choose the relevant image file from a directory on the computer by clicking on .

The images can also be added or replaced by dragging them from the settings window.



4. By clicking on **Save** the new load element is accepted and saved in the list.

Deleting a load element

Proceed as follows to delete a load element:

1. In the **Load management** → **Load elements** menu choose an element from the list and click on **Delete**. By doing this, it gets deleted from the list of load elements available in the list for defining the loading.

After responding to the confirmation prompt, the load element is deleted permanently from the list.

Deleting an image of a load element

Proceed as follows to delete an image of a load element:

1. In the **Load management** → **Load elements** menu, choose an element in the list and click on **Delete image**.
2. The changes are accepted by clicking on **Save**.

Replacing an image of a load element

Proceed as follows to replace an image of a load element with another:

1. In the **Load management** → **Load elements** menu choose an element from the list and click on .

The images can also be added or replaced by dragging them from the settings window.

2. Choose a new image file from a directory on the computer.
3. By clicking on **Save** the new load element is accepted and saved in the list.

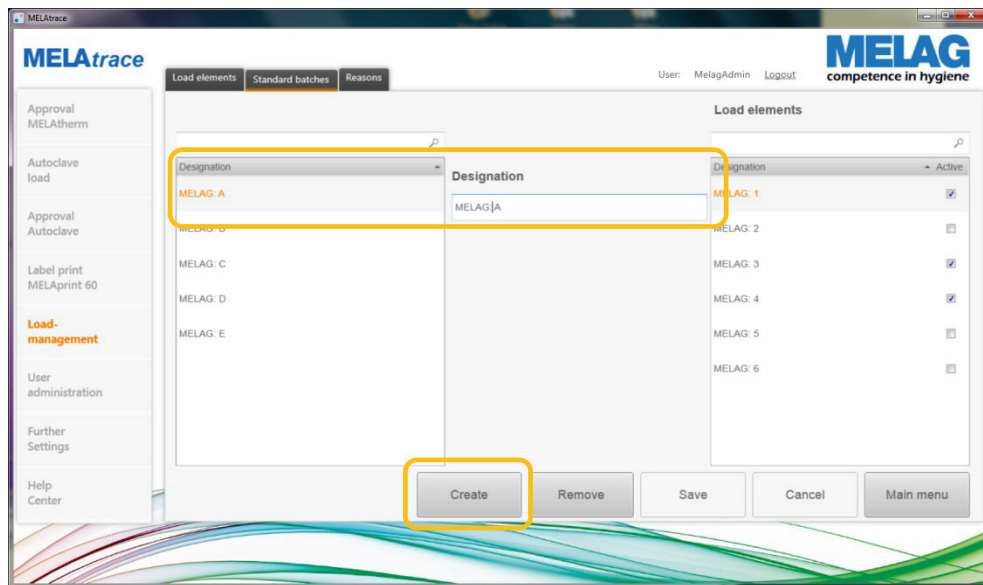
Standard batches

Collections of existing load elements are called standard batches.

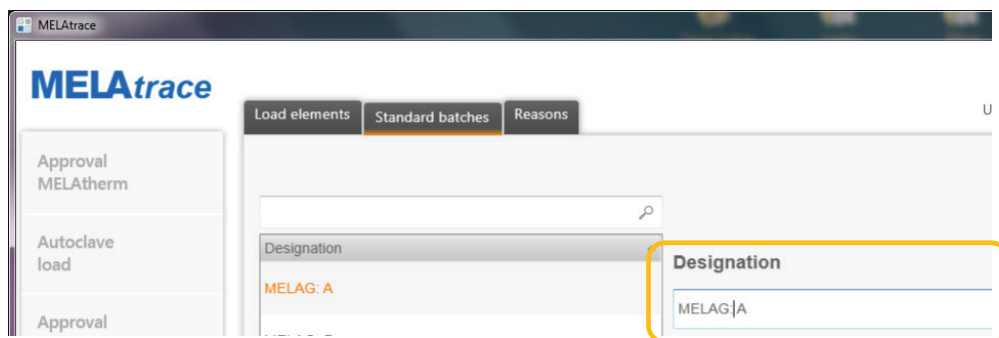
These can be created, edited or deleted here. You can learn in the following how to create and manage such collections:

Creating a new standard batch

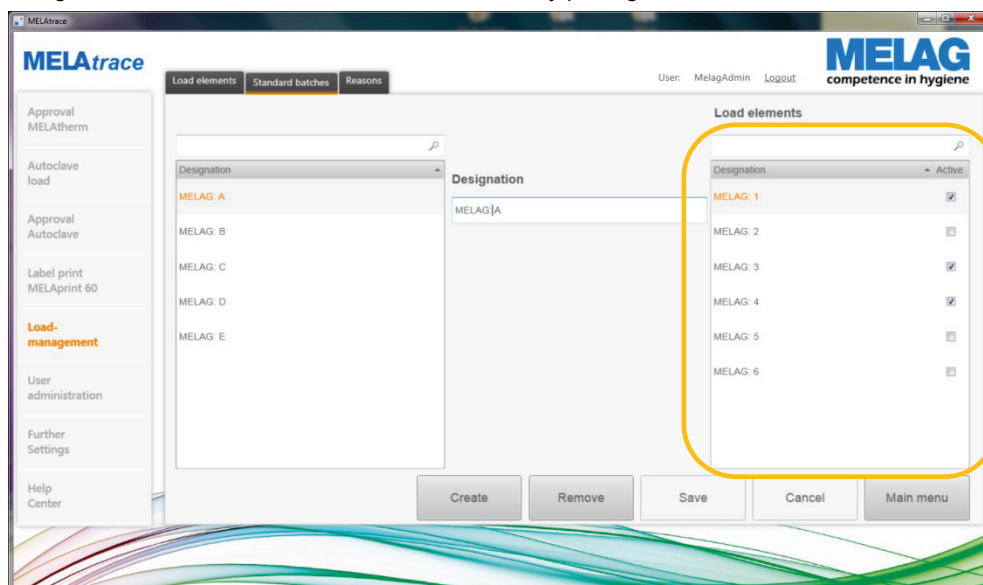
1. In the **Load management** → **Load elements** menu click on the **Create** button.
A new standard batch is created in the list.



2. Enter a meaningful name for this collection in the **Designation** text field in the centre.



3. Assign this collection to the desired load element by putting a tick mark ☒ .



4. By clicking on **Save** the standard batch is accepted and saved in the list of collections.

Deleting a standard batch from the list

Proceed as follows to delete a standard batch from the list:

1. In the **Load management** → **Load elements** menu choose a standard batch from the list and click on **Delete**. By doing this, it gets deleted from the list of standard batches available in the list for defining the loading.

After responding to the confirmation prompt, the standard batch is deleted permanently from the list.

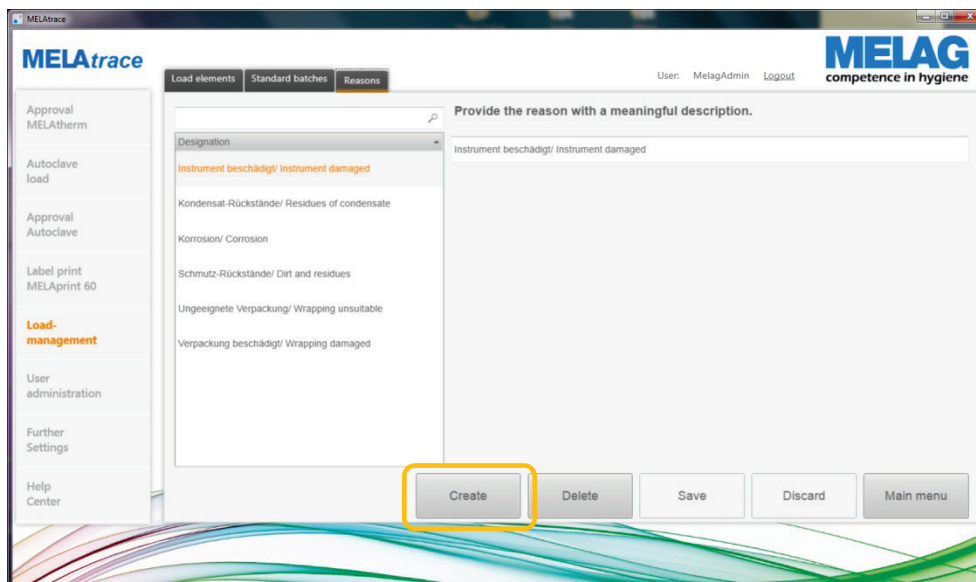
Reasons

The reasons are created, edited or deleted here that are specified in order not to approve load elements or entire batches.

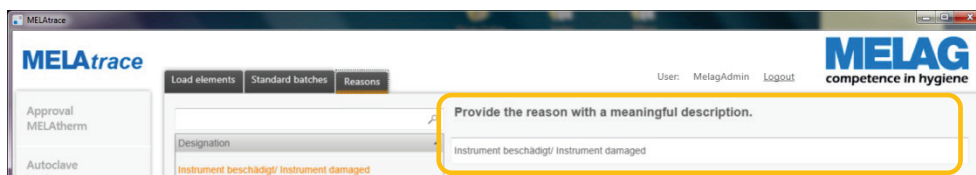
Creating a new reason

1. In the **Load management** → **Reasons** menu click on the **Create** button.

A new reason is created in the list.



2. Enter a meaningful name in the text field on the right side.



3. By clicking on **Save** the new reason is accepted and saved in the list.

Deleting a reason from the list

Proceed as follows to delete a reason from the list:

1. In the **Load management** → **Reasons** menu choose a standard batch from the list and click on **Delete**. By doing this, it gets deleted from the list of reasons available list for not approving a sterilization batch.

After responding to the confirmation prompt, the reason is deleted permanently from the list.

User administration

Practice

In the **User administration** → **Practice** menu, you can enter information on the practice, e.g. practice name, address, homepage.

This information appears on the treatment report.

The information is accepted by clicking on **Save**.

Users

Users who work with MELAttrace are created and administered here.

Setting up a user

1. In the **User administration** → **User** menu click on the **New** button.
A new user is set up.
2. Fill up at least those fields that are marked with *. Only then can the user information be saved.

3. If you would like to add a user image as an option, click on and choose a new image file from a directory on the computer. User images can also be displayed in the treatment report.

The images can also be added or replaced by dragging them from the settings window.

4. Specify the role of each user. Please note that you can administer settings for load management, user administration, etc. only if you are logged in as an administrator (in MELAtrace). These menu options are disabled (hidden) for normal users.
5. By clicking on **Save** the user is accepted and saved in the list.

Locking a user

User accounts cannot be deleted, but they can only be locked, which means that they can no longer log in to MELAtrace and no longer possess approval rights or privileges.

Proceed as follows to lock a user:

6. In the **User administration** → **User** menu choose a user in the list and click on **Lock**.

Based on the lock ( or ) you can view the current status of a user.

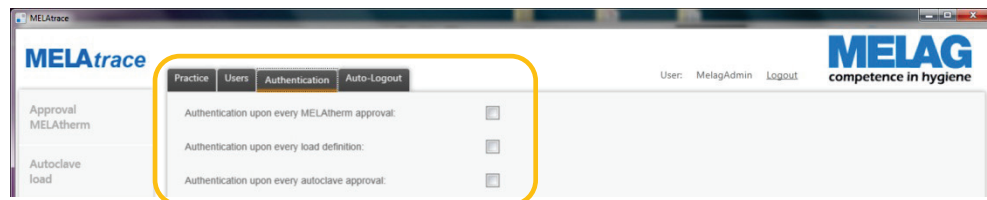
Changing the password

User passwords can be changed whenever required, but this can be done only by administrators. In order to change the password for a user, an administrator password must be entered for authentication.

Authentication

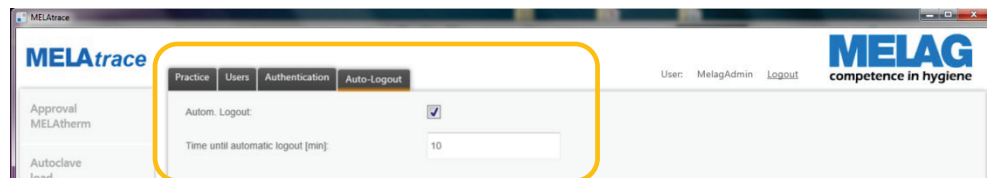
Here, you can specify the situations in which it is necessary to enter the user name and the associated password.

The settings are accepted by clicking on **Save**.



Auto Logout

You can specify here whether a user should be logged out automatically after a certain period of inactivity.

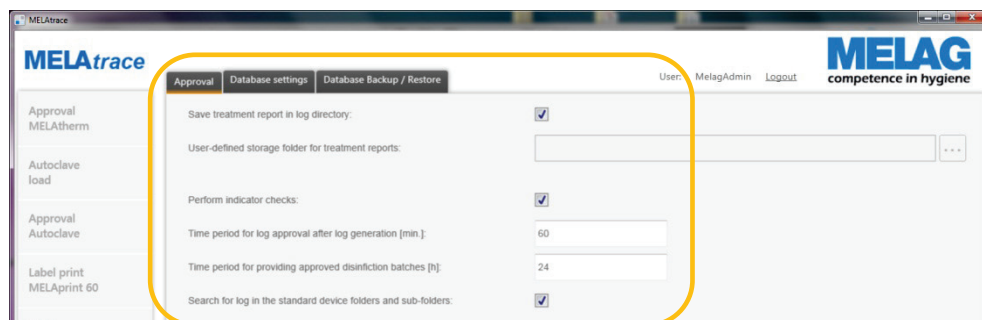


If the tick mark in **Auto logout** is set, the user is automatically logged out in case of inactivity. Moreover, you can configure the time here in minutes after which period of inactivity the user is logged out automatically.

Other Settings

Approval

In the **Further Settings** → **Approval** menu, you can configure the following settings:



The settings are accepted by clicking on **Save**.

Save treatment report in the log directory

Active: The treatment reports are saved in the same directory as the sterilization logs by default.

Inactive: By clicking on  in the second line, a path can be specified to any directory on the computer.



PLEASE NOTE

This directory must be write-enabled so that the treatment reports can be saved in the target directory selected.

Performing an indicator check

You can specify here whether during the approval process after sterilization has been completed, the accompanying indicators should be evaluated.

Time taken for approving the log after it has been created [in min.]

This value specifies how long a log can still be approved in MELAttrace after the end of the program (MELAttherm or the autoclave). The value is specified in minutes.

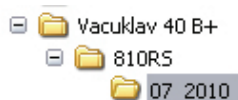
Time period for holding back approved MELAttherm batches [in hours]

This value specifies how long a MELAttherm log approved in MELAttrace can be assigned to a loading for the autoclave. The value is specified in hours.

Searching for logs in the standard device directory and in sub-folders

If this option is enabled, search is conducted even the sub-folders of the device directory, i.e. the monthly directory and, if applicable, the folder "DOUBLE".

Example of a folder structure in MELAG devices:



Database Settings



PLEASE NOTE

For the database settings, particularly for the backup of the database, it is urgently recommended to execute the MELAttrace program as a Windows administrator (**Start menu** → **MELAttrace** → with the right mouse button **Execute as administrator**), since MELAttrace accesses system files and system paths.

All load elements including images, standard batches, reasons, user accounts, device licences, loading definitions and approved MELAtherm logs and other logs are saved in the database.

Standard file name for backup

You can assign a name for the MELAttrace backup file here.

Standard folder for backup

By clicking on  you can specify any directory in the computer as the destination.

The backup folder of the Microsoft SQL Server is predefined as the destination by default.

Backup / Restore Database

It is recommended to create a backup of the database prior to incorporating a software update of MELAttrace.

Backing up the database

Proceed as follows to back up the database:

1. If the database should not be saved in the predefined directory, click on  and select any directory in the computer,
2. Click on **Back up database** to start the backup of the database.

Restoring / Importing the database

If, for example, MELAtrace is executed on another computer and the database is transferred there, you can first back up the database and then import / restore it as follows:

1. If the database should not be loaded from the predefined directory, click on  and select any directory in the computer,
2. Click on **Restore database** in order to import or restore the database from the appropriate directory.

MELAtrace is restarted after restoring the database.

Chapter 6 – Help Center

You can find additional information in the help center, e.g. this operating manual or examples of sample loading for autoclaves.

The documents have been saved in PDF format. This is why a program for opening PDF documents, e.g. Adobe Acrobat Reader should be installed on the computer.

MELAG Medizintechnik oHG

Geneststraße 6-10
10829 Berlin
Germany

E-Mail: info@melag.de

Web: www.melag.de

Responsible for content: Technical Office
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