



MonTe

Monitoring Temperature of Clinical Study Drugs

MonTe Portal User Guide

Storage Temperature Logger Registration

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1. Introduction

This user guide describes how to register and manage storage loggers in the MonTe system. The user guide is relevant for site users and monitors.

2. Logger management

Storage loggers are managed under the Administration menu item in the left-hand side menu. From here you can add/replace a storage logger or update the trial/site association on an existing one.

2.1 Add a new storage logger

Before you add a new storage logger to MonTe, please ensure that your 'Timezone' is correct in the system (Changing your time zone can be done under 'My settings').

The screenshot shows the 'My Settings' page. The 'TIMEZONE' dropdown is highlighted with a yellow box and set to 'Europe/Stockholm UTC +01:00'. Other fields include NAME (Söderström, Hanna), USERNAME (hanna), EMAIL (hanna.soderstrom@tss.se), and PHONE NUMBER (+1). Buttons for 'Link to Single Sign-On', 'Unlink from Single Sign-On', and 'Save' are visible.

To add a new storage logger, go to **Administration - Loggers - Add**, and select Manufacturer "Other". Populate the empty fields.

The screenshot shows the 'Add new logger' page. The 'MANUFACTURER' dropdown is set to 'Other'. Fields for 'LOGGER ID', 'NAME/DESCRIPTION', 'TYPE', 'EXPIRY DATE', and 'VALID FROM' are visible. A table below shows trial/site associations:

TRIAL / SITE	TRIAL / SITE	TRIAL / SITE
AZ demo / 101	AZ demo / 102	AZ demo / 201
AZ demo / 202	AZ demo / 461	AZ demo / 462

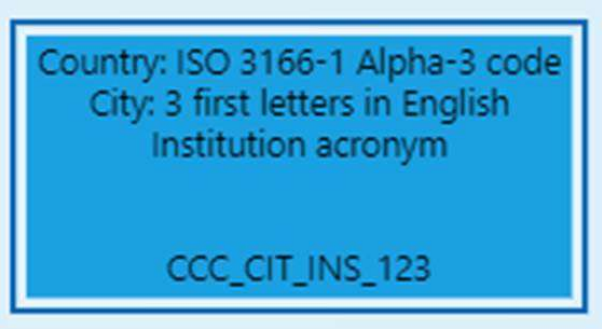
Note: You can only add storage loggers to MonTe. Shipment loggers must not be added to MonTe.

For further support please contact the **MonTe Help Desk** montehelp@tss.se

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Explanation of fields:

Field	Type	Description
Manufacturer	Drop down menu	Select "Other" (for all types of storage loggers).
Logger ID	Text field	<p>The Logger ID must use the ISO Country Alpha 3-code, as shown in the example below.</p> <p>e.g. United Kingdom, London, Charing Cross Hospital</p> <p>GBR_LON_CHA_001</p>  <p>The ISO (3166) Country Alpha 3-code can be found in the MonTe portal, and is also attached to the user guide.</p>
Name/Description	Text field	<p>This field can be used to define the location of the logger in more descriptive terms.</p> <p>e.g. Fridge 2, 1st floor, room 114</p>
Type	Drop down menu	Choose between "Controlled Room Temperature", "Refrigerated" or "Frozen" based on where the logger is placed.
Expiry Date	Date selector	Find the expiry date on the calibration certificate.
Valid from	Date and time selector	Enter the date and time that reflects when the logger is considered ready for use.

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The screenshot shows the 'Select association date for' screen. At the top, it displays 'Trial / Site: NN1218-3854 / 926'. Below this is a calendar for October 2019. The date '16' is highlighted in green. Below the calendar, the time is set to '12 : 57' and the time zone is 'UTC'. A red box highlights the date and time '16-Oct-2019 12:57'. Below this are two buttons: 'Confirm' (green) and 'Cancel' (dark blue). To the right of the calendar is a vertical grey bar with a 'TYPE' label and a 'VALID FROM' field containing '16-Oct-2019 12:56', which is also highlighted with a red box.

When you have completed the data, select **Add Logger**. A confirmation pop up box will appear on screen, select **OK** if completed correctly.

The screenshot shows a confirmation pop-up box titled 'NewCreatedLogger'. It features a blue exclamation mark icon in a circle. Below the icon, the text reads 'Add new logger'. Underneath, it asks 'Are you sure you want to add this logger?'. At the bottom, there are two buttons: 'Ok' (green) and 'Cancel' (dark blue).

You can register more than one active logger at your site for a given trial if the investigational product is being stored in multiple locations. Be aware that the system will always apply the temperature data from all the associated loggers (of the same temperature type as the temperature profiles) to the Kits at site, since the system does not know the exact location of each kit.

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2.2 Logger overview

An overview of all loggers registered to your trial/site can be found under **Administration - Loggers - Overview** in the left-hand side menu.

The logger overview is a list of all the logger details, with several options for sorting and searching:

- You can apply one or several filters. This will automatically filter the list view. Filters are removed by clicking the **X**.
- You can use the search field and type in a keyword.
- You can sort the data by clicking the arrow in one of the columns.




LOGGER ID	MANUFACTURER	DESCRIPTION	TRIAL/SITE	TYPE	EXPIRY DATE	STATUS
1234	Other	Lpro	AZ demo / 101	Frozen	22-Oct-2021	Active
dfsdf	Other	twst	DC00MULTI / 101	Frozen	17-Feb-2022	Inactive
asDF	Other	Test1	3 Trial/Sites	Frozen	28-Feb-2022	Inactive
TestLogger	Other	Test1	2 Trial/Sites	Refrigerated	28-Feb-2022	Active
Test2	Other	Test2	3 Trial/Sites	Refrigerated	28-Feb-2022	Active
ABCD123	Other	Fridge 2 floor Sahl.	DC00MULTI / 101	Refrigerated	30-Apr-2022	Active
4425	Other	Test1	3 Trial/Sites	Frozen	21-May-2022	Active
123	Other	Storage Logger 1	AZ demo / 101	Controlled Room Temper...	31-May-2022	Active

To access the details of a logger, click anywhere in the specific row. From the logger details page you can update the trial/site association, replace the logger or inactivate it. You can also access the storage logger upload repository by clicking on the records for the **TIME OF LATEST TEMPERATURE UPLOAD** or **VALUE OF THE LATEST TEMPERATURE DATA POINT**.

LOGGER ID	NAME/DESCRIPTION	TYPE	TIME OF LATEST TEMPERATURE DATA POINT
123	Storage Logger 1	Controlled Room Temperature	31-Jan-2022 01:00
MANUFACTURER	EXPIRY DATE	VALID FROM	VALUE OF LATEST TEMPERATURE DATA POINT
Other	31-May-2022	01-Oct-2021 02:00	OK
TRIAL / SITE (ASSOCIATION/DISSOCIATION DATE)			
AZ demo / 101	18-Oct-2021 02:00	AZ demo / 102	N/A
D933GC00001 / 3501	N/A	D933GC00001 / 5601	N/A
D9670C00001 / 1001	N/A	D933GC00001 / 7501	N/A

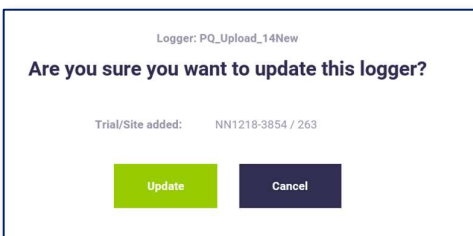
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The logger details view will show you which trials/sites the specific logger is associated with. A green tick mark  indicates the trials/sites the logger is currently associated with and the  sign refers to the date the association was made. A  sign refers to the date a disassociation was made. A yellow plus or minus symbol indicates that an association or disassociation is scheduled.

2.3 Update Trial/Site association for logger

- To associate a logger to a new trial/site, select the checkbox of that trial/site from the specific logger details view
- Select date and time for when the association should be valid from, then click **Confirm**.
- This will prompt a confirmation box, where you click **Update**, if you are done.



Note: You can only associate back in time until: 'Valid from' date of the logger or the last logger temperature date stamp registered for the logger.

Note: If you want to associate forward in time, please be aware of the following:

- If no logger temperature data has been registered for the trial, you can change the association forward in time as needed.
- If logger temperature data has been registered for the trial another storage logger associated to the trial must be in place before moving association forward in time is possible.

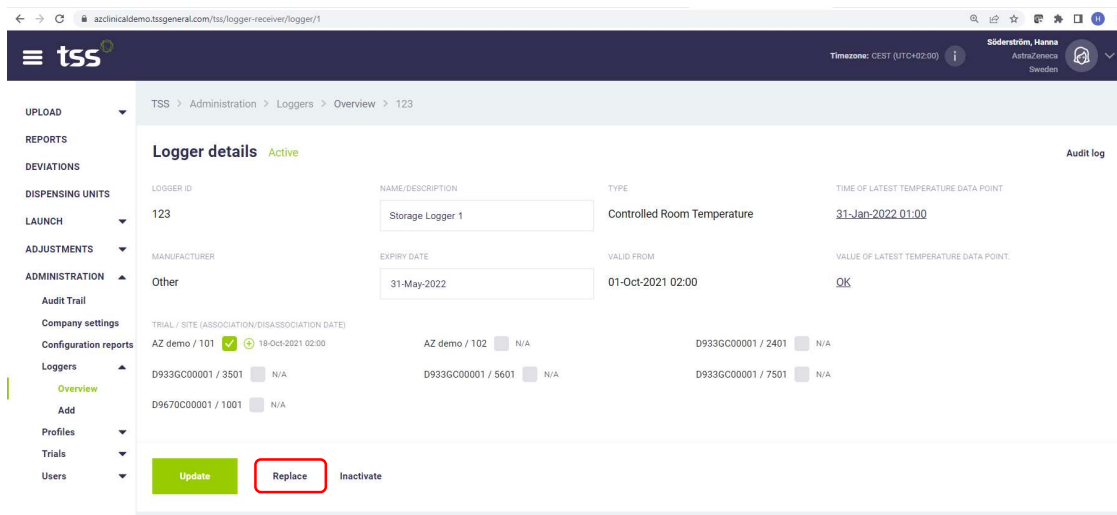
To update an existing trial/site association time, remove the tick for trial/site and then tick off again for the trial/site association. This will prompt you for a popup where new association date can be chosen.

To disassociate a logger from a trial/site, select the check box of that trial/site from the specific logger details view and select date and time for the disassociation to become effective. Click Confirm and then click Update to complete the disassociation.

2.4 Replace a logger

Note: Before replacing a logger, ensure that all excursion data from the existing logger has been uploaded.

To replace a logger, click the **Replace** button in the Logger detail page.



This will open a new page, where you can replace the logger with another logger already registered in the system or replace the logger with a new logger.

Note: Loggers can only be replaced 1 to 1. For example, if you go from two refrigerators, each with a dedicated logger, to just one refrigerator with a single, new dedicated logger, one of the existing loggers would be replaced, and the other would be disassociated and inactivated. Steps for inactivating a logger can be found in section 2.5.

2.4.1 Replace logger with an existing logger

To replace a logger with an existing logger, click the drop-down menu and choose the logger you wish to replace. You can also search for a specific logger name.

Note: A logger can only be replaced by a logger of the same type (Controlled Room Temperature, Refrigerated or Frozen). The drop-down list is automatically sorted by type.

When you click the logger being replaced, a page with the logger details will open.

The screenshot shows the 'Replace logger 123' interface in the TSS application. The breadcrumb trail is 'TSS > Administration > Loggers > Overview > 123 > Replace'. The page title is 'Replace logger 123'. Below the title, there is a dropdown menu for 'WITH AN EXISTING LOGGER' set to 'Demo-CRT-1001 / Demo-CRT-1001'. A table displays the details of the existing logger:

LOGGER ID	NAME/DESCRIPTION	TYPE	TIME OF LATEST TEMPERATURE DATA POINT
Demo-CRT-1001	Demo-CRT-1001	Controlled Room Temperature	N / A

Below the table, there is a 'Cancel replace with existing logger' button. A 'REPLACEMENT DATE' field is set to '01-Apr-2022 02:00', which is highlighted with a red box. A green 'Replace' button is also highlighted with a red box.

- Set the date and time of the replacement. Default time is the date and time you are performing the replacement. If you need to change the replacement date and time, note that the replacement date and time must be after the latest upload or the last association date and must be after the “Valid from” date and time.
- Click **Replace** to replace the old logger with this logger. This will prompt a confirmation box, where you click **Replace**, if you are done.
- If the logger details are not correct, you can cancel the replacement.

The confirmation dialog box is titled 'Are you sure you want to replace this logger?'. It contains the text 'Logger: 123' and 'With logger: Demo-CRT-1001 as of 01-Apr-2022 02:00'. At the bottom, there are two buttons: a green 'Replace' button and a dark blue 'Cancel' button.

2.4.2 Replace logger with a new logger

To replace a logger with a new logger, click the **Create new logger** button on the Replace logger page.

The screenshot shows the 'Replace logger 123' page in the TSS application. The breadcrumb trail is 'TSS > Administration > Loggers > Overview > 123 > Replace'. The page title is 'Replace logger 123'. There are two sections: 'WITH AN EXISTING LOGGER' and 'OR WITH A NEW LOGGER'. The 'OR WITH A NEW LOGGER' section has a red box around the 'Create new logger' button. Below it, there is a 'REPLACEMENT DATE' field with the value '31-Jan-2022 01:00'.

This will open a new page, where you must fill out the logger details for the new logger.

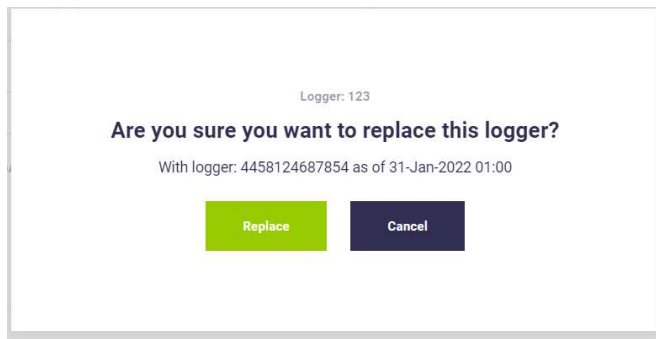
The screenshot shows the 'Replace logger 123' page with the form fields filled out. The breadcrumb trail is 'TSS > Administration > Loggers > Overview > 123 > Replace'. The page title is 'Replace logger 123'. The form has the following fields: 'LOGGER ID' (4458124687854), 'NAME/DESCRIPTION' (Storage Logger 1), 'TYPE' (Controlled Room Temperature), 'MANUFACTURER' (Other), 'EXPIRY DATE' (04-May-2023), and 'REPLACEMENT DATE' (31-Jan-2022 01:00). There is a 'Cancel replace with new logger' button and a green 'Create & replace' button at the bottom.

- Fill out the logger ID, Name/Description, Manufacturer and Expiry date for the new logger (see section 2.1 for explanation of the fields).
- The new logger will automatically inherit the type (I.e. room temp, fridge, frozen) from the logger it is replacing.
- The new logger will also automatically inherit the Trial/Site association from the logger it is replacing.
- You can cancel the replacement process by clicking **Cancel replace with a new logger**
- Set the date and time of the replacement. Default time is the date and time you are performing the replacement. If you need to change the replacement date and time, note that the replacement date and time must be after the latest upload or the last association date and must be after the “Valid from” date and time.

When you are done, click **Create & replace**. This will prompt a confirmation box, where you click **Replace**, if you are done.

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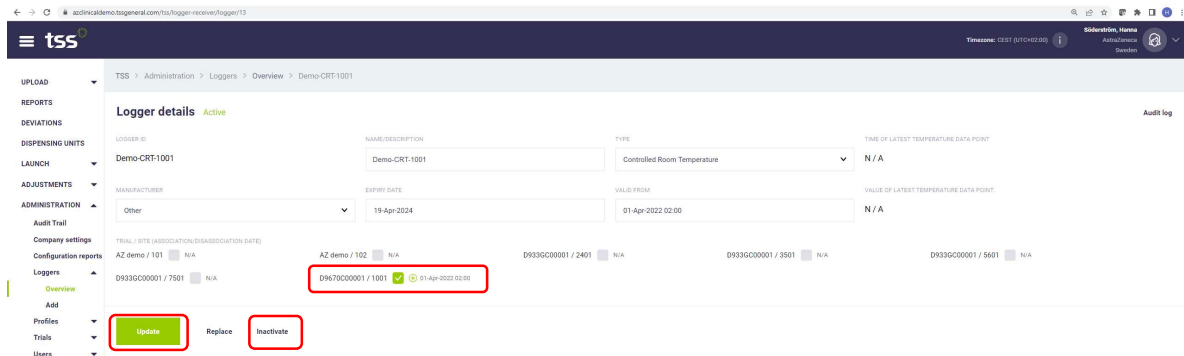
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2.5 Inactivate a logger

A registered logger no longer in use can be deactivated. It is very important the logger is not associated to any active trial/site when it is deactivated. The process is:

- Go to **Administration - Loggers - Overview** in the left-hand side menu
- In the logger overview, find the logger you want to deactivate and click on it
- On the Logger details page for that specific logger, check the trial/site association.
- If the logger is not associated with any trials, click **Inactivate**. This will take you back to the logger overview, where status for the logger will be changed to Inactive.
- If the logger is associated to any active trial, see below:



- Disassociate Trial/site by unchecking the green tick mark in the box.
- When you have unchecked the tick mark, click **Update**. This will prompt a confirmation box, where you click **Update**, if you are done.
- This will take you back to the logger overview page, where you need to click on the specific logger again to deactivate it.

2.6 Reactivate an inactive logger

An inactive logger can be reactivated again, but only if this is within the expiry parameters specified in the calibration certificate.

To reactivate a logger, do the following:

- Find the inactive logger in the **Logger overview**. This can be done by applying the Status filter.
- Open the specific logger details page and click **Reactivate**.
- This will prompt a confirmation box, where you click **Update**, if you are done.

For further support please contact the **MonTe Help Desk** montehelp@tss.se

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The screenshot shows the 'Logger details' page for an inactive logger. The logger ID is 123, named 'Storage Logger 1', with a type of 'Controlled Room Temperature'. The time of the latest temperature data point is '31-Jan-2022 01:00'. The manufacturer is 'Other' and the expiry date is '31-May-2022'. The valid from date is '01-Oct-2021 02:00' and the value of the latest temperature data point is 'OK'. A 'Reactivate' button is highlighted with a red box.

The logger will now appear in the Logger overview as active but have no trial/site associations. See section 2.3 for how to associate loggers to a trial/site.

2.7 Logger Audit Log

Every logger registered in the system, has an audit log of all historic changes. This can be accessed via the Logger details page by clicking Audit log.

The screenshot shows the 'Logger details' page for an active logger. The logger ID is Demo-CRT-1001, named 'Demo-CRT-1001', with a type of 'Controlled Room Temperature'. The time of the latest temperature data point is 'N/A'. The manufacturer is 'Other' and the expiry date is '19-Apr-2024'. The valid from date is '01-Apr-2022 02:00' and the value of the latest temperature data point is 'N/A'. An 'Audit log' button is highlighted with a red box.

The audit log gives you an overview of which changes were made, by whom and when.

The screenshot shows a web browser window with the URL `azclinicaldemo.tssgeneral.com/tss/logger-receiver/logger/1/audit`. The application header includes the TSS logo, the user name 'Söderström, Hanna', and the company 'AstraZeneca Sweden'. The breadcrumb trail is 'TSS > Administration > Loggers > Overview > 123 > Audit log'. The left sidebar contains a navigation menu with categories like 'UPLOAD', 'REPORTS', 'DEVIATIONS', 'DISPENSING UNITS', 'LAUNCH', 'ADJUSTMENTS', and 'ADMINISTRATION'. The 'ADMINISTRATION' section is expanded, showing 'Audit Trail', 'Company settings', and 'Configuration reports'. Under 'Configuration reports', 'Loggers' is expanded to show 'Overview' (highlighted in green), 'Add', 'Profiles', 'Trials', and 'Users'. The main content area is titled 'Logger audit log' and displays two log entries. The first entry is for an inactivated logger (#123) at 09:25 UTC, performed by Hanna Söderström. The second entry is for a reactivated logger (#123) at 09:23 UTC, also performed by Hanna Söderström. Both entries show a 'Status' of 'SUCCESS' and a 'Changed values' table for the 'discontinuedDate' field.

Timestamp	12-May-2022 09:25 UTC						
Description	Inactivated logger #123						
User	Söderström, Hanna (1171, hanna)						
Office	Sweden						
Action	LOGGER_MANAGEMENT						
Status	SUCCESS						
Changed values	<table border="1"><thead><tr><th>Field</th><th>Before</th><th>After</th></tr></thead><tbody><tr><td>discontinuedDate</td><td></td><td>2022-05-12 09:25:07</td></tr></tbody></table>	Field	Before	After	discontinuedDate		2022-05-12 09:25:07
Field	Before	After					
discontinuedDate		2022-05-12 09:25:07					

Timestamp	12-May-2022 09:23 UTC						
Description	Reactivated logger #123						
User	Söderström, Hanna (1171, hanna)						
Office	Sweden						
Action	LOGGER_MANAGEMENT						
Status	SUCCESS						
Changed values	<table border="1"><thead><tr><th>Field</th><th>Before</th><th>After</th></tr></thead><tbody><tr><td>discontinuedDate</td><td></td><td>2022-05-12 09:23:47</td></tr></tbody></table>	Field	Before	After	discontinuedDate		2022-05-12 09:23:47
Field	Before	After					
discontinuedDate		2022-05-12 09:23:47					