



# MonTe

Monitoring Temperature of Clinical Study Drugs

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## MonTe Portal User Guide

Report an Excursion or Gap Deviation

# MonTe

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### 1. Introduction

This user guide describes how to report temperature excursions and temperature data gaps to the MonTe system, and the results you will get from the system. This includes uploads from all types of storage loggers on site.

The user guide is relevant for site users and monitors.

### 2. Reporting a Temperature Excursion

Storage loggers are monitoring the temperature in the storage unit (controlled room temperature, refrigerated or frozen) when the products are stored at the site. **Temperature data from the storage loggers must be uploaded when an alarm is triggered.**

If you have more than one active logger of a particular temperature profile (i.e., controlled room temperature, refrigerated, frozen) registered to a given trial, the system will always apply the worst-case temperature readings from all active loggers to all the kits at the site (with the same temperature profile type), since the system does not know the exact location of each kit.

If you have one active logger of a particular temperature profile (i.e., room temperature, refrigerated, frozen) associated with multiple trials, the system will apply the temperature readings from that active logger to kits across the multiple trials.

#### 2.1 Duration of Excursion

The length of an excursion is from the last time that the temperature was known to be within the correct temperature range, to the next time it is known to be back within the correct temperature range.

For example, a product stored 2-8c:

<u>TIME</u>	<u>TEMPERATURE</u>
08:00	7.6°C
08:15	8.7°C
08:30	9.4°C
08:45	7.2°C

The duration of the excursion shown in the example would be **45 minutes**.

This is because the last known time that the temperature was within the correct temperature range was 08:00 and next known to be back within range at 08:45.

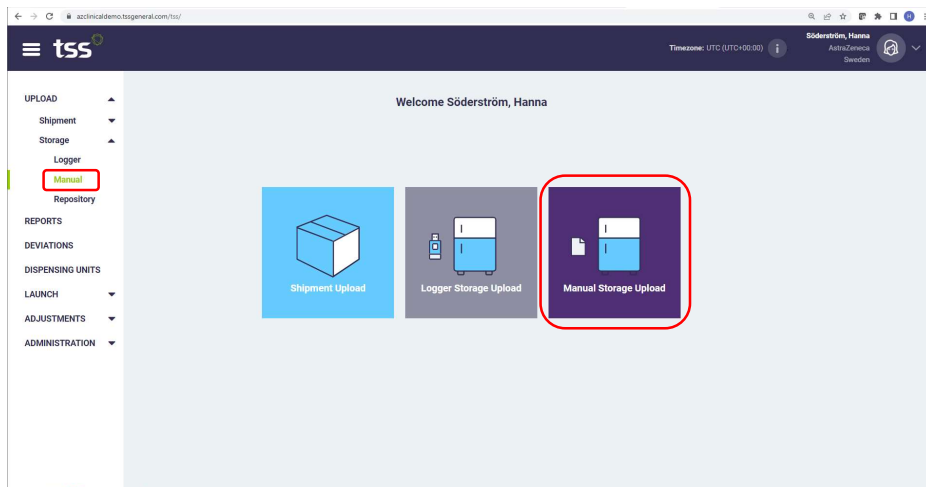
#### 2.2 Manual storage upload – with temperature excursion

Manual loggers refer to all types of storage loggers that are used by your site.

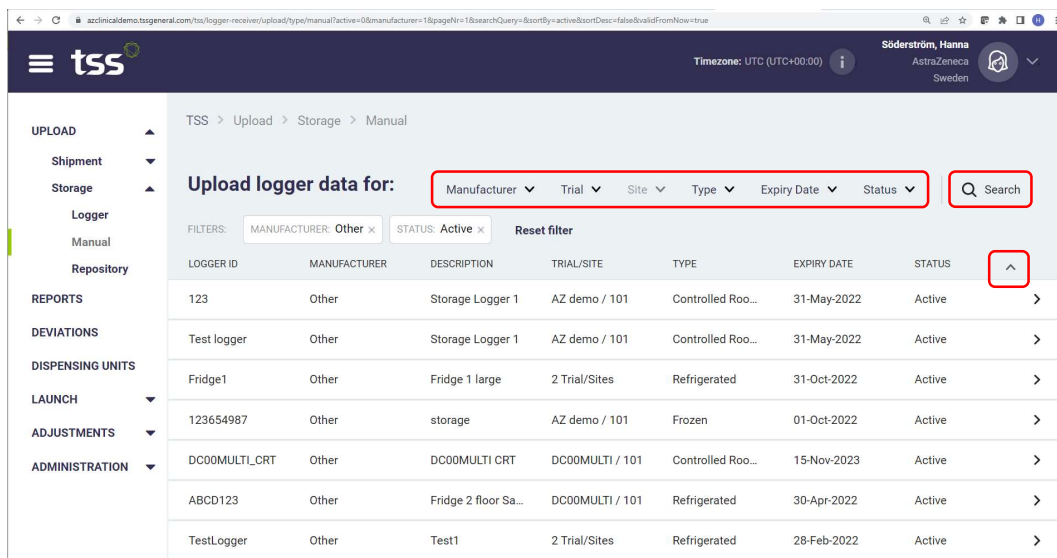
To upload temperature excursion data from a manual storage logger, click on the **Manual Storage Upload** quick link on the opening page or go to **Uploads → Storage → Manual** in the left-hand side menu.

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This will open the Manual Storage Logger Overview.



The **Manual Storage Logger Overview** is a list of all the storage loggers that have been created and associated with your trial(s)/site. The overview has several options for sorting and searching for a specific logger:

1. You can apply one or several filters. This will automatically filter the list view. Filters are removed again by clicking the X.
2. You can use the search field and locate the logger.
3. You can sort the data by clicking the arrow in one of the columns (see status column above)

Select the logger you are uploading temperature data for by clicking the row. This will open the Logger Upload page.

The screenshot shows the 'Upload logger data for period' form in the TSS application. The form is titled 'Upload logger data for period:' and includes the following fields and options:

- FROM:** 31-Jan-2022 00:00
- TO:** 28-Feb-2022 00:00
- Was the temperature in range for the entire period?:**  Yes  No
- Excursion details:**
  - START DATE:** 08-Feb-2022 07:00
  - END DATE:** 08-Feb-2022 14:00
  - TEMPERATURE (ENTER MIN OR MAX TEMPERATURE OR BOTH):** Celsius, Min: 3.0 °C, Max: 16.0 °C
  - COMMENT (OPTIONAL):** Fridge door unintentionally left open.
- Was there any gap(s)?**  Yes  No
- Temperature data file upload:**

To upload logger data:

1. Define the period the upload covers by selecting the date and time in the **To** field. The **From** field will per default be set to the end date of the last upload. Double check that the time has been entered accurately.
2. Specify that temperature was not in range for the entire given period by selecting **No**.
3. Fill out the excursion details. Specify the Start and End date and time for the excursion period. Then fill in the minimum and/or maximum temperature for the excursion. Note that at least one minimum or maximum temperature must be reported, and an End date and time must be entered. A comment can be added, but it is optional.
4. Add the temperature logger data file or other supporting documents: this can be done using drag and drop or clicking **Browse** to locate the file (e.g. pdf, jpeg or png) on your computer.
5. When you are done, click **Confirm**. This will prompt a confirmation box, where you click **Yes**, if you are done.

**NOTE:** Please check that the logger file you are about to upload is for the correct logger ID and trial/sites before you confirm. If not, click **No, I want to change this**.

### 2.3 Manual Storage Logger - Upload Result

When the storage logger excursion upload is successfully submitted, the system will analyse (calculate) the data and conclude if a temperature deviation was generated during last period of storage and if any actions are required.

A conclusion page is shown with product name, batch number and conclusion. A notification of upload and result is also sent by email to site users and monitors, who are associated to the trial and site.

- **“No excursions detected” (green)** means the temperature was in range for the entire period.

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- **“Excursion detected, no action required” (orange)** means the temperature was partly outside of the ideal temperature range for the product but based on the stability data, the product is determined by the system to be ok to use.
- **“Temperature deviations have been detected and relevant resources have been informed. Please refer to your user instructions for further information.” (red)** means that the product must be quarantined (physically and in IRT/RTSM if applicable) and that the sponsor will investigate the deviation and come back with information on how to handle the product.

If a deviation has occurred, the system will automatically notify the relevant people to initiate further evaluation.

Click the underlined sentence **“Click here to enter a deviation comment and next dispensing visit date if applicable.”** to open the comment and date selector field. Enter the next dispensing visit date to help the MonTe team define criticality and review the deviation data.

The screenshot shows the MonTe system interface. At the top, there is a navigation bar with the TSS logo, time zone (CET), and user information (Söderström, Hanna). A sidebar on the left contains menu items: UPLOAD, REPORTS, DEVIATIONS, Kits (DUNs), LAUNCH, ADJUSTMENTS, and ADMINISTRATION. The main content area displays a red warning icon and the message "Upload successful". Below this, a red text block states: "Temperature deviations have been detected and relevant resources have been informed. Please refer to your user instructions for further information." A red underlined link reads: "Click here to enter a deviation comment and next dispensing visit date if applicable." Below the link, it says "Uploaded files:" followed by a file name: "6141de0805fe6ac7f0d01564\_logo-medium.png". A table below shows deviation data:

TRIAL / SITE	PRODUCT NAME	BATCH NO.	CONCLUSION
D9670C00001 / 1001	DS-8201a	9A010A	Quarantine - All Kits (DUNs) <a href="#">View Kits (DUNs)</a>
	MED14736 or PTM	HE1066-CJ2900	Quarantine - All Kits (DUNs) <a href="#">View Kits (DUNs)</a>

The screenshot shows the "Add deviation comment" form. It includes a text area for the comment, a "COMMENT" label, and a "Deviation(s) detected during the upload. Please add a comment to the deviation and register the next dispensing visit date if applicable." instruction. Below the text area, there are three input fields: "TRIAL/SITE" (AZ demo/102), "DEVIATION TYPE" (TEMPERATURE), and "NEXT DISPENSING VISIT" (16-Jun-2022 00:00). At the bottom, there are "Submit" and "Cancel" buttons.

**NOTE:** The system calculates deviations on Kit ID level and while some Kits must be quarantined, others may be okay based on arrival from shipment and/or previous excursions.

On all conclusion pages you can expand the view to Kit ID (DUN) level by clicking **View Kit ID (DUN)**. Please note individual kits may have different status.

Timezone: CEST (UTC+02:00) | Stjernedal, Andreas | AstraZeneca Sweden

View upload result

**Upload successful**

Temperature deviations have been detected and relevant resources have been informed. Please refer to your user instructions for further information.  
[Click here to enter a deviation comment and next dispensing visit date if applicable.](#)

Uploaded files:  
Screenshot 2023-05-05 134842.png

TRIAL / SITE		
AZ demo / 101		
PRODUCT NAME	BATCH NO.	CONCLUSION
Cisplatin 5g	OC0164B01	Quarantine - All Kits (DUNs)
KIT ID (DUN)      SHIPMENT NO.      CONCLUSION		
18064101	2112010101	Quarantine product - await manual deviation handling
18064201	2112010101	Quarantine product - await manual deviation handling
18064301	2112010101	Quarantine product - await manual deviation handling
18064401	2112010101	Quarantine product - await manual deviation handling

### 3. Reporting a Gap Deviation

Sites can trigger a Gap Deviation if a period with missing temperature data is reported. This could happen for example if a logger is replaced by another logger and there is a period of time where no temperature data is available for the storage area.

A Gap Deviation will automatically send notifications to the relevant people and the sponsor will initiate the evaluation process. You must upload any back up temperature data you have or indicate you have no back up data.

### 3.1 Manual Storage Upload – Report Gap

If the temperature data is not continuous, and there is a gap in the data that needs to be reported, follow this process. Before adding it to MonTe the site user/monitor should do a risk assessment of the gap to determine the likely minimum/maximum temperature and duration of that potential excursion. If the risk of temperature excursion is low, it is Good Clinical Practice (GCP) decision to use the material as no excursion has occurred, and a temperature gap does not need to be reported. If the risk of temperature excursion is medium or higher, it must be logged in MonTe and the risk assessment documented separately. This risk assessment must be uploaded to MonTe as a supporting file.

To report a gap deviation:

1. Define the period the upload covers by selecting the date and time in the **To** field. The From field will per default be set to the end date of the last upload.
2. Specify if there were also a temperature excursions in the timer period specified by selecting **Yes** or **No** for the question “Was the temperature in range for the entire period?” .
3. Choose **Yes** when answering “Was there any gap(s)?”, and fill out the gap details. Specify the Start and End date and time for the gap period. A comment should be added describing the situation in which the gap was discovered.
4. Add the temperature logger data file or other supporting document by drag and drop or click Browse to locate the file (pdf, jpeg or png) on your computer.
5. When you are done, click **Confirm**. This will prompt a confirmation box, where you click **Yes**, if you are done.

**NOTE:** Please check that the logger file you are about to upload is for the correct logger ID and trial/sites before you confirm. If not, click **No, I want to change this**.

### 4. Manual adjustment of Manual Storage Logger Upload Result

The ability to perform a manual adjustment functionality is limited to monitors only, and is to correct temperature data if reporting of temperature excursions has not been registered correctly by the site.

Go to **Adjustments** → **Add** in the left-hand side menu and select **Logger Adjustment**.

Select **Logger adjustment** under Type

Select the logger to adjust temperature data for and do the temperature adjustments. Remember to attach temperature data to the adjustment.

The logger adjustment does not have any approval flow, so be sure you have entered correct temperature adjustments before confirming the adjustment.

The screenshot displays the 'Adjustments' page in the MonTe application. The breadcrumb trail at the top reads 'TSS > Adjustments > Add > Logger adjustment'. The left-hand navigation menu includes sections for 'UPLOAD', 'REPORTS', 'DEVIATIONS', 'ADJUSTMENTS', and 'ADMINISTRATION'. Under 'ADJUSTMENTS', the 'Add' button is highlighted with a red box. The main content area is titled 'Adjustments' and contains the following fields:

- TYPE:** A dropdown menu with 'Logger adjustment' selected, highlighted with a red box.
- SELECT LOGGER TO ADJUST:** A dropdown menu with '1099910' selected, highlighted with a red box.
- Temperature Adjustments:** A section with the instruction 'The entered data will result in an adjustment to corresponding interval for the affected time'. It includes:
  - START DATE:** An empty text input field, highlighted with a red box.
  - END DATE:** An empty text input field, highlighted with a red box.
  - TEMPERATURE (ENTER MIN OR MAX TEMPERATURE OR BOTH):** Two input fields for 'Min' and 'Max' temperatures in degrees Celsius. The 'Min' field contains a red dashed box around the input area, and the 'Max' field also contains a red dashed box around the input area.
- Add temperature level:** A green button at the bottom of the form.

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Once done, click **Approve** and confirm the adjustment on the popup.

**Are you sure you want to adjust this logger?**

LOGGER ID  
august12

**Temperature Adjustments**

START DATE	END DATE
01-Aug-2019 00:00	03-Aug-2019 00:00
MIN	MAX
2 °C	6 °C

COMMENT  
N / A

ATTACHED FILE(S)  
N / A

[Confirm](#) [Cancel](#)

After confirming the adjustment, you will be directed to a page where you can see the details of the adjustment including the result of the adjustment

**Adjustment details** Approved [Audit log](#) [Print](#)

ID	TYPE	STATUS DATE
ADJS000298	Logger	16-Oct-2019 13:47
REFERENCE	COMMENT	ATTACHED FILE(S)
N / A	N / A	N / A

LOGGER ID  
august12

**Temperature Adjustments**

START DATE	END DATE
01-Aug-2019 00:00	03-Aug-2019 00:00
MIN	MAX
2 °C	6 °C

**Results**

TRIAL / SITE			
NN8640-4263 / 101			
PRODUCT NAME	BATCH NO.	CONCLUSION	
Open Label Medication1	OL4263B	<span>⚠</span> Quarantine - All DUNs	<a href="#">View DUNs</a>

### 4.1 Storage logger Repository

In the repository the processed reporting for all storage loggers can be retrieved. To narrow the display result you can use search and filter functionalities. From here you can view the storage logger upload reports or add additional documentation to a specific storage logger.

LOGGER ID	MANUFACTURER	DESCRIPTION	TRIAL/SITE	LAST UPLOAD	UPLOADED BY
dfdf	Other	twst	DC00MULTI / 101	09-May-2022 15:56	Maldonado, Sandra
asdf	Other	Test1	3 Trial/Sites	29-Mar-2022 17:26	Maldonado, Sandra
TestLogger	Other	Test1	2 Trial/Sites	24-Mar-2022 12:14	Fardis, Michalis
DC00MULTI_CRT	Other	DC00MULTI CRT	DC00MULTI / 101	16-Mar-2022 14:36	Söderström, Hanna
Fridge1	Other	Fridge 1 large	2 Trial/Sites	24-Feb-2022 09:55	Fardis, Michalis
Test logger	Other	Storage Logger 1	AZ demo / 101	24-Feb-2022 09:55	Fardis, Michalis
123	Other	Storage Logger 1	AZ demo / 101	24-Feb-2022 09:54	Fardis, Michalis
123654987	Other	storage	AZ demo / 101	24-Feb-2022 09:53	Fardis, Michalis
DC00MULTI_REF	Other	DC00MULTI_REF	DC00MULTI / 101	01-Dec-2021 22:15	Stjerndal, Anders

The overview has several options for sorting and searching for a specific logger:

- You can apply one or several filters. This will automatically filter the list view. Filters are removed again 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.

To view previously processed storage logger uploads, click on the logger row. This will open the logger details page, where uploads for that particular logger will be listed at the bottom.

MISSION ID	UPLOADED TIME	UPLOADED BY	START	END
1	16-Mar-2022 14:36	Söderström, Hanna	01-Nov-2021 00:00	09-Mar-2022 02:00

START	END	FILE ( FILE TYPE)	UPLOAD RESULT	VIEW IN CHART
09-Mar-2022 01:00	09-Mar-2022 01:30	Picture1.png ( A )	View upload result	

From the Logger details page click the arrow down. Then you can:

- View the result report by clicking the View Upload result. This will open a PDF file.
- Open the temperature data files by clicking the link under files FILE.

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- Add additional documents to that particular data upload by clicking Additional Upload. This opens a file upload window. Drag and drop the files you want to add to the upload or click Browse to locate the files on your computer. Click Confirm when you are done.
- Export the uploaded temperature data by clicking Export mission data
- View the upload(s) in a chart by ticking the checkbox VIEW IN CHART

### 4.2 Audit log

From the logger details view the audit log for the logger can also be accessed by clicking **Audit Log** in the top right-hand side corner. The audit log gives you an overview of which changes were made, by whom and when.

The screenshot displays the 'Logger audit log' for 'DCC00MULTI\_CRT'. The audit log table shows the following changes:

Field	Before	After
clinicalLoggerType		Controlled Room Temperature
latestLoggerTrialUnits	[ Trial 'DCC00MULTI/Site101' from 2021-11-01 00:00:00 ]	[ Trial 'DCC00MULTI/Site101' from 2021-11-01 00:00:00 ]
active	true	true
description		DCC00MULTI_CRT
office		Svefen (43)
validFrom		2021-11-01 00:00:00
loggerTrialUnits	[ Trial 'DCC00MULTI/Site101' from 2021-11-01 00:00:00 ]	[ Trial 'DCC00MULTI/Site101' from 2021-11-01 00:00:00 ]
expiryDate		2023-11-15 23:59:59
unitSerialNo		DCC00MULTI_CRT
clinicalLoggerModel		(Other)
company		AstraZeneca
id		6
loggerAdjustments	[ ]	[ ]