



MonTe

Monitoring Temperature of Clinical Study Drugs

MonTe Portal User Guide

Shipment webLogger Upload

MonTe

Monitoring Temperature of Clinical Study Drugs

Table of Contents

1. Introduction.....	3
2. Upload webLogger.....	3
2.1 Shipment receipt	3
2.2 Upload loggers.....	3
2.3 Shipment upload result	5
2.4 Shipment upload repository.....	7
3. Product information.....	8

MonTe

Monitoring Temperature of Clinical Study Drugs

1. Introduction

This user guide describes how to upload a webLogger (USB temperature logger) to MonTe. The user guide is relevant for Depot and Site users who are receiving shipments.

2. Upload webLogger

Before upload of a shipment logger, ensure that at least one storage logger is registered for the clinical site (see the User guide Storage Temperature Logger Registration on how to add a logger). Note this is not applicable for a depot.

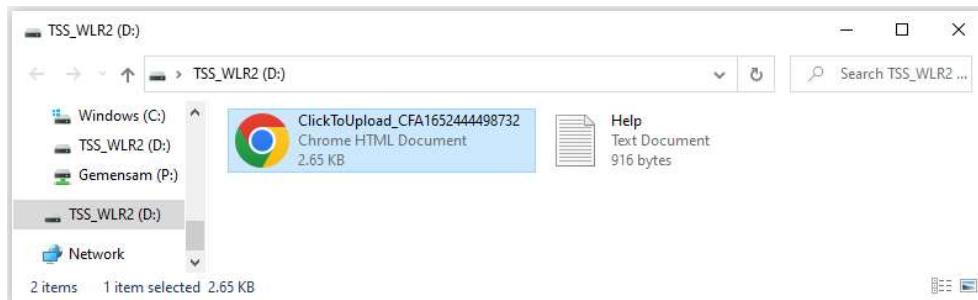
2.1 Shipment receipt

As soon as the shipment is received and the shipment logger is removed from the product, press and hold the STOP button on the logger until the red light turns on (3 seconds).



2.2 Upload loggers

To upload temperature data from a shipment logger, connect the logger to the computer USB port and wait for a dialog box to open on the screen. (If the dialog box doesn't open automatically, browse for "TSS_WLR2" in the file explorer).



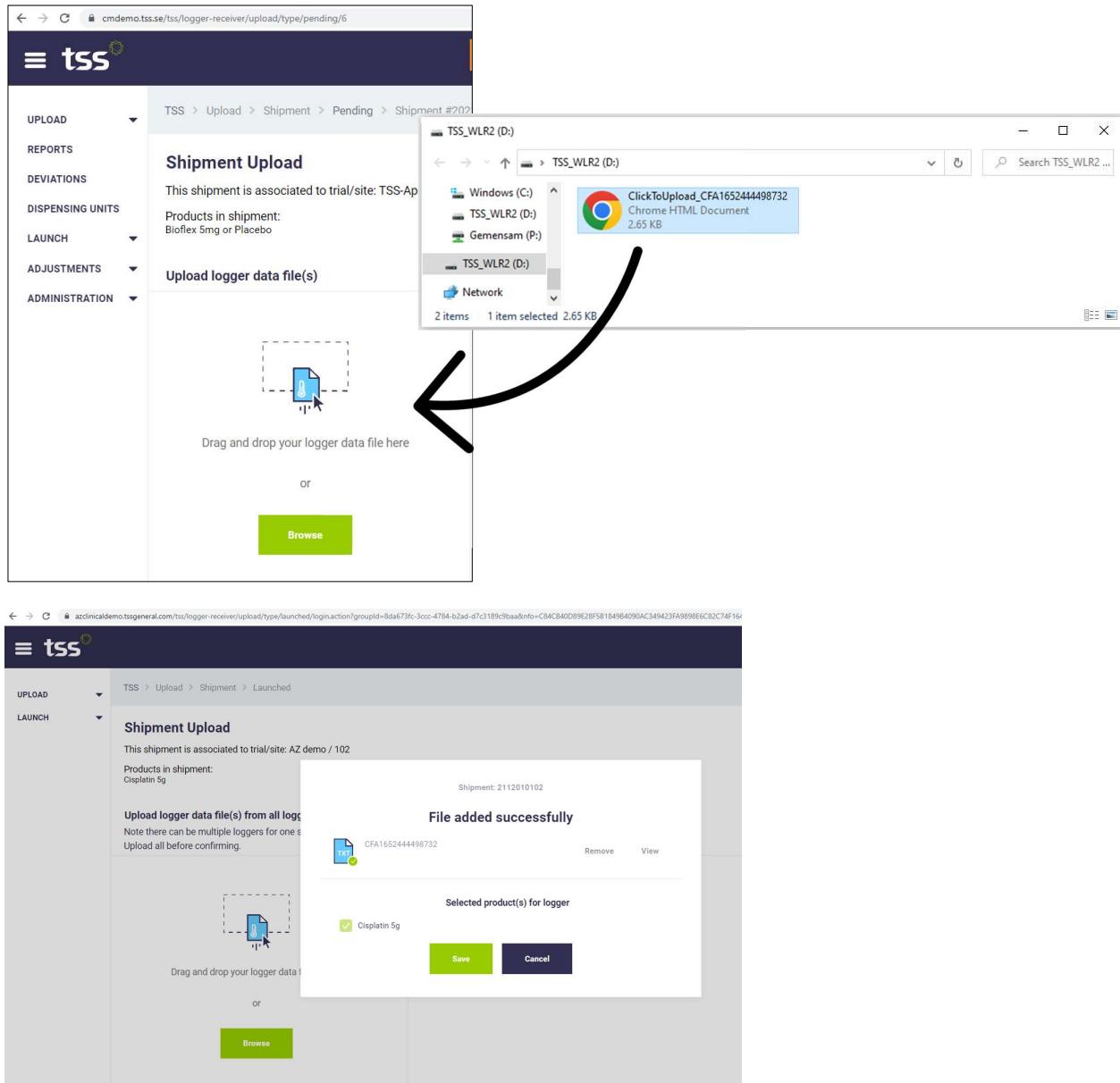
Double click on the "ClickToUpload" file. This will open your web browser, where you need to login to the MonTe system.



MonTe

Monitoring Temperature of Clinical Study Drugs

Drag and drop the file from the shipment logger or click **Browse** to locate the file.



The screenshot shows the MonTe software interface for monitoring clinical study drugs. The top part is a 'Shipment Upload' screen where a file can be drag-and-dropped or browsed. A file named 'ClickToUpload_CFA165244498732' is shown in a file explorer window being selected. A large black arrow points from this file to the 'Drag and drop your logger data file here' field. The bottom part shows a confirmation dialog for a successfully uploaded file, with a 'Save' button highlighted.

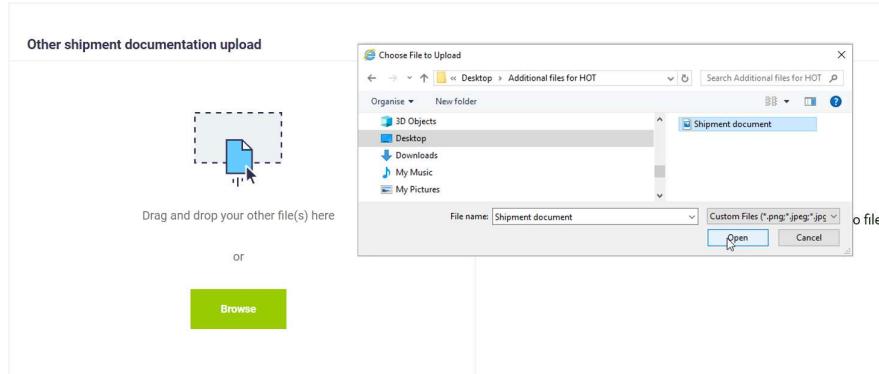
When the file has been successfully uploaded, a new window will appear. Click **Save**, when you are done.

If the shipment included several shipment loggers, drag and drop the file from the next shipment logger or click **Browse** to locate the file and repeat the steps above for all loggers.

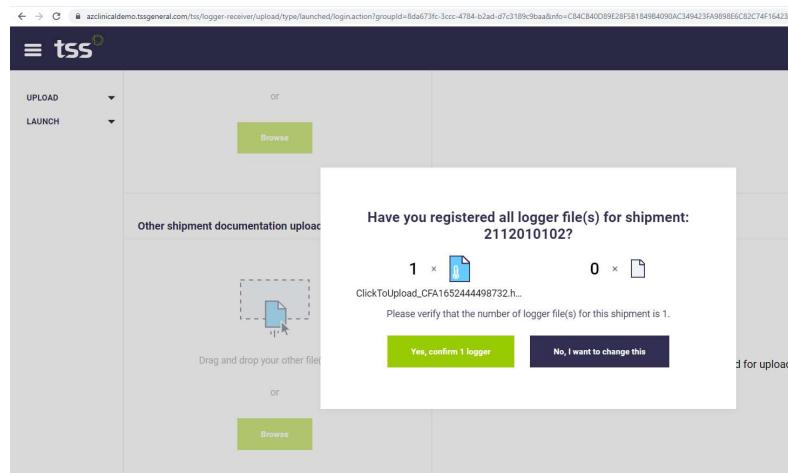
If you need to upload other shipment documentation, drag and drop the file or click **Browse** to locate the file, to the **Other shipment documentation upload** section. You can upload additional files of type pdf, jpeg and png. This is not mandatory.

MonTe

Monitoring Temperature of Clinical Study Drugs



Scroll down and click **Confirm** when you have uploaded data from *all* shipment loggers in the shipment. This will prompt a confirmation box, where you confirm the number of files you have uploaded data for by clicking **Yes, confirm (name) logger**.



2.3 Shipment upload result

When the shipment logger upload is successfully submitted, the system will analyse (calculate/evaluate) the data and conclude if any temperature event (excursion or deviation) was generated during shipment 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 / depot users and monitors.

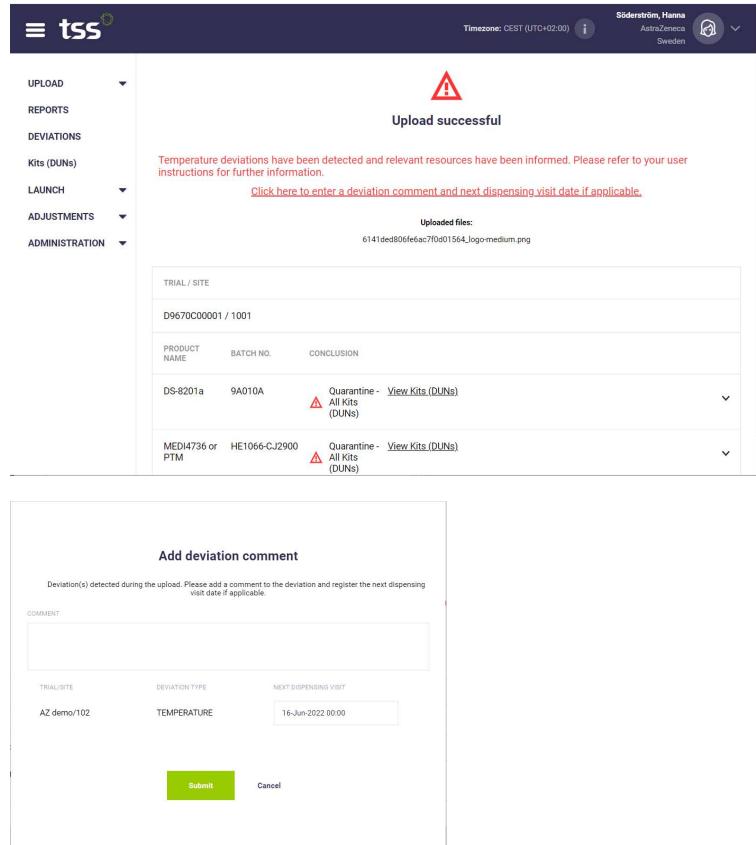
- **No excursions detected** (green) means the temperature was in range for the entire period.
- **Excursion detected, no action required** (orange) means the temperature was partly outside of the ideal temperature range for the product but based on the stability data, the product is determined by the 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 (both physically and in IRT/RTSM if applicable) and that the sponsor will investigate the temperature deviation and come back with information on how to handle the product.

MonTe

Monitoring Temperature of Clinical Study Drugs

If a deviation has occurred, the system will automatically notify the relevant people to initiate further evaluation. You must, however, refer to your user instructions for further information to assess next steps.

You can add a comment and include the next dispensing visit date to help the Monte team define criticality and review the deviation data. Click the underlined sentence to open the comment and date selector field. It is not a mandatory field and can be left blank.

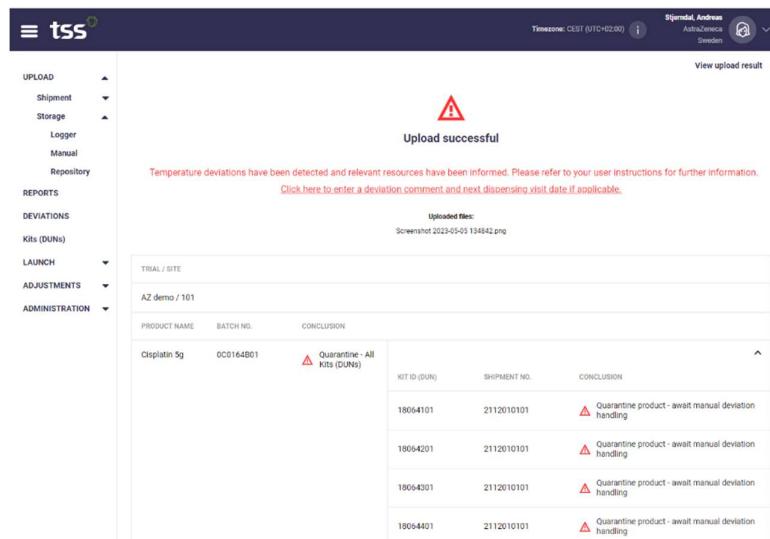


The screenshot shows the MonTe software interface. At the top, there is a navigation bar with 'tss' logo, 'Timezone: CEST (UTC+02:00)', and user information 'Söderström, Hanna AstraZeneca Sweden'. The left sidebar has dropdown menus for 'UPLOAD', 'REPORTS', 'DEVIATIONS', 'Kits (DUNs)', 'LAUNCH', 'ADJUSTMENTS', and 'ADMINISTRATION'. The main content area shows a success message 'Upload successful' with an exclamation mark icon. Below it, a note says 'Temperature deviations have been detected and relevant resources have been informed. Please refer to your user instructions for further information.' A link 'Click here to enter a deviation comment and next dispensing visit date if applicable.' is provided. The 'DEVIATIONS' section shows a table with two rows. The first row for 'DS-8201a' has a 'Quarantine - View Kits (DUNs)' link. The second row for 'MED4736 or PTM' has a 'Quarantine - View Kits (DUNs)' link. At the bottom, a modal window titled 'Add deviation comment' is open, showing a text area for 'COMMENT', a table for 'TRIAL/SITE', 'DEVIATION TYPE', and 'NEXT DISPENSING VISIT' (set to '16-Jun-2022 00:00'), and 'Submit' and 'Cancel' buttons.

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.

MonTe

Monitoring Temperature of Clinical Study Drugs



Timezone: CEST (UTC+02:00) Sjerndal, Andreas Administration Sweden

Upload successful

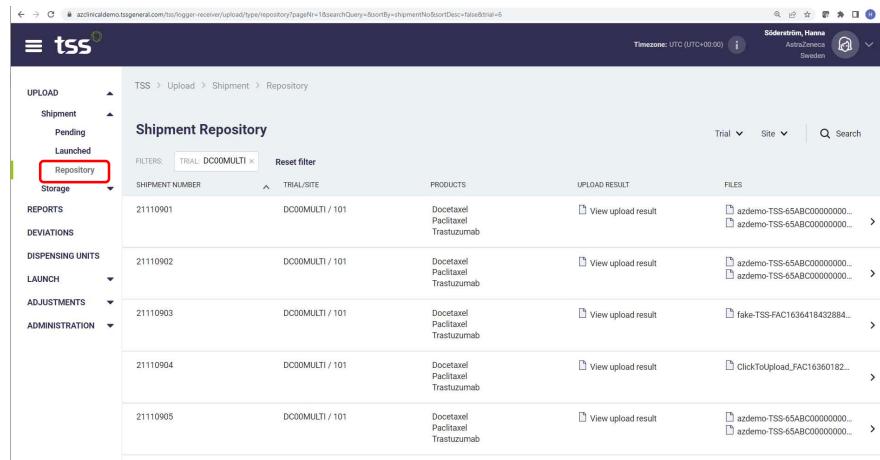
Temperature deviations have been detected and relevant resources have been informed. Please refer to your user instructions for further information.
Click here to enter a deviation comment and next dispensing visit date if applicable.

Uploaded files: Screenshot 2023-05-03 134842.png

TRIAL / SITE	AZ demo / 101	
PRODUCT NAME	BATCH NO.	CONCLUSION
Cisplatin 5g	0C0164B01	⚠️ 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

2.4 Shipment upload repository

To access the shipment upload repository of already processed shipment uploads go to **Upload → Shipment → Repository** in the left-hand side menu. From here you can view the shipment upload reports or add additional documentation to a specific shipment.



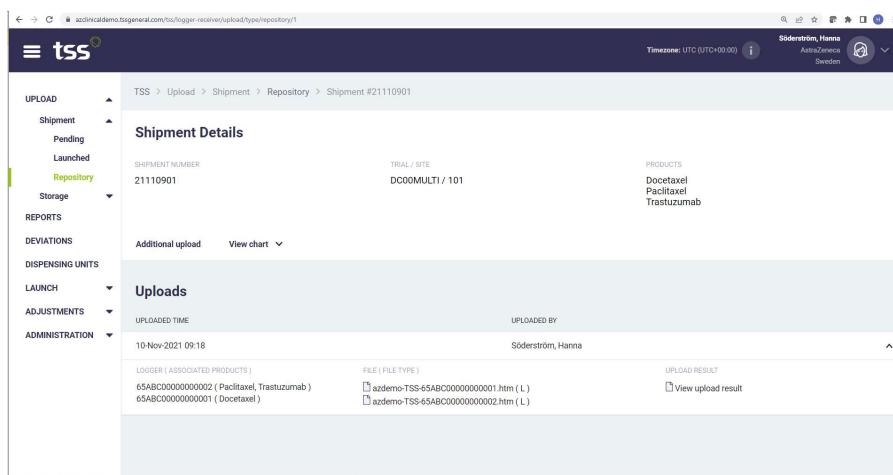
Timezone: UTC (UTC+00:00) Sjerndal, Hanna AstraZeneca Sweden

Shipment Repository

TRIAL: DC00MULTI

SHIPMENT NUMBER	TRIAL/SITE	PRODUCTS	UPLOAD RESULT	FILES
21110901	DC00MULTI / 101	Docetaxel Paclitaxel Trastuzumab	View upload result	azdemo-TSS-65ABC00000000... > azdemo-TSS-65ABC00000000... >
21110902	DC00MULTI / 101	Docetaxel Paclitaxel Trastuzumab	View upload result	azdemo-TSS-65ABC00000000... > azdemo-TSS-65ABC00000000... >
21110903	DC00MULTI / 101	Docetaxel Paclitaxel Trastuzumab	View upload result	fake-TSS-FAC1636418432884... >
21110904	DC00MULTI / 101	Docetaxel Paclitaxel Trastuzumab	View upload result	ClickToUpload_FAC16360182... >
21110905	DC00MULTI / 101	Docetaxel Paclitaxel Trastuzumab	View upload result	azdemo-TSS-65ABC00000000... > azdemo-TSS-65ABC00000000... >

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



LOGGER ASSOCIATED PRODUCTS	FILE FILE TYPE	UPLOAD RESULT
65ABC000000000002 (Paclitaxel, Trastuzumab)	azdemo-TSS-65ABC0000000001.htm (L)	View upload result
65ABC000000000001 (Docetaxel)	azdemo-TSS-65ABC0000000002.htm (L)	

From the Shipment details page you can:

1. View the result report by clicking the **View Upload result**. This will open a PDF file.
2. Open the temperature data files by clicking the link under FILE. Temperature data files are preceded by (L) Open additional files by clicking the link under FILE. Additional files are preceded by (A)
3. Add additional webLoggers or files to the shipment by clicking **Additional Upload**
4. View a temperature graph by clicking **View Chart**.

3. Product information

Do not dispose of the WebLogger until at least 48 hours have passed after upload of data should there be any issues. DO NOT return the WebLogger. Kindly discard the monitor device at your site in line with local recycling requirements. Please note that the product contains a lithium battery.

Please find product specifications and other documentation related to the webLogger on the MonTe support portal help.monterezervat.se