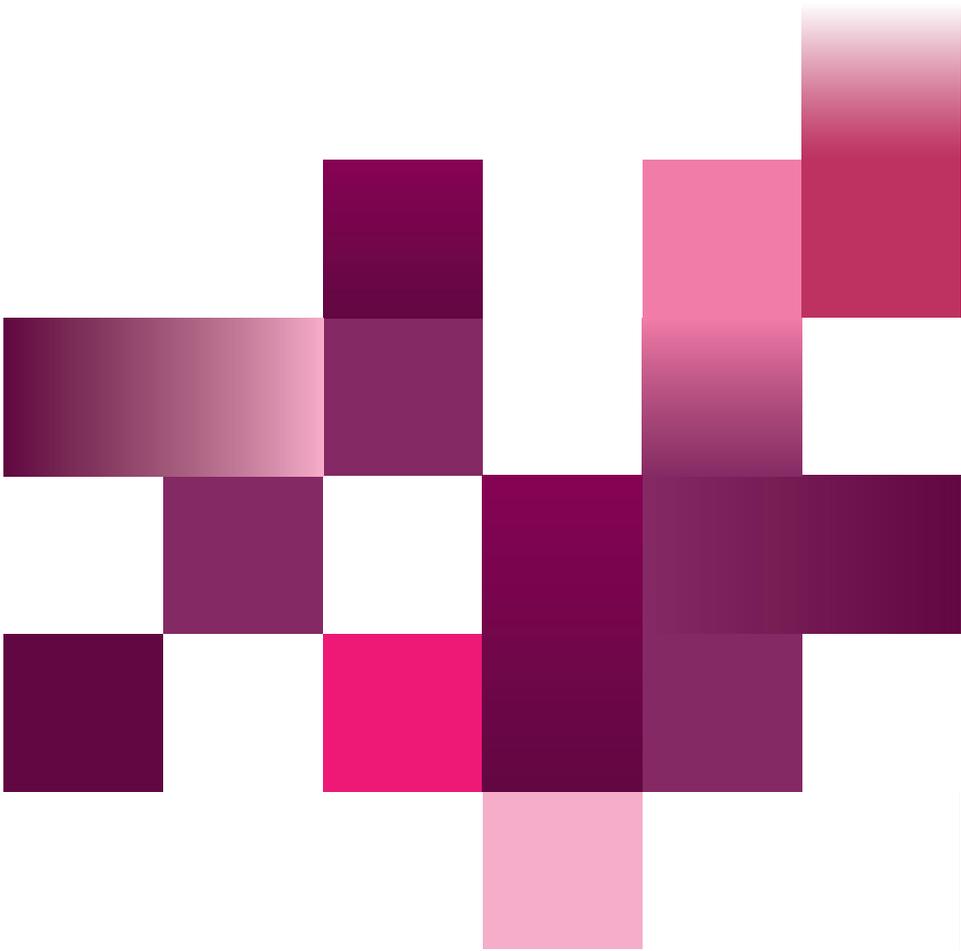
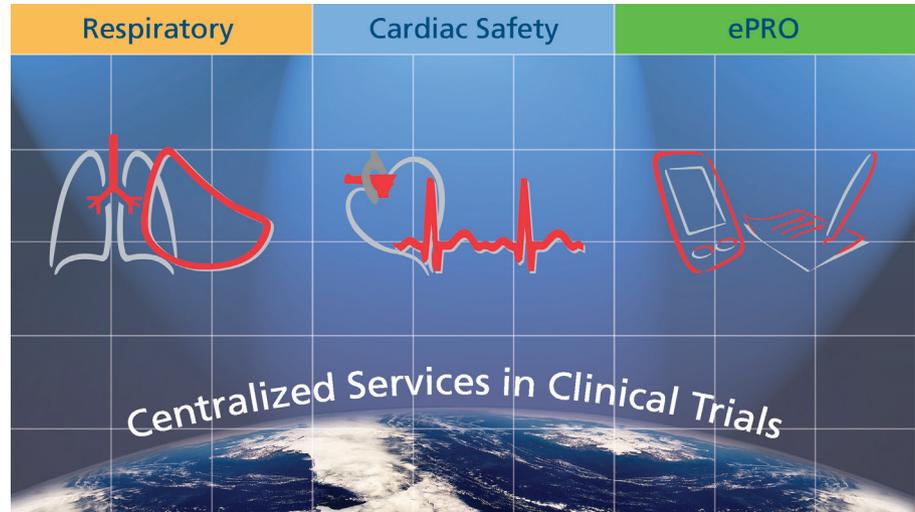


Instructions for Use

MyDataUploader™

- [Online Help](#)





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Notes on Safety in Instructions for Use

Following icons shown in the Instructions for Use:

			Important and useful information. Information does not warn of dangerous or harmful situations.
			Hints for use.

Intended Use

The MyDataUploader™ is a web application that offers a possibility to upload clinical data from a transfer medium to the backend system of Clario in a secure way using any available internet connection.

The MyDataUploader™ will be used for clinical trials when centralized processing of Clario authorized devices data is not possible.

Introduction

Ideally, data from your Clario device is transferred to the study database at Clario via modem. But in some instances a modem connection is not possible. For such cases Clario designed a web based tool: **MyDataUploader™**.

The MyDataUploader™ offers an easy, fast and secure way to upload data from your Clario device to the study database of Clario. For this you will additionally need a site-owned computer with internet connection.

A data storage medium (e.g. SD card or USB stick) labeled “Transfer” is used to transport the data between your Clario device and your site-owned computer with internet connection.



Depending on the Clario device in use at your site, two data transfer modes exist:

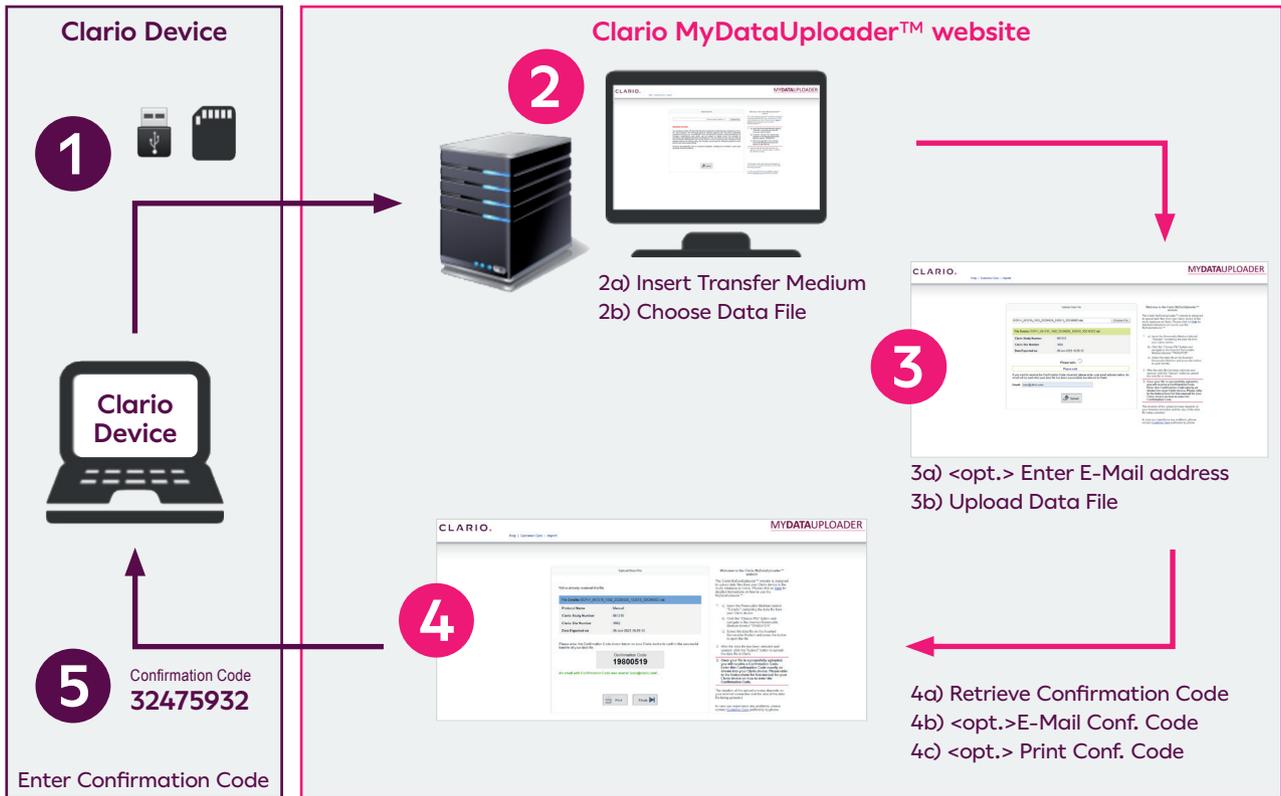
- **data transfer with Confirmation Code or**
- **data transfer without Confirmation Code**

MyDataUploader™ automatically selects the respective mode for your Clario device in use once the data file has been chosen for upload.

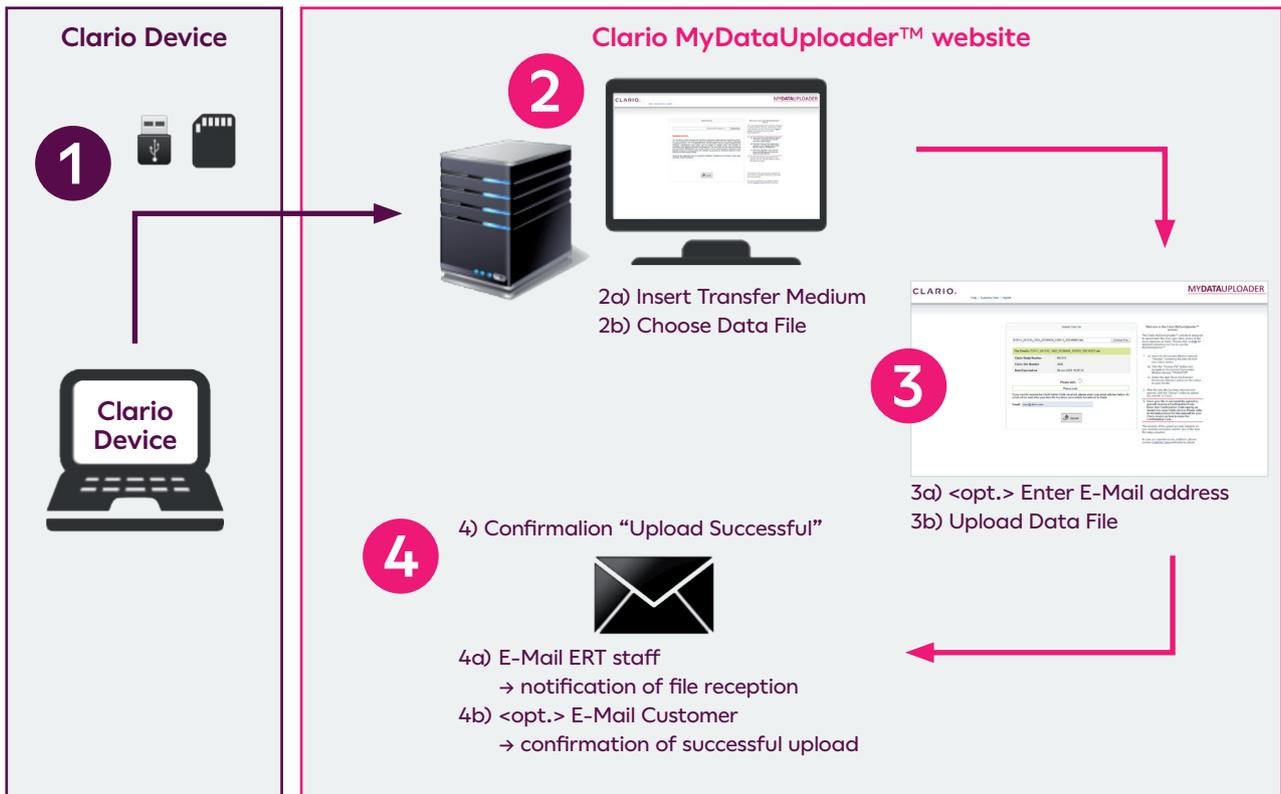
Where applicable MyDataUploader™ creates and displays a Confirmation Code once the data file has been uploaded to the Clario server. This Confirmation Code is to be entered into your Clario device. Please refer to the Instructions for Use manual for your Clario device for further details on how to enter a Confirmation Code.

The following graphs show the workflow of the two modes:
with Confirmation Code or **without** Confirmation Code.

Workflow, Data Transfer **with** Confirmation Code:



Workflow, Data Transfer **without** Confirmation Code:



MyDataUploader™ Functions

Preparing for Data Upload

1. Transfer the data from your Clario device to a data storage medium labeled “Transfer” as described in the Instructions for Use manual for your Clario device.
2. Insert the data storage medium labeled “Transfer” containing the data file from your Clario device into your site-owned computer with internet connection.



If you are using SD cards to transfer the data, please use the SD card reader and the USB extension cable of the SD Transfer Kit, if your computer is not equipped with a SD card reader.

3. Open an internet browser of your choice on your site-owned computer with internet connection and enter the following internet address (URL) to open the MyDataUploader™ website:

<https://mdu.ert.com>

mdu=mydatauploader (MyDataUploader™)

4. Follow the step-by-step instructions shown on the screen of the MyDataUploader™.

Uploading a Data File



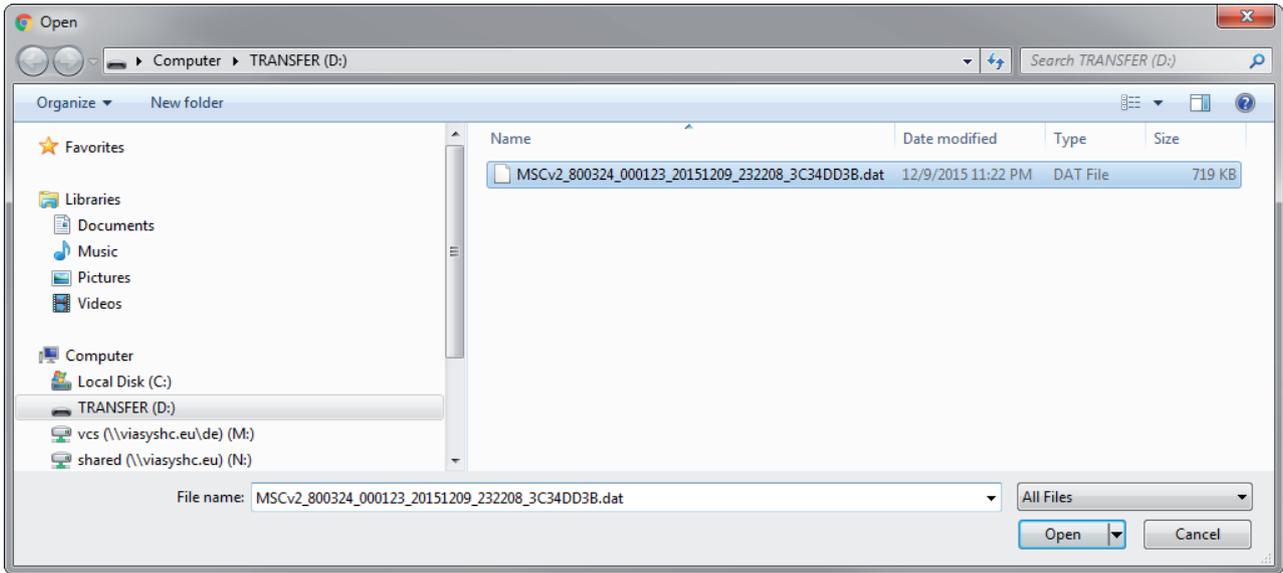
5. Browse for the data file on the inserted transfer medium by clicking on the **<Choose File>** button.



6. A window will open to search for the data file. Select the data file stored on the transfer medium and press the button to open the file.

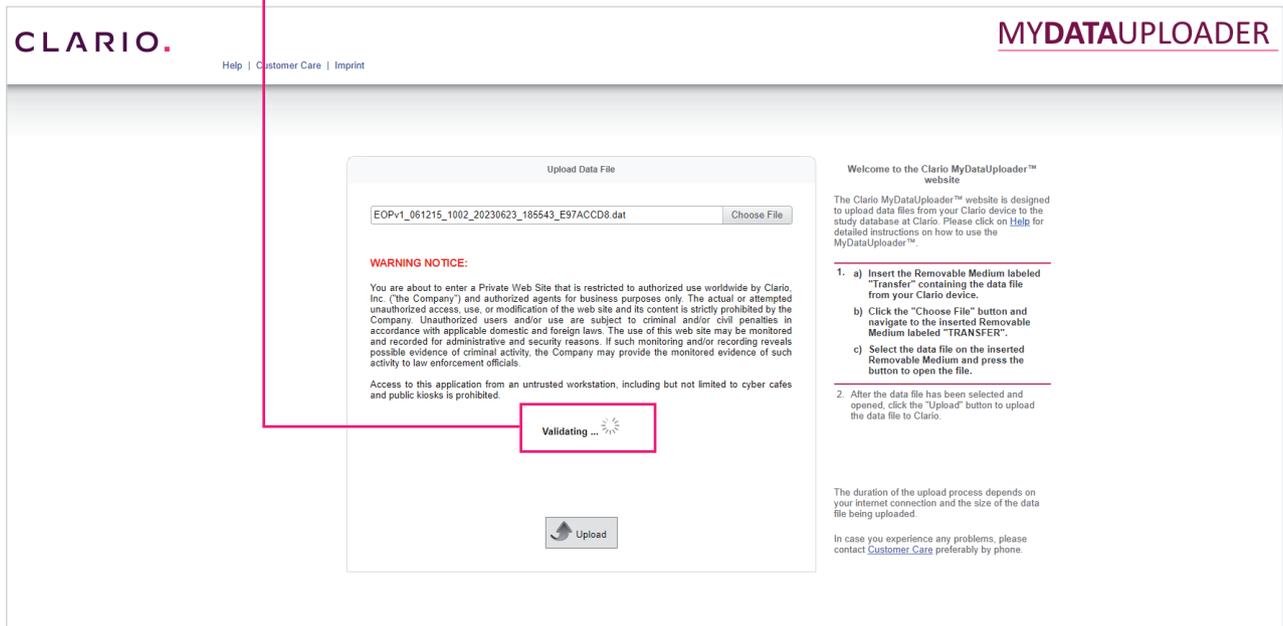


Only one data file is on the inserted transfer medium.

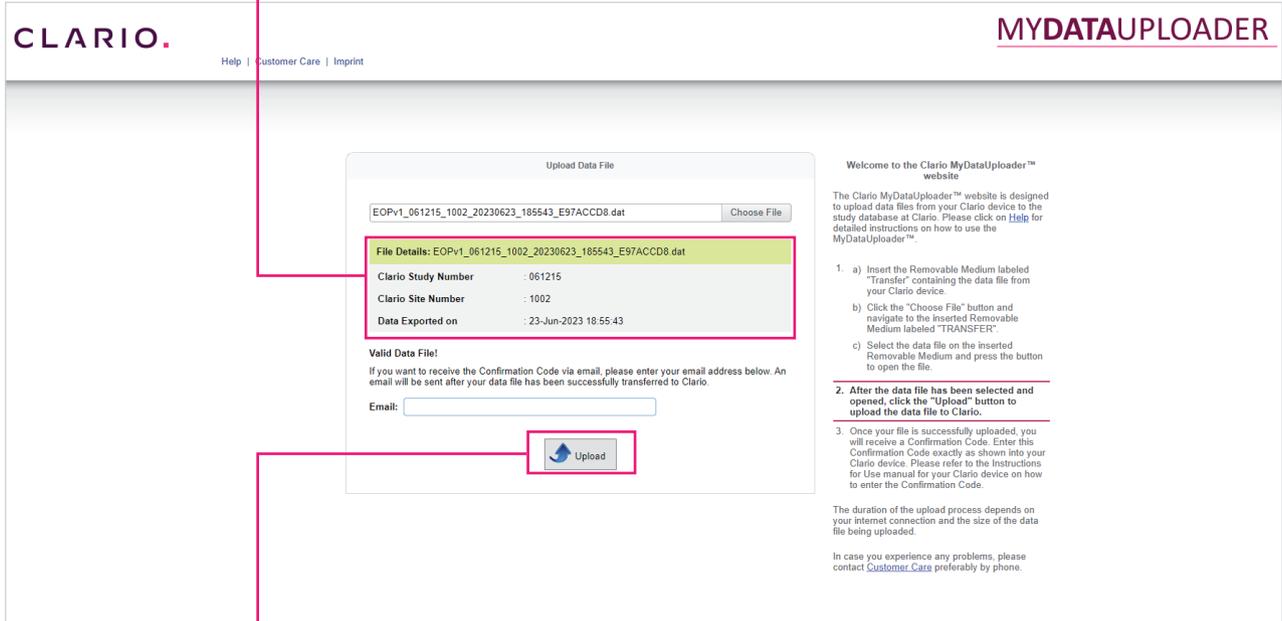


This window depends on the internet browser in use.

- After opening the data file, MyDataUploader™ validates the selected data file.
The progress of this process is shown on the screen.



8. If the opened data file is valid, MyDataUploader™ will display this by showing the study information.



9. Now click the <Upload> button to start the process to upload the data file to the Clario server, which is shown on the screen.

The following screen is shown.

CLARIO.
Help | Customer Care | Imprint
MYDATAUPLOADER

Upload Data File

EOPv1_061215_1002_20230623_205624_DF3D1E1A.dat
Choose File

File Details: EOPv1_061215_1002_20230623_205624_DF3D1E1A.dat

Clario Study Number : 061215

Clario Site Number : 1002

Data Exported on : 23-Jun-2023 20:56:24

Preparing to upload your data.

The data will be uploaded as soon as the other requests are finished. Thank you for your patience.

If you want to receive the Confirmation Code via email, please enter your email address below. An email will be sent after your data file has been successfully transferred to Clario.

Email:

Upload

Welcome to the Clario MyDataUploader™ website

The Clario MyDataUploader™ website is designed to upload data files from your Clario device to the study database at Clario. Please click on [Help](#) for detailed instructions on how to use the MyDataUploader™.

1. a) Insert the Removable Medium labeled "Transfer" containing the data file from your Clario device.
- b) Click the "Choose File" button and navigate to the inserted Removable Medium labeled "TRANSFER".
- c) Select the data file on the inserted Removable Medium and press the button to open the file.

2. After the data file has been selected and opened, click the "Upload" button to upload the data file to Clario.

3. Once your file is successfully uploaded, you will receive a Confirmation Code. Enter this Confirmation Code exactly as shown into your Clario device. Please refer to the Instructions for Use manual for your Clario device on how to enter the Confirmation Code.

The duration of the upload process depends on your internet connection and the size of the data file being uploaded.

In case you experience any problems, please contact [Customer Care](#) preferably by phone.



The duration of the upload process depends on your internet connection and the size of the data file being uploaded.



To ensure a successful upload of the data file to the Clario server, please do not disconnect the transfer medium nor remove the transfer medium during the upload process.

10. A message will appear on the screen once the data file has been successfully uploaded and received on the Clario server. MyDataUploader™ now performs an integrity and virus check.

The screenshot displays the MyDataUploader website interface. At the top left is the CLARIO logo, and at the top right is the MYDATAUPLOADER logo. Below the logos are navigation links: Help | Customer Care | Imprint. The main content area is titled 'Upload Data File' and features a file selection field containing 'EOPv1_061215_1002_20230623_185543_E97ACCD8.dat' with a 'Choose File' button. Below this is a 'File Details' section with the following information:

File Details: EOPv1_061215_1002_20230623_185543_E97ACCD8.dat	
Clario Study Number	: 061215
Clario Site Number	: 1002
Data Exported on	: 23-Jun-2023 18:55:43

A red box highlights the following message: **Your data file has been received.** Now performing integrity and virus checks. This process may take some time. Your Confirmation Code will be available once the process is completed.

Below the message is a loading spinner icon and a text prompt: 'If you want to receive the Confirmation Code via email, please enter your email address below. An email will be sent after your data file has been successfully transferred to Clario.' This is followed by an 'Email:' input field and an 'Upload' button.

On the right side of the interface, there is a 'Welcome to the Clario MyDataUploader™ website' section. It includes a paragraph explaining the website's purpose and a list of three steps for uploading data:

1. a) Insert the Removable Medium labeled "Transfer" containing the data file from your Clario device.
b) Click the "Choose File" button and navigate to the inserted Removable Medium labeled "TRANSFER".
c) Select the data file on the inserted Removable Medium and press the button to open the file.
2. After the data file has been selected and opened, click the "Upload" button to upload the data file to Clario.
3. Once your file is successfully uploaded, you will receive a Confirmation Code. Enter this Confirmation Code exactly as shown into your Clario device. Please refer to the Instructions for Use manual for your Clario device on how to enter the Confirmation Code.

Additional text at the bottom right states: 'The duration of the upload process depends on your internet connection and the size of the data file being uploaded.' and 'In case you experience any problems, please contact [Customer Care](#) preferably by phone.'

11. The following Screen will appear, as soon as the integrity and virus check has been successfully completed.

The screenshot shows the MyDataUploader website interface. At the top left is the CLARIO logo, and at the top right is the MYDATAUPLOADER logo. Below the logos are links for Help, Customer Care, and Imprint. The main content area is titled 'Upload Data File' and displays a confirmation message: 'Transfer successfully performed!'. Below this is a table of file details:

File Details: EOPv1_061215_1002_20230623_185543_E97ACCD8.dat	
Protocol Name	: Manual
Clario Study Number	: 061215
Clario Site Number	: 1002
Data Exported on	: 23-Jun-2023 18:55:43

Below the table, it states: 'Please enter the Confirmation Code shown below on your Clario device to confirm the successful transfer of your data file.' A red box highlights the 'Confirmation Code' field, which contains the code '00525682'. Below the code is an email input field with the label 'Email:' and a 'Send Email' button. At the bottom of the confirmation area are 'Print' and 'Finish' buttons. On the right side of the screen, there is a 'Welcome to the Clario MyDataUploader™ website' message and a list of instructions:

1. a) Insert the Removable Medium labeled "Transfer" containing the data file from your Clario device.
b) Click the "Choose File" button and navigate to the inserted Removable Medium labeled "TRANSFER".
c) Select the data file on the inserted Removable Medium and press the button to open the file.
2. After the data file has been selected and opened, click the "Upload" button to upload the data file to Clario.
3. Once your file is successfully uploaded, you will receive a Confirmation Code. Enter this Confirmation Code exactly as shown into your Clario device. Please refer to the Instructions for Use manual for your Clario device on how to enter the Confirmation Code.

Additional text on the right includes: 'The duration of the upload process depends on your internet connection and the size of the data file being uploaded.' and 'In case you experience any problems, please contact Customer Care preferably by phone.'

12. If a Confirmation Code is displayed as shown above, then either note the code or print it or have it sent to your Email address. This Confirmation Code is to be entered into the Clario device at your site. Please refer to the Instructions for Use manual for your Clario device for further details on how to enter the Confirmation Code.



If no Confirmation Code is displayed, it is not required to enter a code into your Clario device.

13. In any case (with or without Confirmation Code), you can either print or email the data transfer information as shown on the MyDataUploader™ screen.



To print the data transfer information, please click the <**Print**> button. This will open your standard printer dialog window and you can proceed as usual.

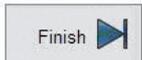
To Email the data transfer information, enter your email address and press the <**Send Email**> button.

If you want to receive this information via email, please enter your email address and click "Send Email" button.

Email:



The Confirmation Code is also mailed, if a Confirmation Code is displayed.



14. To finish the data transfer procedure click the <**Finish**> button.

Possible MyDataUploader™ Errors

Detected Virus

MyDataUploader™ checks the uploaded and received data file for virus infection. If a virus is detected, the MyDataUploader™ will display the following message:

The screenshot displays the MyDataUploader™ interface. At the top left is the CLARIO logo, and at the top right is the MYDATAUPLOADER logo. Below the logo is a navigation bar with links for Help, Customer Care, and Imprint. The main content area is divided into two columns. The left column contains an 'Upload Data File' form. The file name 'EOPv1_061215_1002_20230623_185543_E97ACCD8.dat' is entered in the 'Choose File' field. Below this, the 'File Details' section shows: Clario Study Number: 061215, Clario Site Number: 1002, and Data Exported on: 23-Jun-2023 18:55:43. A red error box highlights the following message: **ERROR** VIRUS DETECTED! Your data has been received and scanned for virus infection. As this data file is potentially virus infected, ERT will not process it any further. Please contact Customer Care immediately for further advice, preferably by phone. Below the error message is a loading spinner and a text prompt: 'If you want to receive the Confirmation Code via email, please enter your email address below. An email will be sent after your data file has been successfully transferred to Clario.' An email input field and an 'Upload' button are also visible. The right column contains a 'Welcome to the Clario MyDataUploader™ website' message, followed by instructions for uploading data files and a note about the duration of the upload process.

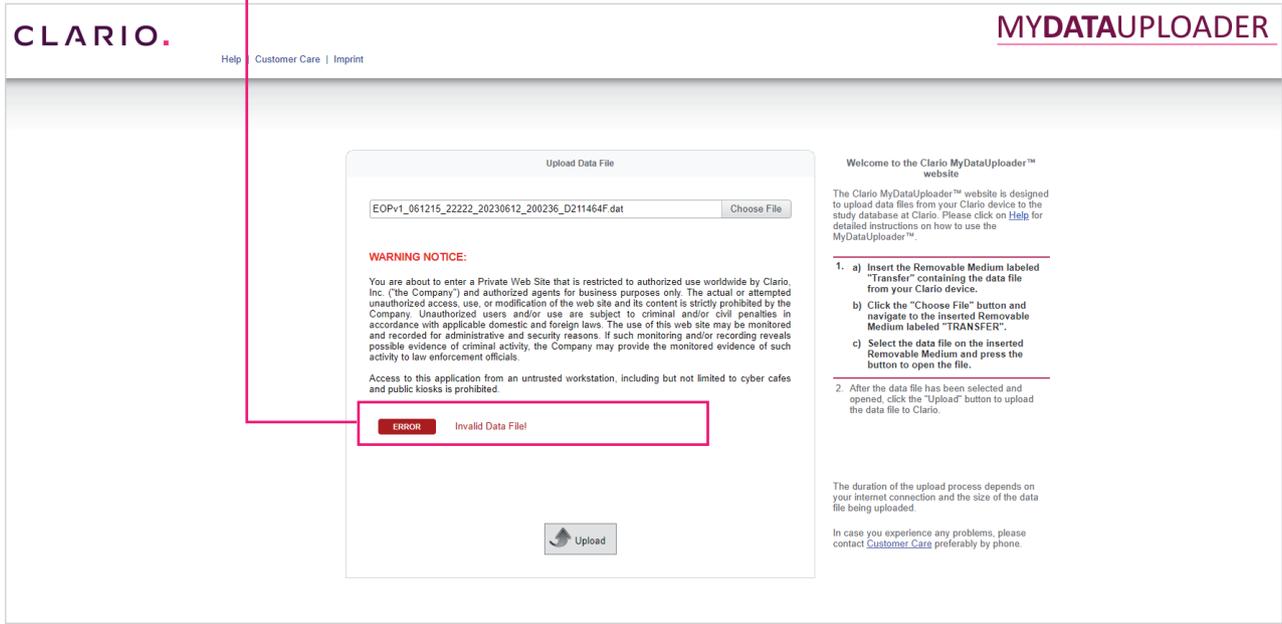


If a virus is detected, Clario will not process the data file any further.

Please contact Clario Customer Care immediately for further advice, preferably by phone.

Invalid Data File

If the data file is invalid, MyDataUploader™ will display the following message:



Please assure that a valid data file is uploaded.

Follow the Instructions for Use of your Clario device on how to create and store a data transfer file onto a data storage medium labeled “Transfer” and retry uploading this data file using MyDataUploader™.

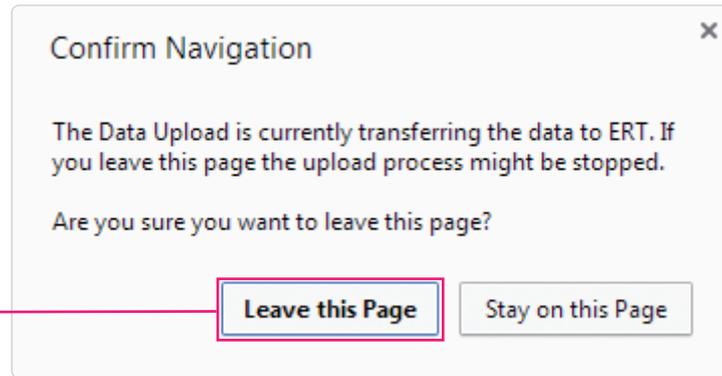


Never change the file name of the data file and avoid choosing an invalid file.

Should you receive this error message again, please contact Clario Customer Care for further advice, preferably by phone.

Closing MyDataUploader™ during Upload

If you try to close the internet browser during the upload process the following message will appear:



This window depends on the internet browser in use.

If you click the <**Leave this Page**> button the upload process will be stopped and the data file will not be received by Clario.



Should it anyway be required to stop the data upload process by pressing the <**Leave this Page**> button, you can upload the data file at any time at your convenience.

Retrieving the Confirmation Code

In case of loss or misplacement of the Confirmation Code, you can retrieve the Confirmation Code at any time after you have uploaded a data file. Simply restart the upload process as described in this Online Help manual. After choosing the data file, MyDataUploader™ will display that Clario has already received this data file and will also display the Confirmation Code.

CLARIO.
MYDATAUPLOADER

Help | Customer Care | Imprint

Upload Data File

We've already received this file.

File Details: EOPv1_061215_1002_20230623_185543_E97ACCD8.dat

Protocol Name	: Manual
Clario Study Number	: 061215
Clario Site Number	: 1002
Data Exported on	: 23-Jun-2023 18:55:43

Please enter the Confirmation Code shown below on your Clario device to confirm the successful transfer of your data file

Confirmation Code
00525682

If you want to receive this information via email, please enter your email address and click "Send Email" button.

Email:

Welcome to the Clario MyDataUploader™ website

The Clario MyDataUploader™ website is designed to upload data files from your Clario device to the study database at Clario. Please click on [Help](#) for detailed instructions on how to use the MyDataUploader™.

1. a) Insert the Removable Medium labeled "Transfer" containing the data file from your Clario device.
- b) Click the "Choose File" button and navigate to the inserted Removable Medium labeled "TRANSFER".
- c) Select the data file on the inserted Removable Medium and press the button to open the file.

2. After the data file has been selected and opened, click the "Upload" button to upload the data file to Clario.

3. Once your file is successfully uploaded, you will receive a Confirmation Code. Enter this Confirmation Code exactly as shown into your Clario device. Please refer to the instructions for Use manual for your Clario device on how to enter the Confirmation Code.

The duration of the upload process depends on your internet connection and the size of the data file being uploaded.

In case you experience any problems, please contact [Customer Care](#) preferably by phone.

Now you can either note the Confirmation Code or print or Email the data transfer information that also includes the Confirmation Code as described previously in this manual.

FAQ's

1. Why is the Sponsor Site ID on my Clario device different than the one presented by the MyDataUploader™?

It is possible that the Sponsor Site ID has been changed on your Clario device and the MyDataUploader™ gets its information from the Clario study database.

2. What happens if I upload a data file more than once?

If a data file is uploaded more than once, MyDataUploader™ will recognize this and a message will inform you accordingly. In case that a Confirmation Code has been created and displayed initially, the same Confirmation Code will appear on the screen again.

3. What happens if I open the MyDataUploader™ in more than one tab using Microsoft Internet Explorer (IE) Versions 6 thru 9?

It is possible that MyDataUploader™ cannot be opened, if these Microsoft Internet Explorer versions are used. It is recommended not to open more than six ☺ tabs at the same time.

4. Which internet browsers are supported by MyDataUploader™?

Safari
Chrome
Firefox
Internet Explorer

CLARIO.

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