
12 Lead Holter - H12+ Help manual



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1. H12+ SOFTWARE INSTALLATION

Pre-Requisites:

- OS: Windows 7 service pack 1 or Windows 8.1, or Windows 10.
- RAM: 4 GB memory (minimum)
- Video: 1024 x 768 resolution (minimum)
- Minimum 20 GB Hard disk space
- .NET Framework 4.6.2
- Installer must have the administrator privileges on the computer.

NOTE: IT Site administrator or User with Administrator privileges must install the application and grant read/write permission to the Holter web upload folder on C drive (in case the user doesn't have the administrator privilege) **after** the Holter web upload application installation.

Supported Web browsers:

- Internet Explorer 9.0 and above, and chrome browser.

How to install the application

Login to IQVIA CDDP SITE GATEWAY <https://cddp.solutions.iqvia.com> using user ID shared by IQVIA.

Please note that user should use same User ID and Password to access all the IQVIA applications mentioned below:

Welcome, Guest

You have access to the following Connected Devices Digital Platform applications, please click the application link below to access the application.

- [Holter Web Upload using H12+](#) ?
- [QBOX](#) ?
- [Cardiac Safety Web Portal](#) ?
- [Study Management Suite](#) ?

[CDDP ClinSpark](#)

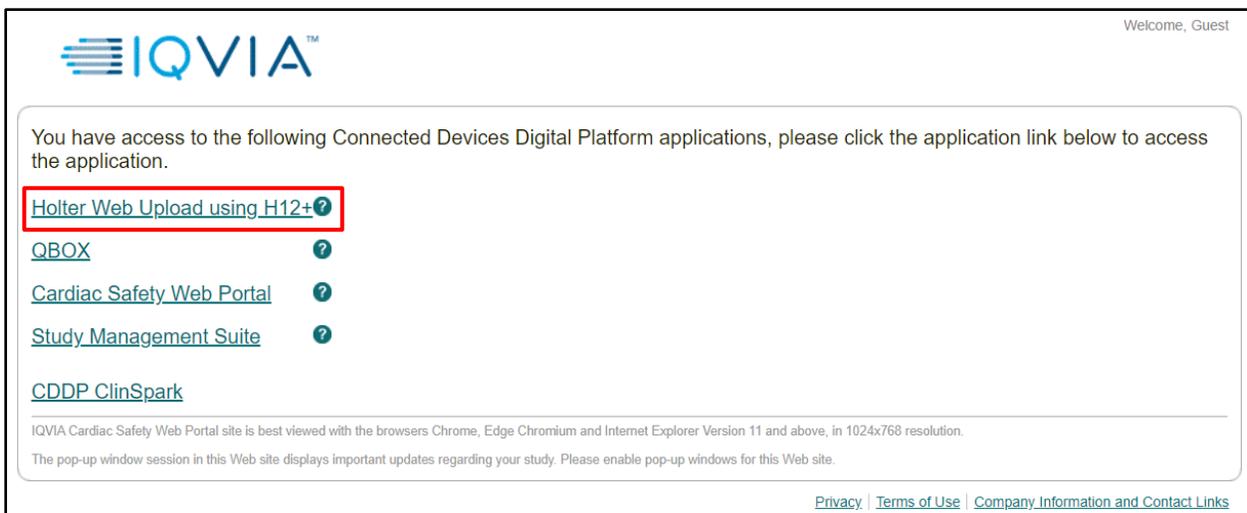
IQVIA Cardiac Safety Web Portal site is best viewed with the browsers Chrome, Edge Chromium and Internet Explorer Version 11 and above, in 1024x768 resolution.

The pop-up window session in this Web site displays important updates regarding your study. Please enable pop-up windows for this Web site.

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1. For first time users who do not have access to any of the IQVIA portals: The user will be directed to the “Holter Web upload using H12+” system home page.





Welcome, Guest



You have access to the following Connected Devices Digital Platform applications, please click the application link below to access the application.

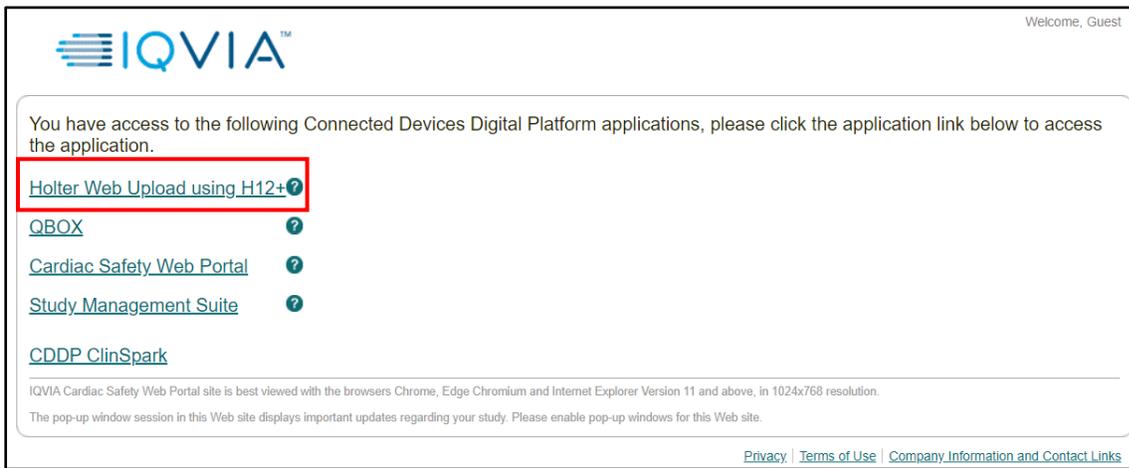
- [Holter Web Upload using H12+?](#)
- [QBOX](#)
- [Cardiac Safety Web Portal](#)
- [Study Management Suite](#)
- [CDDP ClinSpark](#)

IQVIA Cardiac Safety Web Portal site is best viewed with the browsers Chrome, Edge Chromium and Internet Explorer Version 11 and above, in 1024x768 resolution.
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2. For existing users having access to other IQVIA portals:

Click on the Holter link as per screen shot below and click on 'Launch'.



Welcome, Guest



You have access to the following Connected Devices Digital Platform applications, please click the application link below to access the application.

- [Holter Web Upload using H12+?](#)
- [QBOX](#)
- [Cardiac Safety Web Portal](#)
- [Study Management Suite](#)
- [CDDP ClinSpark](#)

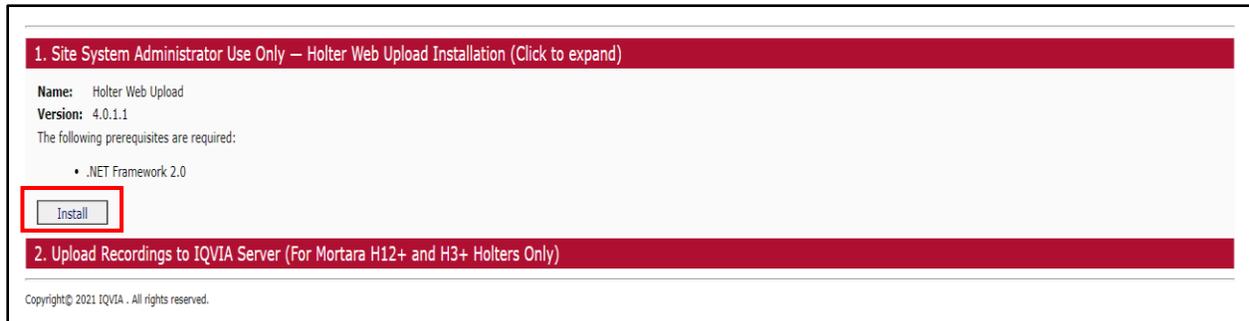
IQVIA Cardiac Safety Web Portal site is best viewed with the browsers Chrome, Edge Chromium and Internet Explorer Version 11 and above, in 1024x768 resolution.
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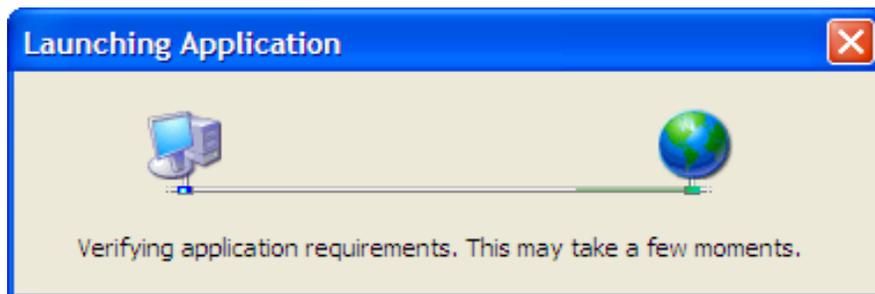
OR

Step 1: Click on section 1 - Site System Administrator Use Only – Holter Web Upload Installation (Click to expand).

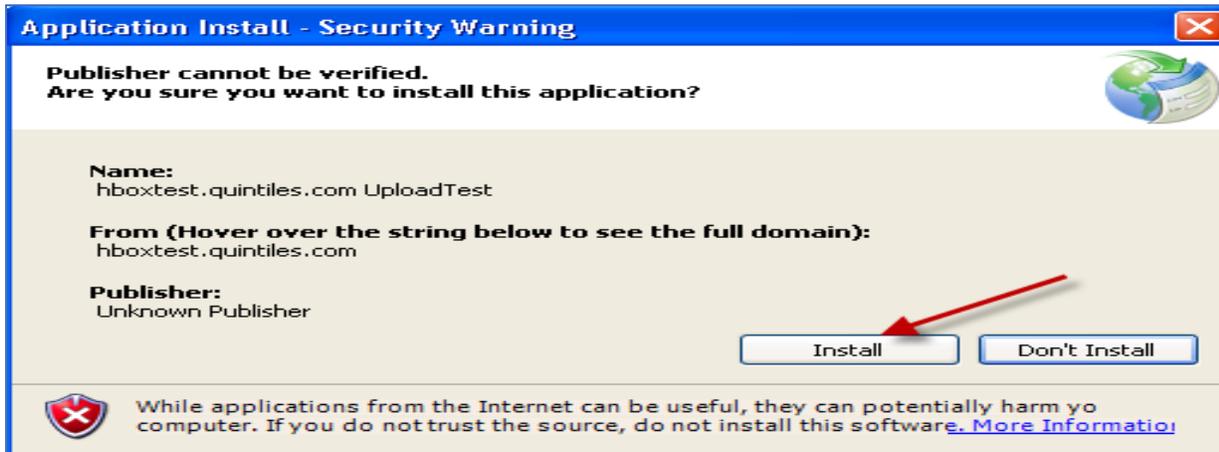
Step 2: Click on the 'Install' button.



Step 3: Launching Application pop-up window will be displayed.



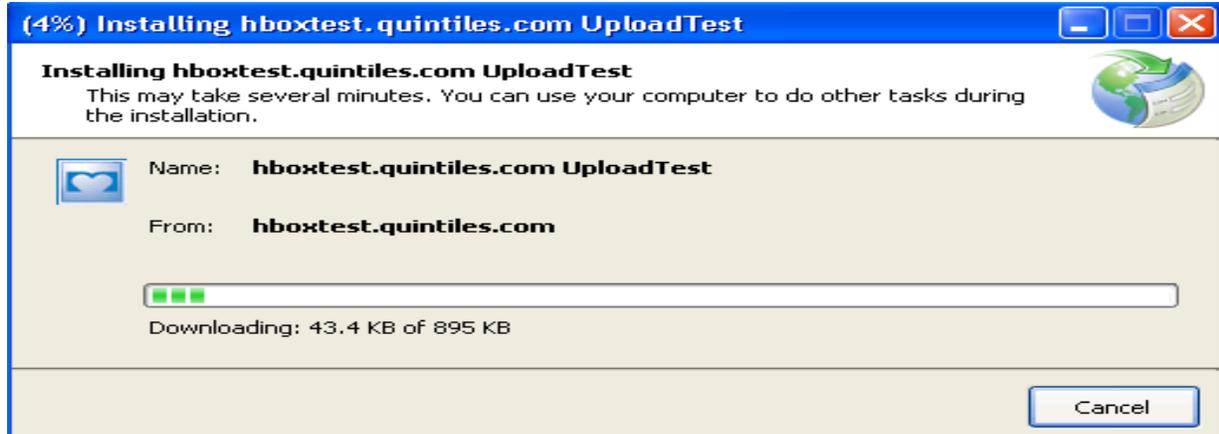
Step 4: Next the Application install – Security Warning window will appear. Click on the 'Install' button.



Step 5: An installation window will appear.

Note:

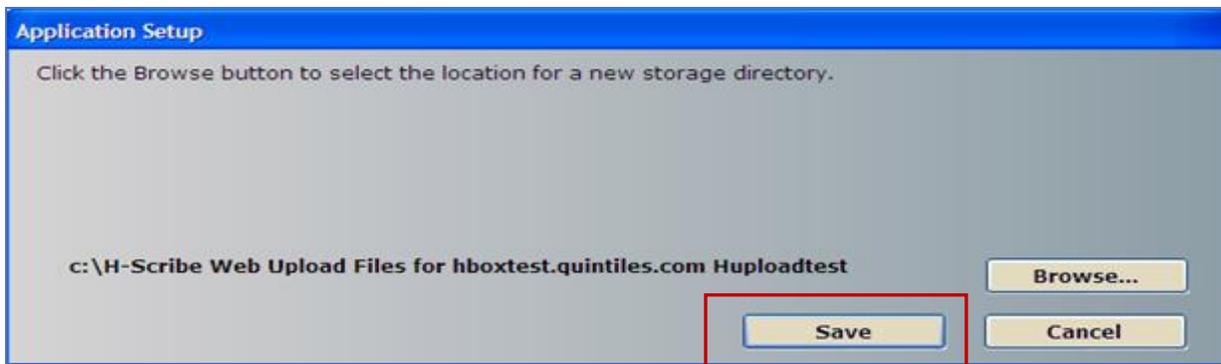
- Please wait till the entire download process is completed.
- Download process may take a few minutes depending on your internet download speed.
- Do not close the window or web browser while the application is being downloaded.



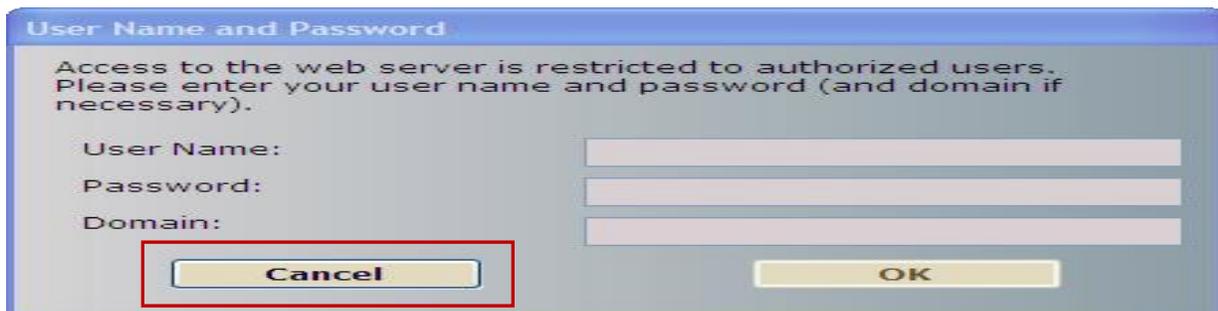
Step 6: Once the application is downloaded the below Application Setup window will appear. Click on 'Save'.

NOTE: It is mandatory to Copy the data to another location on your local computer from the location saved while the application download.

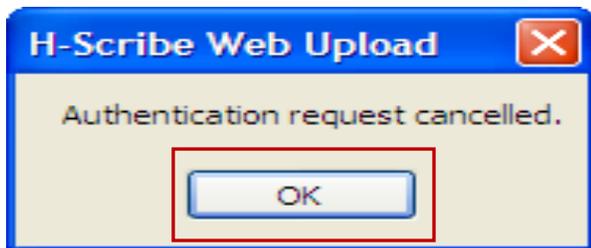
The data should be saved with proper nomenclature as back up until the data base lock activities are completed. The Holter data should be named as below: **INITIALS/SUBJECT NO./VISIT ID.**



Step 7: A username/password window will appear, click on 'Cancel'.

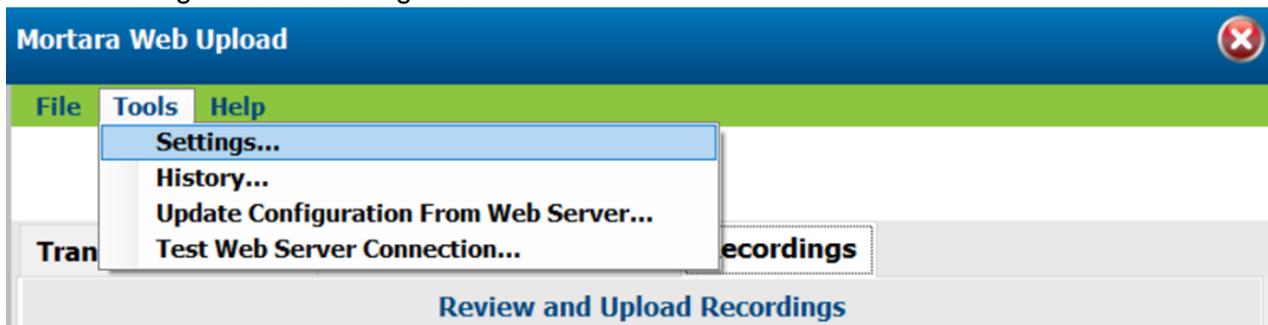


Step 8: Next Click 'OK' on H-Scribe Web Upload window.

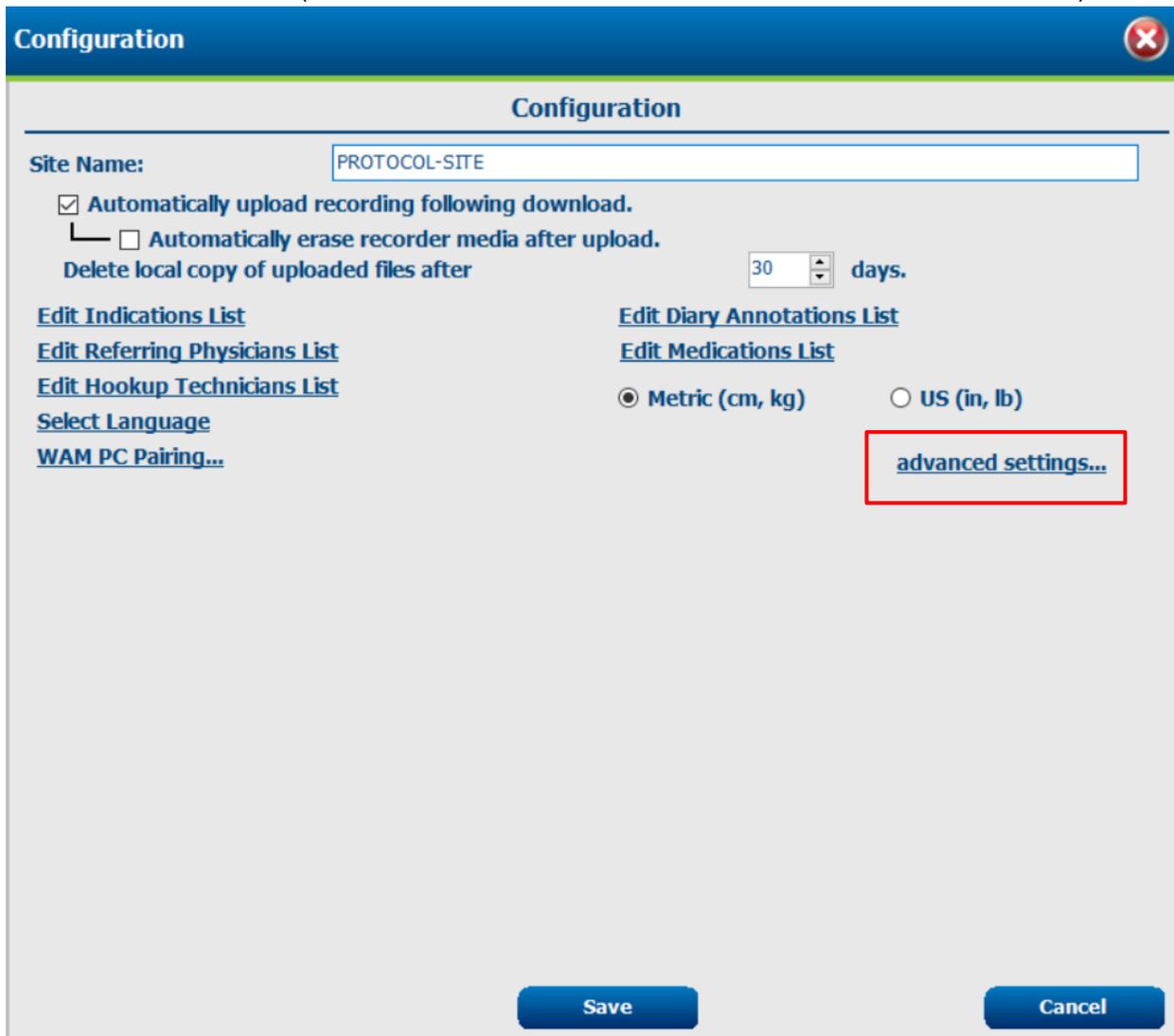


Step 9:

- Next navigate to the Settings tab.



- Enter the site name (which is a combination of the Protocol number and site number).



Configuration

Site Name:

Automatically upload recording following download.

Automatically erase recorder media after upload.

Delete local copy of uploaded files after days.

[Edit Indications List](#) [Edit Diary Annotations List](#)

[Edit Referring Physicians List](#) [Edit Medications List](#)

[Edit Hookup Technicians List](#)

Metric (cm, kg) US (in, lb)

[Select Language](#)

[WAM PC Pairing...](#) [advanced settings...](#)

- Select the check box “Automatically upload recording following download”.
- Enter '30' in days List box for 'Delete local copy of uploaded files after'.

NOTE: It is mandatory to Copy the data to another location on your local computer from the location saved while the application download.

The data should be saved with proper nomenclature as back up until the data base lock activities are completed. The Holter data should be named as below: **INITIALS/SUBJECT NO/VISIT ID.**

- Click on the advanced settings link to show additional setting options.

Configuration ✕

Configuration

Site Name:

Automatically upload recording following download.
└─ Automatically erase recorder media after upload.
Delete local copy of uploaded files after days.

[Edit Indications List](#) [Edit Diary Annotations List](#)
[Edit Referring Physicians List](#) [Edit Medications List](#)
[Edit Hookup Technicians List](#) Metric (cm, kg) US (in, lb)
[Select Language](#)
[WAM PC Pairing...](#) [hide](#)

Storage directory: [Change](#)

Orders directory: [Change](#)

Upload Web Service URL SSL

Automatic
 Manual

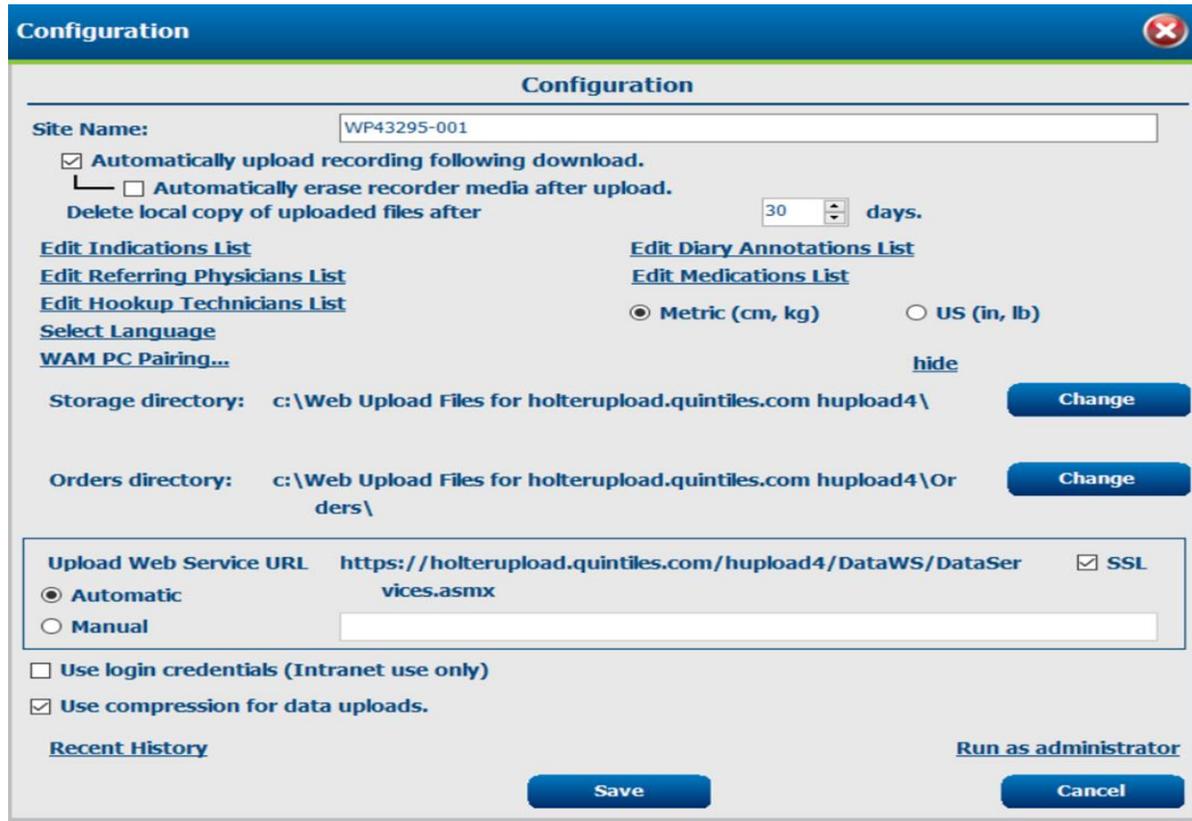
Use login credentials (Intranet use only)
 Use compression for data uploads.

[Recent History](#) [Run as administrator](#)

[Save](#) [Cancel](#)

Step 10:

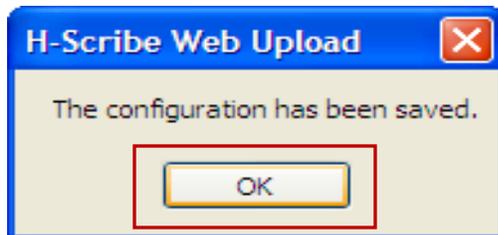
- Once you click on the Advanced settings link the following additional options will be displayed. Select the SSL check box.
- Click on the 'Save' button once all the above changes have been completed in the Settings tab.



The screenshot shows a 'Configuration' window with a blue title bar and a close button. The main content area is titled 'Configuration' and contains the following elements:

- Site Name:** A text box containing 'WP43295-001'.
- Automatically upload recording following download.**
- Automatically erase recorder media after upload.**
- Delete local copy of uploaded files after** [30] **days.**
- Links: [Edit Indications List](#), [Edit Referring Physicians List](#), [Edit Hookup Technicians List](#), [WAM PC Pairing...](#), [Edit Diary Annotations List](#), [Edit Medications List](#)
- Units: **Metric (cm, kg)** **US (in, lb)**
- Storage directory:** c:\Web Upload Files for holterupload.quintiles.com hupload4\ [Change]
- Orders directory:** c:\Web Upload Files for holterupload.quintiles.com hupload4\Orders\ [Change]
- Upload Web Service URL:** https://holterupload.quintiles.com/hupload4/DataWS/DataServices.aspx [Change] **SSL**
- Radio buttons: **Automatic** **Manual**
- Use login credentials (Intranet use only)**
- Use compression for data uploads.**
- Links: [Recent History](#), [Run as administrator](#)
- Buttons: **Save**, **Cancel**

Step 11: The below pop-up window will appear. Click 'OK' on the H-Scribe Web Upload window.



Holter Web Upload User - Password Management:

Password Requirement Criteria:

Note: New password must meet the following password requirements:

Password must be minimum 8 characters long and must contain any 3 of the following 4 categories:

1. English uppercase characters (A-Z)
2. English lowercase characters (a-z)
3. Numeric characters (0-9)
4. Non-alpha-numeric characters (for example: \$, # or %)

The password must not contain 3 or more characters from the user's account name

The new password must not repeat any of the previous 26 passwords used on the account

2. PREPARING RECORDER MEDIA/FLASHCARD FOR NEW RECORDING

Step 1: Insert Flashcard into Flashcard Reader and connect to PC installed with Holter Web Upload application.

Step 2: Login to IQVIA Clinical Devices Digital Platform (CDDP) Site Gateway <https://cddp.solutions.iqvia.com> using secure user credentials. Click on the ‘**Holter Web Upload using H12+**’ link to access Holter link.

Welcome, Guest

You have access to the following Connected Devices Digital Platform applications, please click the application link below to access the application.

- [Holter Web Upload using H12+](#) ?
- [QBOX](#) ?
- [Cardiac Safety Web Portal](#) ?
- [Study Management Suite](#) ?

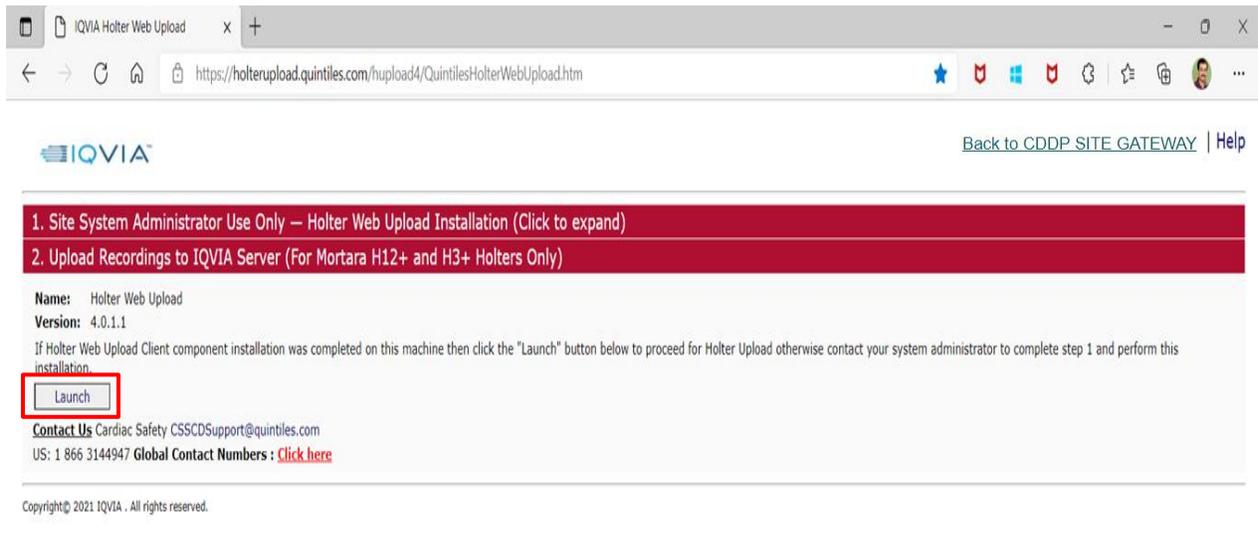
[CDDP ClinSpark](#)

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Step 3: Click on section 2 - Upload Recordings to IQVIA Server. Then Click on 'Launch'.



IQVIA™ [Back to CDDP SITE GATEWAY](#) | [Help](#)

1. Site System Administrator Use Only – Holter Web Upload Installation (Click to expand)

2. Upload Recordings to IQVIA Server (For Mortara H12+ and H3+ Holters Only)

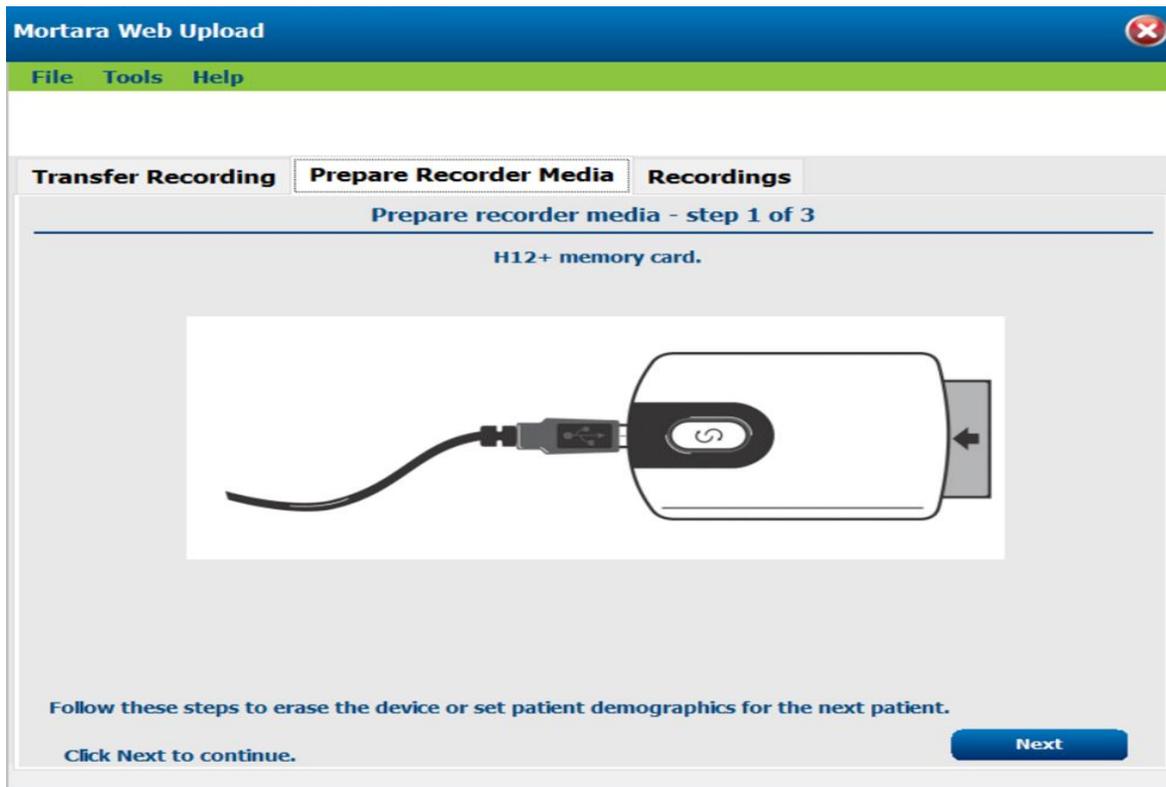
Name: Holter Web Upload
Version: 4.0.1.1

If Holter Web Upload Client component installation was completed on this machine then click the "Launch" button below to proceed for Holter Upload otherwise contact your system administrator to complete step 1 and perform this installation.

Contact Us Cardiac Safety CSSCDsupport@quintiles.com
US: 1 866 3144947 **Global Contact Numbers** : [Click here](#)

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Step 4: Click on Prepare Recorder Media to prepare the H12+ recorder CF Card. The program will automatically detect the type of media connected. Click 'Next'.



Step 5: There may be one of 2 possible scenarios

A. The recording has **NOT** previously been downloaded.

OR

B. The recording has previously been downloaded.

Scenario A: The Recording has NOT previously been downloaded

Step I: The top portion of the screen displays information about the recorder and recording. If the recording has **NOT** previously been downloaded, a WARNING! sign is displayed, and the Erase button will be activated. Click on the 'Erase' button.

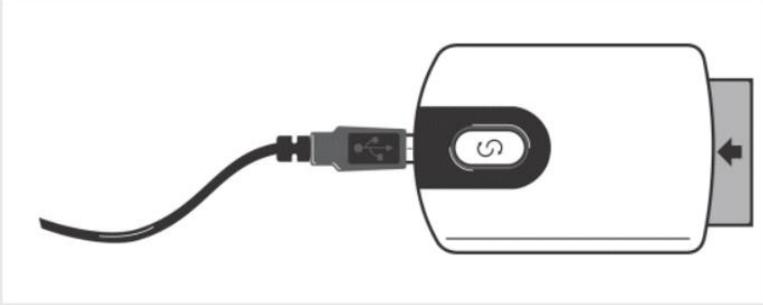
Mortara Web Upload ✕

File Tools Help

Transfer Recording **Prepare Recorder Media** Recordings

Prepare recorder media - step 1 of 3

H12+ memory card.



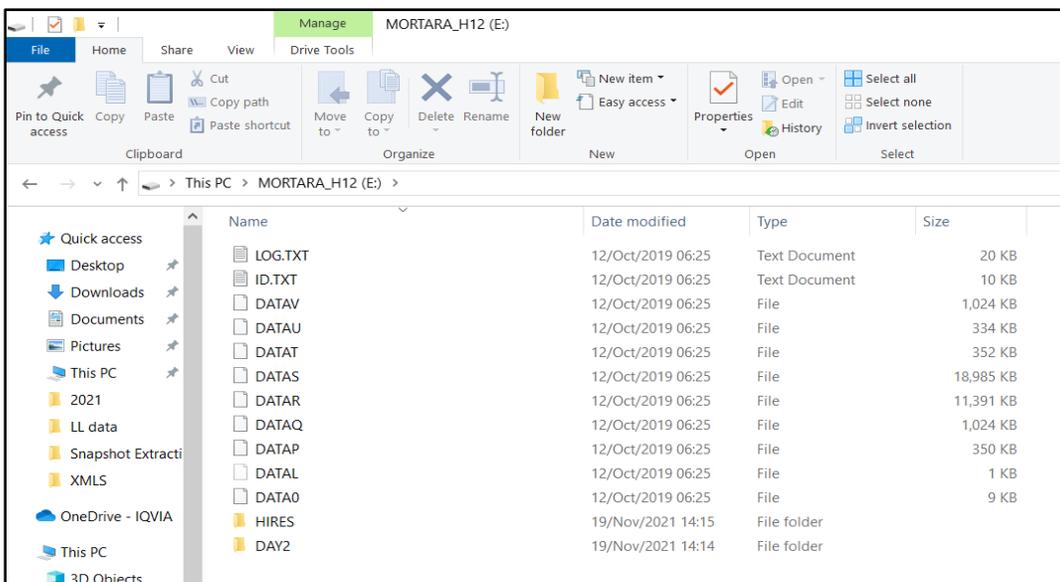
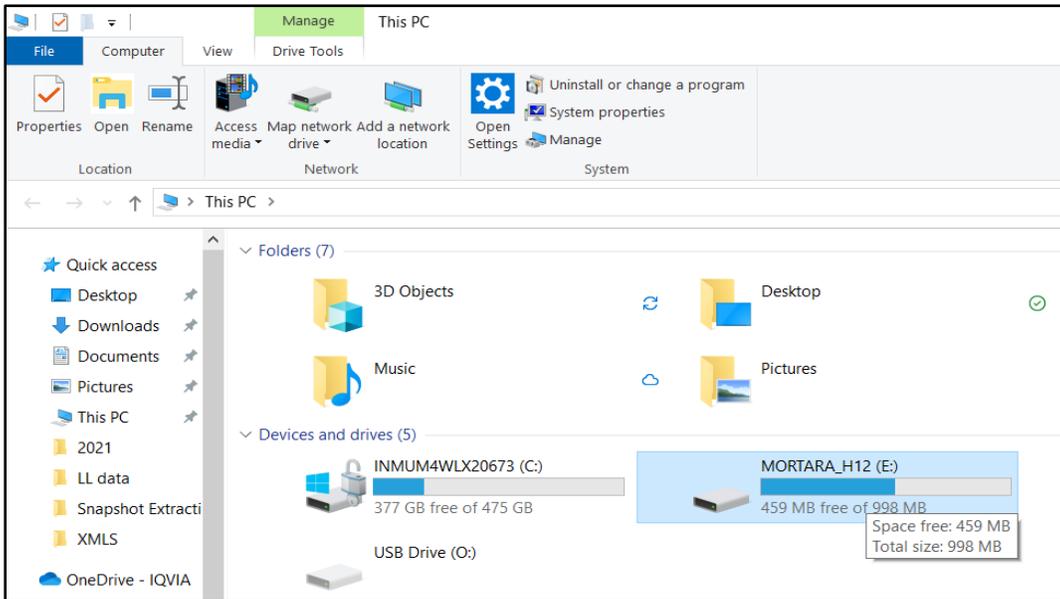
Follow these steps to erase the device or set patient demographics for the next patient.

Click Next to continue. Next

NOTE: IQVIA recommends saving a copy of the Holter data **before** erasing.

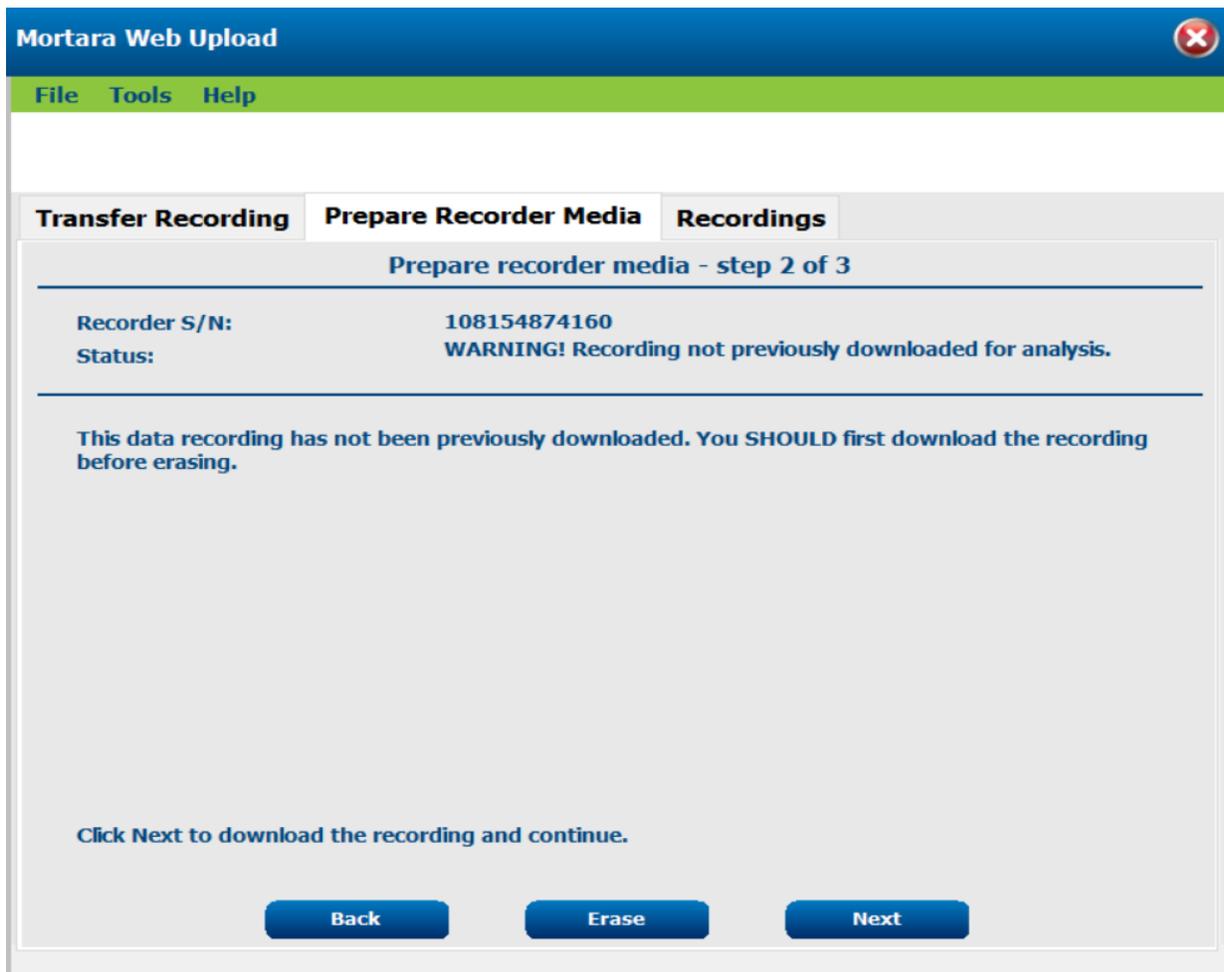
SAVING A COPY on the drive of the computer:

- Go to the My computer of the desktop or the laptop you are using.
- Open the Flashcard reader drive attached to the USB port of your desktop or the laptop as below:



- Copy the entire data from the flashcard drive (there will be 13 items present which will have two folders and 11 files) to a folder on the desktop.
- Name the folder on the desktop with subject ID_Visit.
- Copy the folder to secure location, so that no body have access to that data.

Step II: Click on the erase Button to erase the previous data on the flashcard.



The screenshot shows a web application window titled "Mortara Web Upload" with a menu bar containing "File", "Tools", and "Help". The main content area has three tabs: "Transfer Recording", "Prepare Recorder Media", and "Recordings". The "Prepare Recorder Media" tab is active, displaying the sub-header "Prepare recorder media - step 2 of 3". Below this, a table shows the Recorder S/N as 108154874160 and the Status as "WARNING! Recording not previously downloaded for analysis." A message below the table states: "This data recording has not been previously downloaded. You SHOULD first download the recording before erasing." At the bottom, there are three buttons: "Back", "Erase", and "Next".

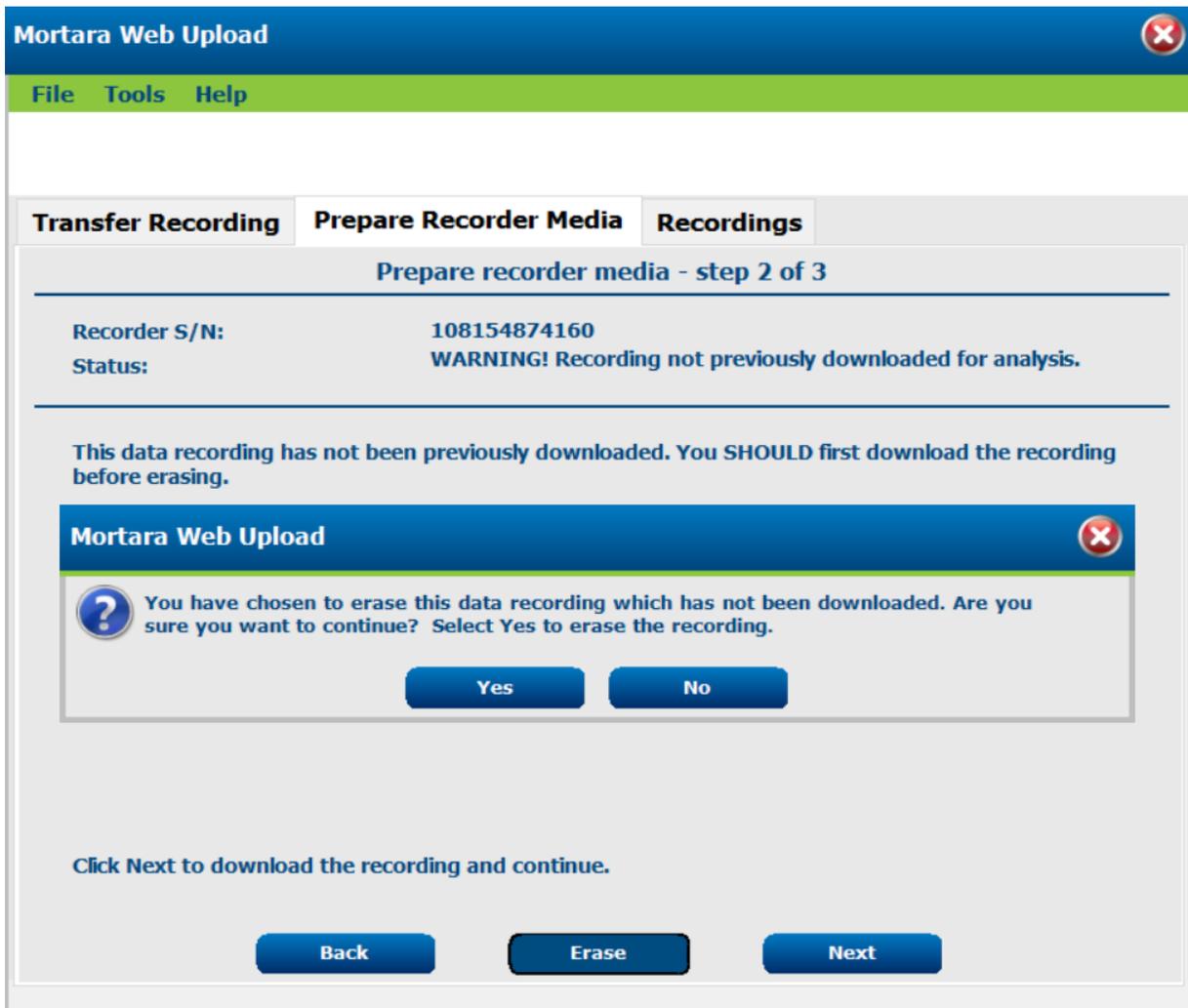
Recorder S/N:	108154874160
Status:	WARNING! Recording not previously downloaded for analysis.

This data recording has not been previously downloaded. You SHOULD first download the recording before erasing.

Click Next to download the recording and continue.

Back Erase Next

Step III: A prompt to confirm erasing the recording will appear. Click on Yes.



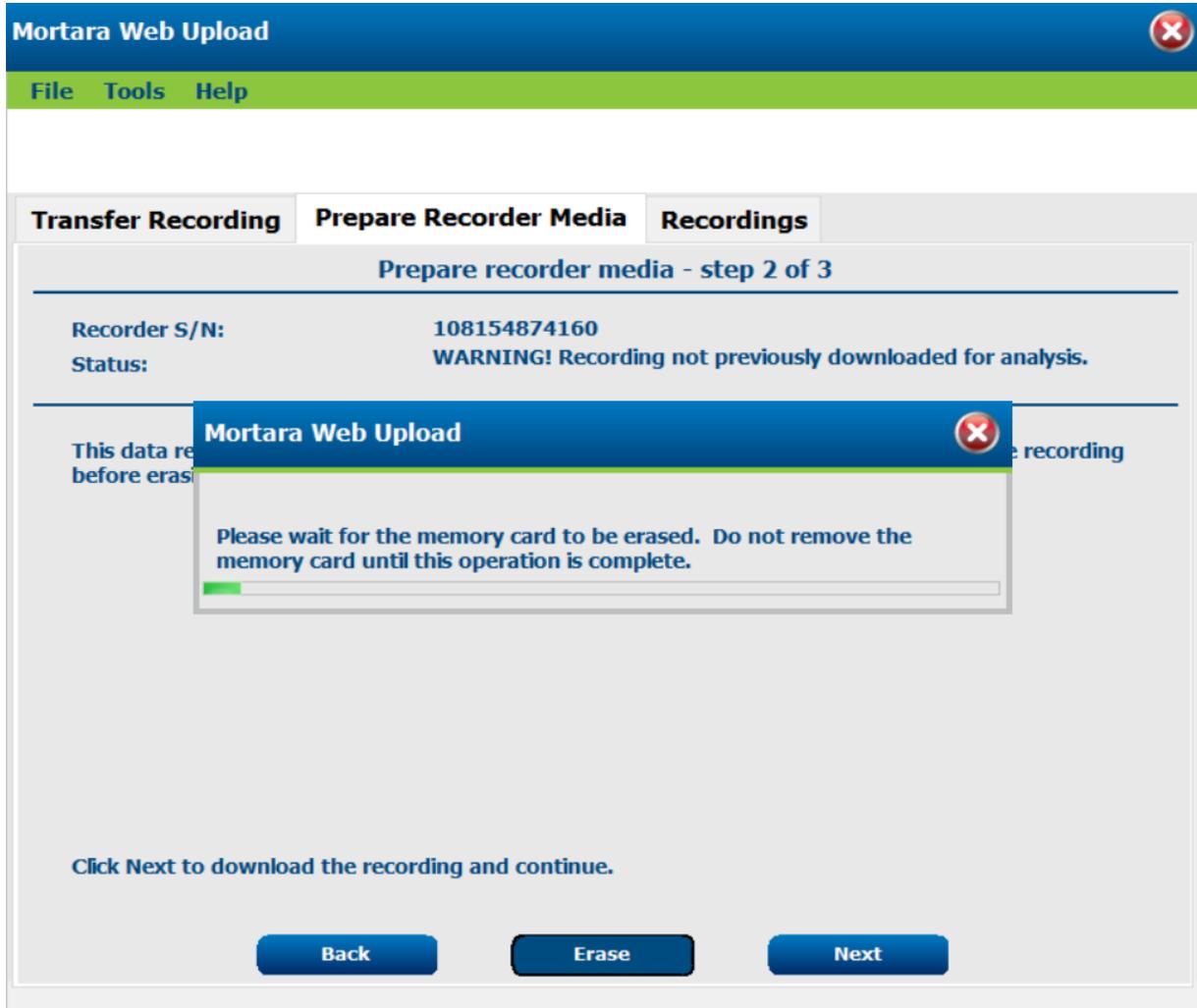
The screenshot shows the 'Mortara Web Upload' application window. The title bar is blue with a close button. Below the title bar is a green menu bar with 'File', 'Tools', and 'Help'. The main content area has three tabs: 'Transfer Recording', 'Prepare Recorder Media', and 'Recordings'. The 'Prepare Recorder Media' tab is active, showing 'Prepare recorder media - step 2 of 3'. Below this, there is a table with the following information:

Recorder S/N:	108154874160
Status:	WARNING! Recording not previously downloaded for analysis.

Below the table, a message states: 'This data recording has not been previously downloaded. You SHOULD first download the recording before erasing.' A dialog box is overlaid on the screen, titled 'Mortara Web Upload', with a question mark icon and the text: 'You have chosen to erase this data recording which has not been downloaded. Are you sure you want to continue? Select Yes to erase the recording.' The dialog box has two buttons: 'Yes' and 'No'. Below the dialog box, there is a message: 'Click Next to download the recording and continue.' At the bottom of the window, there are three buttons: 'Back', 'Erase', and 'Next'.

Step IV: A “wait while erasing” dialog will open and automatically close when finished. Once the H12+ recorder is ready for a new recording, Click Next.

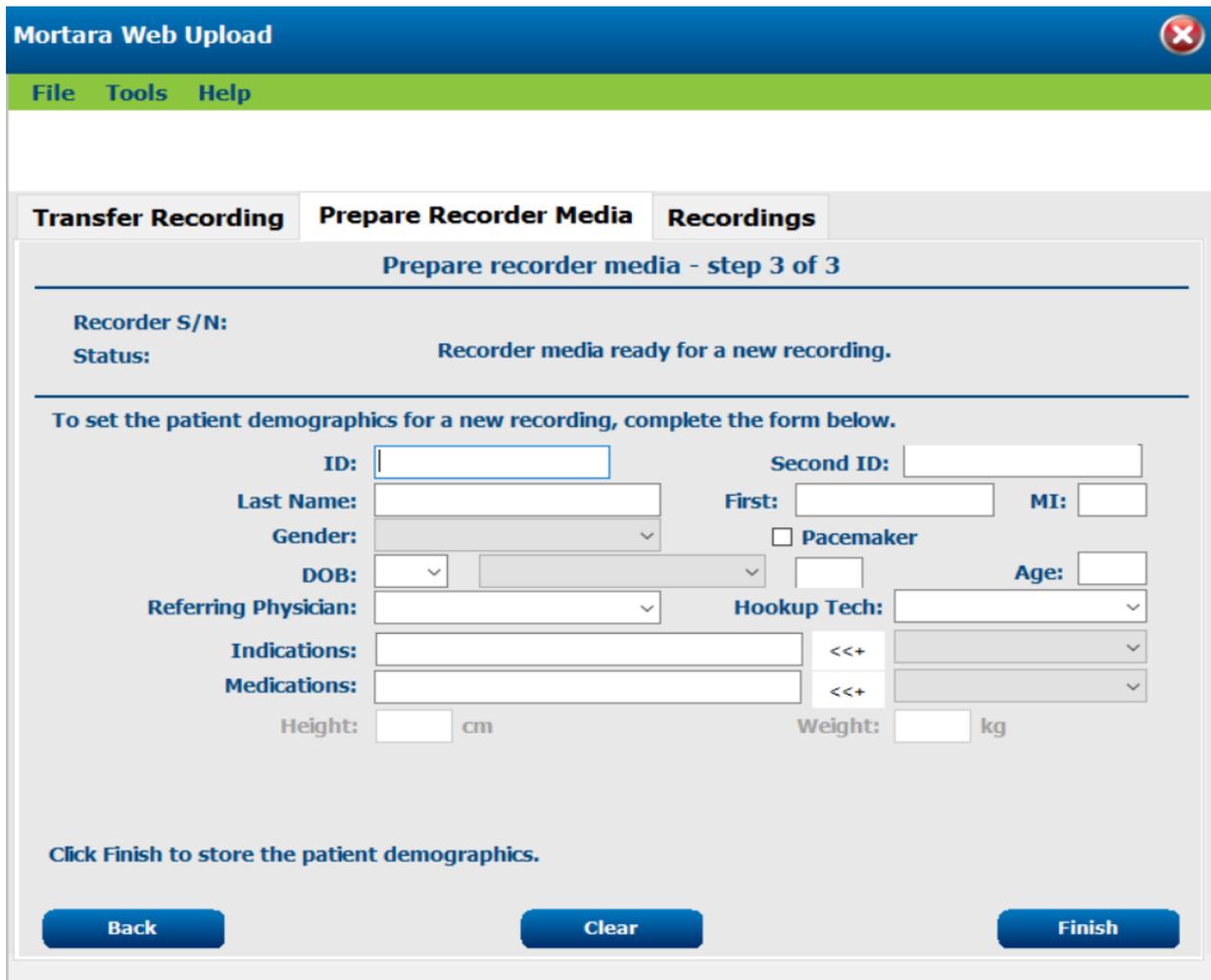
NOTE: Do not disconnect the H12+ from the download cable until this dialog box closes.



Step V: Pre-populate patient demographics or Enter patient demographics and other information using free text and the drop-down lists.

- Enter the correct Protocol ID in Indications and site ID in Medications field.
- Enter the Visit code in Hook up tech.
- Enter Subject Demographics such as Allocation number (Enter under screening Number), Subject Gender, Subject Initials and DOB.

Click 'Finish' when done. **You will be prompted to wait while the information is written to the CF memory card. Do not remove the card from the card reader until this dialog box closes.**



Mortara Web Upload

File Tools Help

Transfer Recording Prepare Recorder Media Recordings

Prepare recorder media - step 3 of 3

Recorder S/N:
Status: Recorder media ready for a new recording.

To set the patient demographics for a new recording, complete the form below.

ID: Second ID:

Last Name: First: MI:

Gender: Pacemaker

DOB: Age:

Referring Physician: Hookup Tech:

Indications: <<+

Medications: <<+

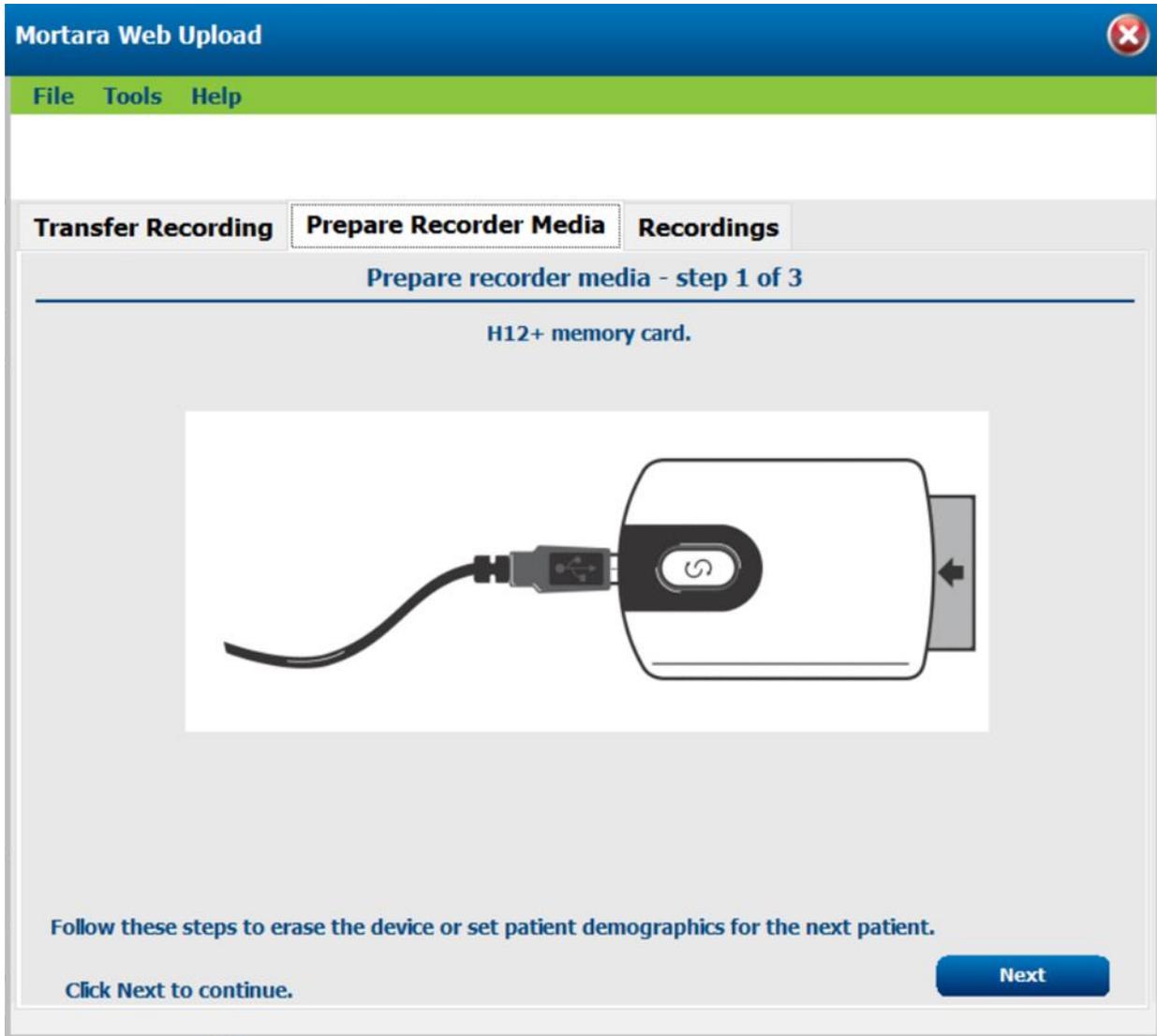
Height: cm Weight: kg

Click Finish to store the patient demographics.

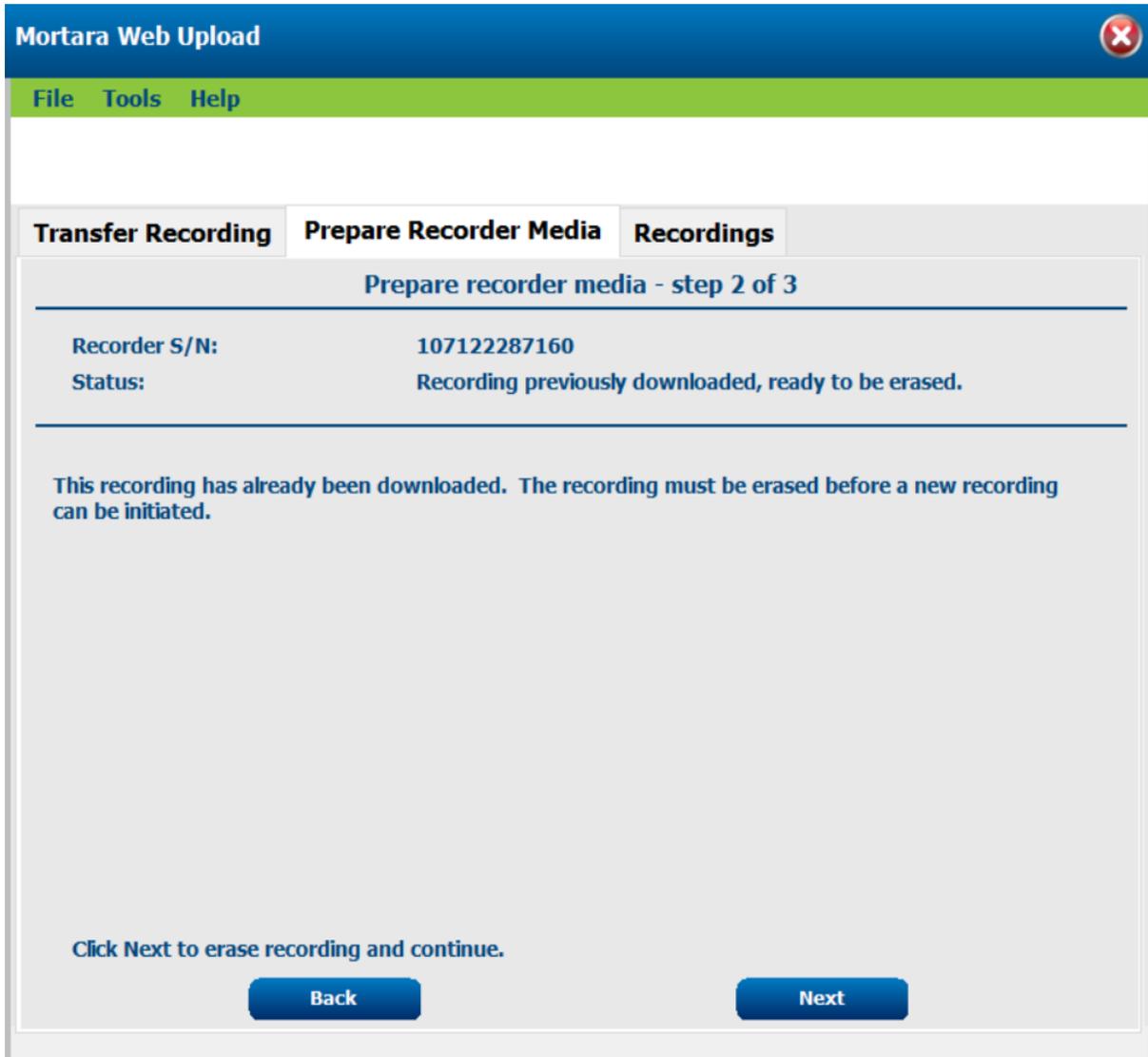
Back Clear Finish

Scenario B: The recording has previously been downloaded.

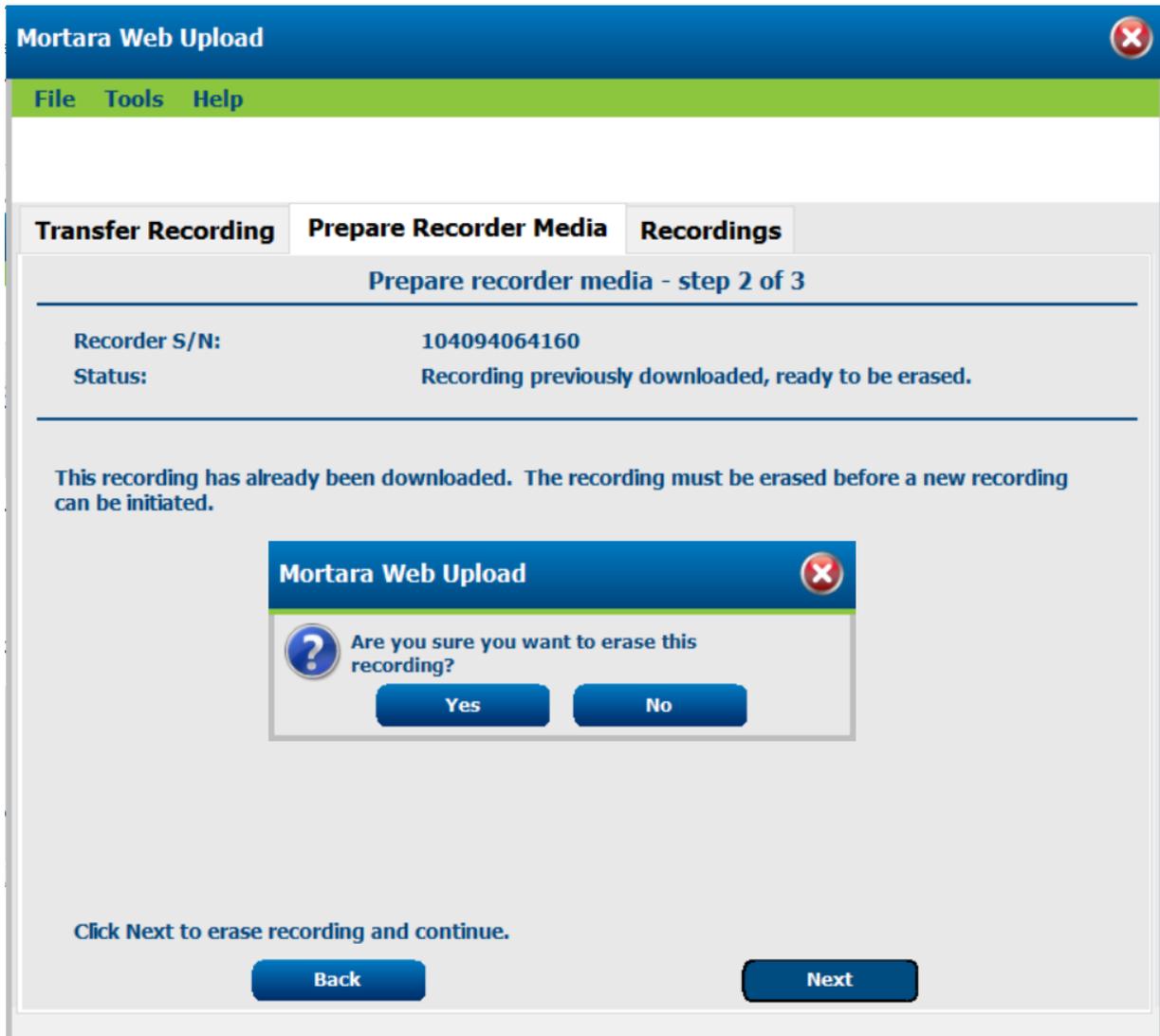
Step I: The top portion of the screen displays information about the recorder and recording. Click 'Next'.



Step II: The Screen will display the option to erase the recording from the previously downloaded recording. Click on 'Erase'.



A prompt to confirm erasing the recording will appear. Click on Yes.

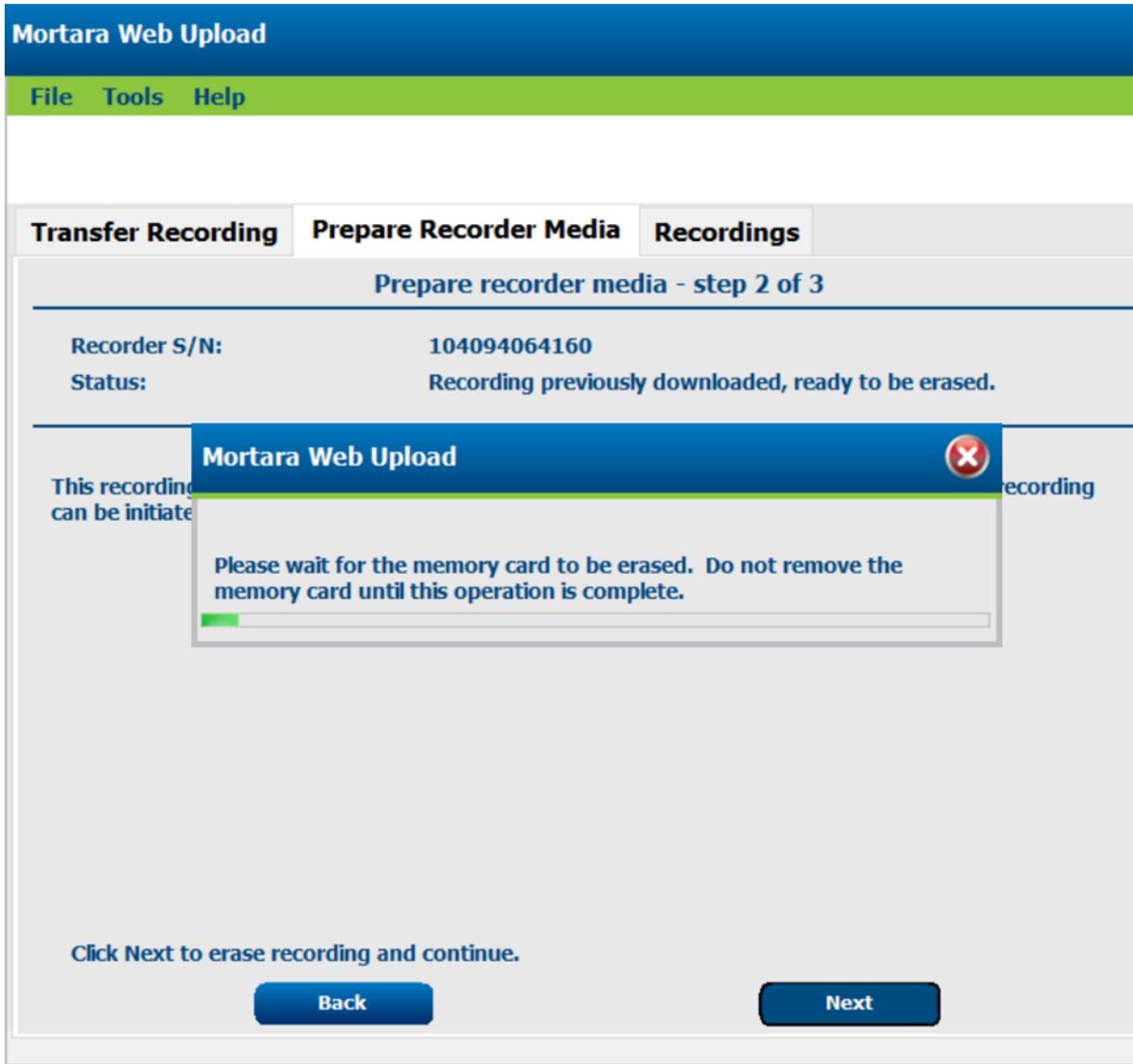


The screenshot shows the 'Mortara Web Upload' application window. The title bar is blue with the text 'Mortara Web Upload' and a close button. Below the title bar is a green menu bar with 'File', 'Tools', and 'Help'. The main content area has three tabs: 'Transfer Recording', 'Prepare Recorder Media', and 'Recordings'. The 'Prepare Recorder Media' tab is active, showing 'Prepare recorder media - step 2 of 3'. Below this, there is a table with the following information:

Recorder S/N:	104094064160
Status:	Recording previously downloaded, ready to be erased.

Below the table, a message states: 'This recording has already been downloaded. The recording must be erased before a new recording can be initiated.' A confirmation dialog box is displayed in the center, titled 'Mortara Web Upload', with a question mark icon and the text 'Are you sure you want to erase this recording?'. The dialog has two buttons: 'Yes' and 'No'. At the bottom of the main window, there is a message 'Click Next to erase recording and continue.' and two buttons: 'Back' and 'Next'.

Step III: A “wait while erasing” dialog will open and automatically close when finished. The CF memory card is now ready for a new recording. Click 'Next'.



The screenshot shows the Mortara Web Upload application interface. At the top, there is a blue header with the text "Mortara Web Upload" and a green navigation bar with "File", "Tools", and "Help". Below this is a tabbed interface with three tabs: "Transfer Recording", "Prepare Recorder Media", and "Recordings". The "Prepare Recorder Media" tab is active, showing a sub-header "Prepare recorder media - step 2 of 3".

Under the sub-header, there is a table-like structure with the following information:

Recorder S/N:	104094064160
Status:	Recording previously downloaded, ready to be erased.

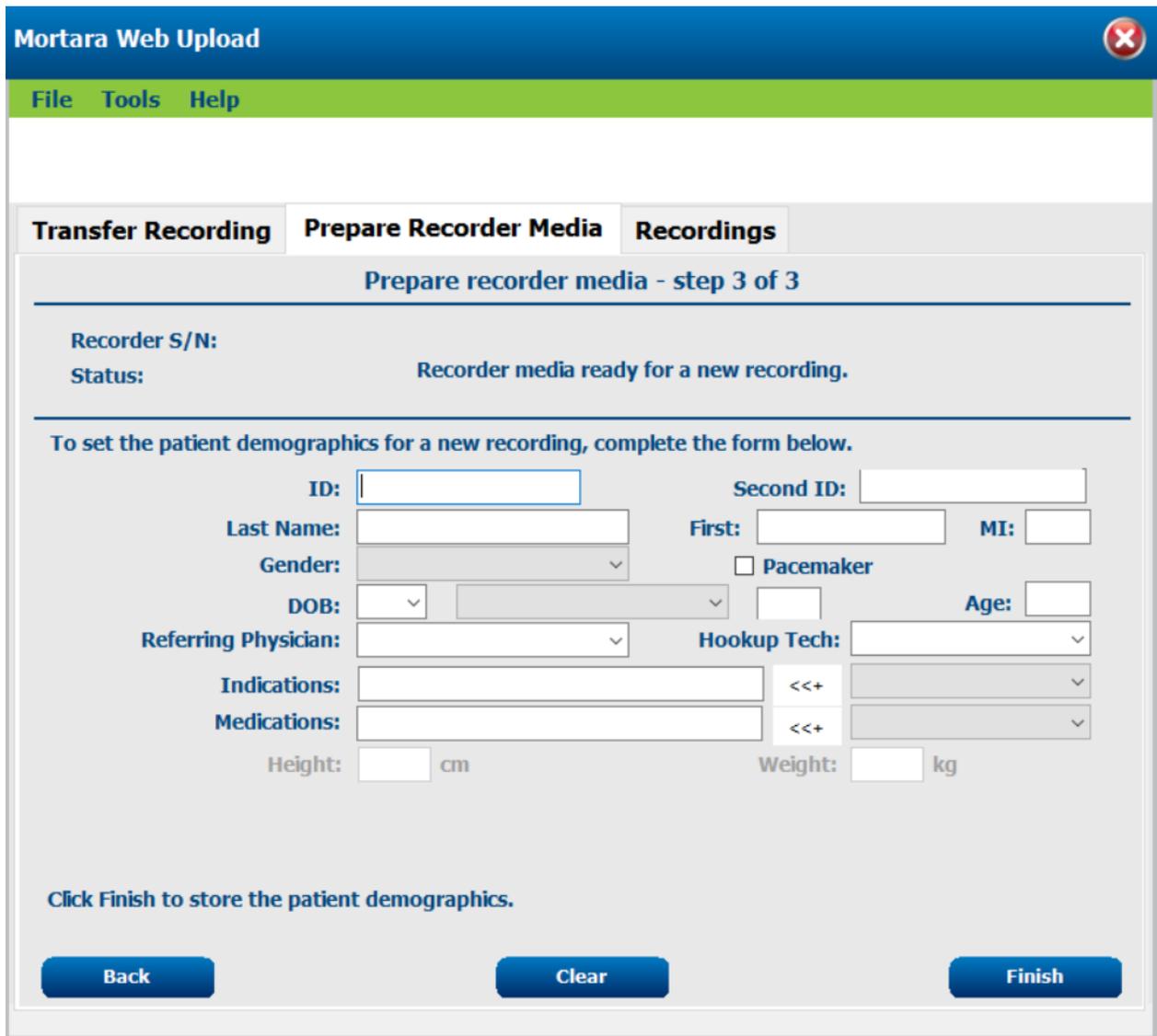
Below the table, there is a modal dialog box titled "Mortara Web Upload" with a red 'X' icon in the top right corner. The dialog contains the text: "Please wait for the memory card to be erased. Do not remove the memory card until this operation is complete." and a progress bar.

At the bottom of the main interface, there is a text prompt: "Click Next to erase recording and continue." and two buttons: "Back" and "Next".

Step 5: Pre-populate patient demographics or Enter patient demographics and other information using free text and the drop-down lists.

- Enter the correct Protocol ID in Indications and site ID in Medications field.
- Enter the Visit code in 'Hook up tech' Field.
- Enter Subject Demographics such as Allocation number (Enter under screening Number), Subject Gender, Subject Initials and DOB.

Click 'Finish' when done. **You will be prompted to wait while the information is written to the CF memory card. Do not remove the card from the card reader until this dialog box closes.**



Mortara Web Upload

File Tools Help

Transfer Recording Prepare Recorder Media Recordings

Prepare recorder media - step 3 of 3

Recorder S/N:
Status: Recorder media ready for a new recording.

To set the patient demographics for a new recording, complete the form below.

ID: Second ID:

Last Name: First: MI:

Gender: Pacemaker

DOB: Age:

Referring Physician: Hookup Tech:

Indications: <<+

Medications: <<+

Height: cm Weight: kg

Click Finish to store the patient demographics.

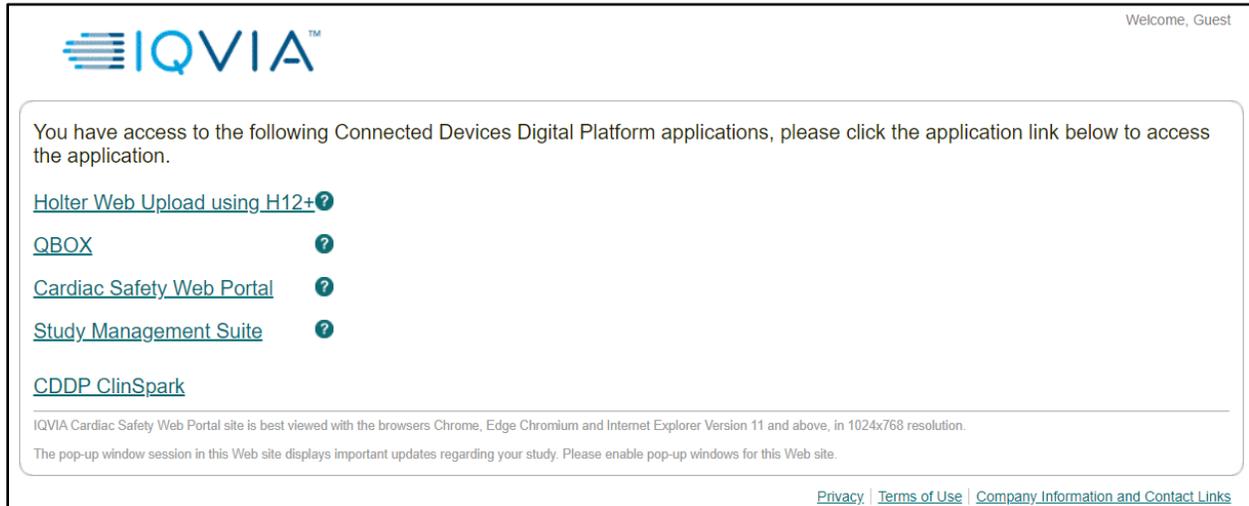
Back Clear Finish

Now the flashcard can be used for recording the Holter data.

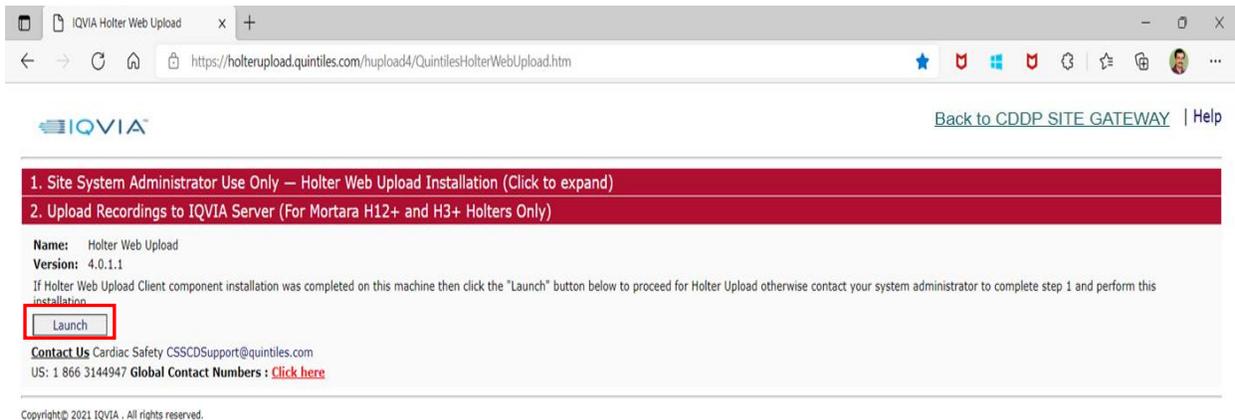
3. HOLTER WEB UPLOAD PROCEDURE

Follow the below steps to upload the Holter data on to IQVIA portal:

Step 1: Login to IQVIA CDDP SITE GATEWAY <https://cddp.solutions.iqvia.com> and Click on the 'Holter Web Upload using H12+' link to access Holter link.



Step 2: Go to 'Holter Web Upload using H12+' tab. The Holter Web Upload home screen should appear. Click on 'Launch'.



Step 3: Insert Flashcard into Flashcard reader and connect the card reader to the Laptop/PC USB port. Once the flashcard is connected, the Transfer Recording page will detect the connected media and show the recorder. A graphic for the H12+ CF memory card reader will display. Click on 'Next'.

Mortara Web Upload ✕

File **Tools** **Help**

Transfer Recording **Prepare Recorder Media** **Recordings**

Transfer recording - step 1 of 3

H12+ memory card.



Click Next to continue.

Next

Step 4: The top portion of the screen displays information about the recorder and recording. Verify all the required demographics including Protocol ID (Indication Field), site ID (Medication Field) and Visit code (Hookup Tech Field). Click Next.

Mortara Web Upload
✕

File
Tools
Help

Transfer Recording

Prepare Recorder Media

Recordings

Transfer recording - step 2 of 3

Recorder S/N: 107122287160

Status: Recording ready for download (previously downloaded).

Recording Start: 12/Oct/2019 06:25 25 hr, 2 min

Review the information below and make any necessary corrections.

ID:

Last Name:

Gender: Male

DOB: 1 Jan 1977

Referring Physician: 0800

Indications: WP43295 <<<+

Medications: 001 <<<+

Height: cm

Second ID:

First: MI:

Pacemaker

Age:

Hookup Tech: P4D1

Weight: kg

Diary Entries:

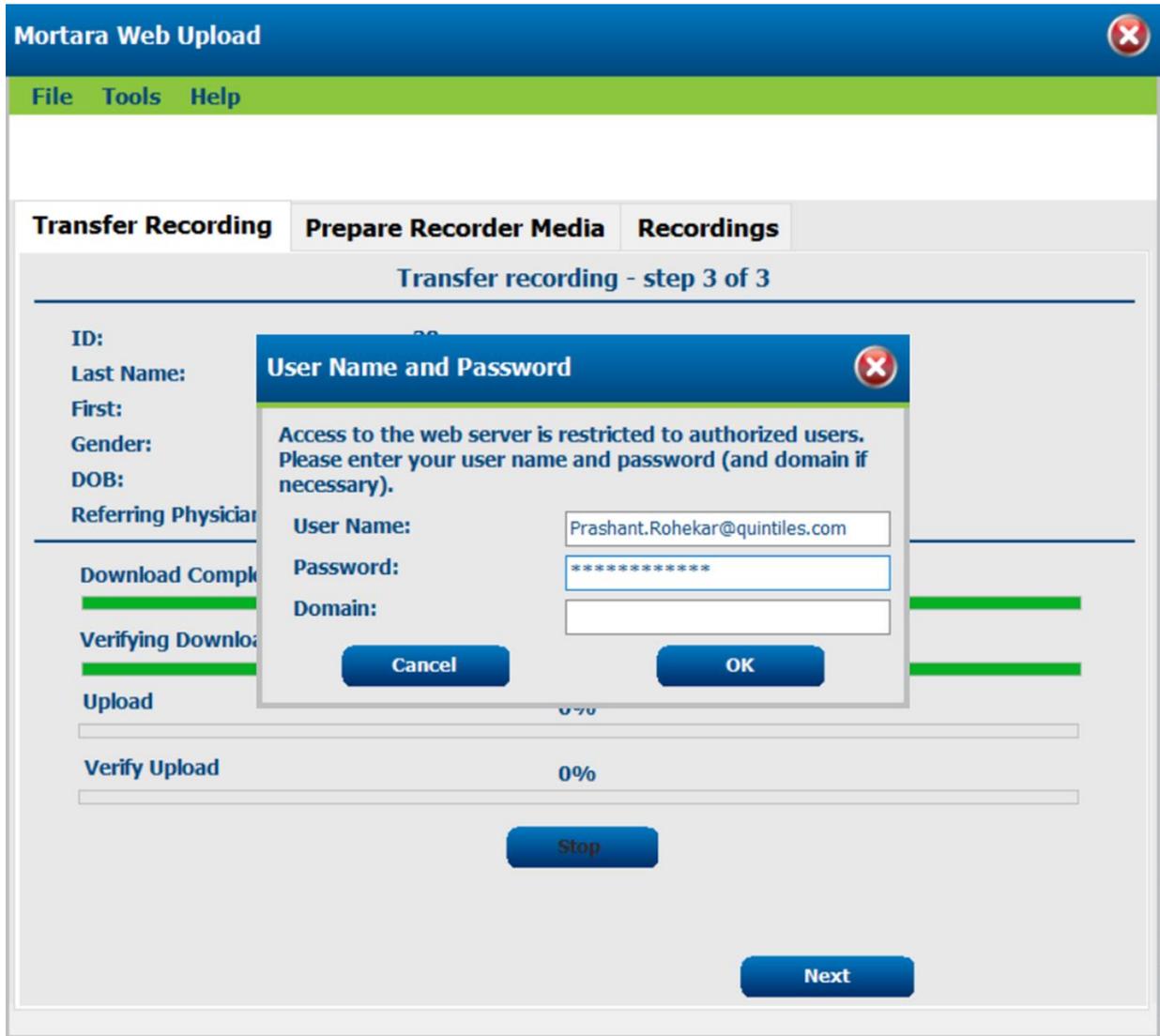
Time	Diary Annotation
06:25:05 12/Oct/2019	
06:25:15 13/Oct/2019	

Back

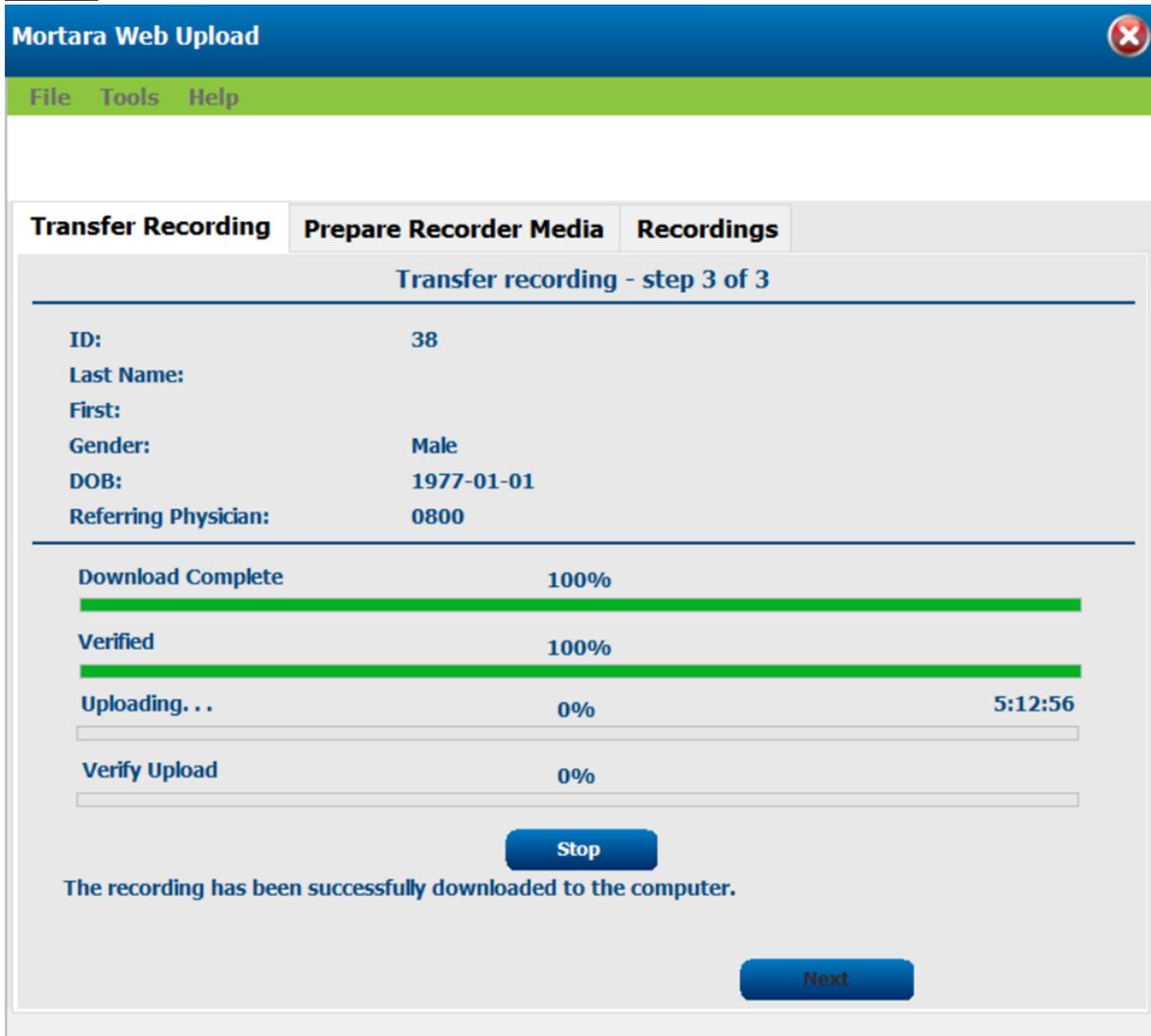
Clear

Next

Step 5: Username and Password window will open. Enter your Username and most updated Password. Click on 'OK', Ensure that the Domain is left blank.



Step 6: The file is downloaded and verified. Click on 'Next'.

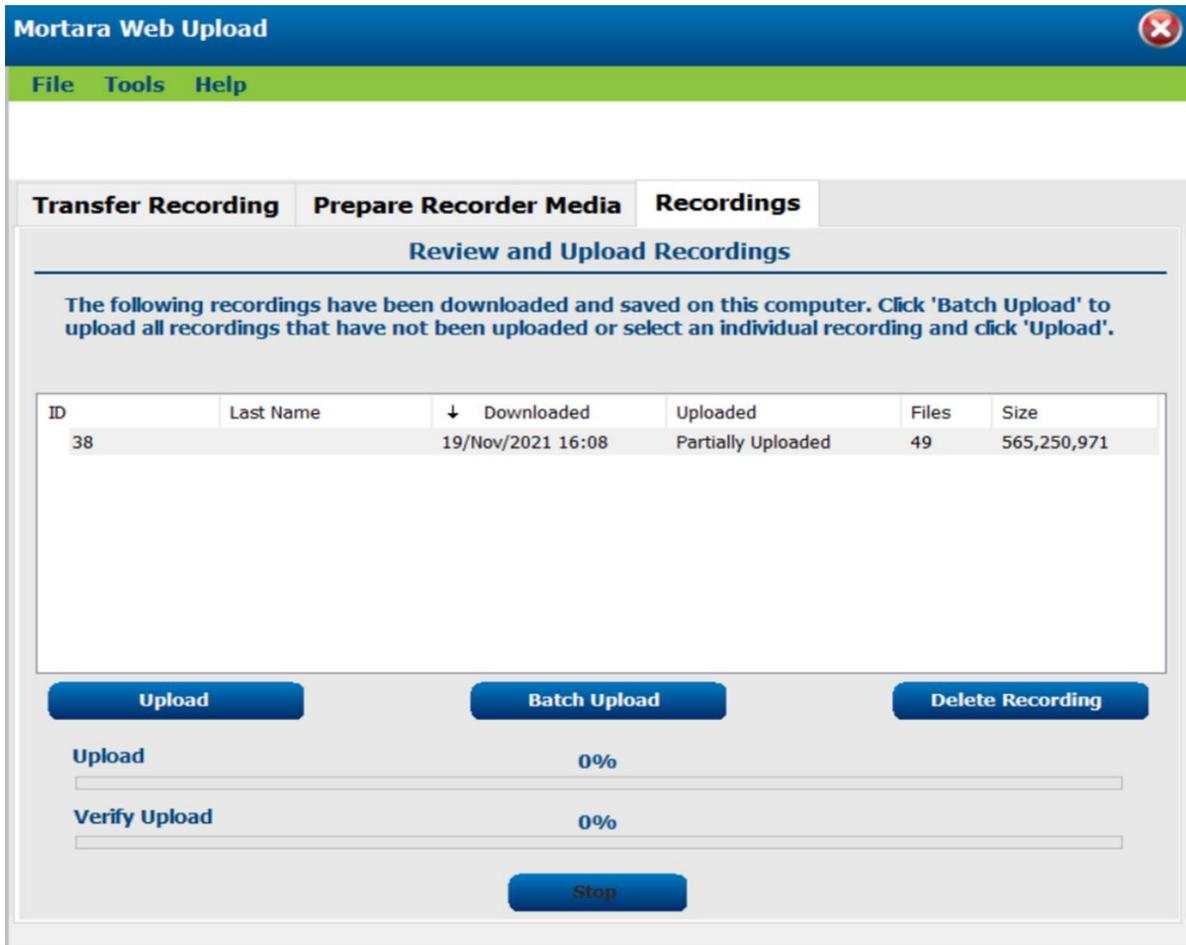


The screenshot shows the 'Mortara Web Upload' application window. The title bar is blue with a close button. Below it is a green menu bar with 'File', 'Tools', and 'Help'. The main content area has three tabs: 'Transfer Recording' (selected), 'Prepare Recorder Media', and 'Recordings'. The 'Transfer Recording' tab displays 'Transfer recording - step 3 of 3'. It lists patient information: ID: 38, Last Name: (blank), First: (blank), Gender: Male, DOB: 1977-01-01, and Referring Physician: 0800. Below this is a progress table:

Task	Progress	Time
Download Complete	100%	
Verified	100%	
Uploading. . .	0%	5:12:56
Verify Upload	0%	

At the bottom of the progress section is a blue 'Stop' button. Below that is the text: 'The recording has been successfully downloaded to the computer.' At the very bottom right is a blue 'Next' button.

Step 7: Click on 'Batch Upload' to upload the Holter files. During upload, the percent uploaded and required time for upload are shown. Transfer time is dependent on recording size (KB) and network connection speed (DSL, T1 line, etc.).



Mortara Web Upload

File Tools Help

Transfer Recording Prepare Recorder Media Recordings

Review and Upload Recordings

The following recordings have been downloaded and saved on this computer. Click 'Batch Upload' to upload all recordings that have not been uploaded or select an individual recording and click 'Upload'.

ID	Last Name	↓ Downloaded	Uploaded	Files	Size
38		19/Nov/2021 16:08	Partially Uploaded	49	565,250,971

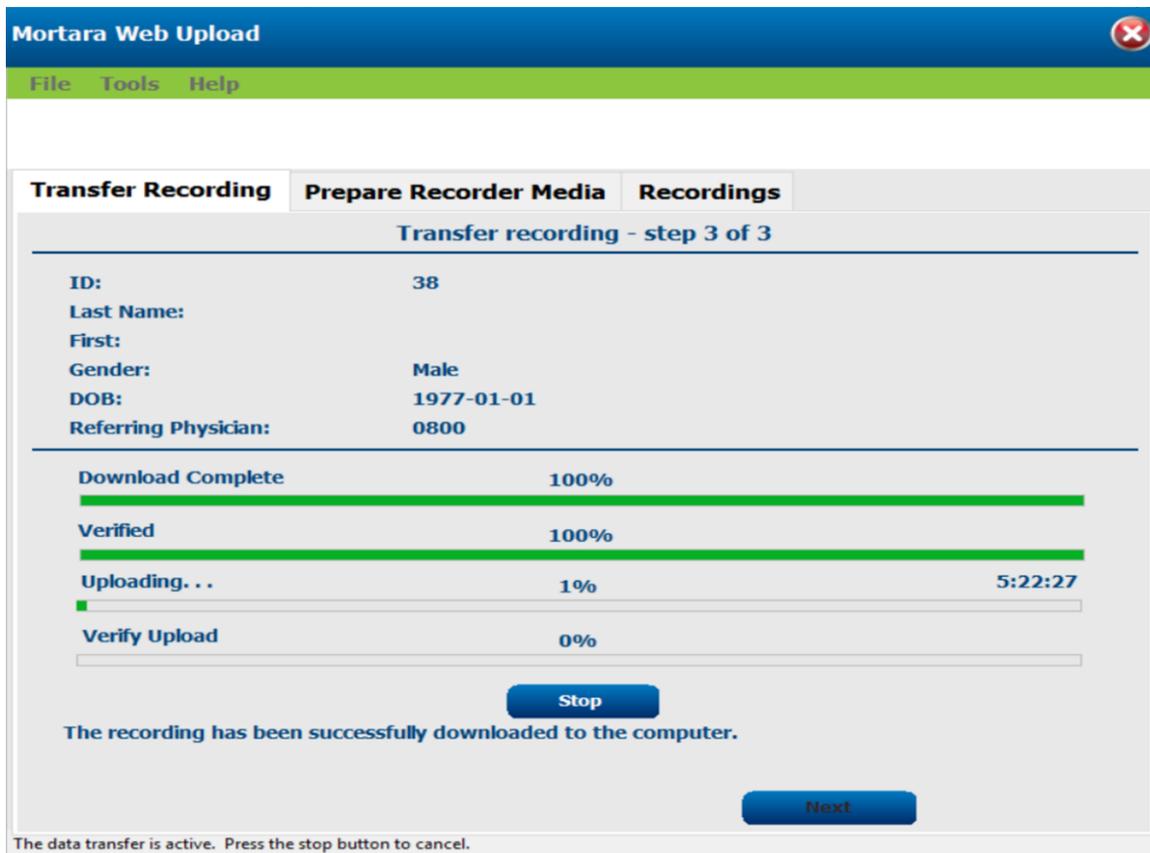
Upload Batch Upload Delete Recording

Upload 0%
Verify Upload 0%

Stop

NOTE:

- A copy gets saved to the local computer.
- Upload can be stopped at any time (partially uploaded) and will resume where it left off the next time the recording is selected for upload.



Mortara Web Upload

File Tools Help

Transfer Recording Prepare Recorder Media Recordings

Transfer recording - step 3 of 3

ID: 38
 Last Name:
 First:
 Gender: Male
 DOB: 1977-01-01
 Referring Physician: 0800

Download Complete	100%	
Verified	100%	
Uploading. . .	1%	5:22:27
Verify Upload	0%	

Stop

The recording has been successfully downloaded to the computer.

Next

The data transfer is active. Press the stop button to cancel.

Note: DATA BACK-UP

1. Once the data is uploaded on IQVIA server, a copy gets saved to your local computer.
2. The software will automatically delete the Holter data as per the set frequency from the path specified in the settings section of Holter Web Upload.
3. It is mandatory to Copy the data to another location on your local computer with proper nomenclature as back up until the data base lock activities are completed. The Holter data should be named as below: **SUBJECT NO/VISIT ID**.

4. HELP AND SUPPORT DETAILS

If you have any queries, please feel free to contact IQVIA help desk or Connected Devices Holter team:

Email: CSSCDSupport@quintiles.com or QECGExternalHolterTeam@quintiles.com