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1. CONFORM Pivotal Imaging

Imaging will be submitted through the EDC system, Medidata Rave, for the applicable time points and events located in *Table 1.0*.

Table 1.0

Visit	Image type required per visit
Screening	<p>Executive Committee Pre-Procedural Review for First 5 Patients:</p> <ul style="list-style-type: none"> • Cardiac CT/TEE: Within 6 months of the date of consent <p>Post-5 Patient Review Imaging Options: Within 6 months of the date of consent (one of the following must be performed)</p> <ul style="list-style-type: none"> • TEE • Cardiac CT • TTE* • Cardiac MRI* <p><i>* TEE or CT is required prior to randomization to fully evaluate all echo exclusion criteria. Note that TTE and Cardiac MRI can only be completed as screening imaging if site has 3+ procedures on a given day. If there are less than 3 procedures, Conformal requires that a CT or TEE is done as screening imaging.</i></p> <p>For patients with a documented history (within 24 months prior to enrollment) of stroke or TIA: Brain Scan with MRI/CT: Historical Imaging post-neurological event per SOC. Otherwise, new imaging is to be taken after consent.</p>
Randomization	<p>Randomization cannot occur until all imaging inclusion/exclusion criteria (as per the imaging modality) have been satisfied by baseline imaging. All patients must have CT or TEE imaging prior to Randomization.</p> <p>Note: The subject will undergo TEE during the Index Procedure, and this timepoint will serve as a review of Echo Exclusion Criteria.</p>

Visit	Image type required per visit
Procedure	<ul style="list-style-type: none"> • TEE <ul style="list-style-type: none"> ○ If 3D imaging is acquired, the 3D raw data should be transferred with the uploaded images • Angio
Pre-Discharge	TTE <ul style="list-style-type: none"> • At least 4 hours post-procedure
45-Day (± 7 Days)	TEE <ul style="list-style-type: none"> • Cardiac CT may be used in lieu of TEE • If there is a finding of a non-trivial leak (>3mm) or device-related thrombus, a TEE will need to be performed as soon as possible. Refer to Protocol for recommended timing.
6 Month (± 30 days)	TEE is only required at 6 Months IF: Subjects at the 45-day visit that had evidence of a non-trivial residual leak (>3mm) or thrombus. The subject will need a repeat TEE at 6 months if there is no TEE imaging documentation of the event resolution.
12 Month (± 30 Days)	TEE <ul style="list-style-type: none"> • Cardiac CT may be used in lieu of TEE. <ul style="list-style-type: none"> ○ If Pericardial Effusion >10mm is detected on CT, TTE evaluation suggested for quantification. • If there is a finding of a DRT or inadequate seal (leak >3mm) is detected on the CT, a TEE is required to be performed as soon as possible. Refer to Protocol for recommended timing. • If a non-trivial leak is noted, a TEE is required to confirm the finding, as soon as possible. Refer to the Protocol for recommended timing.
Unscheduled/Adverse Event	At any time point, if a Subject has evidence of a significant residual leak (>5mm on TEE) or thrombus, subject should be evaluated for treatment with OAC (Warfarin or DOAC), and ASA for 4-6 weeks followed by repeat imaging. Note: If at any time point a CT has a finding of peri-device leak >3 mm, a TEE must be performed for confirmation and evaluation of the leak. Neurological Event requires a Brain CT/MRI <ul style="list-style-type: none"> • Brain imaging is not required for patients with systemic embolism without new findings suggestive of TIA/stroke

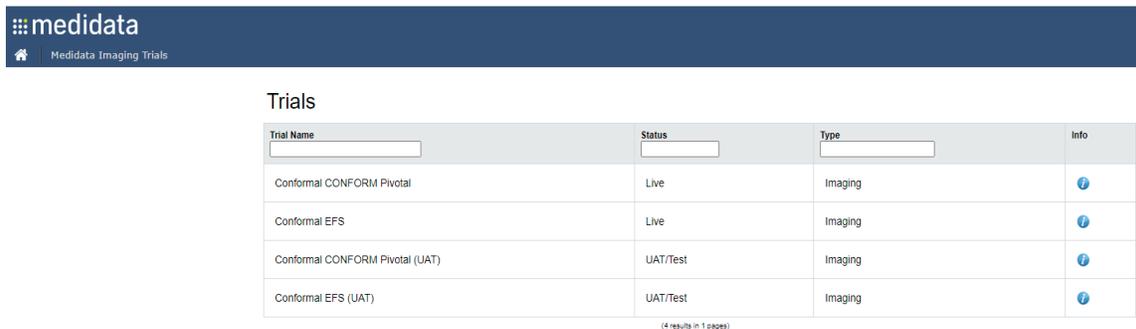
Table 1.0

2. Navigating Imaging Uploads in EDC

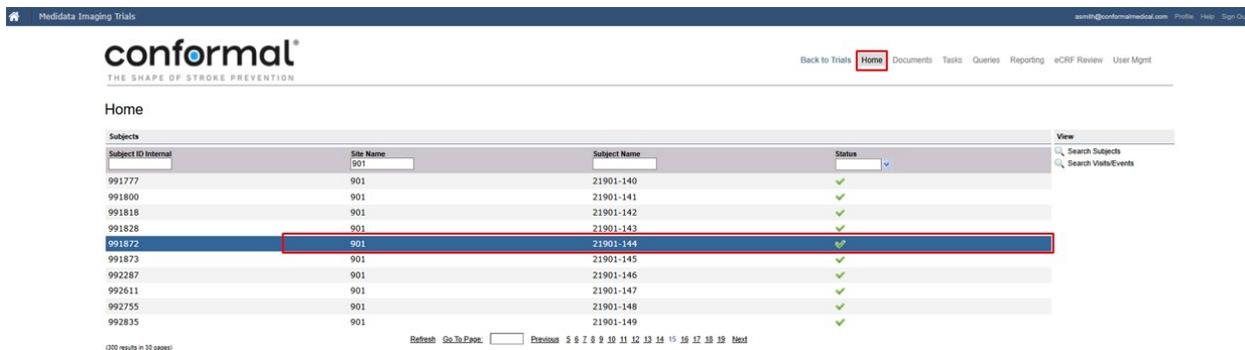
Log in from the Medidata home page. From the home page, go to “Apps” on the left side of the screen. Click the **conformalmedical** link under “Medical Imaging” to bring you to the imaging home page.



Clicking the **conformalmedical** link will take you to the next page shown below. Next, click on “Conformal CONFORM Pivotal”



You will be directed to the imaging home page, where you can see all patients who are currently in the trial at your site. Please note that once you have completed the informed consent and inclusion and exclusion criteria eCRFs and saved complete, these patients will populate in the imaging module:

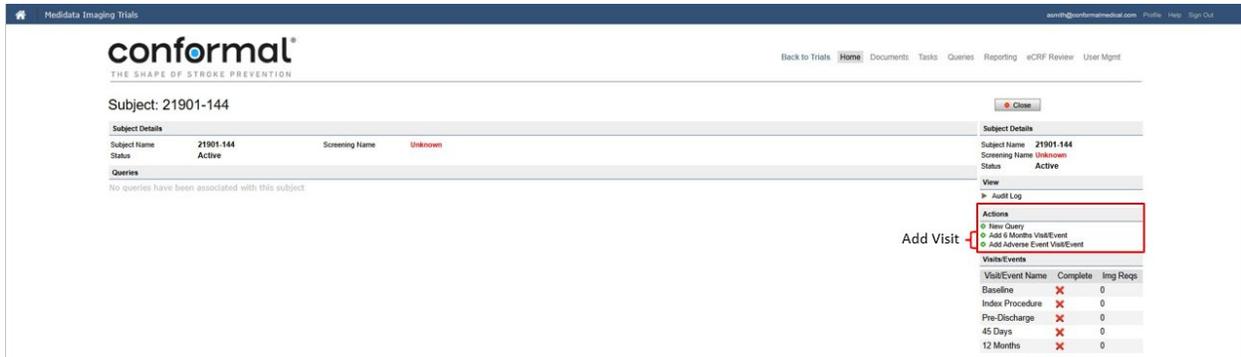


Once you click on a patient (in this case subject 21901-144 has been selected), you will be brought to the patient’s repository page (pictured below). In the middle of the page, on the right-hand side of the screen, you can select the Visits/Events, which will open the specific Visit/Event details, Visit/Event

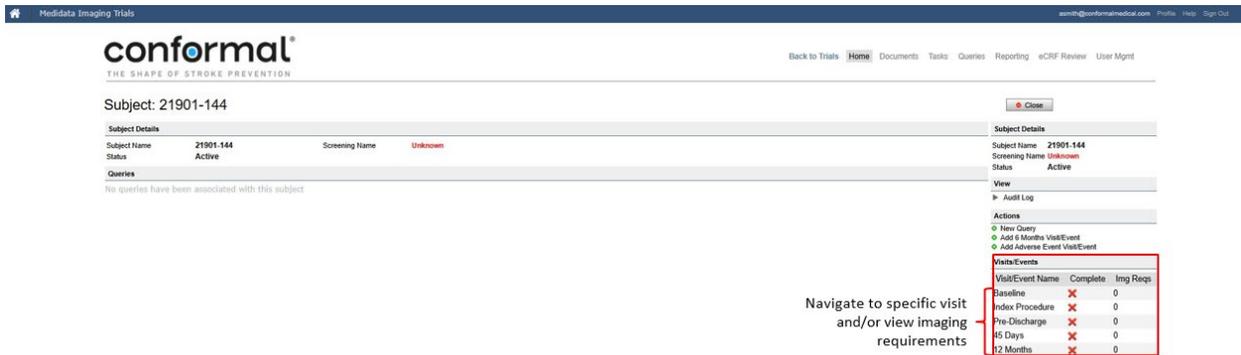
Requirements, and additional sections associated with the patient for that time point including a preview under the Exam Section.

Under the “Actions” section:

- You will also be able to add another visit for the patient (i.e., the patient has a device-related thrombus detected during their 45-day imaging, and the patient is required to come in for a 6-month TEE or add an adverse event visit for adverse events with associated imaging).



By clicking on any of the visits in the Visits/Events section in the bottom right, you will be able to navigate to that specific visit and view the imaging requirements.



If the required imaging exam is not uploaded/has not met the submission requirement, then the box will be highlighted red (as seen for the TTE, and Sonographer Worksheets). Use the Override buttons to overrule the request for a requirement not fulfilled (i.e., CT is uploaded for the baseline visit). By clicking the override button on the TTE and Sonographer’s worksheet, you’re able to confirm the document and exam were not done. This will allow you to complete submission for the visit.

Subject: 21901-144

Baseline Visit/Event Details

Type	Info	Requirement	Commands
Exam	TEE	1 Exam	Upload Exams Comment
Exam	TTE	1 Exam	Upload Exams Comment Override
Document	TTE/TEE Sonographer Worksheet	1 Document	Upload Document Upload via Mobile Device Edit & Finalize Comment Override
Exam	CT	1 Exam	Upload Exams Comment

Submission Problems (4):

1. TTE: Requires an upload of override.
2. TTE/TEE Sonographer Worksheet: Requires an upload of override.

Message(s):

1. TTE: No upload supplied.
2. CT: No upload supplied.

Start CT Review

Start TTE Review

The Baseline visit/event has not satisfied all required items. Please provide all required data in order to finalize the visit/event submission and provide your e-signature.

By clicking on the Upload Exams button, you will be taken to this page below, where you can upload the DICOM formatted imaging directly from your computer.

Subject: 21901-144

Baseline Exam Upload

Partners Upload Control

Click the button below to locate your images...

Select DICOM Folder

Visit/Event Name	Complete	Img Reqs
Baseline	X	0
Index Procedure	X	0
Pre-Discharge	X	0
45 Days	X	0
12 Months	X	0

Once you have uploaded the required images, you will need to re-sign to confirm the upload. On this page, you will now see what was uploaded and when the images and/or sonographer worksheets were uploaded.

Note: if issues uploading DICOM images are encountered, you may need to contact your institution's IT support.

Select the red box to provide your electronic signature

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Subject: 21901-144

Baseline Visit/Event Details

Visit/Event Name	Baseline Status	Visit/Event Date	Unknown
	Active		

Baseline Visit/Event Requirements

Type	Info	Requirement	Commands
Exam	TEE	1 Exam	Upload Exams Comment
Exam	TTE	1 Exam	Upload Exams Comment
Document	TTE/TEE Sonographer Worksheet	1 Document	Upload Document Upload via Mobile Device Edit & Finalize Mobile Uploads Comment Override
Exam	CT	1 Exam	Upload Exams Comment

Submission Problems (1):

- 1. CT: No upload supplied.

Start CT Review

Start TTE Review

Your submission is not final until you click here & provide an electronic signature

Sign to confirm the upload

Select the blue box to confirm “Yes, submit now”

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Subject: 21901-144

Baseline Visit/Event Details

Visit/Event Name	Baseline Status	Visit/Event Date	Unknown
	Active		

Baseline Visit/Event Requirements

Type	Info	Requirement	Commands
Exam	TEE	1 Exam	Upload Exams Comment
Exam	TTE	1 Exam	Upload Exams Comment
Document	TTE/TEE Sonographer Worksheet	1 Document	Upload Document Upload via Mobile Device Edit & Finalize Mobile Uploads Comment Override
Exam	CT	1 Exam	Upload Exams Comment

Submission Problems (1):

- 1. CT: No upload supplied.

Start CT Review

Start TTE Review

You are submitting a Baseline visit/event without including all optional requirements. Would you like to continue anyways?

Yes, submit now

No, abort

Select the blue box “Click Here to Sign”

Select the green check box “Ok”

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Subject: 21901-144

Baseline Visit/Event Details

Visit/Event Name	Baseline Status	Visit/Event Date	Unknown
	Active		

Baseline Visit/Event Requirements

Type	Info	Requirement	Commands
Exam	TEE	1 Exam	Upload Exams Comment
Exam	TTE	1 Exam	Upload Exams Comment
Document	TTE/TEE Sonographer Worksheet	1 Document	Upload Document Upload via Mobile Device Edit & Finalize Mobile Uploads Comment Override
Exam	CT	1 Exam	Upload Exams Comment

Submission Problems (1):

- 1. CT: No upload supplied.

Start CT Review

Start TTE Review

You are submitting a Baseline visit/event without including all optional requirements. Would you like to continue anyways?

Yes, submit now

No, abort

Signature

Click Here to Sign

Ok

Cancel

Select the green check box “Ok”

Once the uploaded exams and documents (if required) have passed QC, a green checkmark will appear showing the visit upload requirements are complete.

At 45 Days and 12 Months, either a TEE and Sonographer Worksheet or a Cardiac CT may be uploaded. A completed and signed Sonographer Worksheet must accompany any uploaded TEE

A comment must be provided if imaging type was performed but not available, in order to successfully override.

Subject: 21901-144

45 Days Visit/Event Details

Visit/Event Name: 45 Days, Status: Active, Visit/Event Date: Unknown

45 Days Visit/Event Requirements

Type	Info	Requirement	Commands
Exam	TEE	1 Exam	Upload Exams Comment Override
Document	TTE/TEE Sonographer Worksheet	1 Document	Upload Document Upload via Mobile Device Edit & Finalize Mobile Uploads Comment Override
Exam	CT	1 Exam	Upload Exams Comment Override

Submission Problems (2):

1. TEE: Requires an upload or override.
2. TTE/TEE Sonographer Worksheet: Requires an upload or override.

✗ The 45 Days visit/event has not satisfied all required items. Please provide all required data in order to finalize the visit/event submission and provide your e-signature.

Queries: No queries have been associated with this visit/event.

Subject Details: Subject Name: 21901-144, Screening Name: Unknown, Status: Active

Visits/Events

Visit/Event Name	Complete	Img Reqs
Baseline	✓	1
Index Procedure	✗	0
Pre-Discharge	✗	0
45 Days	✗	0
12 Months	✗	0

Once imaging is uploaded or override is complete, this will move through to QC. The red x will remain until exams pass the QC process.

Subject: 21901-144

45 Days Visit/Event Details

Visit/Event Name: 45 Days, Status: Active, Visit/Event Date: Unknown

45 Days Visit/Event Requirements

Type	Info	Requirement	Commands
Exam	TEE	1 Exam	Upload Exams Comment
Document	TTE/TEE Sonographer Worksheet	1 Document	Upload Document Upload via Mobile Device Edit & Finalize Mobile Uploads Comment
Exam	CT	2 Exams	Upload Exams Comment

Visit/Event will be reviewed - thank you!

Queries: No queries have been associated with this visit/event.

Comments

Requirement	Date	Source	Comment	User	Actions
TEE	04-Apr-2022 2:42 PM		VERRIDE-TEST	koasan@conformalmedical.com	Remove
TEE	04-Apr-2022 2:43 PM		VERRIDE-TEST	koasan@conformalmedical.com	Remove

Visits/Events

Visit/Event Name	Complete	Img Reqs
Baseline	✓	1
Index Procedure	✗	0
Pre-Discharge	✗	0
45 Days	✓	1
12 Months	✗	0

When scrolling further down this page below the comment section, you will see a section labelled "Exam". This section is where you may preview the imaging, by clicking on the small picture.

Queries: No queries have been associated with this visit.

Comments

Requirement	Date	Override	Comment	User	Actions
TEE	04-Apr-2022 2:42 PM		VERRIDE-TEST	koasan@conformalmedical.com	Remove
TEE	04-Apr-2022 2:43 PM		VERRIDE-TEST	koasan@conformalmedical.com	Remove

Exam

Preview	Requirement	Modality	Study Date	Images / Series	Upload Date	Upload By	Actions
	TEE	US	01-Jan-2021 11:30 AM	Final: 93 / 1 Original: 93 / 1	04-Apr-2022 2:57 PM	koasan@conformalmedical.com	Preview Study Remove Study Download Study Open In PACS Change Req Edit DICOM Headers

Files: No files have been associated with this visit.

Documents

File Name	Requirement	Upload Date	Actions
Sonographers Worksheet - 08.pdf	TTE/TEE Sonographer Worksheet	04-Apr-2022 4:28 PM	Open Document Download Remove Change Req

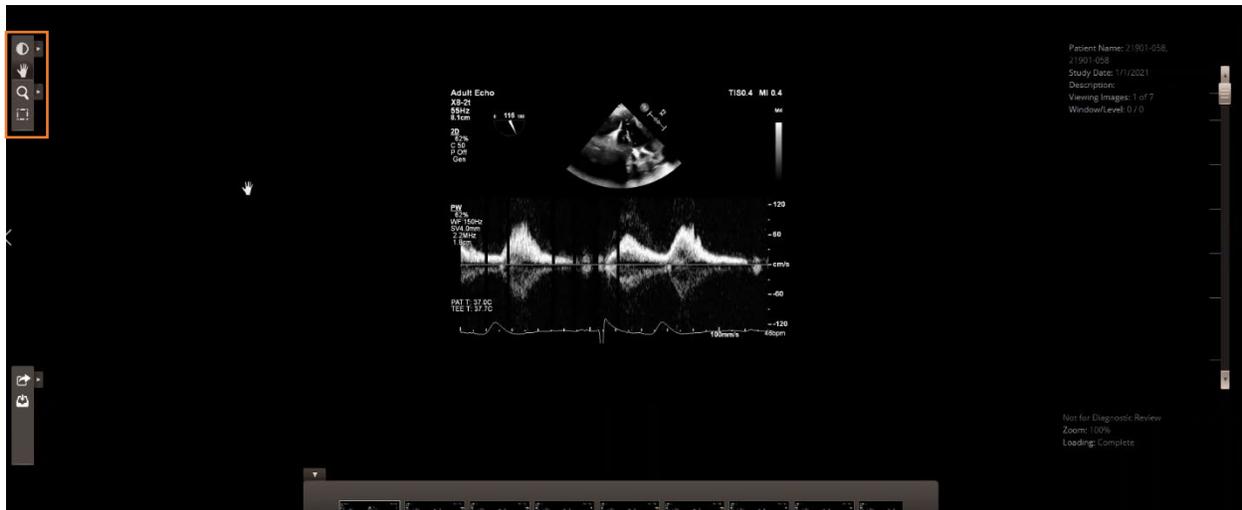
No Documents have been associated with this visit.

Visits/Events

Visit/Event Name	Complete	Img Reqs
Baseline	✗	0
Index Procedure - Pre-Release	✗	0
Index Procedure - Post-Release	✓	1
45 Days	✓	1
12 Months	✓	1

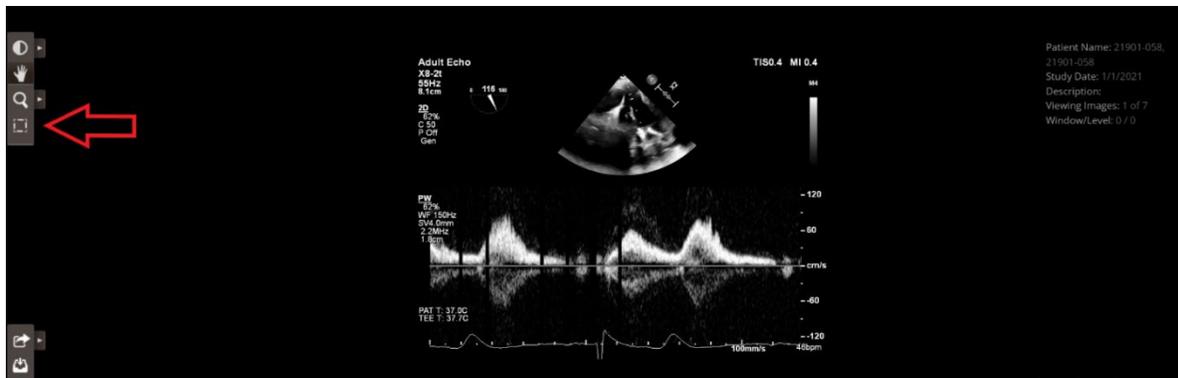
While previewing the images you will be able to see what was uploaded. Inteleimage has a feature which assists with deidentifying remaining PHI.

If needed, you can manually redact information using the box icon at the bottom on the left panel (see red box below) when previewing an image:



3. Redaction/Masking Tool – How to De-Identify PHI

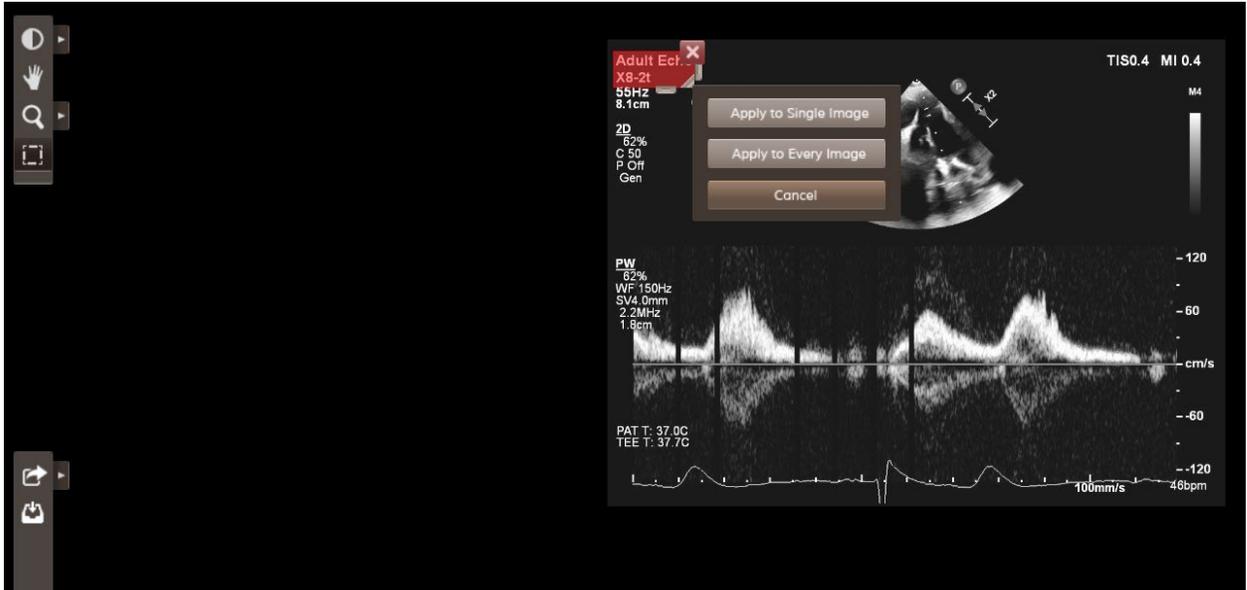
To redact, you will click on the box in the top left in the preview of the image.



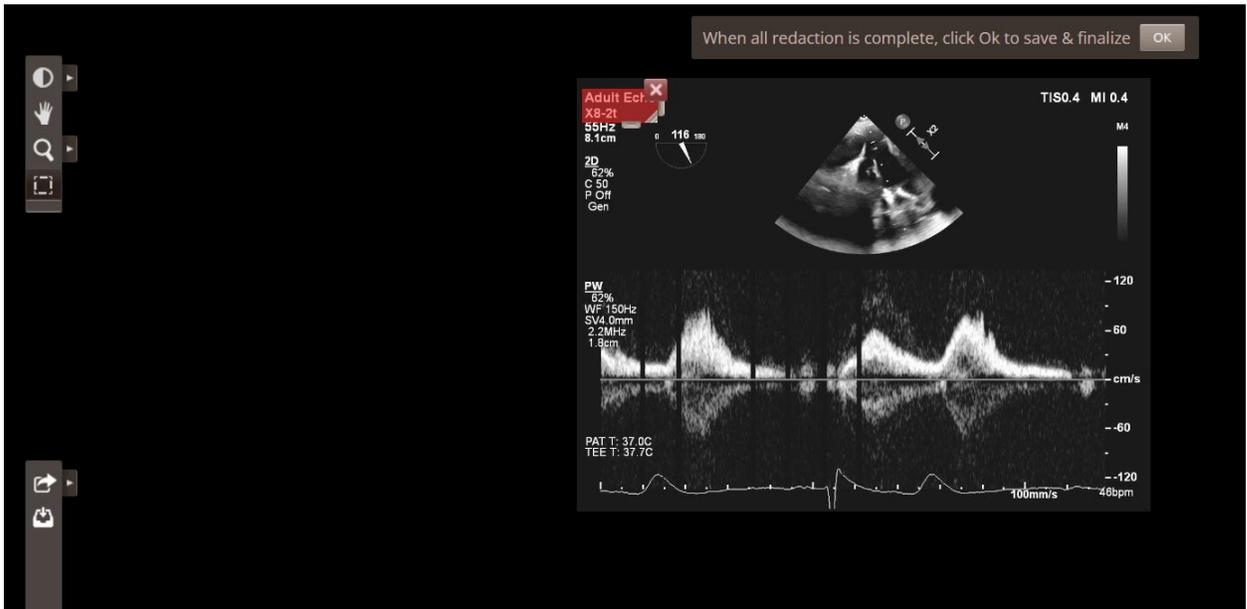
After clicking on the box, you will see a crosshair that appears. You will be able to click and drag your mouse around the area that you would like to de-identify. Once you have created the red shaded area around the PHI, you will see 3 options appear: “Apply to Single Image”, Apply to Every Image”, and “Cancel”.

By clicking on “Apply to Single Image” the mask will only apply to that image.

By clicking on “Apply to Every Image” the mask will apply to all images in upload in the same location. BEWARE: If all PHI is not located in the same area and this is implemented, imaging may get redacted requiring a re-upload.

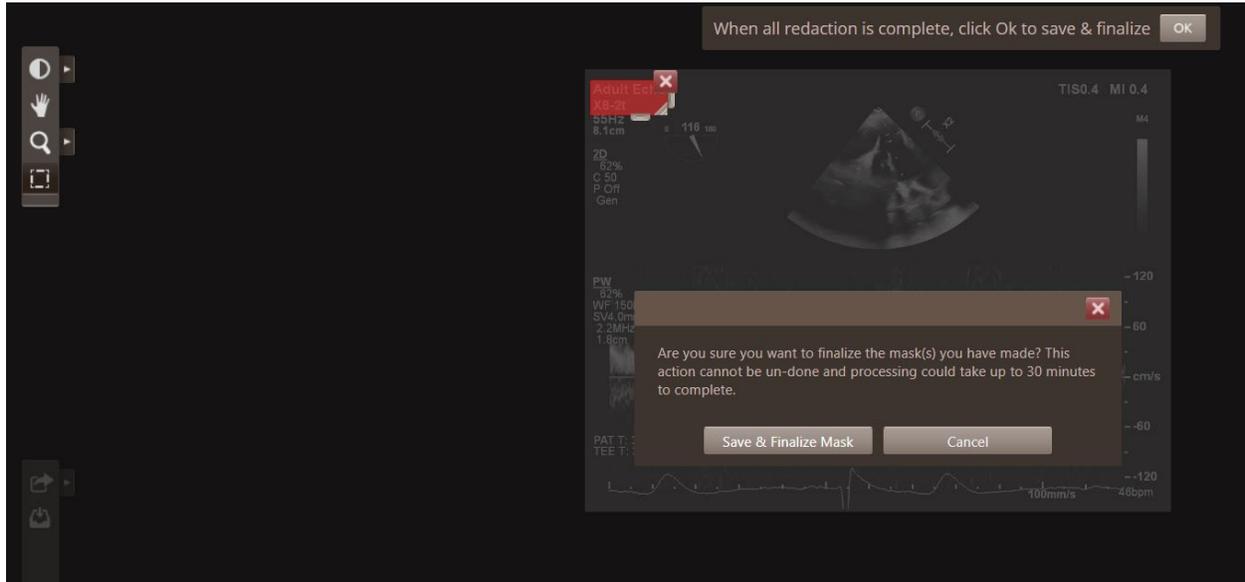


Once you select a masking option, you will see a message pop up that states: “When all redaction is complete, click OK to save & finalize” .

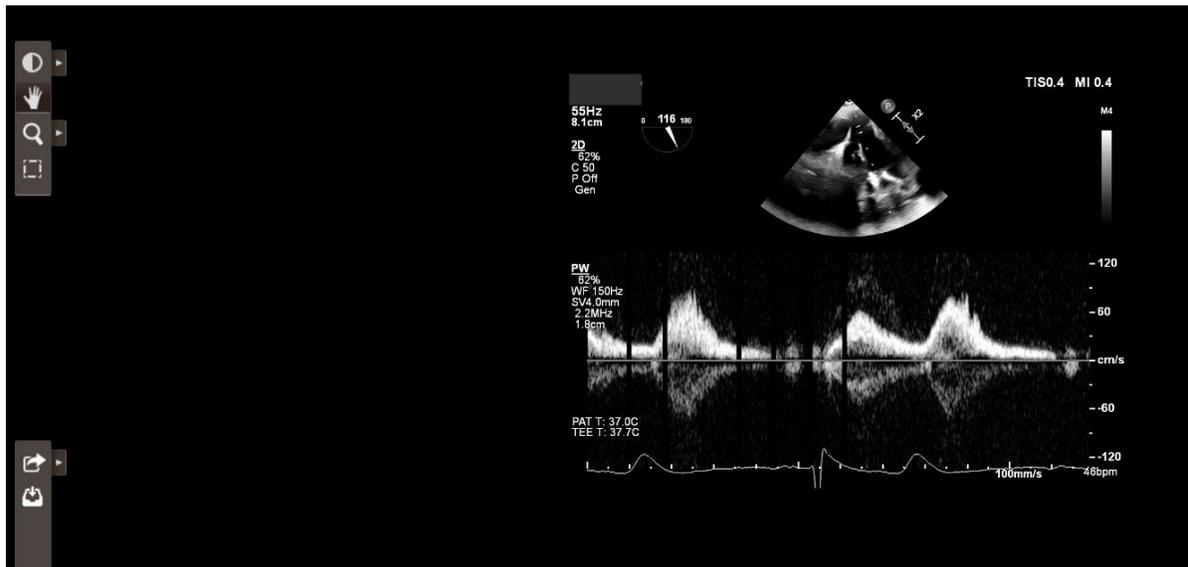


Once you select “Ok”, another message will populate asking if you are sure you would like to finalize. **This action cannot be undone**, so please confirm the masking option and area you are de-identifying are correct.

This process may take up to 30 minutes if you are de-identifying multiple images.



Once you select “Save & Finalize Mask”, the system will begin masking the area you have selected. Below is the result of masking in the top left corner of the image.



4. Addressing Imaging Queries

You will receive an email notification once a query has been assigned to you regarding a visit. Once you log into the portal, the query can be seen under “Queries”.

Subject: 21901-229

Baseline Visit/Event Details

Visit/Event Name	Baseline	Visit/Event Date	Unknown
Status	Active		

Baseline Visit/Event Requirements

Type	Info	Requirement	Commands
Exam	TTE	1 Exam	Upload Exams Comment Override
Document	TTE/TEE Sonographer Worksheet	1 Document	Upload Document Upload via Mobile Device Edit & Finalize Mobile Uploads Comment Override
Exam	CT	1 Exam	Upload Exams Comment

Submission Problems (3):
Errors:

- TTE: Requires an upload or override.
- TTE/TEE Sonographer Worksheet: Requires an upload or override.

Warnings:

- CT: No upload supplied.

[Start TTE Review](#)

✖ The Baseline visit/event has not satisfied all required items. Please provide all required data in order to finalize the visit/event submission and provide your e-signature.

Subject Details

Subject Name: 21901-229
Screening Name: Unknown
Status: Active

View

- View Subject
- Audit Log
- Audit Log Workflows

Actions

- Restore Deleted Items
- New Query
- Add 6 Months Visit/Event
- Add Adverse Event Visit/Event
- Add Optional TEE at Baseline Visit/Event

Visits/Events

Visit/Event Name	Complete	Img Reqs
Baseline	✖ 0	0
Index Procedure	✖ 0	0
Pre-Discharge	✖ 0	0
45 Days	✖ 0	0
12 Months	✖ 0	0

Queries

QID	Title	Assigned To	Status	Category	Created
340185	Overdue visit submission	eokeke@conformalmedical.com	Open	Overdue Visit	07-Mar-2024

[Refresh](#)

Queries can be for reasons including but not limited to an overdue visit, missing sonographer’s worksheet, incomplete upload, etc. Click into the query for information on the request. Once the query has been addressed, reply to it for verification that it has been addressed for faster resolution.

Query History

Date	User	Action	Query/Response Log	Actions
07-Mar-2024 01:26 PM GMT	eokeke@conformalmedical.com	Open	Imaging data for 21901-229, Baseline visit is overdue for submission based on the subject’s visit calendar. Please submit this visit at your earliest convenience.	Edit

Actions

- [Save](#)
- [Send Reminder](#)
- [Comment](#)

5. Imaging Protocol Resources

Please refer to the documents listed below for additional information:

1. CONFORM TEE Image Acquisition Protocol
2. CONFORM CT Acquisition Protocol
3. CONFORM Sonographer Worksheet