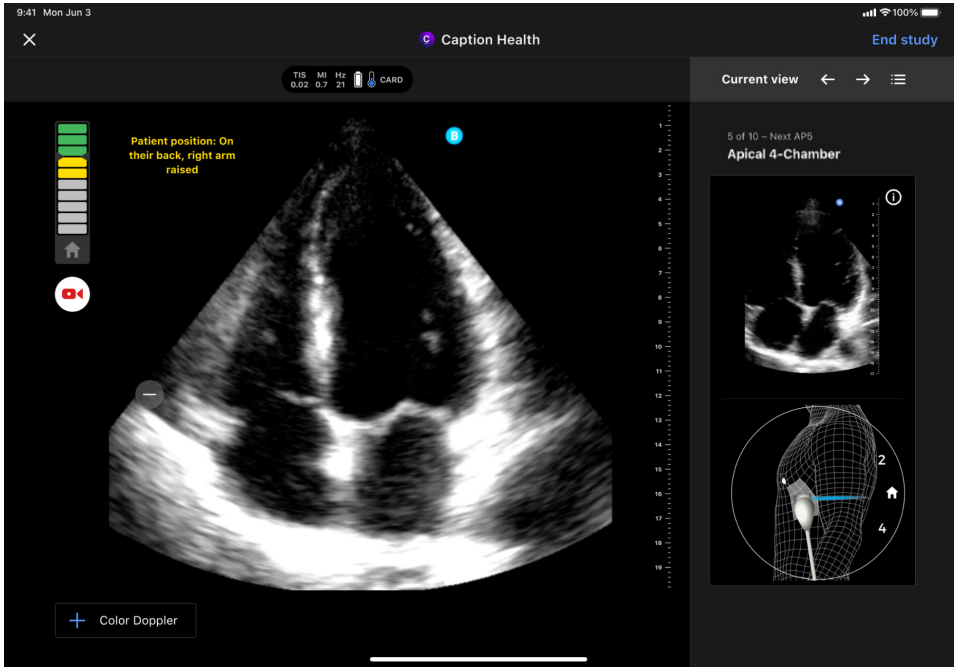
Caption Health

Caption AI™

Echocardiography Guidance Software



Operator's Manual

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Chapter 1: Introduction

About this manual

Caption AI™ Software operates within the *Butterfly iQ+*. It is not designed to be compatible with any other ultrasound systems.

This manual accompanies **Caption AI™** and provides information on configuring Caption AI and using it to capture diagnostic-quality ultrasound images. This manual is intended for healthcare professionals who have received appropriate training on ultrasound basics and Caption AI provided by an authorized trainer using approved training materials.

Report any serious safety incident that occurs in relation to the ultrasound system to Caption AI and to the competent authority of the country in which the user and patient are established.

Note: **Caption Health is the manufacturer of Caption AI. To directly contact Caption Health regarding this product, to request translated versions of this manual, or to request a paper version of this manual, please reach out to Caption Health Customer Support at support@captionhealth.com.** A paper version will be provided at no additional cost, and will be provided within 7 calendar days from the time of request.

This manual describes the most extensive configuration of Caption AI, with the maximum number of options and accessories available. Some functions described in this manual may not be included in your product's configuration.

Conventions used in this manual

This manual uses the following symbols and text to indicate specific types of information:

⚠ **CAUTION** This symbol and term alert you to information regarding patient, operator, or equipment safety. They also indicate information about preventing the loss of patient or product data.

Note:	Indicates supplemental information.
▶	Indicates step-by-step instructions.

Cautions

The following is important information regarding patient, operator, or equipment safety.

Keep the Caption AI system outside the MRI Scanner room.

⚠ **CAUTION**

Legal considerations

Do not use the product for purposes other than those intended and expressly stated by Caption Health, Inc. Do not misuse the product, and do not use or operate the product in an incorrect manner.

Installation, use, and operation of this product are subject to the law in the jurisdictions in which the product is used. Install, use, and operate Caption AI only in a manner that does not conflict with applicable laws or regulations, which have the force of law.

Use of the product for purposes other than those intended and expressly stated by Caption Health, Inc., as well as incorrect use or operation, may relieve Caption Health or its agents from all or some responsibility for resultant noncompliance, damage, or injury.

⚠ **CAUTION**

Image quality and diagnosis

Product users are responsible for image quality and diagnosis. The images acquired using Caption AI are to be interpreted only by qualified medical professionals. A qualified medical professional must inspect the data being used for analysis and diagnosis, and ensure that the data is sufficient and appropriate in anatomical correctness and both spatial and temporal resolution for the measurement being employed.

⚠ **CAUTION**

Intended use/Indications for use

The Caption AI software is intended to assist medical professionals in the acquisition of cardiac ultrasound images. Caption AI software is an accessory to compatible general purpose diagnostic ultrasound systems.

The Caption Guidance software is indicated for use in two-dimensional transthoracic echocardiography (2D-TTE) for adult patients, specifically in the acquisition of the following standard views: Parasternal Long-Axis (PLAX), Parasternal Short- Axis at the Aortic Valve (PSAX-AV), Parasternal Short-Axis at the Mitral Valve (PSAX-MV), Parasternal Short-Axis at the Papillary Muscle (PSAX-PM), Apical 4-Chamber (AP4), Apical 5-Chamber (AP5), Apical 2-Chamber (AP2), Apical 3-Chamber (AP3), Subcostal 4-Chamber (SubC4), and Subcostal Inferior Vena Cava (SubC-IVC).

⚠ **CAUTION**

Other types of studies

Caption AI is not intended for transesophageal echocardiography or any other type of ultrasound study not listed under "Intended Use/Indications for use."

⚠ **CAUTION**

Electrical shock hazard

Shock hazards exist if the AC power adapter for the *Butterfly iQ+* probe or charger is damaged or is not properly grounded. Use only the supplied medical-grade power adapters and power cords. Refer to the *Butterfly iQ™/Butterfly iQ+™ Personal Ultrasound System User Manual* for more information.

⚠ **CAUTION**

Acoustic output and ALARA

The iQ+ probe, with which Caption AI functions as a software accessory, complies with the Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment (UD3-2004).

It is important to observe the MI and TI values that are displayed during scanning. When conducting ultrasound studies, follow the ALARA principle: expose the patient to ultrasound energy at a level that is "As Low As Reasonably

Achievable." Please read the *Butterfly iQ™/Butterfly iQ+™ Personal Ultrasound System User Manual* for important information about acoustic output and ALARA.

⚠ **CAUTION**

Ultrasound-system hazards

General ultrasound-system hazards not specific to Caption AI are described in the *Butterfly iQ™/Butterfly iQ+™ Personal Ultrasound System User Manual*. You must carefully read the *Butterfly iQ™/Butterfly iQ+™ Personal Ultrasound System User Manual* before using Caption AI.

⚠ **CAUTION**

Probe compatibility

Caption AI operates with the *Butterfly iQ+* probe (also referred to as a "transducer" in the Butterfly manual). Do not operate Caption AI with any other probe during AI-assisted scanning.

⚠ **CAUTION**

Caption AI accuracy, use, and image saving

Caption AI provides real-time guidance and automated capture during cardiac ultrasound (echocardiographic) examinations for the 10 standard echocardiographic views. The accuracy of Caption AI in classifying correct echocardiographic views and estimating image quality has been verified and validated, but individual patient variations may introduce errors. Also, many echocardiographic views are similar to other views, and this can introduce errors. As a result, the automated saving functions of Caption AI (AutoCapture and Save Best Clip) may occasionally contain errors. It is important to review saved images independently using experienced clinical judgment prior to making a diagnosis. This may be especially important with saved clips noted as being saved through the Save Best Clip function because in these instances Caption AI did not detect a clip of sufficient quality to meet the AutoCapture threshold. It is also possible that some images obtained during scanning may be correct and have sufficient image quality for diagnosis, but Caption AI does not recognize this and does not auto-capture these images, and using the Save Best Clip option does not capture these images either. In these instances, manual saves may be necessary.

Making a diagnosis based solely on Caption AI, without applying clinical judgment regarding view correctness and quality, is not recommended.

⚠ **CAUTION**

Maintain probe contact during AutoCapture

It is important to maintain the probe contact and position during AutoCapture to ensure the capture of a good clip. If you move the probe, remove it from the patient, or otherwise interrupt the recording, the clip will not be recorded.

⚠ **CAUTION**

Match manually saved clips to the active view

When you perform a manual clip save, the system will assign the active view label to the saved clip. Confirm that the view you are saving manually is the view listed in order to avoid a mismatch between the label and the actual view captured.

⚠ **CAUTION**

Workflow scanning protocol completion

Caption AI provides workflow scanning protocols that guide you through a standard echocardiographic study, including saving clips for multiple views. If you terminate a study prior to scanning and saving clips for all the views, the diagnostic capability of the study may be compromised.

⚠ **CAUTION**

Prescriptive Guidance instructions

Caption AI provides Prescriptive Guidance that gives you suggestions on how to manipulate the probe to capture the desired images. These suggestions have been verified and validated, but individual patient variations may cause the instructions to perform better in some patients than others. It is recommended that you pay attention to the Quality Meter as you scan and make adjustments to the probe position to capture diagnostic-quality studies.

⚠ **CAUTION**

Storing studies

Caption AI is not for permanent storage for patient studies. Caption AI is meant to be a temporary storage for studies you acquire. Refer to the Butterfly Manual on study storage and transfer.

⚠ **CAUTION**

PHI protection

DICOM studies contain Protected Health Information (PHI). Caption AI can operate within a PACS network and can send patient studies to a DICOM PACS server. To protect PHI, please refer to the *Butterfly iQ™/Butterfly iQ+™ Personal Ultrasound System User Manual*.

Caption AI is not intended for long-term storage of studies.

This device adheres to HIPAA security and privacy guidelines. When viewing Caption AI results in your DICOM Viewer, make certain to observe your institution's guidelines and practices for protecting PHI.

Please refer to the *Butterfly iQ™/Butterfly iQ+™ Personal Ultrasound System User Manual* for important information about PHI protection.

Cautions

Below is important information for preventing the loss of patient or product data or for preventing damage to the Caption AI device or environment.

⚠ **CAUTION**

Cybersecurity precautions and practices

Malware, computer viruses, ransomware, and other cybersecurity threats are an increasing concern in healthcare IT systems.

Please refer to the *Butterfly iQ™/Butterfly iQ+™ Personal Ultrasound System User Manual* for important information about cybersecurity provisions and management.

For information and guidance on implementing proper cybersecurity in the healthcare IT environment, see "Health IT Privacy and Security Resources for

Providers" at https://www.healthit.gov/topic/privacy-security-and-hipaa/health-it-privacy-and-security-resources-providers.

⚠ CAUTION

Product compatibility

Caption Health, Inc. Caption AI Software Accessory is a software accessory that operates within the Butterfly iQ App. It is not designed to operate with any other ultrasound systems. Do not attempt to operate Caption AI with other ultrasound systems.

Do not use your system in combination with other products or components unless Caption Health expressly recognizes those other products or components as compatible. For information about such products and components, contact your Butterfly Network representative.

Changes and additions to the system should be made only by Caption Health or by third parties expressly authorized by Caption Health to do so. Such changes and additions must comply with all applicable laws and regulations that have the force of law within the jurisdictions concerned and with best engineering practices.

Intended audience for Caption AI

Caption AI must be operated by or under the direction and supervision of a licensed physician.

⚠ CAUTION

Before using Caption AI, read this manual and strictly observe all warnings and cautions.

About Caption AI/UDI information

▶ To display the About Us screen and UDI information

1. Enter the Profile menu at the bottom right of the screen by clicking the initials, or your avatar.

2. Tap **Caption AI** on the left side of the screen, then tap **About Caption AI**. The **About Us** screen appears.

Figure 1. *About Us screen. The symbols on this screen are described in the table below.*

Table 1. *Product Label Symbols*

Symbol	Definition
	Consult the instructions for use.
MD	This is a medical device.
CE	Authorized for sale in the European Community.
GMDN	The global medical device nomenclature number.
EC REP	Authorized representative in the European Community.

Symbol	Definition
LOT	The product batch code ("lot number").
REF	The product catalog number ("reference number").
Quantity	A single quantity of this device is used to perform the functions associated with the device.
Rx Only	Federal (United States) law restricts this product to sale by or on the order of a physician.
UDI	The unique device identification number.
	The product manufacturer, including address.
	The date of manufacture.
	The product distributor, including address.

Specifications

Please refer to the *Butterfly iQ™/Butterfly iQ+™ Personal Ultrasound System User Manual* for information regarding probe and system specifications. Some of the specifications listed may not be available on your system.

Frequent tasks using Caption AI

Task	Refer to
Set up Caption AI to communicate with the DICOM PACS	Page 35: "Connecting to the network"
Set up Caption AI for scanning	Page 39: *"Chapter 5: Setting up for an exam"*
Perform an ultrasound exam with Caption AI	Page 51: "*Chapter 6: Scanning with Caption AI™"*
Review saved studies	Page 79: "Chapter 7: Working with Saved Studies"

Contacting Customer Support

Caption AI™ Software is designed to be compatible with the *Butterfly iQ+*. It is not designed to be compatible with any other ultrasound systems.

Butterfly Network customer service representatives are available to answer questions and provide product support. Please contact your local Butterfly Network representative for assistance or email support@butterflynetwork.com.

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Chapter 2: Clinical Studies and Non-Clinical Testing

Specialist (Sonographer) Study

Use by specialist-users was evaluated in a prospective clinical study, in which 50 patients were scanned by sonographers with the Caption AI™ system (study exam), followed by a reference scan (control exam) on the same patient using the same ultrasound but unassisted by Caption AI. Study and control exams were assessed by three (3) expert cardiologists who graded each clip using the ACEP scale. The data from this study was used to provide descriptive supportive evidence of the use of Caption AI by users with specialized echocardiography training.

The results of the study indicated that sonographers obtained diagnostic-quality images in a high proportion of clips in both study and control exams, demonstrating comparable (non-inferior) image quality in clips acquired using Caption AI compared to unassisted acquisition. Importantly, the high specificity of the AutoCapture feature (97.85% of auto-captured clips were diagnostic) demonstrated that a registered sonographer can confidently rely on the AutoCapture feature when using Caption AI.

Pivotal (Nurse) Study

A prospective non-specialist study was subsequently conducted to evaluate use by medical professionals without specialized echocardiography training.

Study Design

A minimum of eight (8) RNs were to be trained and evaluated on their performance to acquire a 10-view 2D-TTE protocol. Participants were scanned by the RN (study exam) and 10 standard views were obtained using a Terason ultrasound system with Caption AI software: PLAX, PSAX-AV, PSAX-MV, PSAX-PM, AP4, AP5, AP2, AP3, SubC4, and SubC-IVC.

The study continued enrollment until eight RNs had completed scans of 30 patients each. Enrolled patients were stratified into two groups based on cardiac abnormalities to ensure a sufficient number of patients with cardiac abnormalities. In addition, enrolled patients were evenly stratified into three groups based on BMI to ensure a sufficient distribution of patients by BMI. For

the sake of comparison, participants were also scanned by a trained sonographer without Caption AI and the same 10 views were obtained (control exam) using the same Terason ultrasound system.

Following the study and control exams, a panel of five (5) expert cardiologist readers independently provided assessments of whether the patient study, in its totality, provided sufficient information to assess 10 clinical parameters. In addition, a panel of eight (8) expert cardiologists also independently provided assessments of diagnostic image quality per clip using the ACEP scale; each clip was graded by five (5) expert cardiologists. The readers were blinded to assessments from other panel members as well as to which site the images were obtained at and whether the images were obtained by an RN or a sonographer. The results from the expert-panel reads were used for the statistical analysis. To reduce possible sources of bias in the design, the RNs, sonographers, and cardiologists were all blinded to results determined by others.

Four (4) prospectively defined primary endpoints were evaluated sequentially for the study, all of which assessed whether the patient study exam conducted by the RN, taken as a whole, was of sufficient image quality to make these clinical assessments. Specifically, the endpoints assessed whether, in the judgment of expert cardiologists, the studies permitted qualitative visual assessment of left ventricular (LV) size, LV function, right ventricular (RV) size, and non-trivial pericardial effusion.

Results

The four primary endpoints were satisfied and demonstrated the clinical utility of Caption AI for non-specialist users. Specifically, the eight (8) RNs acquired echocardiographic exams of sufficient image quality to make clinical assessments in the proportion of study exams conducted, as shown below.

Table 2. *Study results: primary endpoints*

Endpoint	Percent of diagnostic quality
Qualitative Visual Assessment of LV Size	98.8% (95% CI: 96.7, 100)
Qualitative Visual Assessment of LV Function	98.8% (95% CI: 96.7, 100)
Qualitative Visual Assessment of RV Size	92.5% (95% CI: 88.1, 96.9)
Qualitative Visual Assessment of Non-Trivial Pericardial Effusion	98.8% (95% CI: 96.7, 100)

Note: Secondary endpoints and additional analyses presented below were not evaluated based on a specific hypothesis. Since the evaluation of secondary endpoints and additional analyses did not allow for control of Type I error, the study results are presented as a descriptive demonstration of the use of Caption AI for the specific secondary endpoints and additional analyses.

Additional secondary endpoints were evaluated and demonstrated the robustness of the data, including six (6) additional patient-level clinical parameters were evaluated and each had a high proportion of scans considered to be of sufficient image quality to make each of the six (6) additional patient-level clinical parameter assessments, i.e., qualitative visual assessment of inferior vena cava (IVC) size, RV function, left atrial (LA) size, aortic valve (AV), mitral valve (AV), and tricuspid valve (TV). Specifically, the eight (8) RNs acquired echocardiographic exams of sufficient image quality to make clinical assessments in the proportion of study exams conducted, as shown below.

Table 3. *Study results: secondary endpoints*

Endpoint	Percent of diagnostic quality
Qualitative Visual Assessment of RV Function	91.3% (95% CI: 85.7, 96.8)
Qualitative Visual Assessment of LA Size	94.6% (95% CI: 90.7, 98.5)
Qualitative Visual Assessment of AV	91.7% (95% CI: 88.0, 95.3)
Qualitative Visual Assessment of MV	96.3% (95% CI: 93.9, 98.6)
Qualitative Visual Assessment of TV	83.3% (95% CI: 77.0, 89.7)
Qualitative Visual Assessment of IVC Size	57.5% (95% CI: 41.5, 73.5)

In addition to assessing if image quality was sufficient to make assessments, cardiologists also made specific qualitative visual assessments based on the study and control exams (e.g., presence or absence of non-trivial pericardial effusion). The proportion of scans in which the diagnostic decision was the same between study and control exams was very high, further demonstrating the usability of Caption AI. For primary clinical parameters, the range was 92.5% to 99.6%. Similarly, for secondary clinical parameters, the range was 83.2% to 95.2%.

To provide a robust assessment of the performance of Caption AI, subjects enrolled in the study included a broad range of patient characteristics representative of the intended use population. In particular, effort was made

to include subjects with known cardiac abnormalities at time of enrollment (63.9%), which would be expected to provide a more technically difficult scan. In fact, the standard of care echo revealed a much higher proportion of known cardiac abnormalities (91.4%). In addition, many of the study patients were inpatient or had other challenging characteristics such as high BMI, history of smoking (42.2%), and cardiac implantables (24.6%).

Subgroup analyses were conducted to evaluate the impact of specific baseline and demographic characteristics (i.e., BMI, presence of known cardiac abnormalities, sex, age, scan sequence number within each acquiring nurse, RN user, and study site) on the outcomes of the primary and secondary endpoints. The results demonstrated consistent performance across subgroups.

Furthermore, it was evaluated whether the RN users were able to obtain a high proportion of clips that were considered of diagnostic quality. Specifically, the eight (8) RNs acquired echocardiographic clips of diagnostic-image quality for each of the standard views in the following proportion of study exams conducted.

Table 4. *Study results: diagnostic-quality clips*[1]

View	Percent of diagnostic quality
PLAX	92.1% (95% CI: 87.9, 96.3)
PSAX-AV	66.3% (95% CI: 59.0, 73.5)
PSAX-MV	75.8% (95% CI: 70.7, 80.9)
PSAX-PM	92.9% (95% CI: 89.1, 96.7)
AP4	88.8% (95% CI: 81.5, 96.0)
AP5	78.8% (95% CI: 66.9, 90.6)
AP2	71.3% (95% CI: 61.6, 80.9)
AP3	80.0% (95% CI: 70.4 , 89.7)
SC4	76.3% (95% CI: 70.2, 82.3)
SC-IVC	59.2% (95% CI: 43.1, 75.2)

The study also demonstrated the safety profile of Caption AI. No device-related adverse events were reported in the pivotal study.

1 Median acquisition time per view ranged from 2.04 to 4.03 minutes.

The following two analyses were performed on the Pivotal Study data to assess the performance of Caption AI using objective quantitative metrics:

- **AutoEF:** The exams acquired in the pivotal study were processed by a previous version of the 510(k) cleared Caption Health AutoEF software (K173780). This version of AutoEF provided an automated estimation of left ventricular ejection fraction, and requires an AP4 and AP2 clip of sufficient quality in order to return an estimate. AutoEF returned an EF estimate in 65.5% of study exams and 85.1% of control exams. The nurse-sonographer root-mean-square deviation was 5.19 EF% and mean absolute deviation was 3.96 EF%, indicating a clinically acceptable amount of variability and within what might be expected between experts. Therefore, the results indicate that there is no clinically significant difference in AutoEF estimation for nurse- and sonographer-acquired exams, provided there is an AP2 and AP4 of sufficient quality as assessed by the AutoEF software.

  Note: The version of AutoEF included in the Caption AI product is updated from the version used in the pivotal study analysis described above. The updated AutoEF includes new features, such as producing an EF estimate from any combination of the PLAX, AP4, and AP2 views, as well as a more accurate estimation algorithm. Nonetheless, the analysis above provides useful quantitative information supporting the effectiveness of Caption AI when used by non-specialist nurses.

- **PLAX Sonographer Measurements:** Three (3) registered cardiac diagnostic sonographers independently provided measurements for each of the PLAX clips acquired in the pivotal study: septal wall thickness (diastole), posterior wall thickness (diastole), left ventricular internal diameter (diastole), left ventricular internal diameter (systole), and aortic root. Measurability of study exam clips ranged from 89.17% to 92.08%. The study-control clip variability (RMSD) was found to be comparable to the inter-sonographer measurement variability. The results demonstrate that PLAX clips acquired by nurses were highly suitable for linear measurements in clinical use.

Human Factors Validation Testing Study

A Human Factors Validation Study was performed with a total of 28 participants to demonstrate the usability of the device. The Caption AI user interface and training materials were developed through a series of preliminary human factors analyses. The device and training were then implemented and tested during the Human Factors Validation Study.

The study enrolled five (5) user groups:

- Physicians (Hospitalists): 4 users
- Nurse Practitioners and Physician Assistants: 4 users
- Registered Nurses (RNs): 9 users
- Medical Residents: 6 users
- Certified Medical Assistants: 5 users

The human factors usability validation testing on 28 users demonstrated 100% of critical tasks passed across all user types. No use errors were found that could cause harm for the scanner nor the patient. In addition, non-critical tasks that are essential for skills assessment and scanning ability were tested and evaluated, including the AutoCapture rate across 10 views. An average of 76% of views were auto-captured per user across all 5 user groups. The results did not indicate significant differences in performance amongst user types. Given the same level of training, medical professionals across the backgrounds that were tested from certified medical assistants to hospitalists performed consistently during independent scans with Caption AI on a patient model.

Supplemental human-factors validation was performed to validate the usability of the Prescriptive Guidance icons visual system, using participants with varying levels of TTE scanning experience. This study tested the accuracy of movements made by 16 users while following the on-screen guidance. Correct movements were made 89.9% of the time, which validated the usability of the visual system to help guide users to a better-quality image during scanning.

Software Verification and Validation

Caption AI was identified as having a moderate level of concern as defined in the FDA guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software documentation included:

1. Software/Firmware Description
2. Device Hazard Analysis
3. Software Requirement Specifications
4. Architecture Design Chart
5. Software Design Specifications
6. Traceability
7. Software Development Environment Description
8. Verification and Validation Documentation
9. Revision Level History
10. Unresolved Anomalies
11. Cybersecurity

A comprehensive risk analysis was provided for the software with detailed description of the hazards, their causes and severity, as well as acceptable methods for control of the identified hazards. Caption Health provided a description, with test protocols including pass/fail criteria and report of results, of acceptable verification and validation activities at the unit, integration, and system level.

Algorithm Performance Testing

Comprehensive non-clinical performance testing of the deep-learning algorithms used in the device was provided to support their clinical performance. Specifically, the performance testing evaluated the performance of the following software functionality:

- Standalone performance
- Feature-level performance:
  - Quality Meter
  - Save Best Clip
  - AutoCapture
  - Prescriptive Guidance

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Chapter 3: Operator-Safety Considerations

Prescription device statement

⚠ **CAUTION**

For product usage in the United States of America, the following labeling statement applies:

Federal law restricts this device to use by or on the order of a physician.

Healthy ergonomic practices

The operation of an ultrasound system may be linked to musculoskeletal disorders (MSDs). In ultrasound imaging, ergonomics may be defined as the physical interaction between the operator, the system, and the probe during exams. It is important for the operator of the system to practice good ergonomic techniques to reduce the risk of injury. This section provides guidelines to help you work more comfortably to possibly reduce the risk of musculoskeletal disorders.

When using an ultrasound system, as with many similar physical activities, you may experience occasional discomfort in your hands, fingers, arms, shoulders, eyes, neck, back, or other parts of your body. If you experience symptoms such as constant or recurring discomfort, pain, throbbing, aching, tingling, numbness, burning sensation, or stiffness, you should promptly consult a qualified health professional. These may be symptoms of MSD. MSDs can be painful and may result in potentially disabling injuries to the nerves, muscles, tendons, joints, or other parts of the body. Examples of MSDs include carpal tunnel syndrome and tendinitis.

Described here are steps you can take to guard against discomfort while scanning or the risk of MSDs. It is also recommended that you consult the guidelines of professional medical societies concerned with ultrasound.

Rest breaks

- In between exams, take breaks to rest and give your body a chance to recuperate from the strained positions and repetitive movements of examinations.
- While scanning, avoid maintaining the same body position for extended periods of time by moving and varying your head, neck, body, arm, and leg positions.

Body position

- Avoid bending or stooping.
- Adjust the position of the device so that viewing or reaching the Caption AI controls does not require strained or awkward body positions.
- Whenever possible, use an adjustable chair with good back support, and adjust the chair height to promote good body posture. If possible, adjust the height of the patient bed to optimize body posture.
- Maintain a comfortable and balanced body position with minimal stress on your joints, minimizing bending and twisting.
- Keep elbows close to your side and relax your shoulders in a level position.

Hand and wrist positions

- Do not grasp the probe with excessive force; hold it as lightly as possible, but firmly.
- Minimize the amount of pressure applied when pressing the probe against the patient.
- Avoid or minimize bending your wrist.

Exercise and stretching

Targeted exercises and stretching may help you avoid the risk of MSDs. Consult with a qualified health professional to define a program suited to your needs.

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Chapter 4: Configuring Caption AI

System components

Caption AI™ is a software-only device for assisting medical professionals in performing echocardiographic studies. Caption AI is used in conjunction with the following third-party products:

- Compatible Apple® tablet (the mobile device)
- The Butterfly iQ Application (App) downloaded and installed on the compatible mobile device
- *Butterfly iQ+* Probe that connects to the mobile device to generate and receive the ultrasound signals

Your customer service representatives can provide support for setting up Caption AI. Please contact your local representative for assistance.

⚠ **CAUTION**

Electrical shock hazard

Shock hazards exist if the AC power adapter for the *Butterfly iQ+* ultrasound system is damaged or is not properly grounded. Use only the supplied medical-grade power adapters and power cords.

Connecting to the network

To use DICOM features, including sending studies to a PACS server or using a modality worklist, setup includes establishing a secure connection between Caption AI and the DICOM PACS network. Refer to the *Butterfly iQ / Butterfly iQ+ Personal Ultrasound System User Manual* for more information on network setup.

⚠ **CAUTION**

Configuration and setup must be done in compliance with your network security policies. Refer to *Butterfly iQ™/Butterfly iQ+™ Personal Ultrasound System User Manual* for more information on network setup.

⚠ CAUTION

To ensure proper operation of Caption AI for patient scanning, system setup and configuration should be performed by your ultrasound service representative or a qualified biomedical engineer.

⚠ CAUTION

Only an authorized IT administrator who logs into the system using their security credentials should configure Caption AI to communicate with the PACS server.

Starting Caption AI

▶ To start Caption AI

Open the Butterfly iQ Application on your compatible mobile device. Once the probe is connected and you are signed into a Butterfly organization with access to Caption AI tap the ( ) icon on the bottom of the screen.

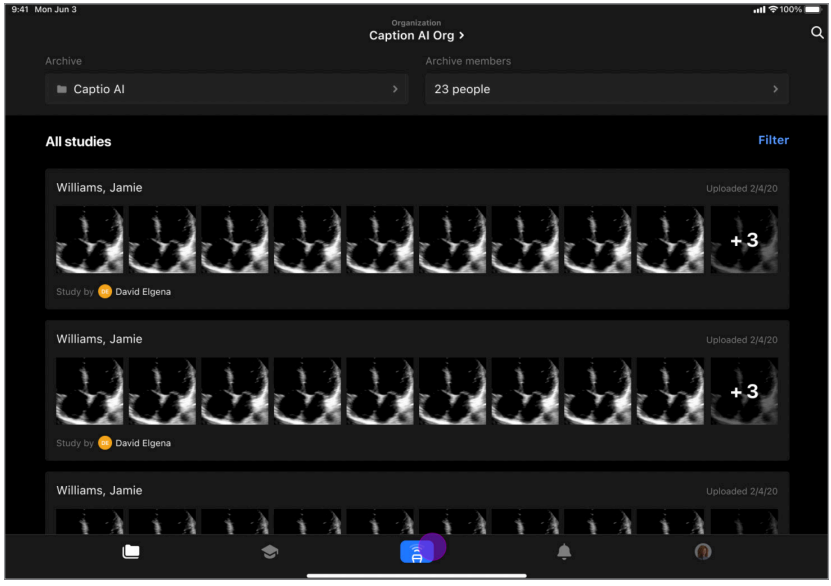

Figure 2. *Access Caption AI*

The **Select a protocol** screen will appear.

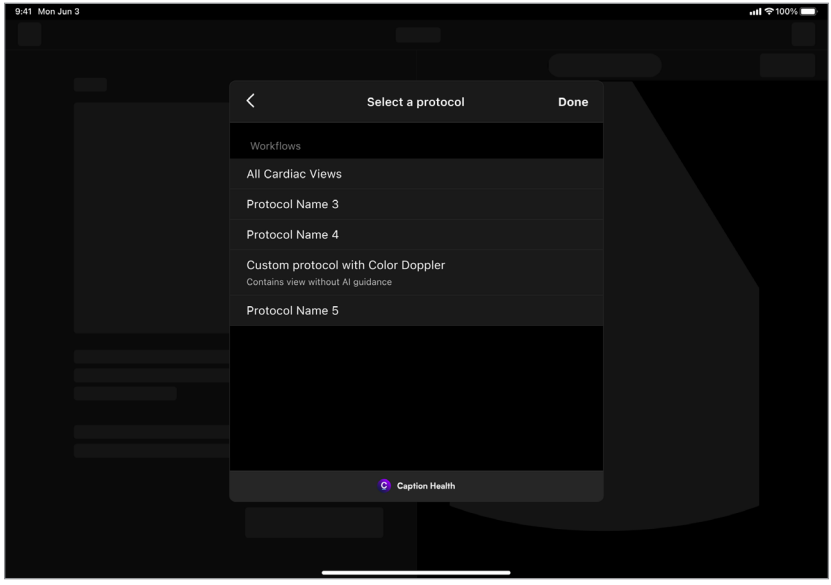

Figure 3. *Caption AI Protocol Selection screen*

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Chapter 5: Setting up for an exam

Working with scanning protocols

During a Caption AI exam, you follow a protocol that specifies the views you'll acquire for the study. Caption AI currently offers one type of protocol:

- **Workflow-based protocols** are based on the particular views you want to acquire. The default workflow protocol provided with Caption AI is All Views.
- **Indication-based protocols** are based on the patient's symptoms, such as shortness of breath.

You'll be prompted to select a scanning protocol when you start a new exam. You can use a protocol provided with Caption AI or create custom protocols specific to your practice.

Creating custom scanning protocols

You can create custom protocols using the Butterfly Cloud, a web-based application that can be accessed at cloud.butterflynetwork.com. If you are a Butterfly Enterprise user, navigate to [YourDomain].butterflynetwork.com.

Only Butterfly Cloud Administrators can create and modify custom protocols for Caption AI. For more information on the Butterfly Cloud, refer to the *Butterfly iQ / Butterfly iQ+ Personal Ultrasound System User Manual*.

To create a custom workflow protocol

1. On the Butterfly Cloud **Organization Settings** screen, click the **Caption Protocols** tab.

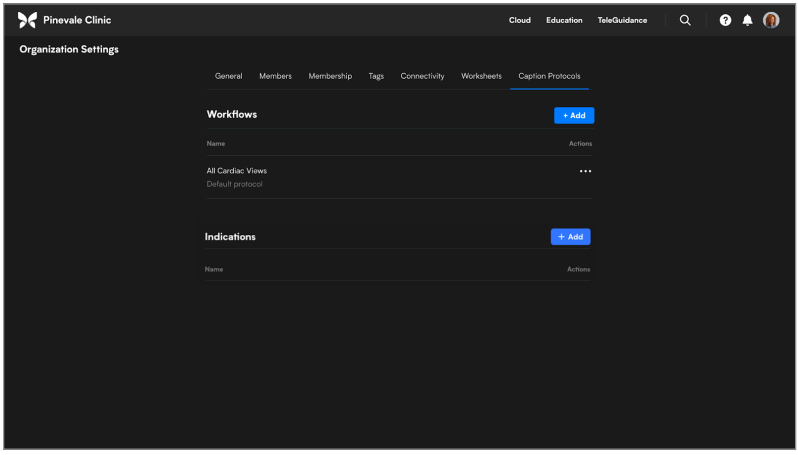

Figure 4. *Caption Protocols screen*

2. Select the **+ Add** button in the top right corner of the protocol list.
3. Enter the name for your new workflow protocol.

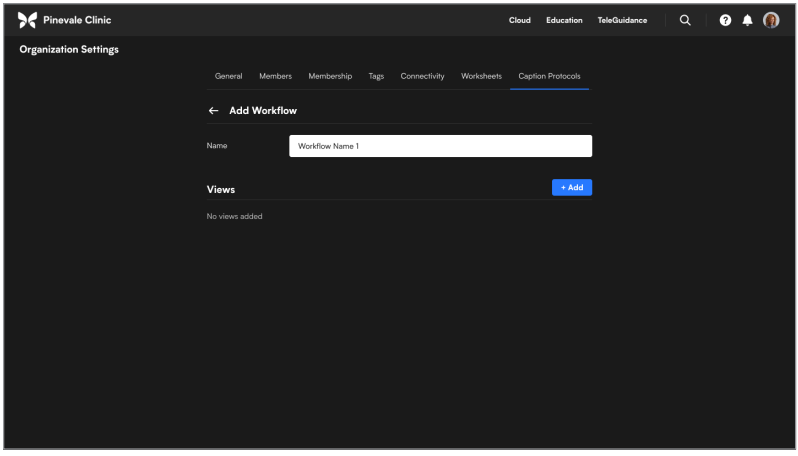

Figure 5. *Scanning Protocols screen: Add custom workflow protocol*

4. Select the **+ Add** button in the views list. The **Add Views** screen will appear. Select the AI-guided views you want in your protocol using the checkmarks to the left of the views' names. You can also add a color doppler view using the **+ Add Color Doppler** button at the bottom of the screen. Multiple color views can be added by clicking the button again. Each color doppler view must be given a unique name.

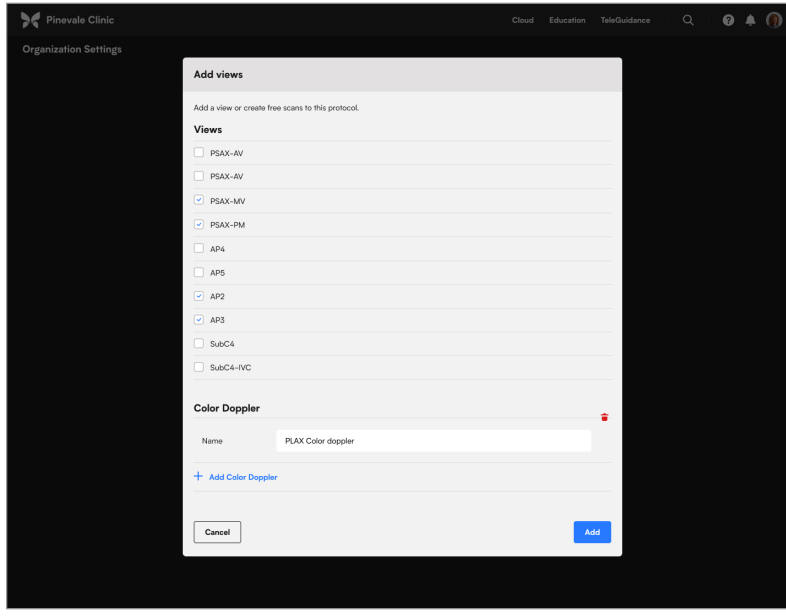

Figure 6. *Add Views screen while creating a custom protocol*

Note: Color doppler views do not have AI Guidance and are not recommended for novice users. The Quality Meter is also not available for these views.

5. Once you have selected the desired views, click the **Add** button in the bottom right corner to add them to the protocol. The views you have selected will appear in the views list. If you want to reorder the views, use the move icon ( ) to drag a view to another location.

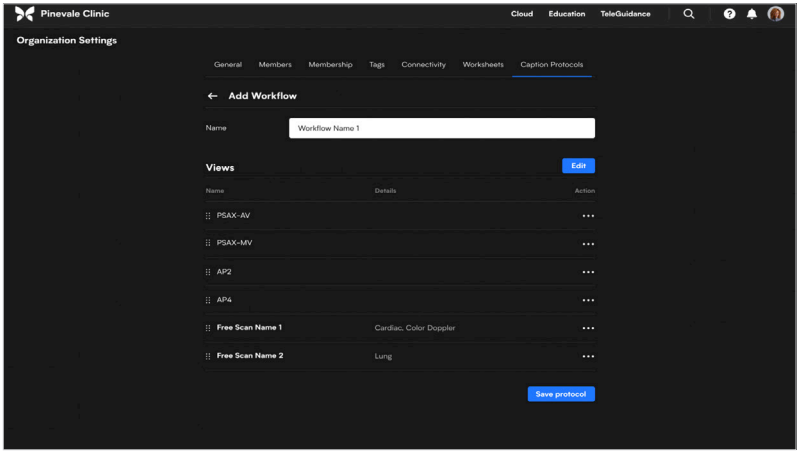

Figure 7. *Reordering views in a scanning protocol*

6. Tap **Save** to make the protocol available for scanning in your organization.

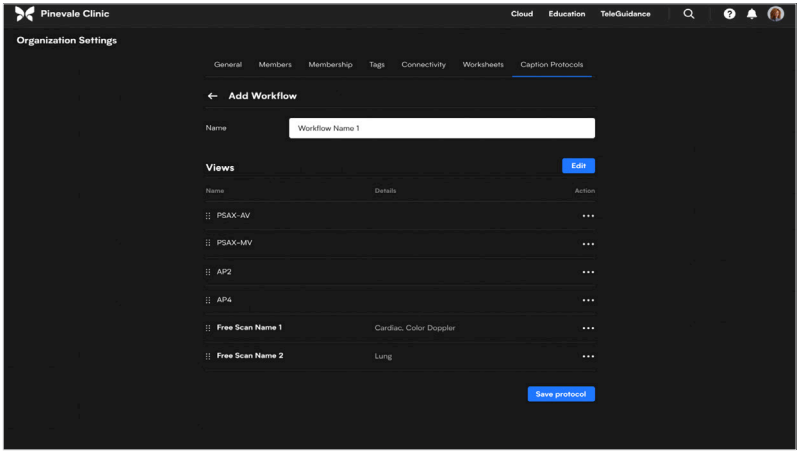

Figure 8. *Saving your protocol*

Once the protocol has been saved, use the actions icon (• • •) to edit the protocol, make it default for your organization, or delete the protocol. Default protocols will be chosen by default when users begin scanning with Caption AI in your organization.

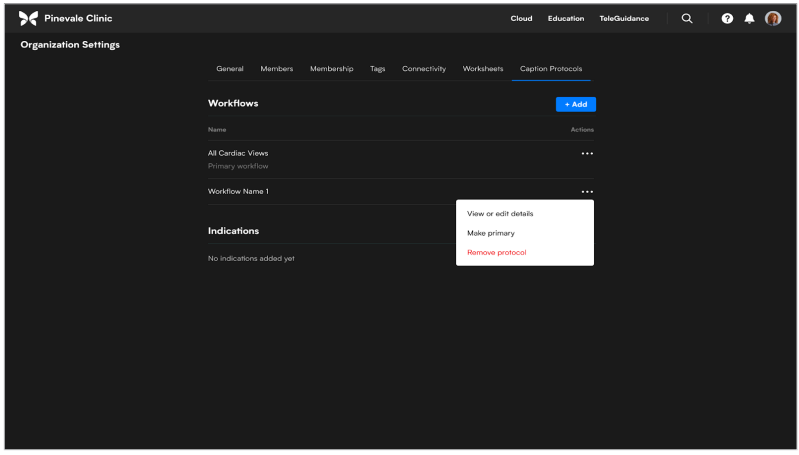

Figure 9. *Actions available for saved custom protocols*

To create a custom indication-based protocol

1. On the Butterfly Cloud **Organization Settings** screen, click the **Caption Protocols** tab.

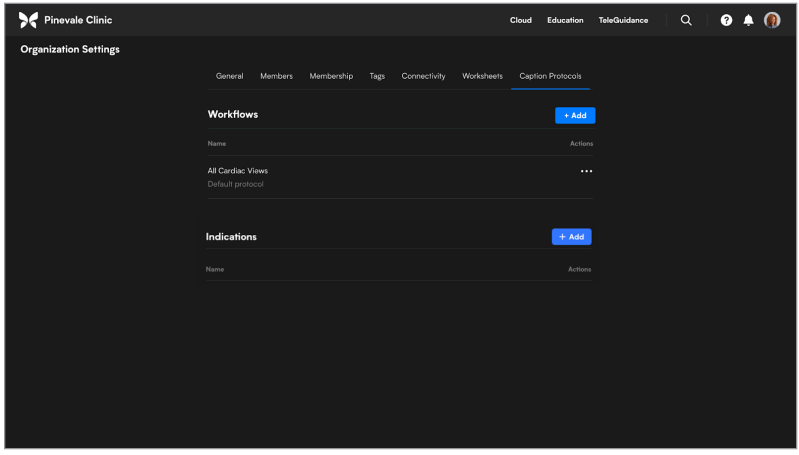

Figure 10. *Caption Protocols screen*

2. Select the **+ Add** button to the right side of the **Indications** section.
3. Enter the name for your new indications protocol.

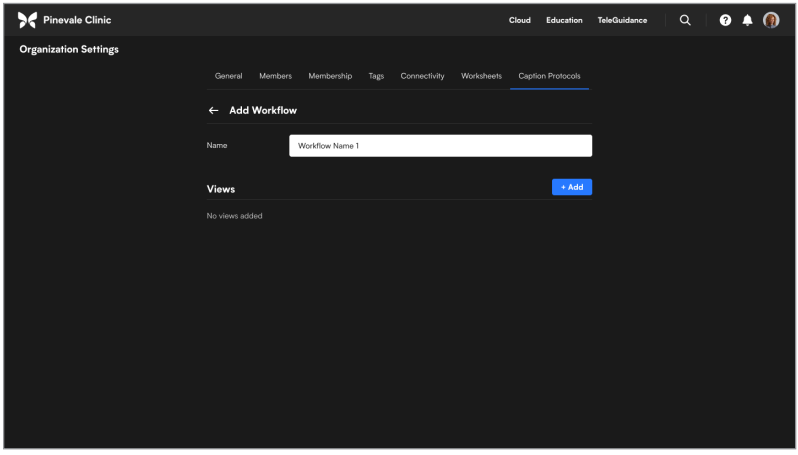

Figure 11. *Scanning Protocols screen: Add custom indications protocol*

4. Select the **+ Add** button in the views list. The **Add Views** screen will appear. Select the AI-guided views you want in your protocol using the checkmarks to the left of the view's name. You can also add a color doppler view using the **+ Add Color Doppler** button at the bottom of the screen. Multiple color views can be added by clicking the button again. Each color doppler view must be given a unique name.

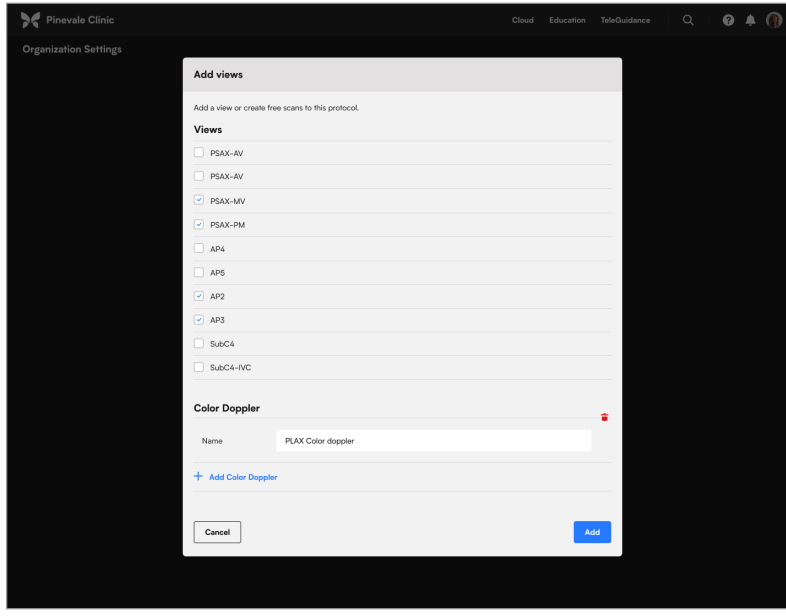

Figure 12. *Add Views screen while creating a custom protocol*

Note: Color doppler views do not have AI Guidance and are not recommended for novice users. The Quality Meter is also not available for these views.

5. Once you have selected the desired views, click the **Add** button in the bottom right corner to add them to the protocol. The views you have selected will appear in the views list. If you want to reorder the views, use the move icon ( ) to drag a view to another location.

6. Tap **Save** to make the protocol available for scanning in your organization. Once the protocol has been saved, use the actions icon (• • •) to edit the protocol, make it default for your organization, or delete the protocol. Default protocols will be chosen by default when users begin scanning with Caption AI in your organization.

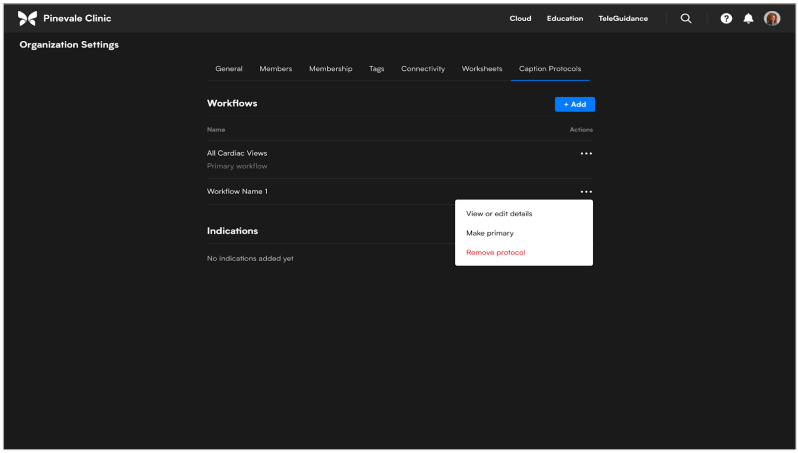

Figure 13. *Actions available for saved custom protocols*

Turning off AutoCapture

Caption AI comes with the AutoCapture feature turned on by default. If, however, you want to acquire clips manually, you can turn off AutoCapture in the settings. For more information on the AutoCapture feature, see "AutoCapture" on page 65.

Note: Manually recording clips should be done only by users who can determine without the assistance of Caption AI that a clip is of sufficient diagnostic quality.

▶ To turn off AutoCapture

1. Enter the Profile menu at the bottom right of the screen by clicking the initials, or your avatar.
2. Tap **Caption AI** on the left side of the screen. Under **Auto Capture**, you can toggle the feature on or off.

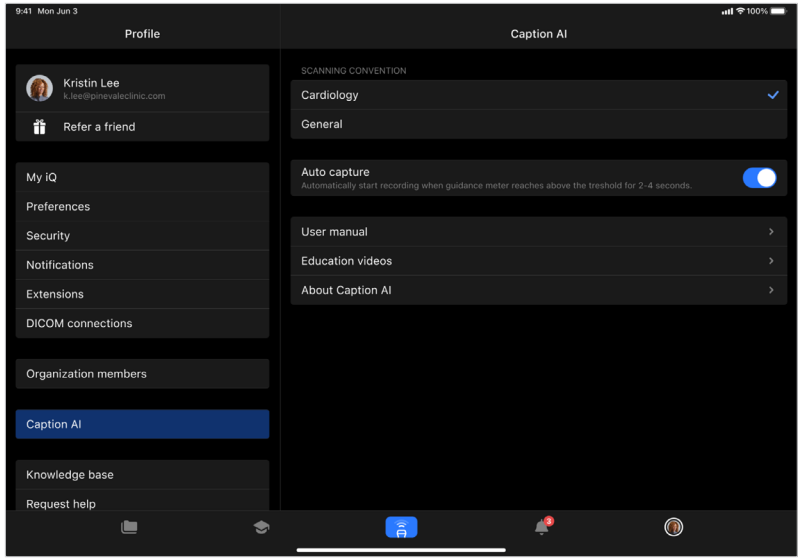

Figure 14. *Caption AI Settings screen: AutoCapture*

Selecting the scanning convention

Caption AI provides two scanning conventions: Cardiology (the default) and General.

▶ To select the scanning convention

1. Enter the Profile menu at the bottom right of the screen by clicking the initials, or your avatar.
2. Tap **Caption AI** on the left side of the screen. Under **Scanning Convention**, select the convention you want to use for cardiac scanning.

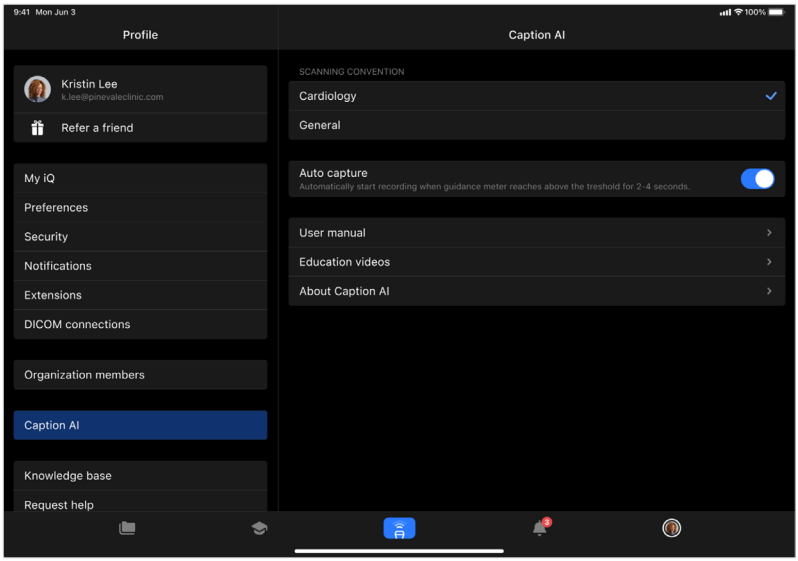

Figure 15. *Caption AI Setting screen: Scanning convention*

Caption AI will use this convention for all future studies, unless it is manually changed here in the settings.

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Chapter 6: Scanning with Caption AI

⚠ CAUTION

If you are not familiar with performing an ultrasound exam using Caption AI™, make sure that you receive the appropriate training before using the system, provided either by Caption Health or by a trained clinician using official Caption AI training materials.

Before you perform a Caption AI exam, it is vital that you are familiar with the *Butterfly iQ+* and Butterfly iQ App. See the *Butterfly iQ™/Butterfly iQ+™ Personal Ultrasound System User Manual* for more information.

⚠ CAUTION

For important safety information regarding the proper use and application of Caption AI, see *"Chapter 1: Introduction"* and *Chapter 3: Operator-Safety Considerations* in this manual.

Starting a Caption AI study

To start Caption AI

1. Open the Butterfly iQ Application on your compatible mobile device. Once the probe is connected and you are signed into a Butterfly organization with access to Caption AI tap the ( ) icon on the bottom of the screen.

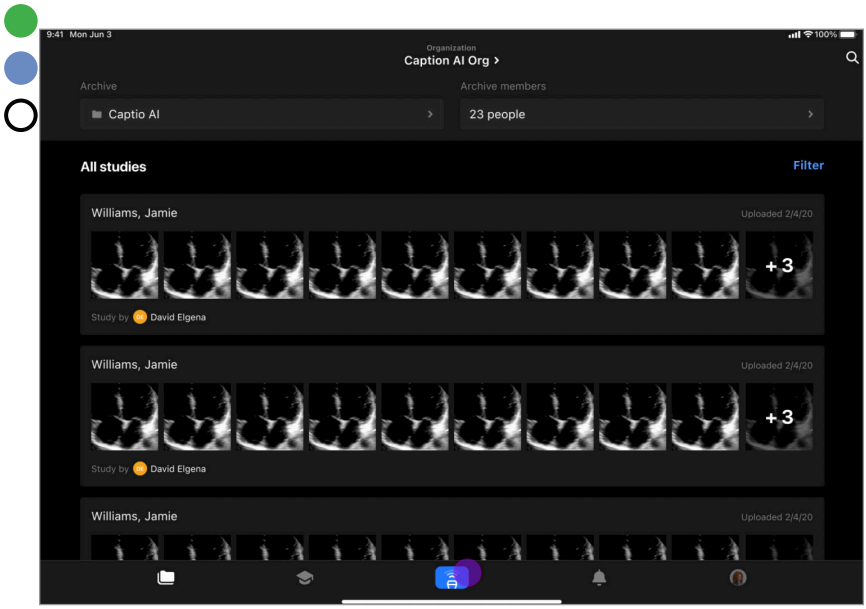


Figure 16. *Access Caption AI*

The **Select a protocol** screen will appear.

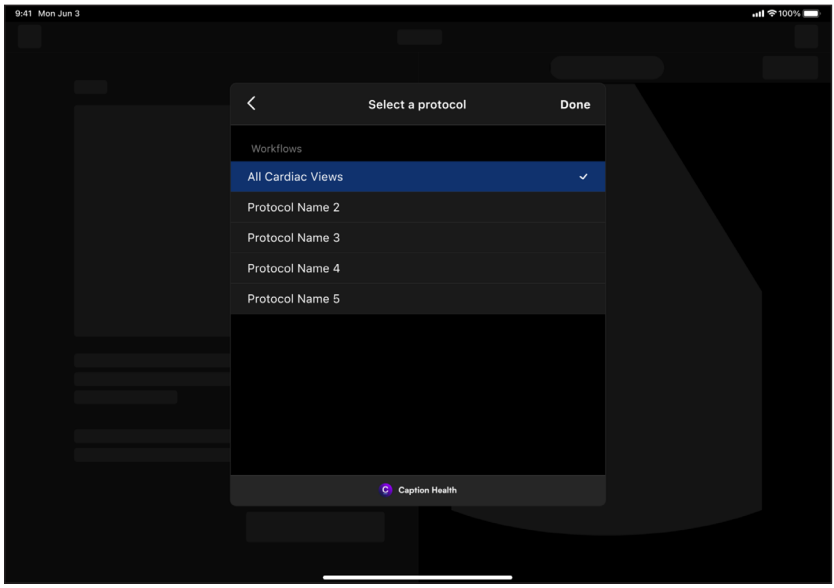


Figure 17. *Caption AI Protocol Selection*

2. Pick the scanning protocol you want to use. The protocol determines the views you will capture in the study.

   Note: If you change your mind about doing the study, tap the back button in the top left corner.

The Caption AI ultrasound display and controls

The first view you will be prompted to scan is based on the protocol you selected. This first view of each echo window is known as the "home" view and provides the foundation for the other clips in that acoustic-window series.

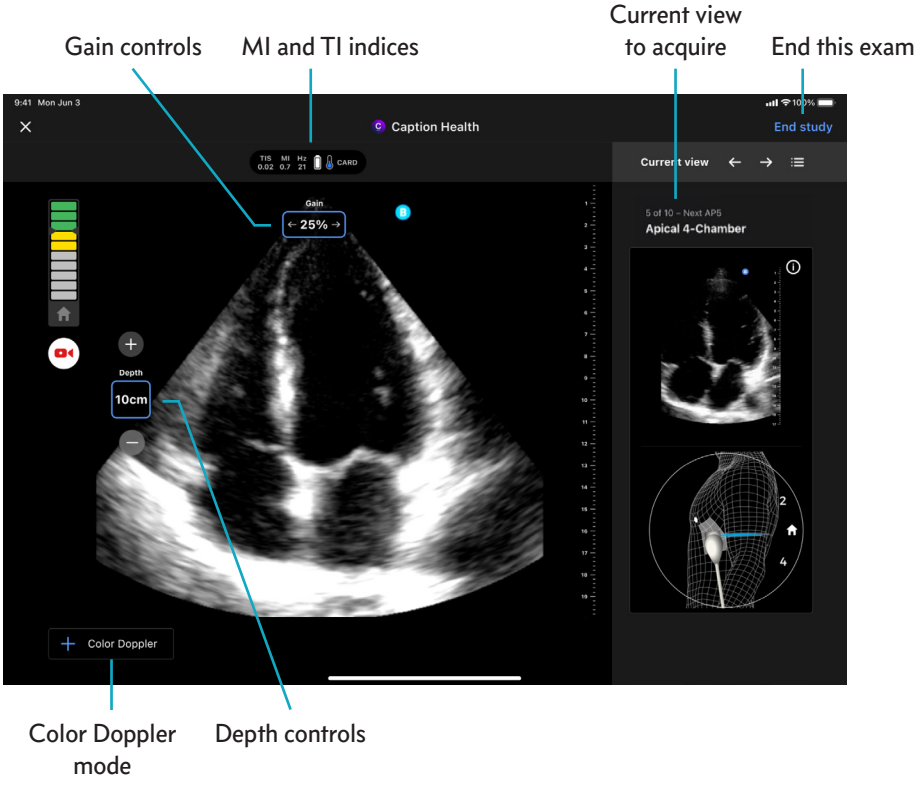


Figure 18. *Basic ultrasound display and controls*

This screen has the following basic features:

- **Details panel** displays the current view in the sequence you are about to record. The first view in an echo window is called the "home" view. This is the foundational view for the particular acoustic-window series. For example, AP4 is the home view for the Apical series.

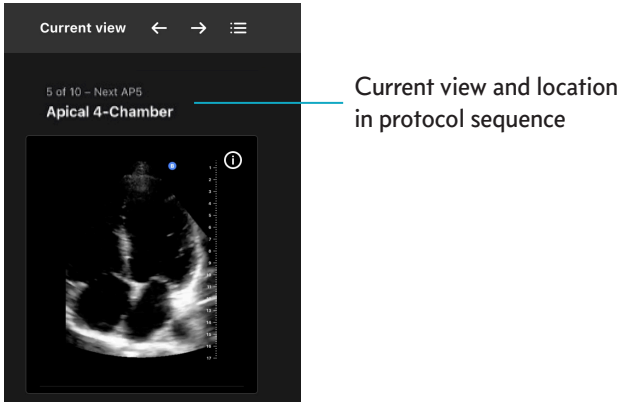


Figure 19. *Details panel*

Beneath the current view is text that tells you which view you are on out of the total number of views in the protocol and what the next view is.

- The **list icon** ( ) takes you to the **All Views** list, which shows all the views in the protocol, in the order that Caption AI will go through them, unless you choose to go in a different order.

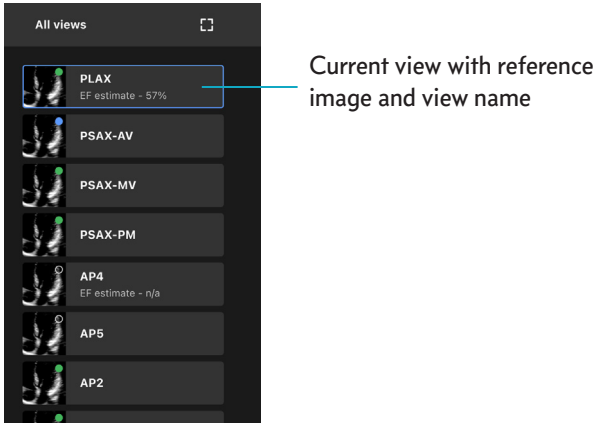


Figure 20. *All Views list*

Each view shows a reference image, the view name, and, if applicable, the Caption Interpretation AutoEF estimate for that view. Views that Caption Interpretation uses for individual-view AutoEF estimates are PLAX, AP4, and AP2. For more information on Caption Interpretation AutoEF, *Appendix A: Caption Interpretation AutoEF*.

The current view is outlined. Views that have been acquired are marked as follows:

- Acquired using AutoCapture
- Recorded using Save Best Clip
- Manually recorded

- **Color Doppler** allows you to go into Color Doppler mode.
- **MI and TI indices** provide real-time display of the thermal and mechanical acoustic output indices. It is important to observe the MI and TI values during scanning. When conducting ultrasound studies, follow the ALARA principle: expose the patient to ultrasound energy at a level that is "As Low As Reasonably Achievable." Please read the the *Butterfly iQ™/ Butterfly iQ+™ Personal Ultrasound System User Manual* for important information about acoustic output and ALARA.
- **Depth** changes the field of view of the image. Changes are in one- centimeter increments. Each view has a default depth setting that provides a good starting point for typical cases. The depth controls are displayed after tapping the ultrasound image. Depth markers are displayed along the right side of the imaging sector (the closer together the dots, the shallower the depth).
- **Gain** controls the overall amplification of the image signal. Setting gain properly, not so high as to introduce extraneous noise or so low as to make targets difficult to distinguish, may optimize the operation of the Quality Meter. Each view has a default gain setting that provides a good starting point for typical cases. To change the gain during scanning, swipe left or right on the ultrasound image.
- **End Study** closes the current study and saves all the clips that have been recorded for this exam. If you have not recorded all the views for the exam, you will be asked to confirm that you want to stop the exam.

  Note: When you save a study, you cannot reopen it later to add new clips or redo existing ones. You can only update patient information, delete the study, or send it to the DICOM PACS. See *Chapter 7: Working with Saved Studies*.

Setting up your scan

On the scanning screen, the following features help you set up your scan.

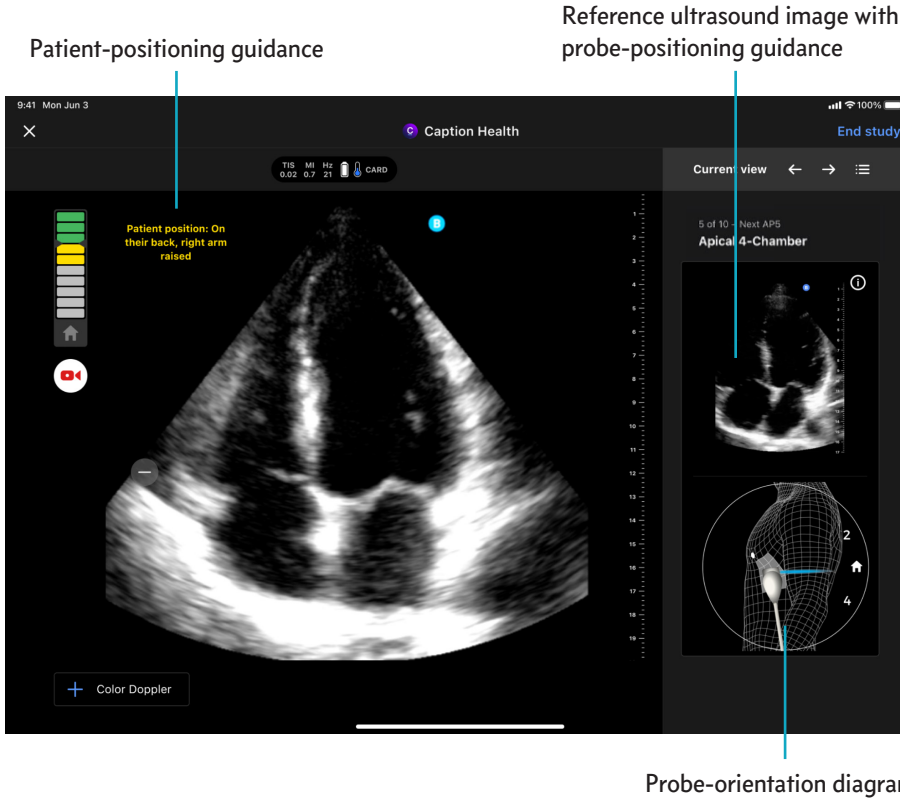


Figure 21. *Ultrasound display: features for setting up to scan*

- The **reference ultrasound image** is an example of an optimized image for the view you are acquiring. For each view in the protocol, the system displays the reference image.
- **Patient-positioning guidance** appears for each echo window home view—Parasternal Long-Axis (PLAX), Apical 4-Chamber (AP4), and Subcostal 4-Chamber (SubC4)—and tells you how to position the patient for those views.
- **Probe-positioning guidance** appears on the reference image for each echo window home view—Parasternal Long-Axis (PLAX), Apical 4-Chamber (AP4), and Subcostal 4-Chamber (SubC4)—and tells you how to position the probe before you start scanning.

- The **probe-orientation diagram** shows where on the patient's body to place the probe and the direction in which to point the indicator for this view. The probe indicator should point in the direction shown by the blue arrow. The "clock" numbers indicate the region in which you may need to explore, because the optimal direction will vary based on the patient.

Starting and optimizing your scan

To optimize your scan, Caption AI provides real-time guidance, which is described next.

Note: Real-time guidance is currently not available for Color Doppler scans.

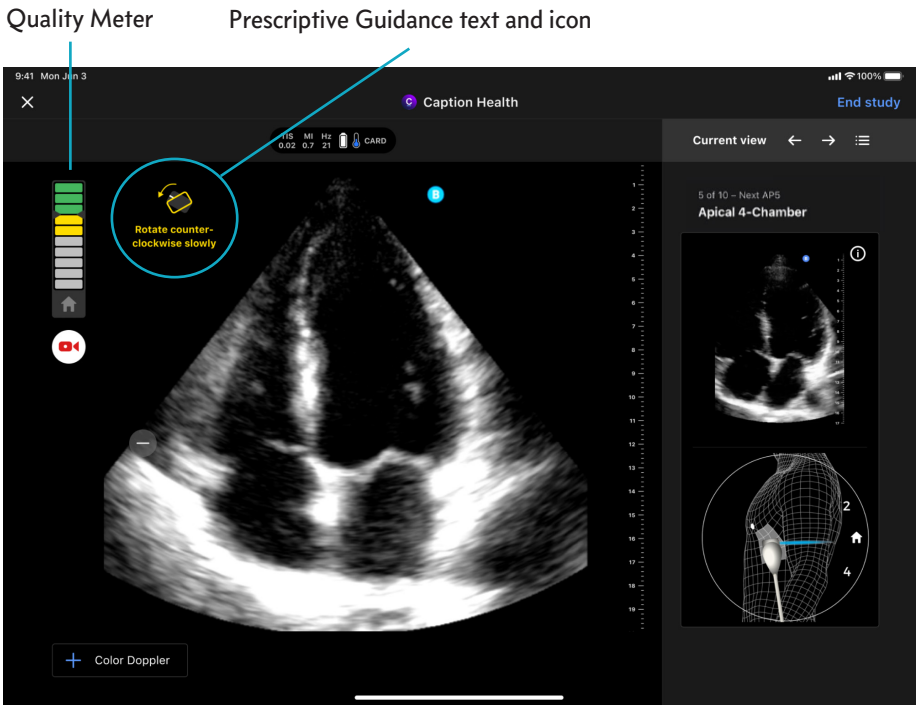


Figure 22. *Ultrasound display: real-time guidance*

- The **Quality Meter** provides real-time feedback as you scan. The bars indicate how close you are to the optimal probe position and orientation.

  As you get closer, the meter fills up toward the triangular notches, which indicate the diagnostic-quality threshold. When the meter reaches or exceeds this threshold, Caption AI automatically records the clip (provided AutoCapture is turned on; it is on by default).

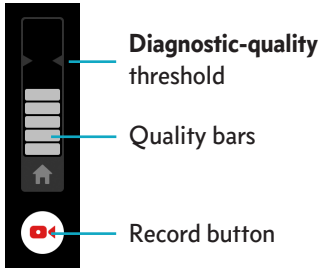


Figure 23. *Quality Meter: basic features*

When scanning for subsequent views within an acoustic-window series, two Quality Meters appear. This dual-meter shows the home view to the left and the current view to the right.

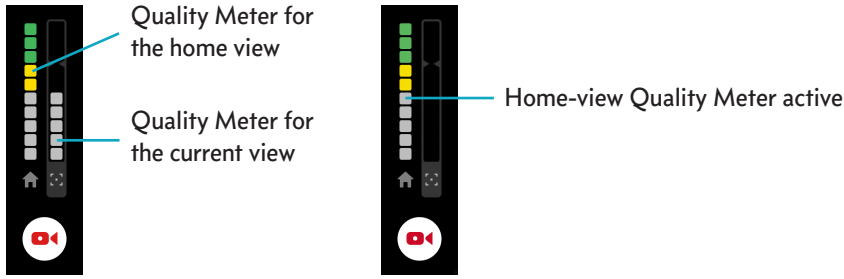


Figure 24. *Dual Quality Meter*

Caption AI displays the dual Quality Meter to help re-orient the operator, where going back to the home view may be helpful in getting to the current view. For example, in getting an Apical 2-Chamber view of the heart, it may be helpful to go back to the Apical 4-Chamber view, establish a good image for that view, and then rotate from there to obtain an Apical 2-Chamber view.

When the dual Quality Meter appears, you may do the following:

- Move the probe to align with the probe position for the home view. The home-view Quality Meter displays the quality bars for the home-view clip.
- Move the probe in very small increments, following any Prescriptive Guidance, to achieve the optimal probe position and orientation for the current view. The current-view Quality Meter will indicate how close you are compared to the reference ideal image.

- **Prescriptive Guidance** may appear while you are scanning. Caption AI presents guidance on how to adjust the probe to optimize the image. This guidance appears as text and, in many cases, as an icon on the active-image area of the screen.

  When Prescriptive Guidance appears, follow the suggestions until they disappear. If you make the adjustments correctly, Prescriptive Guidance disappears and the Quality Meter rises as the image quality gets closer to diagnostic quality. Yellow bars in the Quality Meter mean that you should make smaller, fine-tuned movements. Green bars mean the image is of diagnostic quality.

  The types of Prescriptive Guidance the system presents are shown in Table 5, below. The icons represent the face of the probe; the white line is the probe indicator.

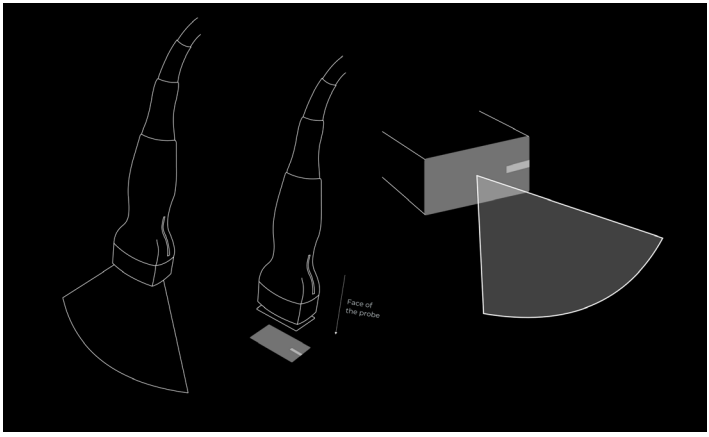
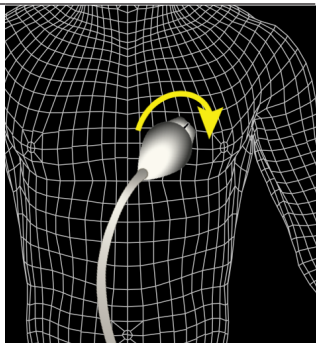
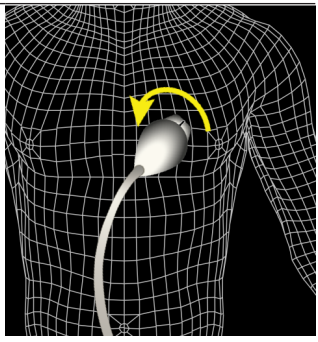
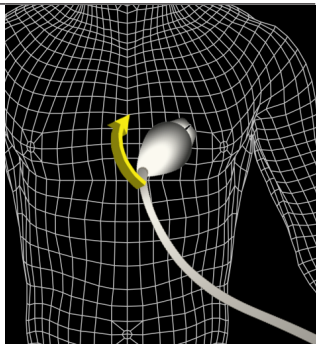
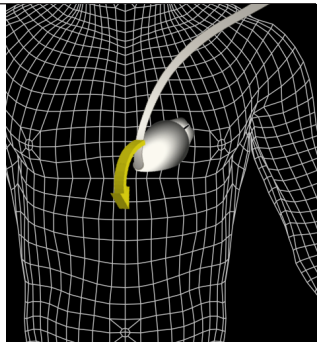
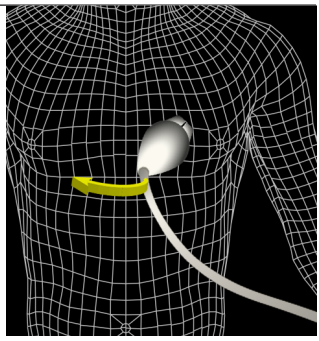
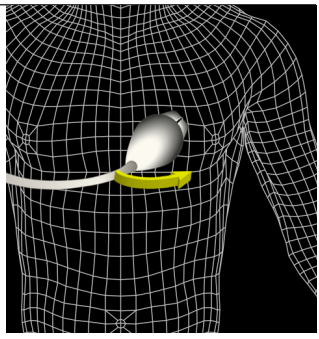
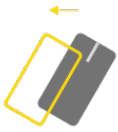
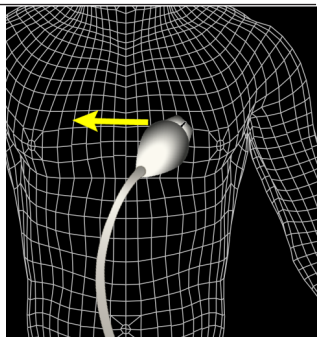


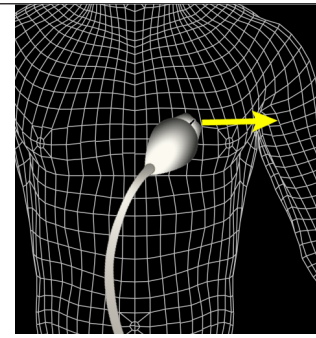
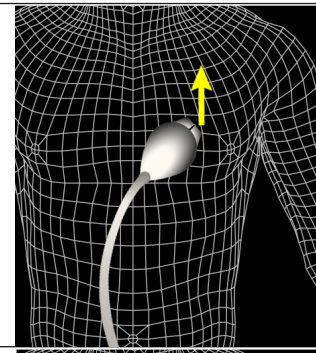
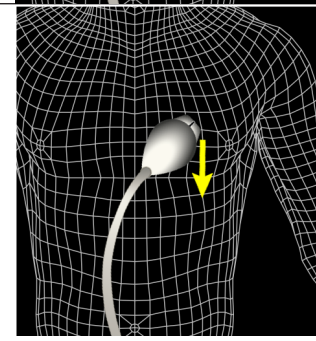
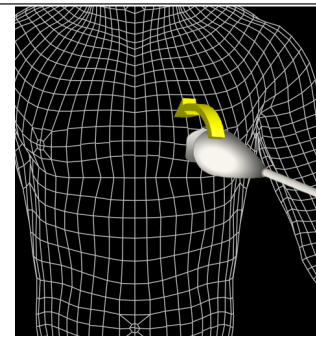
Figure 25. *Visualization for Prescriptive Guidance probe-movement icons*

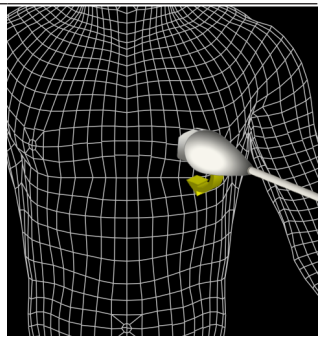
Note: All probe movements are in relation to the patient. For exam
when the guidance says "Tail slowly more lateral," it means t
move the tail away from the patient's midline. Tailing is alwa
the longer, non-indicator axis of the probe face, whereas roc
always on the shorter, indicator axis.

Table 5. *Prescriptive Guidance Examples*

On-screen	Icon	Movement/Action
Rotate clockwise		
Rotate counter clockwise		
Tail up		

On-screen	Icon	Movement/Action
Tail down		
Tail medial		
Tail lateral		
Slide medial		

On-screen	Icon	Movement/Action
Slide lateral		
Slide up		
Slide down		
Rock towards indicator		

On-screen	Icon	Movement/Action
Rock away from indicator		
Increase depth		Tap highlighted **+** button
Decrease depth		Tap highlighted **–** button

If Caption AI does not detect any visual structures, it prompts you with a different message, depending on the view. For the PLAX and AP4 views, it says, “Slow circular sweeps until moving anatomy appears,” and for the SubC4 view it says, “Slowly increase pressure until moving anatomy appears.” See the troubleshooting tips in your training materials. Some techniques to try include rolling the patient, using respiratory prompts such as try taking a slow breath in, or resetting the probe to the correct echo region.

Recording a clip

Caption AI provides three ways to capture clips: AutoCapture, Save Best Clip, and manual recording. The default method is AutoCapture. Manual recording should be used only by those users who are able to determine, without the assistance of Caption AI, that a clip is of sufficient diagnostic quality.

AutoCapture

The AutoCapture function automatically records a clip if the image quality exceeds the diagnostic-quality Quality Meter threshold and stays above it for at least 2 seconds. If you maintain the image above the diagnostic-quality Quality Meter threshold for more than 2 seconds, Caption AI will capture a longer clip, up to 4 seconds. Recordings will capture 62–124 frames, depending on how long you keep the image quality above the threshold. By capturing 2-4 seconds of frames, Caption AI will capture at least one complete heart cycle, provided the heart rate is not lower than 30 beats per minute.

You can turn AutoCapture on and off in the settings. See *Chapter 5: Setting up for an exam*.

After Caption AI has recorded the clip, it progresses you to the next view to acquire in the protocol.

▶ To record a clip using AutoCapture

1. Position the patient according to the positioning guidance.
2. Position the probe on the patient according to the probe-position and acoustic-window guidance, with the probe indicator pointing in the direction of the arrow and clock ranges.
3. As you scan, watch the screen and follow any Prescriptive Guidance suggestions that appear, such as rotating the probe or changing the depth (see Table 5 for an explanation of Caption AI's Prescriptive Guidance).

   The number of bars in the Quality Meter increases and decreases based on the optimal position and orientation of the probe for the view being scanned. Your goal is to reach the diagnostic-quality threshold, indicated by the two small triangular notches.

   Yellow bars mean that you are getting close to the optimal position and should make smaller, more finely tuned movements.

When one or more green bars appear in the Quality Meter, that means the ultrasound image has exceeded the diagnostic-quality threshold and Caption AI immediately starts recording the clip. “Recording...” appears at the top of the screen; the **Record** button turns red, indicating that recording is in progress; and the ring around the button turns blue as the recording progresses.

When the button changes to a circle with two dots, it means that the image quality has been above the threshold long enough for the clip to be saved (at least 2 seconds), however you are encouraged to hold the image above the threshold for an additional 2 seconds, if possible.

⚠ CAUTION

To ensure a diagnostic-quality clip, maintain probe contact and position during recording for at least 2 seconds. If you move the probe or otherwise interrupt the recording, the clip will not be recorded.

When the clip has been recorded, you will hear a “beep” and the **Record** button displays a checkmark while Caption AI processes the clip.

When done processing, Caption AI proceeds to the next view in the workflow protocol. “Saving the clip...” appears at the top of the screen to indicate that Caption AI is processing the saved frames for storage. At this time, you may move the probe.

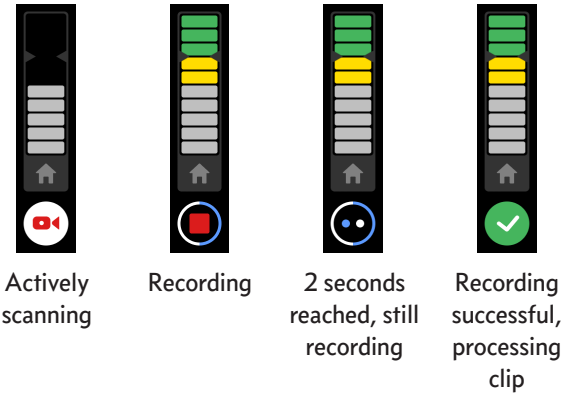


Figure 26. *Quality Meter: AutoCapture states (home view)*

Using Caption AI's Auto Ejection Fraction (AutoEF) feature

While scanning, you can use Caption AI's AutoEF feature to get an estimate of clip quality. Caption Health recommends that you acquire at least two relevant views for best results and for this reason, the AutoEF % does not automatically display until you have scanned two relevant views.

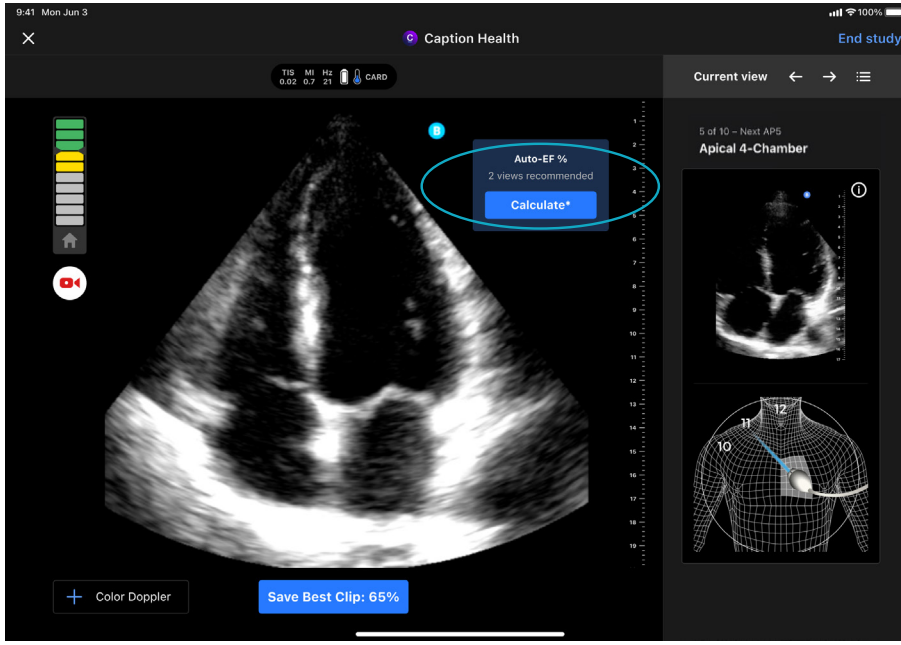


Figure 27. *AutoEF estimate: single view*

After you acquire a single relevant view for EF, you can tap **Calculate** to see the EF estimate. If you choose to calculate a single-view EF, then acquire a second relevant view, the EF estimate will be recalculated automatically, and if you acquire a third relevant view, the EF estimate will automatically be recalculated again. For more information on Caption Interpretation AutoEF, *Appendix A: Caption Interpretation AutoEF*.

Save Best Clip

Another way to record a clip is with the **Save Best Clip** feature, described below.

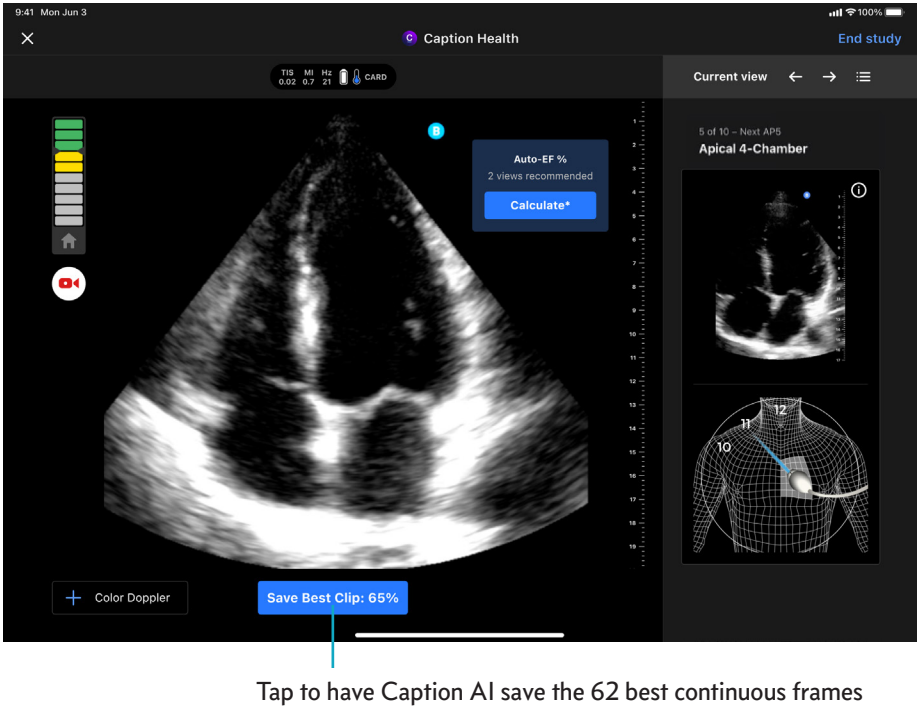


Figure 28. *Save Best Clip feature*

The **Save Best Clip** button appears after you have been scanning for some time without getting what Caption AI determines is a diagnostic-quality image. The button displays a quality "score," which indicates how close your best clip is to the diagnostic-quality threshold. The score is updated at regular intervals as you continue to scan and helps you decide when to save the best clip that the system has seen and move on. If the quality score and image are satisfactory, tap **Save Best Clip**. Otherwise, continue scanning, following the Prescriptive Guidance and general suggestions, to try to get a better quality image.

Manual recording

If you are an experienced user and are able to determine whether a clip is of sufficient diagnostic quality without the assistance of Caption AI, such as a trained sonographer, you might choose to manually record clips. Manual recording is the only way to capture clips for Color Doppler Scans.

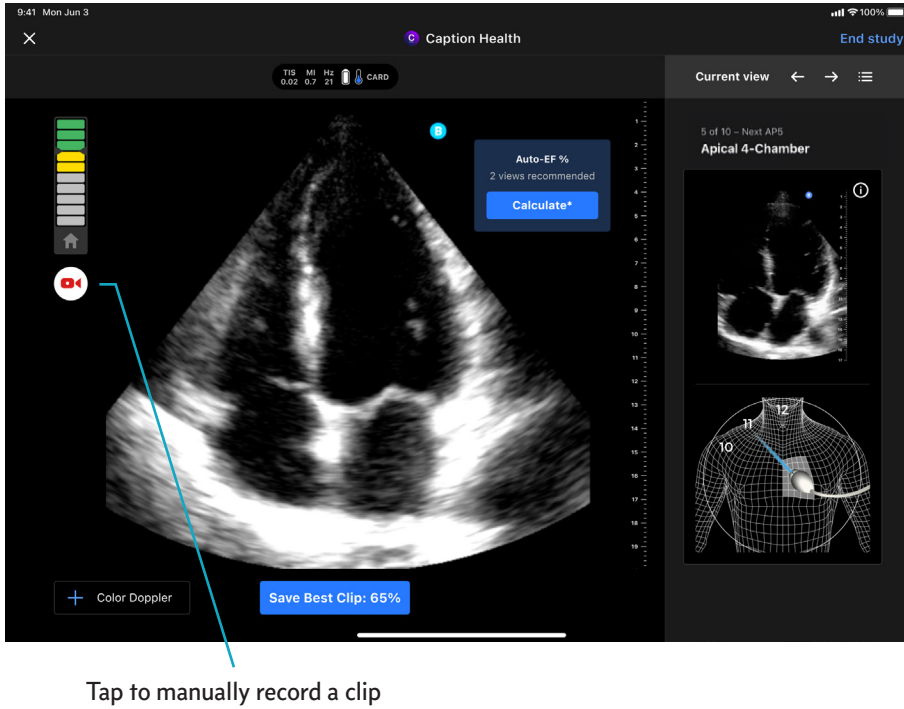


Figure 29. *Record button: manual recording*

To manually record a clip, tap the record button. You must then hold the probe steady for 2 seconds so Caption AI can capture the requisite number of frames. After the recording is complete, the record button displays a checkmark, and "Saving the clip..." appears at the top of the screen. During this time Caption AI is processing the saved frames for storage. At this time you may move the probe.

After Caption AI has stored the clip, it progresses you to the next view to acquire in the protocol.

⚠ CAUTION

Caption AI always presents the Quality Meter and Prescriptive Guidance during scanning of guided echo views, but because manual recording is always available during scanning, and manual recording is the only option for Color Doppler views, Caption AI cannot guarantee the quality of manually captured clips.

⚠ CAUTION

When you manually record a clip, Caption AI assigns the active view label to the saved clip. To avoid a mismatch between the label and the actual view captured, confirm that the view you are saving manually is listed at the top of the screen.

Non-sequential scanning

By default, when you record a study, you step through the views according to the protocol you are using for the exam. However, you may decide that you do not want to record a particular view or that you want to record a clip again before moving on to another view. Caption AI allows you to diverge from the protocol to meet the needs of the specific exam and patient. You can move between views, whether or not you have recorded clips for those views, and you can skip views you do not want to scan.

▶ To move between views

- From the **Details panel**, tap the next or previous arrows below the view name.

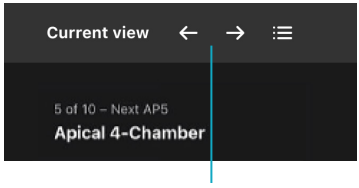


Figure 30. *View navigation*

- In the **All Views** list (from the **Details panel**, tap **Go to All Views**), tap the view you want to display.

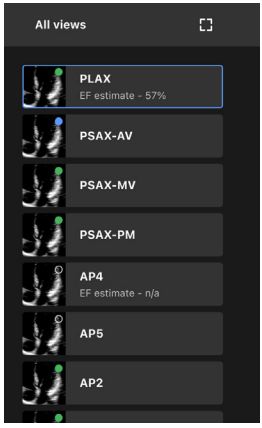


Figure 31. *All Views list*

If you select a view you have already acquired a clip for, you will have the option to record that clip again. Tap **Record Clip Again** and acquire a new clip for that view (see "Recording a Clip" on page 65).

Note: If there are previous views in the protocol that you skipped over during scanning, Caption AI will not automatically go back to those views, but you can select any view for which you want to record a clip. Before you end the exam, make sure you have acquired all the relevant views for the study.

Recording a clip based on Color Doppler

If you want to record a clip using Color Doppler, you can turn on **Color** and record the clip manually.

▶ To record a clip using Color Doppler

1. On the scanning screen, tap **Color Doppler**. The Color Doppler box and options appear.

   Note: The Color Doppler clip will be added above your current position in the protocol list.

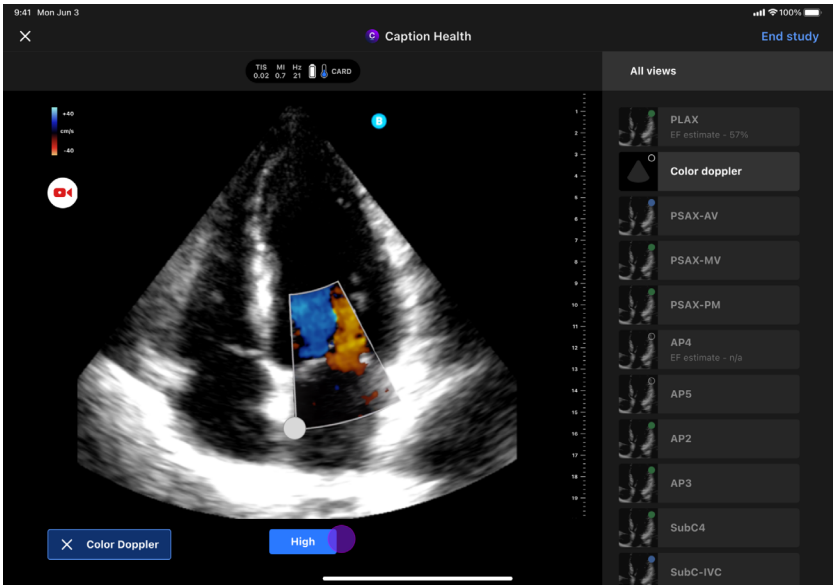


Figure 32. *Scanning screen: Color Doppler mode*

2. Select the color velocity scale. The default is High Flow for most cardiac imaging. Select Low Flow for low velocities.

3. To reposition the Doppler box, tap and drag it. When you release your finger from the screen, the Doppler box reappears in the new location.

4. When you are satisfied with the view in the image sector, tap the **Record** button. The clip is recorded and saved as "Color n," where n is the number of the Color Doppler clip. For example, if you record three Color Doppler clips, they will be named Color 1, Color 2, and Color 3.

Note: After a Color Doppler clip is recorded, a new Color Doppler clip will be created below it automatically. To exit Color Doppler mode without recording a clip, tap the **X** in the top right corner of the scanning screen.

Reviewing acquired clips during an exam

After you finish recording all clips in a protocol, the **All Views** list appears. On this screen you can review all the clips before sending the exam report. This is where you can choose to record clips for any views that you did not already acquire a clip for or that you want to scan again.

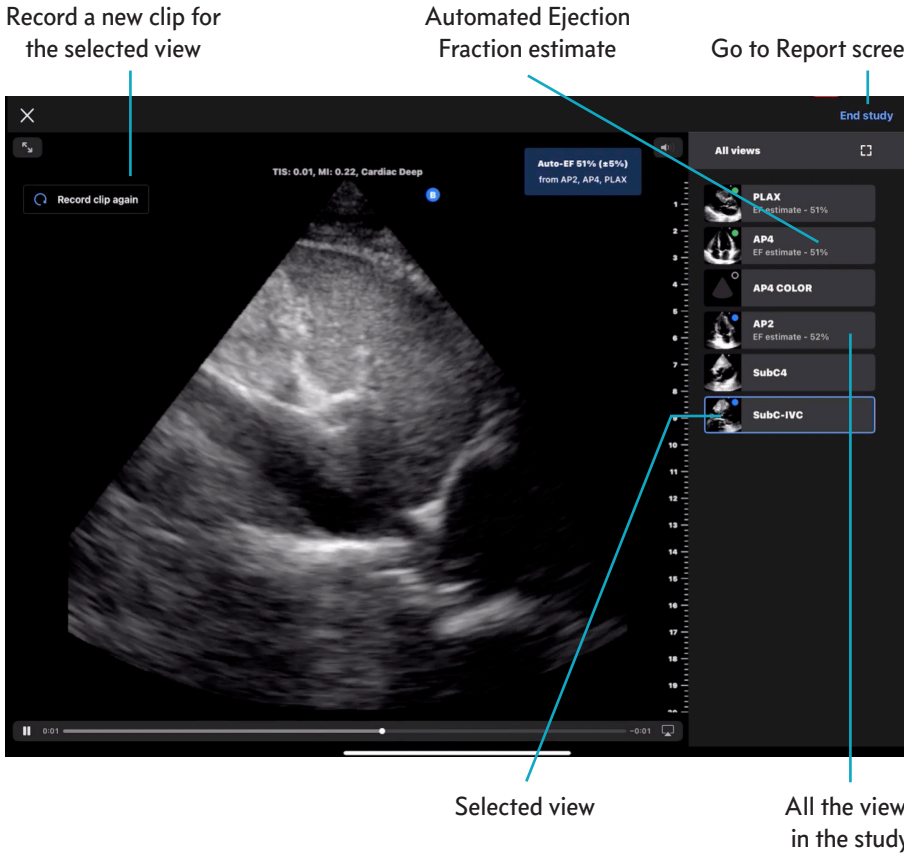


Figure 33. *All Views list for active study*

- **All Views** shows you all the views in the protocol, including views that you did not acquire clips for. In this list, you can select a view to review or record a clip.
- **Record Clip Again** puts you in live-scanning mode for the selected view.
- **AutoEF** shows the Caption AI Interpretation AutoEF information.
- **End Study** takes you to the Report screen where you can review all the clips in the exam before uploading the study to the Butterfly Cloud.

▶ To review all the clips in a study

When the last clip in a protocol is saved, the All Views list automatically appears, with the last-recorded clip selected. If you are in Detail view and want to end the exam without acquiring a clip for the last view in the study, tap **Go to All Views** or **End Study**.

1. In the **All Views** list, select a clip and review it in the scan-image area to determine whether the image is of good-enough quality for the study.
2. If you want to record the clip again, tap **Record Clip Again**. This takes you back to the live-scanning for that view. (See "Recording a Clip" on page 65.)

   ⚠ CAUTION

   When you record a clip again, the new clip will replace the previously recorded clip.
3. Repeat steps 1 and 2 until you have reviewed all the clips you plan to send as part of the exam.
4. When you are satisfied with the study, tap **End Study**. This takes you to the Report screen. See "Reviewing and uploading a study" on page 75.

Reviewing and uploading a study

After you are satisfied with the clips you have acquired for a study, you can review and send the study report. You do this on the **Report** screen.

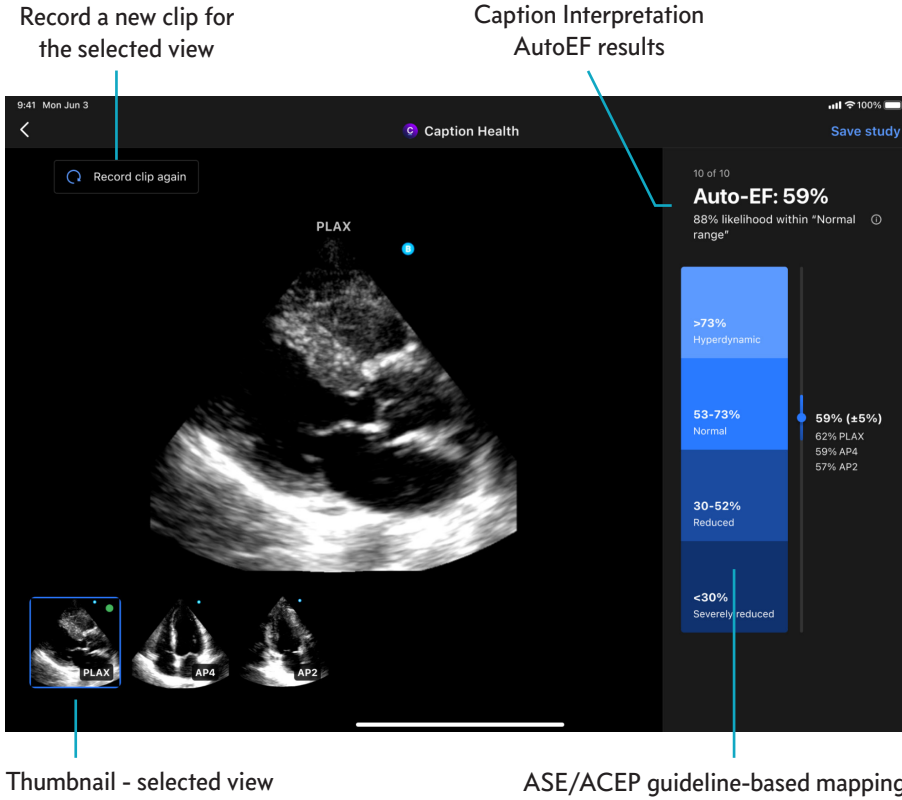


Figure 34. *Report screen*

- **Re-Record** resumes the study and puts you into live scanning for the current view in the image window. This option is only available immediately after you have captured a study. Once the study is resumed, you can record other clips again by selecting them in the All Views list. To return to the Reports screen after you are satisfied with the images, tap the **End Study** button at the bottom of the All views list.
- **Thumbnails** is a visual list of all the clips in the study. A border around a thumbnail indicates the clip that appears in the image window. If the study has more clips than can be displayed at one time in the row of thumbnails, you can swipe left and right to scroll through the set of clips. The thumbnail also indicates how the clip was captured: AutoCapture ( ), Save Best Clip ( ), or manually ( ).

- **AutoEF** shows the Caption Interpretation AutoEF results, if the protocol included a PLAX, AP4, or AP2 view. An Ejection Fraction estimate is shown along with a qualitative assessment of global LV function associated with the Ejection Fraction estimate, using a mapping from ASE[2] and ACEP[3] guidelines, shown in the color-coded chart below the overall estimate.

  A percentage likelihood is shown, to indicate the probability that the displayed qualitative assessment is in fact the true qualitative assessment of global LV function for the patient. For more information on AutoEF, see *Appendix A: Caption Interpretation AutoEF*.

- **Save Study** takes you to the archive screen where you add patient information, attach a worksheet, and upload your study to the Butterfly Cloud.

⚠ CAUTION

Once you export or close a study, the study is complete. It is "locked" and the clips cannot be modified. Before closing or sending a study, make sure you are satisfied with the quality of the clips.

▶ To add or edit patient details

1. On the **Archive** screen, select **Add** or **Edit** in the top right corner of the patient details page.
2. The **Select a Patient** screen will appear. If a modality worklist has been configured, you will be able query it to populate patient information. You can also manually enter patient information.

2 Lang RM Badano LP Mor-Avi V Afilalo J Armstrong A Ernande L Flachskampf FA Foster E Goldstein SA Kuznetsova T Lancellotti P Muraru D Picard MH Rietzschel ER Rudski L Spencer KT Tsang W Voigt JU. "Recommendations for cardiac chamber quantification by echocardiography in adults: an update from the American society of echocardiography and the European association of cardiovascular imaging." Eur Heart J Cardiovasc Imaging 2015;16:233–271.

3 ACEP Emergency Ultrasound Standard Reporting Guidelines. June 2018

To upload a study to the Butterfly Cloud

1. On the **Archive** screen, select **Save Study**. The study will upload to the cloud folder shown under **Archive To**.

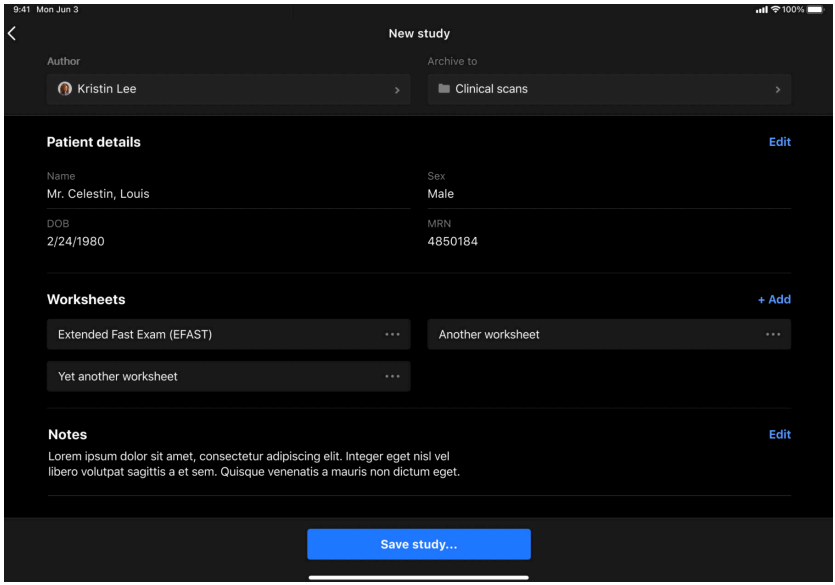


Figure 35. *Saving your study to the Butterfly Cloud*

2. When the save study screen appears, you will be prompted to save the study as draft or finalize the study. If you select **Save As Draft**, you will be able to make further changes after uploading. Selecting **Finalize Study** will prevent future changes.

3. Once you have selected whether to finalize the study, tap **Confirm**. The study will upload to the Butterfly Cloud.

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Chapter 7: Working with Saved Studies

When you first open the Butterfly app or go to the home screen, you will see previous studies completed with Caption AI in the **All Studies** list. Only studies from the current cloud folder indicated under Archive will display in the list. Selecting a study from the list will allow you to review clips captured and the AutoEF report.

If the study was saved as draft, you can also edit the patient information or make other changes. When you are satisfied with your changes, select **Sign Draft** to finalize the study.

For further information on working with saved studies, refer to the Butterfly manual.

▶ To view the AutoEF report of a saved study

1. After selecting a study from the **All Views** list, scroll down to the capture section to view thumbnails for the study's clips. Selecting a thumbnail will play the clip.

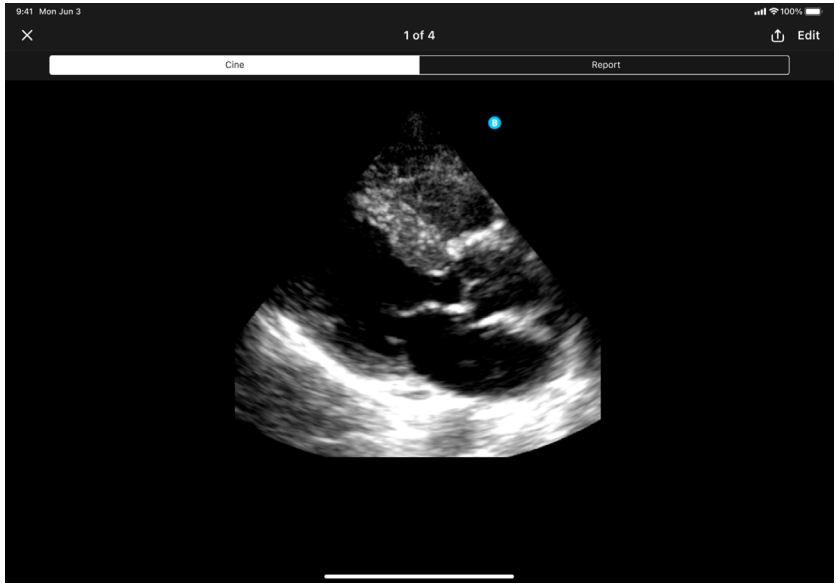

Figure 36. *Cine screen while reviewing a clip from a saved study*

2. If the clip generated an AutoEF interpretation during the study, you will have the option to toggle between **Cine** or **Report** at the top of the screen. Cine will play the clip. Report will display the AutoEF information for the study.

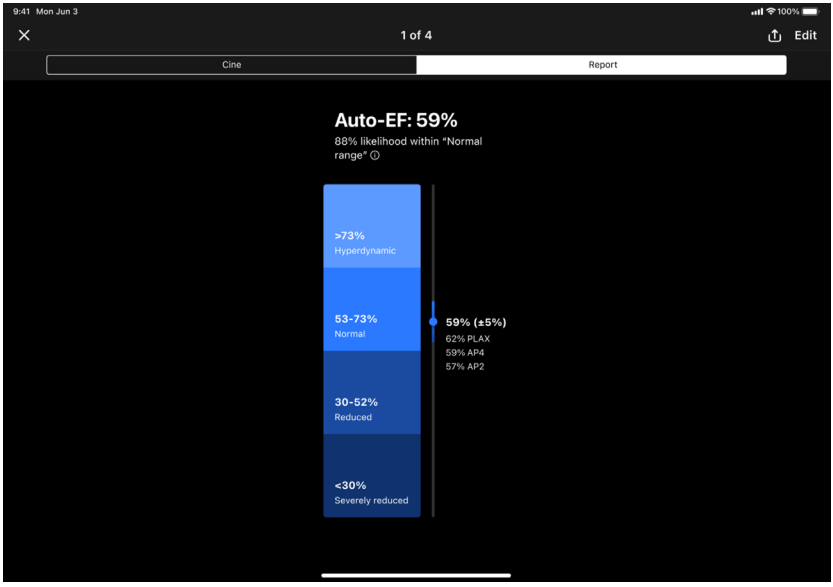

Figure 37. *Report screen while reviewing a clip from a saved study*

Appendix A: Caption Interpretation AutoEF

Introduction

This manual is intended to assist you with the safe and effective operation of your Caption Health product. Before attempting to operate the product, read this manual and strictly observe all warnings and cautions. Pay special attention to the information in the section titled "Safety."

Note: The user information for your Caption Health product may describe the most extensive configuration of the product, with the maximum number of options and accessories. Some functions described may not be included in your product's configuration.

Symbols and terms

This manual uses various warning, caution, and safety symbols and terms. Before using the product, familiarize yourself with these symbols and carefully read this section to understand their use.

⚠ **CAUTION**	This symbol and term alert you to information regarding patient, operator, or equipment safety. They also indicate information about preventing the loss of patient or product data.

Customer service

Customer service representatives are available to answer questions and provide support for your operation of the product. Please contact your local Caption Health representative for assistance or email support@butterflynetwork.com.

Safety information

Prescription Device Statement

CAUTION

For product usage in the United States of America, the following labeling statement applies:

Federal law restricts this device to use by or on the order of a physician.

CAUTION

Do not use the product for purposes other than those intended and expressly stated by Caption Health, Inc. Do not misuse the product, and do not use or operate the product in an incorrect manner.

Installation, use, and operation of this product are subject to the law in the jurisdictions in which the product is used. Install, use, and operate Caption Interpretation™ only in a manner that does not conflict with applicable laws or regulations, which have the force of law.

Use of the product for purposes other than those intended and expressly stated by Caption Health, Inc., as well as incorrect use or operation, may relieve Caption Health or its agents from all or some responsibility for resultant noncompliance, damage, or injury.

CAUTION

Product users are responsible for image quality and diagnosis. Inspect the data that is being used for analysis and diagnosis, and ensure that the data is sufficient and appropriate in anatomical correctness and both spatial and temporal resolution for the measurement being employed.

Intended use/Indications for use

This product is intended to be installed, used, and operated only in accordance with the safety procedures and operating instructions given in the product operator information, and only for the purposes for which it was designed. Nothing stated in the operator information reduces the operator's responsibility for informed clinical judgment and best clinical procedure.

The Caption Interpretation™ software is used to process previously acquired transthoracic cardiac ultrasound images, to store images, and to manipulate and

make measurements on images using an ultrasound device, personal computer, or a compatible DICOM-compliant PACS system in order to provide automated estimation of left ventricular ejection fraction. This measurement can be used to assist the clinician in a cardiac evaluation.

The Caption Health AutoEF software application is indicated for use in adult patients.

Intended audience

This manual is intended for healthcare professionals who operate and maintain the Caption Health AutoEF product.

Prior to using this information and the AutoEF product, operators must be familiar with ultrasound techniques. Sonography training and clinical procedures are not described here.

This product must be operated by or under the direction and supervision of a licensed physician.

Measurement accuracy

Measurements can be done on ultrasound images, which may be used with other clinical information to make a diagnosis. The AutoEF product performs measurements on images that have previously been acquired.

Making a diagnosis based solely on ejection-refraction measurements is not recommended. It is also important to understand limitations and factors that affect the accuracy of ultrasound image measurements. These include speed of sound variations in different tissue types, image quality, patient echogenicity, ultrasound scanner design, and operator skill. These factors must be considered when using any quantified data based upon ultrasound images. Consult your ultrasound system operator's manual for further information.

Echocardiography ejection fraction

Left ventricular ejection fraction (EF) by two-dimensional ("B-Mode") imaging is a measurement of the fraction of blood ejected from the left ventricle during systole. It is conventionally measured by dividing the stroke volume (the amount of blood ejected during systole) by the end-diastolic volume. Ejection fraction is stated as a percentage.

With echocardiography, ejection fraction is typically measured using planimetry to measure end-diastole and end-systole endocardial borders from apical views.

The Simpson's method is commonly used to then calculate volumes and ejection fraction.

The Caption Health AutoEF method uses deep learning algorithms that have been trained on very large datasets of echocardiograms with reported Ejection Fraction percentages. The algorithm operates on Parasternal Long Axis (PLAX), Apical Four Chamber (AP4), and Apical Two Chamber (AP2) images. The algorithm calculates an ejection fraction result but does not calculate chamber volumes. In this regard, it may be conceptually likened to the expert echocardiographer using the "eyeball" method to estimate Ejection Fraction.

Ultrasound systems

The development and testing of Caption Health AutoEF employed a large and diverse number of cardiac ultrasound systems. Provided that the other conditions described in the Operator's Manual are met, it is expected that acceptable performance of Caption Health AutoEF may be expected with images acquired by ultrasound systems that meet the following minimum requirements: multi-channel ultrasound systems operating wide bandwidth linear phased array transducers with DICOM storage and sending compatibility. The systems and transducers used to acquire the clips should be cleared by the FDA for cardiac imaging.

When used in Caption AI, Caption Health AutoEF is compatible with the ultrasound systems that are compatible with Caption AI.

Clip annotation and selection

The AutoEF software includes a function that processes video clips in a study in order to automatically classify clips that are PLAX, AP4, and AP2 views. It also includes a function that selects PLAX, AP4, and AP2 clips that are most appropriate for measurements. It is important to understand this function and to pay attention to the results of the Clip Selector when reviewing studies.

Based on verification and validation testing, with a diverse range of patient types, the Clip Selector may reject studies because it fails to find suitable Parasternal Long Axis, Apical 4 Chamber, and Apical 2 Chamber video clips in the study. Of the 186 studies that the Clip Selector was ran on, 181 (97%) had a suitable AP4 clip, 172 (92%) had a suitable AP2 clip, and 179 (96%) had a suitable PLAX clip. The frequency of rejection may be lower with better images and easier patients, and it may be higher with lower quality images, and difficult patients, such as patients with a high body mass index or technically difficult acoustic windows.

The rate is consistent with echocardiography norms where as many as 20% of adult patients are considered to typically present with sufficient technical difficulty that contrast agent enhancement is considered indicated in order to improve diagnostic quality, particularly of left ventricular function. (Lindner, JR, A Practical Approach to Contrast Echocardiography, American College of Cardiology, July 10, 2017 accessed online at http://www.acc.org/latest-in-cardiology/articles/2017/07/10/09/17/a-practical-approach-to-contrast-echocardiography.) It is also consistent with echocardiography left ventricular ejection fraction studies, where it is typical that approximately 10-13% of patients are considered too technically difficult to be included for EF analysis. (Malm S, Frigstad S, Sagberg E, Larsson H, Skjaerpe T. Accurate and reproducible measurement of left ventricular volume and ejection fraction by contrast echocardiography. Journal of the American College of Cardiology. 2004 Sep 1;44(5):1030-5.)

For best results, and to minimize the rejection of clips presented to the AutoEF software, submit images that meet the requirements for successful manually traced Biplane Simpson's method of disks measurements: minimal endocardial dropout, and minimal foreshortening of the apical views. (Lang RM, Badano LP, Mor-Avi V, et al. Recommendations for cardiac chamber quantification by echocardiography in adults: an update from the American Society of Echocardiography and the European Association of Cardiovascular Imaging. J Am Soc Echocardiography 2015;28:1–39. e14.)

The clips selected for use are displayed with an indication that they have been used to generate the AutoEF. When reviewing AutoEF results, confirm that PLAX, AP4, and AP2 clips that are appropriate for measuring ejection fraction are being used in the AutoEF estimation.

To produce an AutoEF estimate, the Clip Annotator and Selector requires a minimum number of 16 frames, in order to process enough of the heart cycle to estimate ejection fraction.

⚠ **CAUTION**

Review the video clips used in generating AutoEF measurements to ensure that the clips are appropriate for measuring ejection fraction.

Transthoracic and transesophageal echocardiography

The Caption Health AutoEF software has been trained on transthoracic echocardiograms. It is not intended for use on transesophageal echo images. Because of the similarity of many transthoracic and transesophageal

echocardiographic views, the Clip Selector function may occasionally inadvertently select transesophageal images for processing. Ejection fraction results from these images should not be used for diagnosis.

⚠ **CAUTION**

AutoEF is not intended for transesophageal echocardiograms (TEE). Do not operate AutoEF on transesophageal images.

Patient data archival

The Caption Health AutoEF product is not intended to be a permanent archival or storage location of studies. Patient studies should be archived in your permanent location.

⚠ **CAUTION**

The Caption Health product is not a permanent storage device for patient studies.

PHI protection

Patient information contained in DICOM studies contains Protected Health Information (PHI). The Caption Health AutoEF software operates as a module within the Caption AI product and users do not have direct access to any data stored in the Caption Health AutoEF software. Instead, users view the results produced by the Caption Health AutoEF software via the Caption AI software and PACS DICOM Viewer used to read studies. Configuration of Caption Health products and PACS DICOM viewer(s) is performed by authorized IT administrators who log into the system using their security credentials.

The Caption Health AutoEF software is not intended for long-term storage of studies.

When viewing AutoEF results in your DICOM Viewer, make certain to observe your institution's guidelines and practices regarding the protection of PHI.

Cybersecurity precautions and practices

Malware, computer viruses, ransomware, and other cybersecurity threats are an increasing concern in healthcare IT systems. The Caption Health AutoEF software operates as a module inside Caption AI and behind your institution's security firewalls. There is no direct connection between the Caption Health AutoEF software and the outside internet.

For information and guidance on implementing proper cybersecurity in the healthcare IT environment, see "Health IT Privacy and Security Resources for Providers" at https://www.healthit.gov/topic/privacy-security-and-hipaa/health-it-privacy-and-security-resources-providers.

Product compatibility

Caption Health AutoEF is compatible with Caption Guidance as part of the Caption AI product. Do not use your system in combination with other products or components, unless the Caption Health AutoEF software expressly recognizes those other products or components as compatible. For information about such products and components, see "Specifications" and contact your Caption Health representative.

Changes and additions to the system should be made only by Caption Health or by third parties expressly authorized by Caption Health to do so. Such changes and additions must comply with all applicable laws and regulations that have the force of law within the jurisdictions concerned, and best engineering practices.

Performance Testing

Validation testing and performance summary of AutoEF

Caption Health AutoEF performance, including the integrated operation of the Clip Selector, was validated on a dataset of 186 patient studies. These studies were assembled to represent a broad cross-section of patient conditions, including a diverse range of ejection fraction values, and a significant portion of high body mass index patients as is typically associated with technically difficult studies. The validation dataset also included a diverse and representative mix of ultrasound manufacturers and product models. These included:

Manufacturer/Model

- Philips Medical Systems CX50 / Epiq 7C / iE33
- Acuson/Sequoia
- GE US Vivid i / Vivid E9 / Vivid E95 / Vivid7
- Siemens/Acuson SC2000

For each of these studies a reference ejection fraction by 2D echo using the biplane Modified Simpson's method of disks was available. These had been created by expert registered sonographers and read and reported by expert cardiologists. The test compared the Caption Health AutoEF to the expert produced and reported biplane Modified Simpson's ejection fraction. The expert produced and reported biplane Modified Simpson's ejection fraction

was considered the ground truth. The performance target was that the results of the AutoEF software would be within the limits typically represented by inter-observer variability in biplane Modified Simpson's ejection fraction measurements. Root mean squared deviation (RMSD) was used as the endpoint to evaluate this performance. RMSD can be computed from a Bland-Altman analysis. In this test, RMSD is provided in the unit of ejection fraction percentage. The RMSD target was derived from published literature. The performance target was an RMSD of less than or equal to 9.2%. This target was met.

The testing described in this section was performed with Caption Health AutoEF processing operating on a Linux machine using a Python wrapper over the AutoEF software.

Clip annotation performance

The Clip Selector (as known as Clip Annotator) was run on 186 studies. For each study, it identified the most probable clip ("best clip") for each of the following four view/mode categories: PLAX, AP4, AP2, and Color Doppler clip. Three (3) expert registered diagnostic cardiac sonographers (RDCS) with more than five (5) years of professional experience were recruited. For a given clip, each expert was independently presented with the best clip and the Clip Selector's prediction of the view/mode for the clip. The expert was asked whether the Annotator's prediction was correct. This was repeated for all the best clips found for all recruited experts. A consensus paradigm was used to determine ground truth ("reference standard") for each best clip.

The studies for which the Clip Selector was not able to find any clips for a certain view/mode was presented to the panel of 3 sonographers. Each member of the panel was independently asked whether the study contained at least one clip of the view/mode without use of contrast agent or TEE. This was repeated for all such studies and for all applicable view/modes. The resulting data, combined with the above PPV assessment dataset, was used to assess sensitivity.

The study-level positive predictive value (PPV) and sensitivity were computed, and each was tested for whether it exceeded the pre-specified performance goals of 80% PPV and 80% sensitivity.

The results are shown in Table 1. All endpoints were met, demonstrating acceptable performance of the Caption Interpretation Clip Selector feature.

Table 5. *Clip Annotator positive predictive value (PPV) and sensitivity*

	View/ Mode	PPV % [95% CI]	p-value	Sensitivity % [95% CI]	p-value
View	PLAX	99.5% [97, 100]	p <0.001	99.5% [97, 100]	p <0.001
	AP4	98.9% [96, 100]	p <0.001	98.3% [95, 100]	p <0.001
	AP2	97.2% [94, 99]	p <0.001	96.7% [93, 99]	p <0.001
Mode	No color flow present	98.8% [96, 100]	p <0.001	98.8% [96, 99]	p <0.001

Clinical validation

The Clinical Performance Validation study was a retrospective, multi-center study. The test design is summarized here, and the results are discussed in the Results section.

This study included a selection of 186 patient studies from the following three sites: the Minneapolis Heart Institute (MHI), Duke University (Duke), and Northwestern Medicine (NM). A range of body-mass index (BMI) was included in the dataset, with 34% of the patients overweight (25 ≤ BMI < 30 kg/m2) and 29% obese (BMI > 30 kg/m2). In addition, 43% of patients had reduced EF (30% ≤ EF < 53%), and 18% of the patients had severely reduced EF (EF <30%).

All studies were traced by three (3) sonographers using the biplane Simpson's method, and overread by three (3) Level III cardiologists to establish the reference standard.

The primary hypothesis tested in this study was:

- **Objective performance goal (best available view(s)):** Caption Interpretation measurements based on the best available view(s) are superior to a literature derived endpoint of 9.2% root-mean-square deviation (RMSD) for view combinations or 11.024% RMSD for single views.

Results

Caption Interpretation Automated Ejection software produced an EF assessment from at least one view in 183 (98%) studies. An EF assessment based on at least two views was produced in 183 (98%) of the studies.

Objective performance goal—primary hypothesis testing for combination views

Results of the hypothesis testing of Caption interpretation Automated EF software evaluating the performance of the algorithm against its objective performance goal of 9.2% RMSD is shown in Table 2 below. The primary endpoint was met.

Table 6. *Caption Interpretation Automated EF performance compared to the reference standard – primary hypothesis testing*

MAD EF% [95% CI]	RMSD EF% [95% CI]	p-value
5.72 [5.29, 6.15]	7.21 [6.62, 7.74]	< 0.001

Bland-Altman and linear fit plots for Automated EF estimates made from the available views (PLAX, AP4, and AP2) in each patient study are shown below. From the plots, it can be observed that Caption Interpretation estimation of EF is highly linear with the reference EF and performs with comparable accuracy across the range of EFs, including in patients with hyperdynamic and severely reduced LV function.

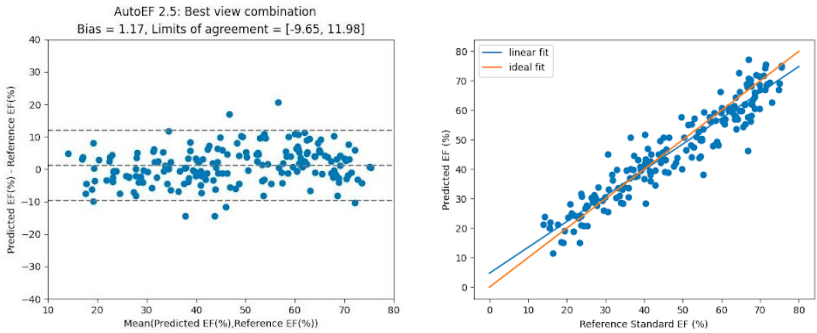

Figure 38. *Bland-Altman (left) and Linear Fit (right) plots for Caption Interpretation Automated EF estimation based on best available view(s)*

Results of the hypothesis testing of Caption Interpretation AutoEF software evaluating the performance of the algorithm against its objective performance goal of 9.2% RMSD for combinations of views are shown in Table 3 below. The endpoints were met.

Table 7. *Caption Interpretation Automated EF performance compared to the reference standard*

#	View Combination	RMSD EF% [95% CI]	p-value
1	AP4 and AP2	7.27 [6.55, 7.92]	< 0.0001
2	AP4 and PLAX	7.50 [6.85, 8.09]	< 0.0001
3	AP4, AP2, and PLAX	7.24 [6.64, 7.80]	< 0.0001
4	AP2 and PLAX	8.04 [7.32, 8.7]	0.0002
5	Best available	7.21 [6.62, 7.74]	< 0.0001

Objective performance goal—primary hypothesis testing for single views

Results of the hypothesis testing of Caption Interpretation AutoEF software evaluating the performance of the algorithm against its objective performance goal of 11.024% RMSD for single views are shown in Table 4 below.

Table 8. *Caption Interpretation Automated EF performance compared to the reference standard – descriptive analysis*

#	View(s)	RMSD EF% [95% CI]	p-value
1	AP4 only	7.76 [7.01, 8.45]	< 0.0001
2	AP2 only	8.27 [7.44, 9.03]	< 0.0001

Sensitivity and PPV of detecting reduced EF

The Sensitivity and PPV of AutoEF in identifying patients with reduced or severely reduced EF (i.e., EF < 53%) was calculated and compared to the sensitivity and PPV of physicians' visual assessments. The results are reported in the tables below.

Table 9. *AutoEF 2.5 PPV (Reduced/ Severely Reduced)*

View(s)	AutoEF PPV [95% CI]
PLAX, AP4, and AP2	95.83% [91.67, 98.96]
PLAX and AP4	95.05% [90.1, 99.01]
PLAX and AP2	96.77% [92.47, 100]
AP4 and AP2	96.12% [92.23, 99.03]
AP4 only	97.14% [93.33, 100]
AP2 only	97.92% [94.79, 100]
Best available	96.12% [92.23, 99.03]

Table 10. *AutoEF 2.5 sensitivity*

View(s)	AutoEF Sensitivity (Reduced/ Severely Reduced) [95% CI]
PLAX, AP4, and AP2	88.46% [81.73, 94.23]
PLAX and AP4	88.07% [81.65, 93.58]
PLAX and AP2	86.54% [79.81, 92.31]
AP4 and AP2	92.52% [86.92, 97.2]
AP4 only	91.07% [85.71, 95.54]
AP2 only	87.85% [81.31, 93.46]
Best available	88.39% [82.14, 93.75]

Outlier assessment

The incidence of outliers in AutoEF assessment relative to the reference standard EF estimate is shown in Table 7 below. The incidence of observed outliers was very low for all EF estimates produced from a combination of views. The observed incidence of outliers was higher for single-view EF estimates, but was lower than the observed outliers of the physicians' estimates.

Table 11. *EF assessment outliers – Caption Interpretation AutoEF*

View(s)	Studies Assessed *n*	AutoEF error >15% EF *n* (%)
PLAX, AP4, and AP2	166	2 (1.20%)
PLAX and AP4	177	2 (1.13%)
PLAX and AP2	168	5 (2.98%)
AP4 and AP2	170	3 (1.76%)
AP4 only	181	4 (2.21%)
AP2 only	172	7 (4.07%)
Best available	183	2 (1.09%)

System Overview and Configuration

System components and workflow

In operation, the Caption Health AutoEF software provides automated measurements of left ventricular ejection fraction integrated into the Caption AI product. Studies are sent to the Caption Health AutoEF module for processing. When the AutoEF process is completed, the outputs are forwarded to the Caption AI software. Using Caption AI, the reading physician reviews the patient study, which now includes the AutoEF outputs, along with the clips used to generate the Ejection Fraction result. The physician may use the AutoEF number as an input in creating the Patient Report.

Hardware and software requirements

The hardware and software requirements for the operation of the Caption Health AutoEF include the hardware platform for the Caption Health AutoEF software module, the operating system software for the Caption Health AutoEF software, and the DICOM-compliant interfaces. These requirements are superseded by the Caption AI hardware requirements. Contact your Caption Health representative for details.

Configuration

CAUTION

The Caption Health AutoEF product is not a permanent storage device for patient studies.

CAUTION

To ensure proper operation of the Caption Health AutoEF software, configuration and setup of Caption AI and PACS DICOM Viewer(s) should be performed by an IT or PACS Administrator.

System Operation

This chapter describes the operation of Caption Health AutoEF. For important information regarding the proper use and application of AutoEF, see *Chapter 2: Safety*.

Caption Health AutoEF processing

Caption AI automatically forwards the images acquired during a study to the Caption Health AutoEF module in parallel to study acquisition. Once the user has acquired two acceptable views, the AutoEF measurement will be displayed, as acquiring at least two views will improve the accuracy of the measurement.

When Caption Health AutoEF receives a study, it automatically processes it to: (1) identify the Parasternal Long Axis, Apical Four Chamber, and Apical Two Chamber view clips; (2) assesses which of the identified clips are suitable for measurement; and (3) of the clips suitable for measurement, selects the best quality clip for each view. At most, three clips will be selected for AutoEF estimation, one for each view. Fewer than three clips may be selected, as few as none, if one or more of the views did not have a clip in the study that was suitable for measurement.

The selected clips are used to produce the AutoEF estimate. An individual Ejection Fraction estimate is produced for each view (PLAX, AP4, AP2) and an overall aggregate Ejection Fraction estimate is produced for the study that averages the Ejection Fraction estimates from each view.

For the aggregate AutoEF estimate produced for the study, the estimate will be accompanied with a list of views used to produce the estimate and an "expected error range" around the estimate to indicate the range in which the true Ejection Fraction is expected to lie. The greater the number of views that the AutoEF estimate is produced from, the more reliable we anticipate the estimate to be.

A qualitative assessment of global LV function associated with the Ejection Fraction estimate will also be displayed below using a mapping from ASE guidelines.

- EF greater than 73% shall be mapped to "Hyperdynamic"
- EF greater than or equal to 53% but less than or equal to 73% shall be mapped to "Normal"
- EF greater than or equal to 30% but less than or equal to 52% shall be mapped to "Reduced"
- EF less than 30% shall be mapped to "Severely Reduced"

For the qualitative assessment of LV function displayed, a likelihood will be shown in % to indicate the probability that the qualitative assessment displayed is in fact the true qualitative assessment of global LV function for the patient. This is estimated by modeling the distribution of the true EF as a normal distribution with the mean at the predicted EF and the standard deviation as the Confidence Metric prediction, and then by computing the area under the curve between the bounds of the qualitative bin.

Single-view EF calculation

In certain circumstances, the user may decide that an AutoEF assessment based on a single view is appropriate, such as for patients for whom it is too technically difficult to obtain additional views, or in time-critical situations. To calculate the AutoEF measurement from a single view, the user selects "Calculate" (Figure 2) and confirms their choice (Figure 3). The AutoEF measurement from a single view will be displayed (Figure 4), and will automatically update if the user is able to acquire an acceptable additional view.

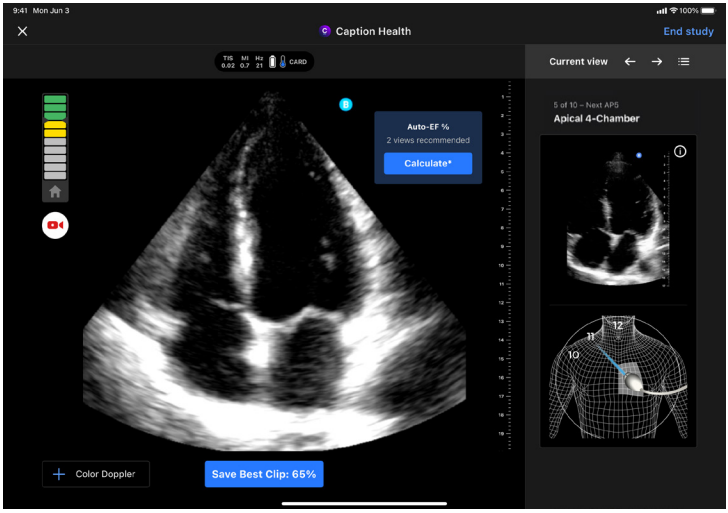

Figure 39. *Detail view with AutoEF*

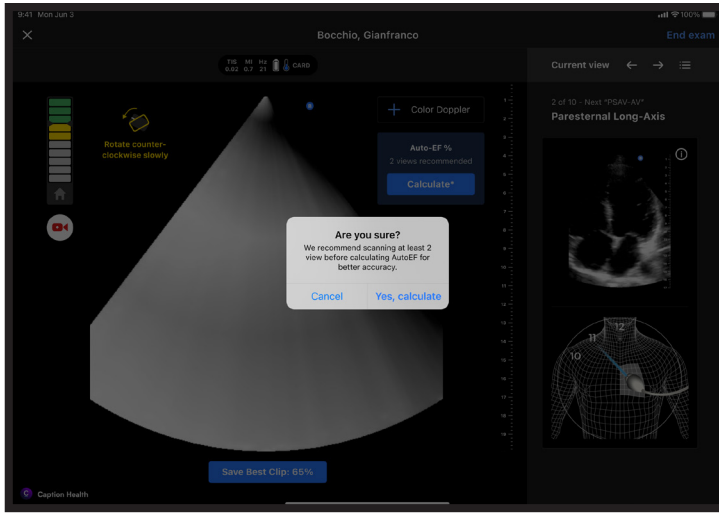

Figure 40. *AutoEF calculation confirmation*

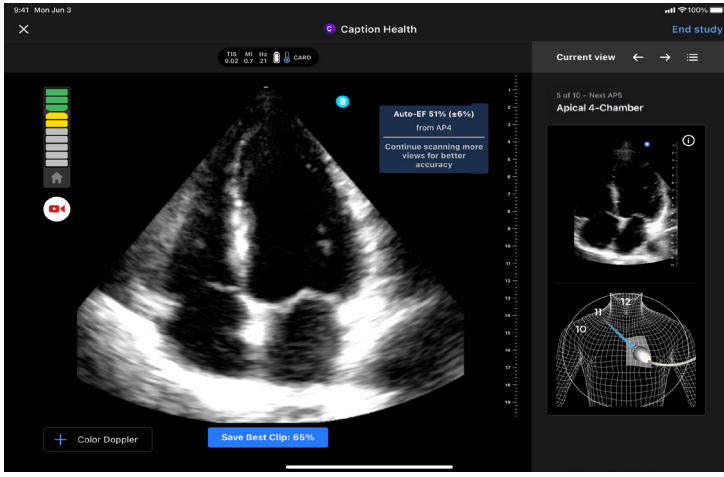

Figure 41. *Detailed view with single AutoEF calculation*

Single-view EF calculation is only available for the Apical Four Chamber and Apical Two Chamber views. If only the Parasternal Long Axis has been acquired, the user will see a message on-screen to capture one of these views instead of the "Calculate" button (Figure 5).

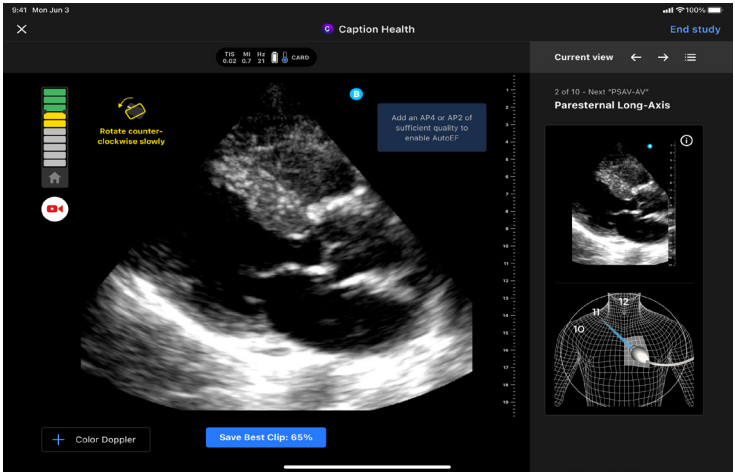

Figure 42. *Plax view with message to acquire additional views*

The user should verify that the images include Parasternal Long Axis, Apical Four Chamber, and Apical Two Chamber views that are appropriate for measurements, as applicable, following standard guidelines and their institution's guidelines regarding anatomical presentation, image quality, and the capture of at least one full heart cycle.

Accompanying information

The AutoEF estimate is accompanied by an "expected error range" (Figure 6) around the estimate to indicate the range in which the true Ejection Fraction is generally expected to lie. This error range is computed by modeling the distribution of the observed difference between the AutoEF estimate and the panel mean EF (i.e., the mean of the cardiologist EF estimates, each of which is produced by a single cardiologist in the panel, for a given study), denoted as $\Delta EF_{AutoEF, Panel}$ across a large population of echocardiographic studies, as a function of image quality. Specifically, for a given study, this error range represents the expected standard deviation of the difference between the AutoEF and expert cardiologist panel estimates ($\Delta EF_{AutoEF, Panel}$), based on the image quality of the study. In other words, the error range represents one standard deviation of $\Delta EF_{AutoEF, Panel}$ that is expected for the image quality.

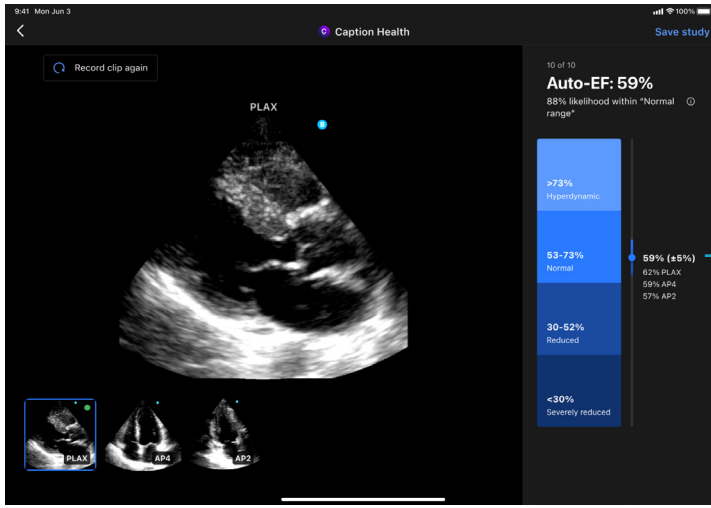

Figure 43. *Report screen with AutoEF estimate: expected error range*

By looking at this expected error range, the user can evaluate the confidence in the estimate and any implications that error range has on their clinical assessment. For instance, a large error range may create uncertainty around whether the patient's Ejection Fraction estimate is normal or abnormal. The error range is estimated taking into account the underlying image quality of the clips in the study and is expected to be smaller in studies with higher image quality as well as in studies where the user captured at least two views that can be used for an assessment of Ejection Fraction.

For the aggregate AutoEF estimate produced for the study, the estimate will be accompanied with a list of views used to produce the estimate and an "expected error range" around the estimate to indicate the range in which the true Ejection Fraction is expected to lie. The greater the number of views that the AutoEF estimate is produced from, the more reliable the estimate is anticipated to be.

A qualitative assessment of global LV function associated with the Ejection Fraction estimate will also be displayed (Figure 7) using a mapping from ASE and ACEP guidelines.[1, 2]

1 Lang RM, Badano LP, Mor-Avi V, Afilalo J, Armstrong A, Ernande L *et al*. "Recommendations for Cardiac Chamber Quantification by Echocardiography in Adults: An Update from the American Society of Echocardiography and the European Association of Cardiovascular Imaging" Eur Heart J Cardiovasc Imaging 2015;16:233–271.
2 ACEP Emergency Ultrasound Standard Reporting Guidelines. June 2018.

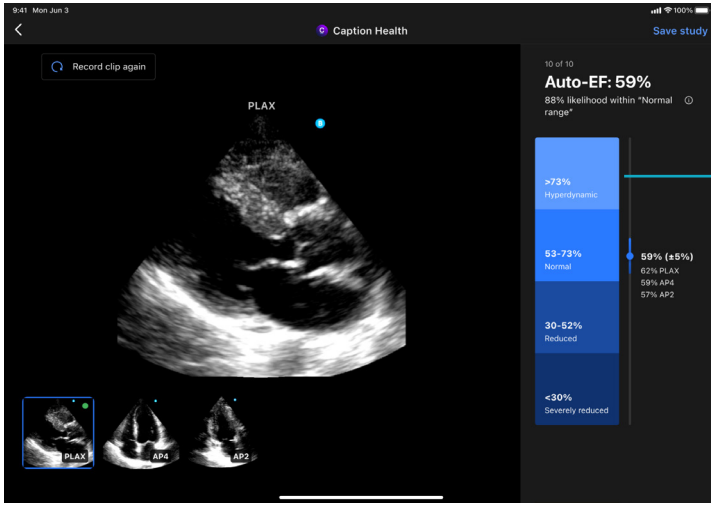

Figure 44. *Report screen with AutoEF estimate: global LV function*

ASE guidelines report the following categories for assessment of left ventricular ejection fraction (EF).

Table 12. *Recommendations for cardiac chamber quantification by echocardiography in adults (ASE/AACVI 2015): left ventricular ejection fraction*

	Normal (%)	Mildly abnormal (%)	Moderately abnormal (%)	Severely abnormal (%)
Male	52–72	41–51	30–40	< 30
Female	54–74	41–53	30–40	< 30

Caption Health made two adjustments to simplify the guidelines for use at the point of care. First, the minor sex-related differences in the guidelines for the normal-hyperdynamic and normal-mildly abnormal boundaries were averaged so that the guidelines were sex-agnostic. These differences are minor, and the reconciled guidelines differ by only a single EF percentage point at these boundaries. Second, these guidelines were used to determine the categories defined by the ACEP in their reporting guidelines, which recommend the following: hyperdynamic, normal, reduced, and severely reduced. In order to reconcile the two guidelines, the ASE "mildly abnormal" and "moderately abnormal" guidelines were collapsed into a single category. Ultimately these changes resulted in the final categorization used by AutoEF, shown in the table below.

Table 13. *AutoEF 2.5 qualitative categorization of EF*

Hyperdynamic (%)	Normal (%)	Reduced (%)	Severely reduced (%)
> 73	53–73	30–52	< 30

The software maps the point Ejection Fraction estimate to one of the categories of LV function defined above. Taking into consideration the expected error range around the point Ejection Fraction estimate, which may result in an overlap across two different categories of LV function, the software provides a "likelihood" (or probability to be more precise) for the displayed category of LV function (Figure 8). This "likelihood"(in %) indicates to the user how confident the software is that the true Ejection Fraction of the patient lies in the same category of LV function as the point Ejection Fraction estimate predicted by the software.

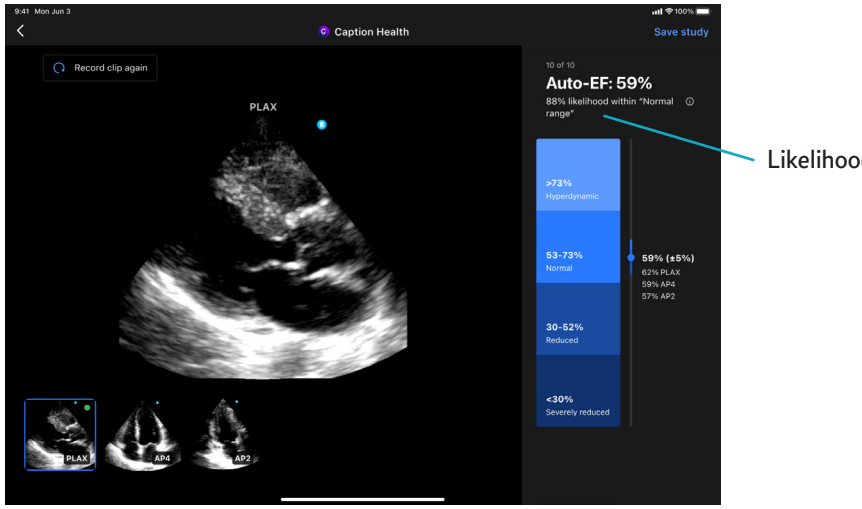

Figure 45. *Report screen with AutoEF estimate: likelihood of LV function*

Note: If the study did not contain any clips from any of the three views that were suitable for measurement, an Ejection Fraction estimate will not be produced for the study and the user will be notified that the software did not have sufficient information to produce an Ejection Fraction estimate for the study.

When AutoEF processing is complete, the updated study is forwarded automatically to the destination PACS server defined in the settings.

CAUTION

Review the video clips used in generating AutoEF measurements to ensure that the clips are appropriate for measuring ejection fraction.

Reviewing results on the PACS workstation

The AutoEF results are integrated into the patient study and are viewed via the Caption AI software, and can be forwarded to your DICOM viewer. The AutoEF outputs and the overall study can be viewed via the DICOM viewer. It is important for the physician preparing the Patient Report to carefully inspect the AutoEF result and the images used, as well as other contents of the study, in order to determine a reported ejection fraction estimate.

Editing results

AutoEF results may manually be made a part of a final Patient Report, so the reviewing physician may edit the result as needed. Users may also use the manual measurement tools of the viewing software to create new calculations, such as manual biplane Simpson's ejection fraction on the original versions of the clips.

Safety and regulatory requirements

The system complies with the following voluntary standards:

- ISO 14971, Application of Risk Management to Medical Devices
- IEC 62366, Application of Usability Engineering to Medical Devices
- Digital Imaging and Communications in Medicine (DICOM) (NEMA Standard PS3)