

Butterfly iQ™ Personal Ultrasound System

User Manual



Notice

Butterfly Network, Inc. (BNI), shall not be liable for errors contained herein or for incremental or consequential damages in connection with the furnishing, performance, or use of this material.

Proprietary Information

This document contains proprietary information, which is protected by copyright.

Limited Warranty

The “Limited Warranty” shipped with BNI products serves as the sole and exclusive warranty provided by BNI with respect to the products contained herein.

Copyright

Copyright © 2020 Butterfly Network, Inc. All Rights Reserved.

Trademark Acknowledgements

Product names mentioned in this manual may be trademarks of their respective owners.

iPhone, iPad, iPod, and Lightning are trademarks of Apple Inc., registered in the U.S. and other countries.

Android is a trademark of Google LLC.

Legal Notice

“Made for iPhone, iPad, or iPod” means that an electronic accessory has been designed to connect specifically to iPhone, iPad, or iPod and has been certified by the developer to meet Apple performance standards. Apple is not responsible for the operation of this device or its compliance with safety and regulatory standards. Please note that the use of this accessory with iPhone or iPad may affect wireless performance.

Manufacturer

Butterfly Network, Inc. 530 Old Whitfield Street Guilford, CT 06437 USA

Telephone: +1 (855) 296-6188

FAX: +1 (203) 458-2514

General inquiries: info@butterflynetwork.com

Support and service: support@butterflynetwork.com

Website: www.butterflynetwork.com



US Patents

Listing of applicable U.S. Patents in compliance with 35 U.S.C. §287:

www.butterflynetwork.com/patents

Disclaimer

The information contained in this document is subject to change without notice. Some feature sets may not be available to certain user groups based on platform and local regulatory restrictions. Names and data used in examples are fictitious unless otherwise noted.

To obtain a printed copy of this manual at no additional cost, contact Butterfly Support at support.butterflynetwork.com.

Table of Contents

1. Introduction	6
Overview	6
Intended Uses	6
Indications for Use	6
Contraindications for Use	7
Training	7
2. Safety Information	8
Safety Conventions	8
Ultrasound Benefits and Risks	8
Ultrasound Benefits	8
Ultrasound Risks	8
Butterfly iQ™ Safety	9
Basic Safety/Usage Environment	9
Electrical Safety	11
Defibrillation Safety	12
Equipment Protection	12
Biological Safety	12
Operator Safety	13
3. System Overview	14
Overview	14
Modes	14
Measurements	14
Probe Types	14
Patient Data Protection	15
Internet Connectivity	15
System Components	15
Butterfly iQ™ App	16
Probe	17
Probe Battery Charger	18
Overview of User Interface	19
Presets	19
4. Setting Up the System	20
Downloading and Installing the App	20
Updating Firmware	20
Managing App Updates	20
Charging the Probe	21
Checking Probe Battery Level	23
5. Using the System	24
Performing a Study	24
Uploading to Butterfly Cloud	25
6. Using Modes	26
Using Color Doppler Mode or Power Doppler Mode	26
Using M-Mode	26
Using Spectral Pulsed-Wave Doppler Mode	26
7. Annotations	29
Adding Annotations	29
8. Manual Calculations Packages	31
Obstetric Calculations	31
Manually Calculate Volume	32
Calculation Package References	32
9. AI-Assisted Tools	34
Automatically Estimating Ejection Fractions	34
Automatically Estimating Bladder Volume	37

Butterfly iQ Educational View Guidance	41
10. Using Butterfly Cloud	43
Overview	43
Accessing Butterfly Cloud	43
Viewing and Managing Studies	43
11. Using Butterfly TeleGuidance	45
Overview	45
12. Maintenance	46
Maintaining the Probe	46
Cleaning and Disinfecting the Probe	47
Cleaning the Probe	47
Disinfecting the Probe	48
Updating the Probe and App Software	50
Performing the Probe Diagnostic Test	50
13. Troubleshooting	51
Troubleshooting	51
14. Getting Support	53
Contacting Butterfly Support	53
Contacting Support through the Butterfly iQ™ App	53
15. Specifications	54
Mobile Device Requirements	54
System Specifications	54
Probe Battery Charger	55
Environmental Operating Conditions	55
Electromagnetic Conformance (EMC)	56
Separation Distances	57
Acoustic Output	57
Acoustic Output Limits	60
Acoustic Output Tables	60
Measurement Accuracy	68
Waste Electrical and Electronic Equipment	68
Recycling and Disposal	68
16. Symbols	69
Symbols	69
17. Notes	71

1. Introduction

This chapter provides an introduction to the Butterfly iQ™ Personal Ultrasound System.

Overview

Butterfly iQ™ personal ultrasound is designed to be easy to use, portable, and battery powered. Its commercial off-the-shelf mobile platform (mobile device) provides a simple interface for the user.

This manual is intended to provide information to guide trained operators in the safe and effective operation and proper maintenance of Butterfly iQ™ personal ultrasound, and applicable accessories. It is important that you read and understand all instructions in this manual before operating the system, and pay careful attention to the warnings and cautions throughout the manual.



NOTE

Depending on your platform, hardware, country and membership type, certain presets, modes and features may not be available.

Intended Uses



CAUTION!

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

Butterfly iQ™ is a general-purpose diagnostic ultrasound imaging system for use by a qualified and trained healthcare professional enabling diagnostic imaging, measurement of anatomical structures and fluid, and other applicable tools.

Indications for Use



NOTE

All presets and features may not be available. Please visit support.butterflynetwork.com for information specific to your device and country.

Butterfly iQ™ is indicated for use by trained healthcare professionals in environments where healthcare is provided to enable diagnostic ultrasound imaging and measurement of anatomical structures and fluids of adult and pediatric patients for the following clinical applications:

- Peripheral Vessel (including carotid, deep vein thrombosis and arterial studies)
- Procedural Guidance
- Small Organs (including thyroid, scrotum and breast)

- Cardiac
- Abdominal
- Urology
- Fetal/Obstetric
- Gynecological
- Musculoskeletal (conventional)
- Musculoskeletal (superficial)
- Ophthalmic¹

Modes of operation include:

- B-Mode
- B-Mode + M-Mode
- B-Mode + Color Doppler
- B-Mode + Power Doppler
- Spectral Pulsed-Wave Doppler²

Use Butterfly iQ™ in accordance with all safety procedures and operating instructions as outlined within this manual, and only for the purposes for which the device was intended.

Contraindications for Use

Butterfly iQ™ should not be used for indications other than the ones approved by the applicable governing agency.

Training

In order to safely and effectively operate Butterfly iQ™, the user shall meet the following:

- Training as required by local, state, provincial, and national regulations
- Additional training as required by the authorizing physician
- A thorough knowledge and understanding of the material presented in this manual

¹Not available in all countries.

²Not available in all countries.

2. Safety Information

This chapter provides important safety information for using Butterfly iQ™ and includes a list of warning and caution messages. This user manual is accessible from the Butterfly iQ™ App and through the website support.butterflynetwork.com.

Safety Conventions

**WARNING!**

Conditions, hazards, or unsafe practices that may result in serious personal injury or death.

**CAUTION:**

Conditions, hazards, or unsafe practices that may result in minor personal injury, damage to the device, or loss of data.

This user manual is intended to assist in the safe and effective operation of Butterfly iQ™. It is important that all users review and understand all instructions in this user manual before operating the device, paying careful attention to the warnings and cautions throughout the manual. The following conventions are used throughout this manual to highlight safety concerns:

Ultrasound Benefits and Risks

Ultrasound is widely used because it provides many clinical benefits to the patient and has an excellent safety record. Ultrasound imaging has been used for over twenty years and there have been no known long-term negative side effects associated with this technology.

Ultrasound Benefits

- Multiple diagnostic uses
- Immediate results
- Cost-effectiveness
- Portability
- Safety record

Ultrasound Risks

Ultrasonic waves can heat the tissues slightly. It is normal that the probe may feel warm to the touch while charging. If you remove the probe from the charging pad before or immediately after charging is complete, it is recommended that you allow the probe to cool down before use. Since the system limits patient contact temperature and will not scan at or above 43°C (109°F), allowing the probe to cool down before use will optimize scan time performance.

Butterfly iQ™ Safety



WARNINGS!

- The Butterfly iQ™ is intended for use by competent users capable of interpreting image quality, diagnosis, and clinical utility of the system.
- Movement of the patient during scanning may impact results. User should exercise clinical judgement in the interpretation of results.
- Do not use Butterfly iQ™ until the materials present in this manual have been reviewed and fully understood. Do not operate Butterfly iQ™ for purposes other than intended in this manual.
- Do not operate Butterfly iQ™ improperly. Failure to do so may result in serious personal injury or death.

Basic Safety/Usage Environment



WARNING!

Butterfly iQ™ is classified as MR UNSafe and may pose unacceptable risks to the patient, medical staff, or other persons within the MR environment.





WARNINGS!

- Use only cables, probes, chargers, and accessories specified for use with Butterfly iQ™. Substitution of non-approved accessories may cause the system to perform improperly or may cause injury to the patient or operator.
- If the probe seems unusually hot, produces an odor or smoke, or leaks, stop use immediately. Unplug the probe from the mobile device or disconnect it from the wireless charger (if applicable). Contact Support at: support@butterflynetwork.com
- Do not use Butterfly iQ™ in the presence of flammable gases or anesthetics. Doing so can result in a possible fire or explosion.
- Butterfly iQ™ has not been evaluated or approved for use in hazardous locations as defined in the National Electric Code standard. In compliance with IEC classification, the Butterfly iQ™ is not to be used in the presence of flammable substances/air mixtures.
- Do not use the Butterfly iQ™ Application on a mobile device that does not meet minimum requirements. Using the Butterfly iQ™ Application on a mobile device that does not meet the minimum requirements may affect performance and image quality, possibly resulting in misdiagnosis.
- Spilling fluids into the system may damage it or present a fire or shock hazard. Do not allow fluids to enter the device.
- Store only within the range of environmental conditions specified in the technical specifications.
- Dangerous high voltages and currents are present. There are no user-serviceable parts. Do not open, remove covers, or attempt repair.
- Portable and mobile radio-frequency (RF) communications equipment can affect Medical Electrical Equipment.
- Internet access is required to view the user manual and Butterfly support portal. If you intend to use Butterfly iQ™ without an internet connection download the user manual locally by visiting support.butterflynetwork.com.
- Use of damaged equipment or accessories may cause the device to perform improperly and/or result in injury to the patient or operator. Refer servicing to qualified service personnel.
- No modification is allowed. Do not modify cables, probes, chargers, or accessories specified for use with Butterfly iQ™. Modification to equipment may cause the system to perform improperly or may cause injury to the patient or operator.



CAUTIONS!

- Cardiac rhythm disturbances during cardiac studies using gas ultrasound contrast agents have been observed in the diagnostic range of Mechanical Index (MI) values. See the specific package insert for the contrast agent being used for further details.
- Butterfly Cloud enables remote viewing of ultrasound images on a variety of platforms and in uncontrolled environments (e.g., ambient lighting). Clinician discretion on the appropriate use of images must be applied.
- Only trained operators should use the instrument for needle placement.

Electrical Safety



WARNINGS!

- Before use, carefully inspect the probe. Always inspect the probe before and after cleaning, disinfection, or use. Check the lens face, cable, housing, seams, and connector for signs of damage such as cracks, chips, abrasions, or leaks. To avoid the risk of electrical hazards, do not use the probe if there is any sign of damage.
- Dropping the probe may cause damage. Always inspect the probe before and after cleaning, disinfection, or use. Check the lens face, cable, housing, seams, and connector for signs of damage such as cracks, chips, abrasions, or leaks. To avoid the risk of electrical hazards, do not use the probe if there is any sign of damage.
- Comply with IEC 60601-1 when using additional equipment along with the ultrasound device.
- Use of accessories, probes, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Electrical shock to the patient or operator may result if voltages exceeding IEC 60601-1 for patient-applied parts are exceeded.
- The probe is designed to remain sealed. Do not attempt to open the probe or tamper with the device internals, including the battery. Doing so may cause injury to the patient or operator.
- Do not immerse probe beyond specified levels. Immersion beyond specified levels may result in electrical shock.



WARNINGS!

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Butterfly iQ™, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.



CAUTIONS!

- Notifications and alerts from other third-party applications running on the mobile device may interfere with the study.
- The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Group 1 Class A). If this equipment is used in a residential environment (for which CISPR 11 Class B is normally required), this equipment might not offer adequate protection to radio- frequency communication services. The user might need to take mitigation measures, such as relocating or re-orientating the equipment.

Defibrillation Safety



WARNINGS!

- Before applying a high-voltage defibrillation pulse to the patient, remove all patient-contact devices that are not indicated as defibrillation-proof.
- Probe covers do not provide protection from defibrillation.

Equipment Protection



CAUTIONS!

- Do not overly bend or twist the probe cable. Always inspect the probe before and after cleaning, disinfection, or use. Check the lens face, cable, housing, seams, and connector for signs of damage such as cracks, chips, abrasions, or leaks. To avoid the risk of electrical hazards, do not use the probe if there is any sign of damage. Do not immerse the probe in water or liquids beyond specified levels.
- To avoid the possibility of internal condensation and possible damage, do not store the device outside of the specified environmental operating conditions.
- Improper maintenance may cause Butterfly iQ™ not to function. Maintain the equipment only as described in the maintenance section.
- Do not sterilize or autoclave the Butterfly iQ™ or its accessories.

Biological Safety



WARNINGS!

- Always use the ALARA (As Low As Reasonably Achievable) principle when performing an ultrasound study. Additional information on the ALARA principle can be found in AIUM's, "Medical Ultrasound Safety" publication. This publication is available as a PDF link in the Butterfly iQ™ App.
- If Butterfly iQ™ is contaminated due to exposure to Creutzfeldt-Jakob disease, there is no adequate disinfecting procedure.
- Use the correct clinical application presets for the associated body part being examined. Some applications require lower acoustic output limits.
- There are no latex parts in the probe. However, some probe sheaths may contain natural latex, which can cause allergic reactions in some people.
- If performing procedures that require transducer covers, follow your institution's protocol and/or the instructions provided with the covers.
- This product can expose you to chemicals including Carbon black, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.



CAUTION!

Avoid contact with mucous membranes (e.g. eye, nose, mouth) and non-intact areas of the skin that have been opened by cuts, abrasions, dermatitis, chapped skin, etc unless probe has been disinfected and protected by sterile, legally marketed probe sheath according to your institution's protocol and/or instructions provided with the covers.

Operator Safety



WARNINGS!

- Use of damaged equipment or accessories may cause the device to perform improperly and/or result in injury to the patient or operator.
- Do not use, connect, or operate the Butterfly iQ™ with non-approved or non-specified equipment or accessories. Doing so may result in injury to the patient or operator.
- Do not use the Butterfly iQ™ Application on a mobile device that does not meet minimum requirements. Using the Butterfly iQ™ Application on a mobile device that does not meet the minimum requirements may affect performance and image quality, possibly resulting in misdiagnosis.



CAUTIONS!

- To minimize the risk of Carpel Tunnel Syndrome (CTS) and related musculoskeletal issues, maintain suitable posture, allow for frequent breaks, and avoid gripping or holding the probe with excessive force.
- Follow your institution's personal protective equipment (PPE) and infection control procedures (e.g. eye, respiratory, and hand protection) when operating, cleaning, or disinfecting the device.

3. System Overview

This chapter provides an overview of Butterfly iQ™. It includes information about its features, the components that are included in the system, requirements necessary to download, install, and use the Butterfly iQ™ App, and an overview of the user interface.

**NOTE**

Depending on your platform, hardware, country and membership type, certain presets, modes and features may not be available.

Overview

Butterfly iQ™ is a hand-held general purpose diagnostic ultrasound imaging device. The system consists of three components:

- Compatible Apple® or Android personal electronic devices including phones and tablets (the mobile device)
- The Butterfly iQ™ Application (App), downloaded and installed on the compatible mobile device
- The Butterfly iQ™ Probe that connects to the mobile device to generate and receive ultrasound signals

**NOTE**

The mobile device is not included with the Butterfly iQ™ Ultrasound System; you must purchase it separately.

Modes

Butterfly iQ™ provides the following modes:

- B-Mode
- M-Mode
- Color Doppler
- Power Doppler
- Spectral Pulsed-Wave Doppler

Measurements

Butterfly iQ™ lets you perform clinical measurements in each available mode. Measurements available include, but are not limited to distance, time, area and heart rate.

Probe Types

Butterfly iQ™ provides a single probe that is capable of performing all indicated clinical applications.

Patient Data Protection



CAUTION!

It is required that you protect patient data by encrypting your mobile device with a password or passcode. You cannot use the Butterfly iQ™ App if your mobile device does not have a passcode enabled and configured. Consult with your IT/Security department to ensure that security and patient data protection is in accordance with the policy of your institution.

Butterfly recommends setting an auto-lock period within the mobile device's settings to prevent unauthorized access. For more information, consult your mobile device's instructions for Auto-Lock settings.

It is recommended to use an Enterprise Mobile Management (EMM) software on all devices that have the ability to acquire, store, and/or transmit electronic Protected Health Information (ePHI).

Internet Connectivity

An Internet connection is required to download, install, or update the Butterfly iQ™ App from the Apple App Store or Google Play Store. An Internet connection is also required to log in and to archive studies to Butterfly Cloud. Otherwise, no Internet connection or wireless connectivity is required to use the mobile device.

In order to ensure the app has the latest updates and safety information, the app requires a connection to the internet once every 30 days. For additional information about internet connectivity requirements and settings please visit support.butterflynetwork.com.

System Components



WARNING!

Upon receiving your Butterfly iQ™, carefully inspect the probe. Always inspect the probe before and after cleaning, disinfection, or use. Check the lens face, cable, housing, seams, and connector for signs of damage such as cracks, chips, abrasions, or leaks. To avoid the risk of electrical hazards, do not use the probe if there is any sign of damage.

The probe and probe charger are included with your Butterfly iQ™. Before getting started, identify each component and ensure that your package is complete.



NOTE

The mobile device is not included with the Butterfly iQ™ Ultrasound System; you must purchase it separately.

Butterfly iQ™ App

The primary function of the Butterfly iQ™ App is general-purpose diagnostic imaging, for use by qualified and trained health-care professionals to enable the visualization and measurement of anatomical structures within the human body.

The App is a free download from the Apple App Store or Google Play Store. The App and Butterfly account are required to use the Butterfly iQ™ personal ultrasound.



NOTE

- If your mobile device does not meet the requirements necessary to download, install, or run the Butterfly iQ™ App, the mobile device displays a notification.
- Information Security: Follow all security and cybersecurity policies of your institution. If you do not know what these policies are, contact your information technology (IT) department. To use the Butterfly iQ™ App, it is required that you set a password, passcode, or other security settings to lock the screen of your mobile device. If you have not done this and do not know how, refer to the security instructions for your mobile device.

Probe

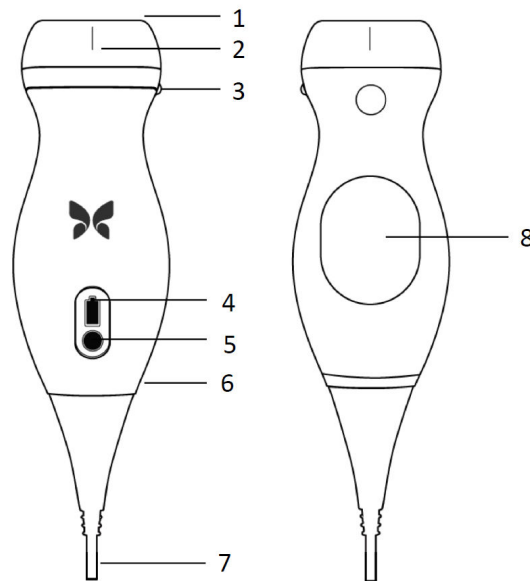


WARNING!

Do not connect third-party probes to the Butterfly iQ™ mobile device and do not attempt to use the Butterfly iQ™ probe with other ultrasound systems.

The Butterfly iQ™ probe is only for use with the Butterfly iQ™ App. Do not attempt to connect the probe to other ultrasound systems. [Figure 1, “Probe Components” \[17\]](#) shows the parts of the probe and describes its parts.

Figure 1. Probe Components



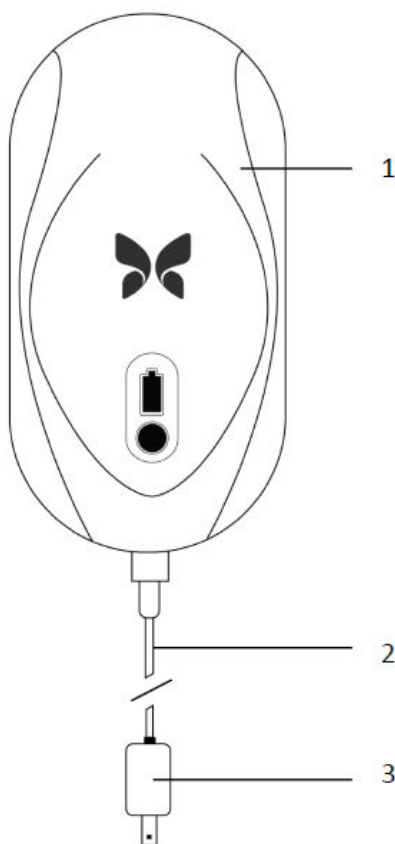
1. Lens
2. Midline Mark
3. Orientation Mark
4. Battery Indicator Lights
5. Battery Indicator Button
6. Probe/Cable Boundary
7. Mobile Device Cable
8. Charging Source

Probe Battery Charger

Only use the charger supplied with the probe.

Figure 2, “Charging Pad Components” [18] shows the battery charging accessories.

Figure 2. Charging Pad Components



1. Charging Pad
2. Charging Cable
3. Wall Adaptor



NOTE

The latest Butterfly iQ™ charger has a matte black finish. If you have a previous model please visit support.butterflynetwork.com for additional information on charging your probe.

Overview of User Interface

This section provides information about the imaging display presented in the Butterfly iQ™ App user interface.

The app user interface will always show information about the Mechanical Index (MI) and the Thermal Index (TI) at the top of the screen.

Depending on your Butterfly membership status and mobile app version, the toolbar at the bottom of the screen may vary.

The toolbar at the bottom of the screen can be used for preset selection, image freeze, image capture and mode/tool selection.

Presets

Presets are a predefined set of imaging parameter values. When selected, the Butterfly iQ™ App automatically operates in accordance with the corresponding set of imaging parameter values. Presets available correspond to the clinical applications details in [Indications for Use \[6\]](#). Preset availability may also vary depending on probe, Butterfly membership status and geographic location.

4. Setting Up the System

This chapter provides information and instructions for downloading and installing the Butterfly iQ™ App, registering the probe, setting up Butterfly iQ™ App, and charging the probe for use.

Downloading and Installing the App

You can download and install the Butterfly iQ™ App by visiting the Apple App Store or Google Play Store on your mobile device. Once in the App Store, search for "Butterfly iQ".

Before downloading and installing the App, make sure your mobile device meets or exceeds the minimum performance specifications. Additional information on the most up to date device requirements can be found at support.butterflynetwork.com.



NOTE

If you cannot install the App, it may indicate that your mobile device does not meet the minimum performance specifications. For details on the requirements, see support.butterflynetwork.com.

Updating Firmware

The firmware on your mobile device must be up-to-date to perform imaging. Certain app updates may require a firmware upgrade of your Butterfly iQ™. Firmware updates will be triggered on the first connection of the Butterfly iQ™ probe following an app update.

Managing App Updates



CAUTIONS!

- Butterfly supports the current and two previous releases of the App. Upgrading across multiple versions of the App may require you to uninstall and reinstall the App resulting in possible data loss.
- If the system has not been connected to a wireless or cellular network in the last 30 days, the system prompts you to connect to the Internet for important updates.
- If you ignore the mandatory updates, the system may lock you out.

Butterfly iQ™ App updates are available in the Apple App Store or Google Play Store.

In your device's settings, you can configure the Butterfly iQ™ App to update automatically or manually.

If your mobile device is configured to automatically update applications, the Butterfly iQ™ App updates automatically when an update is available.

If your mobile device is not configured to update automatically, periodically check for updates in the Apple App Store or Google Play Store.

Charging the Probe



WARNINGS!

- Use only cables, probes, chargers and accessories specified for use with Butterfly iQ™. Substitution of non-approved accessories may cause the system to perform improperly or cause injury to the patient or operator.
- If the probe seems unusually hot, produces an odor or smoke, or leaks, stop use immediately. Unplug the probe from the mobile device or disconnect it from the wireless charger (if applicable). Contact support at support.butterflynetwork.com.
- The probe is designed to remain sealed. Do not attempt to open the probe or tamper with the device internals, including the battery. Doing so may cause injury to the patient or operator.
- The probe battery is not user-replaceable. Replacement of the battery by parties other than Butterfly Support may result in a hazard such as higher temperatures, fire, or explosion.
- A non-medical grade power supply must be used outside of the patient environment so that it is at least 1.5 meters from the patient.



CAUTIONS!

- The probe battery should be charged at least monthly to ensure proper functionality.
- If the probe will not power on after charging, it could indicate a battery failure. Contact Support at support.butterflynetwork.com.

It is important to keep your probe charged. Charge your probe with the supplied battery charging accessories.

The battery charging accessories include the charging pad, charging cable, and wall adapter.

Place the probe on the charger in the orientation shown below

Figure 3. 3rd Generation Probe Charger





NOTE

- The latest Butterfly iQ™ charger has a matte black finish. If you have a previous model please visit support.butterflynetwork.com for additional information on charging your probe.
- Your exact charging pad may vary.
- Butterfly iQ™ uses a wireless charging system. Do not attempt to insert your probe's cable into the charging pad.

Your exact charging pad may vary. For details on the charging pad specifications please visit support.butterflynetwork.com.

To charge the probe:

1. Disconnect the probe from the mobile device. Imaging cannot be performed while charging.
2. Connect the charging cable to the charging pad and the USB end to the wall adapter.
3. Plug the wall adapter into a power outlet. The charger will light up to show that it is powered on.
4. Place the probe onto the charging pad so that the probe lies flat and wait for the probe's battery indicator lights to turn on.

When the probe battery is charging, the probe battery indicator lights indicate the current battery level. When the probe completes its charge, the probe's battery indicator lights turn off. For additional information on the status lights on your specific charger please visit support.butterflynetwork.com.



NOTE

It is normal that the probe may feel warm to the touch while charging. If you remove the probe from the charging pad before or immediately after charging is complete, it is recommended that you allow the probe to cool down before use. Since the system limits patient contact temperature and will not scan at or above 43°C (109°F), allowing the probe to cool down before use will optimize scan time performance.

Checking Probe Battery Level

Use the Battery Indicator Button and Battery Indicator Lights on the probe to check the battery level. For reference, see [Probe \[17\]](#)

Table 1. Probe Battery Level Indicators

Light Pattern	Approximate Battery Level
All 4 lights on	87.5% - 100%
3 lights on	67.5% - 87.4%
2 lights on	37.5% - 67.4%
1 light on	12.5% - 37.4%
1st light flashing	<12%

To check the probe battery level using the probe:

1. Press the Battery Indicator Button to view the Battery Indicator Lights.
2. If the first button flashes, it indicates that the probe battery charge is too low to perform the study.

To check the probe battery level using the Butterfly iQ™ App:




- The probe battery status is displayed in the upper portion of the imaging screen.
- If the battery charge is too low, you may not be able to perform a study until the battery is recharged. Keep the battery fully charged whenever possible.


5. Using the System

This chapter provides information and instructions for using Butterfly iQ™ to begin and end studies. It also provides information and instructions for freezing and unfreezing during live imaging, for performing measurements, and other imaging tools.


Performing a Study

Once the probe is connected to your mobile device follow the prompts on the screen to begin a new study. It is not required to enter patient information to begin or complete a study.

From the main scan screen you can freeze an image , capture still images  and record clips  using the toolbar at the bottom of the screen. The live image must be frozen in order to capture a still image.

Captures may be reviewed from the Capture Reel located in the top right corner of the screen  before the study is completed.

To conclude a patient encounter, enter the capture reel and upload the study.

During scanning, you may swipe horizontally to adjust the gain and swipe vertically to adjust the depth. The Time Gain Compensation (TGC) control button is surfaced upon tapping the screen .



NOTE

You can use the pinch and double-tap gestures to zoom in on an image, and to zoom out on an image. When the image is in a zoomed state, you can use your finger to pan the image (move it around on the screen).

If you do choose to enter patient data in the study, you may do so from the Capture Reel. Depending on your configuration, you may add patient data manually, from a worklist, or by scanning a barcode.

To add or view additional details about the study, such as calculations outputs, utilize the notes field in the Capture Reel.

For additional information on performing a study please visit support.butterflynetwork.com.

Uploading to Butterfly Cloud



NOTE

Depending on your platform, hardware, country and membership type, certain presets, modes and features may not be available.

To archive a study:

1. When you finish capturing ultrasound images, tap the **Capture Reel** in the upper right corner of the screen. The **Study** screen is displayed.
2. OPTIONAL: Associate patient information
3. Tap Save to initiate an upload.
4. Select an archive and press **Upload**.
5. To delete all of the items from the Capture Reel, tap **Clear images**. The system prompts you to confirm the deletion. Clearing the series removes all of the images and clips from the Capture Reel.

6. Using Modes

This chapter provides information and instructions for using modes when performing an ultrasound study.



NOTE

Advanced imaging capabilities may vary depending on the selected preset and status of paid subscription. Please visit support.butterflynetwork.com for the latest details on which preset has access to which modes.

Using Color Doppler Mode or Power Doppler Mode

When using Color Doppler or Power Doppler, you can:

- Adjust the size and position of the ROI.
- Adjust the Gain and Depth.
- Adjust the Scale (also known as Pulse Repetition Frequency (PRF)) to optimize for high or low flow by touching the **High/Low** control at the bottom of the screen


The ROI is displayed on the image. To move the ROI, tap and drag the box. To adjust the angle and size, use the arrows provided.

Color gain and depth controls are available during Doppler imaging.

Using M-Mode

M-Mode display includes speed controls (Fast or Slow), the M-Mode line, B-Mode image, and a move point to move the M-Mode line.

When using M-Mode, you can:

- Adjust the radial scan line by tapping and dragging the move point: 
- Adjust the sweep speed of the M-Mode display by touching the Fast/Slow control in the middle of the screen
- Adjust the **Depth** and **Gain**
- Perform time, distance, and heart rate measurements on the display

Using Spectral Pulsed-Wave Doppler Mode

Spectral Pulsed-Wave Doppler (Pulsed Doppler) is a quantitative mode that graphically displays blood flow velocity measurements over time.

When using Pulsed Doppler, you can:

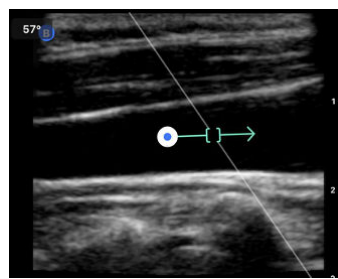
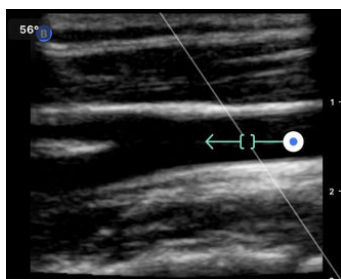
- View and adjust the position of the sample volume by holding and dragging the gate.
- View and adjust the angle correction by holding and dragging the white caliper dot.
- Switch between live Pulsed Doppler mode and live B-mode by touching the Start Spectrum/Update B-mode button.

- Adjust gain of spectral trace by dragging finger left and right on the trace while trace is live.
- Adjust the Scale to optimize for high or low flow by touching the **Low Flow/High Flow** control in the middle of the screen. Note that the control defines your current state.
- Adjust the Scroll Speed of the Spectral Doppler trace by touching the **Slow Scroll/Fast Scroll** control in the middle of the screen. Note that the control defines your current state.

In order to adjust the Gain and Depth of the B-mode reference image, exit Pulsed Doppler mode and optimize image in B-mode, Color Doppler mode, or Power Doppler mode.

Placing the Sample Volume

1. Hold and drag the sample volume gate (the square region in the center of the arrow) to the desired location within the vessel of interest.
2. Once positioned, align the direction of the arrow along the direction of flow. If the flow in the vessel is cranial, point the arrow cranially. If the flow in the vessel is caudal, point the arrow caudally. An example of an appropriately aligned flow in the Carotid Artery (left) and Internal Jugular Vein (right) is given below.



CAUTION!

Flow directionality is represented relative to the direction of the arrow. Misalignment of the arrow may lead to misinterpretation of flow direction. Carefully check that the arrow is aligned with the expected blood flow direction.



NOTE

Flow in the direction of the arrow will always be depicted above the baseline. Flow against the direction of the arrow will always be depicted below the baseline.

3. Tap "Start Spectrum" to start the spectral trace. If you do not see a trace, adjust the position of the sample volume.
4. To adjust the position of the sample volume:
 - a. Hold and drag the arrow, which will automatically pause the spectrum and restart B-mode reference image.
 - b. Tap the Update B-mode button to manually pause spectrum and restart B-mode.
5. To adjust scroll speed of trace, tap the "**Slow Scroll/Fast Scroll**" button.
6. To adjust the velocity scale, tap the button **Low Flow/High Flow** button or drag baseline.
7. To add annotations, freeze the image and tap the annotations button.
8. To add measurements, freeze the image and select linear measurements.



NOTE

Annotations and measurements may only be added to the Spectral trace region.

9. Velocity measurements will be represented in cm/s as Peak Systolic Velocity (PSV), the absolute value of the vertical distance from the baseline first caliper dot, and End Diastolic Velocity (EDV), the absolute value of the vertical distance from the baseline of the second caliper dot.
10. The difference in time between the left and right ends of the caliper will be represented as time (t) in seconds.
11. To save a Pulsed Doppler image, freeze then press the capture button.

7. Annotations

This chapter provides information and instructions for performing annotations on images in the Butterfly iQ™ App. Annotations can include linear measurements, ellipse measurements, and text annotations.


Adding Annotations

You can add annotations while scanning either from the actions menu or the frozen scan screen. After acquisition, you can add annotations to images and clips in the exam reel.


Adding Annotations During Live Scanning

While live imaging, open the Actions menu  and select an annotation to add to the live image.


Adding Annotations to Frozen Images

Tap the freeze  icon to first freeze the image. Select the annotation button which has "Aa" and a line on it.


Performing Linear Measurements

1. Select the  symbol.
2. Select the blue circles to drag the yellow cross-hairs to the start and end positions of your measurement. As you manipulate the ends of the line, the length (in centimeters) is displayed in a box at the bottom of the image. You can drag this box to the desired location on the image.
3. To add another line, select the Annotation button and select the line symbol again. The next line is displayed in a different color and has a letter next to it. You can add up to four linear measurements to each image.
4. To delete a line, select the line or the line's measurement. Select the X next to the corresponding numeric measurement display, and select Delete Line to confirm.


Performing an Ellipse Measurement

1. Select the  symbol.
2. Touch and drag the caliper icons to scale and rotate the ellipse. A box with the ellipse's circumference and area (displayed in centimeters and square centimeters) is displayed in a box at the bottom of the image. You can drag this box to the desired location on the image.
3. To delete an ellipse, select the ellipse or the measurement value and tap the X next to the corresponding numeric measurement display. Select Delete Ellipse to confirm.

Adding a Text Annotation

1. Select the  to display the Search or Create New Annotation screen.
2. To use a preconfigured annotation, select the annotation.
3. To enter your own annotation, use the keyboard to type the annotation.
4. On your mobile device keyboard, select Done.
5. Drag the annotation to the desired location on the image.
6. To delete the annotation, select it and then select its X. Select Delete Annotation to confirm.
7. You can add up to five text annotations to each image.

Adding Annotations to Images or Clips in the Capture Reel

1. After capturing an image or cine click on the  in the top right corner of the scan screen.
2. Click on the image or clip that you wish to annotate.
3. Click "Edit".
4. Select "Label Capture".
5. Click "Aa" and either click a pre-defined label or type your own.
6. Move the label to the proper place on the image.
7. Click "Save"

8. Manual Calculations Packages

This chapter provides information and instructions for using various available calculations packages using the Butterfly iQ™ device and mobile app.





NOTE

Depending on your platform, hardware, country and membership type, certain presets, modes and features may not be available.

Obstetric Calculations

Making an Obstetric Calculation


1. From the scan screen, select the Obstetrics preset.
2. Select the Actions menu  on the bottom right corner of the screen.
3. Under the “calculations” heading, the Amniotic Fluid Index and Fetal Biometrics packages will be available. Select the one you wish to use.
4. Any imaging mode other than M-mode can be used with these calculations. Once the region of interest is in view, tap the freeze  button.
5. Tap the measurement icon on the bottom of the screen. New measurement tools corresponding to available inputs to the calculations package will be available.
6. Select the desired measurement, and calipers (linear or elliptical) will appear on the scan screen.
 - a. In the fetal biometrics package, available measurements are biparietal diameter (BPD), head circumference (HC), abdominal circumference (AC), and femur length (FL).
 - b. In the amniotic fluid index package, available measurements are Q1, Q2, Q3, and Q4.
7. Adjust calipers as appropriate. As the calipers are adjusted, the measurement label will adjust to show the input and, if applicable, the gestational age (GA).
8. Once satisfied with caliper placement, tap the confirm button to add the measurement to the report and capture an image.
9. A measurement may be deleted before confirming or unfreezing by selecting the “x” next to the measurement label or the trash icon in the report.
10. Only one of each input may be added. To edit an input, delete it from the report and re-measure.
11. While in any calculations package, a calculations report is available while the scan screen is frozen.
 - a. In the fetal biometrics package the report contains:
 - i. AUA: average ultrasound age according to the Hadlock equations
 - ii. Hadlock - EDD: Estimating Delivery Date according to the Hadlock equations
 - iii. Hadlock - EFW: Estimated Fetal Weight according to the Hadlock equations
 - iv. Measurement inputs with corresponding gestational ages (GA)
 - v. Patient-reported dates
 - b. In the amniotic fluid index package, the report contains
 - i. AFI: amniotic fluid index

- ii. Measurement inputs
 - iii. Patient-reported dates
12. You will exit the obstetric calculations package when you upload your study. To exit an obstetric calculations package before uploading a study, select the X on the bottom of your screen or select the Actions menu and exit by selecting the X underneath. You will be prompted to confirm exporting or deleting of captured measurements if you exit via the Actions menu or the bottom of your screen.
 13. Once the specified calculation package is exported, the output will be available in the notes field of the study. This can be retrieved and edited in the study reel prior to upload. After uploading the study, notes are available in the archive screen and in the desktop cloud.

Manually Calculate Volume

The manual volume calculation package can be used to generate a volume measurement using the prolate ellipsoid method. This functionality uses the equation $0.52 * (D1) * (D2) * (D3)$ to calculate volume.

Manually Calculating Volume

1. From the scan screen, select the Bladder preset.
2. Select the Actions button  on the bottom right corner of the screen.
3. Under the “Calculations” heading, select Manual Volume.
4. When you have identified a view you would like to capture, select the freeze button to freeze the image.
5. Tap the measurement icon on the bottom of the screen.
6. Select the measurement button to begin measuring. You will have the option of selecting D1, D2, or D3.
7. Adjust calipers as appropriate. As the calipers are adjusted, the measurement label will adjust to show the input.
8. Once satisfied with caliper placement, tap the confirm button to add the measurement to the report and capture an image.
9. Only one of each measurement may be added. To edit an input, delete it from the report and re-measure.
10. At the bottom of the screen, your measurements will be visible. When you take all three measurements, an estimated volume will appear at the bottom of the screen.
11. A measurement may be deleted before confirming or unfreezing by selecting the “x” next to the measurement label or the trash can icon in the report.
12. You will exit the volume calculation package when you upload your study. To exit the calculation package before uploading a study, select the X on the bottom of your screen or select the Actions menu and exit by selecting the X underneath. You will be prompted to confirm exporting or deleting of captured measurements if you exit via the Actions menu or the bottom of your screen.



NOTE

Once the volume calculation package is exited, the inputs may not be edited.

13. When the volume calculation package is exported, the output will be available in the notes field of the study. This can be retrieved and edited in the study reel prior to upload. After uploading the study, notes are available in the archive screen and in the desktop cloud.

Calculation Package References

1. Gestational Age and Estimated Fetal Weight via Fetal Biometrics

- a. Hadlock FP, Deter RL, Harrist RB, Park SK. Estimating fetal age: computer-assisted analysis of multiple fetal growth parameters. *Radiology*. 1984 Aug;152(2):497-501.
 - b. Hadlock FP, Harrist RB, Carpenter RJ, Deter RL, Park SK. Sonographic estimation of fetal weight. The value of femur length in addition to head and abdomen measurements. *Radiology*. 1984 Feb;150(2):535-4.
 - c. Anderson NG, Jolley IJ, Wells JE. Sonographic estimation of fetal weight: comparison of bias, precision and consistency using 12 different formulae. *Ultrasound in Obstetrics and Gynecology: The Official Journal of the International Society of Ultrasound in Obstetrics and Gynecology*. 2007 Aug;30(2):173-9.
2. Amniotic Fluid Index
 - a. Phelan JP, Ahn MO, Smith CV, Rutherford SE, Anderson E. Amniotic fluid index measurements during pregnancy. *The Journal of reproductive medicine*. 1987 Aug;32(8):601-4.
3. Bladder Volume - Prolate Ellipsoid
 - a. Dicuio M, Pomara G, Menchini Fabris F, Ales V, Dahlstrand C, Morelli G. Measurements of urinary bladder volume: comparison of five ultrasound calculation methods in volunteers. *Archivo Italiano di Urologica e Andrologica*. 2005 Mar;77(1):60-2.
 - b. Prolate ellipsoid equation: $\text{Volume} = 0.52 * (D1) * (D2) * (D3)$.

9. AI-Assisted Tools

This chapter provides information and instructions for using AI (Artificial Intelligence)-Assisted tools with Butterfly iQ™.



NOTE

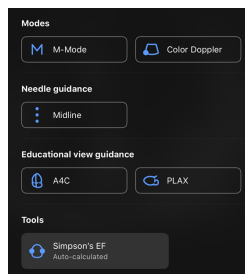
Depending on your platform, hardware, country and membership type, certain presets, modes and features may not be available.

Automatically Estimating Ejection Fractions

The Simpson's Ejection Fraction tool allows you to estimate left ventricular Ejection Fractions (EF) when capturing cardiac studies from an apical four chamber view of the heart. Butterfly iQ™ uses the Simpson's Monoplane³ method to calculate the ejection fraction.

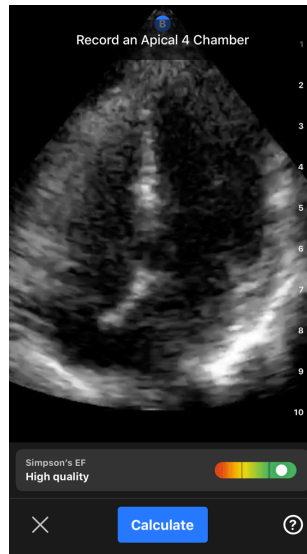
Using the Automatic Ejection Fraction Tool

1. Select the Cardiac preset.
2. Select the Actions button  on the bottom of your screen.
3. Under tools, select Simpson's EF.

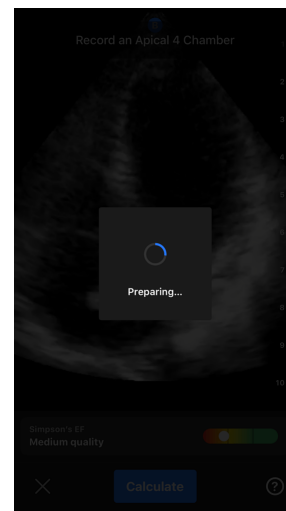


4. The Record an Apical 4 Chamber screen is displayed with an Educational View Guide at the bottom of the screen. The guide uses a scale from red to green , with green indicating a high quality image. Position the probe to acquire a high quality apical 4 chamber view of the heart.

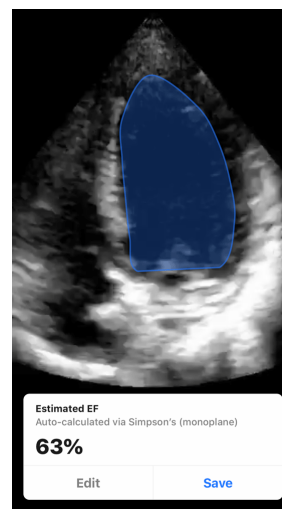
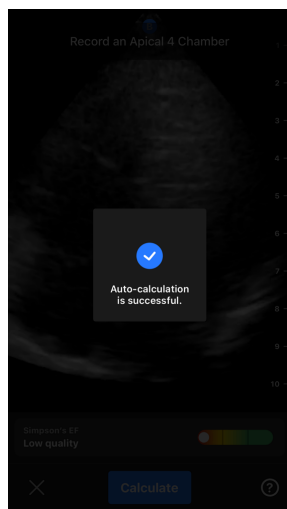
³Lang et al., J. Am. Soc.Echocardiography, 2005: 1440-63. Estimates of the base points of the mitral valve 'points' are used to define the midpoint of the mitral valve and the apex point (furthest point on segmentation mask from midpoint). These two points define an axis about which we perform disk integration. As per convention, 20 disks should be used.






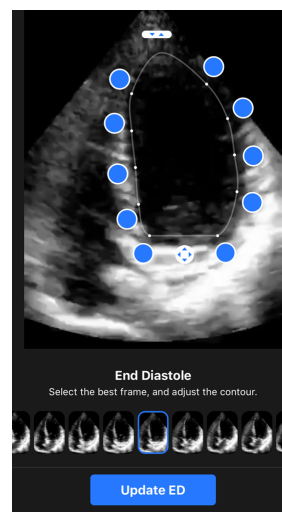
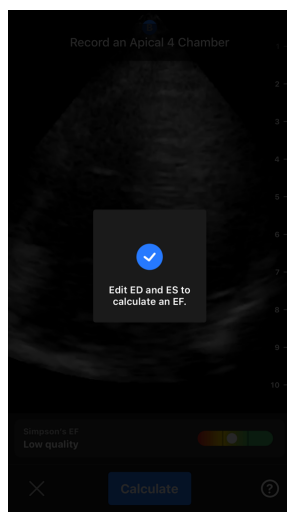
5. Select Calculate and hold the probe steady. A 3-second clip is automatically recorded.



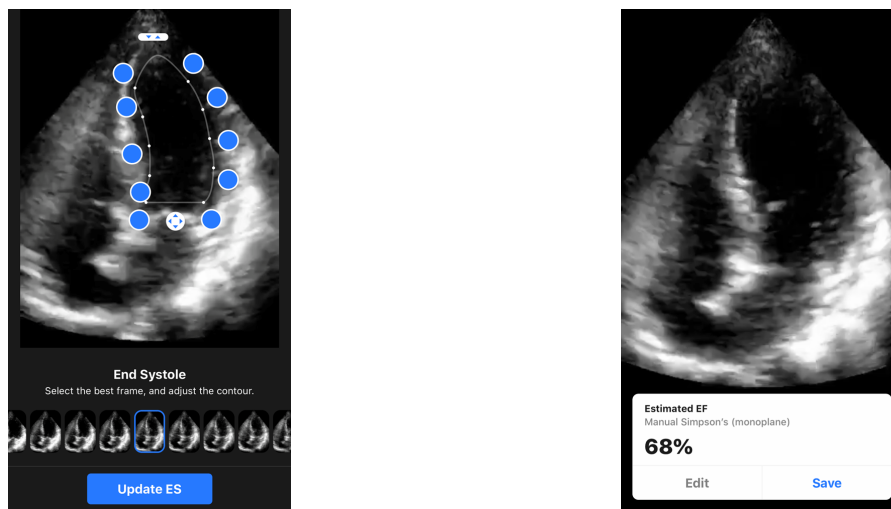
6. If the automatic EF tool is able to calculate an Ejection Fraction, the Automatic Ejection Fraction result screen is displayed, and the calculated Ejection Fraction is marked as an Auto-calculated Simpson's measurement. You have the option to either save this automatic result, edit the result and recalculate, or delete the result and cine.



7. If the tool is not able to calculate an Ejection Fraction or you choose to edit your result, you will be directed to the Edit screen. There, you have the ability to adjust the End Diastole (ED) frame and left ventricle contour.
 - a. Scroll through the frames on the bottom of the screen to the appropriate frame for ED.
 - b. To move the overall position of the contour used to measure the ventricle, press and drag the white anchor point . Release the anchor point when the contour is in the appropriate position.
 - c. To alter the position of the contour sides used to measure the ventricle, press and drag the blue circle that indicates an adjust point  around the contour. Release the adjust point when the contour is in the appropriate position.
 - d. To alter the position of the contour apex, press and drag the Apex Adjust Bar  at the top of the contour. Release the Apex Adjust Bar when the contour is in the appropriate position.
 - e. Once edits are complete, select Update ED.



8. Follow the same process as above for End Systole (ES), and select Update ES when complete. The Ejection Fraction result screen is displayed and the calculated Ejection Fraction is marked as a manual Simpson's Method measurement.



- If you select Save to save the measurement, the captured 3-second cine loop with the Ejection Fraction estimated and associated ED and ES left ventricle contours are saved to the Capture Reel. Note that selecting Delete deletes both the Ejection Fraction result and the 3-second cine used to calculate the result.

Automatically Estimating Bladder Volume

Indications for Use

The Butterfly Auto Bladder Volume Tool is a software application package. It is designed to view, quantify and report results acquired on Butterfly Network ultrasound systems for noninvasive volume measurements of the bladder, to support physician diagnosis. Indicated for use in adult populations.


Contraindications

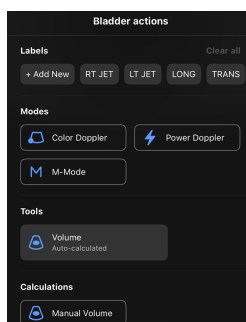
Not intended for fetal or pediatric use or for use on pregnant patients, patients with ascites, or patients with open skin or wounds in the suprapubic region.

Calculating a Bladder Volume

The Auto Bladder Volume tool⁴ allows you to calculate bladder volume when you are using the Bladder preset in B-mode. The Butterfly iQ™ has the capability to acquire a 3D sweep while you hold the probe steady. A volume estimate is then calculated from this 3D sweep.

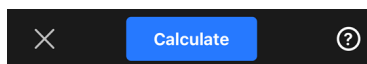
Accessing the Auto Bladder Volume tool from within a preset

- Tap the Actions icon  located at the bottom right corner of the screen.
- Select the Volume option.



⁴Ronneberger, Olaf, Philipp Fischer, and Thomas Brox. "U-net: Convolutional networks for biomedical image segmentation." International Conference on Medical image computing and computer-assisted intervention. Springer, Cham, 2015.


3. Tap X to turn off the Auto Bladder Volume tool.




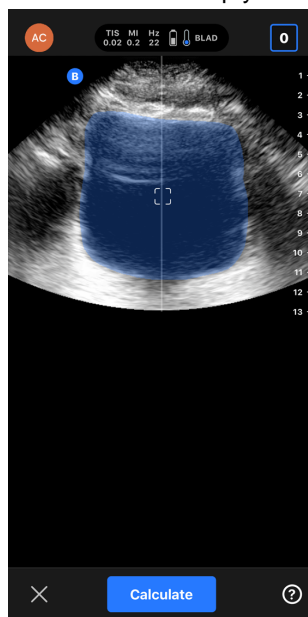
Calculating Bladder Volume



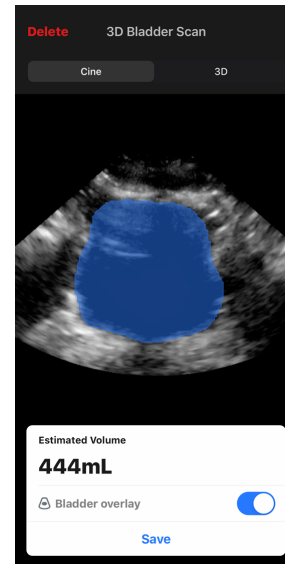
NOTE

For help using the Auto Bladder Volume tool, including information about proper probe positioning, tap  at the bottom right of the screen.

1. Select **Volume** from the Actions menu within the **Bladder** preset.
2. Position the probe so that the bladder appears at its widest and is centered on the screen. A blue shape highlights when the Auto Bladder Volume tool detects a bladder, and the center of the blue shape is marked with a . Use the vertical line down the center of the screen to help you center the bladder.



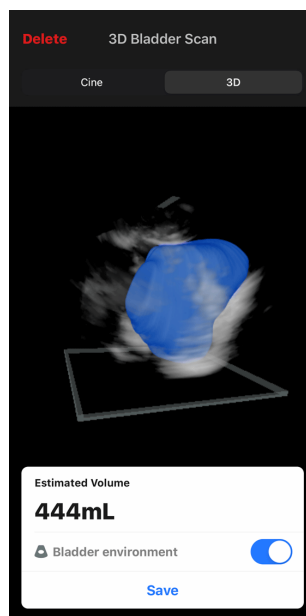
3. Select **Calculate**. A 3D sweep of the bladder area is automatically acquired. Do not move the probe during the sweep.
4. After successfully capturing the bladder, a volume is displayed at the bottom of the screen. The cine above the volume result displays the images and estimated bladder used to calculate the volume.



NOTE

You can disable the blue bladder highlight by tapping the Bladder Overlay toggle.

5. Tap the 3D bar to visualize an interactive 3D render of the bladder.



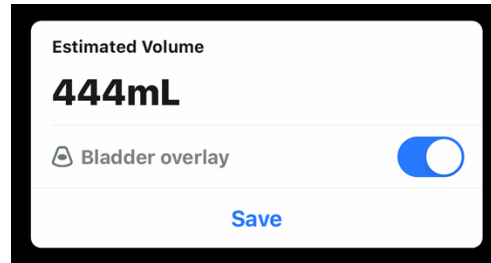
NOTE

The 3D render is not for diagnostic use.

Saving an Automatically Estimated Bladder Volume

The Auto Bladder Volume tool allows you to save the estimated volume result for review in the Butterfly iQ™ Mobile App and Butterfly Cloud.


1. Select Save from the bottom of the Bladder Volume result screen. The captured cine loop with the bladder volume estimate and bladder out line is saved to the Capture Reel.

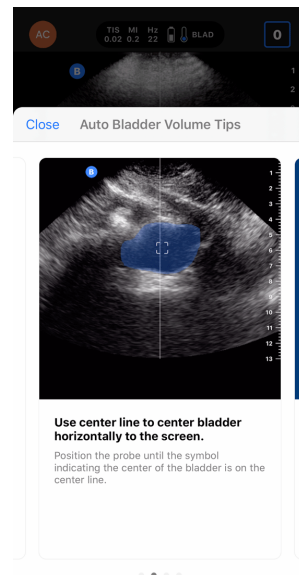
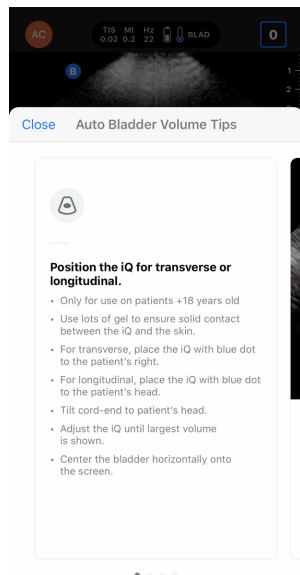


NOTE

Selecting Delete deletes both the bladder volume result as well as the cine used to calculate the result.

User Tool Tips

First time users of the Auto Bladder Volume tool are presented with tips on using the tool. These informational tabs can be accessed by any Auto Bladder Volume tool user at any time by selecting  when in the tool.



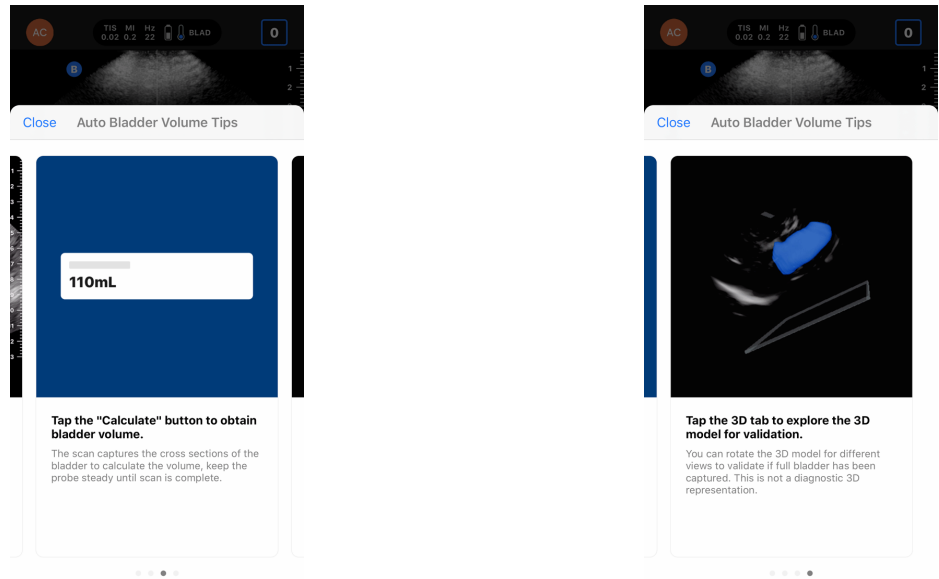


Table 2. Volume Measurement Accuracy

Volume Range	Specification
0-100mL	± 7.5 mL
101-740 mL	± 7.5 %

• The measurement accuracy specifications assume the tool is being used to scan a tissue-equivalent phantom as instructed.

• The volume range of the 3D Auto Bladder Volume Tool is 0-740mL. Although higher volumes may be estimated and displayed, Butterfly Network cannot guarantee the accuracy of measurements outside of this stated range.

Butterfly iQ Educational View Guidance




CAUTION!

The Educational View Guidance tools are for Educational Use Only.


The Educational View Guidance tools provide users with a visual indication of the quality of the image while scanning with the Butterfly iQ. The Educational View Guidance tools support the following views:

- Cardiac Apical 4 Chamber
- Cardiac Parasternal Long Axis
- Cardiac Parasternal Short Axis
- Lung A-Lines/B-Lines

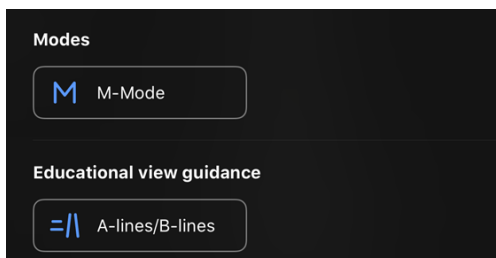
As you scan the subject, the tool provides real-time feedback on image quality using a red to green scale, with green indicating a high-quality image . It indicates the proportion of experts who would assess the anatomical view as measurable.

Accessing Educational View Guidance

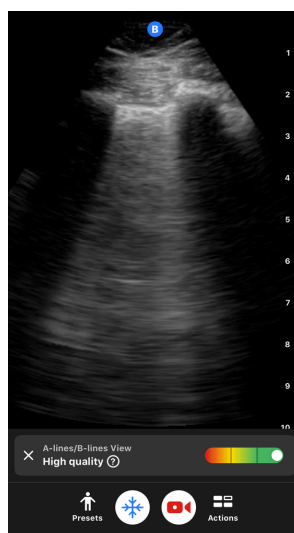
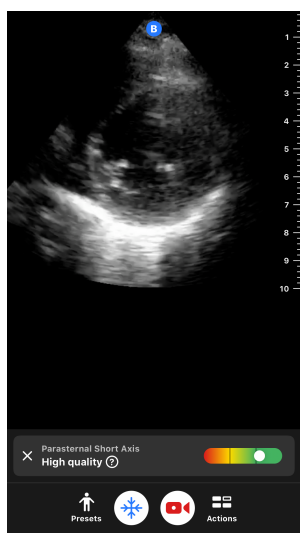
The Educational View Guidance tools can be accessed in the Cardiac or Lung Preset while scanning in B- Mode.

Tap Actions  located at the bottom right corner of the screen. You have the option to select the following tools from the Educational View Guidance section:

- Cardiac preset: A4C (Apical 4 Chamber), PLAX (Parasternal Long Axis) and PSAX (Parasternal Short Axis).
- Lung preset: A-Lines/B-Lines.



The Educational View Guidance tools can be turned off by tapping X on the tool while scanning in B-mode or in the Actions menu.



For additional information on Educational View Guidance, and the latest device compatibility, please visit support.butterflynetwork.com.

10. Using Butterfly Cloud

This chapter provides information and instructions for using Butterfly Cloud to store and access ultrasound exams uploaded from the Butterfly iQ™ App.



NOTE

Your organization may choose to configure Butterfly Cloud using Single Sign On (SSO). SSO is part of Butterfly Enterprise. For additional information on Butterfly Enterprise and enabling SSO configurations please visit support.butterflynetwork.com.

Overview

Butterfly Cloud is a web-based application that allows users to upload and review ultrasound exams from the Butterfly iQ™ App. Users of the cloud can also document, bill and integrate Butterfly iQ™ into existing hospital systems PACS, VNA, EMR, and Modality Worklist. Butterfly Cloud also supports the acceptance of images from third-party ultrasound devices.

A Butterfly Cloud Administrator configures the archives, adds new members, and sets user access levels. Administrators can also configure external connections to Butterfly Cloud.

For additional information on Butterfly Cloud please visit support.butterflynetwork.com.

Accessing Butterfly Cloud

Butterfly Cloud can be accessed from both the Butterfly iQ™ App as well as a desktop web browser at cloud.butterflynetwork.com. If you are a Butterfly Enterprise user, navigate to [YourDomain].butterflynetwork.com.

- Log in to Butterfly Cloud with your Butterfly email and password or Single Sign On (SSO) credentials.

Viewing and Managing Studies

Viewing a Study

1. Log in to Butterfly Cloud.
2. Select the archive (folder) where the study was uploaded.
3. Click on the study to view detailed patient information and review the images and clips.

Moving a Study to a New Archive

1. Log in to Butterfly Cloud.
2. Locate the study that you would like to move. Studies can be moved from the archive screen, or the study detail view.
3. In the top right corner of the study, click the "More" drop-down menu to display the menu. If you do not see "Move Study" please contact your Butterfly account administrator to gain additional access.
4. Select the archive that the study should be moved to.

Deleting a Study

1. Log in to Butterfly Cloud.
2. Navigate to the archive that contains the study you want to move.
3. In the top right corner of the study, click the "More" drop-down menu to display the menu.
4. Select "Delete study." The system prompts you to confirm the deletion.
5. Click "Delete" to delete the study.

For additional information please visit support.butterflynetwork.com.

11. Using Butterfly TeleGuidance

This chapter provides information regarding Butterfly TeleGuidance. The service enables users to call one of your available connections through your Butterfly iQ App for remote collaboration while scanning.



NOTE

Depending on your platform, hardware, country and membership type, certain presets, modes and features may not be available.

Overview

A TeleGuidance call requires both a scanner and remote collaborator.



CAUTION!

- Butterfly TeleGuidance must only be used between two healthcare professionals.
- PHI will be visible to users who accept calls.
- Network conditions can degrade the quality of image and video for remote collaborators

To make a call, as local scanner — on iPhone or iPad

On iOS, click the Actions button on the bottom right of the main scanning screen and then the phone icon on the TeleGuidance row in the bottom right. Select an online connection to call.

To receive a call, as remote collaborator — on a computer running Google Chrome browser

In Google Chrome on a desktop computer log in at cloud.butterflynetwork.com. If you are a Butterfly Enterprise user, navigate to [YourDomain].butterflynetwork.com and log in. Click “TeleGuidance” in the top navigation bar. Make yourself available for calls and make sure your speakers are turned on. When a call comes in, a ringtone will play and an alert will appear on the webpage. Accept the call to begin.

For additional details on how to perform Butterfly TeleGuidance sessions please visit support.butterflynetwork.com.

12. Maintenance

This chapter provides information and instructions for storing, transporting, cleaning, and disinfecting the probe.

Maintaining the Probe

Storing and Transport:



CAUTIONS!

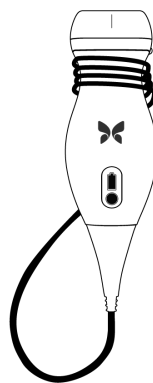
- Avoid storing the probe where the probe or its cable could be easily damaged.
- Avoid transporting the probe unless it is well supported and secured. Secure the cable tightly to the probe when transporting it or carrying it. Avoid swinging the probe or supporting the probe solely from its cable.

The probe should be stored in clean, dry, and moderate temperature conditions.

Follow these steps for daily storage and transport:

- When storing the probe, wrap the cable around the probe so that there is some slack at the bottom of the probe. See [Figure 4, “Wrapping the Cable” \[46\]](#) for reference.
- Avoid placing or storing in areas of excessive hot or cold temperatures or direct sunlight.
- Avoid placing or storing with other equipment or objects that may inadvertently damage the probe, particularly the face.
- Avoid contamination by:
 - Following the cleaning and disinfecting instructions.
 - Making sure the equipment is dry.
 - Carefully handling the probe to prevent damaging the equipment.

Figure 4. Wrapping the Cable



Cleaning and Disinfecting the Probe



WARNING!

Failure to disinfect the probe may result in an increased spread of pathogens.



CAUTION!

Only clean the probe with approved cleaning products and wipes. Improper cleaning or disinfection methods or using non-approved cleaning and disinfecting solutions may damage equipment.

This section provides information and instructions for properly cleaning and disinfecting the Butterfly iQ™ probe. Following these instructions will also help to avoid damaging the probe during cleaning and disinfection. After each exam, clean and disinfect the Butterfly iQ™.

While the Cleaning and Disinfection guidance contained here has been validated for effectiveness, a list of cleaning and disinfection products that are compatible with the Butterfly iQ™ probe, but not tested for effectiveness by Butterfly, can be found in the "Compatible Cleaning and Disinfection Products" article available at support.butterflynetwork.com. The products listed in the Compatible Cleaning and Disinfection Products article will not impact the functionality of the probe when used according to the instructions provided by the manufacturer of the product.

Cleaning the Probe



CAUTIONS!

- Prevent any fluid from entering electrical or metal portions of the cable's connector during the cleaning and disinfecting process. Damage due to fluid in these areas may result.
- Prevent any fluid from splashing on your mobile device's touchscreen during scanning and during cleaning. Damage due to fluid may result.

To clean the probe:

1. After each use of the probe, use one of the recommended liquid saturated wipes (Super Sani-Cloth® Germicidal Disposable Wipes by PDI, Inc., Super Sani-Cloth® AF3 Disposable Wipes by PDI, Inc., or a lint-free cloth moistened with water) to remove ultrasound transmission gel from the probe.
2. Disconnect the probe from the mobile device.
3. Wipe the probe, strain relief, cable, and connector with one of the recommended liquid saturated wipes for one (1) minute and until visibly clean.
4. Change the wipes as necessary and repeat the above step until the probe is visibly clean.
5. To dry the probe, use a soft cloth, blot the lens dry. Do not wipe the lens. Dry the rest of the probe, cable, strain relief, and connector.
6. Visually inspect the probe in a well-lit area to ensure all surfaces are clean. If the probe is not clean, repeat the cleaning steps above.
7. Dispose of cleaning material in accordance with all applicable regulations.

For the most up to date list of approved cleaners please visit support.butterflynetwork.com.

Disinfecting the Probe



WARNING!

Always inspect the probe before and after cleaning, disinfection, or use. Check the lens face, cable, housing, seams, and connector for signs of damage such as cracks, chips, abrasions, or leaks. To avoid the risk of electrical hazards, do not use the probe if there is any sign of damage.

After cleaning the probe, you must disinfect the probe.

To reduce the risk of contamination and infection, it is important to choose the appropriate level of disinfection, based on prior exam usage and whether the use is classified as non-critical or semi-critical. Use [Table 3, “Probe Disinfection Class, Use, and Method” \[48\]](#) to determine the appropriate class and then follow the appropriate intermediate-level or high-level disinfection procedure.

Table 3. Probe Disinfection Class, Use, and Method

Class	Use	Method
Non-Critical Class	Touches intact skin	Cleaning followed by intermediate-level disinfection (ILD)
Semi-Critical Class	Touches mucous membranes and non-intact skin	Cleaning followed by high-level disinfection (HLD)

Intermediate-Level Disinfection (ILD)

It is recommended that you use Super Sani-Cloth® Germicidal Disposable Wipes by PDI, Inc. or bleach (0.6% Sodium Hypochlorite) and clean with non-linting wipes.

To disinfect the probe using the Intermediate-Level Disinfection (ILD) method with Super Sani-Cloth® Germicidal Disposable Wipes by PDI, Inc.:

1. Wipe the probe, cable, strain relief, and connector with a Super Sani-Cloth® Germicidal Disposable Wipe. Use additional fresh wipes as needed.
2. Make sure the treated surface remains visibly wet for a minimum of two (2) minutes paying attention to seams, gaps, gasket material, and recessed areas.
3. Use additional fresh wipes as needed to ensure continuous two (2) minutes of contact time.
4. Allow to air dry.
5. Once clean and disinfected, visually inspect the probe, strain relief, cable, and connector for signs of damage or wear.


To disinfect the probe using the Intermediate-Level Disinfection (ILD) method with bleach (0.6% Sodium Hypochlorite) and clean non-linting wipes:

1. Wipe the probe, cable, strain relief, and connector using a clean non-linting wipe wetted (damp but not dripping) with bleach (0.6%). Use additional fresh wipes as needed.
2. Make sure the treated surface remains visibly wet for a minimum of ten (10) minutes paying attention to seams, gaps, gasket material, and recessed areas.
3. Use additional fresh wipes as needed to ensure continuous ten (10) minutes of contact time.
4. Allow to air dry.
5. Once clean and disinfected, visually inspect the probe, strain relief, cable, and connector for signs of damage or wear.

High Level Disinfection

It is recommended that you use Cidex® OPA by Ethicon US, LLC.

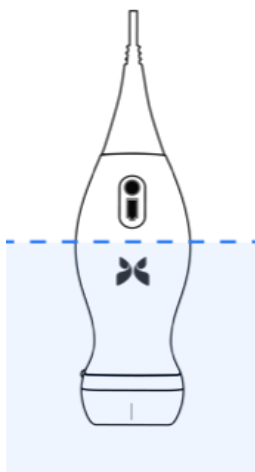
Making sure your probe is compatible with HLD:

1. Tap  to display the Settings screen.
2. Tap **My iQ** to display the **My iQ** screen.
3. Ensure that the **High-Level Disinfection Supported** line indicates **Yes**.
4. Proceed with HLD only if supported on your probe.
5. Disconnect the probe from the mobile device.

Disinfecting the probe using the High-Level Disinfection (HLD) method:

1. After cleaning the probe, you must disinfect the probe. It is recommended that you use Cidex® OPA high-level disinfection solution.
2. Prepare Cidex® OPA high-level disinfection solution for use per the manufacturer's instructions. Fill a tray or basin with the disinfectant solution at room temperature (minimum temperature of 20°C) to a level allowing immersion of the probe up to the immersion line (the dashed line shown in [Figure 5, "Probe Immersion Line"](#) [49]).
3. Immerse the probe in Cidex® OPA solution up to the immersion line and ensure no air or bubbles are trapped. Allow soaking according to the manufacturer's instructions.
4. Thoroughly rinse the probe (up to the immersion line) by immersing it in a large volume of room temperature critical (purified) water for a minimum of one (1) minute. Remove the probe and discard the rinse water. Do not reuse the water. Always use fresh volumes of water for each rinse. Repeat this stage two (2) additional times for a total of three (3) rinses.
5. Thoroughly dry all surfaces of the device using a sterile, lint-free wipe or cloth, changing wipes/cloths when necessary to ensure the device is completely dry. Visually inspect the device to ensure all surfaces are clean and dry. Repeat the drying steps if any moisture is visible.
6. Once clean and disinfected, visually inspect the probe, strain relief, cable, and connector for signs of damage or wear.

Figure 5. Probe Immersion Line



Updating the Probe and App Software

Updates to the Butterfly iQ™ App and probe are handled through the Apple App Store or Google Play Store.

Keep your mobile device's operating system and the Butterfly iQ™ App updated to ensure you have the most up-to-date version.

Performing the Probe Diagnostic Test


Butterfly iQ™ is capable of performing user-initiated diagnostic self-tests designed to assess the system's readiness for use.

Perform the diagnostic test periodically. With normal use, monthly testing is best practice.

The diagnostic test is only for the Butterfly iQ™ ultrasound probe. The App does not have the ability to assess the mobile device's screen integrity.

The diagnostic test runs through a series of diagnostic tests and notifies you when all tests have been successfully completed.

To perform the probe diagnostic test:

1. Make sure the probe is connected to a supported mobile device with the Butterfly iQ™ App installed.
2. Log in to the App using your login credentials.
3. Tap  to display the **Settings** screen.
4. Tap **My iQ** to display the **My iQ** screen.
5. Tap **Run Diagnostics** and then select **Start Probe Diagnostics** to perform the test.

13. Troubleshooting

This chapter provides information and instructions for troubleshooting the system.



WARNING!

Do not use the probe if there is any sign of damage. Contact Support. See [Getting Support \[53\]](#) for more information.

Troubleshooting



CAUTION!

Ignoring the App alerts and messages may result in the system becoming inoperable.

Table 4, “Troubleshooting” [51] lists the troubleshooting issues and resolutions. See [Getting Support \[53\]](#) for more information.



NOTES

- If you are unable to resolve an issue, please note the issue and report it to Support for assistance. For more information, see [Getting Support \[53\]](#).
- Call a health care professional for emergency assistance if troubleshooting reveals a patient health problem rather than a mobile device problem.
- To report a complaint or incident, contact the FDA Problem Reporting Program, MedWatch, at 1-800-332-1088, or on the Internet: www.fda.gov/Safety/MedWatch/.

Table 4. Troubleshooting

Issue	Resolution
App will not start	Unplug the probe, delete and reinstall the App.
App crashes	Close the App and restart the App. Check for software updates in the applicable App Store.
App opens but will not scan images	Close the App and restart the App. Make sure the probe is charged. If the probe is charged, contact Support.
Imaging Issues	
Image quality degraded	Make sure you are using enough approved ultrasound gel. If quality does not improve, contact Support.
Blank screen or screen no longer updates	Close the App and restart the App. Unplug the probe from the mobile platform (mobile device) and reconnect.

Issue	Resolution
Image degradation or occurrence of image artifacts	<p>Make sure you are using the appropriate preset and the depth is appropriate for the anatomy being scanned.</p> <p>Make sure the brightness on your screen is set to the recommended setting of 65%.</p> <p>To determine if your probe is damaged, activate the probe self-test. For details, see Performing the Probe Diagnostic Test [50]</p>
Study Issues	
Cannot upload a study; study remains in Outbox	<p>Make sure your mobile device has network connectivity (WiFi or a cellular connection).</p> <p>Butterfly Cloud service may be undergoing maintenance or may be unavailable. Try again later.</p>
Probe Issues	
Persistent probe connection error	<p>Perform a hard reset:</p> <ol style="list-style-type: none">1. Disconnect the probe from the mobile device.2. Press and hold the probe's Battery Indicator Button for 10-15 seconds until LEDs flash.3. Repeat Step 2 and then try reconnecting the probe to the mobile device.4. You may need to charge the probe for at least six (6) hours.
Probe will not charge	
App Alerts and Messages	
App opens but cannot login: Device Passcode Required	<p>This indicates that your mobile device does not have a passcode. Butterfly iQ™ requires the mobile device to have a passcode for patient data security. Tap Settings to enable and configure the passcode for your mobile device.</p>
App opens but cannot log in: Login Error	<ul style="list-style-type: none">• Make sure your mobile device has network connectivity (WiFi or a cellular connection).• Try to re-enter your credentials.• Reset your password using a desktop computer browser to access Butterfly Cloud (cloud.butterflynetwork.com) <p>If the steps above are not successful, it may indicate that Butterfly Cloud service is undergoing maintenance or is unavailable. Try again later.</p>
Hardware Recall alert appears	<p>The probe cannot be used for imaging if this alert is displayed. Tap Contact Support and follow the on-screen instructions.</p>
Forced Log Out alert appears	<p>This indicates that your mobile device no longer has a passcode. The Butterfly iQ™ App requires that the mobile device to have a passcode for patient data security. Tap Settings to enable and configure the passcode for your mobile device.</p>
Probe Temporarily Disabled alert appears	<p>This alert is displayed when your mobile device has not been connected to the Internet within the last 30 days. Reconnect to the Internet and tap Refresh.</p>
Scanning can resume after cooling is complete alert	<p>This alert is displayed when the probe has become too warm for scanning. The system limits patient contact temperature and will not scan at or above 43°C (109°F). The system provides this alert prior to shutting off. Scanning can continue during this message until the probe reaches the auto-cool initiation. Auto-cool is triggered to ensure patient safety. Scanning will resume after the auto-cool has reduced the probe temperature.</p>

14. Getting Support

This chapter lists contact information if you require support for the probe and Butterfly iQ™ App.

Contacting Butterfly Support

Butterfly Network, Inc.

530 Old Whitfield Street

Guilford, CT 06437 USA

Telephone: +1 (855) 296-6188

FAX: +1 (203) 458-2514

General inquiries: info@butterflynetwork.com

Support and service: support@butterflynetwork.com

Website: www.butterflynetwork.com

EC	REP
----	-----

Authorized European Representative

Emergo Europe

Prinsessegracht 20

2514 AP The Hague

The Netherlands

Australian Sponsor

Emergo Australia

Level 20, Tower II

Darling Park

201 Sussex Street


Sydney, NSW 2000

Australia

Contacting Support through the Butterfly iQ™ App

You can contact Butterfly Support directly through the Butterfly iQ™ App and submit a request for help.

To access support:

1. From the imaging screen, tap your user avatar (user uploaded photo or your initials) in the upper left corner.
2. Tap  to display the **Settings** screen.
3. Scroll down to the **Help** section.
4. Use the **Request Help**, **Submit Feedback**, and **Report a Bug** selections to send messages directly to our customer support team.

15. Specifications

This chapter lists the technical specifications for the probe and Butterfly iQ™ software application. It also includes regulatory information as well as instructions for recycling and disposal of equipment.

Mobile Device Requirements



WARNING!

Do not use the Butterfly iQ™ App on a mobile device that does not meet minimum requirements. Using the Butterfly iQ™ App on a mobile device that does not meet the minimum requirements may affect performance and image quality, possibly resulting in misdiagnosis.

Butterfly iQ™ works on many Apple and Android devices. For the latest list of compatible mobile devices please visit support.butterflynetwork.com.



NOTE

The Butterfly iQ™ App does not affect the mobile device's operating system settings.


System Specifications

Table 5. System Specifications

Item	Specifications
Probe dimensions	185 x 56 x 35 mm (7.2 x 2.2 x 1.4 in.)
Probe weight	313 grams (.69 lbs)
Power	Battery (rechargeable)
Battery Life	2 hours in B-Mode (typical new battery at 25°C). 2 hours refers to continuous scanning vs. traditional scanning patterns.
Languages	The user interface and accompanying documentation is localized in English, Spanish, French, German, Italian, Polish, Portuguese, Dutch, Danish, Norwegian, Swedish, and Finnish.
Display	Variable
Min/Max scan depth	1 cm min / 30 cm max
Ultrasound chip	Integrated CMOS chip
Transducers	9000-element CMUT
Frequency Range	1-10 MHz

Probe Battery Charger

Table 6. Probe Battery Charger Specifications

Probe Charging Pad			
	Item		
	Specification		
	Qi Compliant		
Wireless Charging Standard	DC 5V / 2A		
Input Voltage	Micro-USB		
Input Interface	10W	10W	5W
Wireless Charging Power	> 73%		
Wireless Charging Efficiency	Over voltage protection, Over current protection		
Protection	121 x 62 x 11mm	121 x 62 x 19mm	121 x 62 x 19mm
Dimensions	Black/Blue	Black	Black
Color			

Environmental Operating Conditions

Table 7, “Environmental Operating Conditions” [55] lists the environmental conditions for the Butterfly iQ™ probe only. For details on the mobile device on which you run the Butterfly iQ™ App, refer to the accompanying documentation for your mobile device.

Table 7. Environmental Operating Conditions

Item	Operating Limits
Humidity	Between 18-93% non-condensing
Altitude	Between 150 ft below sea level and 10,000 ft above sea level
Operating Temperature	Between 5°C to 39°C
Brief Storage Temperature	The probe can withstand three days of storage at temperatures between -20°C and 50°C

Electromagnetic Conformance (EMC)

The Butterfly iQ™ is intended to enable diagnostic ultrasound imaging and measurement of anatomical structures and fluids by qualified and trained healthcare professionals. Electromagnetic fields, however, can cause distortion or degradation of this information, affecting this performance.

The Butterfly iQ™ has been designed for use within electromagnetic environments specified in [Table 8](#), “[Electromagnetic Emissions](#)” [56] and [Table 9](#), “[Electromagnetic Immunity](#)” [56]. To avoid radiated and conducted electromagnetic disturbances, the customer or the user of the Butterfly iQ™ should assure that it is used within these stated specifications.

Table 8. Electromagnetic Emissions

Guidance and manufacturer's declaration - electromagnetic emissions		
Emission Test	Compliance	Electromagnetic environment - guidance
RF emission CISPR 11 EN55011	Group 1	The Butterfly iQ™ Ultrasound System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The Butterfly iQ™ Ultrasound System is suitable for use in all establishments, except domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emission CISPR 11 EN55011	Class A	
Harmonic emission EN/IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions EN/IEC 6100-3-3	Not applicable	

Table 9. Electromagnetic Immunity

Immunity test	EN/IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) EN/IEC 61000-4 -2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical transients / bursts EN/IEC 61000-4-4	Not applicable. This device does not function on AC power.	Not applicable.	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m@50Hz or 60Hz 3 orthogonal orientations	30 A/m 50 and 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 610004-6	3 V 0,15 MHz– 80 MHz 6 V in ISM bands between 150 kHz and 80 MHz 80% AM at 1 kHz	3 V 0,15 MHz– 80 MHz 6 V in ISM bands between 150 kHz and 80 MHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the Butterfly iQ™ Ultrasound System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Equations and key recommended separation distances are shown in Separation Distances [57]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	

^aField strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Butterfly iQ™ Ultrasound System is used exceeds the applicable RF compliance level above, the Butterfly iQ™ Ultrasound System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Butterfly iQ™ Ultrasound System.

^bOver the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Separation Distances

Devices such as cellular/mobile phones, radio transmitters, and transceivers transmit radio waves (RF), which can create disturbances. The Butterfly iQ™ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.

If radiated and conducted electromagnetic disturbances are observed and performance is affected, the user or customer should take measures to mitigate, including relocation or reorientation of the system.

Table 10. Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the ultrasound unit			
The ultrasound unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ultrasound unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ultrasound unit as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output of transmitter (P, in watts)	Separation distance according to frequency of transmitter (d in meters)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter's manufacturer. NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Acoustic Output

Ultrasound Safety

Trained professionals should perform diagnostic ultrasound procedures safely for the intended purpose. Butterfly iQ™ and its thermal (TI) and mechanical (MI) safety limits are set to industry standards, as a Track 3 device, and are displayed on the display screen. The TI is displayed as either soft tissue (TIS), bone (TIB) or cranial bone (TIC), and, only one of these indices is displayed at any given time, based on the clinical setting default of a selected exam. TI and MI are displayed in increments of 0.1 over the range of 0.0 to maximum output.

Thermal Index (TI) is the estimate of the temperature increase of soft tissue or bone and its limits are set, based on the NEMA Standard, UD 3: "Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment", Revision 2 and IEC 60601-2-37. Medical electrical equipment. Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment.

Mechanical Index is the estimated likelihood of tissue damage due to cavitation and its limits (1.9) as set by FDA Guidance, "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers."

I_{spta} is the Spatial Peak Temporal Average Intensity and the maximum limit of I_{spta} is 720 mW/cm², which is also set by FDA Guidance, "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers."

Although these acoustic output setting have been limited in compliance with these standards, it is incumbent on the user to be trained in the use of the ultrasound and aware of the potential for ultrasound-induced bio effects and to minimize patient exposure to potential harmful effects and unnecessary risk. Ultrasound users should be knowledgeable in ultrasound procedures and be able to perform them at output levels and exposure times that are As Low As Reasonably Achievable (ALARA). ALARA is defined as ultrasound exposure kept as low as reasonably achievable while optimizing diagnostic information.

ALARA training is provided by the American Institute of Ultrasound in Medicine (AIUM) in a booklet, “Medical Ultrasound Safety.” This booklet is provided as a PDF link in the Butterfly iQ™ App and the Butterfly Cloud web interface. It provides training and educational information on ultrasound bio effects and biophysics, prudent use and implementing ALARA.

An example of the ALARA principle is during obstetric ultrasound. Minimizing, for example, the use of Color Doppler, limiting dwell time, scanning only critical structures required for the study, and avoiding studies for non medical reasons are all manifestations of a reduction in exposure to ultrasonic energy.

Output display uncertainty

MI and TI output display accuracy is dependent on the precision of the measurement system, engineering assumptions within the acoustic model used to calculate the parameters, and variability in the acoustic output of probes. Butterfly compares both internal and 3rd party acoustic and confirms that both measurements are within recommended display quantization of 0.2 as outlined by the standards. Note that all MI and TI values displayed on the device will not exceed the maximum global values (listed in the tables below) by more than 0.2.

Track 3 Specific Information

The Butterfly iQ™ adheres to conformance with FDA Track 3 output settings, output display and ALARA safety principles. In support of Track 3 acoustic output, the following tables provide the global maximum acoustic output indices for the probe and each of its clinical output modes.

Table 11. Probe/Mode Combination Summary System: Butterfly iQ™

Probe Model	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other* (Specify)
Butterfly iQ™	X	X	X		X	X	B+M Mode	

Table 12. Diagnostic Ultrasound Indications for Butterfly iQ™

Transducer: Butterfly iQ™ Ultrasound System transducer							
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:							
Clinical Application		Mode of Operation					
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	Power	PWD	Color Doppler	Combined (Specify)
Ophthalmic	Ophthalmic	X		X		X	B-Mode + Color Doppler B-Mode + Power Doppler
Fetal Imaging & Other	Fetal/Obstetric	X	X	X		X	B-Mode + M-Mode B-Mode + Color Doppler B-Mode + Power Doppler
	Abdominal	X	X	X		X	B-Mode + M-Mode B-Mode + Color Doppler B-Mode + Power Doppler
	Intraoperative (Specify)						
	Intra-operative (Neuro)						
	Laparoscopic						
	Pediatric	X	X	X		X	B-Mode + M-Mode B-Mode + Color Doppler B-Mode + Power Doppler

Transducer: Butterfly iQ™ Ultrasound System transducer							
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:							
Clinical Application		Mode of Operation					
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	Power	PWD	Color Doppler	Combined (Specify)
	Small Organ (including scrotum, thyroid, breast)	X	X	X		X	B-Mode + M-Mode B-Mode + Color Doppler B-Mode + Power Doppler
	Neonatal Cephalic						
	Adult Cephalic						
	Trans-rectal						
	Trans-vaginal						
	Trans-urethral						
	Trans-esoph. (non-Card.)						
	Musculoskeletal (Superficial)	X	X	X		X	B-Mode + M-mode B-Mode + Color Doppler B-Mode + Power Doppler
	Intravascular						
	Other (Musculoskeletal Conventional)	X	X	X		X	B-Mode + M-Mode B-Mode + Color Doppler B-Mode + Power Doppler
	Other (Gynecological)	X	X	X		X	B-Mode + M-Mode B-Mode + Color Doppler B-Mode + Power Doppler
	Other (Urology)	X	X	X		X	B-Mode + M-Mode B-Mode + Color Doppler B-Mode + Power Doppler
Cardiac	Cardiac Adult	X	X			X	B-Mode + M-Mode B-Mode + Color Doppler
	Cardiac Pediatric	X	X			X	B-Mode + M-Mode B-Mode + Color Doppler
	Intravascular (Cardiac)						
	Trans-esoph. (Cardiac)						
	Intra-cardiac						
Peripheral Vessel	Peripheral vessel	X	X	X		X	B-Mode + M-Mode B-Mode + Color Doppler B-Mode + Power Doppler
	Other (Carotid, deep vein thrombosis, arterial studies)	X	X	X		X	B-Mode + M-Mode B-Mode + Color Doppler B-Mode + Power Doppler
	Other (Procedural Guidance)	X	X	X	X	X	B-Mode + M-Mode B-Mode + Color Doppler B-Mode + Power Doppler

Acoustic Output Limits

The ultrasound system maintains acoustic outputs below the appropriate limits for each application listed below.

Non ophthalmic applications:

System Probe	$I_{SPTA.3}$	TI Type	TI Value	MI	$I_{PA.3}@MI_{max}$
Butterfly iQ™	44.9 mW/cm ²	TIB	0.289	0.49	54.6 W/cm ²

Ophthalmic applications:

System Probe	$I_{SPTA.3}$	TI Type	TI Value	MI	$I_{PA.3}@MI_{max}$
Butterfly iQ™	8.12 mW/cm ²	TIB	0.047	0.162	6.48 W/cm ²

For additional information please visit support.butterflynetwork.com.

Acoustic Output Tables

Table 13. Symbols

Symbol	Description
MI	The Mechanical Index.
TISscan	The Soft Tissue Thermal Index in an auto-scanning mode.
TIS _{non-scan}	The Soft Tissue Thermal Index in a non-auto-scanning mode.
TIB	The Bone Thermal Index.
TIC	The Cranial Thermal Index.
A_{aprt}	The area of the active aperture (square centimeters).
$p_{r.3}$	The derated peak rarefactional pressure associated with the transmit pattern giving rise to the value reported under MI (megapascals).
W_0	The ultrasonic power, except for TISscan, in which case it is the ultrasonic power passing through a one centimeter window (milliwatts).
$W_{.3}(z_1)$	The derated ultrasonic power at axial distance z_1 (milliwatts).
$IT_{A.3}(z_1)$	The derated spatial-peak temporal-average intensity at axial distance z_1 (milliwatts per square centimeter).
z_1	The axial distance corresponding to the location of $\max[\min(W_{.3}(z), I_{TA.3}(z) \times 1 \text{ cm}^2)]$, where $z = z_{bp}$ (centimeters).
z_{bp}	$1.69 A_{aprt}$ (centimeters).
z_{sp}	The axial distance at which TIB is a global maximum (i.e., $z_{sp} = z_{B.3}$) (centimeters).
$z@PII_{.3max}$	The axial distance corresponding to the maximum of the derated spatial- peak pulse intensity integral (megapascals).
$d_{eq}(z)$	The equivalent beam diameter as a function of axial distance z . It is equal to $[(4/\pi)(W_0/I_{TA}(z))]^{0.5}$ where $IT_A(z)$ is the temporal-average intensity as a function of z (centimeters).
f_c	The center frequency (MHz). For MI, f_c is the center frequency associated with the transmit pattern giving rise to the global maximum reported value of MI. For TI, for combined modes involving transmit patterns of unequal center frequency, f_c is defined as the overall range of center frequencies of the respective transmit patterns.
Dim. of A_{aprt}	The active aperture dimensions for the azimuthal (x) and elevational (y) planes (centimeters).
PD	The pulse duration (microseconds) associated with the transmit pattern giving rise to the reported value of MI.
PRF	The pulse repetition frequency associated with the transmit pattern giving rise to the reported value of MI (Hz).
$p_r@PII_{max}$	The peak rarefactional pressure at the point where the free-field, spatial peak pulse intensity integral is a maximum (megapascals). See Section 6.2.4.1 of the Output Display Standard, entitled "Measurement Methodology for Mechanical and Thermal Indices".
$d_{eq}@PII_{max}$	The equivalent beam diameter at the point where the free-field, spatial-peak pulse intensity integral is a maximum (centimeters). See Section 6.2.5.1 of the Output Display Standard, entitled "Measurement Methodology for Mechanical and Thermal Indices".
FL	The focal length, or azimuthal (x) and elevational (y) lengths, if different (centimeters).
$I_{PA.3}@MI_{max}$	The derated pulse-average intensity at the point of global maximum reported MI (watts per square centimeter).

Table 14. B-Mode

Index Label			MI	TIS			TIB	TIC
				Scan	Non-Scan		Non-Scan	
					A _{aprt} ≤ 1 cm ²	A _{aprt} > 1 cm ²		
Maximum Index Value			0.485	0.02	-	-	-	(a)
Assoc Acoustic Parameter	Pr.3	(MPa)	0.718					
	W _o	(mW)		4.40	-		-	(a)
	min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]	(mW)				-		
	z ₁	(cm)				-		
	z _{bp}	(cm)				-		
	z _{sp}	(cm)	5.83				-	
	d _{eq} (z _{sp})	(cm)					-	
	f _c	(MHz)	2.19	2.41	-	-	-	(a)
	Dim of A _{aprt}	X (cm)		2.0	-	-	-	(a)
Y (cm)			1.3	-	-	-	(a)	
Other Information	PD	(μsec)	0.295					
	PRF	(Hz)	1066					
	p _r @PII _{max}	(MPa)	1.11					
	d _{eq} @PII _{max}	(cm)					-	
	Focal Length	FLx (cm)		10.0	-	-		
		FLy (cm)		INF	-	-		
	I _{PA.3} @MI _{max}	(W/cm2)	54.6					
Operating Control Conditions	FAST preset		✓					
	Abdomen deep			✓				
Note 1:			Information need not be provided for any formulation of <i>TIS</i> not yielding the maximum value of <i>TIS</i> for that mode.					
Note 2:			Information need not be provided regarding <i>TIC</i> for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.					
Note 3:			Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2aa) and 51.2 dd).					
(a)			Intended use does not include cephalic so TIC is not computed.					

Table 15. B-Mode + Color

Index Label			MI	TIS			TIB	TIC
				Scan	Non-Scan		Non-Scan	
					A _{aprt} ≤ 1 cm ²	A _{aprt} > 1 cm ²		
Maximum Index Value			0.485	-	-	0.13	0.29	(a)
Assoc Acoustic Parameter	Pr.3	(MPa)	0.718					
	W _o	(mW)		-	-		17.4	(a)
	min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]	(mW)				0.74		
	z ₁	(cm)				7.8		
	z _{bp}	(cm)				2.76		
	z _{sp}	(cm)	5.83				7.1	
	d _{eq} (Z _{sp})	(cm)					1.84	
	f _c	(MHz)	2.19	-	-	2.49	2.49	(a)
	Dim of A _{aprt}	X (cm)		-	-	2.0	2.0	(a)
Y (cm)			-	-	1.8	1.8	(a)	
Other Information	PD	(μsec)	0.295					
	PRF	(Hz)	1066					
	p _r @PII _{max}	(MPa)	1.11					
	d _{eq} @PII _{max}	(cm)					1.84	
	Focal Length	FLx (cm)		-	-	10.0		
		FLy (cm)		-	-	10.0		
	I _{PA.3} @MI _{max}	(W/cm2)	54.6					
Operating Control Conditions	FAST preset		✓					
	Bladder					✓	✓	
Note 1:		Information need not be provided for any formulation of <i>TIS</i> not yielding the maximum value of <i>TIS</i> for that mode.						
Note 2:		Information need not be provided regarding <i>TIC</i> for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.						
Note 3:		Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2aa) and 51.2 dd).						
(a)		Intended use does not include cephalic so TIC is not computed.						

Table 16. B + M-mode

Index Label			MI	TIS			TIB	TIC
				Scan	Non-Scan		Non-Scan	
					A _{aprt} ≤ 1 cm ²	A _{aprt} > 1 cm ²		
Maximum Index Value			0.485	0.013	-	-	0.012	(a)
Assoc Acoustic Parameter	Pr.3	(MPa)	0.718					
	W _o	(mW)		2.64	-		0.63	(a)
	min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]	(mW)				-		
	z ₁	(cm)				-		
	z _{bp}	(cm)				-		
	z _{sp}	(cm)	5.83				8.3	
	d _{eq} (z _{sp})	(cm)					2.1	
	f _c	(MHz)	2.19	2.41	-	-	1.56	(a)
	Dim of A _{aprt}	X (cm)		2.0	-	-	2.5	(a)
		Y (cm)		1.3	-	-	1.3	(a)
Other Information	PD	(μsec)	0.295					
	PRF	(Hz)	1066					
	p _r @PII _{max}	(MPa)	1.11					
	d _{eq} @PII _{max}	(cm)					2.1	
	Focal Length	FLx (cm)		10.0	-	-		
		FLy (cm)		INF	-	-		
	I _{PA.3} @MI _{max}	(W/cm2)	54.6					
Operating Control Conditions	FAST preset		✓					
	Abdomen Deep			✓				
	Cardiac THI						✓	
Note 1:			Information need not be provided for any formulation of <i>TIS</i> not yielding the maximum value of <i>TIS</i> for that mode.					
Note 2:			Information need not be provided regarding <i>TIC</i> for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.					
Note 3:			Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2aa) and 51.2 dd).					
(a)			Intended use does not include cephalic so TIC is not computed.					

Table 17. B-Mode + Power

Index Label			MI	TIS			TIB	TIC
				Scan	Non-Scan		Non-Scan	
					A _{aprt} ≤ 1 cm ²	A _{aprt} > 1 cm ²		
Maximum Index Value			0.485	-	-	0.13	0.29	(a)
Assoc Acoustic Parameter	Pr.3	(MPa)	0.718					
	W _o	(mW)		-	-		17.4	(a)
	min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]	(mW)				0.74		
	z ₁	(cm)				7.8		
	z _{bp}	(cm)				2.76		
	z _{sp}	(cm)	5.83				7.1	
	d _{eq} (z _{sp})	(cm)					1.84	
	f _c	(MHz)	2.19	-	-	2.49	2.49	(a)
	Dim of A _{aprt}	X (cm)		-	-	2.0	2.0	(a)
Y (cm)			-	-	1.8	1.8	(a)	
Other Information	PD	(μsec)	0.295					
	PRF	(Hz)	1066					
	p _r @PII _{max}	(MPa)	1.11					
	d _{eq} @PII _{max}	(cm)					1.84	
	Focal Length	FLx (cm)		-	-	10.0		
		FLy (cm)		-	-	10.0		
	I _{PA.3} @MI _{max}	(W/cm2)	54.6					
Operating Control Conditions	FAST preset		✓					
	Bladder					✓	✓	
Note 1:			Information need not be provided for any formulation of <i>TIS</i> not yielding the maximum value of <i>TIS</i> for that mode.					
Note 2:			Information need not be provided regarding <i>TIC</i> for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.					
Note 3:			Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2aa) and 51.2 dd).					
(a)			Intended use does not include cephalic so TIC is not computed.					

Table 18. B-Mode + Ophthalmic

Index Label			MI	TIS			TIB	TIC
				Scan	Non-Scan		Non-Scan	
					A _{aprt} ≤ 1 cm ²	A _{aprt} > 1 cm ²		
Maximum Index Value			0.162	0.0015	-	-	-	0.0021
Assoc Acoustic Parameter	Pr.3	(MPa)	0.354					
	W _o	(mW)		0.0657	-		-	0.0657
	min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]	(mW)				-		
	z ₁	(cm)				-		
	z _{bp}	(cm)				-		
	z _{sp}	(cm)	1.65				-	
	d _{eq} (z _{sp})	(cm)					-	
	f _c	(MHz)	4.80	4.80	-	-	-	4.80
	Dim of A _{aprt}	X (cm)		0.7	-	-	-	0.7
		Y (cm)		0.7	-	-	-	0.7
Other Information	PD	(μsec)	0.181					
	PRF	(Hz)	3000					
	p _r @PII _{max}	(MPa)	0.466					
	d _{eq} @PII _{max}	(cm)					-	
	Focal Length	FLx (cm)		2.2	-	-		
		FLy (cm)		2.2	-	-		
	I _{PA.3} @MI _{max}	(W/cm2)	6.24					
Operating Control Conditions	Ophthalmic		✓					
				✓				
							✓	
Note 1:			Information need not be provided for any formulation of <i>TIS</i> not yielding the maximum value of <i>TIS</i> for that mode.					
Note 2:			Information need not be provided regarding <i>TIC</i> for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.					
Note 3:			Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2aa) and 51.2 dd).					

Table 19. Color + Ophthalmic

Index Label			MI	TIS			TIB	TIC
				Scan	Non-Scan		Non-Scan	
					A _{aprt} ≤ 1 cm ²	A _{aprt} > 1 cm ²		
Maximum Index Value			0.162	0.00145	0.0167	-	0.0477	0.0340
Assoc Acoustic Parameter	Pr.3	(MPa)	0.355					
	W _o	(mW)		0.0633	0.719		0.719	0.719
	min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]	(mW)				-		
	z ₁	(cm)				-		
	z _{bp}	(cm)				-		
	z _{sp}	(cm)	1.65				1.22	
	d _{eq} (Z _{sp})	(cm)					0.0358	
	f _c	(MHz)	4.80	4.80	4.89	-	4.89	4.89
	Dim of A _{aprt}	X (cm)		0.65	0.5	-	-	0.5
		Y (cm)		0.65	0.5	-	-	0.5
Other Information	PD	(μsec)	0.175					
	PRF	(Hz)	1100					
	p _r @PII _{max}	(MPa)	0.507					
	d _{eq} @PII _{max}	(cm)					0.311	
	Focal Length	FLx (cm)		4.0	5.0	-		
		FLy (cm)		4.0	Inf	-		
	I _{PA.3} @MI _{max}	(W/cm2)	6.48					
Operating Control Conditions	Ophthalmic		✓					
				✓				
							✓	
Note 1:			Information need not be provided for any formulation of <i>TIS</i> not yielding the maximum value of <i>TIS</i> for that mode.					
Note 2:			Information need not be provided regarding <i>TIC</i> for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.					
Note 3:			Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2aa) and 51.2 dd).					

Table 20. Pulsed Wave Doppler

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum Index Value			0.21	9.15E-02		0.14		0.10
Index Component Value				9.15E-02	4.08E-02	9.15E-02	0.14	
Assoc Acoustic Parameter	$p_{r,a}$ at z_{MI}	(MPa)	0.44					
	P	(mW)		4.67		4.67		4.67
	P_{1x1}	(mW)		4.48		4.48		
	z_s	(cm)			2.87			
	z_b	(cm)			-		2.87	
	z_{MI}	(cm)	2.87					
	$z_{pii,a}$	(cm)	2.87					
	f_{awf}	(MHz)	4.29	4.29		4.29		4.29
Other Information	pr	(Hz)	3000					
	srr	(Hz)	N/A					
	n_{pps}		1					
	$I_{p,a}$ at $z_{pii,a}$	(W/cm ²)	7.56					
	$I_{spta,a}$ at $z_{pii,a}$ or $z_{sii,a}$	(mW/cm ²)	25.15					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm ²)	58.82					
	p_r at z_{pii}	(MPa)	0.68					
Operating Control Conditions	Pulsed Doppler A							
Note 1:	Only one operating condition per index.							
Note 2:	Data should be entered for "at surface" and "below surface" both in the columns related to TIS and TIB.							
Note 3:	Information on MI and TI need not be provided regarded using TIC for an TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.							
Note 4	If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS, TIB or TIC							
Note 5	If the requirements of 201.12.4.2b are met, it is not required to enter any data in the columns related to MI.							
Note 6	Unshaded cells should have a numerical value. The equipment setting related to the index has to be entered in the operating control section.							
Note 7	The Depths z_{pii} and $z_{pii,a}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,a}$ apply to SCANNING MODES.							

Measurement Accuracy

The Butterfly iQ™ device has been designed to perform the following clinical measurements:

M-mode:

- Distance measurements accurate to within $\pm 3\%$ of the displayed value.
- Time measurements accurate to within $\pm 3\%$ of the displayed value.
- Fetal heart rate measurements accurate to within $\pm 3\%$ of the displayed value.

B-mode:

- Distance measurements (axial) accurate to within $\pm 3\%$ of the displayed value.
- Distance measurements (lateral) accurate to within $\pm 5\%$ of the displayed value.
- Distance measurements (diagonal) accurate to within $\pm 4\%$ of the displayed value.
- Distance measurements (circumference) accurate to within $\pm 5\%$ of the displayed value.
- Area measurements accurate to within $\pm 10\%$ of the displayed value.

Doppler Spectrum:

- Relative flow speed and direction accurate to within $\pm 20\%$ of the displayed value.

Waste Electrical and Electronic Equipment

The crossed-out wheeled bin symbol on this device indicates that this equipment has been put on the market after 13 August 2005, and is included in the scope of the directive 2002/96/EEC on Waste Electrical and Electronic Equipment (WEEE) and of the national decree(s), which transpose provisions of such directive. At the end of its lifetime, this device cannot be disposed of as unsorted municipal waste and must be collected separately at specifically authorized treatment facilities. For recycling assistance, please contact the manufacturer or authorized disposal company.



Recycling and Disposal

Butterfly Network is deeply invested in the preservation of the natural environment. Equipment may contain materials that pose a risk to the environment if proper disposal procedures are not followed. Recycle the Butterfly iQ™ probe and accessories at the end of their useful life and in accordance with local, state, provincial, and/or national regulations.

Prior to recycling, items should be clean and contaminant free.












16. Symbols












This chapter lists and describes the symbols and icons that may be used on the Butterfly iQ™, its accessories, and packaging.

Symbols

Table 21, “Symbols” [69] lists and describes a set of symbols for medical electronic equipment that classify a connection or warn of potential hazards. The symbols listed in Table 21, “Symbols” [69] may be used on the Butterfly iQ™, and on its accessories and packaging. The symbols shown in this document and on the Butterfly iQ™, and on its accessories and packaging, are compliant with current versions of the listed standards.

Table 21. Symbols

Symbol	Standard	Reference	Title	Description
	ISO 15223-1	5.4.4	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	ASTM F2503-1	F2503 - 13 3.1.14	MR Unsafe	Indicates an item which poses unacceptable risks to the patient, medical staff, or other persons within the MR environment.
	ISO 15223-1	5.2.8	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	ISO 15223-1	5.1.3	Date of Manufacture	Indicates the date when the medical device was manufactured.
	ISO 15223-1	5.3.1	Fragile; handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.
	-	-	Global Medical Device Nomenclature Code	A system of internationally agreed generic descriptors used to identify all medical device products.
	-	-	Global Trade Item Number	An identifier to look up product information in a database, often by entering the number through a bar code scanner pointed at an actual product.
IPX7	IEC 60529	-	Ingress protection rating	Ingress Protection rating system showing the degrees of protection from solid objects and liquids. The X indicates insufficient data has been gathered to assign a protection level. The 7 indicates that the system is protected against the effects of immersion in water to depth between 15 cm and 1 meter.
	IEC 60601-1	20	Type BF applied part	Indicates isolated patient connection (Type BF applied part).
	ISO 15223-1	5.3.4	Keep away from rain	Indicates a medical device that needs to be protected from moisture.
	ISO 15223-1	5.1.1	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	ISO 15223-1	5.1.5	Batch code	Identifies the manufacturer's batch code so that the batch or lot can be identified.

Symbol	Standard	Reference	Title	Description
	-	-	Model name	Model name for the device.
	ISO 15223-1	5.2.7	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	ISO 7010	M002	Refer to instruction manual/ booklet	To signify that the instruction manual/booklet must be read
	ISO 15223-1	5.4.3	Operator's manual; operating instructions	Indicates the need for the user to consult the instructions for use.
	ISO 7000	1135	General symbol for recovery/ recyclable	To indicate that the marked item or its materials is part of a recovery or recycling process.
	ISO 15223-1	5.1.6	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1	5.1.7	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	ISO 15223-1	5.3.2	Keep away from sunlight	Indicates a medical device that needs protection from light sources.
	WEEE Directive 2012/19/EU	-	Waste Electrical and Electronic Equipment	Requires a separate collection for electrical and electronic equipment in compliance with the Waste Electrical and Electronic Equipment (WEEE) Directive. When accompanied by Pb or Hg, components of the device may contain lead or mercury, respectively, which must be recycled or disposed of in accordance with local, state, or federal laws. The backlight lamps in an LCD monitor contain mercury.
	MD 93/42/EEC	-	European Conformity	Meets the requirements of the European Medical Device Directive.
	ISO 15223-1	5.1.2	Authorized representative in the European Community	Authorized European Representative: Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands
				Australian Sponsor: Emergo Australia Level 20, Tower II Darling Park 201 Sussex Street Sydney, NSW 2000 Australia

17. Notes