Butterfly iQ™ Personal Ultrasound System

User Manual

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The information contained in this document is subject to change without notice. Names and data used in examples are fictitious unless otherwise noted.

Contents

Chapter 5: Butterfly Cloud Enterprise

Chapter 6: Using the System

Chapter 7: Annotations

Chapter 8: Using Color Doppler

Chapter 9: Using Power Doppler

Chapter 10: Using M-mode Display

Chapter 11: Uploading a Study

Chapter 12: Using the Butterfly Cloud

Chapter 13: Maintenance

Chapter 14: Troubleshooting

Chapter 15: Getting Support

Chapter 16: Specifications

Chapter 17: Symbols

Chapter 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 (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 accessories. It is important that you read and understand all instructions in this manual before operating the device, and pay careful attention to the warnings and cautions throughout the manual.

Butterfly Cloud Overview

The Butterfly Cloud is a cloud storage web application intended to allow users of the Butterfly iQ™ Android mobile application to upload studies (including the images and clips) to an Internet-based storage system. Users accessing the Butterfly Cloud web application are able to access the same content available to them through their Butterfly iQ™ account, which may be shared across an entire organization's members.

For more information, see "Using the Butterfly Cloud" on page 12-1.

Intended Use

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

CAUTION!
Federal law (USA) restricts this device to sale by or on the order of a physician.

Indications for Use

Note — Not all features and presets may be available.

Butterfly iQ™ is indicated for use by qualified and trained healthcare professionals 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 and arterial studies)
- Procedural Guidance
- Small Organs (including thyroid)
- Cardiac
- Abdominal
- Urology
- Fetal/Obstetric
- Gynecological
- Musculoskeletal (conventional)
- Musculoskeletal (superficial)
- Ophthalmic[1]

The product can be used in a variety of settings such as clinics and hospitals for M-mode, B-mode, Color Doppler, and Power Doppler functions.

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 ophthalmic applications unless the Ocular preset is available and used.

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

1. Not available in the U.S.A.

Chapter 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 (www.butterflynetwork.com). For more information, see “Butterfly iQ™ App” on page 3-3.

Safety Conventions

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:

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.

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.
- 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. See “Getting Support” on page 15-1 for more information.
- 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.
- 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.
- The Butterfly Imaging 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 an 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.

CAUTIONS!

- 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.
- 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.

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 musculo-skeletal 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.

Chapter 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.

Overview

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

- Compatible Android™ device (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

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

For details about the components, see “System Components” on page 3-3. For details about the requirements for the mobile device, see “Mobile Device Requirements” on page 16-1.

For a list of clinical applications, see “Indications for Use” on page 1-2.

Modes

Butterfly iQ™ provides M-mode, B-mode, Color Doppler, and Power Doppler functionality.

Measurements

Butterfly iQ™ lets you perform the following clinical measurements:

- M-mode: Distance, time, and heart rate measurements
- B-mode: Distance and ellipse measurements

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

For more information about MDM software and the Butterfly Cloud Enterprise, see "Butterfly Cloud Enterprise" on page 5-1.

Internet Connectivity

An Internet connection is required to download, install, or update the Butterfly iQ™ App from the Google Play Store. An Internet connection is also required to log in and to archive studies to the Butterfly Cloud. Otherwise, no Internet connection or wireless connectivity is required to use the mobile device. However, in order to maintain updates to the Butterfly iQ™ App, you are required to connect to an Internet connection every 30 days.

System Components

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

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.

Note — The Android mobile device is not included with the Butterfly iQ™; 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 Google Play Store. The App prompts you to set up a Butterfly account. The App and Butterfly account are required to use the Butterfly iQ™ personal ultrasound.

Notes:

- 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. For more information, see “Mobile Device Requirements” on page 16-1.
- 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 setting 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

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 3-1 shows the parts of the probe and Table 3-1 lists and describes the parts.

Figure 3-1 Probe Components

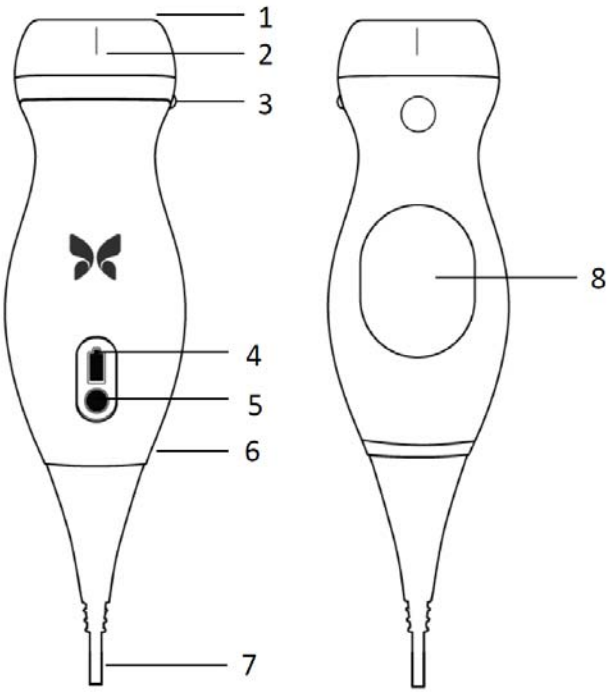

Table 3-1 Probe Components

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

For details on maintaining, cleaning, and disinfecting the probe, see “Maintaining the Probe” on page 13-1.

For details on charging and storing the probe, see “Charging the Probe” on page 4-6. For details on the battery indicator lights, see “Checking Battery Level” on page 4-9.

CAUTION!
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.

Probe Battery Charger

Only use the charger supplied with the probe.

Figure 3-2 shows the battery charging accessories and Table 3-2 lists each accessory.

Figure 3-2 Charging Pad Components

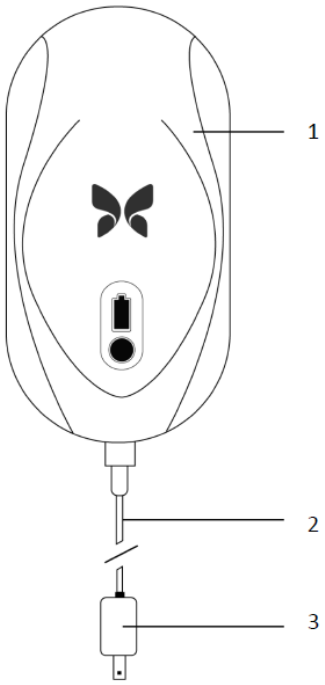

Table 3-2 Charging Pad Components

Item	Description
1	Charging Pad
2	Charging Cable
3	Wall Adapter

For instructions on charging the probe, see “Charging the Probe” on page 4-6. For details on the specifications, see “Probe Battery Charger” on page 16-3.

Overview of User Interface

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

Figure 3-3 shows an example of the imaging display and Table 3-3 lists and describes the items on the display.

Figure 3-3 Imaging Display

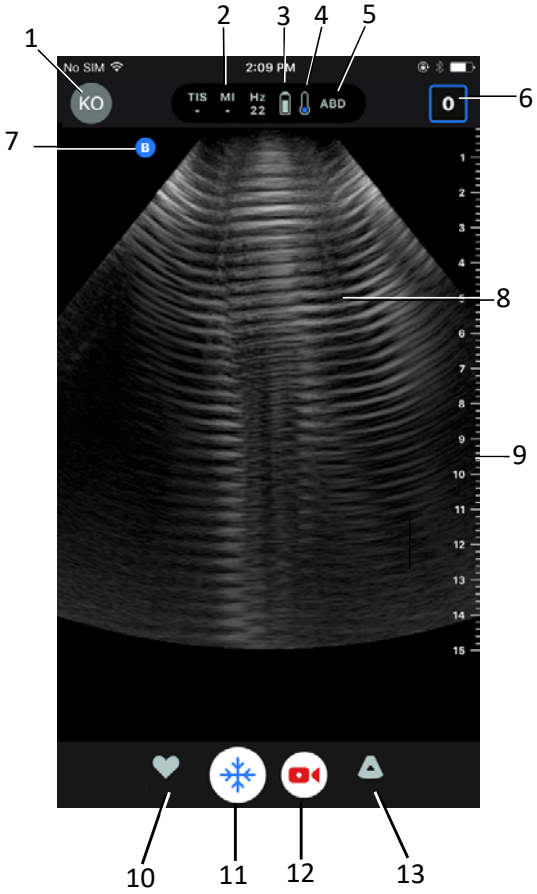

Table 3-3 Imaging Display Items

Item	Description
1	**User avatar**. If a photo has been uploaded, the photo appears here. Otherwise, the user's initials appear here.
2	The Thermal Index (TI), Mechanical Index (MI), and Hz values
3	Probe battery status
4	Probe temperature indicator
5	Current preset (abbreviated)

Table 3-3 Imaging Display Items

Item	Description
6	**Capture Reel**. The number in the icon indicates the number of images and clips that are currently in the **Capture Reel**.
7	Probe orientation marker
8	Image display area
9	Ruler. Provides imaging depth in centimeters. When the image is zoomed, the ruler adjusts accordingly.
10	**Presets** selection
11	**Freeze** control
12	**Record** clip (video)
13	**Modes** 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. The Butterfly iQ™ App includes the following presets:

- Abdomen
- Abdomen Deep
- Aorta & Gallbladder
- Bladder
- Cardiac
- Cardiac Deep
- FAST (Focused Assessment with Sonography for Trauma)
- Lung
- Musculoskeletal
- Nerve
- Obstetric
- Pediatric Abdomen
- Pediatric Cardiac
- Pediatric Lung
- Small Organ
- MSK-Soft Tissue
- Vascular: Access
- Vascular: Carotid
- Vascular: Deep Vein

Notes

- Several presets include a **Midline** tool which you can access using the Tools icon. For more information, see “Reviewing Frames From a Frozen Image” on page 6-7.
- Musculoskeletal and soft tissue presets start at 1 cm depth.
- Some presets support linear or polar boxes depending on the depth.

For details on configuring the **Preset** settings, see “Configuring Preset Settings” on page 4-5.

Chapter 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 Google Play Store on your Android mobile device.

Before downloading and installing the App, make sure your mobile device meets or exceeds the minimum performance specifications. For details, see “Mobile Device Requirements” on page 16-1.

➤ **To download and install the App:**

1. Open the Google Play Store on the mobile device.
2. Click the Search icon ( ) and enter *Butterfly iQ™*.

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 “Mobile Device Requirements” on page 16-1.

➤ **To begin using the system:**

1. Open the Butterfly iQ™ App. The system prompts you to log in.
2. Enter your email address and password and tap **Log In**.

   The **End User License Agreement** screen is displayed for your review and acknowledgment.
3. Use your finger to scroll through the terms and conditions and then tap **Accept** to continue.

   The system prompts you to enable push notifications.

Note — You can also configure **Notifications** in your device’s **Settings**.

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4. Connect the Butterfly iQ™ probe to your mobile device.

5. If prompted to update the firmware, see “Updating Firmware” on page 4-2.

Note — The Master the Butterfly iQ™ videos are displayed upon first login. For details on accessing the videos at anytime, see “Accessing Help” on page 4-5.

6. Begin performing an ultrasound study.
7. When your study is complete, unplug the Butterfly iQ™ probe from your mobile device.

Updating Firmware

The firmware on your mobile device must be up-to-date to perform imaging.

➤ **If prompted to update the firmware, perform the following steps:**

1. Tap **Update**.
2. When the update is complete, tap **Done** at the top right corner.

Managing App Updates

When connected to a wireless or cellular network, the Butterfly iQ™ App automatically checks for mandatory updates.

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.

CAUTION!
If you ignore the mandatory updates, the system may lock you out.

You can configure the Butterfly iQ™ App to update the App manually, or allow the App to be updated automatically.

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 from the Google Play Store to obtain the latest update.

Navigating the App

This section provides information to get you started navigating the App.

Note — The App provides tool tips highlighting key components of App navigation to first-time users.

Using the Touchscreen

The App is designed for ease of use and uses the same touchscreen gestures for opening, closing, zooming, and menu formats as most other Apps. If you are new to using the mobile device, review the documentation and instructions that came with it. You can also visit the mobile device's support pages for basic instructions on using the touchscreen.

Opening and Closing the App

➤ **To open the App:**

Touch the App icon on your mobile device's home screen: 

➤ **To close the App:**

Navigate to the mobile device's home screen.

Logging In and Out of the App

To use the Butterfly iQ™ App, purchase a subscription online at www.butterflynetwork.com or request an account from your administrator. Once you have been provisioned an account, you will receive an invitation to set up a password to associate with your email address. For more information, contact your organization's administrator or Butterfly Support.

➤ **To log in:**

1. Tap **Log In**.
2. Enter your login credentials on the **Log In** screen.

➤ **To log out:**

1. From the imaging screen, tap your user avatar (or your initials) in the upper left corner.
2. Tap  to display the **Settings** screen.
3. Tap **My Account**.
4. Tap **Log Out**.

Note — For information about Single Sign-On (SSO) and other features, see "Butterfly Cloud Enterprise" on page 5-1.

Forgotten Password

Note — Recovering a forgotten password requires you to log in to the Butterfly Cloud from your desktop computer.

➤ **If you forgot the password to your account:**

1. Select **Forgot Password** on the **Log In** screen.
2. Follow the on-screen instructions.

Configuring Your System Settings

Optionally, you can configure your system settings.

Note — For more information about configuring the Butterfly Cloud, see “Using the Butterfly Cloud” on page 12-1.

Settings include the following:

- Use the **My Account** section to view more information about your account and to access the Log Out button. For more information on logging out, see “Logging In and Out of the App” on page 4-3.
- The **Devices** section includes the setting to configure **My iQ:**
  - Use **My iQ** to view information, update the probe software, and to perform the probe diagnostic test. For details, see “Updating the Probe and App Software” on page 13-7 and “Performing the Probe Diagnostic Test” on page 13-8.
- The **Preferences** section includes the following configurable settings:
  - Use the **Presets** section to change the default settings for selected presets. Settings are detailed in “Configuring Preset Settings” on page 4-5.
  - Use the **Auto-Freeze** setting to toggle the Auto-Freeze feature. When **Auto-Freeze** is enabled, the system automatically puts the probe into a battery conservation mode after probe inactivity has been detected.
  - Use the **Upload Studies Over Cellular** setting to toggle on and off the ability to use cellular data to upload studies.
  - Use the **Show Magnifying Glass** setting to toggle on and off the display of zoomed context to help place precise line measurements.
- Use the **Help** section to access **Help** settings. For more information, see “Accessing Help” on page 4-5.
- Use the **About** section to view your version of the Butterfly iQ™ App.
- Use the **Privacy Policy** section to view Butterfly Network Inc.’s Privacy Policy.
- Use the **Terms of Use** section to view Butterfly Network Inc.’s Terms of Use.

- Use the **End User License Agreement** section to view Butterfly Network Inc.'s End User License Agreement.

Configuring Preset Settings

Use the **Presets** settings to configure your individual preferences for each preset's imaging settings to include: Show in Presets Menu, Thermal Index Display, Acoustic Power Setting, Probe Orientation Marker, Color Doppler Flow Velocity, and Trace Scroll Speed.

➤ **To configure preset settings:**

1. From the imaging screen, tap your user avatar (or your initials) in the upper left corner.
2. Tap  to display the **Settings** screen.
3. In the **Preferences** section, tap **Presets**.
4. Tap the preset to configure. The settings that are specific to the selected preset are displayed. The currently selected setting is displayed in blue.
5. Tap a setting to select it.
6. To reset the preset settings to the factory-default, tap **Reset**.

Accessing Help

Use the **Help** section to access the following:

- **Learn Butterfly iQ Basics**
- **Master the Butterfly IQ**
- **User Manual**
- **Medical Ultrasound Safety**
- **Request Help**
- **Submit Feedback**
- **Report a Bug**

➤ **To access Help:**

1. From the imaging screen, tap your user avatar (or your initials) in the upper left corner.
2. Tap  to display the **Settings** screen.
3. Scroll down to the **Help** section.

Charging the Probe

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. For details on the battery charging accessories, see “Probe Battery Charger” on page 3-5.

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. See “Getting Support” on page 15-1 for more information.
- 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. For information on contacting support, see “Contacting Butterfly Support” on page 15-1.
- 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. See “Getting Support” on page 15-1 for more information.

Table 4-1 illustrates the probe charging states for each of the available probe chargers. The charger indicator light is displayed on the side of the charging pad.

Note — Your exact charging pad may vary. For details on the charging pad specifications, see “Probe Battery Charger” on page 16-3.

Table 4-1 Probe Charging States

Probe Charging Pad			
Charge Indicator State			
No Probe			
Charging			
Error			
Fully Charged			

➤ **To charge the probe:**

Note — The Butterfly iQ™ uses a wireless charging system. Do not attempt to insert your probe’s cable into the charging pad.

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1. Disconnect the probe from the mobile device.

Note — You cannot perform imaging while the probe is charging.

2. Connect the charging cable to the charging pad.
3. Connect the USB end of the charging cable to the wall adapter.
4. Plug the wall adapter into a power outlet.

Note — If properly plugged into the power outlet, the charger indicator light will turn blue to indicate the probe is charging (Table 4-1).

5. Place the probe onto the charging pad so that the probe lies flat on the charging pad.

Note — Both the charging pad and the probe should be placed with their Butterfly logos facing up. The probe's charging surface (see Figure 3-1) should be placed directly above the charging pad's Butterfly logo.

CAUTION!
Make sure to place the probe on the charging pad so that it lies flat on the charging pad on a flat surface. Do not hang the charging pad or hang the probe from the charging pad.

6. Ensure that the probe is properly placed on the charging pad so that the probe's battery indicator lights are on and the charger indicator light is blue. If the charger indicator light remains red, reposition the probe on the charging pad until the charger indicator light turns blue and the probe battery indicator lights 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 and the charger indicator light shows Fully Charged, as shown in Table 4-1.

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 Battery Level

Use the Battery Indicator Button and Battery Indicator Lights on the probe to check the battery level. For reference, see “Probe Components” on page 3-4.

Note — To ensure the probe has enough battery to perform a study, try to maintain a charge level above 25%.

Table 4-2 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 (25% or less), you may not be able to perform a study until the battery is recharged. Keep the battery fully charged whenever possible.

Note — You can view the battery indicator percentage by accessing the **My iQ** screen. For details, see “Configuring Your System Settings” on page 4-4.

Chapter 5
Butterfly Cloud Enterprise

This chapter provides information about the Butterfly Cloud Enterprise feature.

Butterfly Cloud Enterprise Functionality

Butterfly Cloud Enterprise functionality provides multiple features for customers requiring advanced security, authentication and device tracking. Please contact support for additional information on upgrading Enterprise. See “Contacting Butterfly Support” on page 15-1 for contact information.

Butterfly Domains

Butterfly Domains enable an enhanced level of control. With a domain, customers are given a custom sub-domain (subdomain.butterflynetwork.com) for access to their Butterfly Cloud organizations. All organizations in your domain will have access to enterprise functionality such as Single Sign On (SSO) and Custom Log Out Duration.

Single Sign-On (SSO)

Butterfly Single Sign-On (SSO) enables institutions to delegate Butterfly authentication to an existing SAML-compliant identity provider, such as Active Directory. With SSO, users only have to remember a single password and administrators can enforce enhanced identification, such as two-factor authentication. SSO also enables centralized account management for secure and simple off-boarding.

Chapter 6
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, and for performing measurements.

WARNING!
It is unsafe to start using the Butterfly iQ™ before reading this manual in its entirety.

Notes:

- Make sure you have read “Setting Up the System” on page 4-1.
- If the Butterfly iQ™ App is open but you are not actively scanning for a period of time, the App goes into sleep mode to conserve battery power. To wake the App from sleep mode, tap this icon: 

Beginning a New Study

Once the probe is connected you can begin a new study.

➤ **To start a new study:**

1. If not already connected, connect the probe.
2. The probe defaults to most recently used preset.

   Note — Tap  to change the preset for the study, and if necessary, tap  to change the imaging mode.

3. Use approved ultrasound gel as a transmission medium.

Notes

- For details on which gel to use, refer to “Recommended Ultrasound Gels” on page 16-4.
- Tegaderm™ Film (1624W) has been tested and is approved for use on the probe over its lifespan.

4. Begin using the probe to image.

Note — The Butterfly iQ™ probe includes a raised orientation mark on the side of the probe head. The probe orientation marker  is also displayed on the imaging screen. Pressing the probe orientation marker on the imaging screen changes the orientation to the other side.

Entering Patient Data

Note — This feature is only available when archiving to the Butterfly Cloud destination. For more information, see “Archives” on page 12-8.

It is not required to include patient data in the study. However you can enter patient details at anytime during the study by tapping **Associate a Patient**.

•

Patient Details include:

- **Patient Name** (**Last Name**, **First Name**, **Middle Name**, **Title**, and **Suffix**)
- **Sex** (**Male**, **Female**, **Other**, and **Unknown**)
- **DOB** (Date of Birth) (A date scroll wheel feature is displayed to select the patient’s DOB)
- **Accession #**
- **MRN** (Medical Record Number)

Adding Patient Details Manually

➤ **To manually add patient details:**

1. On the imaging screen, tap the **Capture Reel** and then tap **Associate a Patient**.
2. In the **Patient** screen, use the keyboard to enter the patient details and then tap **Done**.
3.

Adding a Study Description

You can add a description of the study from the **Study** screen.

Capturing and Recording Images

Notes

- This feature requires a subscription to the Butterfly Cloud. For more information, see “Using the Butterfly Cloud” on page 12-1.
- This feature is only available when archiving to the Butterfly Cloud destination.

This section provides information and instructions for using various features to capture and record images.

When you capture an image or record a video clip, the image or clip is automatically saved to the **Capture Reel**.

Capturing Images

When you begin a study, you can immediately start using the probe to begin scanning images.

➤ **To capture an image:**

1. Tap  to freeze the image.
2. Tap  to capture the image.
3. Tap  to return to live imaging.

Recording a Clip

Use the record feature to acquire and save a clip of the study. The recording defaults to 60 seconds if you do not manually stop the recording.

➤ **To record a clip:**

1. Tap  to begin recording.
2. When finished recording, tap  to end the recording.

Using the Capture Reel

The **Capture Reel** stores all captured images and clips. You can view the images and clips in the study, save the study to an archive, and clear the series of images and clips from the study.

➤ **To use the Capture Reel:**

1. Tap the **Capture Reel**.
2. Do any of the following:

- View the images and clips. You can swipe left and right to view the previous and next item in the reel.
- Save the study to an archive. For details, see “Saving a Study - Uploading to the Butterfly Cloud” on page 6-9.
- 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**.

Using Features and Tools

This section provides information and instructions for adjusting the gain, depth, and TGC, using pan and zoom, freezing and unfreezing an image, and using the midline.

Adjusting the Gain, Depth, and TGC

The **Gain**, **Depth**, and **TGC** controls are available during live imaging.

The **Gain** control, accessed by swiping horizontally anywhere in the image, increases or decreases the gain percentage. When the **Gain** control is activated, the **TGC** (Time Gain Compensation) is also activated to adjust Near, Mid, and Far percentages.

Note — When in Color Doppler or Power Doppler mode, the **Gain** control is labeled **Color Gain**. For more information on using Color Doppler mode, see “Using Color Doppler” on page 8-1.

The **Depth** control, accessed by swiping vertically anywhere in the image, increases or decreases the depth in centimeters. As you increase and decrease the **Gain** or **Depth** control, the border of the control is green. Once you select the value, the border turns to blue.

➤ **To adjust the gain:**

1. Touch anywhere on the screen and slide your finger slightly left or right to activate the **Gain** control.
2. When the **Gain** control is visible, slide your finger right or left to increase or decrease the gain.
3. When done, tap anywhere outside of the **Gain** control or simply wait until the control is no longer active.

➤ **To adjust the depth:**

1. Touch anywhere on the screen and slide your finger slightly up or down to activate the **Depth** control.
2. When the **Depth** control is visible, slide your finger up or down to increase or decrease the depth.
3. When done, tap anywhere outside of the **Depth** control or simply wait until the control is no longer active.

➤ **To adjust the TGC on an image:**

1. Touch anywhere on the screen and slide your finger slightly left or right to activate the **Gain** control. When the **Gain** control is active, the **TGC**  control is displayed at the bottom of the screen.
2. Use the **Near**, **Mid**, and **Far** sliders to adjust the image as needed by tapping a slider and moving your finger right or left to increase or decrease the percentage.
3. If necessary, tap **Reset** to reset the **Near**, **Mid**, and **Far** sliders to 50% (the factory default).
4. Tap **Done** when finished.

Using Pan and Zoom

The Pan and Zoom features on the App use the same functionality as any mobile device application.

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).

When zoomed, a thumbnail of the image is displayed in the upper right portion of the screen with a yellow region of interest (ROI) border. As you pan the zoomed image, the ROI is updated to orient you to the zoomed image.

➤ **To zoom in on an image:**

1. Place two fingers on the screen and spread them apart to zoom in or double-tap the image. The ROI is displayed.
2. Continue using the pinch to zoom or double-tap gestures to zoom in and out on the image.

➤ **To pan a zoomed image:**

1. Touch anywhere on the image and move your finger left, right, up, and down to position the image on the screen.

➤ **To zoom out in an image:**

1. Place two fingers on the screen and spread them in to zoom out or double-tap the zoomed image.
2. Continue using the pinch to zoom or double-tap gestures to zoom in and out on the image.

Freezing and Unfreezing an Image

You can freeze the live image at any time to capture the current or recent frames as images.

➤ **To freeze and unfreeze an image during scanning:**

1. Tap  to freeze the image.
2. To unfreeze the image and resume scanning, tap  .

You can also:

- Tap  to capture the image and save it to the **Capture Reel**. For more details on capturing images, see “Capturing Images” on page 6-3. For details about the **Capture Reel**, see “Using the Capture Reel” on page 6-4.
- Perform Line and Ellipse measurements. For more details, see “Performing a Linear Measurement” on page 7-1.

Reviewing Frames From a Frozen Image

When the image is frozen, tap  to view frames from up to the last ten seconds of live imaging. You can select an individual frame or capture a cine, which is a clip of the series of frames.

To select an image from the series of recent frames, tap **Select** when the frozen frame is outlined. When the image is frozen, you can also perform the following:

- Tap  to capture the image and save it to the **Capture Reel**. For more details on capturing images, see “Capturing Images” on page 6-3. For details about the **Capture Reel**, see “Using the Capture Reel” on page 6-4.
- Perform Line and Ellipse measurements. For more details, see “Performing a Linear Measurement” on page 7-1.

To capture a cine, tap **Capture Cine**. The cine is automatically saved to the **Capture Reel**.

Using the Midline

The **Midline** tool lets you turn on the midline mark to mark the center of the probe during interventional procedures.

The following presets include the **Midline** tool when you are in M-mode, Color Doppler, or Power Mode:

- Musculoskeletal
- Nerve
- MSK-Soft Tissue
- Vascular: Access
- Vascular: Carotid
- Vascular: Deep Vein

Note — Musculoskeletal and soft tissue presets start at 1 cm depth.

➤ **To access the Midline tool from within the preset:**

1. Tap or swipe the Tools icon  , located at the bottom right corner.
2. Tap  to turn the midline markers on.
3. Tap  to turn the midline markers off.

Saving a Study - Uploading to the Butterfly Cloud

Note — This feature is only available when uploading to the Butterfly Cloud.

When you upload a study, you have the option of deleting the images from the **Capture Reel** and defaulting to a new study state.

➤ **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. Tap **Save** to initiate an upload. For detailed information on uploading a study and the various options for saving, see “Butterfly Cloud” on page 11-1.
3. 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**.

Chapter 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 on any frozen image.

To add annotations during live imaging, you must tap  to first freeze the image to display the annotation tools. The annotation tools are displayed below the image area.

Performing a Linear Measurement

You can perform up to four linear measurements on each image.

➤ **To perform a linear measurement:**

1. Tap  to freeze the image.
2. Tap  to access the measurement tools.
3. To perform a linear measurement, tap  and choose the line measurement.
4. Touch the blue circle  and use it to drag the yellow cross-hairs to the start or end position. 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.

Note — The result is the distance between the yellow cross-hairs.

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5. To add another line, tap  . The next line is displayed in a different color with calipers at each end. Repeat the steps above to manipulate the ends of the line.
6. To edit a line, tap the line or tap the line's measurement and adjust the line as needed.
7. To delete a line, tap the line or tap the line's measurement. Tap the **X** next to the corresponding numeric measurement display, and then tap **Delete Line** to confirm.

Performing an Ellipse Measurement

You can perform one ellipse measurement on each image. The ellipse appears on the image with two calipers. As you manipulate the ellipse, the circumference and area are displayed in cm and cm^2 at the bottom of the image.

➤ **To perform an ellipse measurement:**

1. Tap  to freeze the image.
2. Tap  to access the measurement tools.
3. To display the ellipse tool, tap  . The ellipse is displayed with two calipers.
4. Touch and drag the caliper icons to scale and rotate the ellipse. A box with the ellipse's circumference and area (displayed in cm and cm^2) is displayed at the bottom of the page. You can drag this box to the desired location on the image.
5. To move the ellipse, touch anywhere in the ellipse and drag it to the desired position.
6. To delete an ellipse, tap the ellipse to select it and then tap the **X** next to the corresponding numeric measurement display. Tap **Delete Ellipse** to confirm.

Adding a Text Annotation

You can add up to five text annotations on each image. You can select a suggested annotation, depending on the preset, or enter your own annotation. When you add the annotation, you can then move it to the desired location on the image.

➤ **To add an annotation:**

1. Tap  to freeze the image.
2. Tap  to display the measurement tools.
3. Tap  to display the **Search or Create New Annotation** screen.
4. To use a preconfigured annotation, tap the annotation.
5. To enter your own annotation, use the keyboard to type the annotation.
6. Tap **Done**.
7. Drag the annotation to the desired location on the image.
8. To delete an annotation, tap it and then select its **X**. Tap **Delete Annotation** to confirm.

Chapter 8
Using Color Doppler

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

Color Doppler Overview

Use Color Doppler to visualize blood flow (average velocity and direction) overlaid on a B-mode image.

In Color Doppler, a color region of interest (ROI) is displayed on the imaging screen to represent the average velocity and direction of flow. The color scale is displayed to the right of the image.

When using Color Doppler, you can:

- Adjust the size and position of the ROI
- Adjust the Gain and Depth. For instructions, see “Adjusting the Gain, Depth, and TGC” on page 6-5.
- 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

Accessing Color Doppler Mode

➤ **To change to Color Doppler mode:**

Tap the Modes  icon and select **Color Doppler**.

Adjusting the Region of Interest (ROI)

The ROI is displayed on the image. As you move the ROI, the border is blue until positioned.

➤ **To adjust the ROI:**

1. To resize the ROI, tap the icon  and drag your finger up, down, left, or right to adjust the size and steer of the ROI.

Note — When in a linear format, (such as Vascular) use  to adjust the width.

2. To move the ROI, tap inside the ROI and drag the ROI to the new position.

Tip — You can zoom in on the ROI. As you adjust the zoom, a thumbnail of the image is displayed in the upper right portion of the screen with a yellow ROI box. As you pan the zoomed image, the ROI is updated to orient you to the zoomed image.

Adjusting the Gain, Depth, and PRF

The **Gain** and **Depth** controls are available during Color Doppler imaging.

The **Color Gain** control increases or decreases the gain percentage. The **Depth** control increases or decreases the depth in centimeters. To access the **Color Gain** and **Depth** controls, touch anywhere outside of the ROI.

For details on adjusting gain and depth, see “Adjusting the Gain, Depth, and TGC” on page 6-5.

To adjust the color flow state, choose **Low** or **High**.

Chapter 9
Using Power Doppler

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

Note — This feature requires a subscription to the Butterfly Cloud. For more information, see “Using the Butterfly Cloud” on page 12-1.

Power Doppler Overview

Use Power Doppler to visualize the amplitude energy of blood flow (not velocity or direction) overlaid on a B-mode image.

In Power Doppler, the amplitude energy of the flow contained in the region of interest (ROI) is displayed using a red-hued intensity map. This color map is displayed to the right of the image.

When using Power Doppler, you can:

- Adjust the size and position of the ROI
- Adjust the Color Gain and Depth
- Adjust the Velocity Scale to optimize for high or low flow velocities

Accessing Power Doppler Mode

➤ **To change to Power Doppler mode:**

Tap the Modes  icon and select **Power Doppler**.

Adjusting the Region of Interest (ROI)

The ROI is displayed on the image. As you move the ROI, the border is blue until positioned.

➤ **To adjust the ROI:**

1. To resize the ROI, tap the icon  and drag your finger up, down, left, or right to adjust the size and steer of the ROI.

Note — When in a linear format (such as Vascular), use  to adjust the width.

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2. To move the ROI, tap inside the ROI and drag the ROI to the new position.

Tip — You can zoom in on the ROI. As you adjust the zoom, a thumbnail of the image is displayed in the upper right portion of the screen with a yellow ROI box. As you pan the zoomed image, the ROI is updated to orient you to the zoomed image.

Adjusting the Color Gain, Depth, and Velocity Scale

The **Color Gain** and **Depth** controls are available during Power Doppler imaging.

The **Color Gain** control increases or decreases the gain percentage of the Power Doppler output only (not the B-mode output). The **Depth** control increases or decreases the depth of the B-mode and Power Doppler output in centimeters. To access the **Color Gain** and **Depth** controls, touch and drag horizontally or vertically anywhere outside of the ROI.

For more details on adjusting gain and depth, see “Adjusting the Gain, Depth, and TGC” on page 6-5.

You can adjust the velocity scale for high or low velocities using the **High** and **Low** controls at the bottom of the screen. By selecting **Low**, you can increase the sensitivity to lower velocity flows.

Chapter 10
Using M-mode Display

This chapter provides information and instructions for using M-mode display when performing an ultrasound study.

M-mode Display Overview

M-mode display imaging provides high temporal resolution of tissue motion.

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.

Accessing M-mode

➤ **To change to M-mode:**

Tap the Modes  icon and select **M-mode**.

Using M-mode

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

➤ **To use M-mode:**

To adjust the scan line angle, tap the move point  and drag it radially.

Adjusting the Sweep Speed, Gain, and Depth

The **Gain**, **Depth**, and sweep speed controls are available during M-mode imaging.

The **Gain** control, accessed by swiping horizontally on the image, increases or decreases the gain percentage. The **Depth** control, accessed by swiping vertically on the image, increases or decreases the depth in centimeters. Use the sweep speed control to adjust the sweep speed (**Fast** or **Slow**).

For details on adjusting gain and depth, see “Adjusting the Gain, Depth, and TGC” on page 6-5.

➤ **To adjust the sweep speed of the scan line display:**

Tap **Slow** or **Fast** to change sweep speed.

Performing M-mode Measurements

When you perform a measurement in M-mode, the App calculates time, heart rate (bpm), and distance based on the placement of the line.

➤ **To perform a measurement:**

1. Tap  to freeze the image.
2. Tap  to access the measurement tools.
3. To perform a distance measurement, tap  .
4. Use the  to position the cross-hairs.
5. To delete the line, tap the **X** next to the corresponding numeric measurement display, and then tap **Delete Line** to confirm.

Chapter 11
Uploading a Study

This chapter provides information and instructions for uploading a study, retrieving an uploaded study, and configuring upload destination archives.

Note — This feature requires a subscription to the Butterfly Cloud. For more information, see “Using the Butterfly Cloud” on page 12-1.

Overview

A study includes the patient information, study description, and the captures (images and/or clips). When you upload a study, you have the option of selecting the captures that you want to include in the archive. You can also elect to delete the captures that are not included in the archive, or roll them into a new study.

Butterfly Cloud

The Butterfly Cloud is a web-based application that allows users to upload ultrasound exams from the Butterfly iQ™ App. For more information, see “Using the Butterfly Cloud” on page 12-1.

Uploading a Study

➤ **To upload a study:**

1. Once you have captured all of the images that you want to upload, tap the **Capture Reel**.
2. Tap **Save**. If you have not yet associated a patient with the study, or added a study description, the system prompts you to continue without adding study information. For details, see “Entering Patient Data” on page 6-2.
3. Select the Butterfly Archive destination.
4. All images are selected for saving by default. To deselect an image from saving, tap the image.
5. If you deselected an image or images, when you tap **Confirm** in the upper right corner, the system prompts you to discard the images or roll them into a new study. Rolled images remain in the **Capture Reel**.
6. Tap **Confirm**. The imaging screen is displayed. A progress indicator is displayed around your avatar in the upper left corner of the screen. Once uploaded, a check mark is displayed to confirm that the study is uploaded to the selected archive.

Viewing Upload Progress

When uploading studies to multiple archive destinations, the system displays a progress notification at the bottom of the **My Account** screen.

➤ **To view the upload progress:**

1. Tap your user avatar (or your initials) to display your archive screen where you can view an archive feed of all of your uploads.
2. Tap the notification at the bottom of the screen. The **Outbox** screen is displayed with the uploads that are pending, in progress, or failed.
3. You can view the upload progress and cancel the upload if necessary.
4. For failed uploads, you can tap **Retry** or tap the **X** to cancel the upload.

Viewing an Uploaded Study

Once a study has been uploaded, you can access the upload destination to retrieve the study.

Studies are organized in the archive screen with the most recent study listed first.

Use the  to search for a specific study. A keyboard is displayed where you can enter text to help locate the study.

You have the option to share a link of the study or image/images from the study. The link is copied to your mobile device's clipboard where you can then share it with others.

Note — When you share a link, the patient information is NOT included. The study is de-identified to protect the patient's identity.

➤ **To view an uploaded study:**

1. Tap your user avatar (or your initials) in the upper left corner. The archive screen is displayed.
2. Click the drop-down menu to see a list of all available archives. The archives are listed in alphabetical order.
3. Select the archive that contains the study you want to retrieve.
4. Scroll through the list of studies and tap the study to view details.

Note — To refresh the list of studies, swipe down.

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5. Tap the thumbnail image or clip to view it in full-screen mode.
6. In full-screen mode, you can swipe left and right to view the previous and next image or clip.
7. To share a link to the study or image, tap  in the upper right corner of the screen.
8. Tap **Share De-identified Study Link** and then paste the link in the application you use to share information (such as email, text message, and so on).

9. Use the **X** at the top left of the images and the arrow at the top left of the study pages to return to the archive screen.
10. To return to live imaging from the archive screen, tap **Scan**.

Adding and Viewing Comments on Images

You can add and view comments on uploaded images.

➤ **To add or view comments**

1. Tap on your avatar to access the archive screen. The archive destinations are listed in alphabetical order.
2. Select the archive that contains the study you want to retrieve.
3. Scroll through the list of studies and tap the study to view details.
4. Tap the thumbnail image or clip to view it in full-screen mode. The bottom of the screen includes the most recent comment or an empty text box for entering the first comment.

- To enter a new comment, tap in the blank text field to display the keyboard. Enter the text and tap **Post**.
- To view existing comments or add a reply, tap the comment at the bottom of the screen.

Deleting an Archived Study

Deleting an uploaded study deletes the study from the archive.

➤ **To delete an archived study:**

1. Perform the steps to retrieve a study. For details, see “Viewing an Uploaded Study” on page 11-2.
2. Select the study.
3. Tap **Delete Study** to delete the study. A prompt is displayed prompting you to confirm the deletion.
4. Tap **Delete Study**.

Chapter 12
Using the Butterfly Cloud

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

Overview

The Butterfly Cloud is a web-based application that allows users to upload ultrasound exams from the Butterfly iQ™ App. Users have the ability to access ultrasound exams uploaded to the Butterfly Cloud through the Butterfly iQ™ App. Depending on your privileges, you may be able to access an entire organization's Butterfly iQ™ exams uploaded to the Butterfly Cloud.

A Butterfly Cloud Administrator configures the archives, adds new members, and configures each user's access level.

Administrators have the ability to manage users' accounts and configure archives for ultrasound exams to be uploaded to the organization's Butterfly Cloud. Once configured, your administrator sends you an invitation email with details to create an account to access your organization's cloud.

An organization can have multiple archives. For example, City Hospital may have archives for each of its departments such as Radiology, Cardiology, ER, and so on.

Note — Whenever you share data from the Butterfly Cloud, the shared data is anonymized for the recipient, meaning any PHI data is removed. The information is in a view-only window on the Butterfly Cloud. For more information, see "Sharing a Study" on page 12-11.

Accessing the Butterfly Cloud for the First Time

Once you have purchased the Butterfly Cloud, you will receive an email invitation with a link to the URL. If you were invited to a team by someone else who purchased the Cloud, you will receive a similar email invitation. Follow the instructions provided in the email to access the Butterfly Cloud and to create your password.

To begin using your Butterfly iQ, you need to activate your account and download the Butterfly iQ App to your mobile device. For details, see “Downloading and Installing the App” on page 4-1.

Note — Butterfly Network cannot activate your account.

Individual Bundle

If you purchased an individual bundle through our Butterfly Store, check your email for a message from Butterfly Cloud that was sent at the time of purchase. Click the **Get Started** button in this email to activate your account and create a password.

Team Bundle

If you purchased a team bundle, check your email for a message from Butterfly Cloud to set up your team. The email would have been sent to whoever made the purchase. Click the **Get Started** button in this email to activate your account. You will be a team administrator by default.

Team Member

If your organization or team administrator provided your probe, you should have access through a team.

- Check your email for a message from Butterfly Cloud inviting you to the team. Click the **Join Team Cloud** button in this message to activate your user. Follow the instructions provided in the email to access the Butterfly Cloud and to create your password.

Note — Your team administrator may have forgotten to add you to the team. If you did not receive an email, contact your team administrator for access.

- If you are unsure who purchased your probe or do not know who your team administrator is, contact Butterfly Support at support@butterflynetwork.com with your probe's serial number for assistance. Your probe's serial number is on the back of the box or on the probe itself. The serial number begins with (21)BN.

Logging In and Out of the Butterfly Cloud

Use of the Butterfly Cloud on your device is through the App. The functionality in this section is for the Butterfly Cloud website as accessed from a computer.

Web address

Once your account has been established and password created, use the following link to access the Butterfly Cloud: https://cloud.butterflynetwork.com

➤ **To log in:**

1. Use one of the following email addresses, depending on how the Butterfly iQ™ probe was purchased:
   – If you purchased the Butterfly iQ™ probe yourself (Individual Bundle), enter the same email address with which you purchased the probe.
   – If you were invited to join a team (Team Bundle or Team Member), enter the email address on which you received the invitation.
2. Enter your password.

➤ **To log out:**

Click your username in the top right corner and select **Log out**.

Overview of Main Screen

The main screen is comprised of the following sections:

- “Settings” on page 12-4
- “Archives” on page 12-8
- “Studies” on page 12-10

Settings

You can access the following settings configuration sections by clicking your username in the top right corner:

- My Account
- Organization Settings*
- DICOM Connections*
- Members

Note — *You must be an organization administrator to view Organization Settings and to view DICOM Connections in the settings menu.

Configuring Account Settings

You can configure the following account settings:

- **Add Profile Photo** that is shown with your updated studies and comments
- **Change Name** to change your full name as it appears in the Butterfly Cloud
- **Change Email** to change your email address
- **Change Password** to change your Butterfly Cloud password

➤ **To configure your account settings**

1. Click your name in the top right corner and select **My account**.
2. To add a profile photo, select **Add Photo** in the **Profile Photo** section. Following the on-screen instructions.
3. If applicable, in the **Account Info** section, enter your new name and select **Change Name** to change your name, and enter your new email address and click **Change Email** to change your email address. Follow the on-screen instructions.
4. To change your password, in the **Change Password** section, enter your new password, and then enter your new password again in the **Confirm Password** field. Click **Change Password.**

Viewing Organization Settings

Note — You must have administrator privileges to change the name of the organization.

➤ **To view organization settings:**

1. Click your username in the top right corner and select **Organization settings**.
2. If applicable, click **Update** to change the name of the organization.

DICOM Connections

Note — You must be an organization administrator to access and configure DICOM settings.

Butterfly Cloud can be connected to your organization's Digital Imaging and Communications in Medicine (DICOM) endpoints using a secure DICOM-TLS connection. Ultrasound studies acquired on any Butterfly iQ™ in your organization can be transferred to the Butterfly Cloud and then forwarded into one or more of your hospital's DICOM storage systems (for example, Picture Archiving and Communication System (PACS) or Vendor Neutral Archive (VNA)).

Configuring Your DICOM Connections

➤ **To configure your DICOM Connections:**

1. Click your username in the top right corner and select **DICOM Connections**.
2. Click **View Guide** in the **Need Help Getting Started?** section at the top of the screen for more information.

Configuring Your Archives to Send to DICOM Endpoints

You can configure your archives to automatically forward studies to up to three separate DICOM endpoints (such as PACS or VNAs).

➤ **To configure archives to send to DICOM endpoints:**

1. Select the archive from the **Archive** list on the left side of the screen. The archive opens in the center of the screen.
2. In the top right corner of the archive window, click the **Settings** icon.
3. In the **Settings** page for your selected archive, select up to three PACS from the drop-down menus in the PACS Forwarding section to which you want to send studies directly from the selected archive.

   You may choose from any of the available PACS configure with your organization's Butterfly Cloud. For information on configuring PACS with the Butterfly Cloud, see "Configuring Your DICOM Connections" on page 12-5.

Note — An archive that has been configured for a DICOM endpoint (such as PACS or VNA) will have the **DICOM** icon next to it in the archive list on the left side of the screen.

Sending and Resending Studies to DICOM Endpoints

DICOM Management records all DICOM endpoints to which a study has been sent. Studies can be manually sent and resent to any configured DICOM endpoints. Studies that have been edited can also be resent to DICOM endpoints.

Note — Both administrators and regular members can send and resend studies to DICOM endpoints.

➤ **To send or resend studies to DICOM endpoints:**

1. Select the archive that contains the study you want to send or resend. All studies that are available in the selected archive are displayed in the center of the screen.
2. In the right corner of the study you want to send or resend, click the drop-down menu icon to display the menu.
3. Select **DICOM Management**. A **DICOM Management** window is displayed with a list of your DICOM connections.
4. You have the option to send or re-send the study to one or more of your DICOM connections. Click **Send** or **Resend** as necessary.

Members

The **Members** section of the Butterfly Cloud lists the members who can access the archives, and their Access Level.

Viewing Members

Members are listed in alphabetical order, from A-Z.

To change the sort order from Z-A, click the **User** heading in the **Members** section.

Viewing Members' Access Level

The **Access Level**, listed in the **Members** section for each member, is granted by members who have Admin privileges. There are two levels of access:

- **Admin**: Admins can create new archives and invite and edit members. Admins can also remove members from the Butterfly Cloud.
- **Regular** members: Members can upload and view archives and studies and comment on studies.

Adding a New Member

Note — Only members with Admin privileges can add new members to the Butterfly Cloud.

Adding a new member consists of inviting a new member to join the organization.

➤ **To add a new member:**

1. In the **Add a Member** section, enter the member's email address and click **Send invite**.

   A message is displayed confirming the invite has been sent. The member is displayed in the **Members** list as **Pending Invitation** until the member accepts the invitation.

Changing a Member's Access Level

Note — You must have Admin privileges to change a member's access level.

➤ **New members are added as regular members. To change a member's access level:**

In the Members section, click the member's **Access Level** and select from the following:

- **Make admin**
- **Make regular member**
- **Remove from organization**

Archives

Archives are listed in the left side of the screen. Each archive contains the individual studies, and each study contains the saved images and clips.

When you select an archive, you can view the studies within the archive, and then view the saved images and clips within the study.

Creating a New Archive

Note — Only members who have Admin privileges can create a new archive.

➤ **To create a new archive:**

1. Click **Create**. The **Create New Archive** window is displayed.
2. Enter a title for the archive in the **Archive Title** section and then click **Create**.

Selecting an Archive

Archives are listed in alphabetical order on the left side of the screen.

Click an archive to select it.

The archive opens in the center of the screen with information about the archive including the archive name, the study or studies listed within the archive, and the date of each study.

Deleting an Archive

Note — When an archive is deleted, the studies contained within that archive will not allow commenting.

➤ **To delete an archive:**

1. Select the archive from the **Archive** section on the left side of the screen. The archive opens in the center of the screen.
2. In the top right corner of the archive window, click the **Settings** icon.
3. In the **Settings** page for your selected archive, select **Delete Archive**. The system prompts you to confirm the deletion.
4. Click **Delete** to delete the archive.

Restoring a Deleted Archive

Note — Restoring an archive also restores all studies contained in the archive. However, if a study from that archive had been deleted before the archive itself was deleted, the study is not contained in the archive and is not restored at this time. To restore that study, you must first restore the archive in which the study is contained (see instructions below), and *then* restore the deleted study independently. For instructions, see “Restoring a Deleted Study” on page 12-13.

➤ **To restore a deleted archive:**

1. Click the **Deleted Archives** drop-down menu located at the bottom of the list of **Archives** on the left side of the screen.
2. The drop-down menu reveals a list of deleted archives. Click on the deleted archive you want to restore.
3. Select **Restore** at the center of the screen. The system prompts you to confirm the restoration of the deleted archive.
4. Click **Restore** to restore the deleted archive.

Studies

Studies are contained within archives. Each study can contain the following information, if added during the exam:

- **Patient's name** (**Last Name**, **First Name**, **Middle Name**, **Title**, and **Suffix**)
- **Sex** (**Male**, **Female**, **Other**, and **Unknown**)
- **Patient's Date of Birth**
- **Accession Number**
- **Medical Record Number** (MRN)
- Date of the study
- Thumbnail images and clips saved from the exam

You can perform the following tasks when working with studies:

- Search for a study
- Share a study
- Delete a study
- View images and clips
- Download images and clips

Searching for a Study

You can search the archives for a specific study using the **Search** text entry area at the top of all screens.

➤ **To search for a study:**

In the **Search** field in the top part of the screen, enter the keyword or keywords for which to search. As you type, a drop-down menu displays matching results. You can add additional information about the study to narrow the results.

The results are listed in the center of the screen.

Editing Study Details

Note — Only members who have Admin privileges can edit study details.

➤ **To edit study details:**

1. Select the archive that contains the study whose information you want to edit.
2. Click on an image or clip in the study. The image is displayed in the center of the screen.

   The **Patient** and **Information** sections are displayed on the right side of the screen, along with any comments that have been added about the image.
3. Click **Edit** (above the image). The **Edit Study Details** window is displayed where you can enter study details.
4. Edit the study details as needed and click **Save and Sync** to save and sync your changes.
5. To view a history of the edits made to the study details, click **Change History** (above the image).

Note — All members can view the change history of a study in their organization.

Sharing a Study

You can share a study with others. When you select to share a study, the image or clip is de-identified of patient information and a link is created for you to copy and paste into whichever messaging system you use to share information (such as email, text message, pasting into a report, and so on). The link allows the recipient to view the shared data on the Butterfly Cloud. Shared data appears for recipients as anonymized (meaning no patient health information (PHI) is visible) in a view-only window on the Butterfly Cloud.

➤ **To share a de-identified study:**

1. Click the image or clip. The image is displayed in the center of the screen. The **Patient** and **Information** sections are displayed on the right side of the screen, along with any comments that have been added about the image.
2. Click **Share de-identified study** (above the image).
3. Click the copy control. The link is copied to your device's clipboard.
4. Navigate to where you want to share the link (email, text message, document, and so on), and paste the link.

Moving a Study Across Archives

Notes

- Members who have Admin privileges can move any study from one archive to another. Regular members can move a study that they have created.
- When moving a study from one archive to another, the study is sent to any new DICOM endpoints to which the new archive is connected. Studies that were manually sent to DICOM endpoints are not impacted.

➤ **To move a study to a different archive:**

1. Select the archive that contains the study you want to move.
2. In the right corner of the study, click the drop-down menu icon to display the menu. Select **Move Study**. The **Select Destination Archive** window is displayed.
3. Select the new archive destination. The study is moved to the new archive and automatically placed in the proper location based on the upload date within this archive.

Deleting a Study

CAUTION!
Deleting a study deletes it from the archive. Ensure necessary images are transmitted to your medical record before deleting.

➤ **To delete a study:**

1. Select the archive that contains the study you want to delete.
2. In the right corner of the study, click the drop-down menu icon to display the menu.
3. Select **Delete study**. The system prompts you to confirm the deletion
4. Click **Delete** to delete the study.

Restoring a Deleted Study

Deleted studies are listed in the **Deleted Studies** section at the bottom of the left side of the screen.

Note — If you would like to restore a deleted study, the archive in which it was originally contained must be available. If this archive was deleted, you must restore that archive first and then restore the deleted study. For instructions, see “Restoring a Deleted Archive” on page 12-9.

➤ **To restore a deleted study:**

1. Click **Deleted Studies** on the bottom of the left side of the screen. The deleted studies are displayed in the center of the screen.
2. In the right corner of the study, click the drop-down menu icon to display the menu.
3. Select **Restore deleted study**. The system prompts you to confirm the restoration of the deleted study.
4. Click **Restore** to restore the study.

Working with Images and Clips

Images and clips that were uploaded to the Butterfly Cloud include all annotations (linear and ellipse measurements and text annotations) performed on the image. Each image and clip includes patient information, as well as an area to enter comments about the item. Clips include this icon: 

Note — All members who have access to the study can view the comments.

Use the commenting feature to tag other users to take a closer look at an image or clip, and to receive feedback.

Viewing Images and Clips

➢ **To view images, clips, and to enter comments:**

1. Click the image or clip. The image is displayed in the center of the screen. The **Patient** and **Information** sections are displayed on the right side of the screen, along with any comments that have been added about the image or clip.
2. To enter a comment, type your comment in the **Add comment** section and then click **Comment**. Your comment is displayed in the list with your initials.
3. To tag members of your organization, type **@** followed by the member's name (for example, *@Kathy)*. As you type, possible members are suggested. Click a member's name to select it.
4. To view the next image or clip in the study, click the left or right arrows. Clips begin playing automatically.

Use the clip controls to play and pause the clip, turn sound on and off, and to display the clip in full-screen mode.

Downloading an Image or a Clip

You can download an image or a clip.

➢ **To download a image or a clip:**

1. Select the archive and then select the study to review.
2. Select the image or clip to download.
3. Select **Download**. The system may prompt you to specify the download information.
4. Follow the instructions on the screen.

Chapter 13
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.

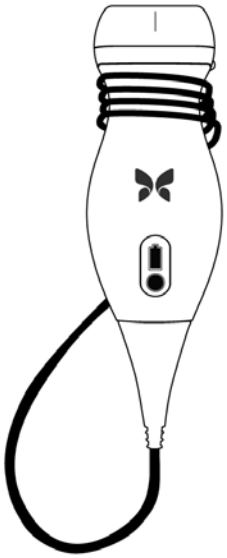
Follow these steps for daily storage and transport:

- When storing the probe, wrap the cable around the probe so that there is some slack at the bottom of the probe. See Figure 13-1 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. See “Cleaning and Disinfecting the Probe” on page 13-2.
  - Making sure the equipment is dry.
  - Carefully handling the probe to prevent damaging the equipment.

Note — Do not expose internal electronics temperature to temperatures exceeding 70°C.

For information on environmental operating conditions, including brief storage temperature conditions, see Table 16-4.

Figure 13-1 Wrapping the Cable



Cleaning and Disinfecting the Probe

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™.

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.

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.

Disinfecting the Probe

After cleaning the probe, you must disinfect the probe.

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

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.

➤ **To disinfect the probe using Super Sani-Cloth® Germicidal Disposable Wipes by PDI:**

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 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.

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 13-1 to determine the appropriate class and then follow the appropriate intermediate-level or high-level disinfection procedure.

Table 13-1 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.

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.

➤ **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 (HLD)

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

Note — Perform the following steps to make sure that your probe is compatible with High-Level Disinfection (HLD) before using the HLD method.

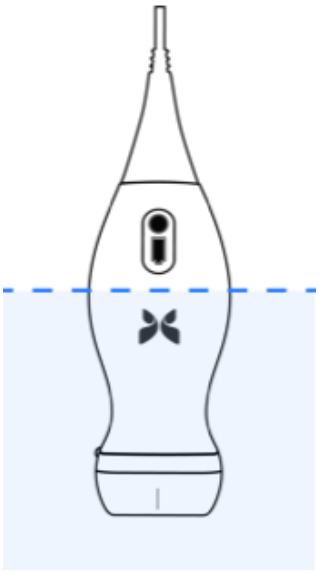
➤ **To make sure your probe is compatible with HLD:**

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.

➤ **To disinfect 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 13-2).

Figure 13-2 Probe Immersion Line



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.

Disinfecting the Mobile Device

It may be necessary to disinfect your mobile device after use. For details, refer to your mobile device's policy and website for support.

Updating the Probe and App Software

Updates to the Butterfly iQ™ App and probe are handled through the 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. However, no degree of testing can assure performance or detect abuse, damage, or a defect that occurred after the most recent test is complete.

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. Butterfly does not require testing with a phantom and does not require mobile devices to be tested.

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. From the imaging screen, tap your user avatar (or your initials) in the upper left corner.
4. Tap  to display the **Settings** screen.
5. Tap **My iQ** to display the **My iQ** screen.
6. Tap **Run Diagnostics** and then select **Start Probe Diagnostics** to perform the test.

- If the self-test passes, the system displays a message stating that the system has passed. You can send the results to Butterfly Support by tapping **Send Results to Support**.
- If the self-test fails, tap **Send Results to Support**.

For a list of supported mobile devices, see www.butterflynetwork.com/specs. Refer to "Getting Support" on page 15-1 for more information.

Chapter 14
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” on page 15-1 for more information.

Troubleshooting

Table 14-1 lists the troubleshooting issues and resolutions. See “Getting Support” on page 15-1 for more information.

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

Notes

- If you are unable to resolve an issue using Table 14-1, please note the issue and report it to Support for assistance. For more information, see “Contacting Butterfly Support” on page 15-1.
- 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 14-1 Troubleshooting

Issue	Resolution
App does not turn on	Unplug the probe, delete and reinstall the App.
App crashes	Close the App and restart the App. Check for software updates in the Google Play 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	Make sure you are using the appropriate preset and the depth is appropriate for the anatomy being scanned. Make sure the brightness on your screen is set to the recommended setting of 65%. To determine if your probe is damaged, activate the probe self-test. For details, see “Performing the Probe Diagnostic Test” on page 13-8.
Study issues	
Cannot upload a study; study remains in Outbox	• Make sure your mobile device has network connectivity (WiFi or a cellular connection). • The Butterfly Cloud service may be undergoing maintenance or may be unavailable. Try again later. For more information, see “Contacting Butterfly Support” on page 15-1.
Probe issues	
Persistent probe connection error Probe will not charge	Perform a hard reset: 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. For instructions, see “Charging the Probe” on page 4-6.
App Alerts and Messages	
App opens but cannot log in: **Device Passcode Required**	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 **Open Settings** to enable and configure the passcode for your mobile device.
App opens but cannot log in: **Login Error**	• 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 the Butterfly Cloud (cloud.butterflynetwork.com). If the steps above are not successful, it may indicate that the Butterfly Cloud service is undergoing maintenance or is unavailable. Try again later. For more information, see “Contacting Butterfly Support” on page 15-1.
Hardware Recall alert appears	The probe cannot be used for imaging if this alert is displayed. Tap **Contact Support** and follow the on-screen instructions. For more information, see “Contacting Support through the Butterfly iQ™ App” on page 15-1.

Issue	Resolution
Forced Log Out alert appears	This indicates that your mobile device no longer has 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.
Cloud Access has Ended alert appears	This indicates that the Butterfly Cloud subscription has expired. Renew your subscription, or contact your administrator to have your subscription renewed, or contact Butterfly Support. For more information, see “Contacting Butterfly Support” on page 15-1.
Probe Temporarily Disabled alert appears	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**.
Scanning can resume after cooling is complete alert	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.

Chapter 15
Getting Support

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

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 (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.
5. Choose your message type and type your message. You can also add images from your phone's camera reel.
6. Click **Send**. The request is submitted to Butterfly support.

Butterfly Support will respond to your request via email.

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

Chapter 16
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

The Butterfly iQ™ App is only available for download, installation, and use on an Android mobile device. The following lists the requirements:

Table 16-1 Mobile Device Requirements

Item	Requirement
Mobile device	**Requires Android 10** (www.android.com/android-10/) • Google Pixel 3 • Google Pixel 3 XL **Requires Android 9** (www.android.com/versions/pie-9-0/) • Samsung Galaxy S10 US Edition • Samsung Galaxy S10 International Edition • Samsung Galaxy S10+ US Edition • Samsung Galaxy S10+ International Edition • Samsung Galaxy Tab S6
Operating System	Android OS version v10 (also known as Q) and version 9

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.

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

System Specifications

Table 16-2 lists the system specifications.

Table 16-2 System Specifications

Item	Specification
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 in English only.
Display	Variable
Min/Max scan depth	2 cm min / 30 cm max
Ultrasound chip	Integrated CMOS chip
Transducers	9000-element CMUT
Frequency Range	1-10 MHz

Probe Battery Charger

Table 16-3 lists the specifications for the available types of probe battery chargers.

Table 16-3 Probe Battery Charger Specifications

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

Recommended Ultrasound Gels

For optimal transmission of acoustic energy between the patient and the probe, you must use an ultrasound transmission gel.

The following ultrasound gels are recommended:

- Aquasonic® by Parker
- Clear Gel Image Singles by Sonotech
- Kendall™ Ultrasound Gel by Covidien
- LiquaSonic Ultrasound Gel by Medline Industries
- SCAN® Ultrasound Gel by Parker
- STERILE Aquasonic® 100 Ultrasound Transmission Gel by Parker

CAUTION!
Use only approved gels or liquids. Non-approved gels and liquids may damage the probe.

Environmental Operating Conditions

Table 16-4 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 16-4 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 16-5 and Table 16-6. 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 16-5 Electromagnetic Emissions

Guidance and manufacturer's declaration - electromagnetic emissions		
Emission Test	**Compliance**	**Electromagnetic environment - guidance**
RF emission CISPR11 11EN55011	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.
RF emission CISPR 11EN55011	Class A	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.
Harmonic emission EN/IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions EN/IEC 6100-3-3	Not applicable	

Table 16-6 Electromagnetic Immunity

Guidance and manufacturer's declaration - 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.

Guidance and manufacturer's declaration - electromagnetic immunity			
Immunity test	**EN/IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
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 Table 16-7. 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] Interference may occur in the vicinity of equipment marked with the following symbol 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	

[a] Field 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.
[b] Over 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 16-7 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/cm^2, 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.

Output display uncertainty

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 16-8 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	B+M mode	

Symbols used

Table 16-9 lists and describes the symbols used.

Table 16-9 Symbols

Symbol	Description
MI	The Mechanical Index.
TISscan	The Soft Tissue Thermal Index in an auto-scanning mode.
$TIS_{non\text{-}scan}$	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).
Wo	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 z1 (milliwatts).
$I_{TA.3}(z_1)$	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($W_{.3}(z)$, $I_{TA.3}(z)$ x 1 cm^2)], where $z \geq z_{bp}$ (centimeters).
Z_{bp}	$1.69\sqrt{A_{aprt}}$ (centimeters).
z_{sp}	The axial distance at which TIB is a global maximum (i.e., $z_{sp} = z_{B.3}$) (centimeters).

Symbol	Description
$z@PII_{.3max}$	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 $[(4/\pi)(W_o/I_{TA}(z))]^{0.5}$ where $I_{TA}(z)$ is the temporal-average intensity as a function of z (centimeters).
fc	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).

The acoustic output information is provided in the tables below for each probe/mode combination. This information includes global maximum index values, associated acoustic and probe parameters, and relevant operating control conditions.

Table 16-10 lists and describes the Acoustic Output Format for B-mode.

Probe Model: Butterfly iQ™

Operating Mode: B-mode

Table 16-10 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/cm^2)	54.6					
Operating Control Conditions	FAST preset		✓					
	Abdomen deep			✓				
Note 1:	Information need not be provided for any formulation of *TIS* not yielding the maximum value of *TIS* for that mode.							
Note 2:	Information need not be provided regarding *TIC* for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.							

Index Label		MI	TIS		TIB	TIC
			Scan	Non-Scan	Non-Scan	
				$A_{aprt} \leq 1\ cm^2$	$A_{aprt} > 1\ cm^2$	
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 16-11 lists and describes the Acoustic Output Format for B-mode + Color.

Probe Model: Butterfly iQ™

Operating Mode: B-mode + Color

Table 16-11 B-mode + Color

Index Label			MI	TIS			TIB	TIC
				Scan	Non-Scan		Non-Scan	
					$A_{aprt} \leq 1\ cm^2$	$A_{aprt} > 1\ cm^2$		
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)		-	-	1.3	1.3	(a)

Index Label			MI	TIS			TIB	TIC
				Scan	Non-Scan		Non-Scan	
					A_{aprt}≤1 cm^2	A_{aprt}>1 cm^2		
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/cm^2)	54.6					
Operating Control Conditions	FAST preset		✓					
	Bladder					✓	✓	
Note 1:	Information need not be provided for any formulation of *TIS* not yielding the maximum value of *TIS* for that mode.							
Note 2:	Information need not be provided regarding *TIC* 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 16-12 lists and describes the Acoustic Output Format for B+M-mode.

Probe Model: Butterfly iQ™

Operating Mode: B+M-mode

Table 16-12 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/cm^2)	54.6					
Operating Control Conditions	FAST preset		✓					
	Abdomen deep			✓				
	Cardiac THI						✓	
Note 1:	Information need not be provided for any formulation of *TIS* not yielding the maximum value of *TIS* for that mode.							
Note 2:	Information need not be provided regarding *TIC* 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 16-12 B+M-mode

Index Label		MI	TIS			TIB	TIC
			Scan	Non-Scan		Non-Scan	
				$A_{aprt} \leq 1\ cm^2$	$A_{aprt} > 1\ cm^2$		
(a)	Intended use does not include cephalic so TIC is not computed.						

Measurement Accuracy

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

M-mode

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

B-mode

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

Color Doppler

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

Safety

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

Recycling and Disposal

Recycle the Butterfly iQ™'s 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.

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.

Chapter 17
Symbols

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

Symbols

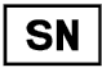
Table 17-1 lists and describes a set of symbols for medical electronic equipment that classify a connection or warn of potential hazards. The symbols listed in Table 17-1 may be used on the Butterfly iQ™, and on its accessories and packaging.

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 17-1 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.

Symbol	Standard	Reference	Title	Description
GTIN	--	--	Globa 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.
LOT	ISO 15223-1	5.1.5	Batch code	Identifies the manufacturer's batch code so that the batch or lot can be identified.
MOD	--	--	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 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.

Symbol	Standard	Reference	Title	Description
	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	Indicted 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 20120/19/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

Notes