

Butterfly iQ Vet™/ iQ+ Vet™ Personal Ultrasound System

User Manual



Notice

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

Proprietary Information

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

Limited Warranty

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

Copyright

Copyright © 2023 Butterfly Network, Inc. All Rights Reserved.

Trademark Acknowledgements

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

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

Android is a trademark of Google LLC.

Legal Notice

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

Manufacturer

Butterfly Network, Inc. 1600 District Ave, Burlington, MA 01803 USA

Telephone: +1 (855) 296-6188

General inquiries: info@butterflynetwork.com

Support and service: support.butterflynetwork.com

Website: www.butterflynetwork.com



US Patents

Listing of applicable U.S. Patents in compliance with 35 U.S.C. §287: www.butterflynetwork.com/patents

Disclaimer

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

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

Table of Contents

1. Introduction	5
1.1. Overview	5
1.2. Intended Uses	5
1.3. Indications for Use	5
1.4. Contraindications for Use	6
1.5. Training	6
2. Safety Information	7
2.1. Safety Conventions	7
2.2. Ultrasound Benefits and Risks	7
2.2.1. Ultrasound Benefits	7
2.2.2. Ultrasound Risks	7
2.3. Butterfly iQ Vet/iQ+ Vet Safety	8
2.4. Basic Safety/Usage Environment	8
2.5. Electrical Safety	10
2.6. Defibrillation Safety	11
2.7. Equipment Protection	12
2.8. Biological Safety	12
3. System Overview	13
3.1. Overview	13
3.2. Modes	13
3.3. Measurements	13
3.4. Probe Types	14
3.5. Patient Data Protection	14
3.6. Internet Connectivity	14
3.7. System Components	14
3.7.1. Butterfly iQ App	15
3.7.2. Probe	16
3.7.3. Probe Battery Charger	17
3.8. Overview of User Interface	18
3.9. Presets	18
4. Setting Up the System	19
4.1. Downloading and Installing the App	19
4.2. Updating Firmware	19
4.3. Managing App Updates	19
4.4. Charging the Probe	20
4.5. Checking Probe Battery Level	22
5. Using the System	23
5.1. Performing a Study	23
5.2. Uploading to Butterfly Cloud	24
5.3. Using the Probe Button Functionality	24
5.3.1. Using the Probe Button Push capture functionality:	24
5.3.2. Using the Probe Button Push unfreeze functionality:	24
6. Using Modes	25
6.1. Using B-Mode	25
6.2. Using Color Doppler Mode	25
6.3. Using M-Mode	25
6.4. Using Biplane Imaging™ (Butterfly iQ+ Vet only)	26
7. Using the Needle Viz™ (in plane) Tool	27
7.1. Introduction	27
7.2. Using Needle Viz (in-plane)	27
8. Annotations	29
8.1. Adding Annotations	29
8.2. Using Protocols	30
9. Using Butterfly Cloud	32

9.1. Overview	32
9.2. Accessing Butterfly Cloud	32
9.3. Viewing and Managing Studies	32
10. Using Butterfly TeleGuidance	34
10.1. Overview	34
11. Maintenance	35
11.1. Maintaining the Probe	35
11.2. Cleaning and Disinfecting the Probe	36
11.2.1. Cleaning the Probe	37
11.2.2. Disinfecting the Probe	37
11.3. High Level Disinfection	39
11.4. Updating the Probe and App Software	40
11.5. Performing the Probe Diagnostic Test	40
11.6. Replacing the Cable on Butterfly iQ+ Vet	40
12. Troubleshooting	46
12.1. Troubleshooting	46
13. Getting Support	48
13.1. Contacting Butterfly Support	48
13.2. Contacting Support through the Butterfly iQ App	48
14. Specifications	49
14.1. Mobile Device Requirements	49
14.2. System Specifications	49
14.3. Probe Battery Charger	50
14.4. Environmental Operating Conditions	50
14.5. Electromagnetic Conformance (EMC)	51
14.5.1. Separation Distances	52
14.6. Acoustic Output	52
14.6.1. Acoustic Output Limits	53
14.6.2. Acoustic Output Tables	53
14.7. Measurement Accuracy	60
14.8. Waste Electrical and Electronic Equipment	60
14.9. Recycling and Disposal	60
15. Symbols	61
15.1. Symbols	61
16. Notes	64

1. Introduction

This chapter provides an introduction to the Butterfly iQ Vet/iQ+ Vet Personal Ultrasound System.

1.1. Overview

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

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



NOTE

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

1.2. Intended Uses



CAUTION!

Federal law restricts this device to sale to or on the order of a licensed veterinarian.

Butterfly iQ Vet/iQ+ Vet is a general-purpose diagnostic ultrasound imaging system for use by trained veterinary professionals enabling diagnostic imaging, measurement of anatomical structures and fluid, and other applicable tools.

1.3. Indications for Use



NOTE

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

Butterfly iQ Vet/iQ+ Vet is indicated for use by trained veterinary professionals in environments where animal healthcare is provided to enable diagnostic ultrasound imaging and measurement of anatomical structures and fluids for the following clinical applications:

- Peripheral Vessel (venous and arterial studies)
- Procedural Guidance
- Small Organs

- Cardiac
- Abdominal
- Urology
- Fetal/Obstetric
- Gynecological
- Musculoskeletal

Modes of operation include:

Mode	Butterfly iQ Vet	Butterfly iQ+ Vet
B-Mode	✓	✓
B-Mode + M-Mode	✓	✓
B-Mode + Color Doppler	✓	✓
B-Mode + Biplane	-	✓
B-Mode + NeedleViz™ Tool	-	✓
B-Mode + Biplane + NeedleViz™ Tool	-	✓

Use Butterfly iQ Vet/iQ+ Vet 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.

1.4. Contraindications for Use

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

1.5. Training

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

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

2. Safety Information

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

2.1. Safety Conventions

**WARNING!**

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

**CAUTION!**

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

This user manual is intended to assist in the safe and effective operation of Butterfly iQ Vet/iQ+ Vet. 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:

2.2. 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.

2.2.1. Ultrasound Benefits

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

2.2.2. 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.

Any serious incident that occurs in relation to the device should be reported to the manufacturer at <http://support.butterflynetwork.com> (and to the competent authority of the EU Member State in which the incident occurred, if applicable).

2.3. Butterfly iQ Vet/iQ+ Vet Safety



WARNINGS!

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

2.4. Basic Safety/Usage Environment



WARNING!

Butterfly iQ Vet/iQ+ Vet 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 Vet/iQ+ Vet. 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). Submit a ticket for support at: support.butterflynetwork.com
- Do not use Butterfly iQ Vet/iQ+ Vet in the presence of flammable gases or anesthetics. Doing so can result in a possible fire or explosion.
- Butterfly iQ Vet/iQ+ Vet 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 Vet/iQ+ Vet is not to be used in the presence of flammable substances/air mixtures.
- Do not use the Butterfly iQ Application on a mobile device that does not meet minimum requirements. Using the Butterfly iQ Application on a mobile device that does not meet the minimum requirements may affect performance and image quality, possibly resulting in misdiagnosis.
- Spilling fluids into the system may damage it or present a fire or shock hazard. Do not allow fluids to enter the device.
- Store only within the range of environmental conditions specified in the technical specifications.
- Dangerous high voltages and currents are present. There are no user-serviceable parts. Do not open, remove covers, or attempt repair.
- Portable and mobile radio-frequency (RF) communications equipment can affect Medical Electrical Equipment.
- Internet access is required to view the user manual and Butterfly support portal. If you intend to use Butterfly iQ Vet/iQ+ Vet without an internet connection download the user manual locally by visiting support.butterflynetwork.com.
- Use of damaged equipment or accessories may cause the device to perform improperly and/or result in injury to the patient or operator. Refer servicing to qualified service personnel.
- No modification is allowed. Do not modify cables, probes, chargers, or accessories specified for use with Butterfly iQ Vet/iQ+ Vet. Modification to equipment may cause the system to perform improperly or may cause injury to the patient or operator.
- When the probe is used in a home environment, the probe should be stored away to prevent any harm from or to pets, pests, or children.
- When the probe is used in a home environment, it is imperative that the cord be properly wrapped around the probe when not in use to avoid the potential for accidental strangulation.



CAUTIONS!

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

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



WARNINGS!

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



CAUTIONS!

- Notifications and alerts from other third-party applications running on the mobile device may interfere with the study.

Class designation	Butterfly iQ Vet	Butterfly iQ+ Vet	Notes
CISPR 11 Group 1 Class A	✓	✓	Devices in this class are suitable for use in industrial areas and hospitals.
CISPR 11 Group 1 Class B	-	✓	Devices in this class are suitable for use in a residential environment. If the device does not meet this designation, the equipment might not offer adequate protection to radio-frequency communication services and the user might need to take mitigation measures, such as relocation or re-orienting the the equipment.

- Do not use probe with a cable that has visible damage. Damage includes, but is not limited to, cable insulation cracks, exposed wires, fraying, or any other visible wear.
- Use of the device with visible cable damage may result in injury to the user and/or patient.

2.6. 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.

2.7. 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 Vet/iQ+ Vet not to function. Maintain the equipment only as described in the maintenance section.
- Do not sterilize or autoclave the Butterfly iQ Vet/iQ+ Vet or its accessories.

2.8. 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 the section on “Ultrasound Safety” under [Acoustic Output \[52\]](#).
- If Butterfly iQ Vet/iQ+ Vet is contaminated due to exposure to any prion disease, there is no adequate disinfecting procedure.
- Do not allow the animal to contact live parts of the ultrasound system or other devices, e.g., signal I/O ports. Electrical shock may occur.
- Use the correct clinical application presets for the associated body part being examined. Some applications require lower acoustic output limits.
- There are no latex parts in the probe. However, some probe sheaths may contain natural latex, which can cause allergic reactions in some people.
- If performing procedures that require transducer covers, follow your institution’s protocol and/or the instructions provided with the covers.
- This product can expose you to chemicals including Carbon black, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.



CAUTION!

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

3. System Overview

This chapter provides an overview of Butterfly iQ Vet/iQ+ Vet. 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.



NOTES

- Depending on your platform, hardware, country and membership type, certain presets, modes and features may not be available.
- The Butterfly iQ Vet/iQ+ Vet and its accessories may be used multiple times on multiple patients.

3.1. Overview

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

- Compatible Apple® or Android personal mobile electronic devices (phones and tablets). Referred to as the mobile device throughout the manual.
- The Butterfly iQ Application (App), downloaded and installed on the compatible mobile device
- The Butterfly iQ Vet/iQ+ Vet Probe that connects to the mobile device to generate and receive ultrasound signals



NOTE

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

3.2. Modes

Butterfly iQ Vet/iQ+ Vet provides the following modes:

Mode	Butterfly iQ Vet	Butterfly iQ+ Vet
B-Mode	✓	✓
B-Mode + M-Mode	✓	✓
B-Mode + Color Doppler	✓	✓
B-Mode + Biplane	-	✓
B-Mode + NeedleViz™ Tool	-	✓
B-Mode + Biplane + NeedleViz™ Tool	-	✓

3.3. Measurements

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

3.4. Probe Types

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

3.5. 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.

3.6. Internet Connectivity

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

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

3.7. System Components

**WARNING!**

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

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

**NOTE**

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

3.7.1. Butterfly iQ App

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

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



NOTE

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

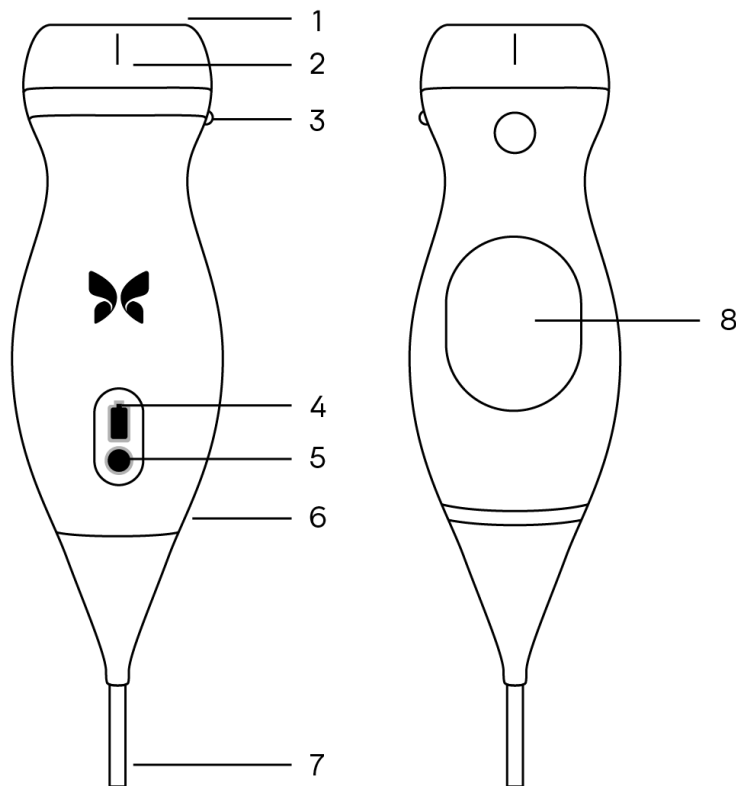
3.7.2. Probe

**WARNING!**

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

The Butterfly iQ Vet/iQ+ Vet probe is only for use with the Butterfly iQ App. Do not attempt to connect the probe to other ultrasound systems. [Figure 1, "Probe Components" \[16\]](#) shows the parts of the probe and describes its parts.

Figure 1. Probe Components



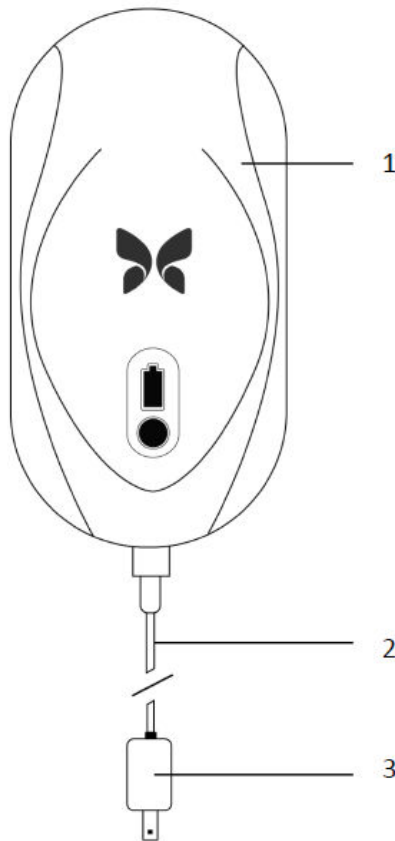
1. Lens
2. Midline Mark
3. Orientation Mark
4. Battery Indicator Lights
5. Battery Indicator Button
6. Probe/Cable Boundary
7. Mobile Device Cable
8. Charging Source

3.7.3. Probe Battery Charger

Only use the charger supplied with the probe.

Figure 2, “Charging Pad Components” [17] shows the battery charging accessories.

Figure 2. Charging Pad Components



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



NOTE

The latest Butterfly iQ Vet/iQ+ Vet charger has a matte black finish and curved probe cradle. If you have a previous model please see [Probe Battery Charger \[50\]](#) for additional information on charging your probe.

3.8. Overview of User Interface

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

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

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

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

3.9. Presets

Presets are a predefined set of imaging parameter values. When selected, the Butterfly iQ App automatically operates in accordance with the corresponding set of imaging parameter values. Presets available correspond to the clinical applications details in [Indications for Use \[5\]](#). Preset availability may also vary depending on probe, Butterfly membership status and geographic location.

4. Setting Up the System

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

4.1. Downloading and Installing the App

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

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



NOTE

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

4.2. Updating Firmware

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

4.3. Managing App Updates



CAUTIONS!

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

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

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

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

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

4.4. Charging the Probe



WARNINGS!

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



CAUTIONS!

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

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

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

Place the probe on the charger in the orientation shown below

Figure 3. 3rd Generation Probe Charger





NOTE

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

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

To charge the probe:

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

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



NOTE

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

4.5. Checking Probe Battery Level

Use the Battery Indicator Button and Battery Indicator Lights on the probe to check the battery level. For reference, see [Probe \[16\]](#)

Table 1. Probe Battery Level Indicators

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

To check the probe battery level using the probe:

1. Press the Battery Indicator Button to view the Battery Indicator Lights.
2. If the first button flashes, it indicates that the probe battery charge is too low to perform the study.
3. If the lights do not flash at all:
 - a. Open the Butterfly iQ App.
 - b. Navigate to the scan screen.
 - c. Wait 10 seconds until the “Run troubleshooting” button appears.
 - d. Follow the troubleshooting steps.

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




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


5. Using the System

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


5.1. Performing a Study

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

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

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

To conclude a patient encounter, click on the capture reel and follow the steps on screen to upload the study.

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



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).
- The ability to rotate from portrait mode to landscape mode while scanning is only available on iPad.

If you do choose to enter patient data in the study, you may do so from the Capture Reel.

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

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

5.2. Uploading to Butterfly Cloud



NOTE

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

To archive a study:

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

5.3. Using the Probe Button Functionality

When using a Butterfly iQ Vet/ iQ+ Vet probe, pressing the probe button can result in one of the following actions: capture a still, capture a cine, or unfreeze the image. The probe button push feature is on by default and it could be adjusted from the preferences menu in the Butterfly iQ app.

5.3.1. Using the Probe Button Push capture functionality:

In order to adjust the actions associated with the Button Push for capturing:

1. Plug in the Butterfly iQ Vet/ iQ+ Vet probe and enter the Profile menu at the bottom right of the screen by clicking the initials, or your avatar.
2. Select the item "Probe button actions".
3. The capture functionality is enabled by default, to turn it off, toggle to the left to deactivate it, or toggle back to the right to activate it again.
4. From the same menu you can choose the action associated with pressing the button during live imaging: the available options are "Capture image" and "Start/stop cine".
5. Return to the scan screen, and start or resume scanning.
6. In order to use the functionality, press the button on the probe.

5.3.2. Using the Probe Button Push unfreeze functionality:

In order to adjust the actions associated with the Button Push for unfreezing an image:

1. Plug in the Butterfly iQ Vet/ iQ+ Vet probe and enter the Profile menu at the bottom right of the screen by clicking the initials, or your avatar.
2. Select the item "Probe button actions".
3. The unfreeze functionality is enabled by default, to turn it off, toggle the option titled: "Unfreeze with battery button" to the left to deactivate it, or toggle back to the right to activate it again.
4. Return to the scan screen, and start or resume scanning.
5. In order to use the functionality, press the button on the probe to unfreeze when auto-freeze is initiated.

6. Using Modes


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



NOTE

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

6.1. Using B-Mode

The B-Mode is the default image displayed when selecting a preset. The brightness of the individual pixels indicates the strength of the echo reflected signal from the tissue. Some presets, such as Cardiac, have multiple versions of the B-Mode which can be accessed through the presets filter button . Tapping on the filter button changes the B-Mode image, giving the user the control over the preferred image to use for diagnosis.

6.2. Using Color Doppler Mode

When using Color Doppler, you can:

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


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

Color gain and depth controls are available during Doppler imaging.

6.3. Using M-Mode

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

When using M-Mode, you can:

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

Accessing M-Mode

1. Select your desired preset and identify the area you'd like to image. Note that imaging will begin on B-Mode.
2. Select Actions on the bottom of the imaging screen.
3. Under Modes, select M-Mode.

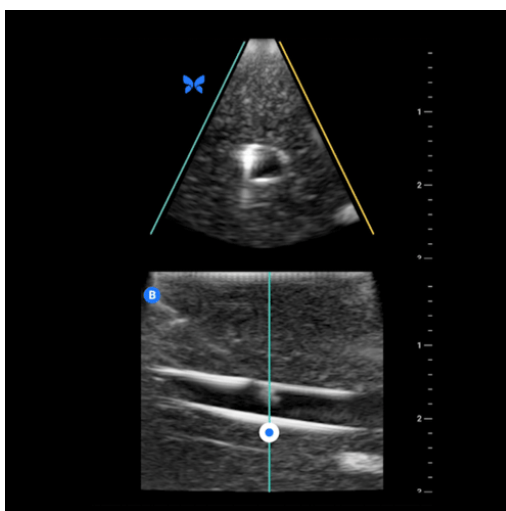
6.4. Using Biplane Imaging™ (Butterfly iQ+ Vet only)

Biplane Imaging is a qualitative mode that displays two planes of imaging, along the longitudinal axis of the probe and the transverse axis of the probe. The longitudinal axis is displayed on the bottom of the screen, called the “reference plane” and the transverse axis is displayed on the top of the screen, called the “perpendicular plane”.

Biplane Imaging is available in the Bladder, Musculoskeletal, Musculoskeletal Equine, and Vascular presets.

When using Biplane, you can:

- View and adjust the position of the perpendicular plane with respect to the reference plane
- Optimize the gain and depth simultaneously in both planes
- Freeze still images and measure in either viewport
- Capture cines and stills
- Activate Needle Viz (In-Plane) tool



In order to start using Biplane Imaging:

1. Enter a preset in which Biplane Imaging is available. Activate Biplane from the actions menu
2. Apply gel to the probe and start scanning
3. To adjust the position of the perpendicular plane, touch and drag the white dot side-to-side in the longitudinal (bottom) plane
4. Freeze, measure, annotate, and capture tools, as well as gain and depth adjustment, are available within Biplane
5. To simultaneously use the Needle Viz (in-plane) tool, activate the tool from the actions menu. The reference plane will display the region-of-interest within which an in-plane needle will be highlighted. Additionally, if the needle crosses the perpendicular plane indicator, the position of the needle in the out-of-plane view will be projected upon the perpendicular plane. To flip the position of the region-of-interest, tap the flip button.

7. Using the Needle Viz™ (in plane) Tool



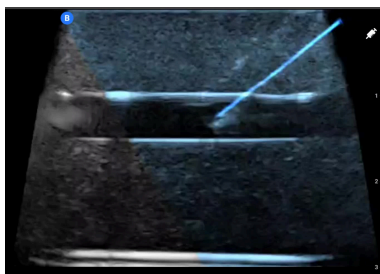
WARNING!

When used alone, the Needle Viz (in-plane) tool will NOT enhance the visualization of needles inserted out-of-plane.

7.1. Introduction

Needle Viz (in-plane) is a tool that overlays a B-mode image optimized for visualizing needles inserted at a 20-40 degree angle on top of regular B-mode. A region of interest in which the needle may be visualized is represented with a blue-tint, and the location of the region of interest (ROI) may be adjusted using the flip button. Needle Viz (in-plane) is available on Butterfly iQ+ Vet in the following presets: Bladder, Musculoskeletal, Musculoskeletal Equine, Small Organ, and Vascular presets. When using Needle Viz (in-plane), you can:

- Adjust the needle approach depth and gain.
- Adjust scan depth.
- Customize needle gain.
- Activate Biplane Imaging



7.2. Using Needle Viz (in-plane)

In order to start using Needle Viz (in-plane):



NOTE

When using Needle Viz (in-plane) with Biplane Imaging, the position of the needle in the perpendicular plane is only highlighted if the needle is visible in-plane in the reference plane, and therefore in the midline of the perpendicular plane. The needle will be visible in the perpendicular plane, but the appearance will not be enhanced if the needle is not visible in the reference plane.

1. From the preset picker, select one of the following presets on Butterfly iQ+ Vet: Bladder, Musculoskeletal, Musculoskeletal Equine, Small Organ, or Vascular preset.
2. Select the Actions button on the bottom right corner of the screen.
3. Under the "Tools" heading, select Needle Viz (in-plane).
4. At the bottom of the screen, select "From left" or "From right" to indicate the direction of needle approach.

5. At the bottom of the screen, select 40°, 30°, or 20° to adjust the angle based on the angle of the needle approach.
6. To adjust the gain of the needle, swipe right or left on the screen. If you need to adjust the gain of the image, exit Needle Viz, adjust the gain to your satisfaction, then reactivate Needle Viz.

8. 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.



8.1. Adding Annotations

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

Adding Annotations During Live Scanning

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


Adding Annotations to Frozen Images

Tap the freeze  icon to first freeze the image. then select the Actions menu .


Adding a Text Annotation

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


Performing Linear Measurements

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

Performing an Area Measurement

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

Adding Annotations to Images or Clips in the Capture Reel

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


8.2. Using Protocols

With the Butterfly Protocols, you can follow common exam types and easily label scans of the appropriate views. The available protocols can be found with the relevant presets below:

- Abdominal FAST Protocol:
 - Abdomen Preset.
 - Abdomen Deep Preset.
- Thoracic FAST Protocol:
 - Abdomen Preset.
 - Abdomen Deep Preset.
 - Lung Preset.
 - Cardiac Preset.
 - Cardiac Harmonics Preset.
 - Cardiac Deep Preset.
 - Cardiac Deep Harmonics Preset.
- FLASH Protocol:
 - Abdomen Deep Preset.

Our Protocol features help veterinarians streamline labeling, potentially increasing efficiency during ultrasound exams to reduce the amount of time spent with each patient. Protocols are available for Butterfly Pro, Pro Team, and Enterprise users.

Adding a label via protocols



1. From the scan screen, select the appropriate preset.
2. Open the actions menu  and press the desired protocol button. The view picker displaying the relevant views for that protocol will appear on the screen.
3. Tap the view you would like to scan.
4. A label will automatically appear at the bottom of the scan screen for the view selected.
5. Capture either a cine or still image.
6. After image or cine capture, the view picker will return. A checkmark indicates that the view has already been captured and labeled.
7. Tap a view to continue labeling.



NOTE

All protocol views are optional. You may select any view, including views you have already acquired if you would like to capture multiple examples of that view.

Editing the Protocol View Label

1. Tap the view label to activate editing. A pencil will appear next to the label .
2. To move the view label, drag the label to the desired position while editing is active.
3. To change the view, tap the pencil . The view picker will reappear and a new view can be selected.

Exiting the Protocol

You can exit the protocol in the following ways:

1. Tap "Exit workflow" in the view picker.
2. Change the preset.
3. Upload a study.
4. Tap the X next to the Protocol button.



NOTE

When you exit a protocol, the images captured using the protocol remain saved in the Exam Reel for review and upload. However, the view picker progress will be reset.

9. Using Butterfly Cloud

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



NOTE

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

9.1. Overview

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

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

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

9.2. Accessing Butterfly Cloud

Butterfly Cloud can be accessed from both the Butterfly iQ App as well as a desktop web browser at cloud.butterflynetwork.com.

Log in to Butterfly Cloud with your Butterfly email and password.

9.3. Viewing and Managing Studies

Viewing a Study

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

Moving a Study to a New Archive

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

Deleting a Study

1. Log in to Butterfly Cloud.

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

For additional information please visit support.butterflynetwork.com.

10. Using Butterfly TeleGuidance

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



NOTES

- Depending on your platform, hardware, country and membership type, certain presets, modes and features may not be available.
- The Butterfly iQ Vet/iQ+ Vet and its accessories may be used multiple times on multiple patients.

10.1. Overview

A TeleGuidance call requires both a scanner and remote collaborator.



CAUTION!

Butterfly TeleGuidance must only be used between two veterinary professionals.

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

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

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

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

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

11. Maintenance

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

11.1. Maintaining the Probe

Receiving and Unboxing the Probe

In the event the packaging of the device is damaged upon receipt of the system, inspect the components as listed in [System Components \[14\]](#) for any visible damage. Confirm system functionality per [Performing the Probe Diagnostic Test \[40\]](#). If there is any visible damage or if the system is not functioning properly as received, contact the Butterfly Support team using one of the methods listed in [Getting Support \[48\]](#).

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. Avoid swinging the probe or supporting the probe solely from its cable.

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

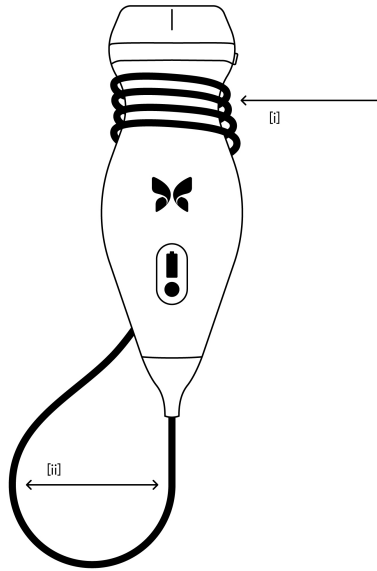
Follow these steps for daily storage and transport:

- When storing the probe, wrap the cable around the probe so that there is some slack at the bottom of the probe. See [Figure 4, “Wrapping the Cable” \[36\]](#) for reference.
- Avoid placing or storing in areas of excessive hot or cold temperatures or direct sunlight.
- Avoid placing or storing with other equipment or objects that may inadvertently damage the probe, particularly the face.
- Avoid contamination by:
 - Following the cleaning and disinfecting instructions.
 - Making sure the equipment is dry.
 - Carefully handling the probe to prevent damaging the equipment.



CAUTIONS! - CABLE WRAPPING

- Leave some slack in the cable where it connects to the probe so as to reduce pinching or other damage to the cable. As shown in [Figure 4, “Wrapping the Cable” \[36\]](#) [i] Loosely wrap the remaining cable around the probe and [ii] leave 2 inches minimum. Please do not wrap the cable around other objects or in any parts of carrying cases that are not Butterfly approved or recommended.
- Insufficient slack may damage the cable and cause premature failure of the cable wires.

Figure 4. Wrapping the Cable

11.2. Cleaning and Disinfecting the Probe

**WARNING!**

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

**CAUTION!**

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

This section provides information and instructions for properly cleaning and disinfecting the Butterfly iQ Vet/iQ+ Vet 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 Vet/iQ+ Vet.

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

11.2.1. Cleaning the Probe



CAUTIONS!

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

To clean the probe:

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

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

11.2.2. Disinfecting the Probe



WARNING!

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

After cleaning the probe, you must disinfect the probe.

To reduce the risk of contamination and infection, it is important to choose the appropriate level of disinfection, based on prior exam usage and whether the use is classified as non-critical or semi-critical. Use [Table 2, "Probe Disinfection Class, Use, and Method" \[37\]](#) to determine the appropriate class and then follow the appropriate intermediate-level or high-level disinfection procedure.

Table 2. Probe Disinfection Class, Use, and Method

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

Intermediate-Level Disinfection (ILD)

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

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

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

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

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

11.3. High Level Disinfection

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

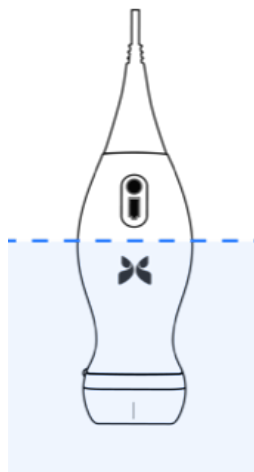
Making sure your probe is compatible with HLD:

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

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

1. After cleaning the probe, you must disinfect the probe. It is recommended that you use Cidex® OPA high-level disinfection solution.
2. Prepare Cidex® OPA high-level disinfection solution for use per the manufacturer's instructions. Fill a tray or basin with the disinfectant solution at room temperature (minimum temperature of 20°C) to a level allowing immersion of the probe up to the immersion line (the dashed line shown in [Figure 5, "Probe Immersion Line" \[39\]](#).
3. Immerse the probe in Cidex® OPA solution up to the immersion line and ensure no air or bubbles are trapped. Allow soaking according to the manufacturer's instructions.
4. Thoroughly rinse the probe (up to the immersion line) by immersing it in a large volume of room temperature critical (purified) water for a minimum of one (1) minute. Remove the probe and discard the rinse water. Do not reuse the water. Always use fresh volumes of water for each rinse. Repeat this stage two (2) additional times for a total of three (3) rinses.
5. Thoroughly dry all surfaces of the device using a sterile, lint-free wipe or cloth, changing wipes/cloths when necessary to ensure the device is completely dry. Visually inspect the device to ensure all surfaces are clean and dry. Repeat the drying steps if any moisture is visible.
6. Once clean and disinfected, visually inspect the probe, strain relief, cable, and connector for signs of damage or wear.

Figure 5. Probe Immersion Line



11.4. Updating the Probe and App Software

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

11.5. Performing the Probe Diagnostic Test

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

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

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

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

To perform the probe diagnostic test:

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

11.6. Replacing the Cable on Butterfly iQ+ Vet



CAUTION

Refrain from excessively removing and installing a cable, as this will lead to premature wear of the o-ring and enable water and dust ingress.



NOTE

Probe cable swap is only available on the Butterfly iQ+ Vet. Attempting to detach the cable on the Butterfly iQ Vet is not supported and may result to permanent damage to the device.

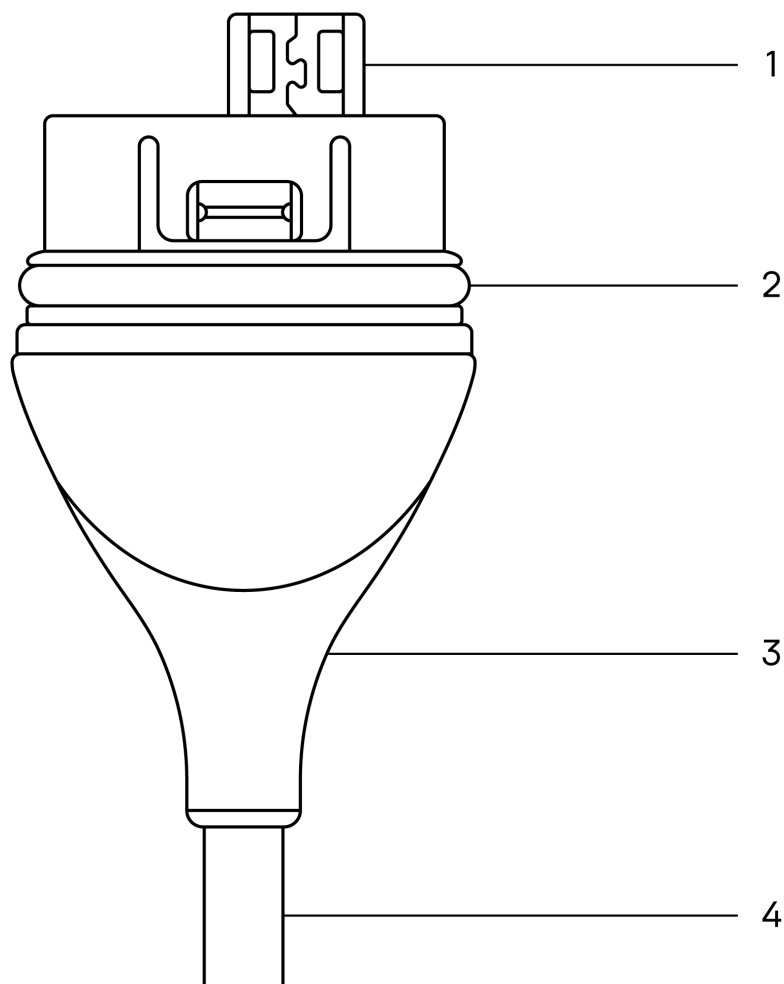
The cable on the Butterfly iQ+ Vet probe can be replaced in the case of damage or a mobile device with a different connector type needs to be used. The probe and cable compatibility is summarized in [Table 3, "Probe and Replaceable Cable Compatibility"](#) [40], "Probe and Replaceable Cable Compatibility".

Table 3. Probe and Replaceable Cable Compatibility

Probe	Accessory Cables	Model Number	Package SKU Number (if applicable)
Butterfly iQ Vet Model Number: 850-20015	WARNING: Cable is not removable. Do not attempt to remove/replace the cable.	-	-

Probe	Accessory Cables	Model Number	Package SKU Number (if applicable)
Butterfly iQ+ Vet Model Number: 850-20023	Butterfly iQ+ Accessory Cable, Lightning, 1.50M	490-00189-02	900-20010-12
	Butterfly iQ+ Accessory Cable, USB-C, 1.50M	490-00187-02	900-20011-12
	Butterfly iQ+ Accessory Cable, Lightning, 2.50M	490-00189-03	900-20010-13
	Butterfly iQ+ Accessory Cable, USB-C, 2.50M	490-00187-03	900-20011-13

Figure 6. Butterfly iQ+ Vet Cable Components

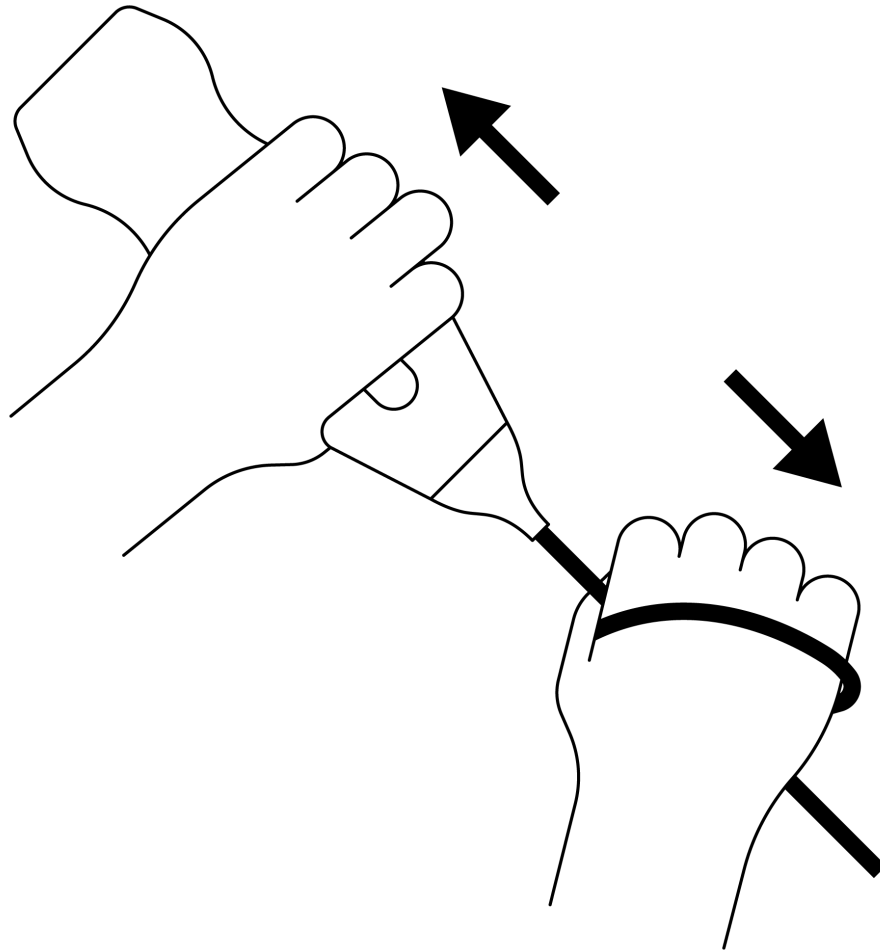


1. USB Plug
2. O-Ring
3. Strain Relief
4. Cord

Replacing the Butterfly iQ+ Vet Cable

1. Remove the existing cable from the Butterfly iQ+ Vet probe. Wrap the probe cable around your wrist while holding the probe firmly in the other hand. Pull the two apart. Do not use tools to grab the strain relief or the cord, as doing so might damage the cable.

Figure 7. Removing the Butterfly iQ+ Vet cable



2. Align the connector and the probe, and push the cable firmly into the probe body. When the cable is fully installed, it should be expected that there will be a small gap between the strain relief and the probe body.

Figure 8. Align the Butterfly iQ+ Vet cable prior to installation

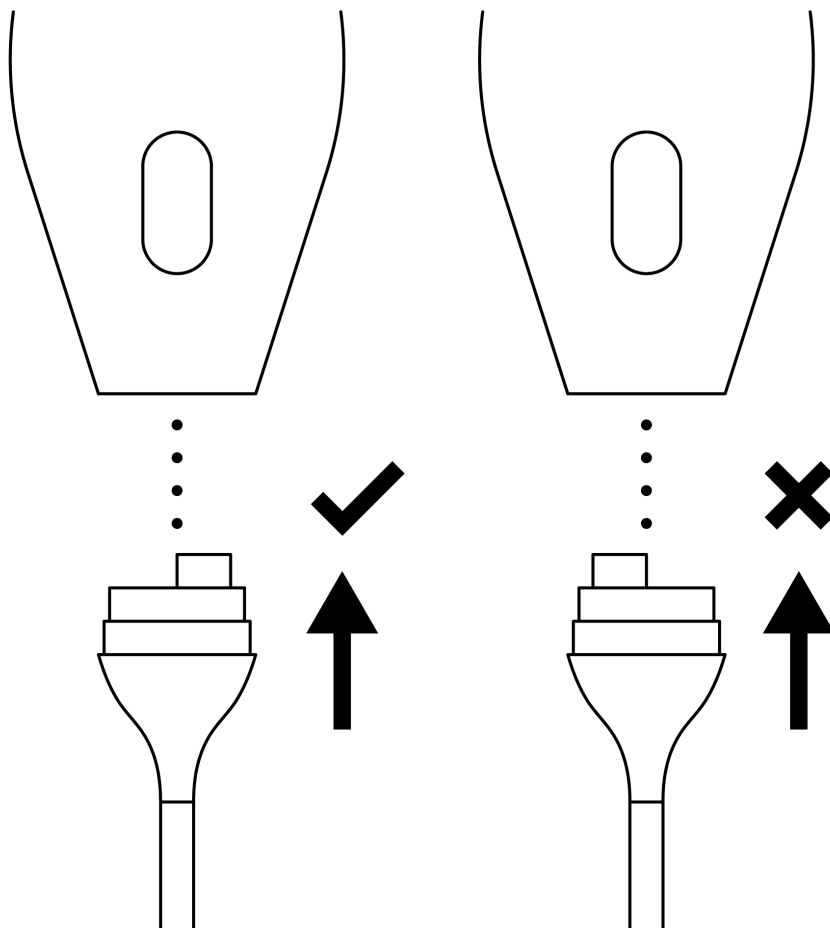
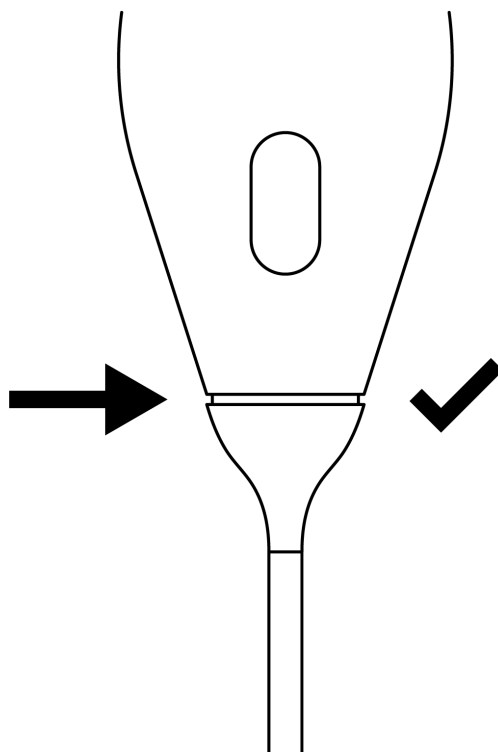


Figure 9. Expected gap between the cable strain relief and probe body after installing the Butterfly iQ+ Vet cable.



If planning on submerging the probe to disinfect the probe using HLD:

1. The probe should never be fully submerged in HLD solution. Refer to [High Level Disinfection \[39\]](#) to see the appropriate submersion line.
2. Carefully inspect the O-ring whenever installing a new cable to make sure it is not damaged. See [Figure 6, "Butterfly iQ+ Vet Cable Components" \[42\]](#) above for an explanation of the location of the o-ring and other cable components.
3. Ensure cable is fully inserted.

12. 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 \[48\]](#) for more information.

12.1. Troubleshooting



CAUTION!

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

[Troubleshooting \[46\]](#) lists the troubleshooting issues and resolutions. See [Getting Support \[48\]](#) for more information.



NOTES

- If you are unable to resolve an issue, please note the issue and report it to Support for assistance. For more information, see [Getting Support \[48\]](#).
- Call a veterinary professional for emergency assistance if troubleshooting reveals a patient health problem rather than a mobile device problem.
- To report a complaint or incident, submit form FDA 1932a "Veterinary Adverse Experience, Lack of Effectiveness or Product Defect Report", by visiting <https://www.fda.gov/animal-veterinary/report-problem/how-report-animal-drug-and-device-side-effects-and-product-problems>.
- To report a complaint or incident, contact the FDA Problem Reporting Program, MedWatch, at 1-800-332-1088, or on the Internet: www.fda.gov/Safety/MedWatch/.

Table 4. Troubleshooting

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

Issue	Resolution
Image degradation or occurrence of image artifacts	<p>Make sure you are using the appropriate preset and the depth is appropriate for the anatomy being scanned.</p> <p>Make sure the brightness on your screen is set to the recommended setting of 65%.</p> <p>To determine if your probe is damaged, activate the probe self-test. For details, see Performing the Probe Diagnostic Test [40]</p>
Study Issues	
Cannot upload a study; study remains in Outbox	<p>Make sure your mobile device has network connectivity (WiFi or a cellular connection).</p> <p>Butterfly Cloud service may be undergoing maintenance or may be unavailable. Try again later.</p>
Probe Issues	
Persistent probe connection error	Perform a hard reset:
Probe will not charge	<ol style="list-style-type: none"> 1. Disconnect the probe from the mobile device. 2. Press and hold the probe's Battery Indicator Button for 10-15 seconds until LEDs flash. 3. Repeat Step 2 and then try reconnecting the probe to the mobile device. 4. You may need to charge the probe for at least six (6) hours.
App Alerts and Messages	
App opens but cannot login: 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 Settings to enable and configure the passcode for your mobile device.
App opens but cannot log in: Login Error	<ul style="list-style-type: none"> • Make sure your mobile device has network connectivity (WiFi or a cellular connection). • Try to re-enter your credentials. • Reset your password using a desktop computer browser to access Butterfly Cloud (cloud.butterflynetwork.com) <p>If the steps above are not successful, it may indicate that Butterfly Cloud service is undergoing maintenance or is unavailable. Try again later.</p>
Hardware Recall alert appears	The probe cannot be used for imaging if this alert is displayed. Tap Contact Support and follow the on-screen instructions.
Forced Log Out alert appears	This indicates that your mobile device does not have a passcode. Butterfly iQ requires the mobile device to have a passcode for patient data security. Tap Settings to enable and configure the passcode for your mobile device.
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.

13. Getting Support

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

13.1. Contacting Butterfly Support

Butterfly Network, Inc.

1600 District Ave

Burlington, MA 01803 USA

Telephone: +1 (855) 296-6188

General inquiries: info@butterflynetwork.com

Support and service: support.butterflynetwork.com

Website: www.butterflynetwork.com

13.2. Contacting Support through the Butterfly iQ App

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

To access support:

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

14. 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.

14.1. Mobile Device Requirements



WARNING!

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

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



NOTE

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



14.2. System Specifications

Table 5. System Specifications

Item	Butterfly iQ Vet	Butterfly iQ+ Vet
Probe dimensions	185 x 56 x 35 mm (7.2 x 2.2 x 1.4 in.)	163 x 56 x 35 mm (6.4 x 2.2 x 1.4 in.)
Probe weight	313 grams (.69 lbs)	309 grams (.68 lbs)
Power	Battery (rechargeable)	
Battery Life	2 hours in B-Mode (typical new battery at 25°C). 2 hours refers to continuous scanning vs. traditional scanning patterns.	
Languages	The user interface and accompanying documentation is localized in English, Spanish, French, German, Italian, Polish, Portuguese, Dutch, Danish, Norwegian, Swedish, and Finnish.	
Display	Variable	
Min/Max scan depth	2 cm min / 30 cm max	
Ultrasound chip	Integrated CMOS chip	
Transducers	~9000-element CMUT	
Frequency Range	1-10 MHz	
Operating system	<ul style="list-style-type: none"> Apple devices require iOS 15.0 or newer. Not compatible with beta or unreleased versions. 	<ul style="list-style-type: none"> Apple devices require iOS 15.0 or newer. Not compatible with beta or unreleased versions. Google Pixel, OnePlus, and Samsung mobile devices require Android version 10 or newer. Not compatible with beta or unreleased versions.

14.3. Probe Battery Charger

Table 6. 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	5W
Wireless Charging Efficiency	> 73%	
Protection	Over voltage protection, Over current protection	
Dimensions	121 x 62 x 19mm	121 x 62 x 19mm
Color	Black	

14.4. Environmental Operating Conditions

Table 7, “Environmental Operating Conditions” [50] lists the environmental conditions for the Butterfly iQ Vet/iQ+ Vet probe only. For details on the mobile device on which you run the Butterfly iQ App, refer to the accompanying documentation for your mobile device.

Table 7. Environmental Operating Conditions

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

Given the device is handheld, it is expected that the device will be subject to various conditions and environments, including those present in the hospital, EMS, and home. While the device was designed to operate safely in wide range of environments and in varying conditions, care should still be taken to protect the device from extreme temperatures, shock, drop, and other extreme conditions.

14.5. Electromagnetic Conformance (EMC)

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

The Butterfly iQ Vet/iQ+ Vet has been designed for use within electromagnetic environments specified in [Table 8](#), “[Electromagnetic Emissions](#)” [51] and [Table 9](#), “[Electromagnetic Immunity](#)” [51]. To avoid radiated and conducted electromagnetic disturbances, the customer or the user of the Butterfly iQ Vet/iQ+ Vet should assure that it is used within these stated specifications.

Table 8. Electromagnetic Emissions

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
Emission Test	Compliance	
	Butterfly iQ Vet	Butterfly iQ+ Vet
RF emission CISPR 11 EN55011	Group 1 ^a	
RF emission CISPR 11 EN55011	Class A ^b	Class B ^c
Harmonic emission EN/IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions EN/IEC 6100-3-3	Not applicable	

^aThe Butterfly iQ Vet/iQ+ Vet 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.

^bThe Butterfly iQ Vet Ultrasound System is suitable for use in all establishments, excluding domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

^cThe Butterfly iQ+ Vet Ultrasound System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Table 9. Electromagnetic Immunity

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

Immunity Test	EN/IEC 60601 Test Level		Compliance Level		Electromagnetic Environment - Guidance
	Butterfly iQ Vet	Butterfly iQ+ Vet	Butterfly iQ Vet	Butterfly iQ+ Vet	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 6 GHz	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 6 GHz	electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b

^aField strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Butterfly iQ Vet/iQ+ Vet Ultrasound System is used exceeds the applicable RF compliance level above, the Butterfly iQ Vet/iQ+ Vet 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 Vet/iQ+ Vet Ultrasound System.

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

14.5.1. Separation Distances

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

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

Table 10. Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the ultrasound unit			
The ultrasound unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ultrasound unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ultrasound unit as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output of transmitter (P, in watts)	Separation distance according to frequency of transmitter (d in meters)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
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.			

14.6. Acoustic Output

Ultrasound Safety

Trained professionals should perform diagnostic ultrasound procedures safely for the intended purpose. Butterfly iQ Vet/iQ+ Vet Thermal Index (TI) and Mechanical Index (MI) acoustic safety limits are set to industry standards, and as a Track 3 device, are displayed on the display screen. The TI is displayed as either soft tissue (TIS) or bone (TIB), and only one of these indices is displayed at any given time, based on the clinical user setting of a selected exam. TI and MI are displayed in increments of 0.01 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:

- NEMA Standard, UD 3: "Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment", Revision 2
IEC 60601-2-37. Medical electrical equipment. Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment

- IEC 62359:2.0/AMD1:2017, Edition 2.0 Ultrasonics -- Field Characterization: Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasound fields

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

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

Although these acoustic output settings 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 bioeffects 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.

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

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

Probe Model	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Butterfly iQ Vet/iQ+ Vet	✓	✓	-	-	✓	B+M-Mode	-

14.6.1. Acoustic Output Limits

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

Non ophthalmic applications:

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

For additional information please visit support.butterflynetwork.com.

14.6.2. Acoustic Output Tables



NOTE

For complete definitions of the measurements used in [Acoustic Output Tables](#) please reference Table 201.101 in IEC 60601-2-37.

Acoustic Output Tables for Butterfly iQ Vet

Table 12. Butterfly iQ Vet B-Mode

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

Table 13. Butterfly iQ Vet B-Mode + Color

Index Label			MI	TIS			TIB	TIC
				Scan	Non-Scan		Non-Scan	
					A _{aprt} ≤ 1 cm ²	A _{aprt} > 1 cm ²		
Maximum Index Value			0.485	-	-	0.13	0.29	(a)
Assoc Acoustic Parameter	Pr.3	(MPa)	0.718					
	W ₀	(mW)		-	-		17.4	(a)
	min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]	(mW)				0.74		
	z ₁	(cm)				7.8		
	z _{bp}	(cm)				2.76		
	z _{sp}	(cm)	5.83				7.1	
	d _{eq} (z _{sp})	(cm)					1.84	
	f _c	(MHz)	2.19	-	-	2.49	2.49	(a)
	Dim of A _{aprt}	X (cm)		-	-	2.0	2.0	(a)
		Y (cm)		-	-	1.8	1.8	(a)
Other Information	PD	(μsec)	0.295					
	PRF	(Hz)	1066					
	p _r @PII _{max}	(MPa)	1.11					
	d _{eq} @PII _{max}	(cm)				1.84		
	Focal Length	FLx (cm)		-	-	10.0		
		FLy (cm)		-	-	10.0		
	I _{PA.3} @MI _{max}	(W/cm2)	54.6					
Operating Control Conditions	Preset: Bladder					✓	✓	
Note 1:	Information need not be provided for any formulation of <i>TIS</i> not yielding the maximum value of <i>TIS</i> for that mode.							
Note 2:	Information need not be provided regarding <i>TIC</i> for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.							
Note 3:	Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2aa) and 51.2 dd).							
(a)	Intended use does not include cephalic so TIC is not computed.							

Table 14. Butterfly iQ Vet 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 ₀	(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	FL _x (cm)		10.0	-	-		
		FL _y (cm)		INF	-	-		
	I _{PA.3} @MI _{max}	(W/cm2)	54.6					
Operating Control Conditions	Preset: Abdomen Deep		✓					
	Preset: Cardiac THI						✓	
Note 1:			Information need not be provided for any formulation of <i>TIS</i> not yielding the maximum value of <i>TIS</i> for that mode.					
Note 2:			Information need not be provided regarding <i>TIC</i> for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.					
Note 3:			Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2aa) and 51.2 dd).					
(a)			Intended use does not include cephalic so TIC is not computed.					

Acoustic Output Tables for Butterfly iQ+ Vet

Table 15. Butterfly iQ+ Vet B-Mode, Biplane

Index Label			MI	TIS		TIB	TIC	
				Scan	Non-Scan			Non-Scan
					A _{aprt} ≤ 1 cm ²	A _{aprt} > 1 cm ²		
Maximum Index Value			0.53	0.017	-	-	(a)	
Assoc Acoustic Parameter	Pr.3	(MPa)	0.94					
	W _o	(mW)		1.997	-		(a)	
	min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]	(mW)				-		
	z ₁	(cm)				-		
	z _{bp}	(cm)				-		
	z _{sp}	(cm)	2.83				-	
	d _{eq} (Z _{sp})	(cm)					-	
	f _c	(MHz)	3.229	2.37	-	-	-	(a)
	Dim of A _{aprt}	X (cm)		2.0	-	-	-	(a)
		Y (cm)		1.33	-	-	-	(a)
Other Information	PD	(μsec)	0.222					
	PRF	(Hz)	949					
	p _r @PII _{max}	(MPa)	0.94					
	d _{eq} @PII _{max}	(cm)					-	
	Focal Length	FLx (cm)		24.0	-	-		
		FLy (cm)		INF	-	-		
	I _{PA.3} @MI _{max}	(W/cm2)	13.73					
Operating Control Conditions	Preset: Lung		✓					
	Preset: Abdomen deep			✓				
Note 1:			Information need not be provided for any formulation of <i>TIS</i> not yielding the maximum value of <i>TIS</i> for that mode.					
Note 2:			Information need not be provided regarding <i>TIC</i> for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.					
Note 3:			Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2aa) and 51.2 dd).					
(a)			Intended use does not include cephalic so TIC is not computed.					

Table 16. Butterfly iQ+ Vet B-Mode + Color

Index Label			MI	TIS			TIB	TIC
				Scan	Non-Scan		Non-Scan	
					A _{aprt} ≤ 1 cm ²	A _{aprt} > 1 cm ²		
Maximum Index Value			0.402	-	-	0.095	0.202	(a)
Assoc Acoustic Parameter	Pr.3	(MPa)	0.798					
	W _o	(mW)		-	-		12.85	(a)
	min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]	(mW)				0.29		
	z ₁	(cm)				7.92		
	z _{bp}	(cm)				2.75		
	z _{sp}	(cm)	2.583				7.2	
	d _{eq} (Z _{sp})	(cm)					1.83	
	f _c	(MHz)	3.93	-	-	2.474	2.474	(a)
	Dim of A _{aprt}	X (cm)		-	-	2.0	2.0	(a)
Y (cm)			-	-	1.3	1.3	(a)	
Other Information	PD	(μsec)	0.077					
	PRF	(Hz)	410					
	p _r @PII _{max}	(MPa)	0.797					
	d _{eq} @ PII _{max}	(cm)				1.83		
	Focal Length	FLx (cm)		-	-	10.0		
		FLy (cm)		-	-	INF		
	I _{PA.3} @MI _{max}	(W/cm2)	8.65					
Operating Control Conditions	Preset: Bladder					✓	✓	
Note 1:	Information need not be provided for any formulation of <i>TIS</i> not yielding the maximum value of <i>TIS</i> for that mode.							
Note 2:	Information need not be provided regarding <i>TIC</i> for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.							
Note 3:	Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2aa) and 51.2 dd).							
(a)	Intended use does not include cephalic so TIC is not computed.							

Table 17. Butterfly iQ+ Vet B-Mode + M-mode

Index Label			MI	TIS		TIB	TIC	
				Scan	Non-Scan			Non-Scan
					$A_{aprt} \leq 1 \text{ cm}^2$	$A_{aprt} > 1 \text{ cm}^2$		
Maximum Index Value			0.53	0.017	-	-	0.014	(a)
Assoc Acoustic Parameter	Pr.3	(MPa)	0.94					
	W _o	(mW)		1.22	-		0.35	(a)
	min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]	(mW)				-		
	z ₁	(cm)				-		
	z _{bp}	(cm)				-		
	z _{sp}	(cm)	2.83				4.81	
	d _{eq} (Z _{sp})	(cm)					1.83	
	f _c	(MHz)	3.229	2.337	-	-	2.37	(a)
	Dim of A _{aprt}	X (cm)		2.0	-	-	2.0	(a)
Y (cm)			1.33	-	-	1.33	(a)	
Other Information	PD	(μsec)	0.222					
	PRF	(Hz)	949					
	p _r @PII _{max}	(MPa)	0.94					
	d _{eq} @PII _{max}	(cm)					1.83	
	Focal Length	FLx (cm)		24.0	-	-		
		FLy (cm)		INF	-	-		
	I _{PA.3} @MI _{max}	(W/cm2)	13.73					
Operating Control Conditions	Preset: Lung		✓					
	Preset: Abdomen Deep						✓	
Note 1:	Information need not be provided for any formulation of <i>TIS</i> not yielding the maximum value of <i>TIS</i> for that mode.							
Note 2:	Information need not be provided regarding <i>TIC</i> for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.							
Note 3:	Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2aa) and 51.2 dd).							
(a)	Intended use does not include cephalic so TIC is not computed.							

14.7. Measurement Accuracy

The Butterfly iQ Vet/iQ+ Vet device has been designed to perform the following clinical measurements:

M-mode:

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

B-mode:

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

Doppler Spectrum:

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

14.8. 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.



14.9. Recycling and Disposal

Butterfly Network is deeply invested in the preservation of the natural environment. Equipment may contain materials that pose a risk to the environment if proper disposal procedures are not followed. Recycle the Butterfly iQ Vet/iQ+ Vet 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.








15. Symbols







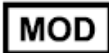





This chapter lists and describes the symbols and icons that may be used on the Butterfly iQ Vet/iQ+ Vet, its accessories, and packaging.





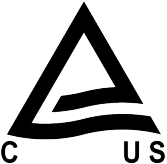

15.1. Symbols

Table 18, “Symbols” [61] 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 18, “Symbols” [61] may be used on the Butterfly iQ Vet/iQ+ Vet, and on its accessories and packaging. The symbols shown in this document and on the Butterfly iQ Vet/iQ+ Vet, and on its accessories and packaging, are compliant with current versions of the listed standards.

Table 18. 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.
	ISO 7010	W001	Warning	Indicates a general warning.
	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
	-	-	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.
	IEC 60529	-	Ingress protection rating	Ingress Protection rating system showing the degrees of protection from solid objects and liquids. Butterfly iQ Vet/iQ+ Vet is protected against the effects of immersion in water below the cable/probe barrier, as indicated.
	IEC 60601-1	20	Type BF applied part	Indicates isolated patient connection (Type BF applied part).
	ISO 15223-1	5.3.4	Keep away from rain	Indicates a medical device that needs to be protected from moisture.
	ISO 15223-1	5.1.1	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	ISO 15223-1	5.1.5	Batch code	Identifies the manufacturer's batch code so that the batch or lot can be identified.
	-	-	Model name	Model name for the device.
	ISO 15223-1	5.2.7	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	ISO 7010	M002	Refer to instruction manual/ booklet	To signify that the instruction manual/booklet must be read
	ISO 15223-1	5.4.3	Operator's manual; operating instructions	Indicates the need for the user to consult the instructions for use.
	ISO 7000	1135	General symbol for recovery/ recyclable	To indicate that the marked item or its materials is part of a recovery or recycling process.
	ISO 15223-1	5.1.6	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.

Symbol	Standard	Reference	Title	Description
	ISO 15223-1	5.1.7	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	ISO 15223-1	5.3.2	Keep away from sunlight	Indicates a medical device that needs protection from light sources.
	WEEE Directive 2012/19/EU	-	Waste Electrical and Electronic Equipment	Requires a separate collection for electrical and electronic equipment in compliance with the Waste Electrical and Electronic Equipment (WEEE) Directive. When accompanied by Pb or Hg, components of the device may contain lead or mercury, respectively, which must be recycled or disposed of in accordance with local, state, or federal laws. The backlight lamps in an LCD monitor contain mercury.
	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-37	-	European Conformity	Conforms to European requirements.
	-	-	USA & Canadian Certification	TÜV Rheinland of North America is accredited as a Nationally Recognized Testing Laboratory (NRTL) by OSHA (The Occupational Safety and Health Administration) in the United States and as a Product Certification Body by SCC (Standards Council of Canada) in Canada. This mark demonstrates compliance with National Electric Code, OSHA, and SCC regulations and requirements.
	Resolution 92/98	-	Argentine Standardization and Certification Institute	Electrical certification mark for Argentinian market.

16. Notes