Commercially available

Ultrasound imaging system*

Country of origin | United States of America
Primary use | Diagnosis/measurement/monitoring
Category | Medical device (including in vitro diagnostics)

Commercial information

List price (USD): 2699
Year of commercialization: 2019
Number of units distributed: 65 000
Currently marketed in: Argentina, Australia, Austria, Canada, Chile, Colombia, Denmark, Egypt, Finland, France, Germany, Iceland, India, Israel, Italy, Kenya, Kuwait, Netherlands (Kingdom of the), New Zealand, Norway, Oman, Pakistan, Poland, Portugal, Qatar, Saudi Arabia, South Africa, Sweden, Switzerland, Türkiye, United Arab Emirates, United Kingdom, USA
Model: Butterfly iQ+ Ultrasound Product System (850-20014)

Product description

The Butterfly iQ Ultrasound System is a hand-held, whole-body single-probe portable ultrasound system that is indicated for use by trained health-care professionals in environments where health care is provided to enable diagnostic ultrasound imaging and measurement of anatomical structures and fluids of adult and paediatric patients for the following clinical applications: peripheral vessels (including carotid, deep vein thrombosis, and arterial studies), procedural guidance, small organs (including thyroid, scrotum, and breast), cardiac, abdominal, urology, fetal or obstetric, gynaecological, musculoskeletal (conventional), musculoskeletal (superficial), and ophthalmic.

Product details

Accessories: Butterfly IQ + Ultrasound System 1.5 m cable USB-C, 2.5m cable USB-C, 1.5m cable lightning, 2.5m cable lightning, charger kit, holster, soft case, hard case, and hard case v2.
Consumables: Gel
Warranty duration: 1 year included, extended to 3 years with cost.
Lifetime: 5 years
Energy requirements: 110/220V for charger to be plugged into outlet.
Facility requirements: Electricity for charging probe at least intermittently, Wi-Fi if cloud use desired.

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*** Information reported by manufacturer, October 2023**

WHO assessment**

Clinical

Clinical → Recommended

Point-of-care ultrasonography is emerging as a new standard of care. By bringing imaging to the bedside, patient examination can be enhanced. The technological advances that made it possible transformed the modern bedside ultrasound into a portable and robust device, allowing deployment in low-resource settings. The widespread availability of ultrasonography allows for better diagnosis and care of many conditions, such as cardiac, pulmonary, or obstetric and gynaecological conditions. Ultrasound guided procedures are safer and often have fewer complications.

This technology leverages the high rate of smartphone ownership to deploy advanced ultrasonography, with artificial intelligence (AI) tools that can assist less skilled operators in more advanced aspects of cardiac or obstetric and gynaecological examinations. Connection to a dedicated cloud service allows for remote proctoring of trainees or expert consults. Despite the AI assistance, operators still require training and proctoring, as AI algorithms still present limitations, and critical judgement is required to interpret results and make clinical decisions. A subscription-based business model may limit deployment in certain settings, as several of the innovative features offered are limited to the payment of a yearly subscription.

**** This assessment was initiated November 2023**

Comparison with WHO technical specifications

Compliant (with minor exceptions).

The manufacturer included in the submission form all the main technical specifications. They are well supported and detailed in the technical specifications sections included in the user manual. The technology proposed is composed of a multi-function ultrasound probe, a software application for portable devices, cloud services, and an optional cloud connector.

WHO has no technical specifications document related to exactly this kind of system, although a very similar technical requirements document (portable ultrasound scanner) can be used to compare only the specifications that describe the same features or characteristics.

Keeping in mind the aforementioned and after assessing the comparator outputs, the proposed technology can be considered compliant with the following exceptions, which might be considered minor since the compared technologies and systems are not identical:

- screen monitor of at least 25 cm;
- operates from an AC power electric line: 100-240V, 50/60 Hz;
- automatic switch AC power electric line/battery operating modes;
- data communication, storage, and transfer interface: USB minimum; zooming capability with automated image optimization;
- transducer ports: at least two active transducer ports permanently available;
- capability of switching between probes.

Moreover, the following applications are not available: intra-vascular, lung, and trans-vaginal.

Regulatory

Pre-market assessment	Proceed
Post-market assessment	Proceed with caution
Quality system assessment	Proceed
Security	Proceed

Pre-market: The product has obtained market approval in the EU. Certification and standards for performance, the documentation submitted is adequate to demonstrate that the product is safe and effective.

Post-market: The manufacturers declared that they have the post-market documentation but did not submit the post-market surveillance and vigilance documentation. According to the submission, there have been recalls, but no adverse events have been reported since the release of the product. They have declared that they have undertaken to resolve the recalls. However, these reports were not submitted for assessment of the safety and performance of the device.

QMS: The manufacturer has submitted risk management documentation and implemented the risk management process required in ISO14971.

Security: The manufacturer has declared conformity to IEC62304 software validation for the lifecycle of the device, which also addresses issues due to cybersecurity risk.

Health technology assessment

Indicators	Evidence assessment	Innovation
Medical	!	✓
Safety	→	
Economy	!	
Organizational	→	✓
Legal	!	
Social	!	
Ethical	N/A	
Green environment	→	

This technology is an innovative design concept in the field of ultrasonography. Given its ergonomic design and a single probe, it can be easy to use and operated by naïve operators. However, it must be used under expert supervision to prevent any misdiagnosis or repercussions. The lack of post-market clinical follow-up represents a gap in continual data collection on device performance and safety.

Although priced lower than competitors, the manufacturer has the opportunity to standardize pricing that is based on health economics. For example, budget impact analysis performed using inputs from authentic sources rather than arbitrary assumptions may provide robust insights into the financial consequences of adopting this technology.

Although no major legal or ethical issues can be foreseen with this technology, it is imperative to use it judiciously without any violation of regulatory norms. Also, rigorous post-market clinical follow-up contributing to the safe and effective use of Butterfly iQ in the real world are recommended, particularly in light of recent product recalls.

Technology readiness level 9

Technology evidence assessment Recommend with caution

Health technology management

- Durability
- Ease of Use
- Ease of maintenance
- Environmental conditions
- Affordability
- Local access to technical support
- Ease of cleaning
- Infrastructure requirements

Health-care delivery platform

The Butterfly ultrasound system is a universal ultrasound sensor with a tablet-based display. The tablet-based user interface is very well developed and makes it easy to annotate images; however, screen size and resolution are dependent on the connected device, which could impact image interpretation. Extensive technical support and training resources are available online, including access to international experts and video-based training. Cloud-based support is available, and devices can be integrated into existing electronic medical records systems. The system has been tested for military-grade durability and can endure drops of up to 1.2 m, electric shocks of up to 100G, and can resist dust and water (IP67). However, as it is a tablet-based system, the maintenance and durability elements of any tablet will also contribute to the longevity of the product. The Butterfly cloud network also integrates artificial intelligence and machine learning in multiple care pathways; systems are in place to enable consistent maintenance and updates for the Butterfly apps to ensure that as software and machine learning improve, users will have near-immediate access. Although the unit costs appear steep at 2699 USD for initial purchase, the comparable cost in this product landscape for the level of features available is reasonable. The Butterfly iQ is a significant step forward in making ultrasound technology more appropriate, accessible, portable and versatile.

Intellectual property and local production

- Technology transferability
- Open source/ access
- Local production

Intellectual property: This technology is patent-protected and has registered trademarks. The use of all intellectual property will require clearance. The use of patented, compatible third-party products may also require clearance.

Local production: The technology has a compliant manufacturing process and is likely to have good volumes in the segment. However, it is not suitable for local production; end-to-end manufacture of this technology requires a high level of multidisciplinary expertise and specialized infrastructure. Some of the manufacturing know-how is likely to be with the contract or licensed manufacturers. In addition, given the intellectual property landscape of the product, the manufacturing know-how is likely to be closely guarded in the immediate future. The business model of the technology should also be considered.

WHO guidance

- WHO recommendations for antenatal care for a positive pregnancy experience. (2016). https://iris.who.int/bitstream/handle/10665/250796/9789241549912-eng.pdf?sequence=1
- Manual of diagnostic ultrasound / 2nd ed. Vol 1 (2011). https://www.who.int/publications/i/item/9789241547451
- Manual of diagnostic ultrasound / 2nd ed Vol 2 (2013) https://www.who.int/publications/i/item/9789241548540