Exemption Request Form

Date of submission: 23 October 2024

1. Name and contact details

1) Name and contact details of applicant:

Company: **Butterfly Network, Inc.**

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2. Reason for application:

Please indicate where relevant:

- ☐ Request for new exemption in:
- ■ Request for amendment of existing exemption in
- ☐ Request for extension of existing exemption in
- ☐ Request for deletion of existing exemption in:
- ■ Provision of information referring to an existing specific exemption in:
  - ☐ Annex III
  - ■ Annex IV

No. of exemption in Annex III or IV where applicable: Exemption 14, Annex IV

Proposed or existing wording: **Current**: lead in single crystal piezoelectric **Proposed**: lead in single crystal piezoelectric materials for ultrasound transducers used in medical ultrasound devices other than handheld ultrasound devices.

Duration where applicable: 21 July 2025

☐ Other: _____

3. Summary of the exemption request / revocation request

Butterfly is kindly requesting the European Commission to set in process and adopt a Decision to amend Exemption 14 of Annex IV of the RoHS Directive by excluding handheld medical ultrasound devices.

The current wording of the Exemption 14 Annex IV presumes the use of lead in single crystal piezoelectric materials for ultrasound transducers in all medical ultrasound devices. However, since 2018, alternative technologies, mainly capacitive micromachined ultrasound transducers (cMUT) technology in ultrasound transducers as a substitute to piezoelectric crystals, have evolved significantly. cMUT technology has become a scientifically and technically practical, reliable and effective alternative to lead piezoelectric crystals in handheld ultrasound devices. Thus there is an opportunity to reduce the risk of environmental and consumer exposure to lead which would continue were the exemption to be prolonged as currently worded.

CMut technology enables comparable durability and equivalent, if not higher imaging quality, in addition to considerably enhancing overall usability of handheld ultrasound devices. cMUT technology does not require lead piezoelectric crystals used by traditional handheld ultrasound devices. For example, Butterfly's devices based on cMUT technology have been deployed in war zones such as Ukraine, affirming the resilience, robustness and dependability of our probes under challenging conditions. Additionally, Butterfly's devices have also been deployed in large enterprise-wide healthcare facilities, demonstrating the versatility of handheld ultrasound devices utilizing cMUT technology.

cMUT technology also enables the "one probe" concept, wherein one device can scan the entire body without the use of multiple probes and/or heads, which are a requirement for piezoelectric crystal devices due to technical limitations. In this sense, handheld ultrasound devices using piezoelectric crystals not only can cost significantly more (with resulting implications for public healthcare budgets), but also often require the end user to purchase multiple attachments and/or probes to perform different scans.

Overall, using the cMUT technology instead of lead piezoelectric crystals is completely feasible in handheld ultrasound devices while also reducing the environmental impact of these devices.

4. Technical description of the exemption request / revocation request

(A) Description of the concerned application:

1. To which EEE is the exemption request/information relevant?

   Name of applications or products: Handheld ultrasound devices.

a. List of relevant categories: (mark more than one where applicable)

- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ 6
- ☐ 7
- ☒ 8
- ☐ 9
- ☐ 10
- ☐ 11

b. Please specify if application is in use in other categories to which the exemption request does not refer: _____

c. Please specify for equipment of category 8 and 9:
The requested exemption will be applied in

☐ monitoring and control instruments in industry
☐ in-vitro diagnostics
☒ other medical devices or other monitoring and control instruments than those in industry

2. Which of the six substances is in use in the application/product?
(Indicate more than one where applicable)

☒ Pb ☐ Cd ☐ Hg ☐ Cr-VI ☐ PBB ☐ PBDE

3. Function of the substance: Pb (lead) is included in many piezoelectric crystals, as a component of some handheld ultrasound devices.

4. Content of substance in homogeneous material (%weight): Lead content varies and is calculated to be about 40 - 65% of the single crystal's weight according to COCIR's application to renew the exemption for the benefit of the traditional piezoelectric devices.

5. Amount of substance entering the EU market annually through application for which the exemption is requested: unknown

Please supply information and calculations to support stated figure.
As a supplier of alternative technologies, we are not in a position to provide a precise estimation of the amount of lead coming into the EU market concerning this exemption. Based on publicly available data provided in light of the latest renewal request of the exemption by COCIR dated 2 January 2020, we know that 500gr of lead is coming into the EU market due to all single crystal medical ultrasound transducers as part of piezoelectric crystals, which is a component of handheld ultrasound devices.

Given the growth of the European ultrasound device market since 2020 of at least 5%, it is very likely that the amount of lead has increased as compared to the number indicated by CoCIR in 2020.

The lack of data and the difficulty in finding an estimated figure for lead imported via ultrasounds can be explained by the fact that manufacturers do usually not publicly report the number of handheld devices they ship. However, key industry representations such as COCIR may be able to retrieve this information, which they likely may not be open to disclosing for this purpose and context, as they

would be in favour of maintaining the exemption in its current form.

6. Name of material/component: Pb (lead)_

7. Environmental Assessment: _____
   LCA: ☐ Yes
   ☐ No

(B) In which material and/or component is the RoHS-regulated substance used, for which you request the exemption or its revocation? What is the function of this material or component?

We are kindly requesting a revocation of the exemption for the use of lead in single-crystal piezoelectric materials for ultrasound transducers used in handheld medical ultrasound devices.

(C) What are the particular characteristics and functions of the RoHS-regulated substance that require its use in this material or component?

Notwithstanding the fact that lead piezoelectric crystals, contrary to what is implied in the question, is no longer needed or required in handheld medical ultrasound devices, Butterfly would state the following:

The lead piezoelectric crystals are commonly used in traditional ultrasound devices to enable medical imaging functionality. However, since 2018, there are scientifically and technically practical as well as effective alternatives to lead piezoelectric crystals in handheld devices – mainly capacitive micromachined ultrasound transducers (cMUT) technology.

Butterfly in particular, replaces traditional piezoelectric crystal-based transducers with a single silicon chip, or cMUT technology. This chip contains a 2D array of 9000 capacitive micromachined ultrasound transducers (cMUTs). Unlike traditional piezoelectric crystals that are tuned to oscillate at defined frequencies, cMUTs have a much wider bandwidth when applied to biological tissues. This means they can be programmed to emit and detect many different frequencies. The result is a single probe with one head capable of whole-body imaging.

5. Information on possible preparation for reuse or recycling of waste from EEE and on provisions for appropriate treatment of waste

1) Please indicate if a closed loop system exist for EEE waste of application and provide information of its characteristics (method of collection to ensure closed loop, method of treatment, etc.)

cMUT technology does not contain substances restricted under RoHS above the relevant thresholds. Hence, section 5 is less relevant in this case as no relevant amount of RoHS substances is present in cMUT devices. However, we provide the following information about the collection of handheld ultrasound devices.

First of all, Butterfly is committed to sustainable manufacturing and device lifecycle management. Butterfly′s initial goal is to ensure that all the devices it places on the market are as durable as possible and remain functional as long as possible. Considering this ambition, Butterfly′s oldest devices (Butterfly iQ) still function and remain in use.

In anticipation of potential future obsolescence, Butterfly ultrasound probes are designed with waste reduction in mind. The probes are built in a way that enables disassembly, and the largest component of the probe, the housing, is made of recyclable aluminium. Together, these factors allow for proper disposal of individual components, such as the aluminium housing, batteries, and plastics; and enhanced recycling capabilities. As to disposal, the replacement of the lead piezoelectric crystals with Butterfly's cMUT technology significantly reduces the environmental impact of these devices further.

Our probes are also designed to be compatible with customers' new or pre-existing iOS or Android devices, which not only allows for flexibility and convenience, but eliminates the need to build additional displays.

Additionally, Butterfly uses recyclable packaging to ship all of our products, and our user manuals are all provided in digital-only format to avoid additional printing and paper waste. We continually explore opportunities to enhance the eco-friendliness of our packaging to further reduce waste, in fact, the packaging for our new iQ3 (which has obtained FDA approval in the US and is pending approvals in the EU) are made from 100% recycled material.

With the U.S. launch of our third-generation Butterfly iQ3 probe in early 2024, we furthered our commitment to proper waste management by launching a new device trade-in program. Through this program, Butterfly customers are encouraged to send us back their existing Butterfly iQ or iQ+ probes in exchange for a credit toward their new iQ3 purchase. With this program in place, Butterfly aims to ensure a larger number of retired devices are disassembled for proper material recycling and disposal. We have established a business plan to continue the U.S. trade-in program indefinitely, as part of our efforts to help mitigate the worldwide issue of medical waste. We are actively exploring additional sustainability advantages for this program, which could include ways to upcycle materials or refurbish eligible probes in support of our social impacts goals, for example, through humanitarian aid deployment.

1) Please indicate where relevant:

☐ Article is collected and sent without dismantling for recycling

☐ Article is collected and completely refurbished for reuse

☐ Article is collected and dismantled:

- ☐ The following parts are refurbished for use as spare parts: _____
- ☐ The following parts are subsequently recycled: Housings, cables, batteries, and other materials that are typically recyclable. Please note that certain IP-sensitive components are purposefully destroyed in order to avoid the risk of confidentiality/IP theft.

☐ Article cannot be recycled and is therefore:

- ☐ Sent for energy return
- ☐ Landfilled

2) Please provide information concerning the amount (weight) of RoHS substance present in EEE waste accumulates per annum:

☐ In articles which are refurbished _____

☒ In articles which are recycled none
of the recycled components include piezoelectric crystals.

☐ In articles which are sent for energy return _____

☐ In articles which are landfilled _____

We do not have insight into this specific information regarding lead piezoelectric crystals since our device does not use such crystals.

6. Analysis of possible alternative substances

(A) Please provide information if possible alternative applications or alternatives for use of RoHS substances in application exist. Please elaborate analysis on a life-cycle basis, including where available information about independent research, peer-review studies development activities undertaken

Butterfly Network has developed a handheld ultrasound system that uses semiconductor technology instead of traditional lead-based piezoelectric crystals. This technology is known as capacitive micromachined ultrasound transducers (cMUTs). cMUTs are silicon-based, micro-electromechanical system (MEMS) devices designed for electrostatic actuation which presents a viable substitute for traditional crystal piezoelectric based materials. A single cMUT unit consists of a thin, conductive membrane separated from another conductive substrate by a vacuum gap, forming a capacitor. When a voltage is applied, the thin membrane acts like a small drum to generate ultrasound vibrations. Sound waves that are reflected from tissues similarly vibrate the thin membrane, generating an electrical signal that is then recorded.

The currently perceived “gap” between handheld semiconductor-based ultrasound systems and traditional handheld lead-based piezoelectric-based systems, used to justify the RoHS exemption permitting usage of lead-based piezoelectric crystals in ultrasound transducers is according to our experiences nonexistent. Butterfly’s semiconductor-based Products offer at least comparable, if not superior capabilities in some instances, to its handheld piezoelectric counterparts.

cMUT’s innovation trajectory is backed by Moore’s Law – a guiding principal of the semiconductor industry first observed in 1965 by Intel co-founder, Gordon Moore. Moore’s Law states that the number of transistors on an integrated circuit will double every two years – meaning the computer processing power of a chip doubles every two years with minimal rise in cost. The observation still holds true today, supporting Butterfly’s commitment to pushing the boundaries of technological advancements in the field of ultrasound. As our chip processing power doubles, our technology becomes greater, among other benefits.

The advanced quality of semiconductor-based ultrasound products is further proven by the adoption of Butterfly users, with more than 145,000 healthcare professionals using Butterfly

Products worldwide after just a few years of commercial activity. The increasing prevalence of Butterfly's Products within the ultrasound market offers an unquestionable endorsement of the viability of semiconductor technology for handheld ultrasound users.

See the below questions as well as the attached letters for further argumentation on why cMUT-based ultrasound systems provide such a viable alternative.

(B) Please provide information and data to establish reliability of possible substitutes of application and of RoHS materials in application

CMUT technology handheld ultrasound devices offer ample reliability in healthcare delivery. Butterfly's probes (in particular iQ3) provide the highest quality of real-time scan imaging, capturing both short and long axes. With its excellent imaging quality, fast data processing and user-centric ergonomic features, Butterfly's technology helps healthcare professionals diagnose conditions considerably faster as compared to traditional ultrasound devices. These features are enhanced through real-time AI tools that simplify complex evaluations (e.g. assessing adults with suspected diminished lung function), support informed decision-making (providing real-time feedback, anatomical identification, and guidance for streamlined imaging), and expand Point-of-Care capabilities.

Moreover, the system has more than sufficient durability as it can endure drops of up to 1,2 meters and electric shocks of up to 100G[1]. This robust design has been validated in real-world scenarios, including deployment in war zones such as Ukraine, affirming the resilience and dependability of our probes under challenging conditions like conflicts and war zones.

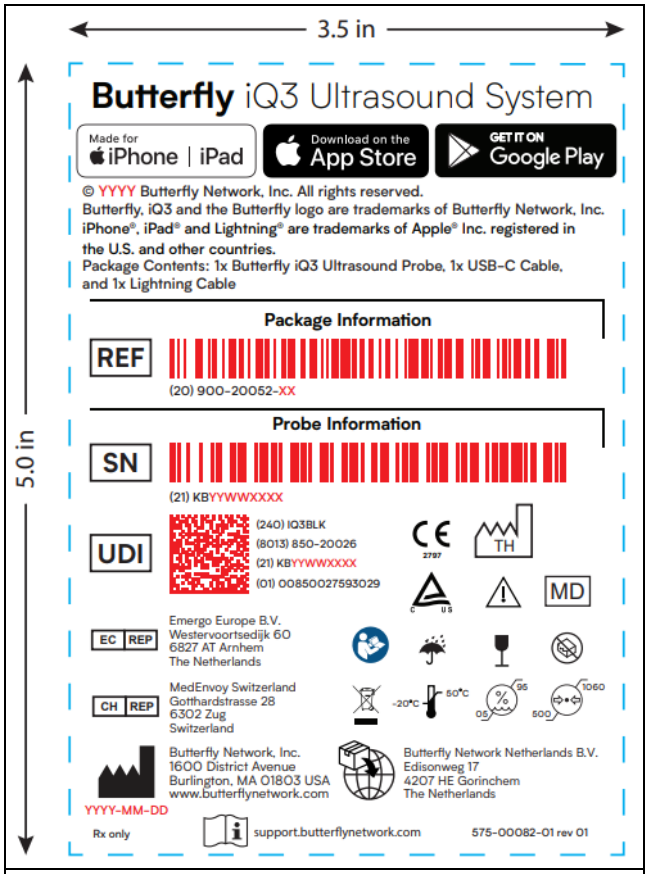
In terms of optimising healthcare service delivery, the system utilises solid cloud computing for unlimited image storage, communication among clinicians, and connection with standard hospital medical record systems. Its optimised electronics are integrated with a power-efficient field-programmable gate array (FPGA) chip, which offers strong battery life and thermal performance, while enabling appropriate scanning time.

More specifically, the reliability of the cMUT technology, in particular as a substitute for handheld ultrasound devices using RoHS materials, is established through its widespread adoption and regulatory approval in approximately 30 countries, among which 16 European countries and 13 EU Member States notably Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Italy, the Netherlands, Poland, Portugal, Spain and Sweden. Butterfly Network has commercialized tens of thousands of handheld probes currently in operation in virtually all clinical settings. As mentioned above, Butterfly's devices have been in use globally by over 145,000 healthcare professionals. Other key benefits are its cost-effectiveness and functionality

[1] 100G's refers to the acceleration the device experienced when it hit the ground after a fall from a certain distance. The acceleration was measured during shock testing. A "G" is a unit of acceleration. It is measured relative to gravity at the surface of the earth. Said differently, if the probe withstood 100G's, this means the probe withstood 100x the acceleration normally due to gravity.

coupled with its warranty, with devices priced under EUR 3,000. See the below responses and the attached letters for further information.

Butterfly's probes are certified and approved by the European Medicines Agency in accordance with the requirements under the EU Medical Device Regulation 2017/745, Chapter I and III, and as such conform with the provisions as classified under risk classification IIA (with the approval process for the new iQ3 ongoing). This also includes the probes' software and all accessories. As such, the devices have a CE-marking (see image).



Butterfly's iQ3 European commercial box label

7. Proposed actions to develop possible substitutes

(A) Please provide information if actions have been taken to develop further possible alternatives for the application or alternatives for RoHS substances in the application.

Butterfly Network developed Butterfly iQ devices. Within two years after its launch, we introduced the enhanced Butterfly iQ+ featuring additional functionalities and improved performance which is both FDA- and EMA-approved (see image above).

In early 2024, Butterfly received FDA approval and launched its third-generation device, the iQ3.

Regulatory approval is under way in the EU and Butterfly plans to launch the iQ3 there as well once all required approvals have been secured. The iQ3 improves image quality even further for cMUT ultrasound probes. Please see the enclosed letter for further information.

(B) Please elaborate what stages are necessary for establishment of possible substitute and respective timeframe needed for completion of such stages.

The substitution of traditional lead-based piezoelectric crystals handheld devices by devices with the new cMUT ultrasound devices is already underway globally. Experience shows that significant advancements can be made within the span of a few years. The further uptake of the substitutes requires a regulatory environment, approvals, and market conditions facilitating the replacement. See the enclosed letters for further details

8. Justification according to Article 5(1)(a):

(A) Links to REACH: (substance + substitute)

1) Do any of the following provisions apply to the application described under (A) and (C)?

- ☐ Authorisation
  - ☐ SVHC
  - ☐ Candidate list
  - ☐ Proposal inclusion Annex XIV
  - ☐ Annex XIV
- ☐ Restriction
  - ☐ Annex XVII
  - ☐ Registry of intentions
- ☐ Registration

2) Provide REACH-relevant information received through the supply chain.

cMUT technology uses a series of materials which contain substances subject to REACH registration. Besides being a totally different technology with many advantages in terms of performance, cMUT removes the need for the use of lead in single crystal piezoelectric materials for ultrasound transducers.

The lead substances used in the manufacture of non-cMUT technology ultrasound transducers are subject to REACH registration requirements under the entries on (i) lead titanium oxide and is registered here: https://echa.europa.eu/registration-dossier/-/registered-dossier/11894 and (ii) Lead titanium zirconium oxide and is registered https://echa.europa.eu/registrationdossier/-/registered-dossier/14607, but most ultrasound transducers are imported into the EU as articles. Single crystal

formulations are not registered.

(B) Elimination/substitution:

1. Can the substance named under 4.(A)1 be eliminated?

   ☒ Yes.

   cMUT technology based handheld ultrasound devices do not contain substances restricted under RoHS above the relevant thresholds and are available an alternative for handheld devices. This alternative technology

   does not use lead in piezoelectric crystals, is more cost-effective and has equivalent or higher functionality than the current devices in use (which exceed the relevant RoHS limits). Substitution is therefore possible.

   Justification: Since 2018, alternative technologies, mainly capacitive micromachined ultrasound transducers (cMUT) technology in ultrasound transducers, has become a scientifically and technically practical , reliable and effective alternative to lead piezo electric crystals in handheld devices. (See enclosed letter for more details).

   ☐ No.

2. Can the substance named under 4.(A)1 be substituted?

   ☒ Yes.

   ☐ Design changes: Replacing piezoelectric crystal-based transducers with a single silicon chip containing capacitive micromachined ultrasound transducers ("CMUTs").

   ☐ Other materials:

   ☐ Other substance:

   ☐ No.

   Justification: _____

3. Give details on the reliability of substitutes (technical data + information):

   In comparison with traditional piezoelectric based crystals, which are tuned to oscillate at defined frequencies, CMUTs have a much wider bandwidth when they are applied to biological tissues and, therefore, a single transducer can be programmed to emit and detect many different frequencies. The broadband response of CMUTs allows output of a very short ultrasound pulse, enabling imaging with a high axial resolution and increased clinical utility. By placing the CMUTs in a 2D array, the device can be programmed to emulate scanning patterns and wavefields from any type of transducer – linear, curved, and phased.

   As a result, a single probe can be used for whole body imaging – a stark contrast to Butterfly's piezoelectric crystal handheld ultrasound counterparts that typically require multiple transducers and/or attachments in order to perform different scan applications. The wide range of frequencies can be leveraged for a broad range of

applications - e.g., from deep abdominal imaging with low frequencies, to shallow high-resolution imaging with high frequencies, all with the same array probe. The acoustic impedance of CMUT devices is commonly quite close to the acoustic impedance of skin and soft tissue which obviates the need for multiple acoustic matching layers commonly used in piezoelectric imaging probes. Being able to conduct these different tests on one device not only makes the procedure more comfortable and time-efficient for the patient, it also ensures a faster diagnosis.

Furthermore, the CMUT technology integrates seamlessly with electronic circuits, enabling the consolidation of wiring onto a single semiconductor chip. The Product utilizes a cost-effective CMOS (complementary metal-oxide semiconductor) process for chip construction, contributing significantly to the device's affordability compared to traditional probes. More specifically, the Product currently costs just under EUR 2,500 and the All-in Bundle (including the Product, a 3-year warranty and all of Butterfly's software features in a single-payment membership that lasts for the entire life cycle of the Product is approximately EUR 4,210. By contrast, typical handheld ultrasound systems that use piezoelectric crystals can cost significantly more and often require the end user to purchase multiple attachments and/or probes to perform different scans.

Another major future potential for the Product is its interface with artificial intelligence (AI) technology. In fact, the 2D array enables more cost-effective AI development compared to traditional piezoelectric based crystals. As an example, in April 2023, Butterfly Network received clearance in the US for a ground-breaking AI-enabled Auto B-line Counter that may simplify how healthcare professionals evaluate adults with suspected diminished lung function and can potentially accelerate their ability to make informed treatment decisions at the point of care. The Product contains numerous other AI components, and Butterfly plans to continue to introduce additional AI products.

This technology effectively replaces lead piezoelectric crystals in the transducers of such devices, while providing the same, if not better, performance than transducers that rely upon the exemption for lead piezoelectric crystals. We believe that the rapid evolution of CMUT technology underscores that the progress achieved thus far represents only a fraction of its potential. The substantial strides observed in recent years serve as an indicator of the accelerated pace of development in contrast to the earlier stages when CMUT within ultrasound was a comparatively lesser-known technology, largely limited to academic research and not viewed as a viable commercial technology. Of course, there are still efforts to innovate the technology further, but those developments will only unlock additional benefits of cMUT and further remove any perceived necessity for lead piezoelectric crystals in handheld ultrasound devices. In light of all of the above, we believe that our Product constitutes a reliable, scientifically and technically practical, and cost-effective substitute to traditional lead based piezoelectric handheld ultrasound transducers. Please see the enclosed letter for additional details.

4. Describe environmental assessment of substance from 4.(A)1 and possible substitutes with regard to
    1) Environmental impacts: When it comes to disposal, replacement of the lead piezoelectric crystals with Butterfly's cMUT technology significantly reduces the environmental impact of these devices.
    2) Health impacts: Butterfly's cMUT-based ultrasound devices offer a greener and safer alternative to traditional lead-based systems, reducing unnecessary exposure to hazardous substances for healthcare professionals, patients and the environment. Butterfly devices can further reduce any potential risks as they are fully RoHS limits compliant, especially for more vulnerable populations such as pregnant women and children.
    3) Consumer safety impacts: _____*addressed under health impacts*

⇨ Do impacts of substitution outweigh benefits thereof?
Please provide third-party verified assessment on this: N/A___

(C) Availability of substitutes:

a) Describe supply sources for substitutes: Butterfly Network manufactures and distributes handheld ultrasound devices that use cMUT technology.

The cMUT semiconductor chips are manufactured in Taiwan, using a silicon-on-insulator wafer built by a manufacturer in Finland. The probe itself is primarily manufactured in Thailand but some probes are manufactured in Nashua, New Hampshire.

b) Have you encountered problems with the availability? Describe: We have not encountered problems in supplying the alternative technology.

In addition, it should be pointed out that after only a few years of commercial activity, more than 145,000 healthcare professionals are using Butterfly iQ worldwide and the company has never failed to answer to the rising demand. Butterfly anticipates a significantly higher demand for our and similar technologies in the future given their versatility, sustainability, and ease of use aspects, and we are ready to meet the needed increase in supply of this technology in any market.

c) Do you consider the price of the substitute to be a problem for the availability?

☐ Yes ■ No

d) What conditions need to be fulfilled to ensure the availability? Continued access to supply chain.

It is worthwhile noting that the EU has recently been prioritizing its semiconductor industry and the international supply chains connected to

it. Notably, The Chips Act has a strong international dimension, given that the EU is highly dependent on the global supply chain, and on China and Taiwan in particular, for semiconductor production. Against this background, we anticipate that these efforts will result in significant growth of the European semiconductors ecosystem and will help prevent any shortages in semiconductor supply chains.

(D) Socio-economic impact of substitution:

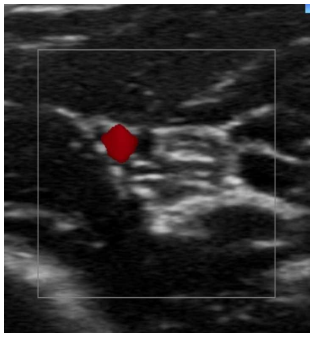
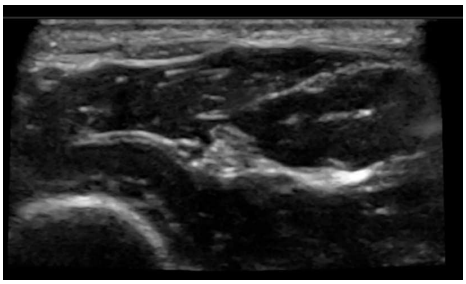
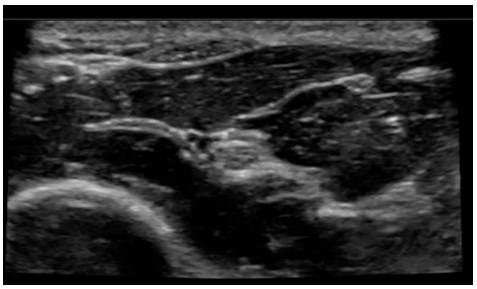
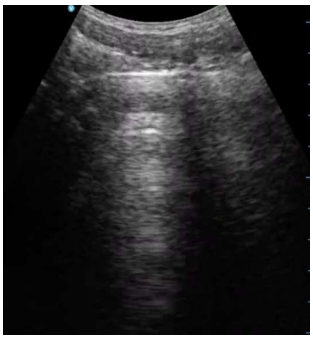
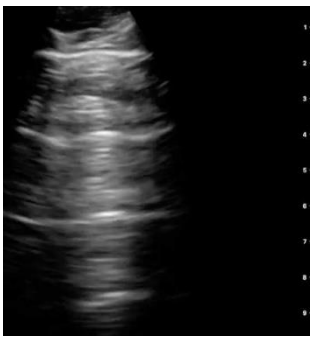
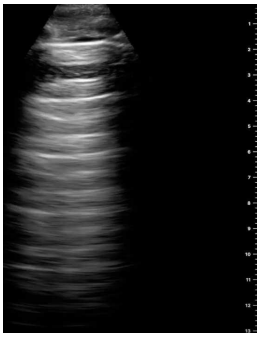
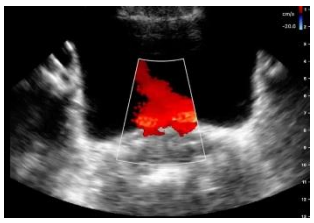
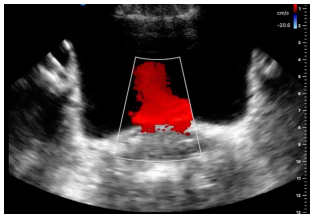
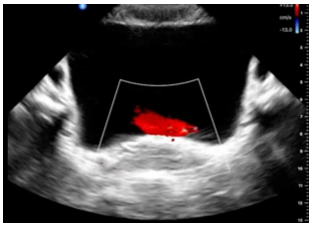
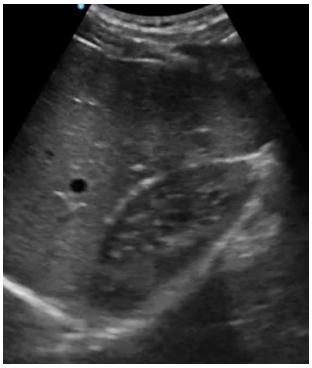
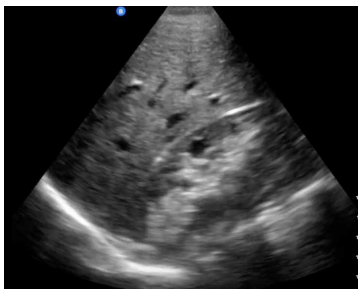
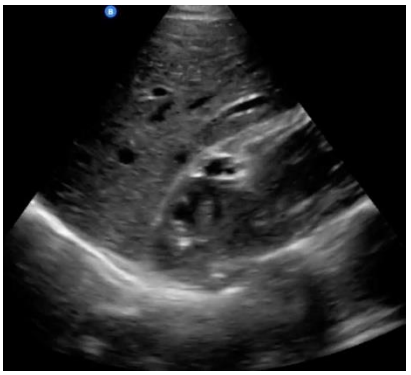
⇨ What kind of economic effects do you consider related to substitution?

- ☐ Increase in direct production costs
- ☐ Increase in fixed costs
- ☐ Increase in overhead
- ■ Possible social impacts within the EU

Not only does the cMUT technology allow Butterfly to provide a greener handheld ultrasound device compared to those that rely upon lead piezoelectric crystals, it also provides rapidly evolving technological capabilities that already meet or exceed those of its comparators, with additional enhancements that can highly benefit various key aspects within healthcare systems that are crucial to advance public health across the EU, including:

- Improved access to healthcare services in remote, resource-limited areas
- Improved early detection and faster diagnosis/ referral (especially in primary care)
- Implementation of telemedicine services across the EU
- Less exposure of vulnerable patients to harmful substances (i.e., lead)

Moreover, a significant reduction of public and private healthcare costs due to the reduced financial cost of the cMUT device compared to lead based piezoelectric crystals could be expected. The versatility,durability and high image quality (see table) of thecMUT device compared to that of lead base piezoelectric crystals also offer more accessibility by enabling usage in a wide range of environments, circumstances, and use cases, spanning from conflict zones, general practices to enterprise-wide healthcare deployments in institutions like Germany's Bonn University. Moreover, the Product currently has approval for 14+ clinical indications, as such making a significant contribution to the efficiency and sustainability of healthcare systems.

Comparative Images: Piezoelectric Crystal Handheld Ultrasound Device VS. Butterfly iQ			
Preset type	**Ultrasound Device Piezoelectric Crystal Handheld**	**Butterfly iQ+**	**Butterfly iQ3 (pending regulatory clearance outside US)**
Nerve Preset			
Lung Preset			
Bladder Preset			
Abdomen Preset			
**The full selection and high-quality comparative images are available in the appendix.*			

The cMUT technology has proven to meet or exceed technical aspects of its piezoelectric

counterparts and nothing speaks louder than the comparative images enclosed as Appendix B. Each generation of the Butterfly iQ products has demonstrated the clinical viability of cMUT technology in increasingly meaningful ways, and Butterfly's iQ3 provides the latest and most obvious example.

The materials used in cMUT chips are also inherently more durable than piezoelectric crystals and are generally more likely to survive a drop. For instance, the system can endure drops of up to 1,2 meters and electric shocks of up to 100G. Additionally, Butterfly's devices have also been deployed in various large enterprise-wide healthcare facilities, remote settings as well as warzones, demonstrating the impressive versatility of handheld ultrasound devices utilizing cMUT technology.

These socio-economic impacts all the more underscore the unnecessary reliance of European healthcare systems on lead-based piezoelectric crystals in handheld ultrasound devices.

☒ Possible social impacts external to the EU

So far, Butterfly Products have received regulatory approval in approximately 30 countries – including numerous EU member states and the UK – and have also been in use globally by over 145,000 users in a wide range of real-world settings including in among others Ukraine and sub-Saharan Africa, affirming the resilience and dependability of our probes under challenging conditions. Butterfly's expansive global presence and user base demonstrate its high value on an international scale.

☐ Other:

⇨ Provide sufficient evidence (third-party verified) to support your statement: _____

9. Other relevant information

Please provide additional relevant information to further establish the necessity of your request:

_____

---

10. Information that should be regarded as proprietary

Please state clearly whether any of the above information should be regarded to as proprietary information. If so, please provide verifiable justification:

None of the above information is proprietary.

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1600 District Ave
Burlington, MA 01803

(781) 557-4800

To: Bio Innovation Systems (contact@bios.eu)

cc: ENV-ROHS@ec.europa.eu; RoHS@bios.eu

Sent by email only

7 February 2024

RE: Requests for renewal of the exemptions under Annex III, n. 7I-I and Annex IV n. 14 of RoHS

To whom it may concern:

I. Introduction of Butterfly Network

We, Butterfly Network, Inc., parent entity of Butterfly Network Limited (Butterfly Network), are a digital health company based in the US with global operations, including within various EU Member States. In 2018 we commercially launched the world's first handheld, single-probe, complete body ultrasound system using semiconductor technology, Butterfly iQ, and in 2020, we launched our second-generation probe, the Butterfly iQ+ with additional features and improved performance (the "Product"). We anticipate introducing our third-generation probe, Butterfly iQ3, in 2024 in certain localities, with a plan to continue launching in additional countries. Notably, all of Butterfly's ultrasound probes rely upon cMUT technology without a trace of lead based piezoelectric crystals. Not only does the cMUT technology allow Butterfly to provide a cleaner handheld ultrasound device compared to those that rely upon lead piezoelectric crystals, it also provides rapidly evolving technological capabilities that already meet or exceed those of its comparators, with additional enhancements on the horizon.

II. Letter to the European Commission

On 5 January 2023 we submitted a letter to the European Commission, providing detailed information about our Product, which we believe constitutes a reliable, practical, and cost-effective substitute for traditional lead based piezoelectric handheld ultrasound transducers. Our request was for this information to be taken into consideration within the ongoing procedures for the renewal, or, as the case may be, non-renewal of the exemptions contained in Annex III, n. 7(c)-I and Annex IV n. 14 of RoHS. The letter is attached in Appendix A.

With this second letter, we aim to enhance the understanding of our Product by providing additional insights. To achieve this, we have prepared responses to specific questions posed by Bio Innovation Systems, UNITAR, and Fraunhofer IZM (referred to as the "Consultants") appointed by the European Commission for the assessment of applications seeking the renewal of exemptions.[1]

The questions were originally intended for the European Coordination Committee of the Radiological, Electromedical, and Healthcare IT Industry (COCIR). However, we consider that COCIR's responses lack sufficiently comprehensive substantiation, appear outdated and may present matters from one perspective only as they focus on perceived shortcomings of the cMUT technology. Indeed, Butterfly is referred to somewhat passively in some of the prior responses and documentation, but without the sufficient depth necessary to fully comprehend the magnitude of cMUT's impact on the handheld ultrasound technology. The references to Butterfly were largely based upon then publicly available materials and did not include the expansive knowledge about cMUT in ultrasound that Butterfly's internal experts are able to provide. Regardless, the Consultant's 2022 report made one thing abundantly clear: they felt that cMUT's could provide a viable alternative to lead based piezoelectric crystals in handheld ultrasound devices, even proposing language

[1] Questionnaire 2 Exemption 14 of RoHS Annex IV, Lead in single crystal piezoelectric materials for ultrasonic transducers.

for a potentially revised exemption to remove handheld ultrasound devices, but the Consultant's lacked sufficient information to reach such a conclusion. We are therefore looking to address the Consultants' questions and the points raised by COCIR by providing a balanced perspective that contributes to a comprehensive understanding of the merits and attributes of our Product.

III. Questions posed by the Consultants

As a preliminary point, we would like to re-emphasize that our position is not that cMUT has already replaced cart-based systems. Instead, our position is that cMUT handheld ultrasound devices are a suitable and practical alternative specifically for handheld piezoelectric crystal ultrasound devices, eliminating any need for lead based piezoelectric crystals in handheld ultrasound devices.

a) Question No. 9 - You mention cMUTs as a mean to potentially eliminate the use of lead in ultrasonic transducers. Could you please explain in more details this technology and its performance capacities, possibly including some graphics illustrating the technology and how it generates (and receives) ultrasonic waves?

- According to COCIR, "cMUTs have the potential to be a lead-free alternative for ultrasound imaging with potentially wider bandwidths and smaller feature size".
    - This statement is factually incorrect since cMUT's are not limited to smaller feature size as demonstrated by the size of Butterfly's active aperture (30x13mm) and by it's element pitch (0.208 mm, appropriate for sector scanning at relatively low diagnostic frequencies).
- COCIR stated that "cMUT technology has yet to overcome significant technical limitations necessary to be a clinically viable alternative, including output pressure, reliability and linearity. Information from studies is provided to allow a comparison between the technologies in relation to insertion loss and reliability results."
    - This is simply not accurate today, and was inaccurate when COCIR stated the same without providing any real evidence in support. cMUT technology has proven to meet or exceed technical aspects of its piezoelectric counterparts and nothing speaks louder than the comparative images enclosed as Appendix B. Each generation of the Butterfly iQ products has demonstrated the clinical viability of cMUT technology in increasingly meaningful ways, and Butterfly's iQ3 provides the latest and most obvious example.[2] Butterfly would like to emphasize that:

- Butterfly has commercialized tens of thousands of handheld probes currently in operations in various clinical settings, ranging from conflict zones, like the Ukraine, to individual practitioner offices, to enterprise-wide deployments in institutions like Germany's Bonn University.
- Butterfly supported Tissue Harmonic Imaging (THI) with an MI > 0.6 at a 40Vpp transmit waveform (original iQ1). The transmit pressure was not limited by the cMUTs themselves, but by the max voltage of the CMOS electronics.
- Since 2018, Butterfly has been commercializing ultrasound handheld devices with cMUT sensors expected to exceed the life expectancy of other components of the probe, which are common to both PZT and cMUT transducers such as LiOn battery.
- Regarding linearity, COCIR consistently highlights this aspect as a drawback of cMUTs but does not provide substantive evidence supporting this claim. When operating in a non-collapsed mode (i.e., conventionally), cMUTs exhibit a strong asymmetric "square-law" behaviour which is likely COCIR's primary concern regarding linearity. This is not relevant for clinical performance. The deflection of the membrane during receive (~1 nanometer) is so small that linearity applies (linear small signal model). Therefore, this would only apply during transmit, and is only relevant when discussing THI and unwanted transmitted 2nd harmonics. Butterfly's cMUT devices operate differently – they:
    - operate in collapse mode,

[2] iQ3 has received FDA approval in the United States and Butterfly anticipates obtaining additional regulatory approvals outside of the United States.

  - adjust Vbias so that the transmitted 2nd is mitigated.
  - have the ability to use multi-level pulsing to pre-distort the waveform for any additional cMUT non-linearity.

- According to COCIR, "recognizing these limitations, researchers have focused their investigations on applications that play to the strengths of cMUTs, namely their ability to produce small feature sizes and wide bandwidths. These applications include catheters, endoscopic probes, high frequency linear arrays and probes with wide clinical coverage."
  - The commercial success and pervasiveness of Butterfly's cMUT technology indicates the opposite is true. Traditional external applications on the Butterfly iQ products exceeds the commercial cMUT availability for "catheters, endoscopic probes, high frequency linear arrays".
- According to COCIR, the technology "is still in development, but it is [...] highly unlikely [...] that sufficient performance will be obtained in the next 5-10 years";
  - We consider that Butterfly has demonstrated sufficient performance since 2018, specifically for the handheld ultrasound market. Butterfly's devices have received regulatory approval in approximately 30 countries – including numerous EU member states and the UK – and have been in use globally by over 145,000 users in a wide range of settings (including the Ukraine, sub-Saharan Africa, and large enterprise facilities). Butterfly's expansive global presence and user base are just clear indications that cMUT technology in handheld ultrasound has unquestionably surpassed the development phase and is very much in use on large scale. Of course, there are still efforts to innovate the technology further, but those developments will only unlock additional benefits of cMUT and further remove any perceived necessity for lead piezoelectric crystals in handheld ultrasound devices.
- An AC signal is injected to control the frequency. There are typically thousands of these "drumheads" on a transducer. Each transducer element consists of a selected group of thedrumheads. Diameter of the drumheads is the main controllingfactor in the resonance of the drumheads. Typically each elementcan have a multitude of different diameters all active in unison,thus generating large bandwidths because of frequency overlaps. A DC bias is necessary for cMUTs as well.
  - It is imperative to note that COCIR's understanding of drum diameter/size is inaccurate. While the use of different drum diameters was pursued in a few academic papers, it is not practiced in most cMUT commercial devices. Butterfly uses a uniform cMUT drum diameter (200um). This allows Butterfly to generate significantly higher pressure than a design that varied the drum diameter over the array. Butterfly does not have to vary the drum size to achieve greater bandwidth; the single drum diameter can achieve over a 160% fractional bandwidth (far greater than the most performant single crystal PZT).

b) Question No. 10 - You put forward that lifetimes of cMUTs significantly degrade as pressures are increased towards routinely applied pressures used and achieved with PZT and single crystal materials. What about the sensitivity of CMUTs for ultrasonic signals? If this sensitivity would be higher, the pressure could be reduced thus increasing the lifetime of the cMUTs provided they function as sending and receiving element at the same time

- COCIR argued that, "due to the insertion losses and linearity as described in the exemption request the sensitivity of the cMUTs is not higher than that of PZT or single crystal materials, so pressure cannot be reduced without unacceptable loss of performance."
  - This is not true for a majority of clinical applications and modes. For almost all high frequency b-mode applications (including 3D) and for all Doppler modes, THI (Tissue Harmonic Imaging) is not used. In this case, the superior receive performance of cMUTs works by design in correlation with lower transmit pressure. This is clearly demonstrated by the excellent sensitivity of Butterfly's Color Flow mode (small jets and other pathologies easily visualized and identified).

- According to COCIR, in THI, transmit pressures at low frequencies crucially may cause SNR reduction, demonstrated by a 1dB reduction resulting in a 2dB signal decrease, with additional complexity due to ultrasound wave attenuation in tissue.
    - While simple transmit/receive reciprocity (1dB/1dB) will not work for THI, Butterfly supports THI in a different way and has achieved clinically viable MI's (mechanical index, a measure of transmit pressure) by:
        - Using a larger active aperture, Butterfly has more focusing gain, and can achieve greater pressures at the focus.
        - Full independent control of unique foci in both the azimuth and elevation dimensions (due to Butterfly's 2D array). This allows Butterfly to increase the depth of field of peak pressures, allowing more distance for the harmonic generation to accumulate.
        - Multi-level digital electric waveform generation, which allows Butterfly to mitigate transmitted 2nd.
        - Superior receive SNR, allowing for better detection of the harmonic signals.
        - Advanced receive digital filtering, allowing Butterfly to better differentiate the harmonic signals from the unwanted fundamental echoes.

c) Question No 11 – You state that some desirable configurations such as 2D arrays for 3D imaging (these use arrays of many elements) use a common bias for all elements. However, if an individual cMUT element fails in such a way as to short the bias, the whole array will no longer function.

a. Could you please also explain why a failing individual cMUT element results in failure of the entire array compared to lead-based piezomaterials which seem not to have this problem?

- COCIR argued that, if a "failing individual cMUT element is due to common DC bias short, then the whole array will not functional. A DC bias voltage is typically applied to common (ground) side of all cMUT elements (e.g. through a capacitor CB to signal ground as in the figure below). If one element is shorted in such a way (e.g. to ground), the DC bias voltage will drop due to current flow by Exemption Evaluation under Directive 2011/65/EU | 6 shorting. The leakage current of shorting also generates extra heating for cMUT. Piezomaterials usually do not need bias to operate, so this failure mode will not occur."
    - In fact both PZT and cMUT phased array devices use a common plane or electrode. In the case of PZT, this plane is typically connected to ground (0 volts). For cMUT's, this is tied to a DC bias voltage (enables cMUTs to detect echoes on receive). COCIR's response is misleading. Whereas PZT's do not require a bias voltage, if there was a short between the individual element electrode and the common ground plane, it too would take out the high voltage rails and then the whole array will not function. Furthermore, PZT is susceptible to de-poling, which leads to a decrease in both transmit and receive efficiency. This will result in a PZT probe that is no longer diagnostic effective (a failure mechanism unique to PZT, and not cMUTs). All ultrasound devices have numerous possible modes of failure. It is up to the engineers and manufacturers to mitigate or negate these.

  Butterfly has addressed the above by focusing on the design and fabrication of the dielectric layer making such failures rare. In addition, Butterfly custom designs the electrical transmit waveform to mitigate damage to the dielectric layer, and ultimately has the ability to disable individual elements should a short occur (currently configured during manufacturing).

In summary, considering the above and contrary to COCIR's assertions, we believe that the clinical viability of cMUTs in handheld ultrasound devices is clearly demonstrated, as evidenced by Butterfly's widespread adoption with tens of thousands of users globally, including throughout the EU, and approval for 14+ clinical indications. The competitive image quality and diverse use cases, spanning from emergency to enterprise-wide deployments, underscore the unnecessary reliance on lead-based piezoelectric crystals in handheld ultrasound devices.

We propose to contact you in the coming days to confirm receipt of this letter, to see if further complementary

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information could be helpful and to seek guidance on the next steps in the consideration of these requests for renewal. We are happy to meet to discuss further and/or provide any additional insight that may be helpful as you continue reviewing the exemption at hand.

We thank you in advance for your attention.

Respectfully,

DocuSigned by:
Joseph DeVivo
B8730F2218340...

Joseph M. DeVivo

President, CEO, and Chairman of the Board

Butterfly Network, Inc.

Appendices:

Appendix A – Letter of 5 January 2024

Appendix B – Comparative Images

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Appendix A- 5 January 2024 Letter

To:
EUROPEAN COMMISSION
Directorate-General for Environment
Directorate B — Circular Economy
Unit B3 — Waste to Resources
E-mail: ENV-ROHS@ec.europa.eu

Sent by email only

5 January 2024

To whom it may concern:

RE: Requests for renewal of the exemptions under Annex III, n. 7I-I and Annex IV n. 14 of RoHS

We, Butterfly Network, Inc., parent entity of Butterfly Network Limited (Butterfly Network), are a digital health company based in the US with global operations, including within various EU member states. In 2018 we commercially launched the world's first handheld, single-probe, complete body ultrasound system using semiconductor technology, Butterfly iQ, and in 2020, we launched our second-generation probe, the Butterfly iQ+ with additional features and improved performance (the "Product"). We anticipate introducing our third-generation probe, Butterfly iQ3, in 2024 in certain localities, with a plan to continue launching in additional countries, subject to applicable regulatory approvals. Contrary to many traditional handheld ultrasound systems that utilise lead based piezoelectric crystals, Butterfly's Product harnesses the capabilities of semiconductor technology to enable ultrasound imaging capabilities with substantially similar results to its piezoelectric handheld ultrasound counterparts without relying upon lead based piezoelectric crystals in its transducers.

The perceived "gap" between handheld semiconductor based ultrasound systems and traditional handheld lead based piezoelectric based systems, used to justify the RoHS exemption permitting usage of lead based piezoelectric crystals in ultrasound transducers is, simply stated, virtually nonexistent. With Butterfly's semiconductor based Products offering at least comparable, if not superior capabilities in some instances, to its handheld piezoelectric counterparts, the numerous benefits offered by semiconductor based ultrasound systems has never been more clear. The advanced quality of semiconductor based ultrasound products is further evidenced by the adoption of Butterfly users, with more than 145,000 users of Butterfly Products worldwide after just a few years of commercial activity. The increasing prevalence of Butterfly's Products within the ultrasound market offers an unquestionable endorsement of the viability of semiconductor technology for handheld ultrasound users. Conversely, the growing utilization of Butterfly's Products serves as a clear indicator of the declining dependence upon lead based piezoelectric crystal ultrasound transducers in the handheld ultrasound market. We are writing you this letter to provide further information about our Product in the context of the ongoing procedures for the renewal of the exemptions contained in **Annex III, n. 7(c)-I** ("Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in capacitors, e.g. piezoelectronic devices, or in a glass or ceramic matrix compound") and **Annex IV n. 14** ("Lead in single crystal piezoelectric materials for ultrasonic transducers") of the Restrictions of Hazardous Substances Directive ("RoHS").[1]

I. Legislative and factual background

The legislative and factual background is as follows:

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02011L0065-20230901

- RoHS applies to electrical and electronic equipment ("EEE") falling within the categories set out in Annex I, including category 8 (Medical devices) and category 9 (Monitoring and control instruments including industrial monitoring and control instruments).

  Lead is listed in Annex II to RoHS as a restricted substance with a maximum allowable concentration of 0.1% by weight in homogeneous materials. This is due to the fact that lead can have detrimental effects on health and the environment. For instance, it may damage fertility or the unborn child, causes damage to organs through prolonged or repeated exposure, is very toxic to aquatic life with long lasting effects, may cause cancer, and may cause harm to breast-fed children.[2]

- Annex III to RoHS contains applications exempted from the restrictions on substances. More specifically, p. 7(c)-I of Annex III contains an exemption for "Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in capacitors, e.g. piezoelectronic devices, or in a glass or ceramic matrix compound."
- Annex IV to RoHS contains applications exempted from the restrictions on substances, specific to medical devices and monitoring and control instruments. More specifically, p. 14 of Annex IV contains an exemption for "Lead in single crystal piezoelectric materials for ultrasonic transducers".
- The exemptions were scheduled to expire on the following dates:
  - 21 July 2021 - Annex IV n. 14, categories 8 and 9, other than in vitro and industrial;
  - 21 July 2021 - Annex III n. 7(c)-I, categories 8 and 9 other than in vitro and industrial;
  - 21 July 2023 - Annex III n. 7(c)-I, category 8 in vitro;
  - 21 July 2024 - Annex III n. 7(c)-I, category 9 industrial.
- Renewal requests for all of the aforementioned exemptions were submitted on 2 January 2020 and are currently undergoing evaluation.

II. Availability of substitutes

It is noteworthy that exemptions under RoHS are granted under the premise that viable substitutes are not currently available.

This is evidenced by recital 18 to RoHS pursuant to which exemptions should be permitted if "substitution is not possible from the scientific and technical point of view, taking specific account of the situation of SMEs or if the negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the environmental, health and consumer safety benefits of the substitution or the reliability of substitutes is not ensured." (emphasis added)

Furthermore, Article 5(1)(a) of RoHS states that "Decisions on the inclusion of materials and components of EEE in the lists in Annexes III and IV and on the duration of any exemptions shall take into account the availability of substitutes and the socioeconomic impact of substitution." (emphasis added)

As a result, the entire exemption-granting process under RoHS relies on the availability of reliable and practical substitutes on the market.

Therefore, we would like to share details about our Product and the underlying technology, which we view as a **viable substitute to handheld ultrasound systems that utilise traditional crystal piezoelectric based materials**.

III. The Product

a) Technology behind the Product

As previewed above, the Product is a handheld ultrasound scanner that differentiates itself from other current commercially available ultrasound technology **by replacing traditional piezoelectric crystal-based transducers with**

[2] https://echa.europa.eu/nl/brief-profile/-/briefprofile/100.028.273

a single silicon chip containing a 2D array of 9000 capacitive micromachined ultrasound transducers ("CMUTs").[3]

CMUTs are silicon-based, micro-electromechanical system (MEMS) devices designed for electrostatic actuation.[4]

A single CMUT unit consists of a thin, conductive membrane separated from another conductive substrate by a vacuum gap, forming a capacitor. When a voltage is applied, the thin membrane acts like a small drum to generate ultrasound vibrations. Sound waves that are reflected from tissues similarly vibrate the thin membrane, generating an electrical signal that is then recorded.[5]

The Product comprises three components, namely (i) compatible Apple or Android mobile devices, (ii) the Butterfly iQ application on the compatible device, and (iii) a probe that facilitates connection with the mobile device to generate and receive ultrasound signals.[6] It utilises cloud computing for unlimited image storage, communication among clinicians, and connection with standard hospital medical record systems.[7] Its optimised electronics are integrated with a power-efficient field-programmable gate array (FPGA) chip, which offers strong battery life and thermal performance, while enabling appropriate scanning time.[8]

b) Benefits of the Product in comparison with traditional handheld piezoelectric based crystal ultrasound systems

In comparison with traditional piezoelectric based crystals, which are tuned to oscillate at defined frequencies, CMUTs have a **much wider bandwidth**[9] when they are applied to biological tissues and, therefore, a single transducer can be programmed to emit and detect many different frequencies. The broadband response of CMUTs allows output of a very short ultrasound pulse, enabling imaging with a high axial resolution and increased clinical utility.

By placing the CMUTs in a 2D array, the device can be programmed to emulate scanning patterns and wavefields from any type of transducer – linear, curved, and phased. As a result, **a single probe can be used for whole body imaging – a stark contrast to Butterfly's piezoelectric crystal handheld ultrasound counterparts that typically require multiple transducers and/or attachments in order to perform different scan applications**. The wide range of frequencies can be leveraged for a broad range of applications - e.g., from deep abdominal imaging with low frequencies, to shallow high-resolution imaging with high frequencies, all with the same array probe.

The acoustic impedance of CMUT devices is commonly quite close to the acoustic impedance of skin and soft tissue which **obviates the need for multiple acoustic matching layers commonly used in piezoelectric imaging probes**.

Furthermore, the CMUT technology integrates seamlessly with electronic circuits, enabling the consolidation of wiring onto a single semiconductor chip. The Product utilizes a cost-effective CMOS (complementary metal-oxide semiconductor) process for chip construction, contributing significantly to the **device's affordability** compared to traditional probes. More specifically, the Product currently costs just under EUR 2,500 and the All-in Bundle (including the Product, a 3-year warranty and all of Butterfly's software features in a single-payment membership that lasts for the entire life cycle of the Product is approximately EUR 4,210. By contrast, typical handheld ultrasound systems that use piezoelectric crystals can cost significantly more and often require the end user to purchase multiple attachments and/or probes to perform different scans.

Our Product also offers ample reliability, especially considering its cost-effectiveness and functionality coupled with its warranty, with devices priced under EUR 3,000. Moreover, the system has more than sufficient durability and can endure drops of up to 1,2 meters and electric shocks of up to 100G. This robust design has been validated in real-world scenarios, including deployment in war zones such as Ukraine, affirming the resilience and dependability of our probes under

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[3] Liu, BA, Joyce; Xu, MD, Jiajun; Forsberg, PhD, FAIUM, Flemming; and Liu, MD, Ji-Bin, "CMUT/CMOS-based Butterfly iQ – A Portable Personal Sonoscope" (2019). Department of Radiology Faculty Papers, available here.
[4] Herickhoff CD, van Schaijk R. cMUT technology developments. Z Med Phys. 2023, available here.
[5] As above.
[6] https://www.medicaldevice-network.com/projects/butterfly-iq-ultrasound-system/
[7] As above.
[8] As above.
[9] Vallet, Maëva et al. "Quantitative comparison of PZT and CMUT probes for photoacoustic imaging: Experimental validation." Photoacoustics vol. 8 48-58. 22 Sep. 2017, doi:10.1016/j.pacs.2017.09.001

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challenging conditions.[10]

Another major future potential for the Product is **its interface with artificial intelligence (AI) technology**. In fact, the 2D array enables more cost-effective AI development compared to traditional piezoelectric based crystals. As an example, in April 2023, Butterfly Network received clearance in the US for a ground-breaking AI-enabled Auto B-line Counter that may simplify how healthcare professionals evaluate adults with suspected diminished lung function and can potentially accelerate their ability to make informed treatment decisions at the point of care.[11] The Product contains numerous other AI components, and Butterfly plans to continue to introduce additional AI products.

IV. Advancements in CMUT Technology

The CMUT technology has swiftly advanced in the past two decades, increasingly so over recent years, optimizing broadband response for unique ultrasound imaging applications. We believe that the rapid evolution of CMUT technology underscores that the progress achieved thus far represents only a fraction of its potential. The substantial strides observed in recent years serve as an indicator of the accelerated pace of development in contrast to the earlier stages when CMUT within ultrasound was a comparatively lesser-known technology, largely limited to academic research and not viewed as a viable commercial technology. This accelerated trajectory bodes well for the continued maturation and widespread adoption of CMUT in diverse applications, promising further breakthroughs in the near future.

As an illustrative example of this swift evolution, within a mere two years after the launch of Butterfly iQ, we introduced the enhanced Butterfly iQ+ featuring additional functionalities and improved performance. Looking ahead to 2024, we anticipate the launch of our next-generation Butterfly iQ3 (subject to applicable regulatory approvals), poised to elevate image quality even further for CMUT ultrasound probes and continue to invalidate any perceived "gap" between CMUT ultrasound products and piezoelectric handheld counterparts. This innovation trajectory is backed by Moore's Law – a guiding principal of the semiconductor industry first observed in 1965 by Intel co-founder, Gordon Moore. Moore's Law states that the number of transistors on an integrated circuit will double every two years – meaning the computer processing power of a chip doubles every two years with minimal rise in cost.[12] The observation still holds true today, supporting Butterfly's commitment to pushing the boundaries of technological advancements in the field of ultrasound. As our chip processing power doubles, our technology becomes greater, among other benefits. Much like the photography industry, when digital camera's image quality became equal to that of analog cameras, digital took over because it brought many other benefits – such as affordability, miniaturization, and advanced features for ease of use. Butterfly is driving that same transformation for the ultrasound industry.

In light of all of the above, we believe that our Product constitutes a reliable, practical, and cost-effective substitute to traditional lead based piezoelectric handheld ultrasound transducers. Accordingly, we would like to respectfully request that you consider the above information in the context of the ongoing procedures for the renewal of the exemptions contained in Annex III, n. 7(c)-I and Annex IV n. 14 of RoHS. We remain ready and available to provide any additional information that may assist in your review of this matter.

We thank you in advance for your attention.

Yours sincerely,

DocuSigned by:
Joseph DeVivo
B8730173213246A...

Joseph M. DeVivo

President, CEO & Chairman of the Board

Butterfly Network, Inc.

[10] https://www.butterflynetwork.com/press-releases/butterfly-razom-ukraine
[11] https://www.butterflynetwork.com/press-releases/fda-clearance-butterfly-auto-b-lines-ai-tool
[12] https://www.intel.com/content/www/us/en/newsroom/resources/moores-law.html#gs.32j81k

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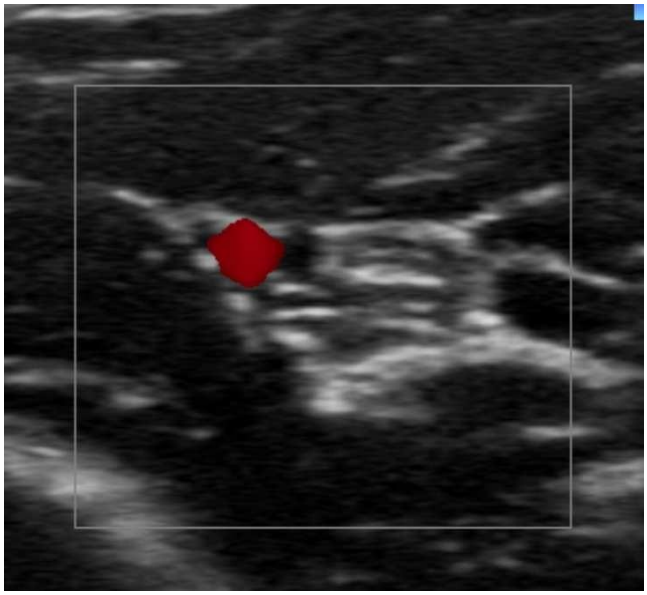
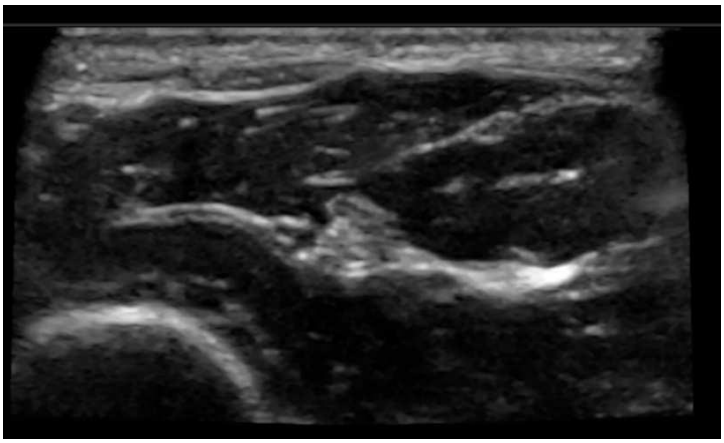
Appendix B- Comparative Images

Nerve Preset (Median Nerve) – Commonly used in Anesthesia procedures

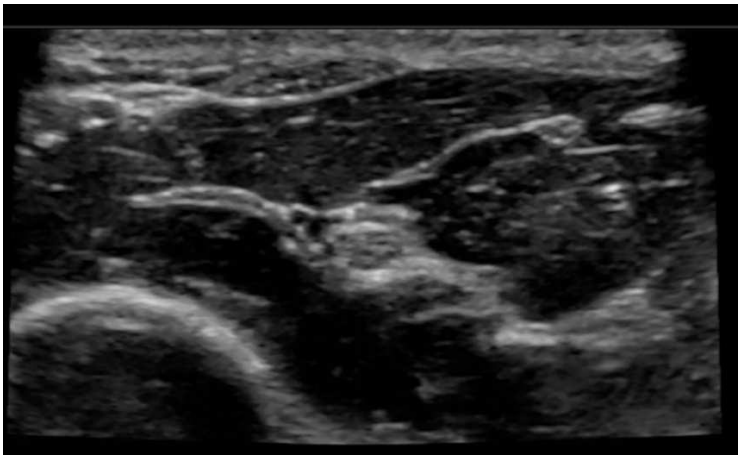
Piezoelectric Crystal Handheld Ultrasound Device



Butterfly iQ+



Butterfly iQ3 (pending regulatory clearance outside US)



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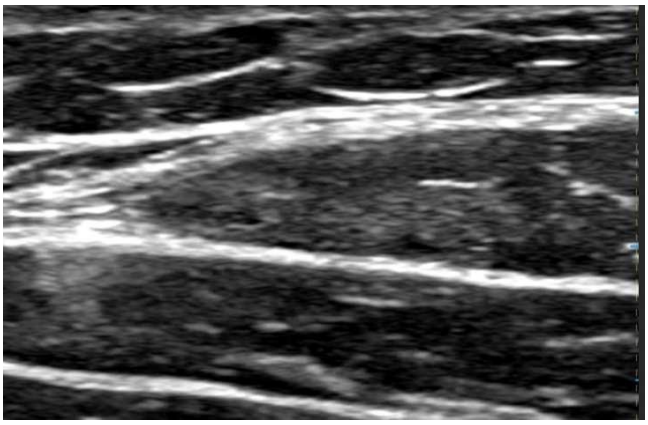
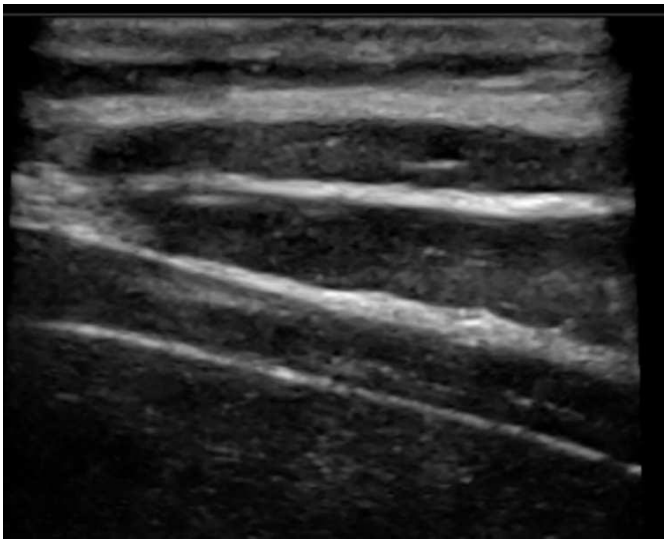
Nerve Preset (Nerve TAP) – Commonly used in Anesthesia procedures

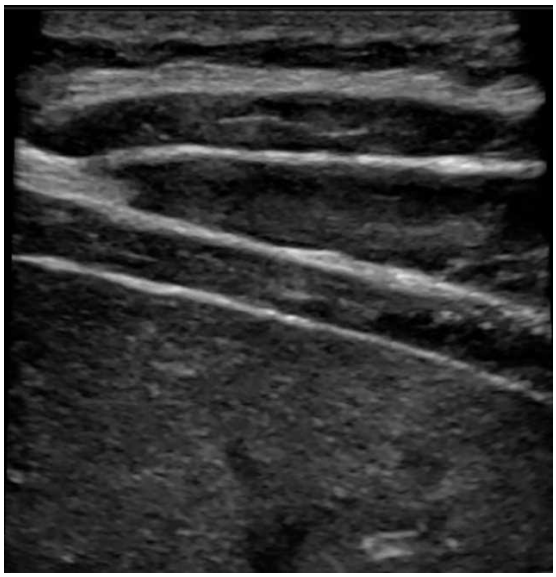
Piezoelectric Crystal Handheld Ultrasound Device



Butterfly iQ+



Butterfly iQ3 (pending regulatory clearance outside US)



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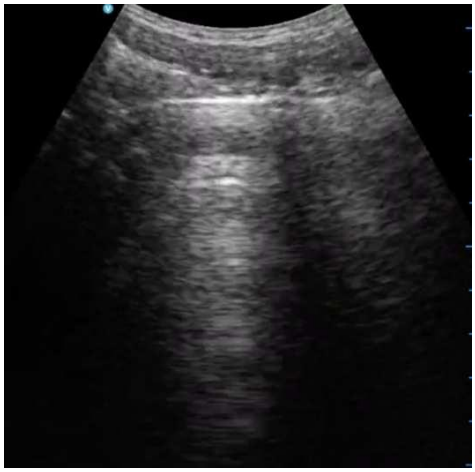
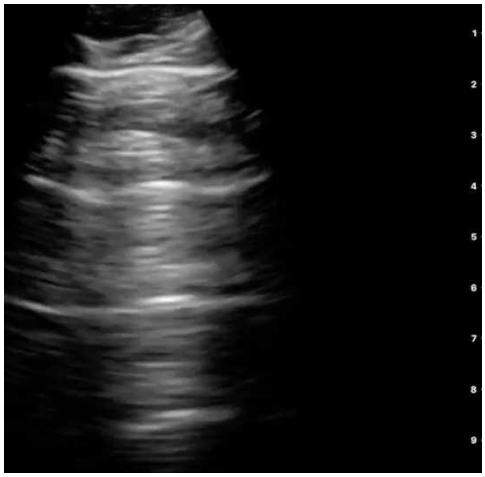
Lung Preset (Lung A-Lines) – Commonly used in emergency medical, hospitals, critical care unit

Piezeolectric Crystal Handheld Ultrasound Device



Butterfly iQ+



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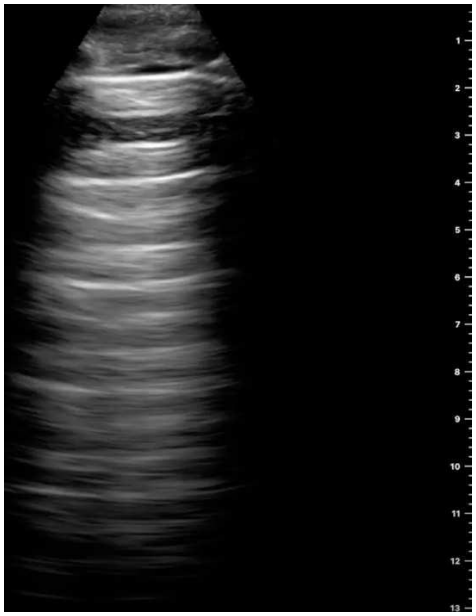

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MSK Preset (Anterior Knee) – Commonly used in emergency medical, general practice, primary care, nursing

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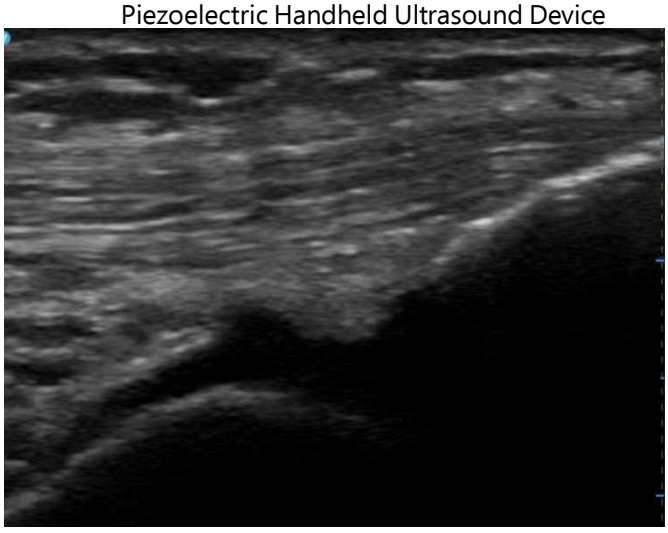

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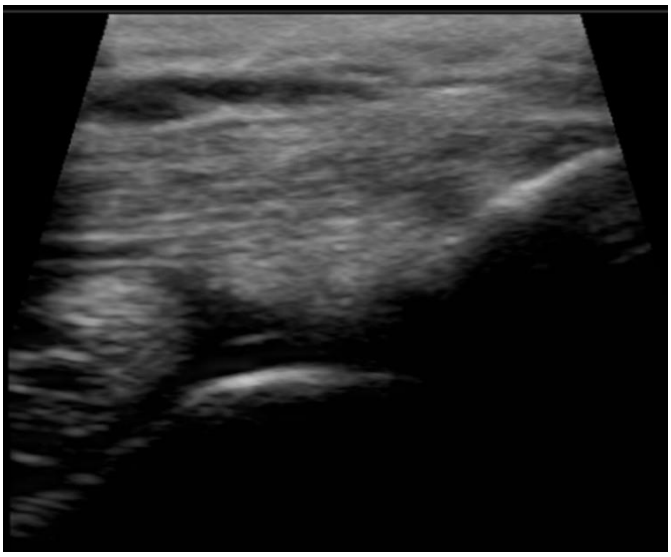

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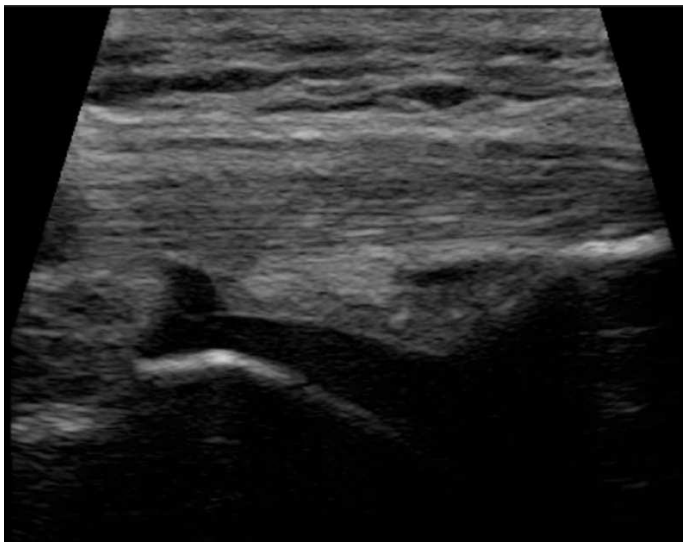

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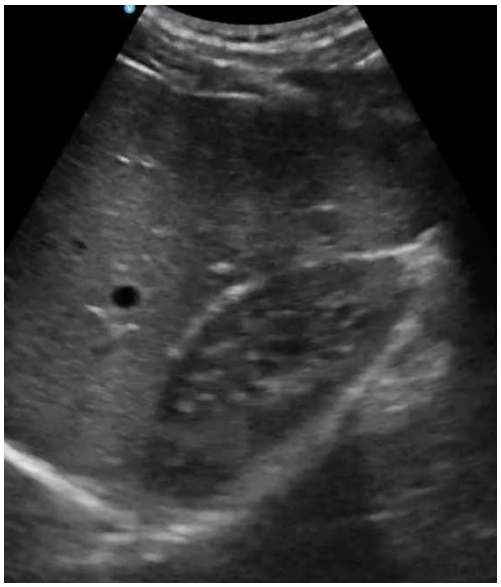
Abdomen Preset (RUQ) – commonly used in hospitals, critical care units

Piezoelectric Handheld Ultrasound Device



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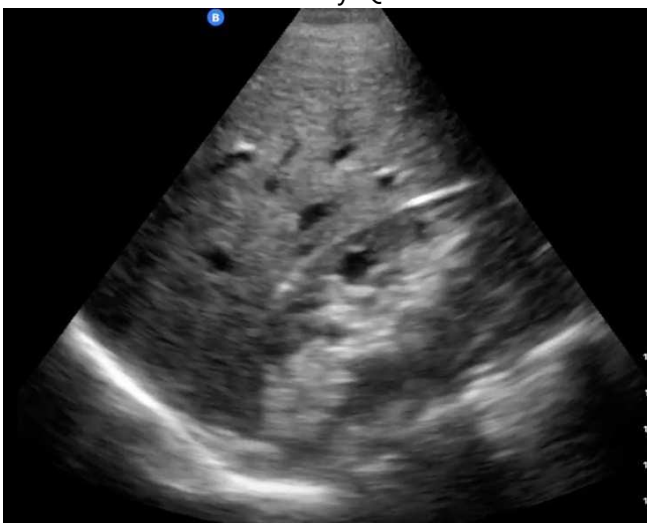
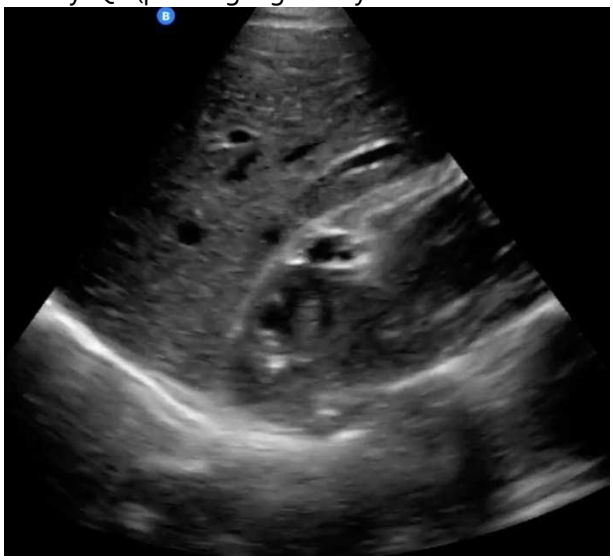


Butterfly iQ3 (pending regulatory clearance outside US)



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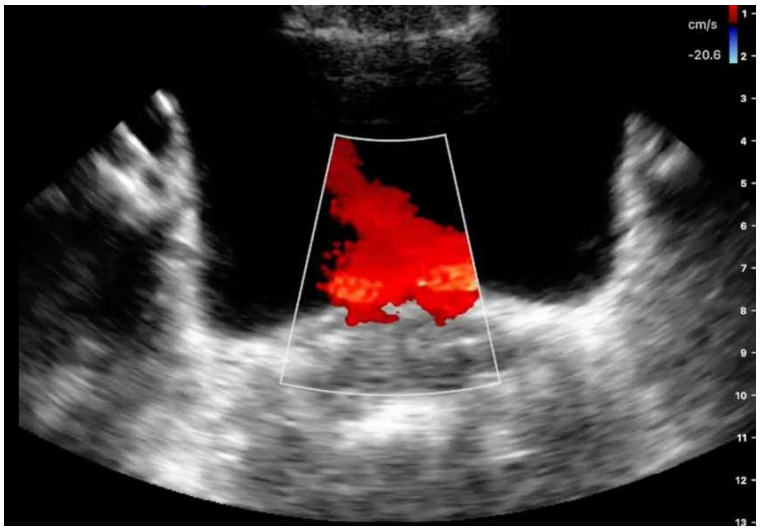
Bladder Preset – commonly used in general practice, primary care, nursing

Piezoelectirc Crystal Handheld Device



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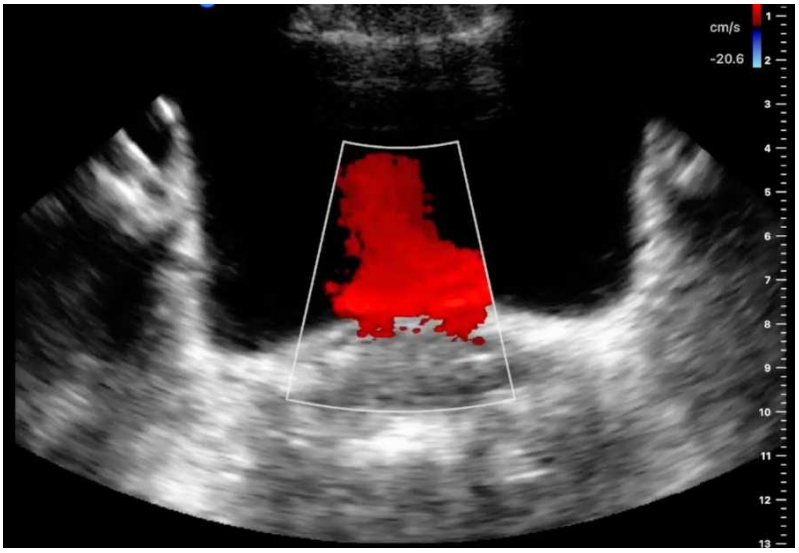

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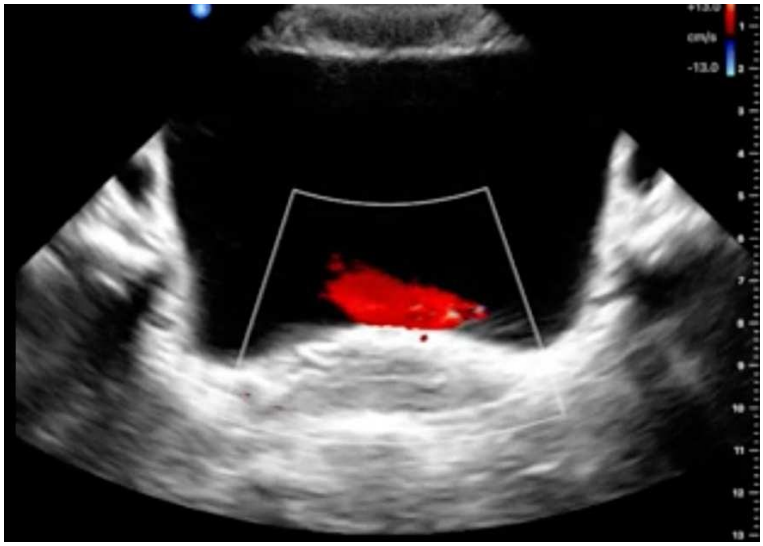

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Small Parts 2 cm Preset (Lymph Node) – commonly used in general practice, primary care, nursing

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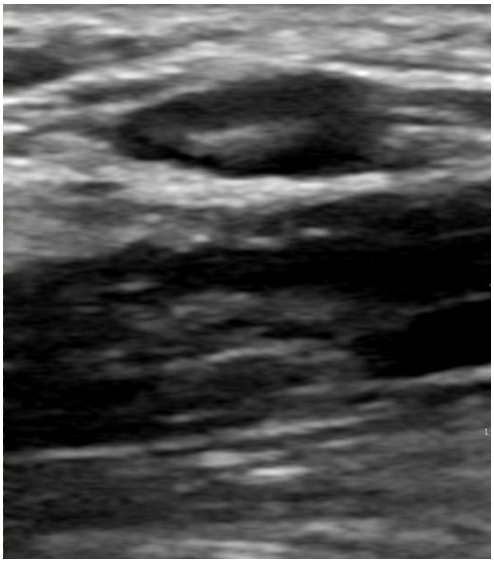

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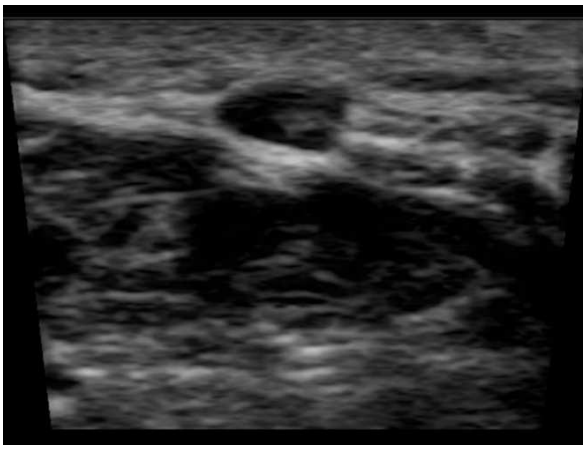

Butterfly iQ3 (pending regulatory clearance outside US)