This document forms GE HealthCare's contribution to Oeko-Institut's consultation on the revocation request to **Directive 2011/65/EU (RoHS 2) exemption Annex IV n. 14**.

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2 Summary

While subsequent sections of this document provide detailed justifications for GE HealthCare's (GEHC) arguments, this summary addresses Oeko Institute's questions in an abbreviated form. The document sections describing the details are referred to in brackets […].

2.1 Do you agree with the arguments put forward by the applicant? Are there any additional reasons that support the requested revocation of the exemption?

GEHC does not agree with the applicant's arguments and no further support for the requested revocation is given.

2.2 In your opinion, what reasons oppose the requested revocation of the exemption?

Numerous reasons oppose the revocation:

- Clinical / technical reasons
    - Single crystal (SC) ultrasound provides unmatched image quality and diagnostic confidence in a large portion of imaging situations [4.1 and 4.1.1]
    - SC is inherently linear, thus creating high quality images [4.1, 4.1.1 and 8]
    - Single crystal transducers (including drive electronics) provide high power efficiency which leads to minimized probe heating and allows for more ergonomic probe designs [4.1.2 and 4.1.2].
- SC materials have established supply chains available to multiple ultrasound manufacturers. There are no established supply chains for lead-free options. Multiple SC suppliers compete for lowest cost and best materials. SC supplier innovations benefit multiple ultrasound manufacturers and a large clinical customer base. [9]
- Socio-economic and public health impacts due to eliminating existing clinical devices. Clinical customer's purchasing options reduced if revoked. [7]
- Revocation would put at risk decades of European innovation in market leading Ultrasound technology and existing EU manufacturing capacity, eliminate innovation pathways towards lower lead content, disrupt established resilient supply chains and reduce the EU's autonomy in a sector that is critical for public health and preparedness, and in turn increase the EU's dependency on ultrasound technology from foreign countries. [7]
- Revoking the exemption would significantly reduce the range of diagnostic tools available to healthcare professionals. Limiting access to proven technologies would constrain clinicians' ability to select the most appropriate equipment for specific patient needs, potentially impacting both diagnostic accuracy and treatment outcomes. [7]

2.3 How do you rate cMUT technology in terms of image quality and reliability? What technical parameters are used to evaluate diagnostic procedures? Based on your experience, how would you rate conventional technology based on lead in single crystal piezoelectric materials for ultrasonic transducers compared to cMUT technology?

- cMUT's image quality is inferior to single crystal in many imaging conditions [4.1 and 4.1.1]. Its main problems are insufficient acoustic output pressure, transmit nonlinearity and power inefficiency [4.1.2]
- cMUT's reliability is questionable to GEHC. Earlier publications have highlighted significant reliability problems. The applicant does not substantiate its assertion that cMUT has higher reliability. The reliability of lead-based probes has been established over many years, even decades and is the technological standard in console-based Ultrasound systems installed in hospitals worldwide. GEHC's Vscan Air fulfills the relevant IEC and MIL standards. [5]

- GEHC is not aware of measurable technical parameters evaluating diagnostic procedures. Several independent researchers have compared different hand-held devices with the general conclusion that the cMUT devices were inferior to conventional ones. [4.1]

2.4 How do you assess the potential negative effects of substitution on occupational health and consumer safety, reliability of the cMUT technology? How do you assess the overall benefits of cMUT technology for the environment, health and consumer safety?

- Occupational Health: The cMUT technology's lower power efficiency increases device heating and requires a larger and heavier probe. This can aggravate repetitive strain injuries and reduces mobility. [4.1.2]
- Consumer safety: no benefit nor disadvantage compared to single crystal [6]
- Reliability addressed in question 2.2
- Environment: cMUT has no lead, but its manufacturing (silicon wafer processing involves lead-based equipment). Lead-based single crystal has insignificant environmental, health or consumer safety impact. [6]

2.5 Are there any other aspects that you believe should be taken into account when assessing this application? Please provide relevant documents and evidence.

- The applicant is the only company with a cMUT product reaching some commercial success. Other cMUT companies, Fujifilm (formerly Hitachi) and Kolo Medical, have not been successful for clinical applications. The applicant however is on an uncertain financial track due to large financial losses and uncertain product pricing. If the revocation were granted, EU's access to handheld ultrasound could be strongly diminished. This is outlined in sections [9 and 10].
- Some of the statements in the revocation application are incorrect or misleading. The subsequent sections will highlight those.
- While lead content is undesirable, the amount of lead used in medical ultrasound is rather small compared to other industries. [6 and COCIR submission]

2.6 What are the limitations of cMUT technology? Which applications cannot be replaced by cMUT technology but are possible with other handheld ultrasonic transducers or vice versa?

- Lack of cMUT's image quality and diagnostic value in a large portion of imaging situations [4.1 and 4.1.1].
- cMUT's limited harmonic imaging capability and subsequent image quality loss [4.1, 4.1.1 and 8].
- cMUT's power inefficiency leading to excessive probe heating and/or larger/heavier probes and/or limitations to features like wireless connectivity [4.1.2 and 4.1.2].

- cMUT transducers cannot be made into convex or micro convex (radius of curvature less than 10mm). Micro convex transducers are essential for endo cavity probes. Applications where linear/flat transducers are preferable would still incur substantial loss of diagnostic value if they were replaced by cMUT [4.1 and 4.1.1]. This is more extensively described in COCIR's submission.

2.7 How do you assess the EU's dependency on other countries in this sector? Would a revocation of the exemption increase the EU's dependency? If so, why?

Several EU countries host ultrasound companies and manufacturing sites, including GEHC, which rely on the lead-based single crystal exemption. A revocation of this established technology would reduce the strategic sovereignty of the EU in its ability to bring EU-made handheld ultrasound medical devices to its market and increase the dependency on non-EU countries in a strategic segment of ultrasound technology. Butterfly's supply chain includes the bare cMUT wafers from Finland; it is however only a small portion of its value chain, while most of the manufacturing occurs outside of the EU. [7]

3 Opening Statement/ Executive Summary

This document is submitted by GE HealthCare (GEHC) in response to the RoHS Annex IV, exemption 14 revocation request consultation.

GEHC does not support the revocation request and would like to address a number of the arguments put forward by the applicant, Butterfly Network Inc. (Butterfly). GEHC would also like to highlight that it has contributed to the COCIR 2025 exemption renewal request with additional reasons why the exemption under consideration **should not be revoked** as suggested by the applicant. The exemption should not be revoked for the following reasons:

(1) Many of the applicant's claims **lack robust scientific evidence** and do not align with the criteria listed in Art. 5 (1) (a) of RoHS.
(2) Approving the revocation would pose a **risk of directly affecting patient outcomes both now and in the future, and of potentially marginalising certain patient categories**. The removal of the single crystal (SC) sensor for handheld devices would **both limit current diagnostic imaging capacities across the EU, as well as hinder innovation and advancements in imaging capabilities**. More specifically, it has not been demonstrated that the applicant's cMUT- based scanner has equivalent or higher functionality across the wide range of possible clinical indications and patient presentations compared to SC based scanners.
(3) There are potential impacts on future innovation and socio-economic factors. Revoking the exemption would **hinder the development of state-of-the-art ultrasound** imaging capabilities in the EU, thereby increasing the EU's dependency on non-EU countries for handheld ultrasound devices. This would have a negative impact on the EU's medical technology value chain and other stakeholders such as healthcare professionals, medical research institutions and charitable organisations.

This revocation response is structured in a way that directly addresses the points put forward by the applicant, grouped by the RoHS criteria,[1] and followed by additional supporting arguments.

Abbreviations and acronyms are listed in Appendix C.

4 Is substitution scientifically or technically practicable?

4.1 Imaging Capability

Capacitive micromachined ultrasound transducer ("cMUT") based sensor devices do not have *'equivalent or higher functionality'* to single crystal ("SC") sensors as claimed in the revocation request. Rather SC devices offer unique technical functionality which is not able to be provided

[1] RoHS exemption/revocation criteria:
- Is substitution scientifically or technically impracticable
- Is the substitute reliable
- Environmental, health and consumer safety impacts.

by cMUT devices. Functionality is interpreted here as imaging capability[2] of the scanning device across the wide range of possible clinical indications and patient presentations[3]. This is the primary function of an ultrasound scanner. Reduced imaging capability also increases the risk of marginalising some patient categories (e.g. high BMI patients). The significance of imaging capability is emphasised in Handheld Ultrasound ("HHUS")[4] comparison studies carried out by independent, external ultrasound experts.[5,6,7.]

As an example of one of these studies[6], Figure 1 shows different characteristics (Image Quality and Ease of Use) for a number of HHUS devices. While the investigators find a certain spread in "Ease of Use," this is likely not related to the cMUT vs. SC question. For image quality however, the cMUT device is found to be inferior to all of the other HHUS devices. This will be further substantiated in a number of examples later. While this study was not done with the latest cMUT device, the results are still indicative of the fact that cMUTs are not an equivalent substitute for SC, or even lead-based ceramic piezoelectric (Lead Zirconate Titanate "PZT") devices.

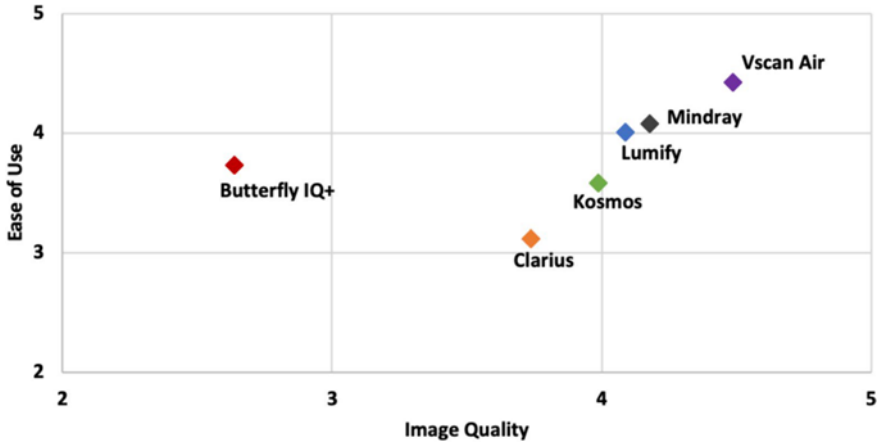


Figure 1: Image Quality / Ease of Use Results from external publication[6]

GEHC SC-based handheld scanners are capable of operating across all of the 12 clinical indications listed[8] in the Butterfly iQ3 manual, but more importantly they can be used in many other clinical indications. It is important to note that although the applicant claims to be able to operate within the 12 clinical indications, there are still occurrences within the clinical indications where only SC devices are able to offer the necessary technical performance. For example, in some scanning scenarios, the transducer needs to be a **certain geometry that cannot be physically achieved with cMUT devices**. Two examples include (1) the micro convex endo-cavity array required for infertility treatment, and (2) larger radius convex arrays typically used for abdominal imaging. The Clarius EC7 is an example of such a handheld endo-cavity probe used in early obstetrics, gynaecology, IVF, pelvic, and urology exams. The development of optimal probe geometries is ongoing at GEHC. The larger radius convex probes are the 'normal' probe to use for abdominal scanning. Scanning with a linear array (as suggested

[2] Imaging capability refers to imaging resolution, depth of penetration and suppression of imaging artifacts like haze or reverberations.

[3] Patient presentation refers to a patient's body habitus, BMI, physiological and anatomical characteristics.

[4] HHUS – Handheld Ultrasound Scanner

[5] Le et al. The Ultrasound Journal 2022 - Comparison of four handheld point-of-care ultrasound devices by expert users.

[6] Perez-Sanchez et al. The Ultrasound Journal 2024 - Comparison of 6 handheld ultrasound devices by point-of-care ultrasound experts: a cross-sectional study. https://pmc.ncbi.nlm.nih.gov/articles/PMC11447175/

[7] Merkel, Lueders, Schneider, Yousefzada, Ruppert, J., Weimer, Herzog, Lorenz, Vieth, Buggenhagen, et al. Prospective Comparison of Nine Different Handheld Ultrasound (HHUS) Devices by Ultrasound Experts with Regard to B-Scan Quality, Device Handling and Software in Abdominal Sonography

[8] Peripheral Vessel (including carotid, deep vein thrombosis and arterial studies), Procedural Guidance, Small Organs (including thyroid, scrotum and breast), Cardiac, Abdominal, Lung, Urology, Fetal/Obstetric, Gynaecological, Musculoskeletal (conventional), Musculoskeletal (superficial), Ophthalmic.

by the revocation applicant) is used in only limited cases like first trimester obstetrics, and is unable to offer the same degree of image quality as non-linear probes. Details of other geometry and transducer arrays that cannot be physically achieved with the cMUT device are presented in the COCIR 2025 renewal submission.

Another key functional requirement of an ultrasound scanner is the **ability to perform across all patient presentations**. Some patients are classified as 'hard to scan.' There are a number of factors which classify a patient as hard to scan. One critical factor is the BMI of a patient. Patients with a high BMI, often termed 'of large body habitus'[9] can be difficult to scan because the ultrasound waves must travel further to reach the target and are weakened in strength by the fatty tissue. SC devices offer higher transmit pressures as indicated by Mechanical Index ("MI") values (iQ3 less than 0.6, others less than 1.9). Additionally, the higher transmit pressure allows for substantially better harmonic imaging which further reduces 'haze' and other image artifacts arising from the adipose tissue. The higher transmit pressures achievable with SC devices mean that these devices are able to perform better than cMUT where patients present with a higher BMI. According to Eurostat,[10] the number *of "overweight and obese people is increasing at a rapid rate in most of the EU countries, with 50.6% of people aged 16 years or over in the EU being overweight"*. So, to ensure an acceptable level of diagnostic care can be offered to an increasingly high proportion of the EU population, it is essential SC devices remain available. There are other factors which can also place patients in the hard to scan category, for example rib spacing/chest wall anatomy, levels of scar tissue, and the presence of COPD[11].

The primary benefit of harmonic imaging is a reduction in imaging artifacts from superficial tissue layers (cartilage, adipose tissue, rib reflections). Reflections within these layers create 'haze' and other unrealistic patterns in the image, reducing the visibility of the true tissue structures. Harmonically generated images are less prone to these image disturbances. These effects are demonstrated in the image comparisons in Section 4.1.1 and Appendix A .

In addition to generating higher transmit pressures, SC devices are also capable of **higher quality harmonic imaging which is an essential imaging mode for diagnosing hard to scan patients**. It balances the need for depth, achieved by transmitting low frequency waves (which penetrate deeper) and detail which is achieved by receiving the higher frequency harmonics (which provide a better resolution). The nonlinear response of cMUT devices, in addition to the lower output pressure, degrades their harmonic imaging qualities. The applicant's statement of having solved the nonlinearity problem is only partially true. The applicant's solution of controlling the transmit voltage to suppress transmitted harmonics reduces the overall output pressure (which then hinders the desired nonlinear wave generation) and degrades power efficiency. The impacts of efficiency are discussed in section 4.1.2.

GEHC would also like to highlight that the applicant's statement "*For almost all high frequency b-mode applications (including 3D) … THI (Tissue Harmonic Imaging) is not used*" is not correct. GEHC and other ultrasound manufacturers extensively use **THI for higher frequency applications like vascular or musculoskeletal (MSK) applications,** again for the purpose of achieving clearer images for the clinicians. Specific examples are given in Section 4.1.1. and Appendix A.

The imaging capability of **SC scanners is considered by GEHC to be superior to that of the cMUT device, a view supported by clinicians in trials comparing device types**[12,13,14]. In the same way the

[9] Ultrasound Limited by Large Body Habitus – Radiology In Plain English, Ultrasound for the Ultra-challenging Patient

[10] Overweight and obesity - BMI statistics - Statistics Explained - Eurostat- data from 2022

[11] Chronic Obstructive Pulmonary Disease

[12] Le et al. The Ultrasound Journal 2022 - Comparison of four handheld point-of-care ultrasound devices by expert users.

[13] Perez-Sanchez et al. The Ultrasound Journal 2024 - Comparison of 6 handheld ultrasound devices by point-of-care ultrasound experts: a cross-sectional study

[14] Merkel, Lueders, Schneider, Yousefzada, Ruppert, J., Weimer, Herzog, Lorenz, Vieth, Buggenhagen, et al. Prospective Comparison of Nine Different Handheld Ultrasound (HHUS) Devices by Ultrasound Experts with Regard to B-Scan Quality, Device Handling and Software in Abdominal Sonography

applicant presented a number of comparative images, GEHC would like to share comparison images in Section 4.1.1 and Appendix A , which highlight the **risk for either missed diagnosis[15] or incorrect diagnosis**.

Due to the inferior imaging capability of the cMUT based device, there is a **real risk to patient outcomes** if the SC devices were to be withdrawn from the market due to the approval of the proposed revocation. This assertion is further supported by a letter from Dr Martin Altersberger[16], head of the echo laboratory in the state hospital of Steyr, Austria (appendix B).

4.1.1 Image comparisons

GEHC would like to highlight performance differences between its handheld device Vscan Air and the applicant's Butterfly iQ3. Both devices are the latest models of handheld SC and cMUT-based devices. Since GEHC does not have the technical details of the iQ3, GEHC showcases the difference in image quality, which is essential to accurate diagnostics. The applicant has also shown image comparisons in its application document, but GEHC believes these were acquired on easy to scan[17] individuals. GEHC maintains that the ultrasound devices must perform well over a wide range of patient presentations and imaging applications. It is therefore not adequate to consider only the 'best' outcomes. In contrast, the following comparisons will focus on "hard to scan" individuals.

The scanned subjects are volunteers; scanning was not done as part of an actual diagnostic procedure. For some subjects, clinical pathologies were known and indicated on the images. The images were acquired by licensed sonographers who were given the following instructions:

- Select the appropriate clinical application for each of the devices (with default settings); the only parameters potentially modified were Gain, Imaging depth and Colorflow box location.

- Select probe position for best possible image.

In each comparison, images were taken by the same sonographer from the same subject at essentially the same time.

It is evident from the images, that the iQ3 frequently exhibits limitations in providing high-quality diagnostic information, which can make the diagnosis more challenging thereby reducing the clinicians' confidence in the diagnosis. GEHC attributes the reduced image quality primarily to insufficient harmonic generation, likely resulting from lower acoustic output pressure (as reflected by the MI values: 1.4 to 1.9 for Vscan compared to less than 0.6 for iQ3) and potentially to transmitted second harmonic components.

The full set of image comparisons is collected in the appendix file: *GEHC_Image_Comparisons_07242025.ppsx*, submitted with this document. The comparisons show Vscan with single crystal on the left, iQ3 with cMUT on the right unless otherwise indicated. The three sets of images below have been selected to emphasise the differences in imaging capability between the cMUT and SC device, and the possible impact on diagnosis and ultimately patient health.

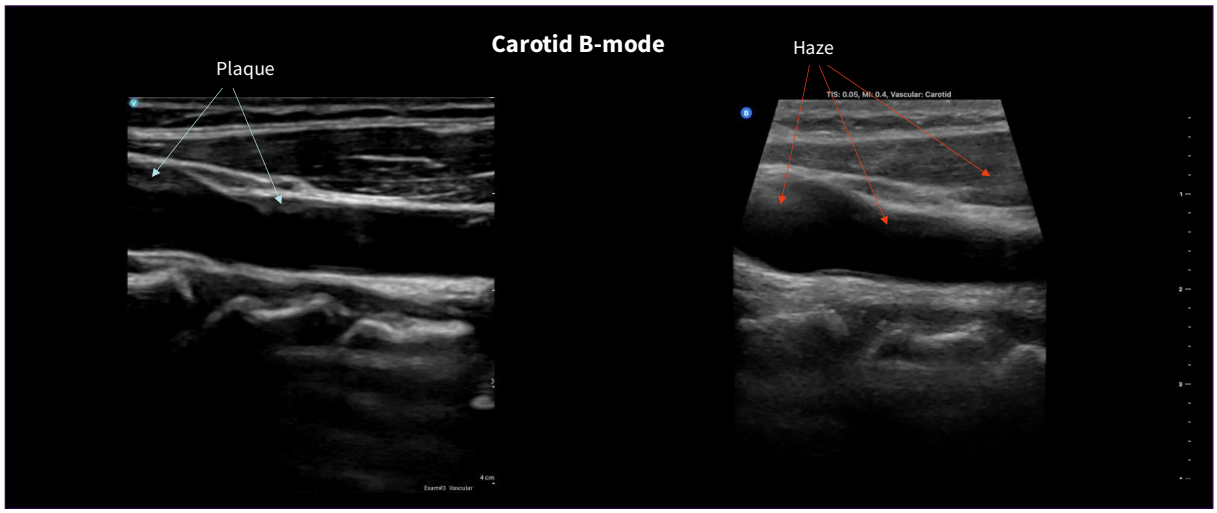
Figure 2 (which is Figure I-10 in the appendix file) shows the carotid artery. The subject has a small amount of plaque buildup which can be seen on the Vscan image (see blue arrows). The iQ3 has a haze overlay in the nearfield which obscures the plaque (red arrows); thus, the plaque would not be detected. Unchecked, the build-up of plaque (carotid artery disease) significantly increases the risk of stroke for a patient. In addition, the 'haze' also hides the fine structure of the muscle layer between the skin and

[15] when a medical condition is not identified during the initial examination of the scan.

[16] Dr. Altersberger is a key opinion leader to GEHC

[17] "Easy to scan", in contrast to "hard to scan" are individuals with typically low BMI, wider rib spacing and other anatomical aspects that cause blurriness and haze in the image.

carotid. Seeing the muscle structure is essential in diagnosing muscle tears[18]. Without it, tears are easily overlooked.



Vscan iQ3 (cMUT)

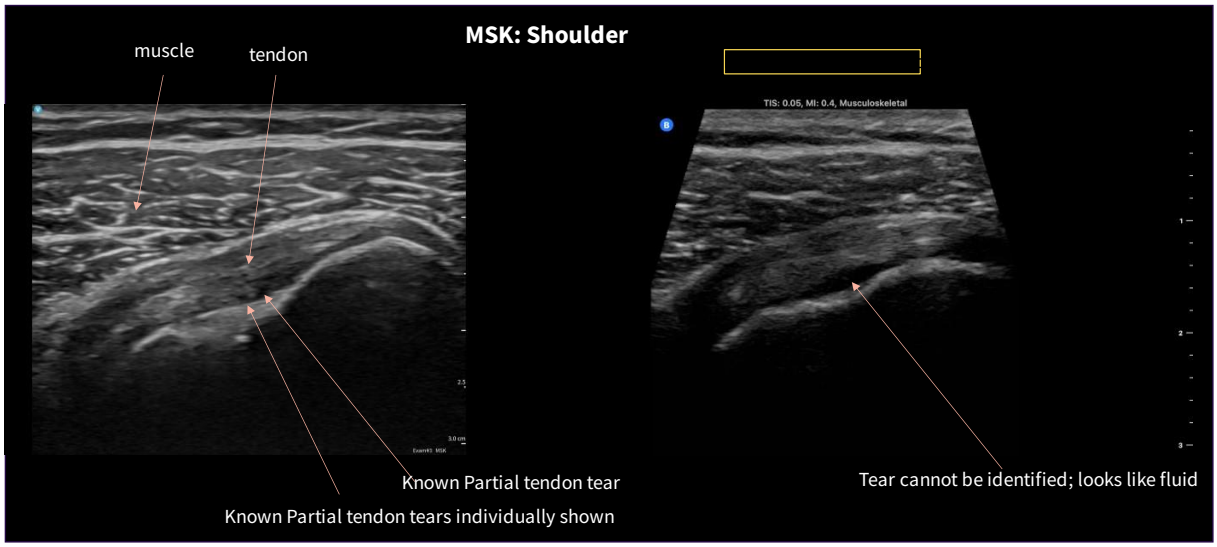
Figure 2: Carotid artery showing plaque on Vscan (left), obscured by haze on iQ3 (right)

Figure 3 (Figure I-12 in appendix file) shows a shoulder tendon with a known tendon tear. The tear appears as small black holes on the far side of the tendon. These are clearly visible and easily diagnosed from the Vscan image. On the iQ3, a large black oval appears which is more indicative of fluid accumulation than a tear. There is a **risk of misdiagnosis with the iQ3 image**. Also, the Vscan shows a clear delineation of the shoulder tendon and detailed visualization of the muscular tissue. This diagnostic exam is usually done on patients who present for pain treatment. The correct diagnosis drives the subsequent therapy which is rest/immobilization for a tendon tear and physical therapy or steroid injection for inflammation (fluid buildup). The iQ3 in contrast shows less definition of both the tendon boundary and muscular structure. GEHC believes from its evidence that Vscan's superior image quality comes from the use of harmonic imaging which the cMUT device cannot do for the higher frequencies needed for MSK[19] imaging. As noted previously, the applicant states that harmonics (THI) is not needed for high frequency – these images are a good example of why it is needed. GEHC does not know the exact reason why the iQ3 doesn't use THI, but conjectures that is either directly or indirectly related to the cMUT sensor.

Similarly, Figure I-11 in the appendix (image not copied in this document) shows the patellar tendon (MSK application). The tendon is more clearly visualized with Vscan with the fine structure of the tendon. A tendon tear, even if minor, would have been easily detected if present. Structures below the tendon are well visualized. There is no visualization of far field structures on the iQ3 image.

[18] https://www.jointpainclinics.co.uk/blog/muscle-tear-while-playing-sports-how-an-ultrasound-scan-can-diagnose-and-guide-recovery

[19] MSK - Musculoskeletal

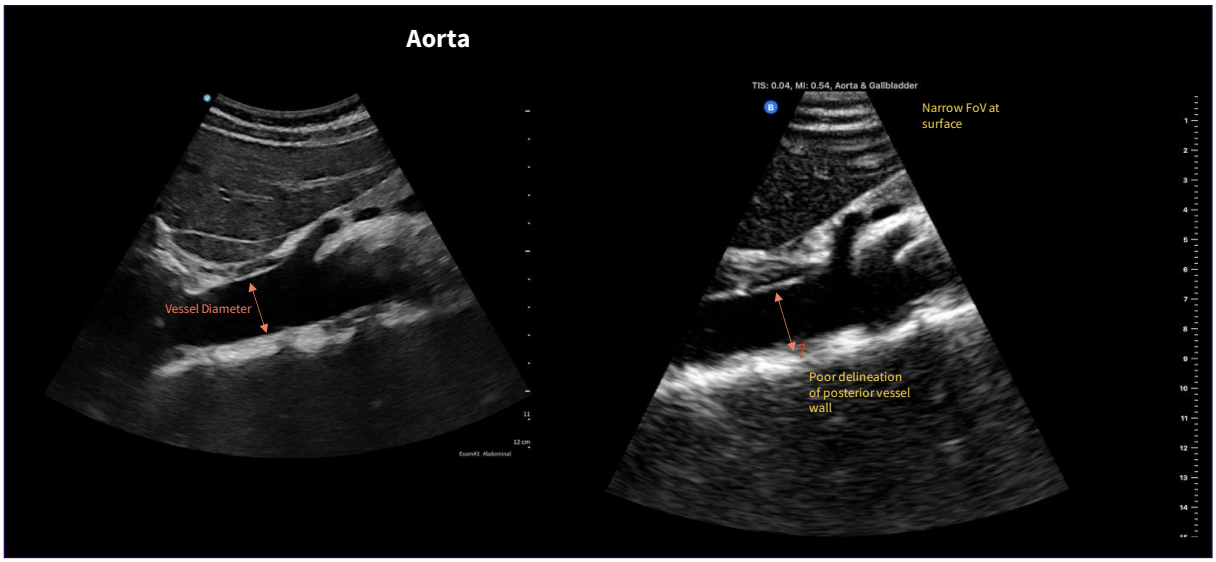


Vscan iQ3 (cMUT)

Figure 3: Shoulder tendon with a known tear. Tear is properly diagnosed with Vscan; ambiguous on iQ3

Figure 4 (Figure I-15 in appendix file) shows the abdominal aorta. The purpose of this image is for measuring the aortic diameter. Measuring the diameter of the abdominal aorta is primarily done to screen for and monitor abdominal aortic aneurysms, which are bulges in the aorta's wall. Early detection through diameter measurement can help prevent rupture, a life-threatening event. To achieve high measurement accuracy, a clear delineation between the blood pool (black) and the vessel wall (bright white) is needed[20]. Both probes show the anterior wall well, but the **posterior wall is blurred on the iQ3 image, making the measurement difficult**. Again, it should be highlighted that the better vessel wall delineation, clearer display of the anterior liver capsule and generally finer structures in the Vscan image come from the use of high-quality harmonics. Also worth mentioning is the wider nearfield of the convex Vscan transducer. The applicant claims that the iQ3's cMUT can emulate a convex transducer array, but the narrow iQ3 nearfield indicates otherwise.

[20] Section 4.2 in https://www.gov.uk/government/publications/aaa-screening-ultrasound-image-quality-guidance/aaa-screening-ultrasound-image-quality-guidance#introduction



Vscan iQ3 (cMUT)

Figure 4: Abdominal aorta – difficult to measure on iQ3 with cMUT technology

More image comparisons are shown in the Appendix. Cardiac exams, essential for HHUS, need to be seen as video clips depicting a complete cardiac cycle. Still images are not as useful for cardiac assessments. The images indicate notable differences in image quality for patients who are difficult to scan. While GEHC suggests that these differences may be due to variations in harmonic imaging quality, this cannot be definitively established. GEHC also assumes that the iQ3's other signal and image processing steps are comparable to other devices, with the primary distinction being the type of sensor used (cMUT vs SC). Based on this assumption, it is inferred that the sensor difference contributes to the observed image quality differences.

The following might appear repetitive, but GEHC wants to demonstrate the performance differences across several cases and different clinical applications, not just preselected, easy to scan examples. It is also aimed at showing that the **higher imaging capability for a variety of applications is technically necessary to reach the right diagnostic interpretations, which has a direct impact on the patient care able to be offered by healthcare professionals**.

Figure I-3 compares 3 different cardiac views (PLAX – parasternal long axis, SAX – short axis, 4Ch – four chamber) with Vscan in the top row and iQ3 in the bottom row. To assess cardiac function, the cardiologist observes, among other things, the regional motion of the myocardium and septum (usually referred to as wall motion). The confidence in the wall motion assessment depends on the clarity with which the walls are shown. Major problems with wall motion observation are blurriness and haze. While virtually all ultrasound machines depict a small amount of nearfield haze, the haze level in the iQ3 images are excessive (as the device comparison shows). Also, the haze covered apex of the heart in the iQ3 would make it difficult/impossible to detect thrombi or other growths.

Figure I-4 shows similar results from a different patient/volunteer.

Figure I-5 shows an apical 3-chamber view, a common view in cardiology, of yet another patient/volunteer. Lots of noise in the iQ3 image makes it difficult to evaluate the left ventricle, outflow tract and aortic valve leaflets.

Figures I-6 through I-9 highlight the differences in Color Flow Doppler (CFD). CFD depicts blood flow in the heart and vessels, and even the difficult to see coronary arteries. Flow abnormalities can point to structural physiological deficiencies.

Figures I-6/7 show aortic valve regurgitation; that is blood flowing back from the aorta into the left ventricle. It is a differential diagnosis[21] that needs to be checked when patients present with a number of symptoms[22] often seen by general practitioners, cardiologists or ER doctors. If the regurgitation is severe enough, aortic valve replacement or repair is indicated[23]. Figure I-6 is a still frame of the cardiac loop in I-7, to highlight what to look for in I-7. The regurgitation is only visible for a short period during the cardiac cycle. The physician is not presented with the still frame, but rather with the dynamic appearance of the video; therefore, the prominence of the regurgitation is critical. In the video loop of Figure I-7, the visibility of the regurgitation is much better. If the patient had a somewhat less severe regurgitation, the iQ3 might have missed it all together. And as per previous images, Figure I-7 shows poorer definition of the cardiac structures in the grayscale image.

Similarly, Figure I-8 shows a regurgitation of the tricuspid valve (backflow from the right ventricle to the right atrium. It has similar clinical implications as the regurgitation in Figure I-7. Here it can only be seen on the Vscan device, but not on the iQ3.

Figure I-9 shows the flow in a coronary artery – only visible on Vscan. While this is of little diagnostic value by itself, it shows the superior doppler sensitivity of the Vscan.

Coming back to B-Mode or grayscale image quality, Figure I-13 shows the popliteal vein and artery. Vscan more clearly shows the vessel delineation and surrounding muscle tissue. This is essential for detecting thrombi, DVT, stenoses, and plaque. These are critical differential diagnoses for patients presenting with a variety of lower extremity ailments (e.g. pain, numbness, tingling, ulcers).[24]

Figures I-14 and I-17 show abdominal and gynaecological images. As described with previous images, the iQ3 images have excessive near field noise that is attributed to the inferior harmonic imaging or plain fundamental imaging. Near field structures like the anterior liver capsule or potentially small lesions cannot be discerned. In contrast, the Vscan displays fine structures in the liver and kidney. Similarly, Figure I-17 demonstrates the near field noise problem of the cMUT device. This noise or haze obscures portions of the uterus and bladder, hiding potential tumors or cysts.

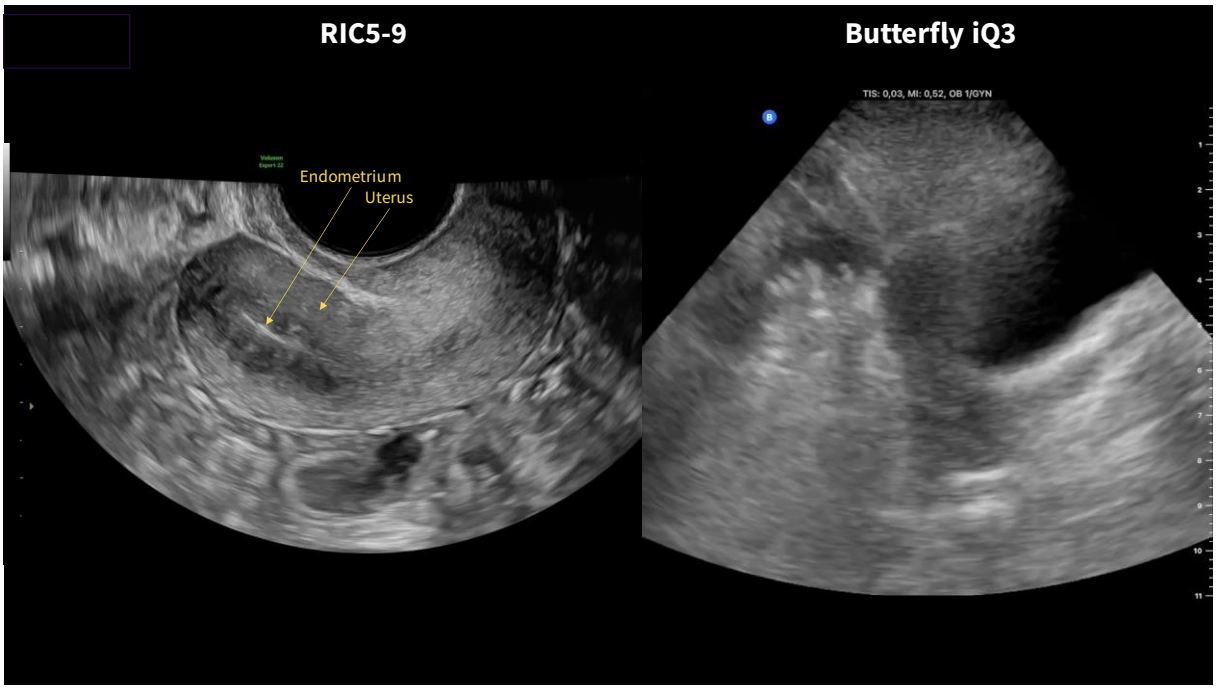
Finally, Figure 5 (Figure I-18 in Appendix) makes a comparison between a console based, single crystal endo-cavity probe (GEHC RIC5-9) and Butterfly's iQ3. The difference in image clarity is obvious. With the endo-cavity probe, the uterus and its boundary are clearly visible, while the iQ3 barely identifies it as a uterine image. Other differences are the display of the endometrium and well-defined surrounding tissue structures. The difference here is not between SC and cMUT, but between a micro convex vs. a linear array geometry. cMUT (at least with today's understanding) cannot be made as micro convex. Currently there are few micro convex handhelds on the market (e.g. Clarius EC7) but there is a clinical need and other manufacturers (at least GEHC) have such devices on their roadmaps. Revoking the SC exemption for HHUS would eliminate or at least restrict the future of handheld for obstetrics and gynaecology.

[21] A differential diagnosis is a list of possible diseases or conditions that could be causing a patient's symptoms, allowing healthcare providers to systematically consider various explanations before arriving at a final diagnosis. It's essentially a process of elimination, where tests and further investigation are used to rule out less likely possibilities and narrow down the potential causes.

[22] https://www.dhzc.charite.de/ratgeber/aortenklappeninsuffizienz/

[23] https://my.clevelandclinic.org/health/diseases/24396-aortic-regurgitation

[24] https://emedicine.medscape.com/article/461910-workup#c10



Vscan iQ3 (cMUT)

Figure 5: Comparison with Endo-cavity probe – Need for micro convex transducers

4.1.2 Thermal Limitation

A further differentiator between cMUT and SC devices is thermal management. There are a number of heat sources in scanning devices, including the transducer itself, the control and signal processing circuitry, the communication devices[25] and the power source (battery). Balancing heat generation with the requirement for a higher power output from the transducer to enhance imaging capabilities is critical. **Failure to manage the heat balance can limit the ability to scan for extended periods of time and potentially cause discomfort to the user or patient**. Whilst cited as a positive in the exemption revocation, the monolithic cMUT/CMOS design, enabling integration with the signal processing, means a substantial portion of the heat generation is focused close to the patient interface. Approaches to dissipate the heat include increasing the surface area, introducing heat sinks, and minimising other heat sources for example **limiting the device to a wired connection rather than wireless**. The applicant's cMUT device, while using a lower power FPGA[26] instead of a microprocessor and a lower power USB device instead of Vscan's higher power Wi-Fi interface still requires a larger surface area and increased thermal mass (308g vs 205g)[27] to manage its total heat generation. This implies that the cMUT device with its ASIC[28] requires more power when compared to available SC devices and their drive/processing components[29]. For this reason, it is **very challenging to create a wireless cMUT device** without further increasing the device's mass and surface area (all of which are undesirable for the clinicians' ergonomics). The **advantage of a wireless probe is easy manoeuvrability in tight or sterile environments without the hindrance of the cable**, making it ideal for point-of-care diagnostics, emergency settings, interventional procedures, ambulances and helicopters. It streamlines workflows

[25] Wired USB is approx. 600mW less for typical ultrasound applications.

[26] FPGA – Field-Programmable Gate Array

[27] Weight comparison with GEHC SC Vscan probe

[28] ASIC – Application Specific Integrated Circuit

[29] Comparison made with GEHC Vscan.

by enabling quick image sharing and integration with mobile devices, while also reducing clutter and the risk of cross-contamination in sterile fields. Smaller, lighter probes are also beneficial to the operator, reducing the risk of repetitive strain injuries and fatigue. Approving the revocation request would limit the wireless handheld options to PZT devices (still containing lead) with inferior imaging capability to that of SC.

The importance of light, wireless and agile probes to clinicians is expressed in the letter in Appendix B, written by Dr Martin Altersberger, head of the echo laboratory in the state hospital of Steyr, Austria.

5 Is the substitute reliable?

The reliability of a substitute is interpreted as performance[30] and lifecycle reliability[31]. The EU RoHS exemption guidance[32] defines this as "*The probability that EEE using the substitute will perform the required function without failure for a period of time comparable to that of the application in which the original substance is in use".*

The applicant's revocation request states that *"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".* This statement implies that technology adoption and regulatory approval are measures of reliability. There are, however, many examples of the adoption of technologies which are later shown to not meet requirements[33]. This often only becomes apparent after the technology has been in service for a statistically significant period of time. The first Butterfly IQ system was commercialised in 2018[34]. By contrast, the first GEHC SC device was commercialised in 2010 and is based on a PZT technology which has followed a road map of innovation spanning over 50 years. Figure 6 shows the evolution of GEHC handheld devices since 2010. **GEHC SC handheld devices have been adopted in over 100 countries, and over 60,000 units[35] have been sold globally since 2010. However, whilst GEHC recognises that repeat sales are an indicator of customer satisfaction and therefore indirectly could be linked to product reliability, this is not a direct indicator**.

[30] Performance reliability: Ensuring the device delivers consistent results in its primary function.

[31] Lifecycle reliability: Confirming the device performs reliably over its expected operational lifespan.

[32] RoHS exemption guidance

[33] The European medical device sector had 3,306 recalls in 2023, a ten-year high and 20.0% more recall events than in 2022. 2023 was a record-breaking year for European product recalls | Sedgwick

[34] Butterfly Announces FDA Clearance of its Next-Gen Handheld Ultrasound System, Butterfly iQ3

[35] Sales across the full Vscan handheld range.

Vscan legacy of leadership in handheld ultrasound

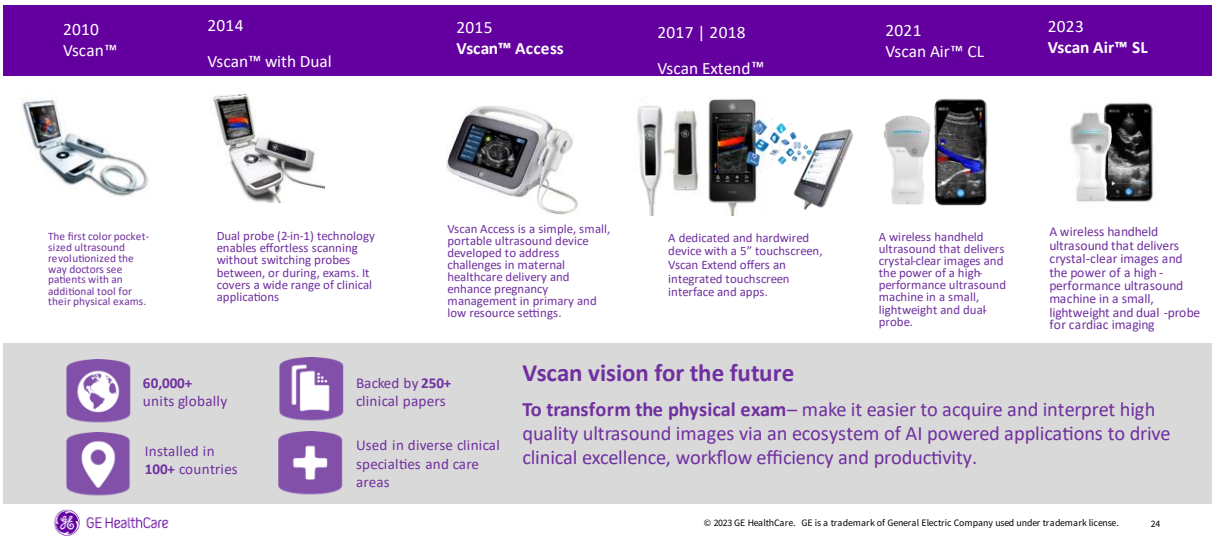


Figure 6 - GEHC Handheld Range 2010 - present

Regulatory approval cannot be taken as an indication of reliability either. For example, "*the Medical Device Regulation does not differentiate between performance levels offered by different product types, rather on an assessment of whether the equipment is safe for its intended uses and is capable of safely carrying out the procedures for which they are specified. The Medical Device Regulation requires devices to be placed on the market in line with the (clinical) state-of-the-art. The manufacturer has the obligation to define the intended use of the device and ensure that the image quality is sufficiently high to allow its intended use (e.g. sufficient precision for diagnosis). The manufacturer is required to provide evidence for such a claim, including technical and clinical data collected and analysed as part of the clinical evaluation. This evidence is reviewed by the Notified Body (on a sampling basis) and is commonly determined by comparing the new device to a predicate device. The manufacturer can select a predicate device that was previously approved for the same clinical indication. However, it can be an older device which at its time might have been excellent but is no longer so in today's standards".*[36] The GEHC Vscan CL (SC handheld device) has approvals in over 104[37] countries, however GEHC would not claim this to be a measure of reliability, it purely verifies that it meets the legislative requirements of a medical device in these countries.

The lifecycle reliability of a scanning device, measured in terms of service life, is dependent on usage patterns and usage in accordance with the manufacturer's intended operating environment, storage, and maintenance conditions. The service life quoted in the Butterfly IQ3 manual is 5 years, which is identical to the GEHC SC system, so for this measure there is equivalence in reliability.

Another factor impacting the lifecycle reliability of a scanning device is its robustness and quality. The revocation request claims that the level and rate of adoption is proof of quality, stating that "*the advanced quality of semiconductor-based ultrasound products is further proven by the adoption of Butterfly users,*

[36] Ref. the COCIR 2025 exemption renewal

[37] Data based on the Vscan Air CL

with more than 145,000 healthcare professionals using Butterfly Products worldwide after just a few years of commercial activity."

The ability of the Butterfly device to endure drops, mechanical impacts and deployment in war zones such as Ukraine are cited as evidence of robustness. Typically, robustness and quality are achieved through the application of recognised standards. The GEHC SC device meets these standards. For example, the drop test requirement for medical ultrasound probes, as part of compliance with IEC 60601-1, is specified in Clause 15.3.4.1 of the standard. This clause outlines the mechanical strength testing for portable and handheld medical electrical equipment and accessories, including the requirement for devices to withstand a free fall from a height of 1 meter onto a hardwood surface placed over concrete. This test ensures that devices like ultrasound probes can endure the mechanical stresses of accidental drops during normal use without compromising safety or functionality. The drop robustness of the GEHC SC device is further verified by compliance to the relevant clauses of MIL-STD-810G. MIL-STD-810G is a higher level of robustness for military and battlefield use. Meeting the IEC60601 standard series is required for the EU's CE marking under the Medical Device Regulation (MDR) as well as U.S. 510(k) clearance requirements and several other country specific approvals.

GEHC refutes any claims in the revocation request suggesting that the cMUT technology has any lifecycle reliability advantages over GEHC. In fact, some references[38] indicate that cMUTs have reliability issues. These are discussed in detail in the COCIR 2025 exemption renewal and therefore not reiterated here.

Reliability is the probability, at a desired confidence level, that a device will perform a required function, without failure, under stated conditions, for a specified period of time. The revocation request as submitted does not appear to provide any evidence that Butterfly's IQ scanner range is more reliable than GEHC's Vscan range of handheld scanners. Indeed, **to verify the reliability of a handheld scanner for all the permutations of clinical indications** (and therefore patient presentations) for which it is claimed suitable **would require extensive trials over a prolonged period of time**. Therefore, there is a very real element of doubt. **Approving the revocation would risk there being no alternative in the event that a scenario presents itself for which the cMUT scanners' performance or lifecycle reliability falls short**. As discussed in section 4 and demonstrated by the images, GEHC considers the performance reliability of the cMUT device to be questionable, and due to the relative 'newness' of the technology, the lifecycle reliability unproven. **Given the potential consequences on patient outcomes, GEHC believes this element of doubt to be sufficiently significant as to justify not revoking the exemption**.

6 Environmental, health and consumer safety impacts

The preceding sections highlight concerns related to the imaging capability and reliability of the proposed alternative to SC-based handheld scanners. Due to the intended use of the device, all have the potential to impact health / patient outcomes. Likewise, the socio-economic impacts and impacts on innovation discussed in the sections below, will all ultimately have the potential to impact health, both within the EU and globally.

The revocation application states:

> *"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*"

[38] Jeong B.G., Kim D.K., Hong S.W., Chung S.W., Shin H.J. Performance and reliability of new CMUT design with improved efficiency. Sens Actuators, A. 2013;199:325–333. doi: 10.1016/j.sna.2013.06.001.

GEHC refutes the implied assumptions that lead-based ultrasound transducers expose healthcare professionals or patients to lead, and that "vulnerable populations" are at any risk of lead exposure.

As it pertains to the use of lead in the SC probes, it is important to consider the form in which lead is used in PZT and single crystal transducers. PZT ceramics and lead-based single crystals contain lead in the form of a complex perovskite crystal structure (e.g. $Pb(Zr_xTi_{1-x})O_3$). Lead in this structure is ionically bonded and not present as free or loose lead. Under operating conditions below 600˚C, these structures are chemically and physically stable, with negligible lead release. There are a number of studies conducted which collectively reinforce this view and suggest that lead free piezoelectric alternative compounds do not necessarily have a better environmental profile.[39,40,41,42,43]

Additionally, the lead containing piezo layer is not in contact with patient or user but inside of the probe. At the patient contact area, a number of lens and acoustic matching layers as well as moisture barriers lay between the patient and the piezo layer.

Amount of lead used

It should be highlighted that in comparison to many other applications using lead, the amounts are relatively insignificant. For example, it would require approximately 20,000 ultrasound probes to match the lead content in a single lead-acid automotive battery. However, the benefits of advanced handheld ultrasound scanning capability to public health now and in the future are significant.

7 Socio-economic Impacts

The EU has launched several initiatives to strengthen resilience and independence in the medical equipment sector, particularly in response to recent global developments. For example, the establishment of HERA (Health Emergency Preparedness & Response)[44] following the COVID pandemic and the opinion statement from the European and Economic Social Committee[45] which highlights the need to improve Europe's resilience in the medical technologies value chain and to reduce dependencies on non-EU countries. GEHC as a major EU-based manufacturer of handheld ultrasound devices, would like to highlight the very real possibility of impacting **the strategic sovereignty and resilience of the EU in the medical imaging sector if the exemption is revoked, thereby prohibiting the marketing of single crystal devices and threatening the viability of manufacturing in the EU**. As an EU-based manufacturer, GEHC is able to react quickly and logistically supply handheld units to European and neighbouring countries in times of crisis. For example, the invasion of Ukraine[46] (50 units donated as part of a $4 million donation in March 2022), Turkey[47] earthquake disaster relief 2023 (100 units donated) and the Moroccan[48] earthquake disaster relief 2023 (20 units donated). 63 units were also supplied to French NGO "Chaine de l'Espoir" in Dec. 2023 for a donation to Ukraine. Aside from these voluntary donations, GEHC also supplies government organisations in support of their disaster preparedness and resilience planning. For example, the APHP (Paris Public Hospital Group in

[39] Bell & Deubzer (2018): Environmental and regulatory considerations of lead-free versus lead-based piezoelectrics

[40] Wu et al. (2017): Environmental comparison of lead-free piezoelectrics versus PZT

[41] Roedel et al. (2021): Lifecycle assessment of lead-free piezoelectrics compared to PZT

[42] Electrodegradation mechanisms of PZT ceramics (2023)

[43] PubChem (Lead Oxide): Stability and toxicity profile

[44] Health Emergency Preparedness and Response (HERA) - European Commission

[45] https://eur-lex.europa.eu/eli/C/2025/767/oj/eng

[46] GE Healthcare Donates Additional $1 Million in Ultrasound and Monitoring Equipment to Support Ukraine | GE HealthCare (United States), CEO LinkedIn announcement about Ukraine donation

[47] Field Volunteers and Mobile Imaging Devices Provide Relief After Turkey Earthquake | GE HealthCare (United States)

[48] CEO LinkedIn announcement about Moroccan donation

France) purchased 30 units using EU funding to establish a strategic stock of medical equipment. These were all handheld GEHC Vscan units incorporating SC sensors.

From a global health perspective, GEHC is supporting a number of initiatives in low- and middle-income countries (LMIC). For example, GEHC has been actively involved in numerous projects supporting African countries such as Ghana, Nigeria and most recently the AMREF project in Ethiopia, focusing on obstetric ultrasound. This project resulted in the procurement of 81 GEHC Vscan Air through various funding sources including the EU, the national postcode lottery of the Netherlands, and the Bill and Melinda Gates Foundation. GEHC is actively involved in not only providing the technology, but in supporting the training required to ensure its ongoing use[49].

GEHC handheld scanners are made in Europe for the advancement of global health, revoking this exemption will impact the global landscape of ultrasound provision and the capacity that the EU has to support LMICs and the UN's sustainable development goals.

According to Signify Research[50], the total segment for handheld ultrasound is $48M. GEHC is an important player in this area with estimated share of more than 30%. GEHC currently has 3 facilities in 3 different EU countries manufacturing product for and supporting the EU and wider global market. Its global headquarters for Women's Health Ultrasound and a pioneer in 3D/4D ultrasound technology, in Zipf, Austria, recently became a zero-greenhouse gas emissions facility[51]. Approximately 10% of the employees at these sites are focused solely on the handheld scanner market and would be at significant risk due to expected business adjustments (with potential EU job losses) if the revocation is accepted. There would also be wider impacts on the GEHC EU workforce, supply chain and logistics infrastructure. For example, 50% of the top-level assembly components are supplied by tier-1 suppliers located within the EU which represents more than €10M worth of parts and a total value add of more than €20M annually. This EU value chain would be potentially at risk, if the revocation was approved leading to a loss of the EU market.

Aside from GEHC, other European ultrasound manufacturers (Vermon, Supersonic Imagine, Esaote, Oldelft) with an estimated workforce of 500 people contribute to the EU's medical ultrasound ecosystem which would face market impacts and potential job losses.

8 Impacts on Innovation

As discussed in section 5, GEHC has a long and established history of innovation in the field of ultrasound scanning, and in particular, handheld scanning devices. This innovation supports the development of state-of-the-art scanners that consistently outperform[52,53,54] competitive SC scanners and the applicant's cMUT scanner, particularly where imaging capability is concerned. The **scanners are used in research to develop best practice in order to optimise patient outcomes**. GEHC freely

[49] According to the WHO, 70% of complex medical devices in low-resource settings are non-functional, making adequate training essential.

[50] Signify Research Ultrasound Equipment – World – 2024

https://research.signifyresearch.net/reportaction/ULS-MI-2024-UE/Toc?SearchTerms=ultrasound

[51] global headquarters for Women's Health Ultrasound and a pioneer in 3D/4D ultrasound technology

[52] Le et al. The Ultrasound Journal 2022 - Comparison of four handheld point-of-care ultrasound devices by expert users.

[53] Perez-Sanchez et al. The Ultrasound Journal 2024 - Comparison of 6 handheld ultrasound devices by point-of-care ultrasound experts: a cross-sectional study

[54] Merkel, Lueders, Schneider, Yousefzada, Ruppert, J., Weimer, Herzog, Lorenz, Vieth, Buggenhagen, et al. Prospective Comparison of Nine Different Handheld Ultrasound (HHUS) Devices by Ultrasound Experts with Regard to B-Scan Quality, Device Handling and Software in Abdominal Sonography

shares peer reviewed articles[55] to help medical professionals understand the current state of research related to their various devices, technologies, and applications.

The SC-based handheld scanner is embedded in many areas of medical research and innovation. One in particular is that of cardiovascular health. The European Commission announced a Cardiovascular Health Plan to be published in the course of 2025, putting forward a series of measures aimed at improving cardiovascular health in the EU, focusing specifically on ***screening, early detection,*** *treatment, rehabilitation,* ***and advancing research and innovation*****.**[56] The handheld ultrasound scanner is a key tool in the screening and early detection of cardiac issues. Ultrasound screening must be fast and reliable for a broad patient population[57,58] and therefore relies on SC devices. GEHC's acquisition of CaptionHealth[59] in 2023, demonstrates its commitment to supporting this EU plan by developing technologies that can facilitate the use of GEHC scanners by a wider range of healthcare professionals across a variety of settings such as operating rooms, home and alternate sites of care, potentially preventing hospitalizations and supporting improved clinical outcomes. At the 2024 Global Cardiovascular Awards, GEHC and the Vscan Air innovative contributions were recognised by the award for "Innovation in Cardiac Imaging," and GEHC was commended for "digital innovation"[60]. Images I-3 to I-9 in Appendix A demonstrate the superior imaging capability of the SC based Vscan device for the detection of cardiovascular issues and its benefits in this area of medicine are further supported by user testimonials and peer reviewed articles[61].

GEHC currently has 2-transducer devices (electrically switchable) that are capable of covering the equivalent bandwidth of the Butterfly IQ3 system (without the need for multiple sensor probes for whole body imaging). In the pursuit of optimising the imaging capability of ultrasound scanners, which will result in better diagnostic capability and minimise the lead content, GEHC has invested upwards of EUR 100M since 2016 and continues to invest in solutions for lead-free ultrasound that achieves the same bandwidth as today's 2-transducer solution, but with the higher pressure output and sensitivity of the SC. This will effectively halve the lead content of the current 'Vscan Dual' solution. More detailed technical information is shared in the COCIR 2025 exemption renewal submission and not duplicated here; however, it should be emphasised that this device will match but is not limited to the bandwidth of the Butterfly IQ3 and will have superior imaging capability due to an approx. 7dB better transmit. 7db higher transmit pressure results in 14dB higher echo signals for harmonic imaging, as the harmonic wave generation follows an approximate square law[62] . This single transducer device targets the full set of applications with the same transducer. **Revoking the exemption will halt the development of the state-of-the-art ultrasound imaging capability in a single probe. The enhanced diagnostic capability associated with further advancement in SC image capability will be stopped**. The development programme started in 2020 and is expected for productization in the near future.

[55] bibliography_vscan-family_2024.pdf

[56] https://www.consilium.europa.eu/en/press/press-releases/2024/12/03/cardiovascular-health-council-calls-for-more-robust-efforts-to-help-prevent-cardiovascular-diseases/

[57] Unlocking Care (Cardiology): https://www.youtube.com/watch?v=TNkQzbh6-sY&list=PLMpbsoz7hP4qiGx35jVOelEOYt2zNQNCd&index=20

[58] N Laskar , S Bhattacharyya , G Lloyd , "Prevalence of heart valve disease and left ventricular systolic dysfunction in a multiethnic,migrant community", https://esc365.escardio.org/person/291559

[59] GE HealthCare to Acquire Caption Health, Expanding Ultrasound to Support New Users Through FDA-Cleared, AI-Powered Image Guidance | GE HealthCare (United States)

[60] https://cardiovascularnews.com/global-cardiovascular-awards-the-full-list-of-winners-and-highly-commended-entries/?hilite=vscan

[61]Handheld cardiac ultrasound | Vscan Air™ SL | GE HealthCare

[62] B. Haider, K. Krishnan and K. Thomenius, "Higher order nonlinear ultrasound propagation in tissue-simulation study," 2002 IEEE Ultrasonics Symposium, 2002. Proceedings., Munich, Germany, 2002, pp. 1737-1740 vol.2, doi: 10.1109/ULTSYM.2002.1192633. keywords: {Ultrasonic imaging;Frequency;Apertures;Computational modeling;Nonlinear wave propagation;Ultrasonic transducers;Acoustic imaging;Attenuation;Nonlinear distortion;Medical simulation},

One emerging area of innovation in ultrasound scanning is the **integration of AI capabilities to support practitioners**, not only in optimising the use of the scanner, but also in the analysis of the images captured and subsequent diagnostic determination. The revocation request cites this as an area of innovation for the cMUT based device. It should be clarified, however. that this is **not sensor type dependent**. **GEHC already has integrated AI capability for its devices,**[63] and is actively engaged in researching and developing these capabilities further. For example, in 2023 GEHC was awarded a $44M grant from the Bill and Melinda Gates Foundation to create user-friendly, AI-assisted ultrasound imaging auto-assessment tools, with a goal of expanding access to LMIC and across diverse sites of care. Similarly, Phillips (another manufacturer of SC devices) received $60M from the same foundation, to also develop this capability.

The exemption revocation request states that *"cMUT's innovation trajectory is backed by Moore's Law – a guiding principle of the semiconductor industry first observed in 1965 by Intel co-founder, Gordon Moore.*" Moore's Law is an observational law that identified that the number of transistors in an integrated circuit can be doubled about every 2 years. It is unclear whether the applicant is implying that the number of cMUT sensing cells in its device can follow a similar trajectory and double every two years, or whether it is implying that the scanning device as a whole will benefit from Moore's Law and the advancement of microchips. If it is the latter, then all handheld ultrasound devices will benefit from this in their control and signal processing circuitry, whether the sensor is SC, cMUT, or other. If the former is being claimed, then GEHC contests this statement. cMUTs are not transistors and their physical size is a determinant of the sensing device's performance, i.e. the 'elements' size is designed to meet requirements for the propagation of the ultrasound waves. If the size is too large it creates image artifacts (grating lobes), and if too small, the processing complexity increases without benefits to the image quality. Similarly, the cMUT's gap distance is a trade-off between maximum transmit pressure and receiver sensitivity. Therefore, Moore's law would not make sense in this context.

GEHC would like to highlight, that a key part of the process of innovation in the ultrasound imaging space is working with clinicians to share knowledge, develop scanning techniques and best practices to better understand their needs to achieve advancement in patient diagnosis. To this end, GEHC is currently engaged in 14 studies (50% of which are based in EU countries), utilising GEHC SC handheld devices across a range of care areas including but not limited to cardiology, perioperative, obstetrics and oncology. This represents a significant investment of time and money as well as commitment to contributing to the EU's ultrasound innovation ecosystem, which would no-longer be feasible if the exemption is revoked and the SC handheld device withdrawn from the EU market.

9 Availability of a substitute

In the context of a medical device, availability of a substitute is addressed as "availability for healthcare providers" and "availability for manufacturers".

Availability for Healthcare Providers

In Butterfly's 2024 K-10 SEC Filing[64], the following statement is made:

"We have a limited operating history on which to assess the prospects for our business, we have generated limited revenue from sales of our products, and we have incurred losses since inception[65]. We anticipate that we will continue to incur significant losses for at least the next several years as we

[63] Vscan Air™ with Caption AI™ | GE HealthCare (United States)

[64] https://ir.butterflynetwork.com/financials/sec-filings/sec-filings-details/default.aspx?FilingId=18240381

[65] Butterfly has lost more than 90% of its market value (share prices: $25.97 as of 15. Feb. 2021 vs $1.84 14. Jul. 2025)

continue to commercialize our existing products and services and seek to develop and commercialize new products and services."

Whilst the availability of a substitute is categorised as an 'Additional Parameter' for consideration under the RoHS guidance[66], GEHC feels it is appropriate to highlight this statement, as it should be a factor for consideration when weighing the risk of impacting availability if the revocation is approved and SC based scanners are removed from the market. **Approval of the revocation will limit the choice of handheld scanners for clinicians and health providers** to the applicant's device with its limitations as highlighted in this document, or PZT based devices with lower imaging capability and also reliant on a RoHS exemption for lead. There is no substitute available which offers the necessary technical performance of the SC device that is lead-free.

Availability for Manufacturers

To substitute a single crystal transducer with a cMUT is not a matter of requesting a cMUT from a vendor and integrating it into the ultrasound probe (like a different type of resistor or microchip). There are no vendors selling cMUT transducers of acceptable performance.

10 Claims made in the revocation request not considered of relevance to RoHS.

For the following claims made in the revocation request, GEHC claims that they either do not relate to the RoHS criteria, and/or are not directly attributable to the substitution of a SC sensor for a cMUT sensor.

Claim: *"a significant reduction of public and private healthcare costs"*

Whilst it is recognised that the cost of the device is a consideration for healthcare providers, arguments relating to cost are not a criterion for the consideration of a RoHS exemption[66]. That aside, the total cost of ownership should be considered when making comparisons, not only the initial device cost, but other aspects including the software pricing model (subscription or one-off), warranty and support package etc. A direct correlation cannot be made between the sensor technology, cMUT or SC and the final cost of ownership. Additionally, the price mentioned in the revocation application (EUR 2500) has since been increased to EUR 4400 bringing it more in line with Vscan.

Claim: "*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."*

Packaging claims are not of relevance to RoHS, as they are requirements under the EU Packaging and Packaging Waste Regulation[67].

Claim: "*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."*

[66] https://environment.ec.europa.eu/document/download/f1f65e3d-1b90-4dd1-a0d4-797bd6cabe98_en?filename=Guidance_Document.pdf

[67] https://environment.ec.europa.eu/topics/waste-and-recycling/rohs-directive/implementation-rohs-directive_en

The cloud storage of images and energy efficiency of the device are not of relevance to RoHS. Scanning time can be limited by the thermal performance of the device, this is discussed in section 4.1.2.

Appendix A - Image Comparisons

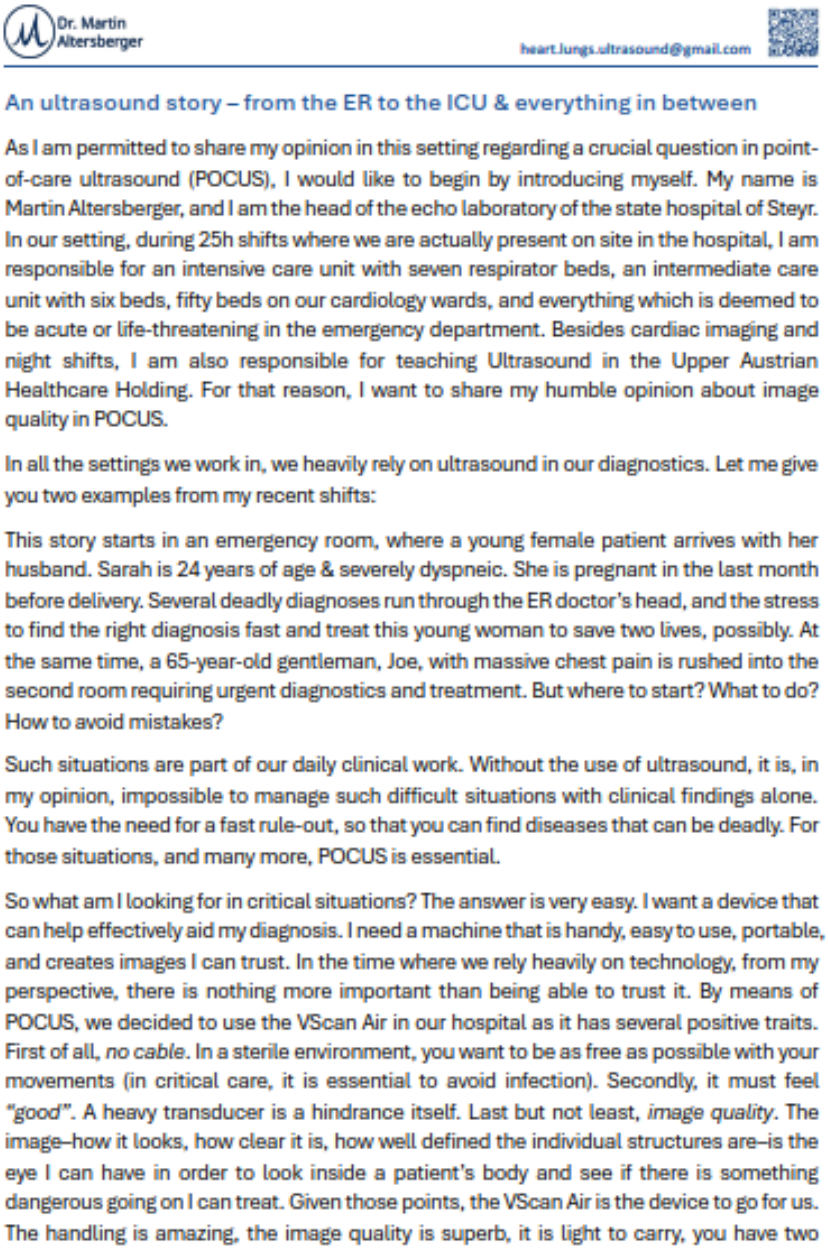
Due to the large file size, the image comparisons can be found in document:

GEHC_Image_Comparisons-2.ppsx

submitted via download link at the same time as this response document.

Appendix B – Stakeholder letter

The importance of image capability and light and agile probes to clinicians is expressed in this letter, written by Dr Martin Altersberger[68], head of the echo laboratory in the state hospital of Steyr, Austria.



Dr. Martin Altersberger

heart.lungs.ultrasound@gmail.com

An ultrasound story – from the ER to the ICU & everything in between

As I am permitted to share my opinion in this setting regarding a crucial question in point-of-care ultrasound (POCUS), I would like to begin by introducing myself. My name is Martin Altersberger, and I am the head of the echo laboratory of the state hospital of Steyr. In our setting, during 25h shifts where we are actually present on site in the hospital, I am responsible for an intensive care unit with seven respirator beds, an intermediate care unit with six beds, fifty beds on our cardiology wards, and everything which is deemed to be acute or life-threatening in the emergency department. Besides cardiac imaging and night shifts, I am also responsible for teaching Ultrasound in the Upper Austrian Healthcare Holding. For that reason, I want to share my humble opinion about image quality in POCUS.

In all the settings we work in, we heavily rely on ultrasound in our diagnostics. Let me give you two examples from my recent shifts:

This story starts in an emergency room, where a young female patient arrives with her husband. Sarah is 24 years of age & severely dyspneic. She is pregnant in the last month before delivery. Several deadly diagnoses run through the ER doctor's head, and the stress to find the right diagnosis fast and treat this young woman to save two lives, possibly. At the same time, a 65-year-old gentleman, Joe, with massive chest pain is rushed into the second room requiring urgent diagnostics and treatment. But where to start? What to do? How to avoid mistakes?

Such situations are part of our daily clinical work. Without the use of ultrasound, it is, in my opinion, impossible to manage such difficult situations with clinical findings alone. You have the need for a fast rule-out, so that you can find diseases that can be deadly. For those situations, and many more, POCUS is essential.

So what am I looking for in critical situations? The answer is very easy. I want a device that can help effectively aid my diagnosis. I need a machine that is handy, easy to use, portable, and creates images I can trust. In the time where we rely heavily on technology, from my perspective, there is nothing more important than being able to trust it. By means of POCUS, we decided to use the VScan Air in our hospital as it has several positive traits. First of all, *no cable*. In a sterile environment, you want to be as free as possible with your movements (in critical care, it is essential to avoid infection). Secondly, it must feel *"good"*. A heavy transducer is a hindrance itself. Last but not least, *image quality*. The image–how it looks, how clear it is, how well defined the individual structures are–is the eye I can have in order to look inside a patient's body and see if there is something dangerous going on I can treat. Given those points, the VScan Air is the device to go for us. The handling is amazing, the image quality is superb, it is light to carry, you have two

[68] Dr. Altersberger is a key opinion leader to GEHC

transducers in one device to choose from, depending on the indication, and the functionality is top-notch in my opinion.

Before we selected this machine for our department, we tested numerous devices, including the Lumify (requiring a cable and several transducers), the Butterfly (heavy, requiring a cable, and experiencing blurry imaging after approximately half a year (different technology)), and many more (too heavy, too large, lesser image quality). Overall, we decided to stick with the image quality that felt best to us, which was the VScan air, utilizing the long-established technology of piezoelectric crystals.

So to summarize, for us, the VScan Air was and is the machine to use in a POCUS setting for critically ill patients, for outpatients who need a quick answer, in the OR for pacemaker vascular access, on our ward during rounds... Literally in every circumstance where it's possible to give answers to questions by performing an ultrasound, I will definitely use VScan Air to ensure patients' safety.

Why not use point-of-care ultrasound? With the right device, you can find the right diagnosis. To summarize the two prior discussed patients, Sarah had a case of peripartum cardiomyopathy, and Joe was diagnosed with aortic dissection. Both patients survived with a good outcome due to prompt diagnosis.

Thank you for the opportunity to express my thoughts in this document.

With best regards,

Dr. Martin Altersberger, May 19th, 2025

Appendix C – Abbreviations and Acronyms

AAA	Abdominal Aortic Aneurysms
AMREF	Amref Health Africa
APHP	Assistance publique–hôpitaux de Paris
ASIC	Application Specific Integrated Circuit
BMI	Body Mass Index
BMS	Business Management System
BOM	Bill of Materials
CFD	Color Flow Doppler
4CH	Four Chamber
CMOS	Complementary Metal Oxide Semiconductor
COCIR	European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
COPD	Chronic Obstructive Pulmonary Disease
CRM	Customer Relationship Management
cMUT	Capacitive Micromachined Ultrasonic Transducer
3D	Three Dimensional
4D	Four Dimensional
EEE	Electrical and Electronic Equipment
ER	Emergency Room
EU	European Union
Ex.	Exemption
FDA	US Food and Drug Administration
FPGA	Field-Programmable Gate Array
GEHC	GE HealthCare
HERA	Health Emergency Preparedness & Response
HHUS	Handheld Ultrasound Scanner
LMIC	Low Middle Income Countries
Ltd.	Limited
PLAX	Parasternal long axis
PMD	Priority Medical Device
MDR	Medical Devices Regulation
MI	Mechanical Index
MSK	Musculoskeletal
N/A	Not Applicable
NGO	Non Government Organisation
PZT	Lead Zirconate Titanate
RINA	RINA Tech UK Limited
RoHS	Restriction of Hazardous Substances

SAX	Short axis
SC	Single Crystal
THI	Tissue Harmonic Imaging
USB	Universal Serial Bus
WHO	World Health Organization