Questionnaire 6 Exemption 14 of RoHS Annex IV

Lead in single crystal piezoelectric materials for ultrasonic transducers

Acronyms and Definitions

US	ultrasonic

1. Background

Bio Innovation Service, UNITAR and Fraunhofer IZM have been appointed[1] by the European Commission through for the evaluation of applications for the review of requests for new exemptions and the renewal of exemptions currently listed in Annexes III and IV of the RoHS Directive 2011/65/EU.

You submitted information to substantiate your request for the renewal of the above-mentioned exemption. This information was reviewed and as a result, we ask you to kindly answer the below questions for further clarification of your request until 16 August 2021.

We hope that the following elaboration might be helpful in understanding the differences between cMUT/pMUT and single crystal image quality.

Image quality = diagnostic confidence.

Ultrasound image quality (IQ) is patient dependent. Low-Image Quality devices can give acceptable images to perform diagnostics of easy-to-scan (usually slim) patients but give unreadable images on harder-to-scan patients. The latter are a large portion of the patients in the Western World. Other common limitations are lack of sensitivity and dynamic range, which may manifest itself as inability to give reliable quantification or even detection of blood velocities in cardiac lesions

Multiple attempts have been made to introduce cMUTs into the console market over the past 12 years, including companies like Hitachi and Kolo. So far, none has been successful due to technology limitations. The combination of B-mode image quality and Doppler sensitivity has not been competitive.

2. Questions

General remark:
We understand the importance of single crystal materials with lead for US medical imaging and are already aware that there is no technology which can replace them (completely). At the same time, other certified US imaging technologies are on the market. We kindly ask you to focus on their current and intended uses, not meaning that it is not important for us to understand the limitations of these alternative technologies.

[1] It is implemented through the specific contract 070201/2020/832829/ENV.B.3 under the Framework contract ENV.B.3/FRA/2019/0017

1) We found research on the internet for US transducers produced with lead-free ceramics (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4090606/). How would you see the prospects of this technology in the light of this article?

   This application is based on BZT-BCT which was discussed in the exemption renewal request Table 1. As such it does not offer suitable performance to be identified as a suitable alternative. Comparing a few attributes as an example:

   - The electromechanical coefficient outlined by this paper is only 0.4 compared to >0.5 on PZT ceramic and single crystal.
   - The dielectric constant outlined by this paper is 2800, compared to 6000 for single crystal
   - The piezoelectric coefficient outlined by this paper is 600 pC/N, compared to 1500 pC/N for single crystal
   - The materials Curie temperature is 93C, compared to 130-140C for single crystal, meaning that the piezoelectric depolarisation occurs at much lower temperature, causing aging and operational depolarization occur in imaging modes that require high acoustic output (for example shearwave elastography which is commonly used for cancer detection).

   The performance shown in the paper is below acceptable performance criteria for medical devices, potentially this could be due to the compositions tending to more brittle behaviour, but this would have to be fully investigated.

   This research white paper only shows the possibility of using BZT-50BCT at high frequencies (30.5 MHz) for a needle (IVUS) transducer. That frequency range is well above the typical center frequency used on the medical applications. Although the authors compare their BZT-50BCT transducer to two transducer, one is the built with single crystal and one is built with PZT ceramic, this is not a like for like comparison due to the discrepancy between the frequencies, as the other two transducers have a higher frequency ~45MHz. This imbalance puts the single crystal at a disadvantage purely based on frequency since acoustic attenuation drastically increases and sensitivity decreases with frequency. The first thing would be to compare at the same frequency.

   The performance of BZT-BCT may prove to be suitable for non-medical applications where high performance is not required, but COCIR has no knowledge of these.

2) pMUTs use piezoelectric materials based on PZT. In the last questionnaire, you provided an estimate as to the amounts of lead used in pMUT-based transducers compared to a bulk PZT material as reference instead of a single crystal piezoelectric transducer. Could you please provide this estimate for transducers based on pMUTs versus transducers based on single crystal piezomaterials with lead?

   Q2b of questionnaire 5 compared pMUT with polycrystalline PZT transducers because pMUT performance can never match that of single crystal transducers. They are therefore unsuitable as substitutes and so a material mass comparison is not possible or meaningful. It is also true that the lead contents of transducers made of polycrystalline PZT and transducers made of single crystal materials cannot be compared as polycrystalline PZT cannot provide the essential performance needed for the medical applications where single crystal transducer performance is necessary. Another complicating factor, which would affect lead quantity used is that the lifetimes of cMUT and pMUT (as explained in our exemption renewal request and our answer to Q2b of questionnaire 5) are usually much shorter than traditional types of transducers.

3) We understand from the previous communication that *"The certification […] does not differentiate between performance levels offered by different product types but 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."

Does the safety for intended use or any other certification criterion include that the image quality of a US device is at least sufficient to diagnose what needs to be diagnosed in the use situations and indicated uses for which the device is certified?

The Medical Device Regulation does not set detailed performance levels for the image quality of ultrasound devices. Instead, it 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 then ensure that the image quality is sufficiently high to allow this intended use (e.g. sufficient precision for diagnosis). The manufacturer is then required to provide evidence for this claim, via 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). This is usually 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.

It is important to understand that different professional users have different requirements for imaging the same target organ, for example the heart. In the ER, a quick look from an approved hand-held device may provide critical information, such as detection of a pericardial effusion. Which can be done from one single view of the heart. While the same imaging device would be considered grossly inadequate in the hands of a Cardiologist, because of inability to visualize the all the structures and/or measure the blood velocities he/she needs to perform even a standard exam.

For some diagnostic procedures (in any of the listed indications) the minimum requirement might be sufficient; for others, better quality of the diagnostic equipment translates into higher confidence of diagnostic result. For example, consider detecting a malignant tumour. If it is a large tumour, a moderately good ultrasound system can detect that. But if the tumour is small and has echogenicity similar to surrounding tissue then the quality of the ultrasound plays a crucial role for the doctor to come to the correct diagnosis. The problem is that medical images can be ambiguous, yet the doctor has to make a decision on what to do next. For example, images which have good signal to noise ratio help in that decision process. The issue with cMUT, pMUT or other materials that do not provide the best image quality is loss of diagnostic value or diagnostic confidence.

It is true that a cMUT device can be used to diagnose a cancer (or any of the other indicated uses), but many healthcare providers will select a device that gives a higher chance of getting the correct diagnosis. This is why the clinicians are willing to pay tens or maybe hundreds of thousands of Euros instead of paying €2000 for a hand-held device. Both have their place in the medical practice, but they do not replace each other.

4) Butterfly Network list the following indicated uses for their cMUT-based US transducers under the section "certifications" on their webpage (c.f. https://support.butterflynetwork.com/hc/en-us/articles/360029435091-Indications-for-Use, also the user manual https://manual.butterflynetwork.com/butterfly-iq-user-manual_rev-al-en.pdf):

"Use in environments where healthcare is provided to enable diagnostic ultrasound imaging and measurement of anatomical structures and fluids of adult and pediatric patients for the following clinical applications:

- *Peripheral Vessel (including carotid, deep vein thrombosis and arterial studies)*
- *Procedural Guidance*
- *Small Organs (including thyroid, scrotum and breast)*
- *Cardiac*
- *Abdominal*

- *Urology*
- *Fetal/Obstetric*
- *Gynecological*
- *Musculoskeletal (conventional)*
- *Musculoskeletal (superficial)*
- *Ophthalmic*

Modes of operation include B-Mode, B-Mode + M-Mode, B-Mode + Color Doppler, B-Mode + Power Doppler, and B-Mode + Needle Viz Tool; Spectral Pulsed Wave Doppler mode is available only in the United States.[2]

According to Butterfly Network (2021), they have been certified by the BSI in regards to the design and manufacture of general use portable ultrasound systems for the purpose of diagnostic imaging for use by qualified and trained healthcare professionals. They have an Annex II device, and were tested and found to meet the quality assurance requirements for a Class II imaging device utilizing non-ionizing radiation."

Notably, CW Doppler is a missing mode. This is acceptable for a hand-held device but a requirement for an exam by a cardiologist. To date, nobody has demonstrated CW Doppler with a cMUT device.

a) You stated in the previous questionnaire that cMUTs and pMUTs play a role in providing sufficient technical function in specialised applications. Do the above indicated uses fall into this specialized applications where cMUTs can or even should be applied? If yes, could you please describe when these transducers are used instead of the piezo-based ones?

The above "indicated uses" cover a large portion of the uses that many other ultrasound devices cover. However, the claimed "indicated uses" are only one aspect. As said in question 3, the other aspect is the diagnostic quality that a specific device can achieve. So your question "Do the above indicated uses fall into this specialized applications where cMUTs can or even should be applied?" cannot be answered yes or no but needs to be qualified with what the clinician tries to diagnose. For example, a patient in an ambulance needs to be checked for internal bleeding. Here a hand-held device (cMUT or otherwise) is the only practical option. In the hospital however, a more advanced device would be used. This is not reflected in the list of "intended uses" but is decided by the clinical practitioner based on the diagnostic capability that their assessment requires.

b) If no, are only single crystal piezo transducers used for the above indications, meaning that the cMUT-based transducers are of no importance in these fields?

cMUT and pMUT transducers can be manufactured and used in the above applications but will result in image quality much less than what can be realized using piezo-based materials and architectures. It is not that are of no importance, just that the image quality is insufficient compared to current materials/designs.

c) Could you please explain other specialised applications where cMUTs and pMUTS play a role in providing sufficient technical function in specialized applications?

cMUT/pMUTs are not used in medical imaging applications where a high degree of performance is required. Where diagnosis is easy to establish, lower image quality can be acceptable and therefore cMUT/pMUT devices may offer the required diagnostic

[2] Butterfly Netwoks, https://support.butterflynetwork.com/hc/en-us/articles/360042392612

capability. However, given ultrasound image quality is patient dependent a cMUT/pMUT device will only be able to serve a smaller number of patients.

Other specialised applications outside of medical imaging applications may be possible, such as air flow, but COCIR is not positioned to answer questions on this.

Please note that answers to these questions may be published as part of the evaluation of this request. If your answers contain confidential information, please provide a version that can be made public along with a confidential version, in which proprietary information is clearly marked.

It would be helpful if you could kindly provide the information in formats that allow copying text, figures and tables to be included into the review report.

3. References

Butterfly Network (2021): Answers to questionnaire 1 received from Butterfly Network support by Dr. Otmar Deubzer, Fraunhofer IZM, via e-mail.