Questionnaire 4 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 201ylj1/65/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 17 June 2021.

2. Questions

1) We understand that the following applications can already use the cMUT technology because they benefit from this technology's strengths more than might be affected by its weaknesses.
    - Catheters
    - Endoscopic probes
    - High frequency linear arrays:

      https://verasonics.com/cmut-hf-transducers/
    - Probes with wide clinical coverage

    Could you please let us know which of the below products are related to which of the above applications? If you know other cMUT-based product examples, we ask you to kindly add them. We already added HF linear arrays, which were easy to allocate. Please see below for suggested categorisations of the links provided:

    - https://www.butterflynetwork.com/ Probes with wide clinical coverage. In this case, the "wide clinical coverage" must only be considered from the perspective of a point of care clinical use. That is, the market and clinical value of the device is designed for

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

point of care diagnoses which are less performance based (from an absolute clinical image quality viewpoint) because the prominent diagnoses are primarily for emergency medical use and such things as pregnancy assessments, etc. The performance level of the cMUT based transducer as compared to a ultrasound cart-based system + transducer (non-cMUT) requires exhaustive, careful, lengthy analysis to fully understand subtle yet "make or break" detail resolution, which takes years to undertake.

- https://www.hitachi-medical-systems.co.uk/products/ultrasound/transducers/4g-cmut.html Probes with wide clinical coverage. Similar to the Butterfly clinical use cases, it is a lengthy proposition in order to factually determine if the Hitachi cMUT transducer can perform adequately in clinical situations that require, for example, THI (harmonics) for difficult patients, by merely trying to compare data sheets or images presented thusly. Harmonics are extremely important, and very widely used, yet the performance differs greatly as a feature in ultrasound systems. Again, the full analysis would require a timeframe in many months, if not years.
- https://www.exo.inc/ One of the potential applications listed on their website includes Catheters, however this is based on the pMUT technology, not cMUT. It is well-known that pMUT sensor based transducers, although similar in technology to cMUT, are much worse in image quality.
- https://verasonics.com/ge-transducers-for-vantage-systems/ High frequency linear arrays. High frequency transducers especially must be evaluated perhaps even more stringently than the lower frequency transducers, due to the expected higher resolution and anatomy differences trying to be discerned. In particular, THI performance is even more essential because naturally higher frequencies offer lower tissue penetration, and the THI performance associated with cMUT transducers has been either entirely absent until recently (Hitachi) because of fundamental physics problems of unwanted multiple frequency bands overlapping. For instance, low transmit pressure and nonlinearity of cMUT are not good for tissue harmonic imaging. Proof of adequate performance cannot be overstated.

2) You state in the previous questionnaire that large acoustic pressures require a large vibration amplitude especially for lower frequencies which in turn requires a large drive voltage of 1,000 V to achieve the same quality like with single crystal elements. You mention safety, due to insulation performance with high voltages, as well as performance requirements as challenges.

   We found this presentation: https://www.salland.com/wp-content/uploads/2019/06/11-Rob-van-Schaijk-Philips-InS-MEMS-Seminar-2019.pdf. Page 19 shows a low frequency example.

   Could you please comment this example in the light of your above statement?

   Although a low frequency cMUT example is shown on page 19 in the presentation, it is very clear that the image quality on the cMUT transducer is worse than the PZT transducer, especially the penetration. The insufficient performance of low frequency cMUTs makes it difficult to provide superior image quality, compared to PZT/Single crystal probes. Unless there is a break-through in the cMUT technology, its poor performance will prohibit it from replacing PZT/Single crystal for low frequency applications.

   These differences in performance are not just limited to the above-mentioned examples, as the Hitachi 4G cMUT offers wide operating frequency (2-22MHz), which is controlled by one of the operating voltages (DC Bias). However, their cMUT shows less penetration and poor image quality.

3) In line with Art. 5(1)(a), we propose the above state of science and technology to be reflected in the exemption scope as follows:

Lead in single crystal piezoelectric materials for ultrasonic transducers for uses others than the following:

- *Catheters;*
- *Endoscopic probes;*
- *High frequency linear arrays;*
- *Probes with wide clinical coverage.*

Would you agree to this wording and exemption scope?

Although there are examples of products immerging that do not require the exemption, given the criticality of function these products perform, a multitude of tests and analyses are required to undertake a comparative study. There are also concerns over the insufficient acoustic output pressures which degrades penetration and overall produces poor image quality. These tests need to be undertaken in a number of clinical situations where equivalency must be proven and important "end cases" where a misdiagnosis could result are not missed. Until such clinical equivalence has been proved, cMUT devices cannot be deemed as substitutes.

An estimation of the timeframes to complete such work are challenging to estimate given the number of tests involved and the requirement to resolve any issues discovered along its development. A non-exhaustive list of examples of the developments which still need to be undertaken include:

- With respect to the internal application of image guided therapy, cMUT technology has yet to be proven biocompatible.
- The safety of the much higher bias voltage and drive voltage required to power the device as compared to that in current use by PZT catheter technology would require electrical isolation that still needs to be tested.
- Demonstration of the reliability of the manufacturability of cMUT and the imaging capabilities of the technology would require a full system development to interface with a catheter probe.

There are also instances where the listed categories cannot be applied to all diagnostic capabilities. For example in state of art high frequency intravascular ultrasound (IVUS) (~20MHz), there are size limitations which would limit the use of cMUT:

- The catheter would have a size of >3.6F (1.2mm diameter + catheter imaging window) which is generally considered too large for coronary imaging.
- The non-bending length appears to be >5mm which would be too long to navigate tortuous, diseased coronary arteries.

However, until a detailed analysis is undertaken for each diagnostic capability, all the limitations cMUT pose are unable to be identified and only estimated to grow in number.

There is also the concern in the proposal of 'probes with wide clinical coverage' as its definition would be open to interpretations and without clarity in understanding these terms which would cause difficulties with compliance and enforcement. It is foreseen that many probe manufacturers

could make a claim of 'wide clinical coverage' to increase sales of the items but does not differentiate between the number of clinical treatments which would trigger this classification, nor what would constitute the boundary of one clinical treatment compared to another.

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.